GW Faculty Proposals for Medical Student Summer Research Projects

Please review this packet of faculty proposals for medical student 2020 summer research projects.

Email any faculty who list a program of interest. We encourage faculty to interview three students before selection.

Remember that you can also identify your own faculty research mentor and develop a project not in the packet.

Once a faculty member has selected you to work on the project, you can use that proposal, along with that research mentor, to apply for funding for the project.

You are encouraged to develop the proposal to apply to multiple funding sources. This increases the likelihood you will receive a competitive fellowship, since no single source is guaranteed.

Consider fellowship opportunities for medical students:

a. External national summer fellowships
b. External diversity-targeted national fellowships
c. Diversity Supplement to the mentor's NIH grant
d. External Medical student opportunities at other institutions
e. GW Gill fellowships - Apply here
f. GW Health Services Scholarship Program
g. External national year-out fellowships

Click here for steps for a student to apply for funding. Work with your faculty research mentor to develop their proposal into your joint fellowship application.
Faculty Proposal for MD Student Research by Hana Akselrod

* 1. Faculty Sponsor

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* 2. Daily Supervisor

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* 3. Project Title (250 character limit)

Title: "Evaluation of Barriers to Antiretroviral Therapy among HIV-Positive Patients at GW." Summary: Timely and effective engagement of people with HIV (PWH) in antiretroviral therapy (ART) is crucial to achieving viral suppression and immunologic reconstitution, improving survival, and reducing transmission of the virus to others ("Undetectable = Untransmittable"). Treatment initiation and continuation are high-priority targets in national and regional plans to end the HIV epidemic. Despite efforts to improve access to treatment, PWH continue to face significant structural, socioeconomic, and psychological barriers to retention in care. Washington, DC, has a generalized HIV epidemic with current prevalence of 1.8%. Among DC residents newly diagnosed with HIV in 2018, 84% were linked to medical care within 30 days, but only 68% persisted with treatment and had viral suppression within 6 months. Since 2018, our group has been conducting a prospective survey of HIV-positive patients at the George Washington University Hospital (GWUH) who report being out-of-care and not currently taking. In 2019, with the aid of a Gill Fellow, we expanded study enrollment to include eligible patients at the GW MFA Infectious Disease clinic, and collected data on 50 patients. We invite another Gill Fellow in 2020 to take the
project to the next level by continuing data collection, conducting more robust data analysis with higher numbers, and further expanding study enrollment to a third location (GWUH Emergency Department). By identifying the barriers experienced by PWH who receive their care at all GW settings, we can plan better interventions to improve their outcomes.

4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


5. Sponsor's Research Focus:
Yes - Infectious Disease

6. Sponsor's translational level
(Please select ONE)
T4: Translation to Population Health

7. Hypotheses (200 word limit)
Self-identified barriers to ART will differ based on some or all of the following: participant demographic and socioeconomic factors, HIV risk factors (injection drug use, male-to-male sexual intercourse, heterosexual intercourse, or other/multiple risk factors), physical and mental health co-morbidities, history of homelessness or incarceration, history of prior referrals for HIV care, and care setting (hospital vs. clinic vs. emergency department). Among respondents who report being previously referred to HIV care, some or all of the following factors will correlate to not starting ART: fears about confidentiality, fears about side effects of medication, experiences of bias or discomfort in interactions with the health care system, concurrent mental health conditions, concurrent substance use, lack of family or social support, difficulty in coordinating care between multiple settings, and other. Among those previously started on ART, reasons for discontinuing treatment may include: lack or loss of insurance, other financial barriers, transportation or other logistical barriers, lack of family/social support, difficulty remembering medication, side effects of medication, high pill burden, lack of clear instructions from health care providers, lack of trust with health care providers, ongoing issues with mental health or substance use, or other.

8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).
The project goal is to identify barriers to initiation of ART and retention in care for HIV among PWH who receive their care in any setting (inpatient, outpatient, or emergency-only) at GW. A previous iteration of this project, completed in 2018-2019, identified several key areas, including stigma (“I did not want anyone finding out I had HIV”), financial barriers (lack of insurance, homelessness), co-occurring conditions (including mental health and substance use), concern about the number of pills or their side effects, and lack of trust in the physician or medical staff. In order to test more specific hypotheses (e.g. relationships between individual characteristics and key barriers) with appropriate statistical power, a higher number of participants is needed. Additionally, in the process of working on the study, we determined that the site of care (hospital vs. clinic) was predictive of some barriers. For
instance, patients encountered in the hospital were more likely to have financial barriers, a greater burden of disease symptoms, and lower CD4 counts. The population of patients encountered in the emergency department is distinct from these, and their needs should be assessed in the next phase of the study.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.

Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

Background/Significance: Washington, DC, continues to have one of the nation’s highest rates of HIV, with disproportionate burden among specific demographic groups with histories of social disadvantage. Under the Ending the HIV Epidemic Initiative announced by the federal government in 2019, DC is designated as one of the “hotspot” locales with the highest burden of disease, and in need of the greatest efforts towards prevention, diagnosis, and treatment. Historically, immediate commencement of ART shortly after diagnosis of HIV was the exception rather than the rule for most patients. Over time – with the development of safer antiretroviral medications, multidisciplinary patient-centered care approaches, expansion of treatment access, and appreciation of the role of viral suppression in reducing HIV transmission on the population level – attitudes among both physicians and community members have shifted in favor of early treatment. The HIV Care Continuum model highlights the importance of linkage and continuation of care at every step between diagnosis and viral suppression. However, many barriers to ART persist. Unfortunately, our Internal Medicine and Infectious Disease teams at GW still too-frequently encounter patients hospitalized with advanced HIV and AIDS-defining conditions such as Pneumocystis jirovecii pneumonia and Kaposi’s Sarcoma; some result in death. Our patient-centered study aims to explore the reasons why HIV-positive patients encountered in a variety of settings at GW have not received ART or have been unable to stay engaged in care. It will provide valuable insights for planning future services to help improve medical care for these vulnerable patients in DC and beyond. Detailed Plan: We are conducting a prospective study consisting of a structured survey (with optional narrative comments) exploring individual and structural barriers to ART. The study protocol was approved by the GW Office of Human Subjects Research Institutional Review Board (IRB #031545) and recruitment began in 2018, with approximately 60 participants completing the survey to date. Eligibility is determined by the PI and study staff on a rolling basis from current Infectious Disease inpatient consultation lists and clinic schedules. Eligible patients are approached by study staff and offered participation, which is strictly voluntary and does not affect medical care in any way and is not compensated. (Anecdotally, several participants have expressed appreciation of being asked to share their past experiences in a supportive and non-judgmental manner.) Select clinical information (CD4 count and HIV viral load) is obtained from the medical record. Data is then entered into a secure, de-identified research database maintained by study staff in RedCap. Data analysis on the first 50 participants was completed in fall 2019; further data collection is ongoing. Timeline: Phase 1 (2019 Gill Fellow): - 50 participants enrolled and data collected: 2018-2019 - Initial data analysis: fall 2019 - Presentation of findings at GW Research Day: spring 2020 Phase 2 (2020 study team and Gill Fellow): - Enrollment and data collection for the next 50 participants: ongoing - Second data analysis: mid-summer 2020 - Presentation of findings to local stakeholders: late summer 2020 - Abstract/poster/manuscript preparation: end of summer 2020

* 10. Describe the student's role in the project (200 word limit)

The student will work closely with the Principal Investigator and will be an instrumental and valued member of the research team. He or she will become proficient in multiple research-related skills, including screening patients for eligibility, administering informed consent, and conducting interviews using the structured survey tool; coding and entering response data; and managing the secure RedCap database; carrying out basic statistical analysis of the updated database using Microsoft Excel and SPSS software; and presenting the study findings to local stakeholders (e.g. Whitman Walker Health, and other partner organizations in the DC Center for AIDS Research). The data analysis will be supervised by the PI and reviewed with a statistician; the GWU Biostatistics and Epidemiology Consulting Service can be accessed as needed for additional analytical support. At the end of the summer, the
The student will write and submit a research abstract to a regional or national conference (e.g. American College of Physicians meeting, ID Week, or a conference on LGBTQ health). We encourage the student to prepare a manuscript for publication in a peer-reviewed journal, and will provide support and guidance to do so.

* **11. Describe the mentor's role in the project. (200 word limit)**

Dr. Akselrod will be responsible for mentorship and supervision of the student. This will take the form of weekly meetings (in person or by phone) to set goals, monitor the acquisition of skills and completion of tasks, and discuss professional development. The student will have plentiful opportunities to shadow attending physicians in the Division of Infectious Diseases during clinic sessions and inpatient rounds. He or she will be invited to join the weekly ID case conferences and lectures on HIV-related or general ID topics. Additional members of the research team will include the study coordinator (Physician Assistant or Nurse Practitioner assisting with resource access, IRB materials, and study recruitment), biostatistician (through the GW Biostatistics and Epidemiology Consulting Service), and possibly a graduate student from the Milken School of Public Health (assisting with data collection and analysis). The faculty mentor (Dr. Akselrod) will be directly responsible for coordinating and supervising all research tasks as well as effective collaboration between team members. More senior members of the Division of Infectious Diseases (Dr. Afsoon Roberts, Dr. Gary Simon) will be available for additional mentorship and advice.

* **12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)**

Dr. Akselrod is an experienced teacher and supervisor of student projects. She served as the primary supervisor/mentor of the Gill Fellow who worked on this project in 2019, and who was able to achieve the goals set for the projects including the completion of a written report and poster to be presented at the GW Research Days in spring 2020. Dr. Akselrod serves as a Clinical Public Health Mentor in the GW School of Medicine and Health Sciences, and on the Executive Committee of the DC Cohort Longitudinal HIV Study. She teaches about HIV pathogenesis, treatment, prevention, and epidemiology, to learners ranging from medical students to infectious disease fellows. She directly supervises research and quality improvement projects by ID fellows and Internal Medicine residents, and has also served as Practicum mentor for students from the Milken School of Public Health.

* **13. Do you have or will you obtain IRB approval for this project?**

**Please note:** Students cannot begin a human subjects project without IRB approval.

*(Please select ONE)*

**Selected** Yes

Please provide IRB number and date

* **IRB Number:** 031545

* **IRB Date:** 4/24/2019
Faculty Proposal for MD Student Research by Keith Boniface

* 1. Faculty Sponsor

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* 2. Daily Supervisor

Name: Keith Boniface
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Title: Professor of Emergency Medicine
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* 3. Project Title (250 character limit)
Pericardial effusions and malignancy - a retrospective review of echocardiograms of patients presenting with pericardial effusion to the emergency department to identify characteristics predictive of malignancy

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.

Boniface KS, Drake A, Pyle M, Moideen F, Mehta S, Poovathumparambil V, Shokoohi H, Douglass K. Learner-centered survey of point-of-care ultrasound training, competence, and implementation barriers in emergency medicine training programs in India. Accepted for publication, Academic Emergency Medicine Education and Training

* 5. Sponsor's Research Focus:
Yes - Emergency Medicine

* 6. Sponsor's translational level
* (Please select ONE)
T2: Translation to Patients

* 7. Hypotheses (200 word limit)
Pericardial effusion is a potentially dangerous collection of fluid around the heart. As the fluid collects, it exerts pressure on the heart, causing the right side of the heart to collapse, impairing filling of the left ventricle, and can lead to cardiac collapse in the setting of pericardial tamponade. Pericardial fluid collections can occur secondary to a wide range of causes, from blood in the setting of trauma, to inflammatory fluid in conditions such as lupus and connective tissue disease, to malignant cells in the case of metastatic cancer. We have observed a gelatinous substance adherent to the visceral pericardium in some cases of pericardial effusion and have noted anecdotally an association with a final diagnosis of malignant pericardial effusion. In this study, we will systematically examine all pericardial effusions diagnosed by point-of-care ultrasound in the emergency department to identify the diagnostic performance of this finding of “pericardial jelly” in prediction of malignant effusion. We hypothesize that the finding will be specific for the identification of a malignant etiology.

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
All point-of-care ultrasound examinations are recorded and archived on the Qpath PACS system. Worksheets containing user interpretations are archived with the images, and ultrasound faculty review all images for quality of image acquisition and accuracy of interpretation. These worksheets are searchable through Qpath to locate records where pericardial effusions were identified. We will have multiple trained researchers review these images in blinded fashion, abstract data from the echo, compare inter observer agreement, and review the chart for final etiology. We will aim to submit the findings of this project as an abstract to an emergency medicine or ultrasound conference, and subsequently to prepare and submit a manuscript describing the results.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research
The project is a retrospective cohort study of adult patients who had a point-of-care ultrasound of their heart that revealed a pericardial effusion. The IRB application will be submitted this winter, with anticipated approval by expedited procedures by April 2020. Upon approval, a search of QPath database for pericardial effusion will generate our cohort of patients. These ultrasound images will be reviewed for specific features (size of effusion at max diameter, presence of diastolic collapse, echogenic debris or fibrinous material in effusion, and echogenic gelatinous material adherent to visceral pericardium). The trained reviewers will note details on a data abstraction form, and interobserver agreement will be assessed. Subsequently, blinded chart reviewers will abstract comprehensive echocardiogram data as well as final diagnosis features from the medical record to determine the cause of effusion. We anticipate that this review can take place over the course of an 8-week summer project, in addition to drafting abstract.

*10. Describe the student's role in the project (200 word limit)*

The student will integrate into activities of the emergency ultrasound section at George Washington University. They will learn the basics of interpretation of echocardiograms, and will have the opportunity to sit in on our July two-day introduction to ultrasound course. They will be primarily responsible for data abstraction from ED echocardiograms and from medical records. If they demonstrate initiative and are effective in completing the research tasks for this project, they will be given the opportunity to present their findings at a regional or national meeting and participate in manuscript preparation.

*11. Describe the mentor's role in the project. (200 word limit)*

The mentor will orient and train the student, teach them how to review the echos with a brief training, hold regular ongoing meetings to ensure progress of research and quality of results, and lead the student through data collection, data analysis, abstract preparation, and manuscript submission stages of the research process. In addition, there will be opportunities to learn ultrasound techniques as well as opportunities to observe multiple aspects of emergency medicine practice.

*12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)*


*13. Do you have or will you obtain IRB approval for this project? Please note: Students cannot begin a human subjects project without IRB approval.*

* (Please select ONE)

Selected No (Pending)
Faculty Proposal for MD Student Research by Claire Boogaard

* 1. Faculty Sponsor

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* 2. Daily Supervisor

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* 3. Project Title (250 character limit)

Pediatric Mobile Health Care- Current State and Proposed Changes to the current programming at CHC-THEARC

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.

none

* 5. Sponsor's Research Focus:

Yes - Pediatrics
* 6. Sponsor's translational level
* (Please select ONE)
T3: Translation to Practice

* 7. Hypotheses (200 word limit)
We are working on defining the current state of Pediatric Mobile Health Care in the US and then will propose various changes to the programming of the mobile medical unit at CHC-THEARC and study its impact

* 8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).
We will study number of patients reached by mobile services and other outcomes will be based on the new goal we have for mobile health (i.e. vaccinations, decreased ED visits, etc).

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research
- Gather data on current state of Pediatric Mobile Health in the country
- Identify local barriers to successful usage of the Mobile Health unit
- Develop a Quality Improvement (QI) plan for usage of the two mobile health units at CHC-THEARC
- Complete rounds of PDSA cycles (Plan, Do Study, Act) to determine effectiveness of implementation of proposed new plan
- Report back on lessons learned

* 10. Describe the student's role in the project (200 word limit)
- Help gather data and design PDSA cycles
- Help analyze the data from the revised plans
- Contribute to manuscripts and poster presentations of the work

* 11. Describe the mentor's role in the project. (200 word limit)
- Help organize the team to stay on the timeline (goal to complete by Spring 2021)
- Partner with the team members to gather data, develop plans, execute the PDSA cycles, and report on findings

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
This is a new team, so no previous training of students.

* 13. Do you have or will you obtain IRB approval for this project?
* Please note: Students cannot begin a human subjects project without IRB approval.
* (Please select ONE)
Selected No (Pending)
Faculty Proposal for MD Student Research by Marjorie P. Brennan

* 1. Faculty Sponsor

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* 2. Daily Supervisor

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Degrees: 
Title: 
Organization: 
Address: 
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* 3. Project Title (250 character limit)

Early PACU complications in a pediatric ASC.

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


5. Sponsor's Research Focus:
Yes - Anesthesiology
Yes - Surgery

6. Sponsor's translational level
(Please select ONE)
T3: Translation to Practice

7. Hypotheses (200 word limit)
Ambulatory Surgery Centers (ASC’s) are increasingly providing a larger share of surgical care to patients, driven by exceptional outcomes and high patient satisfaction scores at substantially lower costs. ASC centers have proliferated while the outpatient surgical population has increased in complexity, and many centers are providing services to children. Free standing ASCs come with their own set of safety concerns and unique challenges. An important key to success in patient safety lies in careful selection, screening and preparation of prospective patients. Well defined patient selection criteria must be established and strictly adhered to by all surgeons at the facility. Our study will perform a retrospective chart review of the recovery room clinical course of all patients who underwent an operative procedure at the CNMC Rockville Ambulatory Surgical Center from January 2001 to December 2020 to identify specific characteristics of patients that have early adverse post-operative events.

8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
Our study will perform a retrospective chart review of the recovery room clinical course of all patients who underwent an operative procedure at the CNMC Rockville Ambulatory Surgical Center from January 2001 to December 2020 to identify specific characteristics of patients that have early adverse post-operative events. We will review 2000-3000 patient records.

9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

Research design and Methodology: We propose to conduct a retrospective cohort design. Study population: All children that underwent a procedure at the Montgomery County Ambulatory Surgery Center in Rockville between January 2001 to December 2020. Exclusion criteria: none Data management: Each subject will be assigned a study ID, and all data will be entered on line to a RedCap database via a secure log in. Project timeline: • June 2107 to February 2018: IRB submission and approval • March 2018: begin data collection • December 2020: Data collection complete, begin analysis

10. Describe the student's role in the project (200 word limit)
Student will review medical records and enter information into RedCap database. Student will have opportunity to observe surgery and anesthesia to better understand flow and function of Ambulatory Surgery Centers.

11. Describe the mentor's role in the project. (200 word limit)
-Will support in learning RedCap databases for input of research data. - Will discuss valid and effective research methods - Will supervise observations in operating room

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

No previous medical students, but on-boarded a special category volunteer with masters of public health applying to medical school for same project.

* 13. Do you have or will you obtain IRB approval for this project? Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected Yes

Please provide IRB number and date

* IRB Number: Pro0009797

* IRB Date: 6/24/2019
Faculty Proposal for MD Student Research by Randall S. Burd

* 1. Faculty Sponsor

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* 2. Daily Supervisor

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* 3. Project Title (250 character limit)

Predicting Context-based Goal Pursuit during Pediatric Trauma Resuscitation

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


5. Sponsor's Research Focus:
Yes - Pediatrics
Yes - Emergency Medicine
Yes - Surgery

6. Sponsor's translational level
(Please select ONE)
T2: Translation to Patients

7. Hypotheses (200 word limit)
Treatment and management goals relevant to trauma resuscitation can be recognized in real time by tracking human activity, use of medical objects, the output from patient monitors and data from digital devices.

8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).
This project will be supported by an NIH grant awarded to Dr. Burd. The goal of this project is to develop an approach for predicting the goals of resuscitation using observable information available during the initial management of injured children. The management of injured children relies on identifying the need for and pursuit of goals that includes maintenance of normal oxygenation, maintenance of normal blood pressure and others. Decision support that aids teams in this setting requires identification of required goals, either by direct user input or automatically by sensors that detect data in the environment. The project objective is to develop a model that predicts that likelihood of a set of goals relevant to trauma resuscitation based on data obtained from sources available in the trauma bay. Event logs were obtained from the resuscitation of >200 injured children during the resuscitation phase. The student will use video review to annotate these logs with resuscitation goals that were pursued or needed to be pursued by the team. A model will then be developed that predicts the probability of the need for goal pursuit using static (e.g., age, type of injury) and dynamic (e.g., vital sign values) obtained from sources.

9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

This project will leverage existing data and methods available to Dr. Burd’s research group. Existing data includes: event logs of >200 resuscitations, downloaded vital sign data, and patient and resuscitation features available in the trauma registry. Current available methods and materials include: video annotation software, procedures, and annotation definitions. These resources increase the likelihood of success of this project. The student will review the videos of trauma resuscitations to identify the need for and pursuit of a set of goals. This task will be accomplished using the video annotation software package Manigold that is available in Dr. Burd’s laboratory. Using data obtained from sources in the trauma bay, a model will be developed that will predict the need for pursuit of each goal. Based on our previous experience with similar research, it is anticipated that video annotation will take about four weeks. The number of goals labels that will be applied will be modified to ensure that this project can be accomplished within the summer. With the assistance of engineers on our team, the student will then develop
models for predicting these goals using data obtained from the trauma bay. We anticipate that neural networks will be best suited for this purpose and will initially pursue this approach. We will use a 80/20 train/test split and will assess model performance using standard evaluation approaches. The deliverable of this project will be the demonstration of the feasibility predicting goal pursuit using contextual information available during trauma resuscitation. This initial work will be performed offline but an online approach will be later developed based on the results of this summer project.

* 10. Describe the student's role in the project (200 word limit)

The student will perform the following tasks: 1. Annotate videos with goals that need to be pursued or have been pursued. 2. Collate and format contextual data available in the trauma bay. 3. Assist (with engineer support) in the development of models predicting the need for goal pursuit or accomplishment using contextual data. 4. Evaluate (with engineer support) the performance of models developed in #3.

* 11. Describe the mentor's role in the project. (200 word limit)

I am the lead PI for this project. My work is funded by the NIH and NSF. This project will satisfy a key objective of this work. I will meet with the student in advance of the summer to develop a proposal appropriate for submission for intramural or extramural funding. I will meet with the student weekly or more often as needed to ensure that objectives of the proposed project are achieved. I oversee two team meetings each week that the student will participate in: one with intramural and one with extramural collaborators. I will assist the student in generation of research reports and materials that may include posters and manuscripts.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

I have mentored seven Gill fellows and GWU medical students over the past 10 years.

* 13. Do you have or will you obtain IRB approval for this project?

Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected Yes

Please provide IRB number and date

* IRB Number: Pro00000343

* IRB Date: Approved 5/22/12 (expires 3/22/20)
Faculty Proposal for MD Student Research by Katherine Chiappinelli

**1. Faculty Sponsor**

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**2. Daily Supervisor**

Name:
Degrees:
Title:
Organization:
Address:
Apt/Suite:
City:
State:
Zipcode:
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Email Address:

**3. Project Title (250 character limit)**

Regulation of repetitive elements in cancer by P53 and epigenetic mechanisms

**4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.**

DOI: 10.1158/2326-6066.CIR-18-0758
DOI: 10.1186/s13148-018-0602-0
DOI: 10.1073/pnas.1712514114

**5. Sponsor's Research Focus:**
* 6. Sponsor's translational level
* (Please select ONE)
T0/T1: Basic Science Discovery and Initial Translation to Humans

* 7. Hypotheses (200 word limit)
The premise of this proposal is that P53 and epigenetic mechanisms regulate REs in cancer and thus mutant TP53 will affect response to epigenetic therapy. In our preliminary data, DNMTi/HDACi treated TP53 hotspot mutant cell lines exhibit significantly increased chromatin accessibility and transcription at REs compared to TP53 wild type cell lines. We hypothesize that mutant TP53 aberrantly activates REs, increasing the DNMTi/RE-induced immune response.

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
Aim 1: Examine how wild type and mutant P53 cooperate with epigenetic mechanisms to transcriptionally regulate REs and the interferon response. Using isogenic human OC cell lines (wild type, null, and mutant P53 created by CRISPR engineering), we will 1) characterize the transcription and epigenetic state of REs and 2) determine the differences in DNMTi and HDACi-induced RE transcription and interferon signaling in different TP53 backgrounds. Aim 2: Assess p53-induced RE regulation and immune response to epigenetic therapy in preclinical models. We will determine the effects of p53 genetic alterations on immune cell recruitment and activation, tumor burden, and response to epigenetic and immune therapy in a mouse model of ovarian cancer in which we have already observed differential response to DNMTi based on p53 status. Aim 3: Determine how P53 status affects RE transcription, tumor immune microenvironment, and response to immune therapy in primary human tumors. In a cohort of 100 ovarian cancer tumors, we will validate top hits from Aim 1. In addition, by using RNA-seq data and clinical outcomes from samples obtained from an OC clinical trial, we will analyze and correlate REs with sensitivity to immune checkpoint blockade.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

Therapies that activate the immune system to kill cancer cells, including anti-PD-1 checkpoint blockade, have shown vigorous and durable responses, but the majority of patients, including those with ovarian cancer (OC), fail to respond. The underlying mechanism remains unclear. Repetitive elements (REs) comprise about 45% of the human genome. In most somatic tissues, REs are silenced by DNA methylation and other epigenetic modifications to prevent their transcription. We demonstrated that treating OC cells with DNA methyltransferase inhibitors (DNMTis) increases immune signaling from tumors through demethylation of REs and production of RE double-stranded (ds)RNA to activate the interferon response. Further, we showed that DNMTis plus the epigenetic modulator histone deacetylase inhibitors (HDACis) cause RE transcription and interferon signaling in OC, which recruits CD8+ T cells and NK cells to sensitization tumors to anti-PD-1 immunotherapy. Approximately half of all cancers have mutations in TP53, the gene encoding the P53 protein, 90% of which are “hotspot” mutations located in the DNA binding domain. These missense mutations encode functional proteins with reduced transcriptional activity at canonical cell cycle target genes and may also exhibit oncogenic gain of function transcriptional activity at new targets. High grade serous OC makes up about 70% of OC and is characterized by nearly 100% mutant
TP53. While the critical role of P53 in cell cycle regulation and apoptosis is known, P53 regulation of REs in cancer remains poorly defined. Approximately 30% of P53 binding sites are found in REs, strongly suggesting a role for this DNA sequence-specific binding transcription factor in the regulation of RE activity. The premise of this proposal is that P53 and epigenetic mechanisms regulate REs in cancer and thus mutant TP53 will affect response to epigenetic therapy. In our preliminary data, DNMTi/HDACi treated TP53 hotspot mutant cell lines exhibit significantly increased chromatin accessibility and transcription at REs compared to TP53 wild type cell lines. We hypothesize that mutant TP53 aberrantly activates REs, increasing the DNMTi/RE-induced immune response. We will test this hypothesis with the following Aims: Aim 1: Examine how wild type and mutant P53 cooperate with epigenetic mechanisms to transcriptionally regulate REs and the interferon response. Using isogenic human OC cell lines (wild type, null, and mutant P53 created by CRISPR engineering), we will 1) characterize the transcription and epigenetic state of REs and 2) determine the differences in DNMTi and HDACi-induced RE transcription and interferon signaling in different TP53 backgrounds. Aim 2: Assess p53-induced RE regulation and immune response to epigenetic therapy in preclinical models. We will determine the effects of p53 genetic alterations on immune cell recruitment and activation, tumor burden, and response to epigenetic and immune therapy in a mouse model of OC in which we have already observed differential response to DNMTi based on p53 status. Aim 3: Determine how P53 status affects RE transcription, tumor immune microenvironment, and response to immune therapy in primary human tumors. In a cohort of 100 ovarian cancer tumors, we will validate top hits from Aim 1.

* 10. Describe the student's role in the project (200 word limit)
The medical student's role in this project will be to sequence the TP53 gene in the cohort of 100 primary ovarian cancer patient samples. This will be done with PCR and deep sequencing of amplicons across the TP53 gene. If this is accomplished quickly and well, the student can then move on to validation of RE hits from Aim 1 in the RNA samples from the ovarian cancer patient samples. This would be accomplished by performing qRT-PCR on specific RE loci. The medical student would receive authorship on any posters or publications resulting from this work and would be encouraged to present their work at conferences.

* 11. Describe the mentor's role in the project. (200 word limit)
Dr. Chiappinelli will train the medical student in the assays indicated (PCR, library preparation, cDNA preparation, qRT-PCR). Dr. Chiappinelli will meet with the medical student formally for one hour on Mondays, following the submission of a written "Weekly Checkin" by the medical student turn in to the mentor on Fridays. In addition, the medical student will participate in weekly roundtable lab meetings on Wednesdays when all lab members present their work and at formal joint lab meetings on Fridays with the Villagra Lab.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
Juan Nogues- trained Summer 2017, 2018, METEOR student. Kyle Roche- trained Summer 2018, Gill Fellow. Author on a manuscript currently in review at Scientific Reports.

* 13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.
* (Please select ONE)
  Selected No (Not Required)

Please specify why it is not required.
The 100 OC DNA and RNA samples were blinded and given numbers before being sent to us by collaborators in Germany. We have no information about patient identifiers and thus IRB review is not required.
Faculty Proposal for MD Student Research by Shayna Coburn

* 1. Faculty Sponsor

Name: Shayna Coburn

* Degrees: Ph.D. Psychology
* Title: Assistant Professor
* Organization: Children's National Hospital
* Address: 111 Michigan Ave NW

* 2. Daily Supervisor

Name:

Degrees:

Title:

Organization:

Address:

Apt/Suite:

City:

State:

Zipcode:

Office Phone:

Email Address:

* 3. Project Title (250 character limit)

Developing and validating a measure of disease-specific quality of life in children with celiac disease

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:
Yes - Gastroenterology
Yes - Pediatrics
Yes - Psychiatry

* 6. Sponsor's translational level
* (Please select ONE)
T3: Translation to Practice

* 7. Hypotheses (200 word limit)
Hypothesis 1.1. Expert review of the adult Celiac Disease Quality of Life (CD-QOL) measure will identify question items pertaining to concepts and experiences that are also relevant to children with celiac disease (CD). Hypothesis 2.1. Children with CD and their parents will identify refined question items as relevant and acceptable to their experiences in daily life. Hypothesis 3.1. Acceptable internal and external reliability and validity will be achieved to facilitate the preliminary completion of a pediatric measure, the PedsCD-QOL.

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
The purpose of this study is to develop a CD-specific quality of life (QOL) measure to administer with children ages 0-18. The central hypothesis is that children with CD experience challenges associated with their condition and treatment with the gluten-free diet that affect QOL. This study will result in a validated screening measure with immediate value for evaluation of children with CD for research purposes, and would also be applicable in a clinical setting. Specific Aims: Aim 1. Review and modify existing CD-QOL items (n=8 clinicians who work with children with CD); (2) Iterative item refinement through a series of focus groups with children with CD and parents of children with CD (n=30); and (3) Administration and validation of the PedsCD-QOL measure in children with CD and parents (n=100 children and n=100 parents for total n=200). In Phase 3, we will evaluate psychometric properties such as internal and external validity, including factor analysis and convergent and discriminant validity using other QOL and CD-specific measures (PedsQL,17 PROMIS,18,19 and GFD Experiences). This process will be guided by criteria defined by Holmbeck & Devine for measure development. This project will be completed within the Celiac Disease Program at Children’s National, with mentorship from Dr. Randi Streisand, Chief of Psychology as well as consultation with (1) Dr. Benny Kerzner, Medical Director of the Celiac Disease Program and (2) Dr. Douglas Drossman from the Rome Foundation, developers of the CD-QOL. Funding provided by the CTSI Discovery Pilot...
Award will allow for a part-time research coordinator, questionnaire licenses, and participant incentives. We will also use CTSI resources including Biostatistics and REDCap. We already have a proposal under review with the Children's National IRB (Pro00013204, submitted 10/7/19) and are on track to begin Phase 1 of the project in early 2020. Significance: This study is important for three primary reasons: (1) CD is increasingly diagnosed in childhood, with age of diagnosis often 8 years or younger; (2) the only treatment for CD is a strict gluten-free diet, which is complex, expensive, and anxiety-provoking; and (3) QOL is often negatively impacted in CD,12–14 yet there is no validated measure for clinical practice or research across the full childhood period. Innovation: This original research project would develop the first validated CD-specific QOL measure offered for youth of all ages (0-18 years). It will consist of both youth-report and parent-proxy report forms to facilitate ease of administration and relevance to the target population.

* 10. Describe the student's role in the project (200 word limit)
The student would have a key role in data collection and analysis, with an emphasis on assisting with Phases 2 and 3 of the project (item refinement and final validation of the measure). This would include learning to facilitate interviews/focus groups, use qualitative behavioral coding strategies of interview transcripts, and conduct psychometric evaluation of a quality of life measure.

* 11. Describe the mentor's role in the project. (200 word limit)
The mentor is the principal investigator and would oversee all aspects of the project. The student would have consistent personalized supervision and mentorship regarding behavioral and translational research.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
Psychology undergraduate and graduate students as well as doctoral interns have been trained over the past several years. This would be the first time our team would formally mentor a medical student.

* 13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)
Selected No (Pending)
Faculty Proposal for MD Student Research by Keith Cole

* 1. Faculty Sponsor

* Name: Keith Cole
* Degrees: DPT, PhD, MBiomedE
* Title: Assistant Professor
* Organization: George Washington University
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* Apt/Suite: 2000
* City: Washington
* State: District of Columbia
* Zipcode: 20006
* Office Phone: 2029940423
* Email Address: keithcole@gwu.edu

* 2. Daily Supervisor

Name: Ellen Costello
Degrees: PT, PhD
Title: Associate Professor
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Zipcode: 20006
Office Phone: 202 994 0056
Email Address: ecostell@gwu.edu

* 3. Project Title (250 character limit)
The effect of a simple vs a complex cognitive task while learning a simultaneous visuomotor task in healthy adults

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.
Tseng SC1, Cole KR1, Shaffer MA, Petrie MA, Yen CL, Shields RK. Speed, resistance, and unexpected accelerations modulate feed forward and feedback control during a novel weight bearing task. Gait Posture. 2016;52:345-353. 1 The first and second authors contributed equally to the manuscript
In order to functionally move through one’s community, it’s vital to be able to perform simultaneous motor and cognitive tasks (cognitive-motor dual-task). This allows us to talk to another person, scan the environment for oncoming traffic, and avoid objects that are in our path when walking. This even allows high level sporting participation, such as predicting an opponents’ path when sprinting and cutting to score a goal. Although investigations suggest a relationship between physical and cognitive capabilities, little is known regarding the appropriate level of cognitive task difficulty that will result in improvements or delays in learning a motor task and transferring a learned task to a new condition. In this study, we plan to determine the effects of cognitive load on motor learning in healthy humans, and then use this data as a benchmark in the development of interventions for individuals who experience movement control impairments. We hypothesize that increased cognitive load will decrease the rate of learning and decrease the ability to transfer to new conditions. We also hypothesize that the rate of learning will be related to working memory capacity while the impact of the cognitive task on the motor task will be related to executive function.

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).

Objective 1: To determine the effect of a simple and a complex simultaneous cognitive task on the ability to acquire a novel, weight-bearing, visuomotor task Objective 2: To determine the effect of a simple and a complex simultaneous cognitive task on the ability to transfer an acquired weight-bearing visuomotor task to new motor conditions. Objective 3: To determine the effect of a simple and a complex simultaneous cognitive task on the ability to consolidate an acquired weight bearing visuomotor. Consolidation is defined here as the process through which learning is remembered (through resting) 24-48 hours after initial learning took place. Objective 4: To analyze the association between cognitive function and performance on simultaneous cognitive and motor tasks.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.

Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

Testing will take place on three different days within an 8 day period. Subjects will be asked to fill out questionnaires which will include information about medical, physical and social life, activity level, and pain levels (see attached forms). Subjects will then be asked to undergo computerized testing of general cognitive function via the NIH Toolbox Cognition Battery. A test of balance is performed asking the individual to stand on a pressure sensitive mat (Zeno Mat) to record foot pressures and amount of body sway. They will be asked to stand in place with their 1) eyes open and 2) eyes closed, while standing on each foot (single limb stance). Subjects will then be asked to perform a Timed Up and Go (TUG) test under conditions of while counting back from 100 by 7’s (TUG
Cognitive), and without a secondary task (TUG). The following describes procedures performed on all three days of the experiment. Wireless electrodes will be placed over the skin of lower extremity muscles in order to collect surface electromyography. Following placement of electrodes subjects will be asked to perform three maximal volitional isometric contraction (MVIC) for each muscle. Subjects will then be asked to perform either a visuomotor task only (control group), or a visuomotor task with a simultaneous cognitive task (simple cognitive group and complex cognitive group). The visuomotor task is the same regardless of group assignment. The visuomotor task consists of performing a standing in-place march, lifting alternating knees to 60 degrees of hip flexion, eight cycles on each leg. A custom computer program displays a real-time video of the individual on the screen with an overlay of markers indicating computerized detection (Microsoft Kinect) of the knee joint. A prescribed marching rate is determined by an ellipse on the screen that prescribes the displacement (degrees of hip flexion) and rate of movement (speed) in which to move. The cognitive task is displayed on the same screen as the motor task. Letters of different orientations and colors appear and disappear on the screen. The individual is instructed to count the total of a pre-defined set of letters throughout the duration of the task. The complexity of the cognitive task is altered by changing the number of pre-identified characters to count. Subjects will perform the cognitive and/or motor task up to 20 repetitions each at a fixed rate to establish a training learning curve, followed by three sets of five trials at varying rates of movement (speed of the ellipse on the screen) to establish transfer of learning to new physical task conditions (speed). Rest is provided as needed. Testing on the first and last days will last no longer than 2 hours, while testing on the second day will last no longer than one hour.

* 10. Describe the student's role in the project (200 word limit)
The student will be responsible for recruitment of healthy controls. Students will screen and consent healthy individuals. The student will assist with assessment of healthy controls including administration all study tests after demonstrating proficiency in testing. Some aggregation and analysis of data may also be a part of the student’s role.

* 11. Describe the mentor's role in the project. (200 word limit)
The mentor will oversee training of the student for recruitment, screening, and consenting study participants. The mentor will also oversee training of the student in study specific assessment measures. The mentor will oversee data collection, storage, and analysis.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
No previous medical student training by our team.

* 13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.
* (Please select ONE)
  Selected Yes

Please provide IRB number and date
* IRB Number: 041833

* IRB Date: Expires 6/20/2020
Faculty Proposal for MD Student Research by Katie Donnelly

* 1. Faculty Sponsor

* Name: Katie Donnelly
* Degrees: MD, MPH
* Title: Assistant Professor of Pediatrics and Emergency Medicine George Washington University School of Medicine and Health Sciences
* Organization: Children’s National Hospital
* Address: 111 Michigan Avenue NW
* Apt/Suite: 
* City: Washington
* State: DC
* Zipcode: 20010
* Office Phone: 202-476-4177
* Email Address: KDonnell@childrensnational.org

* 2. Daily Supervisor

Name: Marci Fornari
Degrees: MD
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Apt/Suite: 
City: Washington
State: DC
Zipcode: 20010
Office Phone: 202-476-4177
Email Address: MFornari@childrensnational.org

* 3. Project Title (250 character limit)

Risk of Recidivism for Violent Injury Among Assault Injured Youth in a Pediatric Emergency Department

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


Assault is a common cause of youth emergency department (ED) visits. Studies have shown that assault-injured youth seeking ED care report higher levels of previous violence, weapon experience, and substance use compared with children seeking care for other complaints. However, there have been few studies specifically investigating how ED use changes among youth after an initial assault. This study's primary objective is to determine the risk of recidivism for violent injury among assault-injured youth in our urban pediatric ED compared to unintentionally injured youth. Our secondary objectives are to compare time to representation with assault amongst the two groups and to analyze the severity of injury at representation for the assault injured group.

The goal of this project is to determine the relative risk of recidivism for violent injury among assault-injured youth. Within this larger goal, we plan to define the average time to next injury, identify if subsequent assaults are more severe and characterize the co-morbidities that increase risk for assault. This research will, in part, be used to support our efforts to establish a violence intervention program at Children’s National Hospital for our highest risk youth. This research could make a strong argument for primary and secondary intervention programs that could decrease the morbidity and mortality due to violence related injury. We anticipate reviewing approximately 1000 charts (300 assault and 600 controls) from the year 2013 to 2019. The cohort study of the assaulted patients will include about 300 patients. The nested case control study of the assaulted patients compared to the controls will include about 600 patients.

The project will be a retrospective cohort study with a nested case-control study. For the cohort study we will measure the relative risk of ED re-presentation for assault related injury using survival curves from 2013-2019. For the case-control study we will measure the relative risk of ED re-presentation for assault related injury as compared to matched patients who presented to the ED for an accidental injury. We will also analyze time to re-presentation, severity of injury at re-presentation, and co-morbidities of patients. We will look at this data for patients seen at both our Sheik Zyaed campus ED and the ED at the Southern Avenue campus. We will exclude patients who were transferred to us from outside hospitals.
* 10. Describe the student's role in the project (200 word limit)
During Summer 2020, the student will focus primarily on the chart review. The data they ascertain from the chart review will be inputted into Statistical Analysis System (SAS). Throughout the chart review we will meet to discuss cases where it is difficult to determine if it qualifies as an assault. Once the chart review/data input is complete, the student will work with us on data analysis and interpretation using SAS. The student is encouraged to stay involved in the data analysis and manuscript writing after the summer is over.

* 11. Describe the mentor's role in the project. (200 word limit)
Dr. Fornari will be intimately involved in all steps of this research project. She will meet with the student three times per week for the first two weeks and twice per week for the remainder of the summer. She will be available (by phone or in person) to meet more frequently if needed. Dr. Donnelly will oversee the project and provide support to both Dr. Fornari and the medical student. Dr. Donnelly has experience with similar chart reviews and primary data analysis, so she will be a critical resource when questions arise.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
Dr. Donnelly has mentored two previous summer research students. 1. Dariush Kafashzadeh - Gill Fellow, Summer 2018 - Project: Assessing Barriers to Firearm Research 2. Katherine Markin - Health Services Scholarship Summer 2019 - Project: Assessing ICD codes for determining mechanism of injury in a pediatric emergency department Dr. Donnelly also serves as the co-director of the Medical Student Clerkship in Pediatric Emergency Medicine

* 13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)
Selected No (Pending)
* 1. Faculty Sponsor

* Name: Tatiana Efimova  
* Degrees: PhD  
* Title: Assistant Professor of Anatomy & Cell Biology, and Dermatology  
* Organization: GW SMHS  
* Address: 800 22nd Street NW  
* Apt/Suite: SEH Room 8160  
* City: Washington  
* State: DC  
* Zipcode: 20052  
* Office Phone: 202-994-2753  
* Email Address: tefimova@gwu.edu

* 2. Daily Supervisor

Name: 
Degrees: 
Title: 
Organization: 
Address: 
Apt/Suite: 
City: 
State: 
Zipcode: 
Office Phone: 
Email Address:

* 3. Project Title (250 character limit)

Targeting p38 Isoforms in Human Cutaneous Metastatic Melanoma Invasion

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:
Yes - Cancer

* 6. Sponsor's translational level
(Please select ONE)
T0/T1: Basic Science Discovery and Initial Translation to Humans

7. Hypotheses (200 word limit)
Advancing our understanding of the mechanisms of cutaneous metastatic melanoma (MM) invasion is paramount for developing new mechanism-based therapies and improving MM outcomes. To reliably model early invasive behavior of human MM in the proper three-dimensional (3D) tissue microenvironment, our laboratory has recently developed an optimized 3D organotypic human skin equivalent co-culture system of primary epidermal keratinocytes, malignant melanoma cells, and normal stromal fibroblasts. Here we propose to use this innovative 3D model system that closely resembles cutaneous human melanoma metastasis to study the molecular mechanisms underlying the invasive capacity of human MM. Our preliminary findings showed that in 3D human skin equivalents harboring human MM cells, pharmacologic inhibition of p38alpha and p38beta resulted in markedly augmented invasion of MM cell nests into the dermis, a phenotype that was reversed by a co-inhibition of p38delta. These data suggest that p38alpha/p38beta may function to restrict MM cell invasion, while p38delta signaling may be required to promote invasion in this model system. These exciting data support our hypothesis that keratinocyte-intrinsic and/or melanoma cell-intrinsic p38 mitogen-activated protein kinase (MAPK) family members have isoform-specific roles in regulating early human cutaneous metastatic melanoma invasion. Here we propose to test this hypothesis as outlined below.

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
The main purpose of the present proposal is to characterize the roles of keratinocyte-intrinsic and melanoma cell-intrinsic p38 MAPK isoforms in early human MM invasion in 3D human skin equivalents harboring human MM cells, by means of genetically targeting the p38 isoforms, individually or in combination, in a cell-specific manner, using RNA interference (RNAi) technology. To this end, we will determine the roles of keratinocyte-intrinsic p38alpha and p38delta isoforms (Specific Aim 1) and melanoma cell-intrinsic p38alpha and p38beta isoforms (Specific Aim 2) in the regulation of early melanoma invasion and characterize the underlying mechanisms. We will employ genetic small inhibitory RNA (siRNA)-based loss-of-function (LOF) approach to knock down, individually and in combination the above mentioned p38 family members in the specified cell types. We will then use both control cells (keratinocytes or MM) and cells with si-RNA-mediated silencing of the p38 isoforms for generation of the 3D human skin equivalents harboring human MM cells, and carry out functional characterization of the effects of the LOF of these isoforms on MM cell invasion in this model system as detailed below.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
The project fulfills discovery/original research

i) siRNA-mediated knock-down of p38 isoforms in keratinocytes and melanoma cells: In preparation for this project, we have validated and optimized the pools of siRNAs selectively targeting human p38 isoforms in keratinocytes and MM cells, and confirmed the efficiency and specificity siRNA-mediated knockdown of p38 isoforms in these cells. We will use primary normal human epidermal keratinocytes isolated from de-identified neonatal human foreskins, tissue that is otherwise to be discarded. To ensure generalizability of our findings, we will use keratinocytes isolated from three individual donors, and will employ three human MM cell lines: A375, SK-MEL-2, and C32, which are purchased from ATCC. ii) Generation of 3D organotypic human skin equivalents harboring MM cells: Our laboratory has recently developed an optimized 3D organotypic human skin equivalent co-culture system of primary epidermal keratinocytes, malignant melanoma cells, and normal stromal fibroblasts, using modified protocols established in previous studies. This model allows the study of metastatic melanoma cell invasion in an experimental setting that accurately mimics the human disease pathology. Briefly, organotypic raft cultures are created using BJ normal human fibroblasts (purchased from ATCC) suspended in Type I collagen plated into the bottom of six-well plates fitted with hanging inserts for two days, then seeded with primary human keratinocytes admixed with melanoma cells at specific ratios. Following keratinocytes and melanoma cells attachment to collagen-fibroblast plugs, the cultures are maintained at an air-liquid interface. Our optimized protocol allows formation of full-thickness 3D melanoma human skin equivalents within ten days after air-lifting the cultures. At this time point MM cells form invasive nests budding off the basal cell layer, reproducing in vivo behavior of metastatic melanoma. The shorter time course (ten days) is advantageous compared with longer protocols (up to 5 weeks) previously reported in the literature. iii) Analysis of melanoma cell invasion, proliferation, viability, and signaling: Functional characterization of the effects of the p38 isoforms knockdown in keratinocytes or melanocytes will be carried by quantitative assessment of MM invasion, proliferation, viability and signaling. We will employ Proteome Profiler Human Phospho-Kinase Array Kit (R&D systems) to for the parallel determination of the relative levels of protein kinase phosphorylation/activation in response to p38 isoform silencing in keratinocytes or melanoma cells. Statistical analysis will be conducted using GraphPad Prism software. Student’s t-tests are used to evaluate differences between groups with P<0.05 considered statistically significant. In summary, in the present proposal, we will use this 3D model of MM invasion as an effective tool to gain major insights into the understanding of the keratinocyte-melanoma cell interactions and cell-type specific signaling pathways that control MM cell dissemination. We will specifically focus on the isoform-specific contributions of the p38 MAPK family members expressed in keratinocytes and MM cells to the regulation of the invasive capacity of MM, and will elucidate the underlying mechanisms. The successful completion of the proposed studies will improve our understanding of the pathophysiology of malignant melanoma, which may help establish future translational research projects to design additional therapeutic strategies for treatment of patients with metastatic melanoma.

* 10. Describe the student's role in the project (200 word limit)

The student will design and perform the experiments outlined in this proposal, under the guidance and supervision provided by Dr. Efimova and Dr. Alexi Kiss, a Research Scientist in Dr. Efimova’s lab. The student will learn how to perform all the relevant techniques, including, but not limited to, the monolayer and 3D organotypic cell culture methods, siRNA-mediated knockdown methodology in keratinocytes and melanoma cells, immunoblot, immunohistochemistry, fluorescent microscopy, histomorphometric analyses, kinome profiling, etc., as needed for the assessment of the functional outcomes of targeting the p38 kinases on melanoma cell invasion, proliferation, survival, and the relevant signaling pathways. The student will be trained to carry out data analysis and preparation of the figures for presentation(s) and future manuscript, and will participate in weekly group meetings and regular individual meeting with Drs. Efimova and Kiss to assess his/her progress. To further enhance the translational appreciation of the proposed work and broaden his/her medical training, the selected student will have the opportunity to attend relevant basic science and clinical didactics offered by the Dermatology Residency Training Program as well as rotate one half day every other week in the MFA dermatology practice with Dr. Adam Friedman.

* 11. Describe the mentor's role in the project. (200 word limit)
Dr. Efimova has the expertise, leadership, training, and enthusiasm necessary to successfully serve as the mentor in the proposed project. She has a broad background in skin biology and mechanisms of skin neoplasia, and a long-standing interest in elucidating the cell type-specific roles of p38 isoforms in cutaneous carcinogenesis, using mouse models as well as human organotypic models of skin cancer development. Dr. Efimova will provide guidance and supervision to the student in designing and performing the studies outlined in the proposal. She will present the student with the literature pertinent to the project and challenge him/her to search the literature independently. Dr. Kiss, a Research Scientist in Dr. Efimova's laboratory who is an expert in 3D organotypic human skin equivalents technology and has an extensive experience with the methodologies to be employed in this project, will provide hands on training and directly oversee the student's performance. Dr. Efimova will involve the student in weekly group meeting as well as weekly individual meetings to assess his/her progress. Dr. Efimova has an open door policy and welcomes frequent informal interactions and discussions. Dr. Friedman will offer a valuable perspective regarding the potential translational and clinical relevance of the research findings.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

Current: Chapman Wei, 07/2019 - present, Pre-Doctoral Dermatology Research Fellow (MD expected May 2021), a recipient of the 2019 Washington DC Dermatologic Society Grant to conduct a research project in my lab

Previous: Ramsin Yadgar, summer of 2016
Stephanie Kao, summer of 2017, a 2017 Gill Fellow
Rose Milando, summer of 2018, a 2018 Gill Fellow
Emily Murphy, 07/2018 – 07/2019, Pre-Doctoral Dermatology Research Fellow, a recipient of the 2019 Washington DC Dermatologic Society Grant to conduct a research project in my lab
Samuel Yeroushalmi, summer of 2019, a recipient of 2019 Health Services Scholarship
Sarah Millan, summer of 2019, a recipient of the 2019 Dermatology Foundation Diversity Research Supplement Award

* 13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected No (Not Required)

Please specify why it is not required.

Our project does not require IRB, IBC, or IACUC approval, as it does not involve any human or animal subjects, nor does it involve recombinant DNA.
Faculty Proposal for MD Student Research by Julia Finkel

* 1. Faculty Sponsor

* Name: Julia Finkel
* Degrees: MD
* Title: Director of Pain Medicine Research
* Organization: Children's National Research Institute
* Address: 111 Michigan Ave. NW,
* Apt/Suite:
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* State: DC
* Zipcode: 20010
* Office Phone: 202-841-0362
* Email Address: jfinkel@childrensnational.org

* 2. Daily Supervisor

Name: Julia Finkel
Degrees: MD
Title: Director of Pain Medicine Research, SZI
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* 3. Project Title (250 character limit)

Developing a Method to Objectively Determine Pain Type

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:
Yes - Anesthesiology  
Yes - Pediatrics  
Yes - Pharmacology  
Yes - Neurology

* 6. Sponsor's translational level
* (Please select ONE)
T2: Translation to Patients

* 7. Hypotheses (200 word limit)
The overarching Aim of this proposal is to objectively measure the relative sensitivities of the three sensory nerve fiber types in order to define the presence and severity of a given pain phenotype. Specific Aim 1: To assess the fiber-specific impact of pain types on the neurostimulus evoked pupillary reflex dilation (nPRD). i. Hypothesis 1a: Acute post-operative pain will produce nPRD AUC that are significantly larger for the nociceptive fibers relative to the A beta fiber type. ii. Hypothesis 1b: Large fiber neuropathy and allodynia will produce significantly larger A Beta AUCs than small fibers. iii. Hypothesis 1c. There will not be a differential between the small and large fibers in chronic pain states (e.g., Sickle Cell Disease)

* 8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).
This pilot study develops a novel pupillary reflex, the nPRD to characterize a pain phenotype. The nPRD is being established as a physiologic biomarker of pain. By determining the type of pain, one can be more mechanistic and effective in its treatment. Once the nPRD is established as a pain biomarker, we will further develop it as a pharmacodynamic biomarker to monitor analgesic effect. The investigation presented here is to provide initial analytical validation. The primary measurable endpoint for Aim 2 are the relative changes in the AUCs of the three sensory nerve fiber types that exist in the various pain conditions being examined.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

This is a single center device study that monitors the pupil responses, indicating a nociceptive profile that will be used to characterize a pain phenotype. The device is the AlgometRx Nociometer that integrates non-painful, neurospecific neurostimulation with infrared pupillometry to produce a pupillary dilation. For Aim 1, the AlgometRx device will be used to assess the pupillary light reflex. The researcher will place the device over the patient’s eye; the device will flash a light and track the pupillary reaction using an infrared camera for 5 seconds. No more than 3 tries will be attempted until the successful reading is obtained. Successful readings are defined as the acquisition of 7 parameters (maximum pupil size, minimum pupil size, average constriction velocity, maximum constriction velocity, latency to constrict, average dilation velocity, and time to 75% recovery of initial pupil size). A second light reflex reading of the pupil during a continuous light stimulus will occur after this is complete. For Aim 2, the AlgometRx device will be used to assess the neurostimulus induced pupillary reflex dilation. A threshold
for the electrical stimulus level will be determined for each test subject. This will occur by measuring the pupillary response to a neurostimulus, starting at 50µA and increasing by 50µA until an nPRD appears that demonstrates a 20% increase in pupil size above the initial pupil size. Each sensory nerve fiber will be assessed for the stimulus intensity to be used at the frequency of stimulation that corresponds to their activation (5 Hz, 250 Hz, and 2000 Hz for C, Ad, and Aβ, respectively). This determination of intensity serves as the baseline nPRD measurement. After the baseline nPRD assessments, an analgesic intervention will be administered to the patient per their standard of care. After the intervention, PLR and nPRD measurements will occur at regular intervals. For low-dose infusions, once the infusion has been administered the study team will return every hour for the duration of the infusion, being approximately 5 hours. For intranasal analgesics, the testing will be completed before the analgesic administration and every 15 minutes for 90 minutes, or until the patient has been cleared to leave by the attending physician. For non-pharmacologic interventions such as acupuncture, measurements will occur twice at 15 minute intervals. The patient/parent is free to consent to multiple days of testing for as long as they are continuing to receive the intervention during their hospital stay. Pain scores will be recorded at every visit with the patient. Pain Diagnosis Sample Size Anticipated Weekly Estimate Seen by the CNMC Pain Clinic or on the inpatient Pain Service Acute post-operative 40 20 Chemo-induced peripheral neuropathy (CIPN) 20 9 Sickle Cell Disease 20 10 Complex Regional Pain Syndrome 20 5 Neonatal/Infant/ 20 5-10 (separate protocol) Peripheral neuropathies 20 6

* 10. Describe the student's role in the project (200 word limit)
The student would be directly involved in the recruitment, enrollment and data collection for this project. The student would be trained in the use of the devices associated with the protocol and be given the responsibility of recruiting participants from the patient population at CNMC. This would maximize the student’s contact with patients as well as their time spent working with other staff and physicians to identify potential participants. The student would work directly with study participants for the duration of the study and serve as their main point of contact with the research team. The student will also be involved in the processing and analyzing of data generated from this study and be a major contributor to this potentially revolutionary method.

* 11. Describe the mentor's role in the project. (200 word limit)
The mentor will facilitate and oversee the involvement of the student in the project. The mentor will ensure that the student is able to conduct research and interact with patients with some independence. This will not only serve to benefit the student but will also greatly benefit the development of this technology. In addition, the mentor will provide lectures on material pertinent to the technology which will serve as supplemental education for the student.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
In the past couple of years, this team has mentored medical students from GW and other schools. The students have participated in various capacities on numerous research projects. After conducting the research and analyzing the data, many have gone on to present their research. More specifically, this team has mentored three Gill Fellows (David Strum, Tess Whiteside and Christina Shincovich) who have gone on to present their research at GW Research Day as well.

* 13. Do you have or will you obtain IRB approval for this project? Please note: Students cannot begin a human subjects project without IRB approval.
* (Please select ONE)
Selected Yes

Please provide IRB number and date
* IRB Number: Pro00009586
* IRB Date: 8/11/2020 (extended yearly)
Faculty Proposal for MD Student Research by Sarah Frasure

* 1. Faculty Sponsor

* Name: Sarah Frasure
* Degrees: M.D.
* Title: Assistant Professor of Emergency Medicine
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* Zipcode: 20037
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* 2. Daily Supervisor

Name: Sarah Frasure
Degrees: M.D.
Title: Assistant Professor of Emergency Medicine
Organization: George Washington University Hospital
Address: 2120 L St
Apt/Suite: Suite #450
City: Washington, DC
State: District of Columbia
Zipcode: 20037
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* 3. Project Title (250 character limit)

An examination of the incidence of false positive and false negative point-of-care FAST (Focused Assessment with Sonography in Trauma) ultrasound imaging when compared to computed tomography (CT) imaging in trauma patients in a large urban academic emergency department

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


5. **Sponsor's Research Focus:**
Yes - Emergency Medicine

6. **Sponsor's translational level**
(Please select ONE)
T2: Translation to Patients

7. **Hypotheses (200 word limit)**
The majority of trauma patients undergo point-of-care ultrasound imaging in the emergency department to determine whether there is internal bleeding. The ultrasound examination includes an assessment of the heart, lungs, and abdomen. Residents perform the FAST exam (Focused Assessment with Sonography in Trauma) as the patient undergoes a comprehensive trauma evaluation. Unstable patients, or those in which the ultrasound reveals concern for internal bleeding, subsequently undergo computed tomography (CT) imaging to determine whether operative management is necessary. Occasionally there are false positive or false negative ultrasound findings when compared to the CT scan images. We wish to examine all false positive/false negative ultrasound scans performed in the emergency department over the course of one year to determine if medical/surgical management of patients was impacted and what might have led to the disparate findings.

8. **Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).**
Over the last year there were 31 true positive, 518 true negative, 5 false positive, and 15 false negative ultrasound images compared to CT findings in trauma patients in the emergency department. The student will complete a database which describes the false positive and false negative ultrasound images, the subsequent CT findings, and the ultimate medical/surgical management of the patient. We would like to determine the cause for the disparate ultrasound findings (for example, ascites is a well-described false positive sonographic result for internal bleeding) and whether patient care was impacted based on these findings. With the help of the mentor, the student will also put together a rough draft of the manuscript (introduction, methods, results, discussion) based on the findings after performing a literature review of similar publications.

9. **Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.**
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

1. Database completion of 5 FP and 15 FN ultrasound scans 2. Database completion of 20 CT reads for the above FN and FP ultrasound scans 3. Examination of patient records for outcomes, operative interventions, and final discharge diagnosis 4. Discussion with mentor and ultrasound division as to what might have accounted for each of these disparate sonographic results (poor scanning technique, ascites etc) 5. Help with manuscript writing by performing a literature review of similar publications and putting together a rough draft

10. **Describe the student's role in the project (200 word limit)**
The student will fill out a comprehensive database of trauma patients who underwent both point-of-care ultrasound imaging and CT imaging at George Washington University Hospital over the course of one year in the emergency department. The student will compare the false negative and false positive ultrasound findings to the CT read. The student will examine the patient’s medical record to record the ultimate medical or surgical management of these patients. Once we have collected the data and performed a statistical analysis, the student will aid in the manuscript preparation process.

* 11. Describe the mentor's role in the project. (200 word limit)

The mentor will help put together a database for the student to fill out. The mentor will teach the student how to use Qpath, an ultrasound workflow solution, which captures ultrasound images obtained in the emergency department. The mentor will teach the student how to use Cerner, the electronic medical record used by George Washington University Hospital. The mentor will teach the student how to read ultrasound images. If the student is interested, the mentor will also teach him/her how to perform point-of-care ultrasound applications including FAST exams, ECHOs, and lung ultrasound, in the emergency department. Finally, the mentor will help the student learn how to write a manuscript for publication.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

Prior Gill mentees for the Ultrasound Division at GWU: Jason Adler and Kristin Miller Gill fellows 2004 (Keith Boniface MD was the primary mentor) Audra Siegel 2011 (Hamid Shokoohi MD was the primary mentor)


* 13. Do you have or will you obtain IRB approval for this project?

Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected No (Pending)
Faculty Proposal for MD Student Research by Linda Fu

* 1. Faculty Sponsor

* Name: Linda Fu
* Degrees: MD, MS
* Title: Director of Academic Development, Goldberg Center
* Organization: Children's National Hospital
* Address: 111 Michigan Ave, NW
* Apt/Suite: 
* City: Washington
* State: DC
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* Office Phone: 202-476-3931
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* 2. Daily Supervisor

Name:
Degrees:
Title:
Organization:
Address:
Apt/Suite:
City:
State:
Zipcode:
Office Phone:
Email Address:

* 3. Project Title (250 character limit)

The Healthy Baby Bottoms Study: A Trial of Theraworx Spray-Foam Formulation for the Prevention and Treatment of Diaper Dermatitis

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.

5. Fu L, Zimet GD, Latkin CA, Joseph JG. Associations of trust and healthcare provider advice with HPV vaccine acceptance among African American parents. Vaccine. 2017; 35:802-807. PMID: 28063706; PMCID: PMC5290730

* 5. Sponsor's Research Focus:
Yes - Pediatrics

* 6. Sponsor's translational level
* (Please select ONE)
T3: Translation to Practice

* 7. Hypotheses (200 word limit)
Diaper dermatitis is one of the most common dermatologic diseases affecting infants and young children, and has been reported to affect 7-50% of infants. It is caused by skin exposure to a combination of excessive moisture, topical irritants, reduced pH, friction, maceration and bacterial infection. When infants soil their diaper, diaper contents saturate the area raising the pH of the skin leaving the area vulnerable to maceration from friction. Irritants in urine and feces are then able to penetrate the skin, causing inflammation and greater skin friability. An elevation in the skin pH allows pathogenic bacteria to overgrow, and can lead to bacterial infection. Theraworx is a skin protectant with use for temporary protection of minor cuts, scrapes, burns and chapped or cracked skin. As such, Theraworx may be beneficial for protecting skin against diaper rash wounds, and assisting with wound healing. The purpose of this study is to determine caregivers' perceptions of the benefits of using Theraworx Foam on their infant's diaper area as part of their hygienic routine, including whether they feel the product is pleasant and easy to use, and whether they feel it helps prevent and reduce the severity of diaper dermatitis in their infants.

* 8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).
Among a sample of 100 parent-child dyads, we will examine 2 outcome measures. Primary outcome measure: Caregiver's self-report of prevention of diaper dermatitis in infant. Determine whether caregivers perceive Theraworx Spray Foam to be superior to usual care for prevention of diaper dermatitis among infants 1-14 months old. Caregivers will track days with diaper rash (yes/no) and report this at the end of each week via online survey. Secondary outcome measure: Caregiver's self-report of treatment of diaper dermatitis in infant. Determine whether Theraworx Spray Foam is superior to usual care for reduction of severity of diaper dermatitis among infants 1-14 months old. On the days on which the infant has a diaper rash, caregivers will use a modified Diaper Dermatitis Scale to track the rash's characteristics, and report this at the end of each week via online survey.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

Potential participants will be initially identified when bringing their children to the Children's Health Center at Children's National for care. Study personnel will access electronic health records to identify potential participants based on the age of their child. Parents of children ages 1-12 months old will be approached for study participation in a private treatment room or in the waiting room. Potential participants will be told briefly that they may qualify to participate in a 7 week study to help determine the effectiveness of a new diaper rash product called Theraworx that is currently being used as a skin protectant and for wound care. They will be told that the study will involve using Theraworx with every diaper change for 4 weeks, and also answering 8 surveys starting with a baseline, in-person survey on the day of enrollment, followed by 7 weekly, online surveys. Those who are interested in learning more
about the study will be invited to conduct the screening process, and if applicable, the informed consent process. For those who meet eligibility requirements, study staff will obtain written informed consent, verbally administer the baseline, in-person survey. This survey will assess infant race/gender, diet, daily stool frequency, history of parental and sibling atopic dermatitis, frequency of diaper dermatitis, creams/products used in diaper area, and who is involved in changing diapers. It will also assess participant accuracy with rating visual severity of diaper rashes according to the modified Diaper Dermatitis Scale after being trained by staff. Lastly, participants will be asked to recall total number of days their infant had a diaper rash over the last 7 days, and if the number is greater than 0, to rate the rash using the modified Diaper Dermatitis Scale. Upon completion of the baseline survey, the participant will receive an incentive debit card which will be activated for the patient and charged with $10. The participant will be instructed to keep this card for the next 7 weeks to receive future incentive disbursements for completing the online surveys. There will be a 3 week run-in period starting just after enrollment during which time parents will be instructed to continue their usual diapering care, and to respond to the weekly survey requests. After completing the run-in period, parents will be sent via Fed-Ex a sufficient supply of Theraworx to last the 4 week duration of the trial period. Starting on the first Monday morning that falls at least 8 days from completion of the baseline, in-person survey and repeating each Monday morning for a total of 7 occurrences, a unique online survey link will be emailed to each participant. Weekly online surveys will assess whether the infant had any diaper dermatitis over the past 7 days, and if so, the total number of days with rash, and severity of rash on its worst day. It will also assess for any use of other products and adjuvant therapies, diarrheal illnesses, and new foods initiated.

* 10. Describe the student's role in the project (200 word limit)
The student will be involved in all aspects of the study including participant screening, obtaining informed consent, administering the verbal baseline survey, tracking participant follow-ups, contacting unresponsive participants, and sending online surveys and text message reminders for the surveys. The student may also participate in interim data analysis if desired. We do not anticipate being at a point in the study at which we will be writing up results. However, there are other ongoing studies on which the student could participate in drafting manuscripts if so desired. Also, the student is welcome to continue being active on the Healthy Baby Bottoms Study after the summer and contribute to eventual scholarly works, as well.

* 11. Describe the mentor's role in the project. (200 word limit)
The mentor will oversee all aspects of this research project and be primarily responsible for training the student. After training the student, the mentor will meet with the student at least weekly to problem solve as needed and track progress. The student will work directly with the research assistant on a daily basis.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
As director of academic development for all outpatient pediatrics at Children's National as well as director of research for the general academic pediatric fellowship, I have mentored faculty, fellows, residents, medical students, and undergraduates for over 15 years including dozens of medical students from GWU and Howard University. Most medical students I have worked with have had the opportunity to be co-authors on my publications. However, this generally requires a commitment beyond the Gill fellowship timeframe.

* 13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)
Selected Yes

Please provide IRB number and date

* IRB Number: 12239
Faculty Proposal for MD Student Research by Andrew Garrett

* **1. Faculty Sponsor**

* Name: Andrew Garrett  
* Degrees: MD, MPH, FAEMS, FAAP  
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* Office Phone: 2029940904  
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* **2. Daily Supervisor**

Name: same  
Degrees:  
Title:  
Organization:  
Address:  
Apt/Suite:  
City:  
State:  
Zipcode:  
Office Phone:  
Email Address: 

* **3. Project Title (250 character limit)**
Examining and mitigating the barriers to emergency medical services personnel for reporting for duty during a public health emergency

* **4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.**

* **5. Sponsor's Research Focus:**
Extensive research has determined that a significant percentage of the healthcare workforce may not report for duty during a serious public health emergency where they fear they could become sick, or where they could potentially infect a family member. This has the potential to negatively impact the health security of the community during a time of increased demand for health care service. Based on previous research in this area that has focused mostly on hospital-based healthcare providers (including my previous research), I suspect that there are consistent barriers that may prevent prehospital personnel such as EMTs and paramedics from reporting for duty during a serious public health emergency such as a pandemic or Ebola outbreak. These barriers are likely be amenable to mitigation.

**8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).**

Goal is to survey a large population of EMS providers (EMTs and Paramedics), likely from a single state or national-level organization of EMS professionals. Goals: 1. Assess a baseline "willingness to work score" (WTWS) for the EMS personnel when presented with a hypothetical scenario of a serious public health emergency affecting their community (e.g. imported case of Ebola or an influenza pandemic) 2. Determine the main barriers that EMS personnel face in making the determination to report for duty or not during a public health emergency that could involve the risk of infection 3. Based on the barrier reported, assess the effectiveness of potential interventions intended to mitigate the responder's willingness to report for duty, as determined by a reassessment of their WTWS after each proposed intervention. Interventions include options such as providing prioritized access to medical countermeasures or reimbursement for dependent care.

**9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.**

Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

We will use multiple methodologies- starting with a literature review, then a series of virtual focus groups or social media research to identify and validate the top barriers to reporting for duty in the setting of a hypothetical public health emergency such as a pandemic. Finally, a large scale internet-based survey tool (survey field to be determined) will be deployed to determine barriers to reporting for duty and the receptiveness of EMS personnel to accepting mitigation for these barriers, based on their responses. This methodology has already been used to assess a similar question in hospital-based healthcare personnel, and it was very effective in answering the research question.

**10. Describe the student's role in the project (200 word limit)**

A medical student can be an integral partner in this project. The student will complete an annotated literature review on this topic and will then assist with the study design and implementation, including preparation of an IRB application. They will also assist with the development of the online survey tool using SurveyMonkey or Google Forms. I can be extremely flexible with the scheduling and level of effort for the medical student. We will meet regularly on the progress of the project, and we can offer workspace for a few days a week in the Department of Clinical Research and Leadership offices if desired, or they can work remotely. The student would need to provide
their own laptop. I do not currently have funding for this position. I assure the student that anyone who works with me in any capacity on any project is included in the authorship for the publication.

* **11. Describe the mentor's role in the project. (200 word limit)**
I will be the P.I. and the mentor for the student. We will meet regularly to set goals and expectations and to check in on the progress of the project.

* **12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)**
I currently work with two students on projects related to EMS. The first is a project that is assessing the criteria used by different EMS jurisdictions to determine if a patient is a child vs. an adult, and to assess the potential impact of these highly variable and inconsistent criteria. The second project is assessing the use of social media as a tool to provide lifesaving information to the lay public during a mass casualty incident. No Gill Fellows...

* **13. Do you have or will you obtain IRB approval for this project?**
  **Please note:** Students cannot begin a human subjects project without IRB approval.
  * (Please select ONE)
  
  **Selected** No (Pending)
* 1. Faculty Sponsor

- Name: Andrew T. Goldstein
- Degrees: MD Clinical Professor, Obstetrics & Gynecology GWU Director, The Centers for Vulvovaginal Disorders
- Title: President
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- State: DC
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- Email Address: obstetrics@yahoo.com

* 2. Daily Supervisor

Name: Andrew Goldstein
Degrees: MD
Title:
Organization:
Address:
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City:
State:
Zipcode:
Office Phone:
Email Address:

* 3. Project Title (250 character limit)

A rapid, high-volume, cervical cancer see-and-treat program using self-sampling, HPV PCR testing, and digital colposcopy in Iquitos, Peru and Busoga Region, Uganda.

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.

Sovannara Thay, MD1, Andrew T. Goldstein, MD3,4, Lena S. Goldstein2, Vaishnavi Govind, MS3, Kruy Lim, MD1 Chanthou Seang, MD1 A Prospective Cohort Study Examining Cervical Cancer Screening Methods in HIV-positive and HIV-negative Cambodian Women: A Comparison of Human Papilloma Virus Testing, Visualization with Acetic Acid, and Digital Colposcopy. BMJ Open. 2019 Feb 24;9(2):e026887. doi: 10.1136/bmjopen-2018-026887


* 5. Sponsor's Research Focus:
   Yes - Cancer
   Yes - Obstetrics/Gynecology

* 6. Sponsor's translational level
   * (Please select ONE)
   T4: Translation to Population Health

* 7. Hypotheses (200 word limit)

This study will further demonstrate a cost-effective, rapid, mobile, economical, and practical strategy that can be used to screen-and-treat hundreds of millions women in resources poor countries for cervical cancer. HPV self-sampling facilitates high-volume screening. Specimens can be tested with new PCR-based testing systems. The AmpfireTM system to be used in this study is highly portable, simple to use, and can test 92 specimens in 65 minutes for US$4 per specimen. Digital colposcopy (DC) will then performed on high risk HPV+ women with a portable digital colposcope. DC doesn’t add significant time or cost to screening and may improve sensitivity and specificity (over VIA) as the high-resolution digital images can be greatly magnified to see changes consistent with CIN2+ lesions. Additionally, DC produces permanent images that can be used for documentation, quality control, and expert consultation. Additionally, these images will be used to test artificial intelligence algorithm that to be able to predict CIN2+ lesions.

* 8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).

We will screen-and-treat 2000 women in both Iquitos, Peru and Busogan, Uganda. The Peru project will be 10 days in middle of May 2020 and the Uganda project will be June 28th-July 7th, 2020. These two projects are part of a large project sponsored by the Gynecologic Cancers Research Foundation and the National Cancer Institute to develop a smart phone based artificial intelligence algorithm for high grade cervical dysplasia detection. Additional screening programs will occur in Vietnam, China, and Cameroon but will be occurring while the medical students are in classes. Approximately 15,000-20,000 women will be screened and images will be obtained from approximately 4,000-5,000 +hrHPV women. It is expected that 10% will have CIN2+ lesions.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.

Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research
Objective The goal of this study is to validate a rapid, high-volume, screen-and-treat, cervical cancer screening protocol that uses HPV self-sampling, HPV PCR testing, digital colposcopy, and automatic visual evaluation in 2000 women between 30-50 years of age in an 8 day period from June 29th – July 6th, 2020. Study Methodology Subject Selection: This study will use consecutive convenience sampling where subjects will be recruited non-randomly based on accessibility. All eligible subjects will be included, as they become available. Inclusion criteria: Women aged 30 to 50 years old who give consent to be included in the study. Exclusion criteria include women in the following categories: • Pregnant or thinks she might be pregnant • Unable to give informed consent • Seriously ill • Gross cervical mass • History of previous treatment for cervical cancer • Complete hysterectomy • Has had cervical cancer screening within the last 5 years Number of Subjects: This study aims to recruit a total of 2100 women in the Jinja District and Buyende District, Busoga Region Uganda and from surrounding rural areas. Study Period: An eight day period from June 29th – July 6th, 2020. Study Sites: Jinja Regional Referral Hospital, Buyende Health Center IV, Kidera Health Center IV Study Design: This study will use a screen-and-treat strategy to prevent cervical cancer in Ugandan women. The following will occur in the study: STUDY PART ONE, INITIAL SURVEY: • Informed consent, demographic information, and urine pregnancy test will be obtained. • A rapid test for HIV will also be offered. • Subjects will be instructed on how to obtain a sample for vaginal self-HPV testing and then obtain the sample. The results of the test should be available within 4 hours of collecting the specimen. All women will be asked to stay until their results are available. Lunch will be provided for women while they wait for results. • The self-collected samples will be analyzed with the AmpFire system (Atila). • All subjects who are high risk HPV positive (hrHPV+) will be informed of their results. • Digital cervicography (DC) and Automatic Visual Evaluation AVE will be performed on subjects who are hrHPV+ -If either the DC or AVE is positive for cervical abnormalities, a cervical biopsy will be performed. - If the DC is insufficient for evaluation (the entire transformation zone is not visualized, or lesion extends into the endocervix) then an endocervical curettage will be performed. - If the DC or AVE are positive, after the cervical biopsy has been performed, the subjects will be triaged into one of four treatment groups based on the severity of the lesion(s) visualized on the DC/AVE. Thermocoagulation will be performed on subjects with suspected CIN1 lesions. LEEP will be performed on subjects when the DC or AVE are suspicious for a CIN2+ lesions. Patients whose DC or AVE is suspicious for invasive carcinoma will be referred to Jinja Regional Referral Hospital for evaluation and treatment. Biopsies will be sent to the US for pathologic confirmation of dysplasia.

* 10. Describe the student's role in the project (200 word limit)
Student(s) will assist in teaching women to obtain self-swabs for HPV. Additionally, they will assist in management of the database of information obtained from the patients. Additionally, they can assist in testing the specimens with the mobile PCR system. They can observe the screen-and-treat process which will include colposcopy, thermo-coagulation and LEEP. Up their return, they can work with scientist at NCI as they interpret the pathology and digital images. They can help to prepare abstracts for presentation at the annual meeting of ASCCP.

* 11. Describe the mentor's role in the project. (200 word limit)
I am the team leader and will be bring a group of 6 doctors, additional volunteers and several students (both undergraduate and medical students). My team has done previous screening projects in Iquitos, Peru, Cambodia, and three very large scale cervical cancer screening projects in China. We have extensive experience with working with local NGOs to ethically provide high-quality care while obtaining that has been used to develop more cost-effective, high-volume, rapid screening strategies.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
I have worked with many undergraduate student in several programs including those sponsored by Timmy Global Health. Additionally, I have taken Ob/Gyn residents on my trips to Peru. I have not taken med students as of yet, but one med student from University of Texas will be coming to Peru. These screening programs are so high volume and fast paced that will be an incredible experience for any student interested in global medicine, infectious disease, or gynecology.
13. Do you have or will you obtain IRB approval for this project?

Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected Yes

Please provide IRB number and date

* IRB Number: pending

* IRB Date: pending
Faculty Proposal for MD Student Research by Karen Goodman

* 1. Faculty Sponsor

* Name: Karen Goodman
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* Title: Visiting Assistant Professor
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* 2. Daily Supervisor

Name:
Degrees:
Title:
Organization:
Address:
Apt/Suite:
City:
State:
Zipcode:
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* 3. Project Title (250 character limit)

Virtual Reality as a method to measure dose of vestibular rehabilitation

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:
Disorders of vestibular function result in dizziness, decreased balance, and increased fall risk. 20% of adults over the age of 60 report vestibular symptoms prompting medical attention, including vestibular rehabilitation, over a one-year period. A common exercise during vestibular rehabilitation targets adaptation of the Vestibular-Ocular Reflex (VOR). Exercises consist of visually fixating on a target while moving the head and/or the object on which the subject is fixating. To progress exercises, parameters are altered including visual background complexity, patient position, and duration. Many factors have limited the ability to determine the efficacy of treatment including poor measurement of exercise, compliance of subjects, and inability to control visual environment. This has limited quality studies, resulting in exercise prescription based largely on expert opinion. We aim to use a virtual reality device to deliver vestibular exercises, while using the device’s inbuilt sensors to accurately measure head movement, speed and duration. We will also assess compliance and dose of exercise required to reduce symptoms. Additionally, we aim to determine if performing exercises in a virtual reality environment will provide similar results to that of usual rehabilitation, and determine if exercises allow for the return of performance comparable to that of healthy controls.

Objective 1: To determine the optimal dose of vestibular exercises that are required to achieve clinical improvements in symptoms of dizziness and imbalance using a virtual reality headset. Measurements of dose will include duration, amplitude, speed, posture, and visual flow. Objective 2: To assess if outcomes of vestibular exercises using a virtual reality device are similar to that of usual physical therapy without using a virtual reality device. Objective 3: To determine if vestibular rehabilitation results in functional outcomes similar to healthy controls without vestibular function disorders for those performing usual physical therapy and those using a virtual reality headset to perform exercises.
rehabilitation or virtual reality (VR) group based on each of the following diagnostic categories: UVH, BVH, and post-Concussion. Therefore, there will be a total of three (3) usual rehabilitation and three (3) VR groups. Each of the three usual rehabilitation groups will perform usual physical therapy including a home VOR retraining exercise program without the use of the virtual reality headset. Subjects in the three VR groups will be asked to perform the same type of exercises as the usual rehabilitation group, but use a virtual reality device that will be issued to the patient for home use. Reassessment of all study measures will occur at weeks 4, 8, and 12 weeks for the vestibular dysfunction groups. These measures will be used to compare usual treatment to virtual reality treatment as well as compare performance to that of healthy controls. This study will allow improved recommendation of exercise dose in order to improve efficiency and efficacy of symptom reduction and elimination in individuals with vestibular dysfunction to allow them to return to near normal or normal vestibular function as compared to healthy controls. Results and findings from this research will be presented in peer reviewed publication and national presentation forum.

* 10. Describe the student’s role in the project (200 word limit)
The student will be responsible for recruitment of healthy controls. Students will screen and consent healthy individuals. The student will assist with assessment of healthy controls including administration of vestibulo-ocular assessments, balance and clinical functional outcome measures, surveys of subject satisfaction, and vestibulo-ocular reflex exercises. The student may also be responsible for screening, consenting, and assessing individuals with vestibular hypofunction.

* 11. Describe the mentor’s role in the project. (200 word limit)
The mentor will oversee training of the student for recruitment, screening, and consenting study participants. The mentor will also oversee training of the student in study specific assessment measures such as vestibulo-ocular assessments, balance and clinical functional outcome measures, surveys of subject satisfaction, and vestibulo-ocular reflex exercises. The mentor will oversee data collection and storage.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
N/A

* 13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.
* (Please select ONE)
Selected Yes

Please provide IRB number and date
* IRB Number: NCR180548
* IRB Date: 10/31/2019
Faculty Proposal for MD Student Research by Monika Goyal

* 1. Faculty Sponsor

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* 2. Daily Supervisor

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* 3. Project Title (250 character limit)
Sexually transmitted infections and medication adherence in the ED: Development of a mHealth intervention

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.

* 5. Sponsor's Research Focus:
Yes - Pediatrics
Yes - Infectious Disease
Yes - Emergency Medicine

* 6. Sponsor's translational level
* (Please select ONE)
T3: Translation to Practice

* 7. Hypotheses (200 word limit)
This qualitative study designed to understand adolescent attitudes towards the use of mobile health (mHealth) technologies for the delivery of sexual health information hypothesizes that adolescents will be useful in helping to inform the design of a text message based intervention to improve prescription fill rates and treatment adherence among adolescents diagnosed with sexually transmitted infections in the ED.

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
The overarching goal of this research study is to increase prescription fill rates and medication adherence through the development of a text message-based intervention for adolescents diagnosed with an STI and prescribed antibiotic treatment in the ED. The objectives focus on understanding attitudes towards mHealth for the delivery of sexual health information to inform the development of a text message-based intervention using semi-structured interviews with adolescents. Objectives 1a and 1b will help us understand adolescent attitudes towards mHealth and the objectives 2a and 2b will help us develop targeted messages to remind patients to pick up and take their medication as well as messages to address potential barriers. 1. mHealth attitudes: a. To understand adolescents’ attitudes toward mHealth for the delivery of sexual health information. b. To assess the acceptability and feasibility of a text messaging intervention to address prescription fill and medication adherence among adolescents diagnosed with a STI in the ED. 2. Text message development: a. To elicit feedback on the content of text messages developed by the research team. b. To explore how to best address barriers to prescription filling and medication adherence through text messaging.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

Although adolescents and young adults represent only 25% of the sexually active population, they account for nearly 50% of all new diagnosed STIs annually. Failure to diagnose and treat STIs in a timely manner can lead to pelvic inflammatory disease, ectopic pregnancy, infertility, and facilitation of human immunodeficiency virus (HIV) transmission. We recently found that less than 40% of our patients had filled their prescriptions for treatment of STIs. In addition, interviews with almost 20 adolescents who were diagnosed with STIs in our ED elicited the following barriers to treatment adherence: forgetfulness (88%), transportation (88%), cost (94%), and lack of insurance card (94%). Given our recent findings, we propose using mHealth technology to address this issue as nearly all teens have a smartphone and one-third send more than 100 text messages daily.
To thoughtfully develop a text messaging intervention, we need to understand adolescent attitudes toward the use of mHealth. In addition, their feedback on the text message content and design will be helpful to ensure the success of the intervention. Semi-structured one-on-one interviews will be conducted with 20-30 male and female adolescents aged 15-21 years in the ED. The interviews will allow the exploration of adolescent attitudes towards mHealth as well as their feedback of text message content. The activities include screening for eligible participants in the ED, conducting interviews, transcribing the audio-recorded interviews, comparing the audio-recorded interviews to the transcript for quality assurance, thematic data analysis, text message development, and end-user pilot testing of messages using a HIPAA-compliant text messaging platform. This is publishable research that will also lead to a larger intervention study on medication adherence and mHealth.

**10. Describe the student's role in the project (200 word limit)**
The student will participate in all the activities associated with this research study, including screening for participants in the ED, conducting interviews, transcribing interviews, conducting quality assurance, helping with data analysis, text message development, and pilot testing.

**11. Describe the mentor's role in the project. (200 word limit)**
Dr. Goyal and her team will oversee and lead all the research activities.

**12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)**
Since 2012 our mentoring team has had over 10 medical students participate in research, of those 4 students were Gill Fellows. The medical students engaged in a myriad of activities including medical record reviews, data entry using REDCap, phone interviews, literature reviews, in person surveys, and interviews. Three of our students have presented their research at national conferences and two of our students completed their projects including publications in JAMA Pediatrics, Journal of Adolescent Health and Pediatric Emergency Care.

**13. Do you have or will you obtain IRB approval for this project?**
Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

**Selected No (Pending)**
Faculty Proposal for MD Student Research by Andrea Gropman

* 1. Faculty Sponsor

* Name: Andrea Gropman
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* 2. Daily Supervisor

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* 3. Project Title (250 character limit)

Biomarkers of neurological injury in urea cycle disorders using multimodal imaging and EEG

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:
Yes - Pediatrics
Yes - Biochemistry
Yes - Neurology
Yes - Radiology

* 6. Sponsor's translational level
* (Please select ONE)
T2: Translation to Patients

* 7. Hypotheses (200 word limit)
Aim 1: To determine the prevalence, chronology, and natural history of Electrographic Seizures in patients with UCD. Hypothesis: We posit that ES are far more common than appreciated during acute HA and that improvement in, or resolution of, EEG abnormalities will reflect the resolution of HA effects on the brain. We further hypothesize that the onset of ES is associated with a rise in ammonia in the blood and may correlate with changes in the underlying brain anatomy and biochemistry (brain swelling and metabolic disturbance detectable by neuroimaging) that accompany HA. Aim 2: To correlate ES frequency, severity, duration and EEG background parameters with neurocognitive outcome. Hypothesis: We hypothesize that early ES and alterations in EEG background will impact cognitive outcome and alter neural circuitry and brain biochemistry as measured by standard cognitive battery and MRI respectively. We further hypothesize that UCD patients with HA.

* 8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).
Considerable evidence shows that HA compromises brain energy metabolism which predisposes the patient to seizures due to neuronal depolarization in association with lower energy. Thus, the significance of this study is the validation of electro-clinical biomarkers and outcome measures for clinical trials readiness, advancing diagnostic and prognostic models, and contribution to clinical care and treatment guidelines for HA. These studies aim to further stratify patients into subgroups in which a specific treatment might be effective. There are two components to the project. In the first, over 12 years of longitudinal study data on over 800 patients with urea cycle disorders will be mined for incidence/prevalence of seizures, types, treatments, correlation with ammonia levels, imaging and cognitive outcome. The second part is the prospective analysis of neonates with hyperammonemia using bedside video EEG, timed imaging including fNIRs and subsequent developmental assessments.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research
The data mining study is as described above. The student will work from a data set that has been mined by the study statisticians. The student will help define the search terms and variables for the search. We will also use a graph theory analysis to look at associations between seizures, type, ammonia level, structural imaging, MR spectroscopy, and cognitive testing/outcomes at one year out. For the prospective studies, all infants with hyperammonemia (HA) will be consented (parental consent) and placed on a bedside video EEG for 3 days to look for seizures, interburst interval, sleep state and transient discharges. Routine care such as checking plasma amino acids, ammonia, etc. will be done. Treatment of seizures will occur according to standard care. All subjects who have HA due to a diagnosed urea cycle disorder will remain on study and at 4 and 14 days will undergo MRI, MRS, and fNIRs. A repeat EEG will be done after the subject is seizure free for 24 hours. Repeat EEG, MRI battery and cognitive testing will be done at one month and one year follow up.

* 10. Describe the student's role in the project (200 word limit)

The student will work with the mentor and her associates to collect prospective data as outlined above, as well as be part of a team that will apply a machine learning approach to over 12 years of data collected on subjects with urea cycle disorders (and age matched controls). This will involve subject interviews and the student will be taught to administer several computer based neurocognitive assessments. The student will be introduced to neuroimaging and EEG analysis, but given the limited time, it will not be possible to teach the student how to run an MRI experiment. He/she will be able to observe such session, but will be able to screen and position the subject.

* 11. Describe the mentor's role in the project. (200 word limit)

The mentor will meet with the student at onset to set goals and priorities and to develop the project with the student's interests, experience and time frame. The last week will be reserved for the student to work with the mentor on a poster that will be submitted to either GW poster day or the CNMC research week and/or a national meeting. The mentor will meet weekly with the student. Additional opportunities to learn specific techniques from collaborators will be provided depending on scope of project. The student will also have the opportunity for clinical shadowing.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

This research team has had a Gill student almost every year since 2006. These students have produced posters that have been displayed at the GW poster day (one Gill student won a ribbon at this, and has since gone on to become a neurology fellow and attending in our division) as well as regional/national meetings. Several of the students were authors on publications emanating from the work.

* 13. Do you have or will you obtain IRB approval for this project?

Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected No (Pending)
Faculty Proposal for MD Student Research by Kaiane Habeshian

* 1. Faculty Sponsor

* Name: Kaiane Habeshian
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* 2. Daily Supervisor

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Email Address: akirkori@cnmc.org

* 3. Project Title (250 character limit)
Characterizing pediatric anogenital lichen sclerosis (LS), creating an activity scale to assess severity of disease and response to treatment of pediatric LS, and proposing standardized treatment guidelines for pediatric LS.

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.

* 5. Sponsor's Research Focus:
Pediatric anogenital lichen sclerosis (LS) is an autoimmune disease that can lead to pain, constipation, permanent scarring, and effacement of normal anogenital anatomy, leading to psychosexual dysfunction and difficulty with child bearing. It is also a risk factor for anogenital squamous cell carcinoma, which can be fatal. The natural history, risk factors, and optimal treatment is of LS is poorly characterized, especially in non-Caucasian patients. In the vulvar dermatology-gynecology joint clinic at Children's National in DC, patients of Ethiopian descent seem to represent a disproportionate number of patients with LS, which has not been reported or explored in the literature. Based on experience in the vulvar dermatology clinic, sub-optimal hygiene seems to be a contributing factor to the development of pediatric LS, but hygiene recommendations for the anogenital region vary among primary care providers. The degree of activity in LS can be difficult to assess clinically, and there is no published pediatric LS activity scale. Adult scales for LS activity are not applicable to pediatric patients, as their anogenital anatomy is different, which poses a challenge in monitoring response to treatment. The treatment of LS varies across pediatricians, dermatologists, and gynecologists.

**8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).**

- Review approximately 200 charts from patients seen in the vulvar dermatology clinic at Children's National between 2015 and 2019.
- Characterize the demographics and diagnoses of the patients seen in this clinic, with a specific focus on LS.
- Explore whether certain ethnic populations living in the US are disproportionately affected by anogenital LS and identify contributing factors.
- Identify risk factors in general for pediatric LS, including relationship to hygiene practices.
- Develop an activity scale for pediatric LS to more accurately characterize severity of disease and monitor response to treatment.
- Develop a standardized treatment guideline for the treatment of LS.

**9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.**

Selection criteria include:

- The project design makes it likely that the objectives will be achieved.
- The project is likely to result in a report of interest to other scholars.
- The project fulfills discovery/original research.

The study will be retrospective chart review of data from approximately 200 patients seen in the Children's National vulvar dermatology clinic between 2015 and 2019. There are substantial knowledge gaps in pediatric LS, as identified above. Therefore, the potential for novel observations and ensuing publications is significant. It will be feasible to collect relevant data, perform data analysis, and note clinically meaningful trends within one summer. Natural history data will be the root of all future associated projects and publications. This data would serve as the root for the creation of high-impact clinical tools including 1) a novel pediatric LS activity scale and 2) pediatric LS treatment guidelines, the creation of which would influence the practice of primary care providers, gynecologists, and dermatologists alike.

**10. Describe the student's role in the project (200 word limit).**
The student will carry out a retrospective chart review and assist with the analysis of the data toward the objectives stated above. The student will draft and submit manuscripts associated with important clinical findings. In addition to a productive summer research experience, the student would be able to further their work as desired throughout medical school (and beyond) with our team.

* 11. Describe the mentor's role in the project. (200 word limit)

The mentor will provide pediatric dermatology expertise and guide the chart review, data analysis, and creation of manuscripts for publication. Children's National will provide assistance with biostatistics through the Center for Translational Research. In addition, the gynecologist staffing the vulvar dermatology clinic has significant clinical research experience and will contribute her experience in clinical research (first author listed below):

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

Dr. Habeshian is a new attending as of August 2019 (completed pediatric dermatology fellowship in July 2019), and this would be her first formal medical student mentoring opportunity. Dr. Kirkorian has served as Gill Fellowship mentor to a student with whom she has published 6 articles, as well as a Minority student mentor to a student from an outside institution.

* 13. Do you have or will you obtain IRB approval for this project?
**Please note:** Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected No (Pending)
Faculty Proposal for MD Student Research by Andrea Hahn

* 1. Faculty Sponsor

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* 2. Daily Supervisor

Name: Andrea Hahn

* 3. Project Title (250 character limit)

Impact of Empiric Antibiotic Algorithm for Cystic Fibrosis Pulmonary Exacerbations on Antibiotic Spectrum and Clinical Outcomes

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:
  Yes - Pediatrics
  Yes - Infectious Disease
  Yes - Pulmonology

* 6. Sponsor's translational level
* (Please select ONE)
  T3: Translation to Practice

* 7. Hypotheses (200 word limit)

Cystic fibrosis (CF) is an autosomal recessive disease that affects more than 30,000 people in the United States. Pulmonary disease remains the major morbidity, with recurrent episodes of lung infection and inflammation called pulmonary exacerbations (PEx) that require treatment with antibiotic therapy. Pseudomonas aeruginosa is one of the most common bacteria to cause PEx events, and national consensus guidelines support ceftazidime and tobramycin as the mainstay of therapy for P. aeruginosa infection. While P. aeruginosa can develop antibiotic resistance with repeated antibiotic exposures, the current literature does not support frequent use of broad spectrum antibiotics. At our institution, we found a wide array of antibiotics being chosen to treat PEx, and currently there are no PEx guidelines on optimal antibiotic selection. The pulmonary and infectious disease divisions, in conjunction with pharmacy, developed an empiric antibiotic algorithm as a quality improvement project to support best practices in prescribing empiric antibiotic therapy for PEx events. Hypothesis: We hypothesize that the initiation of an empiric antibiotic algorithm for the treatment of CF PEx events will lead to a reduction in broad-spectrum antibiotic use and no worsening in lung function recovery compared to treated PEx events before initiation of the empiric antibiotic algorithm.

* 8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).

This study will assess the use of broad spectrum antimicrobials for inpatient treatment of a CF PEx. The primary outcome measure will be comparing broad spectrum antibiotic use (specifically meropenem and piperacillin-tazobactam) one year preceding and one year following implementation of an empiric antibiotic algorithm for treatment of inpatient CF PEx events. Secondary outcome measures will include 1) the proportion of patients who had improved percent predicted forced expiratory volume in one second (FEV1) within 90% of their best in the preceding 6 months at the end of antibiotic therapy, 2) length of hospital stay, and 3) acute kidney injury. Process metrics that would be measured would include 1) the proportion of patients that received an Infectious Disease consult and 2) the proportion of patients whose empiric antibiotic choices were consistent with the empiric antibiotic algorithm. Balancing measures would include 1) readmission to the hospital within 30 days and 2) proportion of patients who received > 14 days of antibiotic therapy (as a proxy of treatment failure).
9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.

Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

This study will be a retrospective chart review utilizing an existing REDCap data repository that contains demographics and clinical features (including antibiotics used, microbiologic data, and pulmonary function outcomes) of 120 patients with CF who are cared for at Children’s National Hospital. Study participant enrollment and data collection for this repository began in 2015. An empiric antibiotic algorithm for inpatient treatment of PEx events was published in Lexicomp (the hospital’s main formulary) in July 2018. Data will be extracted from the REDCap database for the 75 PEx events treated with IV antibiotics that occurred from July 2017 – July 2018 as the PRE group and 75 pulmonary exacerbations treated with IV antibiotics that occurred from July 2018 – July 2019 as the POST group. Inclusion criteria will be initiation of IV antibiotics for a PEx during a hospital admission. Exclusion criteria will include those treated with IV antibiotics as an outpatient, those who received IV antibiotics for an indication besides PEx (e.g. prior to sinus surgery), or those who received antibiotics for an organism not included on the empiric antibiotic algorithm (e.g., nontuberculous mycobacteria or fungi). Data that will be utilized in this study includes the following: 1) antibiotics used for each PEx, 2) microbiologic data during the PEx and the preceding 6 months, 3) pulmonary function testing during the PEx and treatment period and the preceding 6 months, 4) length of hospital stay, 5) length of antibiotic therapy, 6) serum creatinine during the PEx and treatment period, and 7) the occurrence of hospital readmission within 30 days of completing antibiotic therapy. The primary outcome measure (use of broad spectrum antibiotic therapy) will be compared using a bi-monthly statistical process control (SPC) chart. The use of other antibiotics for treatment of PEx will also be visualized using an SPC chart. Secondary outcome measures, process metrics, and balancing measures will be compared using generalized estimated equations to account for the potential of repeated exacerbations within patients. For dichotomous outcomes, we will assume the binomial family and the log link function. For continuous outcomes, we will assume the Gaussian family and the identity link. We will also use robust variance estimators due to the small sample sizes.

10. Describe the student's role in the project (200 word limit)

The student will be responsible for verifying the data collected as part of the data repository by cross-checking results with the patient’s electronic medical record (EMR) and collecting data not previously obtained. The student will also determine whether the antibiotic course received was in accordance with the empiric antibiotic algorithm. As the algorithm is based on the patient’s prior culture and susceptibility results, this will require both review and interpretation of the data. As this project is human subjects research, the student will need to complete CITI training and REDCap training prior to the project start date. At the end of the project, the student would be expected to present the research findings to the ID division and submit an abstract for GWU and CNH Research Days. The student would also be included as an author on any manuscripts published with the data from this project. The skills and knowledge gained from this experience will include an understanding of cystic fibrosis disease and management, common statistical analyses methods used in quality improvement and scientific research, and scientific presentation and writing skills.

11. Describe the mentor's role in the project. (200 word limit)

The mentor has already obtained IRB approval for this project and has collected the majority of the data for the 150 pulmonary exacerbations eligible for study inclusion. After the student is added as a study staff, the mentor will guide the student through the REDCap database and the EMR system so the student can determine eligibility, verify data, and collect any missing data. The mentor will also teach the student how to interpret the empiric antibiotic algorithm so the student can determine if the antibiotics selected were in line with the protocol. The mentor will be available on site to assist the student with any questions, and will set up a weekly meeting during the 8 week project to discuss the student’s progress.
12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

I have mentored two Gill Fellows (summer 2015 and summer 2016) and another medical student who received a G.E.R.M. (Grants for Emerging Researchers/Clinicians Mentorship) award from the Infectious Disease Society of America (summer 2019). The first student presented a research poster at GW and CNH Research Days, and was second author on a published research manuscript. The second student presented posters at GW and CNH Research Days, as well as at the American Thoracic Society International Meeting. She was second author on one published research manuscripts and middle author on a second manuscript. The third student has submitted an abstract for the American Thoracic Society International Meeting, will submit abstracts for GW and CNH Research Days, and will be first author on the submitted manuscript.

13. Do you have or will you obtain IRB approval for this project?

Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected Yes

Please provide IRB number and date

* IRB Number: Pro0006781

* IRB Date: 12/8/2015
Faculty Proposal for MD Student Research by Rana Hamdy

* 1. Faculty Sponsor

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* 2. Daily Supervisor

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Title: Assistant Professor of Pediatrics
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Zipcode:
Office Phone:
Email Address:

* 3. Project Title (250 character limit)
Temporal Trends in the Treatment of Acute Otitis Media in the Primary Care Setting: Implications for Antimicrobial Stewardship

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:
Yes - Pediatrics
Yes - Pharmacology
Yes - Infectious Disease

* 6. Sponsor's translational level
* (Please select ONE)
T3: Translation to Practice

* 7. Hypotheses (200 word limit)
We hypothesize that we will see an increasing trend of prescribing intramuscular ceftriaxone over time, and that children < age 2 years and those with concurrent conjunctivitis will be more likely to receive intramuscular ceftriaxone for treatment of acute otitis media.

* 8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).
Through this project, the student will receive training and learn skills in clinical research and apply them to this clinical epidemiologic research study. Measurable objectives include: 1) Completion of research ethics curriculum (CITI training; 1-2 days) 2) Completion of database training (REDCap training 1-2 days) 3) Completion of training on review of the medical literature (with PI and/or medical librarian; 1 day) 4) Completion of a literature review on the subject (3-4 days) 5) Completion of training for using the electronic health record system at Children’s National (1-2 days) 6) Data collection through chart reviews (approximately 150 charts; 4-5 weeks) 7) Data analysis of completed charts reviewed (1 week) 8) Presentation of project to research team at conclusion of fellowship

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

Background: Acute otitis media is the most common indication for antibiotics in the pediatric ambulatory setting. Watchful waiting without antibiotics is recommended for children > 2 years old without severe disease. When antibiotics are indicated, the first line recommended antibiotic treatment for children with acute otitis media is high-dose amoxicillin. This antibiotic choice targets Streptococcus pneumoniae, which is the most common bacteria causing acute otitis media. If the child does not clinically improve with high-dose amoxicillin, then broadening of therapy to include amoxicillin-clavulanic acid is recommended. This is primarily to cover additional bacteria such as Haemophilus influenzae and Moraxella catarrhalis, the second and third most common bacteria causing acute otitis media. In cases of treatment failure with amoxicillin-clavulanic acid, treatment with intramuscular ceftriaxone is recommended. Anecdotally, primary care pediatricians at Children's National have noted an increase in frequency of treatment failure due to amoxicillin-clavulanic acid. If this observation is verified, possible explanations include increasing resistance of Streptococcus pneumoniae and/or Haemophilus influenzae to amoxicillin-clavulanic acid.

Study Objectives: The objectives of this study are to: (1) describe the temporal trends of antibiotic treatment of acute otitis media in the primary care setting, and (2) determine the risk factors associated with treating acute otitis
media with intramuscular ceftriaxone. Study Design: This is a single-center retrospective cohort study of children with acute otitis media. We will identify children with acute otitis media seen at the Children's National CP&A Foggy Bottom practice between 1/1/2018 and 12/31/2019. Demographic, clinical, and treatment data have been extracted from the electronic medical record. The student's role will be to collect data on additional clinical variables through structured manual chart review and to clean and analyze the data. The student’s role in the study and timeline will be as follows: 1) Completion of research ethics curriculum (CITI training; 1-2 days) 2) Completion of database training (REDCap training 1-2 days) 3) Completion of training on review of the medical literature (with a medical librarian; 1 day) 4) Completion of a literature review on the subject (3-4 days) 5) Completion of training for using the electronic health record system at the Children's National primary care practices (1-2 days) 6) Data collection through chart reviews (approximately 4-5 weeks) 7) Data cleaning and analysis of completed charts reviewed (1 week) 8) Presentation of project to research team at conclusion of fellowship

* 10. Describe the student's role in the project (200 word limit)
The student will meet with the principal investigator (PI) to design a curriculum covering basic concepts of clinical research throughout the summer, including research ethics, literature review, database development and management, data collection, and data analysis. The student’s primary role in this study will be data collection, data management, and data analysis. Greater involvement in different roles would be considered given the student’s time and interest. The student will be expected to present his or her work to the multidisciplinary research team at the conclusion of the summer. Additional structured training to be included in the summer curriculum includes: a) training in research ethics through the CITI training course, b) in-person training in database development using REDCap, and c) one-on-one training in literature review with the PI and/or a medical librarian.

* 11. Describe the mentor's role in the project. (200 word limit)
Dr. Hamdy will meet with the student for 1-2 hours per day during the first week to develop a schedule for the next eight weeks, to discuss the study and clarify the student's role and expectations. During the remaining 7 weeks, Dr. Hamdy will meet with the student during scheduled times approximately 3-4 hours per week, and will be available to answer any questions that arise in the interim. The student will have access to office space at Children's National, where Dr. Hamdy has her office space. Dr. Hamdy will be accessible during times that she is not on clinical service and will be available to answer any questions that arise.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
1. Marissa Hennelly; MD Candidate, George Washington University School of Medicine and Health Sciences, Class of 2020. o 2017 W.T. Gill Summer Fellowship from GWSMHS for this work o Awarded the 2017 IDSA Medical Scholars Award for this work o Third place award for best oral poster presentation at GW Research Day, April 2018 o First author poster presentation at the 2018 Pediatric Academic Societies Annual Meeting in Toronto, Canada, May 2018 2. Hannah Chase, MD Candidate, George Washington University School of Medicine, Class of 2021. o 2018 W.T. Gill Summer Fellowship o First author poster presentation at the 2019 Pediatric Academic Societies Annual Meeting in Baltimore, Maryland, May 2019 3. Meghna Sharma, MD Candidate, George Washington University School of Medicine, Class of 2022. o 2019 W.T. Gill Summer Fellowship from GWSMHS for this work o First author poster presentation at the 2019 Infectious Diseases Society of America annual conference (IDWeek) in Washington, DC, October 2019. 4. Nina Hu, MD Candidate, George Washington University School of Medicine, Class of 2022. o 2019 Health Services Scholarship Award o First author abstract being prepared for submission to Pediatric Academic Societies Annual Meeting, Philadelphia May 2020

* 13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.
* (Please select ONE)
Selected Yes
Please provide IRB number and date

* IRB Number: Pro00013061

* IRB Date: 9/18/19
Faculty Proposal for MD Student Research by Eugenie Heitmiller

* 1. Faculty Sponsor

<table>
<thead>
<tr>
<th>Name</th>
<th>Eugenie Heitmiller</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degrees</td>
<td>MD</td>
</tr>
<tr>
<td>Title</td>
<td>Professor and Chief, Anesthesiology, Pain and Perioperative Medicine</td>
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<tr>
<td>Organization</td>
<td>Children's National</td>
</tr>
<tr>
<td>Address</td>
<td>111 Michigan Ave NW</td>
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<tr>
<td>City</td>
<td>Washington</td>
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<td>State</td>
<td>DC</td>
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<tr>
<td>Zipcode</td>
<td>20010</td>
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<tr>
<td>Office Phone</td>
<td>202-476-2025</td>
</tr>
<tr>
<td>Email Address</td>
<td><a href="mailto:eheitmil@childrensnational.org">eheitmil@childrensnational.org</a></td>
</tr>
</tbody>
</table>

* 2. Daily Supervisor

Name:                    Eugenie Heitmiller
Degrees:                 MD
Title:                   Professor and Chief, Anesthesiology, Pain and Perioperative Medicine
Organization:           Children's National
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Apt/Suite:              
City:                   Washington
State:                  DC
Zipcode:                20010
Office Phone:           202-476-2025
Email Address:          eheitmil@childrensnational.org

* 3. Project Title (250 character limit)
Reducing Perioperative Delays for Pediatric Surgical and Procedural Services

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.
5. Sponsor's Research Focus:
Yes - Anesthesiology
Yes - Pediatrics

6. Sponsor's translational level
*(Please select ONE)*
T3: Translation to Practice

7. Hypotheses (200 word limit)

Delayed start time for elective cases in the operating room and procedure areas is a significant source of discontent for health care teams, patients and their families. Delays result in increased stress for already worried families who have to wait with hungry children, longer fasting times for patients resulting in dehydration and even hypoglycemia, longer days that may result in stress on staff who have after-work obligations, and tension for those who have no role in the delay but must deal with unhappy families. Additionally, delays result in a greater cost to the institution in overtime pay. The reasons for delays are numerous. On a cursory review of the operating rooms at Children’s National, we found that nearly 50% of cases are delayed on a daily basis. Because perioperative personnel often have preconceived ideas of the reasons for delays, having independent, impartial data collectors not affiliated with the perioperative area prospectively collect delay information using standardized definitions will likely provide more objective observations. Our hypothesis is that if we collect detailed, accurate information on frequency and reasons for delays, we can then develop effective initiatives to reduce delays that will be sustained over time.

8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).

The ultimate goal of this project is to reduce delay of cases in the operating room and procedural areas. In order to target the most impactful reasons for delays, we first need to collect accurate delay data, which is the primary goal of the current project and is the first phase of this larger quality improvement project. The data collected during this first phase (observation and discovery) will be used for the second phase (intervention design and implementation), which will involve a multidisciplinary task force of front-line staff and leadership to determine best processes to reduce delays and to implement those processes. During the third phase (study phase) of the project, we will examine the initiatives implemented and determine whether any process changes need to be revised. Because data will need to be collected throughout all phases of this project, this will be ongoing for at least a year. A secondary goal is developing a means to collect these data via download from the electronic record. Using data collected during this first phase, standardized metrics and times that most accurately identify delays and causes of delays will be used for ongoing data collection from Cerner and its surgical scheduling product.
9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.

Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

Operating room delays plague many hospitals. Although much has been written about operating room efficiency in adult hospitals, there is little published on this issue specifically for children’s hospitals. There are many differences in dealing with children and their families and how they are managed perioperatively when compared to adults. Accurately identifying the more common reasons for delays and developing initiatives to reduce them would be of interest to pediatric surgical services in general. Quality improvement (QI) initiatives have been shown to effectively improve processes and outcomes when applied to a pediatric otolaryngology surgical service (Verghese et al Pediatrics 2013;132; e219). Thus, we chose to use QI methodology in designing our project. A key driver was developed with the overall project aim of reducing operating room (OR) and Procedure Room (PR) case delays by 50% with a target date of January 2021. This project has three phases. During the first phase of observation and discovery, data will be collected over a 2-month period using standardized definitions, with the goal of 30 business days of data. Each day an OR/PA will be assigned as the data collection site. The data collection site will have at least three elective cases scheduled for the day. Time data to be collected are: 1. Patient arrives to the hospital 2. Patient arrives in Same Day Prep (SDP) 3. Times of completed assessments by various specialties in SDP ('Go Green' times). 4. Patient ready to leave SDP 5. Anesthesiologist arrives in SDP for patient pick-up 6. Patient leaves SDP for OR/PR 7. OR start or wheels into OR/PR (in-room time) 8. Anesthesia ready 9. Surgery start 10. Surgery end 11. Patient out of OR/PR 12. Arrival in Post Anesthesia Care Unit (PACU) 13. PACU nurse arrival to bedside 14. Anesthesia finish 15. Arrival of team in OR to set up for following case 16. OR/PR ready for next case

Additionally, detailed information on any delays between the first and last time point will be documented. Frequency of delays will be determined by the number of case delays divided by the total number of cases. The data collected during this first phase (observation and discovery) will then be used for the second phase (intervention design and implementation), which will involve a multidisciplinary task force of front-line staff and leadership to determine processes to reduce delays and to implement those processes. These initiatives will be implemented with the involvement of leadership to ensure staff realize their importance and urgency. During the third phase (study phase) of the project, we will examine the impact of the initiatives implemented and determine whether any of the process changes need to be revised. Data in tabular and graphical form will be shared with all staff so that they can see ongoing progress. Although data collection for phase one should be completed over approximately two months, data will need to be collected throughout all three phases of this project, so the QI project will be ongoing over the year for interested students.

10. Describe the student's role in the project (200 word limit)

The student will first be oriented to the perioperative area (Registration, Same Day Prep, Operating Room Suites and Procedure areas, Post Anesthesia Care Unit) and will be given access to these areas. A laptop computer will be assigned to the student for data collection that will be kept in a locked office when not in the student's possession. The student will need to be familiar with Microsoft Excel, where the data will be entered. The student will be assigned to an operating room or procedure room each day and will collect the information as listed in #9 above using standardized definitions as developed by the improvement team.

11. Describe the mentor's role in the project. (200 word limit)

The mentor will orient the student to the perioperative areas and educate the student on the standardized definitions of times and causes of delays and guide the student in collecting data. The mentor will also provide education on the development of quality improvement initiatives and how to measure success. The mentor will guide the student in analyzing the data and for the interested student, will show how to create a presentation for Children's National Perioperative Research Day 2020. An abstract of the data will be submitted at a national meeting, with the hopes of an eventual peer-reviewed publication. The mentor will meet with the student each day, whenever possible.
12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

Several medical students have been involved with research in Anesthesiology, Pain and Perioperative Medicine at Children's National. Most recently, Andrew Garcia was mentored by Dr. Claude Abdallah examining the effect of midazolam premedication on recovery and discharge times after adenotonsillectomy. Dr. Sophie Pestieau mentored Catherine Nagira, a Gill Medical Student, this past year on the project "Femoral Nerve Block with or without Sciatic Nerve Block for Analgesia after Pediatric Anterior Cruciate Ligament Repair: a Retrospective Review." Dr. Elisha Peterson is currently mentoring a medical student for clinical skills in our Chronic Pain Clinic.

13. Do you have or will you obtain IRB approval for this project? Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected No (Not Required)

Please specify why it is not required.

This research is only collecting times and causes of operating room and procedural delays and is considered nonhuman research.
Faculty Proposal for MD Student Research by Nobuyuki Ishibashi

* 1. Faculty Sponsor

Name: Nobuyuki Ishibashi
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* 2. Daily Supervisor

Name:
Degrees:
Title:
Organization:
Address:
Apt/Suite:
City:
State:
Zipcode:
Office Phone:
Email Address:

* 3. Project Title (250 character limit)
Optimizing neurodevelopmental outcomes in children with congenital heart disease (CHD)

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:
Yes - Pediatrics
Yes - Cardiology
Yes - Neurology
Yes - Surgery

* 6. Sponsor's translational level
* (Please select ONE)
T0/T1: Basic Science Discovery and Initial Translation to Humans

* 7. Hypotheses (200 word limit)

Hypothesis 1 (Project 1): Impaired generation and maturation of neural stem/progenitor cells due to developmental hypoxia are the underlying cellular mechanisms in the brain immaturity in patients with CHD. Hypothesis 2 (Project 2): Mesenchymal stromal cell (MSC) delivery to the early postnatal brain promotes endogenous regeneration of damaged neuronal and glia cells in children with CHD.

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).

Based on student’s interest and discussion with mentor team, the student will participate in one of two projects. Both projects are federally funded. Project 1: Following two goals are designed to test hypothesis 1. Goal 1: to determine the effect of developmental hypoxia on generation and maturation of neural stem/progenitor cells using immunohistochemistry. Goal 2: to determine the effect of developmental hypoxia on microstructural maturation of developing brain using clinically-relevant image biomarkers. Project 2: Following two goals are designed to test hypothesis 2. Goal 1: to determine the effect of MSC treatment on maturation of neuronal and glia cells using immunohistochemistry. Goal 2: to determine the effect of MSC treatment on microstructural maturation of developing brain using clinically-relevant image biomarkers.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.

Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

Significant neurodevelopmental delay is emerging as one the most important current challenges for patients with congenital heart disease (CHD). Clinical studies demonstrate that reduced oxygen delivery due to CHD in utero results in subnormal brain development. However, cellular mechanisms underlying delayed brain maturation in CHD remain poorly understood. Our previous studies have led to our first hypothesis to be tested by the proposed study (Project 1), namely that: Impaired generation, migration and maturation of neural stem/progenitor cells are the underlying cellular mechanisms resulting in the brain immaturity observed in patients with CHD. Neonatal piglets
will be placed in a hypoxia chamber to simulate the perinatal hypoxia that results from CHD and to test our first hypothesis. Our previous studies have demonstrated that structural alterations of the porcine brain due to this innovative experimental paradigm are very similar to those observed in newborns with CHD. The proposed studies will define crucial cellular mechanisms underlying the causes of brain immaturity in the neonate with CHD. The findings will assist decision-making regarding optimal timing and techniques of surgery. Newly-developed brain injury after cardiac surgery is also common in neonates whose brains are already immature at the time of surgery. However no treatment options are currently available for brain damage in children with CHD. Our previous findings have led to our second hypothesis (Project 2) that: MSC delivery to the early postnatal brain promotes endogenous regeneration of damaged neuronal and glia cells in children with CHD. Pediatric cardiac surgery provides a unique opportunity to control cerebral perfusion of the developing brain through cardiopulmonary bypass (CPB). We are proposing the use of CPB itself as a new MSC delivery system in the CHD population. Three goals will be immunohistologically determined using our unique piglet hypoxia and CPB model. The goal of the proposed project is to design novel cell-based therapy aimed at regenerating damaged neural and glia cells, and thereby to improve neurodevelopmental outcome in children with CHD. The proposed studies have the potential to identify and assess novel strategies to treat brain immaturity and brain injury, and define new standards of perinatal care in the patient with CHD. The resulting improved neurodevelopmental outcomes would be of enormous benefit to those individuals with CHD.

10. Describe the student's role in the project (200 word limit)

The program is intended to provide the highest quality experience for medical school students with a strong interest in pursuing careers as physician-scientists. To define hypoxia-induced alterations on the gyrencephalic brain and the effect of MSC delivery through CPB during CHD surgery, the student role will be focused on either immunohistochemical assay or MRI-based structural analysis of the developing brain in our clinically relevant experimental models. We offer students the opportunity to: 1) learn uniquely integrated research field in developmental neuroscience and pediatric cardiology/cardiac surgery; 2) gain experience in hands-on laboratory research; 3) interact with faculty, postdoctoral fellows, and other summer interns; 4) attend weekly luncheon/seminar presentations by members on specific research projects and cutting-edge research tools; and 5) improve presentation, writing, and communication skills. In partnership with Children's National Heart Institute, students can participate in weekly surgery case discussions and daily Cardiac ICU rounds to learn more about congenital heart disease. Our pediatric cardiac surgery team performs hundreds of cardiac surgeries. World-renowned, pediatric cardiac surgeon Richard Jonas, MD, is the co-director of the Heart Institute.

11. Describe the mentor's role in the project. (200 word limit)

The nature of Dr. Ishibashi’s training plan will entail multiple sessions, so that he/she can overcome the technical obstacles that are intrinsic to the study in the piglet brain. Daily supervisor - Drs. Leonetti, Maeda, Li, or Saric (Post-doc research associates in my lab) - and he/she will meet one-on-one before each experiment in order to establish the best experimental approach to be used and to determine how to avoid any difficulties that may naturally arise with the use of different samples. The training will be provided through multiple hands-on sessions at the time of actual analysis of samples and imaging data. Once he/she has acquired data, meetings with Dr. Ishibashi will be focused on data interpretation and building hypotheses relevant to our future study.

12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

**13. Do you have or will you obtain IRB approval for this project?**  
*Please note: Students cannot begin a human subjects project without IRB approval.*
* (Please select ONE)

**Selected** No (Not Required)

**Please specify why it is not required.**

All proposed projects are pre-clinical studies.
Faculty Proposal for MD Student Research by Rebecca Kaltman

* 1. Faculty Sponsor

* Name: Rebecca Kaltman
* Degrees: MD
* Title: Assistant Professor of Medicine
* Organization: Division of Hematology/Oncology
* Address: 2150 Pennsylvania Avenue
* Apt/Suite: Suite 1-100
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* State: DC
* Zipcode: 20037
* Office Phone: 202-741-2210
* Email Address: rkaltman@mfa.gwu.edu

* 2. Daily Supervisor

Name: Christiane Morecock
Degrees: BS Biology
Title: Research Assistant
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Address: 2150 Pennsylvania Avenue
Apt/Suite: 
City: Washington
State: DC
Zipcode: 20037
Office Phone: changing
Email Address: cmorecock@mfa.gwu.edu

* 3. Project Title (250 character limit)
The feasibility of incorporating telemedicine visits for breast cancer patients receiving active therapy

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.
**5. Sponsor’s Research Focus:**
Yes - Cancer

**6. Sponsor’s translational level**
* (Please select ONE)
T3: Translation to Practice

**7. Hypotheses (200 word limit)**
Hypothesis: Incorporating telemedicine visits into routine care for stable breast cancer patients receiving active therapy is a feasible means of providing breast cancer care. This feasibility study will provide crucial preliminary data in support of a larger-scale study to compare outcomes between in-person and virtual visits. This future project would include a larger number of participants, a control arm, and would seek to assess the impact of this intervention on patient adherence, patient and provider satisfaction, and provider reimbursement patterns. This project could also be expanded to include any solid tumor or hematologic malignancy. Such a project may also include the use of a chronic care health application and an assessment of any potential benefit from chronic care billing within the field of cancer care.

**8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).**
The primary objective of this study is to determine whether incorporating telemedicine visits for oncology patients receiving active therapy requiring regular surveillance is feasible. The secondary objectives are to 1) to obtain preliminary survey data for a future pilot study on the effects of telemedicine on patient and clinician satisfaction with the use of the Telehealth Usability Questionnaire (TUQ) and 2) compare reimbursement patterns of in-person to telemedicine visits.

**9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.**

Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

The study will enroll approximately 30 patients who are receiving breast oncology care at the George Washington Medical Faculty Associates. Once consented, participants will be provided with a set of instructions on how follow-up visits via Zoom, a HIPAA compliant video conferencing tool, will be conducted. Additionally, patients will be given an instruction guide on the proper methods to assess their vital signs with recommendations for a dependable thermometer, pulse oximeter and blood pressure cuff. A virtual office visit will be scheduled prior to leaving the in-person office visit. The Zoom application will be set up at the enrollment visit on the same day as consent, with the clinical research assistant. A care plan will be established for each type of new therapy. This care plan will include a particular frequency of in-person visits and virtual visits. The patient will be provided with an outline of their care plan at the time of their enrollment. Times and dates of virtual and in-person visits will be established. At the time of the first scheduled...
telemedicine appointment, the virtual visit will be initiated via Zoom with the patient, during which
the patient will use automated at-home tools to assess her/his vital signs and report them to the
provider. The provider will then review the patients’ symptoms and will make suggestions to
improve symptom management and review any modifications needed for the next part of the
planned therapy. To ensure that we create a user-friendly, practical, and billable virtual office visit,
we will utilize the GW Worldwide Emergency Communications Center’s (WECC) expertise and
resources. This includes telemedicine training for providers, video applications for consults and
existing infrastructure for documentation and billing. In-person clinic visits will alternate with up to
4 virtual visits. All visits will occur at varying increments depending on the patient’s specific
therapeutic regimen, generally every 2 to 4 weeks, and the patient will have the option to schedule
an in-person visit at any point if they feel it is necessary. Each session will consist of one
approximately 20-minute-long virtual office visit. No psychological tests, educational tests, nor
specimen collection will be performed as part of research. However, lab work or imaging may be
ordered and performed remotely as part of clinical care, if deemed medically necessary at the
conclusion of the virtual visit. With regard to patient satisfaction, patients will be asked to complete
two questionnaires: 1) The Pre-Study survey (TUQ + Pre-Study supplemental questions) in clinic
at their first in-person visit prior to their first telehealth visit, and 2) The Post-Study survey (TUQ +
Post-Study supplemental questions) in clinic at the in-person visit following their last virtual visit.
Pre-Study (13.4) and Post-Study (13.5 surveys to assess patient satisfaction will be distributed
through REDCap via password protected iPad.

* 10. Describe the student’s role in the project (200 word limit)
We are submitting the protocol to the Cancer Center's Protocol Review Committee within the next
week. Once through, estimated within a one month period, it will be sent on to the IRB. We
anticipate being able to start enrollment in the spring of 2020. The enrollment period will be a total
of 6 months. The summer student will get first hand experience working with the research staff to
identify patients appropriate for the study, perform proper informed consent, instruct patients on
using the telemedicine platform and vital sign instruments. He/she will also be administering the
surveys and learning how to collect data in RedCap. Due to the short period of enrollment, and
the fact that the protocol is about to be submitted now, this is a perfect opportunity for a student to
work on a project during the enrollment and data collection phase. It will also be completed in time
to be reported on for Research Days the following Spring 2021, if not sooner. We also hope to
submit an abstract on this work to the San Antonio Breast Cancer Symposium.

* 11. Describe the mentor's role in the project. (200 word limit)
I am the clinical and research attending that will serve as the student's mentor for the project. I am
already mentoring a 3rd year medical student on the project. My Cancer Genetics Program also
has a full-time research assistant working with us as well who is experienced with getting
investigator-initiated projects through the IRB and enrolling on other investigator initiated studies
that our group is currently running. I have a research meeting with our research students and staff
weekly to go over each project and assess any roadblocks. I also make myself available
throughout the week, as needed, to address any issues.

* 12. Describe the current and previous medical student training by your mentor team.
Indicate any Gill Fellows. (200 word limit)
We have had several students working with my research team, many who are represented on the publications posted above. Amy Marino Anja Frost Dustin Marks, Gill Fellow Sarit Toltzis Kipnis, Gill Fellow Nicole Casasanta, KACIF Grant recipient, who won the William H Beaumont Society first prize for medical student research for Research Days 2018 based on her work on our project looking at the relationship between hereditary cancer syndromes and Oncotype DX Recurrence Score in breast cancer patients.

* 13. Do you have or will you obtain IRB approval for this project?
**Please note:** Students cannot begin a human subjects project without IRB approval.
* (Please select ONE)
  **Selected** No (Pending)
* 1. Faculty Sponsor

* Name: Brandon Kohrt
* Degrees: MD, PhD
* Title: Charles and Sonia Akman Professor of Global Psychiatry
* Organization: Department of Psychiatry
* Address: 2120 L St NW
* Apt/Suite: 600
* City: Washington
* State: DC
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* Office Phone: 4048951643
* Email Address: bkohrt@gwu.edu

* 2. Daily Supervisor

Name: same as above
Degrees:
Title:
Organization:
Address:
Apt/Suite:
City:
State:
Zipcode:
Office Phone:
Email Address:

* 3. Project Title (250 character limit)

Reducing Stigma among Healthcare Providers to Improve Mental Health: A Cluster Randomized Controlled Trial in Rural Nepal (RESHAPE)

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


5. Sponsor's Research Focus:
Yes - Psychiatry

6. Sponsor's translational level
(Please select ONE)
T3: Translation to Practice

7. Hypotheses (200 word limit)
Aim 1 – To evaluate the impact of the RESHAPE service user engagement on stigma among primary care workers. Hypothesis: Primary care workers in the RESHAPE arm will have less stigma toward persons with mental illness (measured with the Social Distance Scale) three months after training compared with primary care workers in the standard training. Aim 2 – To evaluate the impact of the RESHAPE training on accuracy (sensitivity and specificity) of detection, as measured by the proportion of true positive and true negative diagnoses among patients presenting to primary care facilities, as confirmed by a psychiatrist’s structured clinical interview; and to evaluate stigma as a mediator of differences in accuracy. Hypothesis: Primary care workers in the RESHAPE arm will have greater accuracy of detecting mental illness. Secondary analyses: We will evaluate the implementation arm differences in patient quality-adjusted life years and cost-utility.

8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
A barrier to accurate detection of mental illness is stigma among primary care workers against persons with mental illness. We will conduct a cluster randomized controlled trial to evaluate the impact of service user engagement on stigma among primary care workers, and the health systems impact on accuracy of detection of mental illness in primary care. Successful completion of this study will contribute to the NIMH Strategic Plan employing implementation science to maximize the public health impact of research and involve service users to improve accuracy of mental illness detection in primary care settings. The study will be conducted in 18 municipalities in Nepal, this will include 54 health facilities, 270 health workers, 11,664 patients screened, and 2,900 patients evaluated for mental illness.

9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research
The research involves a cluster randomized controlled trial to improve training for primary care providers on mental health providers. This study will compare training as usual to a training intervention that involves narratives from former recipients of mental health care from primary care providers (referred to as service users). For the training intervention, service users will be trained on how to construct a photovoice narrative (photography training, the confidentiality of photos, and narrative construction) and be asked to create a photovoice story of their personal experiences. These photovoice stories will then be shared by the service user with service providers during the training. Training as usual, is standard WHO mhGAP training with didactics on diagnosis and treatment of mental disorders. (See mhGAP manual for additional details) RESHAPE training includes the mhGAP didactics as well as testimonials from service users about living with mental illness. Service users use photographs in addition to their in-person presentation. They take their photographs during photovoice training. Photovoice training is approximately 10 sessions structured around photography and storytelling techniques. (See RESHAPE manual for additional details). The service users are patients who are in recovery from a mental illness. Before confirming the service user's participation, a research study psychiatrist will administer a clinician-administered assessment scale along with a functionality test to ensure service user recovery and adequate functionality for participation in the research study. Patient Participant Follow-up Assessments: 3-month and 6-month follow-up assessments will occur with patient participants who have been identified by the health worker as having a heart-mind problem, if they score above a cut-off in PHQ-9, AUDIT, WHODAS, and PANSS questionnaires, and are among 10% of patients chosen for the 3-month follow-up, and subsequently a 6-month follow-up. Only participants invited in the 3-month follow-up will be invited for the 6-month follow-up but not all 3-month invitees will participate at 6 months. We will only invite those participants who have received the correct diagnosis and treatment by their health worker. The purpose of the 6-month evaluation is to measure the benefit of the primary care worker mental health treatment. If the primary care worker treatment is incorrect in 3-month, the treatment will be changed so we will drop the patients with psychiatrist corrected treatment from the 6-month evaluation. In addition, 2 participants from each health facility will be randomly chosen for 2 interviews about their treatment experience. These interviews will occur with a research team member at the beginning of the study and at 6 months. Training outcomes will be evaluated using quantitative methods and qualitative methods.

* 10. Describe the student's role in the project (200 word limit)

The student will be primarily involved in qualitative and quantitative data analysis, based on the level of expertise and interest. This involves data cleaning, coding, and analysis. The student will work with a diverse team of researchers from London, Nepal, and the US to contribute to the research implementation in a global health setting. Besides data analysis, s/he will attend weekly meetings and engage in designing training materials to assist the GW-based team. Finally, the student will be involved in manuscript writing and will have an opportunity to publish papers given his/her interest and contribution to the project.

* 11. Describe the mentor's role in the project. (200 word limit)

GW is the prime recipient of federal funds for this research and the role of the mentor is to a) fund the research activities via sub-award TPO Nepal, and b) receive de-identified data from data collection activities in Nepal, as well as identified photos and videos generated as part of the development of the training materials. The mentor will supervise and train data collectors in Nepal, but all data collection activities are carried out in Nepal. Supervision of data collection includes a) data quality checks using de-identified data b) monitoring recruitment and enrollment statistics using de-identified data c) monitoring adverse event reporting and response using de-identified data d) receive training photos and videos and help design the training using those materials. Training of data collection personnel will involve mixed qualitative and quantitative training covering a) ethics b)informed consent c) data collection procedures, and d) blinding procedures. The mentor will also lead the qualitative and quantitative data analysis and manuscript writing.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

I have worked with numerous medical students previously while at the Duke Global Health Institute. Medical students spent 5 months in Nepal conducting research and working with the local Nepal research team.
13. Do you have or will you obtain IRB approval for this project?

* Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected Yes

Please provide IRB number and date

* IRB Number: NCR191416

* IRB Date: 8/11/2020
Faculty Proposal for MD Student Research by Ioannis Koutroulis

* 1. Faculty Sponsor

<table>
<thead>
<tr>
<th>Name</th>
<th>Ioannis Koutroulis</th>
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<tbody>
<tr>
<td>Degrees</td>
<td>MD, PhD, MBA</td>
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<tr>
<td>Title</td>
<td>Assistant Professor/Attending physician</td>
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* 2. Daily Supervisor

<table>
<thead>
<tr>
<th>Name</th>
<th>Claire Hoptay</th>
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<tbody>
<tr>
<td>Degrees</td>
<td>PhD</td>
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<td>Title</td>
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* 3. Project Title (250 character limit)

The use of extracellular vesicles in sepsis

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:
Yes - Genomics
Yes - Pediatrics
Yes - Emergency Medicine

* 6. Sponsor's translational level
* (Please select ONE)
T0/T1: Basic Science Discovery and Initial Translation to Humans

* 7. Hypotheses (200 word limit)
We hypothesized that extracellular vesicles will decrease inflammation and mortality rate in septic mice

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
We will use 15-20 mice that will be made septic and then treated with a dose of extracellular vesicles. Mortality rates as well as inflammatory markers will be measured to assess efficacy.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

Mice will become septic with silecal slurry injections using a standardized scoring system/protocol. They will then be injected with a dose of extracellular vesicles and scored q2-4h for sepsis signs until euthanized. A survival curve will be analyzed and measurement of inflammatory markers (interleukins) will allow us to assess changes in inflammatory response and mortality rate.

* 10. Describe the student's role in the project (200 word limit)
The student will participate in all lab activities including lab meetings and will be responsible to present an article in journal club. He/she will work with lab members in experimental techniques and sample handling.

* 11. Describe the mentor's role in the project. (200 word limit)
I will personally supervise the student in all experiments. We will meet at the beginning of his/her time here to discuss about the details, orient him/her in the lab and identify the focus areas. I will also teach the student all the necessary techniques to complete experiments and how to perform a literature review and critique a paper. There will be a formal meeting/evaluation at the end of the rotation.
12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

The Freishtat lab within the Center of Genetic Medicine had multiple medical students working in projects. This past summer I had Muhammad Rehman as a gill fellow working with me.

13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected Yes

Please provide IRB number and date

* IRB Number: Pro00001107
* IRB Date: 11/13/2019
Faculty Proposal for MD Student Research by Norman H Lee

1. Faculty Sponsor

* Name: Norman H Lee
* Degrees: PhD
* Title: Professor of Pharmacology
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* State: DC
* Zipcode: 20037
* Office Phone: 202-994-8855
* Email Address: nhlee@gwu.edu

2. Daily Supervisor

Name: Norman H Lee
Degrees: PhD
Title: Professor of Pharmacology
Organization: GW Cancer Center/GWU
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Apt/Suite:
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State: DC
Zipcode: 20037
Office Phone: 202-994-8855
Email Address: nhlee@gwu.edu

3. Project Title (250 character limit)

Role of platelets derived from African American prostate cancer patients in promoting aggressive behavior in prostate cancer

4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:
Yes - Genomics
Yes - Cancer

* 6. Sponsor's translational level
* (Please select ONE)
T0/T1: Basic Science Discovery and Initial Translation to Humans

* 7. Hypotheses (200 word limit)
Over the past 10 years, we have published on the molecular and genetic differences between African American (AA) and European American (EA) prostate cancer (PCa) (Nature Review Cancer, 2012; Nature Communications 2017; Molec. Cancer Research 2019). Differences in gene mutations, gene expression, RNA splicing, signal transduction, and epigenetic modification of genomic DNA explain in part the more aggressive nature of AA PCa compared to EA PCa. More recently, we have identified differences in RNA splicing events involving over 300 genes in an RNA-Seq comparison between AA and EA platelets from healthy volunteers. The vast majority of differential splicing events involves genes encoding cell surface and intracellular signaling protein isoforms involved in extracellular matrix-platelet and cell-platelet interactions, leading to functional differences in the way AA platelets signal and interact with their microenvironment compared to EA platelets. Of interest, platelets have been demonstrated to directly interact with cancer cells via cell surface proteins, which increases the aggressive phenotype of cancer cells (e.g. increased proliferation, invasiveness, metastasis) (Cell Reports 23, 808–822, 2018).
Based on these findings, we propose the novel hypothesis that AA platelets uniquely interact and signal with PCa cells, which may contribute to the more aggressive nature of AA PCa.

* 8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).
Goal 1: Assess ability of platelets from AA PCa patients to promote aggressive behavior in PCa cells. We hypothesize that AA platelets will interact with and promote a more aggressive phenotype in EA and AA PCa cell lines (e.g. increased proliferation, invasion, anti-apoptosis).
Goal 2: Assess platelets from EA to promote aggressive behavior in PCa cells. We hypothesize that the interaction of EA platelets with EA and AA PCa cell lines will lead to a less aggressive phenotype compared to AA platelet-PCa cell interactions.
Goal 3: Perform RNA-Seq of RNA isolated from platelets of AA and EA PCa patients. This data will be compared with the RNA-Seq data already generated from platelets derived from AA and EA healthy volunteers. The goal here is to identify differences in RNA splicing events between AA and EA platelets that may portend differences in the way AA platelets promote an aggressive PCa phenotype. We hypothesize that differential RNA splicing events in AA platelets are responsible for encoding unique protein isoforms (i.e. involved in cell surface interactions and/or signal transduction) that allow AA platelets to uniquely interact with PCa cells to exacerbate oncogenesis in a manner not afforded to EA platelets.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research
Research design and experimental protocols will be implemented in accordance to prior publications from the Lee lab (Wang et al., Nature Communications, 2017; House et al., Sci Reports, 2015; Wang et al., Clin. Cancer Res., 2015; Olendar et al., Molec. Cancer Research, 2019). Research design as follows: 1) We will investigate whether or not platelets can impact oncogenic behavior of AA (MDA PCa 2b, RC77T/E) and EA PCa cell lines (PC-3, VCaP). A pure platelet population will be isolated from whole blood drawn from AA PCa patients (Gleason score ranging from 6–9), using CD45 magnetic microbeads and a negative selection approach as per manufacturer’s protocol (Miltenyi Biotech). Blood draws will be provided by Drs. Jianqing Lin and Michael Whalin (MFA) on approved IRB protocol 041723. During the purification of platelets, plasma will be archived for future analysis. Four different PCa cell lines (MDA PCa 2b, RC77T/E, PC-3, VCaP) will be incubated with saline buffer (control) or platelets from an individual AA patient at different MOI’s (platelet:cancer cell = 1, 50, 100, 500) for 24, 48 and 72 hours in a Matrigel invasion assay. This experiment will be repeated with platelets derived from other AA PCa patients for a total of N = 5-10 independent determinations for each PCa cell line, providing ~80% power to distinguish 2-fold differences in invasive activity. Invasion assay is part of Goal 1; time line of proposed work is weeks 1-6. Platelet-PCa cell interactions will be confirmed by microscopy. 2) In addition to cancer cell invasion, we will also test the effects of AA platelets on proliferation and caspase activity (i.e. apoptosis) in PCa cell lines. Proliferation assay is based on a high-throughput (i.e. 96-well plate) fluorescent-based protocol measuring BrdU incorporation in PCa cell lines pre-treated with AA platelets. Proliferation assay will be performed on N=5-10 independent determinations for each cell line using same MOI approach. Proliferation assay is part of Goal 1; time line of proposed work is weeks 2-8. Apoptosis assay is based on a high-throughput (i.e. 96-well plate) fluorescent-based Apo-ONE caspase-3/7 protocol performed in PCa cell lines pre-treated with AA platelets. Apoptosis assay will be performed on N=5-10 independent determinations for each cell line. Apoptosis assay is part of Goal 1; time line of proposed work is weeks 1-6. 3) We will investigate the ability of EA platelets to impact PCa cell line invasive, proliferative and apoptotic activities. The exact same approach will be employed for AA platelets in Bullet points 1 and 2. The effects of EA platelets on the oncogenic behavior of PCa cell lines are part of Goal 2; time line of proposed work is weeks 5-10. Time line for these experiments will run concurrent with AA platelets. 4) Unused platelets isolated from PCa patients for experiments outlined in Bullet points 1-3 will be used for RNA-Seq analysis to investigate differential RNA splicing in AA versus EA platelets. Time line for this experiments will run concurrent with Bullet points 1-3. RNA-Seq analysis is part of Goal 3.

10. Describe the student's role in the project (200 word limit)
The Gill Fellow will be responsible for the implementation of Goals 1-3 as outlined in Section 9, under the daily supervision of Dr. Lee’s PhD graduate students, as well as direct supervision by Dr. Lee in the form of personal one-on-one meetings, group lab meetings, and group journal club presentations. If time permits, the Gill Fellow will work with a PhD student in Dr. Lee's lab to follow up findings in Goal 3 (e.g. functional validation by gene knock-down studies).

11. Describe the mentor's role in the project. (200 word limit)
As mentor, Dr. Lee will provide mentorship to the Gill Fellow on all aspects of experimental design (e.g. generation of hypothesis, hypothesis testing, independent measures versus repeated measures, sources of experimental error - systematic error versus random error), data interpretation, statistical analysis, and data presentation during weekly lab meetings. Lab meetings will comprise the Gill Fellow, PhD graduate students (2), Fulbright fellow, postbac fellow and Dr. Lee.

12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
* 13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected Yes

Please provide IRB number and date

* IRB Number: 041723

* IRB Date: 04/15/19
Faculty Proposal for MD Student Research by Wei Li

* 1. Faculty Sponsor

* Name: Wei Li
* Degrees: Ph.D
* Title: Assistant Professor
* Organization: Children's National Hospital
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* Zipcode: 20010
* Office Phone: 2024764986
* Email Address: wli2@childrensnational.org

* 2. Daily Supervisor

Name: 
Degrees: 
Title: 
Organization: 
Address: 
Apt/Suite: 
City: 
State: 
Zipcode: 
Office Phone: 
Email Address: 

* 3. Project Title (250 character limit)
Modeling Functional Genes using CRISPR/Cas9 Screening

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.
Lin Yang, Yuqing Zhu, Hua Yu, Sitong Chen, Yulan Chu, He Huang, Jin Zhang, Wei Li. scMAGECK Links genotypes with multiple phenotypes in single-cell CRISPR screens. Accepted, Genome Biology.

* 5. Sponsor's Research Focus:
Yes - Genomics
Yes - Cancer

* 6. Sponsor's translational level
* (Please select ONE)
T0/T1: Basic Science Discovery and Initial Translation to Humans

* 7. Hypotheses (200 word limit)
The overall goal of this project is to identify novel drug targets in the public data from CRISPR/Cas9 functional screening. We hypothesis that we are able to systematically investigate critical genes for various cancer types from the mining of large-scale functional genetic screening. Screening technology is a high-throughput functional assay based on the latest CRISPR/Cas9 genome engineering system, and has been widely used to study various cancer types. By collecting and analyzing public available screening data on over hundreds of cell lines, genes that are essential for tumor growth, and genes that suppress tumor growth can be systematically identified. These findings have the potential to discover (1) potential biomarkers that are indicative of patient survival, and (2) possible drug targets to treat certain types of pediatric cancer. Our group has the track record for the design, modeling, visualization and interpretation of genome-wide CRISPR/Cas9 screens. We already developed eight algorithms and web servers, including MAGeCK algorithm that has >350 citations and >50,000 downloads. Using these softwares, we identified possible mechanisms and potential drug targets for endocrine resistance in ER+ breast cancer, ER-mutant breast cancer, primary and castration-resistant prostate cancer, published in PNAS and Cancer Cell.

* 8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).
This pure computational biology project will process and analyze the screening data of over hundreds of cancer cells. The objectives are to (1) collect public available datasets and evaluate the quality of these datasets in the public domain, (2) identify consensus signals that exist between different screening technologies, (3) identify the functions of top genes that are biologically meaningful, and (4) if possible, develop a program or pipeline to standardize and visualize the results above.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
  ● The project design makes it likely that the objectives will be achieved
  ● The project is likely to result in a report of interest to other scholars
  ● The project fulfills discovery/original research
Aim 1. Collect and evaluate the quality of existing screening datasets. Many screening datasets are available from the public domain, including RNA interference (RNAi) screens, CRISPR screens of different libraries and types (knockout, inhibition or activation). Furthermore, the Achilles project (and other similar projects) includes screens over hundreds of cell lines, providing opportunities to study the genetic landscape of different tumors. We will use the established MAGeCK-VISPR/MAGeCKFlute pipeline we developed for data processing (e.g., normalization, copy number correction, batch removal, and score calculation). Aim 2. Make genome-wide screens from different technologies/libraries comparable using canonical correlation analysis (CCA). It is a common task in genomics analysis to integrate measurements from multiple platforms on the same set of samples. Heterogeneous data from
different platforms cannot be combined directly or using batch removal approaches, as the latter assumes an equal impact of batch on both datasets. Canonical correlation analysis (CCA) is a way of identifying the consistent patterns of two related datasets, by finding the linear combinations of features that maximize the correlation between the two. CCA has been used to identify consistent patterns between gene expression and DNA copy number variations, and most recently, to integrate single-cell RNA-seq data generated from different platforms and technologies. We will use CCA to combine datasets from screens of two different technologies. The outcome of CCA is the weights of individual cell lines (or genes), and the corresponding linear transformation of the data such that the common source of variances between two datasets are captured. On the other hand, variances that are specific to one dataset (e.g., library biases demonstrated in preliminary results) will be assigned a lower weight and are filtered out after transformation. CCA also provides a projection from high-dimension raw data into a low-dimension transformed data, enabling us to perform integrated downstream analysis and visualization.

* 10. Describe the student's role in the project (200 word limit)

The student is responsible for (1) getting familiar with the computational tools our group previously developed, (2) collecting and processing public screening data, and (3) performing additional analysis based on the proposed research aims. In addition, the student will interact frequently with the PI (1-3 meetings/week), collaborators across the country, and other members of the lab/department.

* 11. Describe the mentor's role in the project. (200 word limit)

The PI (Wei Li) will oversee the whole project: he will provide instructions for all the resources needed to perform the aims, and guide the student in all aspects (data collection, programming, biological interpretation, etc.). Furthermore, the PI will create a vibrant, interactive environment to support the career development of the student, including but not limited to (1) sharing experience on research, skill development, communication, presentation, etc.; (2) encouraging discussion with other faculties and members of the department that has a variety of scientists working on different disease problems; (3) providing opportunities to connect to collaborator laboratories and industrial partners.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

The PI has joined CNMC 1 year ago so has not mentored any medical student. However, in the past the PI already supervised several graduate students and published six (co)corresponding authored papers.

* 13. Do you have or will you obtain IRB approval for this project?

Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected No (Not Required)

Please specify why it is not required.

This is an informatics project that involves only public data and does not require IRB.
Faculty Proposal for MD Student Research by Maureen E Lyon

* 1. Faculty Sponsor

* Name: Maureen E Lyon
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* 2. Daily Supervisor

Name: NA
Degrees: 
Title: 
Organization: 
Address: 
Apt/Suite: 
City: 
State: 
Zipcode: 
Office Phone: 
Email Address: 

* 3. Project Title (250 character limit)

Family Centered pediatric Advance Care Planning (FACE-pACP) for Teens with Cancer and for Spanish Speaking Teens and their Families

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor’s Research Focus:
Yes - Pediatrics
Yes - Cancer
Yes - Infectious Disease
Yes - Psychiatry

* 6. Sponsor’s translational level
* (Please select ONE)
T2: Translation to Patients

* 7. Hypotheses (200 word limit)
Opportunity to examine secondary data from one of two ongoing randomized clinical trials: 1) 4-site R01 funded by the National Institute of Nursing Research/NIH; and 2) a pilot study funded by the American Cancer Society (ACS) on palliative end-of-life care for teens with cancer. Both qualitative (patient-family videotapes of pACP conversations) and quantitative data (physical and psychological symptoms, religiousness, spirituality, caregiver appraisal, end-of-life treatment preferences) are available for analysis. PI can assist in developing hypotheses of interest. ACS pilot study is conducted in Spanish and is adapting the FACE pACP intervention for Spanish speaking teens and their families and looking at initial efficacy. FACE-TC covers four dimensions relevant to decision making competence: understanding of their illness, appreciation of complications that could occur, expressing a choice, and stating their reasoning for that choice. End-of-life treatment congruence, operationally defined as the family accurately reporting the adolescent’s treatment preferences, will be used as a marker for minor adolescents’ decision-making capacity. Findings will increase the knowledge base of age group effects [age of majority (=18 and <21 years) versus adolescent minor (ages =14 and <18)] in the context of a patient-centered family-supported pACP process. Findings will have implications for children’s competence,

* 8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).
Objective 1: To determine if congruence in EOL treatment preferences (agreement to continue all treatments or limit treatments) varies by age group at T1 and T2, overall for 4 disease-specific situations. Hypothesis (H)1.1 The intervention effect on the treatment congruence at T1 and T2 will not vary by age group. H1.2 Intervention effect on change of EOL treatment preference over time will not vary by age group. Objective 2: To determine if participation in FACE TC causes psychological distress to adolescent minors at Time 2. H2.1. The intervention effect on symptoms of anxiety or depression will not vary by age group at T2, controlling for baseline levels. R01: N=130 adolescents with cancer/family dyads for a total of 260 participants. All baseline and 3 month outcome data are available. ACS: N=30 Spanish speaking adolescents with cancer/family dyads for a total of 60 participants. Adaptation of protocol is completed currently enrolling and randomizing dyads to FACE-TC vs. treatment as usual control. Data are in REDCap data base.
9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.

Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

Pediatric advance care planning (pACP) for adolescents and young adults (AYA) with cancer is occurring in the context of recognition of adolescent decision making capacity, but a gap in our knowledge exists as to whether there is a difference in decision making capacity between adolescent minors (ages =14 and <18) and AYAs who have reached the age of majority (ages =18 and <21). This is due, in part, to the reluctance of IRBs to approve pACP research for adolescent minors (Dr. Wiener, personal communication, regarding Voicing My Choices). Currently, adolescent minors have no legal right to make decisions about their own end-of-life care in most US states. A common ethical dilemma includes protecting vulnerable minors from psychological distress (anxiety, depression) versus respect for autonomy and self-determination. Furthermore, brain development impacts adolescents’ decision making process. Thus, the parent grant provides a valuable opportunity to provide an evidence-base with respect to knowledge about adolescent minors’ competence to consent to pACP, compared to age of majority AYAs, in the context of a facilitated family-supported pACP decision making. Parent Grant. The evidence-based intervention, Family Centered (FACE) pACP for Teens with Cancer (FACE-TC), is being tested in a longitudinal, multi-site, randomized, intent-to-treat, 2-arm, controlled trial. Results will let us know if FACE-TC helps families to understand what their teens would want for their own end-of-life (EOL) care. We will also see if increased treatment congruence continues over time, even as adolescents’ choices change. We aim to enhance quality of life, psychological, and spiritual well-being for patients and families. pACP is important because avoiding these conversations may contribute to serious adverse consequences such as inappropriate and unwanted costly care or parents being charged with neglect. FACE-TC is a culturally sensitive and developmentally appropriate, manualized family intervention based on transactional stress and coping theory, which prepares the adolescent/family dyad for EOL decision-making through problem solving. We have completed recruitment and enrolled our targeted 130 adolescent/family dyads from 4 hospital-based clinics and randomized adolescent/family dyads at a ratio of 2:1 to either FACE-TC Intervention or Treatment as Usual Control. Three 60- to 90-minute sessions have been conducted with a certified facilitator at weekly intervals: FACE-TC: Session 1: Lyon Advance Care Planning Survey© Session 2: The Respecting Choices Interview® Session 3: Five Wishes© advance directive. Control received Treatment as Usual. Assessments are at baseline, post-Session 2, and 3, 6, 12 and 18 month post-intervention.

10. Describe the student's role in the project (200 word limit)

Student's role would be to work with the PI and study data analyst to examine the potential hypotheses, which could be amended to more closely match the interest of the student. Student would conduct an updated review of the literature on the subject of interest (qualitative or quantitative data). Student will analyze study results and write an abstract for submission to a professional meeting and, if accepted, present the data. If time permits, student will write up findings for publication.

11. Describe the mentor's role in the project. (200 word limit)

Student and PI will meet weekly face-to-face. Student will attend weekly staff meetings and be part of the study team, which may mean helping with some day to day activities in the running of the two ongoing clinical trials. Mentor will review study findings and oversee writing of abstract and manuscripts as appropriate.

12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

Katherine Schreiner was our last Gill Fellow. She completed qualitative analysis of the Respecting Choices interviews and is taking the lead on an abstract submission to a professional meeting and on a manuscript for publication. She is now in Year 2 at GW medical school and I am sure would be happy to speak to any medical student who is interested in participating in our study.
* 13. Do you have or will you obtain IRB approval for this project?  
Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)  
Selected Yes

Please provide IRB number and date

* IRB Number: 5648

* IRB Date: Expires 4/04/2020
Faculty Proposal for MD Student Research by Paul Marvar

* **1. Faculty Sponsor**

  * Name: Paul Marvar
  * Degrees: PhD
  * Title: Associate Professor
  * Organization: SMHS
  * Address: 2300 Eye Street Ross Hall 457
  * Apt/Suite: 
  * City: Washington
  * State: DC
  * Zipcode: 20037
  * Office Phone: 202-994-5584
  * Email Address: pmarvar@gwu.edu

* **2. Daily Supervisor**

  Name:
  Degrees:
  Title:
  Organization:
  Address:
  Apt/Suite:
  City:
  State:
  Zipcode:
  Office Phone:
  Email Address:

* **3. Project Title (250 character limit)**

  Project Title: The Role of the Brain Angiotensin Peptide System and Hypertension in Alzheimer’s disease (AD) progression

  Abstract: Targeting the renin angiotensin system (RAS) as well as promoting the non-classical protective angiotensinogen derived peptides is currently considered a potential therapeutic intervention for AD. Furthermore an emerging risk factor for cognitive impairment and/or dementia, a cardinal clinical marker of early onset AD, is hypertension. Despite encouraging recent clinical progress in this field to date, the neurobiological mechanism(s) for the role of brain RAS; angiotensinogen derived peptides and hypertension, in AD progression is still not well established. The proposed project will help fill this gap and may provide novel therapeutic opportunities to prevent the onset and/or delay progression of AD through improved understanding of the brain RAS function, or dysfunction. We hypothesize that (1) hyperactivity of the brain RAS modulates early to late stage AD and that (2) pre-existing hypertension mediated by brain RAS peptides accelerates cognitive decline and AD neuropathology. The following specific aim will be tested: (1) To examine the angiotensin peptides of the brain RAS and hypertension in an animal model of early and late stage Alzheimer’s disease (AD) progression.
4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.

5. Sponsor's Research Focus:
Yes - Psychiatry
Yes - Cardiology
Yes - Endocrinology

6. Sponsor's translational level
(Please select ONE)
T0/T1: Basic Science Discovery and Initial Translation to Humans

7. Hypotheses (200 word limit)
We hypothesize that (1) hyperactivity of the brain RAS modulates early to late stage AD and that (2) pre-existing hypertension mediated by brain RAS peptides accelerates cognitive decline and AD neuropathology.

8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
The goal of this summer research proposal is to begin evaluating the role of the brain angiotensin peptides in Alzheimer's Disease (AD) progression. The medical student will have an opportunity to work with a common genetically engineered mouse model of AD progression, to examine early and late or advanced AD progression to interrogate the role of the angiotensin peptides of the brain RAS. To achieve these goals the student will use the 3xTg-AD mouse model combined with a unique ultra sensitive mass spectrometry (MS) platform to measure brain angiotensin peptides. Goals: 1. To perform tissue isolation of mouse brain obtained from the hippocampus and the cerebral cortex of an AD mouse model (3xTg-AD mouse model). 2. To quantify hippocampal and cerebrocortical angiotensin peptide levels using LC/MS. See Lombard Banek et al., 2019

9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

The proposed Gill Fellowship will build upon the growing pre-clinical and clinical evidence that supports a role for the RAS in Alzheimer’s Disease (AD) neuropathology. Targeting the RAS as well as promoting the non-classical protective angiotensinogen derived peptides is currently considered a potential therapeutic intervention for AD and hypertension risk in AD. The goal of this project described here is to evaluate the role of brain RAS peptides and receptors in early to late stage AD and the role of hypertension in accelerating cognitive decline and AD neuropathology.
10. Describe the student's role in the project (200 word limit)
For this project the student will collect and analyze brain tissue from above described mouse model of AD and work with my research team as well as Dr. Peter Nemes from the University of Maryland (sub-award) for the MS peptide analysis for brain angiotensin II.

11. Describe the mentor's role in the project. (200 word limit)
The student will meet with me on a regular, once a week (or as needed) basis to discuss progress, address current and future experimental plans, data analysis, trouble shoot problems and general planning. In addition they will participate in our weekly lab meetings / journal clubs and have the opportunity to present and obtain group feedback on their research and progress during this fellowship.

12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
Hira Mohyuddin 2019 Gill Fellow

13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.
* (Please select ONE)
Selected No (Not Required)

Please specify why it is not required.
animal based study - IACUC approved project.
Faculty Proposal for MD Student Research by Andrew Matisoff

* 1. Faculty Sponsor

* Name: Andrew Matisoff
* Degrees: MD
* Title: Assistant Professor of Anesthesiology and Pediatrics
* Organization: Children's National Hospital
* Address: 111 Michigan Ave NW
* Apt/Suite:
* City: Washington
* State: DC
* Zipcode: 20010
* Office Phone: 202-476-5391
* Email Address: amatisof@cnmc.org

* 2. Daily Supervisor

Name: Tiffany DeFreitas
Degrees: B.S.
Title: LEAD CLINICAL RESEARCH COORD, Anesthesiology
Organization: Children's National Hospital
Address: 111 Michigan Ave NW
Apt/Suite:
City: Washington,
State: DC
Zipcode: 20010
Office Phone: 202-476-2025
Email Address: TDeFreit@childrensnational.org

* 3. Project Title (250 character limit)
1. Echocardiographic evaluation of IVC/aorta diameter ratio for volume status assessment in children
2. Point of Care Ultrasound in the NICU

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


5. Sponsor's Research Focus:
Yes - Anesthesiology
Yes - Pediatrics

6. Sponsor's translational level
(Please select ONE)
T2: Translation to Patients

7. Hypotheses (200 word limit)
We are using point of care ultrasound to non-invasively measure various parameters in children. In the 1st study we are looking at inferior vena cava ultrasound to estimate volume status in children undergoing cardiac catheterization procedures compared to the measured values by the cardiologist. We hypothesize that IVC/aortic ration and IVC collapsability index correlates with volume status and changes with volume administration. In the second study we are using ultrasound to confirm endotracheal tube positionn in NICU patients having surgery in the operating room. The hypothesis is that we can accurately predict the appropriate tube location using ultrasound compared to chest radiograph.

8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
1. Goal is to enroll at least 50 patients (15 enrolled so far). Hopefully after training the medical student can scan up to 20 patients.
2. Goal is to enroll at least 50 patients (0 enrolled so far). Hopefully after training the medical student can scan up to 20 patients.

9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research
1. The 1st study is ongoing and has not been performed in children as of yet. The ability to noninvasively assess volume status in children is of great value in patient care. The challenge so far has been having someone available to do the measurements and record the data. 2. The second study has yet to enroll patients and would benefit greatly from a student to both enroll and obtain the measurements needed for the exam. The project is likely to result in a report of interest to other scholars.

10. Describe the student's role in the project (200 word limit)
The student will assist with enrolling patients and with the PI will obtain consent. After being trained to perform the ultrasound exams they will obtain the images and measurements needed for the studies and store the images. They will also manage the database and enter data as obtained. After the enrollment is closed and the data analysis has been performed, they will help write the manuscript for the studies.
11. Describe the mentor's role in the project. (200 word limit)
The mentor will train the student in obtaining the data and how to manage the database. They will also mentor the student about point of care ultrasound, pediatric cardiac anesthesiology and pediatric cardiology.

12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
Dr. Pranathi Ari-Gil fellow, 2 publications Jasri Iyer, B.S - Gil fellow, 1 publication and 1 pending

13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.
* (Please select ONE)
Selected Yes

Please provide IRB number and date
* IRB Number: Pro00010016
* IRB Date: 11/14/2019
Faculty Proposal for MD Student Research by Tim McCaffrey

* **1. Faculty Sponsor**

* Name: Tim McCaffrey
* Degrees: Ph.D.
* Title: Professor of Medicine, Director, Division of Genomic Medicine
* Organization: School of Medicine
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* State: DC
* Zipcode: 20037
* Office Phone: 2029948919
* Email Address: mcc@gwu.edu

* **2. Daily Supervisor**

Name:
Degrees:
Title:
Organization:
Address:
Apt/Suite:
City:
State:
Zipcode:
Office Phone:
Email Address:

* **3. Project Title (250 character limit)**

Blood RNA Biomarkers of Coronary Artery Disease: RNA sequencing of Patients Undergoing Elective Coronary Angiography.

* **4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.**

Blood RNA Biomarkers of Coronary Artery Disease: RNA sequencing reveals a signature of regulatory T cell imbalance Ian Toma1,4,7, Richard Katz2,8, Jonathan Reiner2,8, Ramesh Mazhari2,8, Palak Shah10, Michael Tackett3, Dan Jones3, Georges St. Laurent1,3,4, III, Dmitry Shtakalo4,9, Denis Antonets4,9, Justin Ertle1, Tisha Jepson3,4,8, and Timothy A. McCaffrey1,4,6,8 American Heart Association Nov 2019 Conference.


* 5. Sponsor's Research Focus:
Yes - Genomics
Yes - Cardiology

* 6. Sponsor's translational level
*(Please select ONE)*
T3: Translation to Practice

* 7. Hypotheses (200 word limit)
Deep sequencing can identify an RNA signature in whole blood of patients presenting with a clinical suspicion of CAD.

* 8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).
Two cohorts of 96 and 80 patients presenting for elective angiography were used. Whole blood was collected in an RNA preservative (Tempus) and frozen at -80°C. Blood RNA was DNase treated, depleted of ribosomal RNA, and analyzed by single-molecule sequencing of RNA (RNAseq) to identify transcripts associated with CAD (TRACs). The resulting reads were aligned and the number of reads per kilobase of exon per million total reads (RPKM) was determined for each transcript and compared between groups by a combined fold-change/p-value filter.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:

* The project design makes it likely that the objectives will be achieved
* The project is likely to result in a report of interest to other scholars
* The project fulfills discovery/original research

In this ongoing research project, a set of transcripts associated with Coronary Artery Disease (CAD) are being validated in a multicenter trial of patients undergoing elective coronary angiography. The results will hopefully comprise an FDA-cleared blood test for CAD.

* 10. Describe the student's role in the project (200 word limit)
The student can be involved in all phases of this clinical research project. They may observe coronary angiography, CT angiography, transport samples, process blood samples into RNA, process RNA for RNA sequencing, align and interpret the RNA sequencing results, and prepare data for publication.

* 11. Describe the mentor's role in the project. (200 word limit)
The mentor will oversee all aspects of the research project and the student will be an integral part of the research team.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
It is likely that a Gill Fellow has participated in our research program for ~20 years. Many have participated even after their summer fellowship is completed.

* 13. Do you have or will you obtain IRB approval for this project?  
**Please note:** Students cannot begin a human subjects project without IRB approval.  
* (Please select ONE)  
Selected Yes

Please provide IRB number and date

* IRB Number: 081709

* IRB Date: 6/25/19 updated
Faculty Proposal for MD Student Research by Nichole McCollum and Jaclyn Kline

* 1. Faculty Sponsor

* Name: Nichole McCollum and Jaclyn Kline
* Degrees: MD
* Title: CNMC Emergency Medicine Fellow/GW Faculty Researcher Instructor, Department of Pediatrics(McCollum); Assistant Professor of Pediatrics and Emergency Medicine (Kline)
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* State: DC
* Zipcode: 20010
* Office Phone: 2024764177
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* 2. Daily Supervisor

Name:
Degrees:
Title:
Organization:
Address:
Apt/Suite:
City:
State:
Zipcode:
Office Phone:
Email Address:

* 3. Project Title (250 character limit)

How “informed” is “informed consent”? What are parents’ understanding of the risks/benefits of ketamine for procedural sedation in the Emergency Department? Primary aim of project is to improve understanding of the risks/benefits of ketamine. Secondary aim of project is to standardize physician consent process and satisfaction with consenting process.

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.

5. Sponsor's Research Focus:
Yes - Pediatrics
Yes - Emergency Medicine

6. Sponsor's translational level
(Please select ONE)
T3: Translation to Practice

7. Hypotheses (200 word limit)
1) Parents’ understanding of the risks/benefits of ketamine for procedural sedation in the Emergency Department will improve with addition of using a written handout as part of the informed consent. 2) Physician satisfaction will increase with standardization of consent forms. 3) Variability of risks/benefits included on the consent form will decrease with standardization of consent forms.

8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).
Goals: 1) Increase parent’s understanding of risks/benefits of ketamine sedation in the emergency department 2) Standardize the form used for consent for procedural sedation 3) Improve physician’s satisfaction with consenting process measurable outcomes: 1) Compare parental understanding of risks/benefits of ketamine procedural sedation. This will be achieved through a survey of parents on key points of the risks/ benefits of ketamine sedation given during their child’s ED stay and scored for percent of correct responses on each item before and after our interventions. This data will be presented on a p chart over the course of the project. We will use the IHI Method for Improvement to both formulate and execute interventions targeted at improving parental understanding of the use of ketamine for sedation for children in the ED starting with an educational handout provided to parents. 2) Physician satisfaction with consent forms will be assessed using a survey of providers utilizing a Likert scale. 3) Variability and rates of omission/commission of key terms listed on the consent forms will be assessed by physician survey and chart audit of past consent forms for ketamine sedation looking for inclusion or omission of key points/phrases and comparing this to the standardized consent.

9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

Overall design of the project is based on the IHI Method for Improvement. All interventions will be made in a stepwise approach, assessing for improvement after each cycle. There will be two groups of individuals that are the focus of these interventions- parents of patients and physicians. Both groups of individuals will be interviewed for each patient enrolled. Time frame and activity breakdown: Fall 2019- formulate research proposal, IRB submission January 2020- determine questionnaire to be completed by parents and physicians to obtain baseline data. February 2020- draft ketamine handout and submit to ED for approval Spring 2020- upon IRB approval: 1)Begin chart audit assessing items used in consent forms completed by physicians 2) start recruiting patients to obtain baseline data for
parents and physicians. March/April 2020- draft standard consent form. Submit to hospital forms committee for
approval Fall 2020- first intervention: give parent educational handout. Winter 2020- Assess success of initial
intervention, and utilize QI methodology to formulate further interventions and continue assessing for change.

* 10. Describe the student's role in the project (200 word limit)
Students will learn quality improvement methodology in the clinical setting by working in a busy pediatric
emergency department. The student’s main focus will be to collect data by interviewing parents of children
undergoing ketamine procedural sedation and the physicians treating the enrolled patients. Students will
also be involved in any applicable chart review to collect baseline data on variability of information included on
consent form. If interested, the student may also aid in the development of the educational handout that will be given
to the parents as an intervention. If the student desires, there will be opportunity to continue working on this project
beyond his/her summer internship- opportunities include data analysis, manuscript drafting and planning further
interventions with likely anticipated authorship. Summer is anticipated to be peak for enrollment because most
patients undergo ketamine sedation in the emergency department for long bone fractures which mostly occur during
the summer months.

* 11. Describe the mentor's role in the project. (200 word limit)
The mentors are overseeing the development, operations and execution of this project. The mentors will meet with
the student at defined intervals to discuss how the project is fitting their educational goals and research desires. The
mentors will focus on teaching QI methodology, data collection via chart auditing and interviewing/enrolling
participants into a research study.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill
Fellows. (200 word limit)
Nichole McCollum MD: current GW Clinical Apprenticeship Program (CAP) student- Christian Flagons (MS1)
Jaclyn Kline: 3 prior CAP students – Wesley Ng (MS1 and MS2 year, current MS4), Deepika Potarazu (MS1 and
MS2 year, current MS3), Khasayar Mozaffari (MS1 year, current MS2)

* 13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.
* (Please select ONE)
Selected No (Pending)
Faculty Proposal for MD Student Research by Andrew Meltzer

* 1. Faculty Sponsor

* Name: Andrew Meltzer
* Degrees: MD, MS
* Title: Associate Professor
* Organization: Emergency Medicine
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* Email Address: ameltzer@mfa.gwu.edu

* 2. Daily Supervisor

Name: Nataly Montano
Degrees: BS
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Apt/Suite: 
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State: DISTRICT OF COLUMBIA
Zipcode: 20037
Office Phone: 2027412952
Email Address: nmontano@mfa.gwu.edu

* 3. Project Title (250 character limit)

SHARed Decision Making for Abdominal Pain in The ED “SHARED” – A Feasibility and Pilot Study

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:
Yes - Gastroenterology
Yes - Emergency Medicine

* 6. Sponsor's translational level
* (Please select ONE)
T2: Translation to Patients

* 7. Hypotheses (200 word limit)
11.1. Study Hypothesis Aim 1: We hypothesize that implementation of an SDM training program is practically feasible for ED physicians defined by outcomes related to time, resources and satisfaction. Aim 2: We hypothesize that use of SDM will be non-inferior to SOC regarding clinical feasibility and process measures such as time with patient, time in the ED and acceptability of patients. Aim 3: We hypothesize that SDM will be non-inferior to SOC for pilot comparison of clinical outcomes related to diagnostic testing, disposition and return visits.

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
Aim 1: To demonstrate feasibility of an implementation strategy to train attending ED physicians on the use of SDM in practice regarding the use of CT scans for patients with abdominal pain. Implementation strategy will include (a) toolkit, (b) video training, (c) just-in-time (JIT) reminder cards and, (d) regularly scheduled e-mail reminders. Outcomes measured include (1) total training time, (2) perceived barriers to training, (3) acceptability of information conveyed, (4) acceptability of training regimen by physicians and, (4) physician control preference score (CPS). Aim 2: To demonstrate feasibility of incorporating SDM in the acute setting for ED patients with abdominal pain we will be measuring physician time spent with patient, total ED patient length of stay and the acceptability of patients (measured by Trust in Physicians (TIP), Decision Conflict Scale (DCS) and CPS). A subgroup analysis of feasibility will be conducted per characteristics of patient (age, gender, SES), physician (age, gender, experience) and ED (crowding, “boarders”, average wait time, patients in waiting room). Aim 3: To pilot the association between the use of SDM and clinical outcomes including (1) rate and yield of diagnostic testing decisions (US versus CT scan versus observation), (2) disposition decisions (admission versus discharge) and, (3)

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

This is a single-center randomized control pilot study examining the utility of a structured shared decision making (SDM) process for ED patients with abdominal pain. Study participants will be enrolled in the GWU Emergency Department (ED) in the Washington, DC area and will receive care from existing board-certified emergency medicine physicians. Randomization will occur at the clinician level and not at the patient level. Approximately 50% of physicians will be randomly assigned prior to participant encounter to undergo a training curriculum to implement SDM into clinical practice. We anticipate enrolling 60 doctor-patient dyads or approximately 3 patients per 20 physicians randomized to SDM training or control. We currently anticipate enrolling 10 patients per week over 6 weeks.
* 10. Describe the student's role in the project (200 word limit)
Student will work with research assistants to screen and enroll subjects. Student will be stationed in ER to directly observe interactions between doctors and patients and record those interactions. Student will assist with transcriptions of interviews and coding of interviews. Student will assist with data preparation and data management. Student will write up a report for end of project summarizing findings and be expected to give an oral presentation.

* 11. Describe the mentor's role in the project. (200 word limit)
Meet weekly with student on 1:1 basis. Include student in all research lab meetings and section meetings. Encourage student to present at a regional or national conference. Instruct student on academic career in medicine. Provide letter of recommendation for residency at completion of fellowship.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
Hamza Ijaz* (5 published manuscripts) Dan Berman* (2 manuscripts) Erica Chemtob (active) Chris Wong* (1 manuscript, active) M Boumezrag (1 publication) et.al. *Gill

* 13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)
Selected Yes

Please provide IRB number and date

* IRB Number: 071613

* IRB Date: 07/29/2020
Faculty Proposal for MD Student Research by David Mendelowitz

* 1. Faculty Sponsor

* Name: David Mendelowitz
* Degrees: Ph.D.
* Title: Professor and Interim Chair
* Organization: GWU, Dept of Pharmacology and Physiology
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* Apt/Suite:
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* State: DC
* Zipcode: 20037
* Office Phone: 2029943466
* Email Address: dmendel@gwu.edu

* 2. Daily Supervisor

Name: Vivek Jain
Degrees: MD
Title:
Organization:
Address:
Apt/Suite:
City:
State:
Zipcode:
Office Phone:
Email Address:

* 3. Project Title (250 character limit)

In our initial pilot study we found that a single 40 i.u dose of intranasal (IN) oxytocin, when given to patients with OSA, decreased the duration of apneas and hypopneas, as well as the oxygen desaturations and incidence of bradycardia that were associated with these events. The data from our more recent double blinded randomized control trial duplicated many of these pivotal findings. However the long term effectiveness of IN oxytocin therapy for OSA is not known, hindering progress for this exciting and novel approach to mitigate OSA. The overarching goal of this proposal is therefore to determine the long term efficacy of IN Oxytocin to provide a new, safe and effective treatment for OSA and ameliorating the adverse cardiovascular and respiratory consequences. We will randomize patients with untreated OSA to receive 40 i.u nightly intranasal oxytocin for 8 weeks in a simple 2-arm cross over double blinded randomized placebo controlled trial (DBRCT) design. Polysomnographic changes, including sleep architecture and apnea associated events (incidence, duration of events, associated changes in oxygenation and heart rate) will be measured at the specified end-point of 8 weeks. After a washout period of 1 week, subjects will receive the alternative treatment, followed by measurement of the same polysomnographic
outcomes. We will also assess for possible adverse effects of oxytocin.

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


(SLEEP-2019-0502.R1) entitled "GABA and glycine neurons from the ventral medullary region inhibit hypoglossal motoneurons" has completed peer review at SLEEP. I am pleased to inform you that your manuscript is now accepted for publication in the journal.


* 5. Sponsor's Research Focus:
  Yes - Pharmacology
  Yes - Cardiology
  Yes - Pulmonology
  Yes - Neurology

* 6. Sponsor's translational level
  *(Please select ONE)*
  T2: Translation to Patients

* 7. Hypotheses (200 word limit)

Our preliminary results indicate intranasal Oxytocin is a promising new treatment to help ameliorate the adverse consequences of OSA. Our initial pilot study showed that a single dose of intranasal oxytocin, a naturally occurring neurotransmitter in the brain, when given to patients with OSA increased self-reported sleep satisfaction, total sleep time, decreased the duration of apneas and hypopneas, and decreased the number of arousals associated with these apneas and hypopneas, thus improving sleep architecture. In a subsequent randomized, double-blind, crossover study of 19 subjects we found that intranasal (IN) application of oxytocin significantly decreased the duration of obstructive events, as well as the oxygen desaturations and incidence of bradycardia that were associated with these events. In both our initial pilot study and the subsequent randomized, double-blind, crossover study, we were limited to testing the effect of oxytocin for just a single night. It is unknown if these beneficial effects are maintained or possibly enhanced over a longer duration of time. In the proposed study, we will significantly advance from these initial findings.

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).

In a DBRCT we will study the effects of 8 weeks of 40 i.u vs placebo on sleep outcomes (AHI, duration, apnea associated changes in heart rate, apnea associated changes in oxygenation), effects on cardiovascular end-points (blood pressure, arterial stiffness, markers of inflammation), and subjective changes in sleep quality (Epworth Sleepiness Scale and Pittsburgh Sleep Quality Index). The primary endpoint for the DBRCT will be that with the statistically most significant response to intranasal oxytocin.
9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.

Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

The impact of developing a new treatment for obstructive sleep apnea (OSA), and for ameliorating the adverse health consequences of OSA, mainly cardiovascular consequences, cannot be overstated. This project will allow us to determine the long term efficacy of intranasal Oxytocin for the treatment of OSA, which has shown remarkable promise in single night studies, by implementing an appropriate longitudinal 8 week large scale DBRCT.

10. Describe the student's role in the project (200 word limit)

The student’s role in the animal study will be test these hypotheses by conducting and analyzing the experiments, and in the clinical studies the fellow will analyze the data on the data from at home auto-CPAP devices.

11. Describe the mentor's role in the project. (200 word limit)

The mentors, Drs. David Mendelowitz and Vivek Jain will have direct, hands-on involvement and training of the trainee.

12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

Previous pre-Medical and Medical School Trainees: Cory Evans, currently Assistant Professor, General Surgery, University of Tennessee Health Science Center, Sunit Baxi, currently Internal Medicine, University of Maryland Medical Center, Chris Stephens, currently Assistant Professor, Department of Radiology, University of Tennessee, Ryan Bateman, currently resident, Emergency Medicine, Thomas Jefferson University, and former GWU Gill Fellow, Whitney Wolaver currently medical student, Virginia Commonwealth University, Kyung-min Lee, currently medical student, George Washington University and former GWU Gill Fellow.

13. Do you have or will you obtain IRB approval for this project?

Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected Yes

Please provide IRB number and date

* IRB Number: GWU_IRB_031857

* IRB Date: 10/16/19
*1. Faculty Sponsor*

- **Name:** Sephora Morrison
- **Degrees:** M.B.B.S, M.SCI, M.B.A Director, Patient Experience & Clinical Service Innovation
- **Title:** Assistant Division Chief, Director of Clinical Operations EMTC
- **Organization:** Children's National Health System
- **Address:** 111 Michigan Ave, NW
- **City:** Washington
- **State:** DC
- **Zipcode:** 20010
- **Office Phone:** 202.476.4177
- **Email Address:** smorriso@childrensnational.org

*2. Daily Supervisor*

Name: Robert Freishtat  
Degrees: MD, MPH Associate Director, Research Center for Genetic Medicine, Children's National Research Institute Professor of Pediatrics, Emergency Medicine, and Genomics and Precision Medicine George Washington University School of Medicine and Health Sciences  
Title: Chief of Emergency Medicine, Children’s National Hospital  
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*3. Project Title (250 character limit)*

Patient Experience and Emergency Department Discharge Callbacks

*4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.*

Morrison S MBBS, MSCI, MBA, Jones N MD, Koutroulis I MD, MBA, Chamberlain J MD. A Prospective Look at Career Aspirations Among Pediatric Emergency Medicine Trainees. Accepted for publication Pediatric Emergency Care 2019

Morrison S MD, MSCI, MBA, CPE, Sigman L MD, JD. Consent, Refusal and Shared Decision Making in the Pediatric Emergency Department. Accepted for publication Pediatric Emergency Medicine Practice 2019

* 5. Sponsor's Research Focus:
   Yes - Pediatrics
   Yes - Emergency Medicine

* 6. Sponsor's translational level
* (Please select ONE)
  T3: Translation to Practice

* 7. Hypotheses (200 word limit)
Instituting a discharge callback process for a patient group with high negative comments received from the Press Ganey (PG) survey who have been discharged from an Emergency Department visit will increase future positive feedback comments on the PG survey and thus improve the patient experience in the ED for this group of patients.

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
Identify ? Target ESI group from Press Ganey comment data with most negative comments ? The list of patients to be called back using the previous day (24hr) ED Discharge report (#s to be determined by target patient group seen and discharged from the ED on the previous day) Call back attempts ? 3 Identify discharge calls requiring follow up ? Flag patient with concerns for follow up with appropriate provider Track ? Patients reached ? Patients with no concerns ? Patients with concerns ? Concern type ? Concern follow up ? Patients who returned to the ED Outcome ? Primary ? Analysis of change in Press Ganey comments for identified ESI group ? Secondary ? % patients reached (within a 3 day period) ? % patients reached with no concerns ? % patients reached with concerns ? % patients reached with concerns resolved ? % patients returned to the ED

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

This project will take 8 weeks - 6 weeks for the study, 2 weeks to analyze the data and develop a manuscript outline. The activities will include 1. Identifying ED patient target group from PG survey comments (Single analysis) 2. Pulling patient discharge report from previous 24 hours and identifying patients to receive discharge callbacks (#s to be determined by identifying target group patients seen and discharged from the ED) 3. Creating spreadsheets which will include patients to be called back, the results of the callbacks - Patients with no concerns, Patients with concerns, Concern type, Concern follow up, Patients who returned to the ED 4. Identify patients from the callback group and required follow ups for the appropriate provider. 5. Track follow up calls completed. 6. Review and analyze outcomes of the study listed in 8. Work after the study will include 1. Creation and submission of a completed manuscript for publication of the work.
* 10. Describe the student's role in the project (200 word limit)
The student will 1. Learn how to utilize an excel databases to extract and track desired data 2. Learn how to access and utilize Cerner databases 3. Call back identified target group patients discharged from the ED 4. Identify discharge calls to patients which require feedback 5. Track the results of the patient callbacks 6. Analyze the outcomes identified

* 11. Describe the mentor's role in the project. (200 word limit)
The mentor will supervise and guide the student through the steps of the project to ensure understanding and allow project completion. They will also teach the student about patient experience and it's importance.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
The mentor team has provided educational opportunities for medical students through capstone courses, didactics, workshops and the clinical settings.

* 13. Do you have or will you obtain IRB approval for this project? Please note: Students cannot begin a human subjects project without IRB approval.
* (Please select ONE)
Selected Yes

Please provide IRB number and date
* IRB Number: Pro00011835

* IRB Date: 3/29/2019
Faculty Proposal for MD Student Research by Sarah Mulkey

* 1. Faculty Sponsor

* Name: Sarah Mulkey
* Degrees: MD, PhD
* Title: Fetal-Neonatal Neurologist
* Organization: Children's National
* Address: 111 Michigan Ave. NW
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* City: Washington
* State: DC
* Zipcode: 20010
* Office Phone: 202-476-5815
* Email Address: sbmulkey@childrensnational.org

* 2. Daily Supervisor

Name: Dr. Sarah Mulkey
Degrees: MD, PhD
Title: Fetal-Neonatal Neurologist
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Address: 111 Michigan Ave. NW
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* 3. Project Title (250 character limit)
Fetal intracranial hemorrhage- fetal diagnosis and postnatal outcome

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.

* 5. Sponsor's Research Focus:
Yes - Neurology

* 6. Sponsor's translational level
* (Please select ONE)
T3: Translation to Practice

* 7. Hypotheses (200 word limit)
In the Fetal Medicine Institute at Children’s National Hospital we see prenatal referrals for fetal intracranial hemorrhage. While this is a relatively rare fetal condition, we see a large enough number of cases to contribute important knowledge to the literature regarding this condition. Due to advances in prenatal diagnostics including fetal MRI, the diagnosis of this fetal condition has increased, however reported outcomes are sparse in the literature and those reported are often severe. Furthermore, reports in the literature are based on prenatal diagnosis by ultrasound and so may tend towards only reporting more severe cases. We hypothesize that neurodevelopmental outcome following fetal intracranial hemorrhage has a wider spectrum of outcome than previously reported and that factors identified on fetal imaging (i.e. size, location) may correlate well with outcome prediction.

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
The objective of the study is to describe the spectrum of neurologic injury, etiology, and postnatal outcome for fetal intracranial hemorrhage diagnosed using fetal MRI. Given the number of cases we have seen over the past 8 years, we have a unique opportunity to describe the fetal condition in a large number of cases and report the spectrum of outcomes. Number of patient records: 82 Goals: Describe cases of fetal intracranial hemorrhage, diagnosis, etiology if identified, pregnancy outcome, and child neurodevelopmental outcome.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research
This is a retrospective chart review. All cases referred to the Fetal Medicine Institute for a fetal brain abnormality and found to have a fetal intracranial hemorrhage in the past 8 years will be included. All types of fetal intracranial hemorrhage will be included. We will review the referral records and prenatal diagnostic evaluations, fetal imaging including US an MRI, any additional diagnostic workup including for congenital infections and genetics as performed by or recommended after consultation by neurology at the Fetal Medicine Institute. The findings, severity, and etiologies will be described and tabulated. Pregnancy outcome will be determined for each case. Postnatal evaluation and imaging will be reviewed. Any data on patient outcome will be recorded. Cases will be identified through an established clinical patient database in the Fetal Medicine Institute and data will be abstracted through chart review using the Children’s National Electronic Medical Record. We have found that this type of project is do-able during a summer for a student, provides a significant amount of learning in neurology and brain development, and will result in a quality finished project by the end of the summer that will be able to be presented and prepared for publication.
* 10. Describe the student's role in the project (200 word limit)
The student will be provided with a list of cases and a database to complete through performing the detailed chart review. The student will have the opportunity to review brain MRI findings with the neurologist and with the neuroradiologist. The student will present findings to the research team during our research meetings.

* 11. Describe the mentor's role in the project. (200 word limit)
The mentor will be available throughout the project to teach the student about fetal intracranial hemorrhage, guide the student in learning how to abstract the data and the importance of the different elements of the data. The mentor will review medical records and neuroimaging with the student. The mentor will be available for the student and questions as the data is reviewed.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
The Fetal Medicine Institute had three summer students in 2019 and typically has 2-3 students per summer. In 2019, Dr. Mulkey mentored a Gill Student who completed a project on Autonomic Nervous System development in high risk newborns. This project will yield a publication in early 2020.

* 13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)
Selected No (Pending)
Faculty Proposal for MD Student Research by Daniel Newman

1. Faculty Sponsor

Name: Daniel Newman
Degrees: MD
Title: Assistant Professor of Pediatrics
Organization: Children's National
Address: 1630 Euclid St. NW
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Office Phone: 202-476-5415
Email Address: DNewman@childrensnational.org

2. Daily Supervisor

Name: Daniel Newman

3. Project Title (250 character limit)

Immigration Legal Screening in a Primary Care Pediatric Office

4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.

"Immigration Legal Screening in a Primary Care Pediatric Office" - Poster presentation at the 2019 National Center for Medical Legal Partnerships
"Strategies for Teaching Medical Students: A Faculty Development Workshop for Pediatric Preceptors in the Community Setting" - accepted publication on MedEdPORTAL, October, 2019

5. Sponsor's Research Focus:

Yes - Pediatrics

6. Sponsor's translational level

T4: Translation to Population Health

7. Hypotheses (200 word limit)

Over 5 million children living in the U.S. were born to undocumented/unauthorized parents, and 90% of these children are U.S. citizens. Undocumented immigrants experience a lack of employment rights, limited access to social service networks and health care, and a constant fear of deportation and family separation. This has profound implications for the health and wellbeing of children in these immigrant families. A large number of undocumented immigrants may qualify for legal protected status based on past or present life circumstances. However, due to lack of awareness or lack of access to quality and affordable immigration legal services, many undocumented immigrants never pursue this option. Children's Health Center at Columbia Heights cares for a large immigrant population, most having roots in Central America. Many of our patients' parents are undocumented yet have never explored potential immigration legal options.

8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).

We aim to: 1. Use a brief online screening tool for parents of patients to identify if they may qualify for a form of protected legal status, and connect families with affordable and reliable community immigration legal organizations. 2. Measure the effect that helping families identify legal possibilities and make connections to legal organizations has on the parents' stress and anxiety around immigration status. 3. Measure the need for immigration legal services in our health center.

9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.

Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research
For the past two years we have been piloting and enhancing this research project- now with IRB approval (Pro00010598). Current workflow is based on availability of medical student volunteers. Volunteers recruit and enroll eligible and interested participants (parents of patients) in the primary care office. After IRB consent, volunteers assist families in completing a "pre-intervention" survey of anxiety/stress/awareness around immigration status. Then an online legal screening tool is administered to ascertain if a person may be eligible for a form of immigration relief. If screened positive (possible legal relief attainable), then participant is assisted in connecting to an affordable immigration legal resource. After a few weeks, participants are contacted again and after connection to a legal resource is made, a similar "post-intervention" survey on anxiety/stress/awareness around legal status is completed.

10. Describe the student's role in the project (200 word limit)
Student researchers will be involved in all areas of this research, including but not limited to volunteer recruitment and training, enhancement and changes to research workflow to optimize our resources, direct recruitment and engagement with study participants, participation in publications around the data collected and the project in general. The student researcher will also be involved in fostering connections to community immigration legal partners in order to facilitate connecting study participants to these resources. Day to day responsibilities will be a mix of all of these, with focus on recruiting and conducting the legal screening tool with parents of patients.

11. Describe the mentor's role in the project. (200 word limit)
The mentor has been involved with this research since it's inception two years ago. He has worked with a past Gill fellow, and then another summer research volunteer on the project. He, along with a team of other clinician/researchers at the health center, will work with the student researcher on day-to-day operations and strategic changes to the workflow. He, or others from the study team, will be available at all times for assistance and to help the student researcher work as independently as possible.

12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
The mentor team includes four community pediatricians, all with an interest in immigrant health and medical trainee education. With a combined decades of experience working with and teaching medical students (in both classroom and clinical settings), the team is ready and able to optimize this research experience for a student trainee. A Gill fellow took part in this research in the summer of 2018, and a GWU MS1 student took part in the research in 2019. This work will be a natural continuation of their efforts.

13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.
(Please select ONE)
Selected Yes

Please provide IRB number and date
10/1/2019

IRB Number: Pro00010598
IRB Date: 10/1/2019
Faculty Proposal for MD Student Research by Robert Nickel

* 1. Faculty Sponsor

* Name: Robert Nickel
* Degrees: MD, MSc
* Title: Assistant Professor
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* 2. Daily Supervisor

Name: 
Degrees: 
Title: 
Organization: 
Address: 
Apt/Suite: 
City: 
State: 
Zipcode: 
Office Phone: 
Email Address: 

* 3. Project Title (250 character limit)
Minimizing toxicity in HLA-identical sibling donor transplantation for children with sickle cell disease (SUN Trial)

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.
* 5. Sponsor's Research Focus:
Yes - Pediatrics

* 6. Sponsor's translational level
* (Please select ONE)
T3: Translation to Practice

* 7. Hypotheses (200 word limit)
The SUN Study is a multicenter clinical trial (NCT03587272) seeking to determine if a nonmyeloablative transplant approach can decrease the toxicity of transplant while achieving a high cure rate for children with sickle cell disease with an HLA-identical sibling donor. To help with study recruitment, we plan to screen all hospitalized patients with SCD for eligibility and offer HLA typing if not already done. We hypothesize that HLA typing will be accepted by a majority (>50%) of hospitalized sickle cell patients with full siblings and this screening will help with the clinical trial recruitment.

* 8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).
Student will screen all hospitalized patients with sickle cell disease for clinical trial eligibility and offer referrals for HLA typing for patients with full siblings if not already done. About 10 patients with sickle cell disease are hospitalized at Children's National each day and over the course of 2 months over 100 patients are likely hospitalized. Student will keep secure database of this screening via REDCap.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

Children's National Health System (CNHS) cares for one of the largest populations of children with sickle cell disease in the entire nation. CNHS is thus an ideal location for the current study and given its patient volume, enough patients will be hospitalized during one summer to conduct the study evaluating the effectiveness of screening and offering HLA typing to inpatients. It is not currently known if hospitalized families will be interested in HLA typing, especially at an institution that already routinely offers HLA typing to patients at clinic visits. If this screening is effective, it could also significantly help recruitment on the active clinical trial.

* 10. Describe the student's role in the project (200 word limit)
After training, the student will be responsible for approaching hospitalized families and maintaining a screening database.

* 11. Describe the mentor's role in the project. (200 word limit)
Mentor will train student in how to review patients' medical records and offer referral for HLA typing to hospitalized patients. Mentor will assist student in organizing screening log via REDCap. Mentor will assist student in analyzing the effectiveness of this screening.

12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

Adam Greenfest (GW medical student) volunteered on the clinical research project Quick Start Hydroxyurea Initiation Project during part of his summer. This project has resulted in two oral abstracts at national meetings and a publication in the Journal of Pediatrics in which Adam is a co-author.

13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.

(Please select ONE)
Selected Yes

Please provide IRB number and date

IRB Number: Pro00010322
IRB Date: 4/19/2018
Faculty Proposal for MD Student Research by Shilpa Patel

* 1. Faculty Sponsor

* Name: Shilpa Patel
* Degrees: MD, MPH
* Title: Assistant Professor of Pediatrics and Emergency Medicine
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* Email Address: spatel@childrensnational.org

* 2. Daily Supervisor

Name: Shilpa Patel

Degrees: MD, MPH

Title: Assistant Professor of Pediatrics and Emergency Medicine

Organization: Children's National Hospital

Address: 111 Michigan Avenue

Apt/Suite: 

City: Washington

State: DC

Zipcode: 20010

Office Phone: 2024764177

Email Address: spatel@childrensnational.org

* 3. Project Title (250 character limit)

Firearm Safety Screening and Counseling Among Emergency Department Visits for Behavioral Health Complaints

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


5. Sponsor's Research Focus:
Yes - Emergency Medicine

6. Sponsor's translational level
* (Please select ONE)
T3: Translation to Practice

7. Hypotheses (200 word limit)
We aim to describe provider documentation of access to firearms in suicidal youth presenting to the ED. We hypothesize that rates will be low overall and standardized suicide screening and assessment will be associated with higher rates of documentation of access to firearms and safety counseling. Standardized assessments of patients at risk for suicide was initiated on May 2, 2019.

8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
To identify the frequency and thoroughness of clinician-documented screening for firearm possession, accessibility and storage during Emergency Department visits for patients presenting with a behavioral health chief complaint. The primary outcome measure is documentation of firearm access and safety counseling. Our secondary objectives are to determine patient-level, visit level and provider specific factors associated with documentation of firearm access and safety counseling. The student will be one of a team members responsible for chart abstraction.

9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

Our team will review the electronic health records of children presenting to the CNMC Sheik Zayed or United Medical Center Emergency Departments with behavioral health chief complaints between January 1, 2018 and December 31, 2019. The primary outcomes include documentation of firearm possession, storage and/or accessibility. Additionally, we will abstract the following patient-level and visit-level information: age, gender, race, ethnicity, insurance status, home address, chief complaint, substance use, discharge diagnosis(es), and provider role in documentation (e.g. physician, nurse, social worker). Data will be abstracted from the EHR and directly entered into the study database in REDCap, a secure, web-based application for building and managing online surveys and databases. We will evaluate the number of patients who have documentation of firearm possession, storage/accessibility, and counseling as well as the role of provider who made that documentation. We will also identify any patient-level and visit-level information that is associated with documentation. We will calculate the proportion of visits during which firearm accessibility and/or safety counseling was recorded in the EHR. Secondary outcome measures will examine patient- and visit-level factors associated with firearm accessibility documentation. Analysis will consist of descriptive statistics for frequency estimates and to summarize demographic variables, including means, medians, and ranges for continuous variables. Bivariate and multivariate logistic regression modeling will be performed to evaluate factors associated with documentation of firearm access.
* 10. Describe the student's role in the project (200 word limit)
The student will assist with chart abstraction and manuscript preparation.

* 11. Describe the mentor's role in the project. (200 word limit)
The mentor will meet with the student on a weekly basis and check in daily in addition to participate in chart abstraction and data analysis.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
Dr. Patel has no prior experience with Gill fellows however has mentored other GW medical students. Mentorship focus has mostly been around career/clinical shadowing however most recently she is serving as faculty mentor for Genevieve Donahue in her fourth year public health advocacy project. The mentor team has mentored many medical students (some Gill) and the collaboration has resulted in several publications.

* 13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.
* (Please select ONE)
  Selected Yes

Please provide IRB number and date
* IRB Number: Pro00011985
* IRB Date: 5/7/2019
Faculty Proposal for MD Student Research by James P. Phillips

* 1. Faculty Sponsor

* Name: James P. Phillips
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* 2. Daily Supervisor

Name: Robert Shesser
Degrees: MD
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State: DC
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Email Address: rshesser@mfa.gwu.edu

* 3. Project Title (250 character limit)

Creation and Implementation of a Novel, Online, Just-In-Time Disaster Response Toolkit for Emergency Medicine Providers

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:
Yes - Emergency Medicine

* 6. Sponsor's translational level
* (Please select ONE)
T3: Translation to Practice

* 7. Hypotheses (200 word limit)
Funding and training requirements are being cut nationwide for emergency departments responsible for disaster preparedness and response. No-notice mass casualty events such as active shooter events, vehicular ramming attacks, and chemical/biological/radioactive/explosive attacks are real, constant threats in the US, yet emergency preparedness and disaster medicine training are not priorities in medical schools nor residencies. The result is emergency physicians and hospital systems under-prepared to respond after the immediate notification of an incoming influx of injured or severely ill patients. Existing emergency disaster plans for hospitals typically lack detailed operational steps and key considerations that providers must remember under extreme duress. We hypothesize that the creation and implementation of a novel, online, just-in-time disaster response toolkit and resource repository can be created, made available worldwide, and will improve emergency medicine provider readiness and immediate response to no-notice mass casualty incidents. To date, there has not been a comprehensive, free, online resource of this type. The web domain DisasterConsult.com has been secured for this project

* 8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).
The overall goal for the project is a live online database for medical providers to utilize in the event of an unexpected mass casualty event, including administrative suggestions, operational considerations, staffing suggestions, and can't-miss reminders. The student scholar would have an important role in the initial development of the material directly available to users. The scholar would be responsible for the no less than five distinct topic areas (e.g. Sarin gas attack, vehicle-ramming attack, tornado, flash flooding, etc) to be chosen in consultation with the existing research team (Dr. Phillips and Disaster Fellows Dr. Jordan Selzer, Timur Alptunaer, and Samantha Noll). Measurable objectives include the research and selection of existing literature for the topic resource repository, as well as mentored creation of immediate response recommendations for emergency medicine providers. For each topic, the scholar would be mentored through peer-reviewed literature searches, book chapters, evaluation of "grey literature," and consulting with experts while becoming subject matter authorities themselves. The final objective will be publication of the materials and plans online, following review by the disaster physician research team, making it available for users by the beginning of the following academic year.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.

Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research
Week one will consist of meeting with the research team (above) and mapping out the overall project and its current progress. Expectations will be reviewed and the process to achieve each objective provided. By the end of week one the five topics will be selected by the scholar and the team in conjunction. Additional topics will be chosen and reserved for the scholar should the goals be achieved early. Research meetings/mentoring sessions will be held at least weekly. Week two would begin the research process into each topic. An overview of each topic will be given to the scholar by a member of the disaster medicine section and to identify key topics and considerations to be researched. Weeks three through seven would consist of literature reviews of the topics including peer-reviewed papers, gray literature from government entities, existing recommendations from various federal agencies, and discussions on the existing plans at GW Hospital and affiliates. A compilation of the relevant resources will then be created as a basis for the emergency plans to be provided for online users. The resources will be hosted online to allow for non-emergency education of the user as well. The emergency plans will be created in collaboration with Dr. Phillips and the disaster medicine fellows listed above. Week eight will serve as a time for final reviews of the scholar's resource libraries and collaborative emergency plans, followed by online publication.

* 10. Describe the student's role in the project (200 word limit)

As described in the prior sections, the student will be mentored throughout the process to perform thorough reviews of peer-reviewed papers, gray literature from government entities, existing recommendations from various federal agencies, and existing GW Hospital plans. The student will then compile the relevant resources and work with our webmaster to facilitate translation into the online repository. The student will be mentored in the development of emergency plans relevant to their topics with an expectation that they are useful at the level of an attending physician in the emergency department.

* 11. Describe the mentor's role in the project. (200 word limit)

The mentor will be responsible for the overall project, in conjunction with Fellow Dr. Jordan Selzer, creator and research lead. There will be weekly meetings as well as online collaboration during the process. The mentor will ensure that the scholar is not only completing the tasks but becoming a subject matter authority by reviewing the literature and considering how to apply it in real life.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

Dr. Phillips is currently co-director of the Disaster Medicine Scholarly Concentration at GW. There are three current fellows in his Disaster and Operational Medicine Fellowship. Each member of our team currently teaches clinically in the emergency department with rotating students and residents. Dr. Phillips has published peer-reviewed research with medical students recently and created a similar research team of three medical students last year focused on vehicular ramming attacks and resulting in multiple research forum presentations locally and internationally.

* 13. Do you have or will you obtain IRB approval for this project?

Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected No (Not Required)

Please specify why it is not required.

The research does not involve human subjects or patient records. Per the GWU IRB exemption, we believe our project is exempted under the clause: "research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on instructional strategies; or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods."
Faculty Proposal for MD Student Research by Adrienne Poon

* 1. Faculty Sponsor

* Name: Adrienne Poon
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* Title: Assistant Professor of Medicine
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* 2. Daily Supervisor

Name:
Degrees:
Title:
Organization:
Address:
Apt/Suite:
City:
State:
Zipcode:
Office Phone:
Email Address:

* 3. Project Title (250 character limit)
Systematic review and estimation of burden of dementia in the Middle East and Africa

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:
Yes - Geriatrics

* 6. Sponsor's translational level
* (Please select ONE)
T4: Translation to Population Health

* 7. Hypotheses (200 word limit)
Prevalence and population estimates of dementia suggest an underdiagnosis of dementia with a growing burden in the Middle East and Africa

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
Project goal includes development of a manuscript ready for submission to a journal for peer review. Conduct a systematic literature search and review. Assist with designing display of results. Conduct analyses directly if has had prior statistical training; otherwise assist statistician with compiling data for analysis. Summarize results and discussion.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research
Prevalence of dementia and cognitive impairment amongst elderly in the Middle East and Africa has been uncharacterized. The goals of this research project are to understand the prevalence of dementia and help develop estimates and projections for the region of the Middle East and Africa. With increasing life-span and chronic diseases as well as under diagnosis, it is projected that the prevalence and rise of dementia is under-recognized and understood within these regions. We aim to review prior literature and use existing population based studies to estimate the regional burden of dementia in the Middle East and Africa. Given the limited understanding and diagnosis of dementia amongst the population in these regions, the results of this original research will add to the growing body of research on this topic.

* 10. Describe the student's role in the project (200 word limit)
A student will be asked to be a part of an international team of researchers in collaboration with the University of Edinburgh Center for Global Health to assist in conducting a systematic review of the literature surrounding prior epidemiology of dementia in the Middle East and Latin America. If previously trained in statistics, the student may be responsible for conducting analyses; otherwise will assist a statistician in conducting analyses that include estimating the prevalence and projecting the dementia burden in years to come. The student will also assist in preparing a manuscript in a peer-reviewed journal as a co-author. An understanding of basic epidemiology and statistics is a must. A background in public health especially with training to use statistical analytic tools are highly
* **11. Describe the mentor's role in the project. (200 word limit)**
The mentor will guide the student through the different steps in designing a research study, analyzing results, and manuscript writing.

* **12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)**
Currently, I am working with a 4th year medical student with a public health background on a study of social deprivation in China.

* **13. Do you have or will you obtain IRB approval for this project? Please note: Students cannot begin a human subjects project without IRB approval.**

* (Please select ONE)

Selected No (Not Required)

Please specify why it is not required.

We would be conducting secondary analysis of the data already published and publicly accessible. A meta-analysis will be performed on this existing data. Therefore and IRB is not required.
* 1. Faculty Sponsor

* Name: Nikki Posnack
* Degrees: PhD
* Title: Assistant Professor
* Organization: Children's National Hospital
* Address: 111 Michigan Avenue, NW

* 2. Daily Supervisor

Name:
Degrees:
Title:
Organization:
Address:
Apt/Suite:
City:
State:
Zipcode:
Office Phone:
Email Address:

* 3. Project Title (250 character limit)

Project 1: Does Biocompatibility Contribute to Transfusion-Related Adverse Effects? Nearly 15 million transfusions are performed in the United States each year. Despite the frequency, transfusion procedures are not without risk. Blood transfusion complications may be attributed to heavy exposure to plastic devices, which are fabricated with chemicals that exert endocrine disrupting properties. Our laboratory is investigating whether medical device biocompatibility and chemical exposures are underlying contributors to cardiovascular and autonomic dysfunction. We are also investigating alternative materials in an effort to identify safer biomaterials, chemicals and/or surface coatings for transfusion devices and blood banking. Project 2: Assessing Pediatric Cardiac Safety, Toxicity and Therapeutic Targets Pediatric cardiac research can be stalled by a shortage of appropriate models. Despite differences in neonatal, pediatric and adult hearts, our current knowledge is largely limited to adult heart physiology. Unfortunately, current pharmacological agents have been developed with the adult population in mind and can target mechanisms that are only found in the mature myocardium. A more representative model is needed to drive pediatric cardiovascular research. Our laboratory is working to establish a pediatric animal model to monitor
developmental changes in cardiac electrical activity and mechanical function. We are also working to translate these findings to humans by using tissue samples from pediatric patients undergoing cardiac surgery.

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.

* 5. Sponsor's Research Focus:
Yes - Pediatrics
Yes - Pharmacology
Yes - Cardiology

* 6. Sponsor's translational level
* (Please select ONE)
T0/T1: Basic Science Discovery and Initial Translation to Humans

* 7. Hypotheses (200 word limit)
Project 1: The proposal’s objective is to assess whether medical device biocompatibility and chemical exposures are underlying contributors to cardiovascular and autonomic dysfunction, and to identify safer biomaterials, chemicals and/or bioactive-surface coatings for transfusion procedures. The main hypothesis is that plastic devices are not universally biocompatible – and that local and systemic reactions to chemical byproducts contribute to transfusion-related cardiac complications. Project 2: We hypothesize that development differences (delayed t-tubule/intercalated disk formation, calcium handling machinery, adrenergic receptor expression) impacts the efficacy of pharmacological therapies. Further, we hypothesize that myocardial response to pharmacological therapies is blunted in the cyanotic myocardium due to impaired postnatal maturation.

* 8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).
Project 1: Measure the impact of plasticizer chemical exposure on cardiac electrophysiology and calcium handling (approximately n=20 studies). Project 2: Measure age-dependent effects of a pharmacological agent on cardiac electrophysiology and contractility (approximately n=20 studies).

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

Mentor will work with the student to design their project based on previous expertise (e.g., animal handling, cell culture, molecular biology) or goals for research experience. Goal will be to complete at least one full set of experiments related to the overall project. The student will work with a team of research technicians in the laboratory to learn techniques, protocols and data analysis.
* 10. Describe the student's role in the project (200 word limit)
Student's role will be to shadow a research technician to learn relevant techniques, begin to implement techniques (individually) for their respective portion of the project, data analysis, and weekly progress reports at group lab meetings.

* 11. Describe the mentor's role in the project. (200 word limit)
Mentor will work with the student to design an appropriate project, given the student's schedule and time frame. Mentor will pair the student with 1-2 research technicians to learn relevant protocols and meet with the student weekly at lab meetings, and 1-on-1 biweekly to discuss research progress/problems/troubleshooting.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
My laboratory has not yet mentored a Gill Fellow. I have mentored multiple graduate students, undergraduate students, postdoc fellows and clinical fellows.

* 13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.
* (Please select ONE)
Selected Yes

Please provide IRB number and date
* IRB Number: 12146

* IRB Date: 7/22/2019
Faculty Proposal for MD Student Research by Zeina Saliba

* 1. Faculty Sponsor

* Name: Zeina Saliba
* Degrees: MD
* Title: Inpatient Medical Director, Assistant Professor
* Organization: MFA
* Address: 900 23rd St.
* Apt/Suite: 
* City: Washington
* State: DC
* Zipcode: 20037
* Office Phone: 202-741-3433
* Email Address: zsaliba@gwu.edu

* 2. Daily Supervisor

Name: Drs. Claudia Ranniger & Andrea Anderson
Degrees: 
Title: additional faculty mentors
Organization: 
Address: 
Apt/Suite: 
City: 
State: 
Zipcode: 
Office Phone: 
Email Address: 

* 3. Project Title (250 character limit)

Efficacy of a De-Escalation Training Program on Learner Knowledge, Attitudes and Practice

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


A Practical Guide to Emergency Department Telemedicine, chapter author, in progress

5. Sponsor's Research Focus:
Yes - Psychiatry
Yes - Emergency Medicine

6. Sponsor's translational level
*(Please select ONE)*
T3: Translation to Practice

7. Hypotheses (200 word limit)
We postulate that a correctly designed de-escalation training program for staff and residents will decrease security/safety incidents across the hospital and increase trainee/staff comfort with agitation management.

8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).
Purpose of the study is to: - Publish the results of a de-escalation training program for GW that can be used for interdisciplinary code strong training in ED and on the wards - Evaluate the curriculum using pre/post knowledge and opinion surveys, performance checklists, and qualitative evaluation of debriefing themes. - Evaluate GWU code strong responses and use of chemical/mechanical restraints and security activations before and after the training to assess efficacy at the patient outcome (T3) level.

9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

The project will be in its second year and is expanding. The educational training activity was initially piloted among emergency and psychiatric residents and subsequently extended to 4th year medical students entering psychiatry with further expansion in March 2020 to those entering fields of emergency and family medicine. Data analysis will occur over the subsequent months and the next phase will include tailoring of program for interdisciplinary teams and creation of Mock Code strong training with evaluation of impact on both frequency as well as efficacy of hospital response teams.

10. Describe the student's role in the project (200 word limit)
The student will: - learn about validation of surveys and help with creation of new educational research tool - send out post-training surveys to study subjects - perform preliminary data analysis on spring 2020 trainings - review clinical charts of patients who were restrained and any that involved behavioral health codes - prepare submission of educational training materials to MEdEd portal It is expected that the student will both produce a poster for research day as well as draft a manuscript and the student will have the option to be involved in future projects that arise from this study.

11. Describe the mentor's role in the project. (200 word limit)
The mentor takes responsibility for the overall organization of the project, including working with the CLASS center in training staff and communicating with hospital quality team to obtain data for review. Mentor will maintain IRB approval and coordinate student EMR access. The mentor will make time to meet with the student to discuss future plans, career counseling and highlight opportunities for shadowing. The mentor welcomes student involvement in other projects, including telepsychiatric ED follow-up.

12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

All three faculty members are heavily involved in medical student education, in the preclinical and clinical years, as well as advising. In addition, Dr. Ranniger is the medical director for the simulation center and Dr. Saliba is the GW mentor for the nationwide Choosing Wisely STARS (Students and Trainees Advocating for Resource Stewardship) program, a value-based care education and practice initiative. 1st year student last summer was chosen for health services scholarship program and has been invited to submit their paper to peer-reviewed journal. A 3rd year clinical student worked with primary mentor on clinical rotation and produced poster that won 3rd place at an international conference. Another 3rd year student used research elective to work with mentor on preparing retrospective chart review that was precursor to current prospective study.

13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.

(Please select ONE)

Selected Yes

Please provide IRB number and date

IRB Number: 180658
IRB Date: renewed 12/4/19
Faculty Proposal for MD Student Research by Charles P Samenow

* 1. Faculty Sponsor

Name: Charles P Samenow  
Degrees: MD, MPH  
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* 2. Daily Supervisor

Name: Charles P Samenow  
Degrees: MD, MPH  
Title: Associate Professor  
Organization: MFA  
Address: 2120 I Street NW  
Apt/Suite: Suite 600  
City: Washington  
State: DC  
Zipcode: 20037  
Office Phone: 2027412900  
Email Address: CSAMENOW@mfa.gwu.edu

* 3. Project Title (250 character limit)

Role of Mental Health Defense on Convictions and Sentencing for Online Sexual Offenses Against Minors

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:
Yes - Psychiatry

* 6. Sponsor's translational level
* (Please select ONE)
T4: Translation to Population Health

* 7. Hypotheses (200 word limit)
Mental health defenses play an important role in mitigating sentencing for individuals convicted of online sexual offenses. We will look at how defenses such as depression, mania, addiction, autism spectrum and other mental health conditions influence judicial opinions.

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
To review current federal and state court opinions to see how mental health testimony influence conviction and sentencing of online sexual offenses against minors. We will also review medical literature and law reviews.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research
The project will look at (inclusion criteria): - federal and state cases - district/local and appellate courts - cases from the past 10 years - online sexual offenses of adults (age 18 and up) involving minors (below age 18*) including child pornography (possession, production, and distribution) and solicitation. Corruption of a minor, lewd sexual acts, etc... will also be considered as long as it is an online offense. *State cases will defer to age of consent for that state
The project will appeal both to legal and medical professionals. There are applications to psychology, criminal justice, sociology, social work and forensic science. This is original research in that there are few studies that have tracked how mental health defenses have influenced convictions and sentencing. This is an important area because some argue that current sentencing is draconian and is based on archaic notions of sex offenders (e.g. they cannot be treated). Others argue that sentencing does not reflect the seriousness of the crime and impact on victims. Understanding how judges view mental health defenses can be helpful to attorneys and clinicians involved in these cases.

* 10. Describe the student's role in the project (200 word limit)
The student will assist with: - Literature Review - Mining Cases and Literature for Relevant Judicial Opinions - Creating a database of findings and references - Writing the paper for peer review/publishing

* 11. Describe the mentor's role in the project. (200 word limit)
The Mentor will assist with: - Guiding student on literature review - Frequent review of project progress - Writing of paper

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

Sponsored Gill Fellows on establishing a survey of alcohol, drug and mental health issues among medical students at GW. Findings were presented at the International Conference on Physician Health (Chicago, IL) and published in Academic Psychiatry. Similar to those projects, this is a great opportunity for a student to take the lead on a project that will result in publication.

* 13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected No (Not Required)

Please specify why it is not required.

Review of publicly available court records and journal articles. There are no human subjects.
Faculty Proposal for MD Student Research by Roopa Kanakatti Shankar

* 1. Faculty Sponsor

* Name: Roopa Kanakatti Shankar
* Degrees: MBBS, MS (Clinical and Translational Research)
* Title: Assistant Professor of Pediatrics, GWU and Director, Turner Syndrome Program
* Organization: Children's National Hospital
* Address: 111 Michigan Avenue NW
* Apt/Suite: Ste 200, WW 3.5, Division of Endocrinology
* City: Washington
* State: DC
* Zipcode: 20010
* Office Phone: 202-476-2121
* Email Address: roopa.shankar@childrensnational.org

* 2. Daily Supervisor

Name: Lauren Clary
Degrees: PhD
Title: Assistant Professor of Psychiatry, Behavioral Sciences and Pediatrics, GWU and Director, Endocrine and Diabetes Clinical Psychology Services
Organization: Children's National Hospital
Address: 111 Michigan Ave NW
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City: Washington
State: DC
Zipcode: 20010
Office Phone: 202-476-2231
Email Address: LClary@childrensnational.org

* 3. Project Title (250 character limit)

Association of Clinical Phenotype with the Neurocognitive and Behavioral profile of patients with Turner syndrome.

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:
Yes - Pediatrics
Yes - Endocrinology

* 6. Sponsor's translational level
* (Please select ONE)
T3: Translation to Practice

* 7. Hypotheses (200 word limit)
Turner syndrome (TS) is a genetic disorder characterized by the absence of part or whole X-chromosome in a phenotypic female. The clinical phenotype is extremely variable even in individuals with the classic 45, X karyotype and includes skeletal abnormalities, short stature, lymphedema, cardiac and renal abnormalities, primary ovarian insufficiency, and increased incidence of autoimmune diseases, hearing loss, metabolic syndrome and neurocognitive issues. Challenges in neurocognitive domains and a higher incidence of depression, anxiety and social isolation have a significant impact on quality of life of these girls. Aim 1: Retrospective chart view and description of the neurocognitive profile in the cohort of patients with TS and assessment of correlation to the clinical phenotype. Hypothesis 1: Younger age at diagnosis of TS and lower birth weight are associated with decreased visual-spatial reasoning and fine motor skills. Aim 2: Assessment of self-reported outcomes of anxiety, depression and peer relationships and their correlation to the clinical phenotype. Hypothesis 1: Aggregate scores on patient and parent self-reported outcomes for anxiety, depression and peer relationships assessed by Patient-Reported Outcomes Measurement Information System (PROMIS) short forms is correlated to age at start of estrogen therapy (if applicable) but is not correlated with height standard deviation score.

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
We expect to have IRB approval soon for the TS Redcap Database at Children’s National Hospital (CNH), a prospective registry that includes the genetic and extended clinical phenotype of all girls with TS seen in the multidisciplinary program. Clinical, laboratory, and radiological data, as well as biospecimens will be collected on these patients and maintained in a RedCap database and biorepository respectively. This specific project will involve retrospective medical record review, and input into the Redcap database, as well as analysis of specific outcomes of interest. In the past year, 50 unique patients have been seen in the TS clinic and will be consented for inclusion in the database. We expect neuropsychological /PROMIS data to be available on 50% of these patients. Clinical data will be abstracted including but not limited to age at diagnosis, birth weight, height SD, age at initiation of estrogen therapy, with special attention to scores on neuropsychological assessments and PROMIS short forms. Descriptive statistics will be used to describe the neurocognitive profile and self-reported outcomes on anxiety/depression and peer relations in this cohort. Spearman Rank order correlation will be used to test the hypothesis of correlations between the clinical parameters and the outcomes of interest.
9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.

Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

Turner syndrome is associated with an extremely variable medical phenotype even in girls with similar karyotypes. While some neuropsychological issues are correlated to the genotype, their association with a clinical phenotype is under-reported and the impact of the clinical phenotype on behavioral issues is largely unknown. Studies show that girls receive endocrine and cardiac care but often do not receive appropriate and timely screening for neurocognitive and behavioral challenges that can have a significant impact on their academic achievement and quality of life. The TS program at CNH includes a multidisciplinary clinic with endocrinology / gynecology / cardiology / genetics and psychology. In addition, all patients are referred for detailed neuropsychological testing. We seek to report the overall neurocognitive and self-reported behavioral profile in this cohort of patients with TS. We will test the hypothesis that specific clinical attributes will be correlated with performance in specific neurocognitive domains. As an example, we hypothesize that the birth weight and age at diagnosis (suggesting an intrauterine factors) may be correlated with visual-spatial and fine motor development. We will also assess for the self-reported behavioral outcomes in relation to short stature and estrogen therapy that are thought to have a significant psychosocial impact in this population. Several other associations may be evidenced by the data that are not expected a-priori and the student will have the opportunity to explore these associations. Since this is a retrospective chart review in a limited number of patients, we may not have sufficient power to confirm these associations but will serve as pilot data for future hypothesis-driven research to explore the common developmental origins of the neuropsychological and clinical phenotype in TS. The ability to predict a neurocognitive outcome in relation to a clinical phenotype will significantly impact clinical practice and will inform counseling and referral for services. We are currently submitting for IRB approval of the TS registry and consented recruitment to the TS database is anticipated to start no later than March 2020, for prospective surveillance and establishment of the biospecimen repository. A waiver of consent for retrospective medical chart review of all these patients is sought from the IRB to abstract data relevant to this project. Data on variables of interest will be abstracted by the student from the medical record will be input into the Redcap database and the analysis of findings will be completed in the summer of 2020. We expect to report the findings at a national conference.

10. Describe the student's role in the project (200 word limit)

The research student on this project will complete the medical record review, data abstraction and input into the Redcap database, as well as the data analysis with supervision using descriptive statistics and Spearman Rank correlation. We expect to have other ongoing retrospective and prospective research protocols based on the TS database that the student can observe or participate. It is expected that the student will prepare an abstract for presentation at a national conference and take the lead in manuscript preparation for this project. The student will also participate in the monthly multidisciplinary TS clinic, present on relevant topics at the pre-clinic case conference, and interact with multiple specialists at the clinic to formulate a comprehensive care plan. This will encourage the student to gain interdisciplinary clinical knowledge on management of congenital heart disease, growth hormone therapy, primary ovarian insufficiency and hormonal induction of puberty, and counseling on fertility preservation, genetics and behavioral health screening. The student is also invited to participate in the endocrine and diabetes didactic sessions, and case presentations in the division of endocrinology at Children's National hospital.

11. Describe the mentor's role in the project. (200 word limit)
The faculty mentor (Dr. Kanakatti Shankar) will take primary responsibility for the day to day supervision along with Dr. Lauren Clary, our clinical psychologist within the Division of Endocrinology and Diabetes. The faculty mentor will directly provide guidance and supervision for chart review, data abstraction and input into RedCap, and data analysis. The mentor will encourage and supervise the development of an abstract for conference submission and manuscript preparation. The mentor will also engage the student in all ongoing aspects of research and foster understanding of the research process, ethical and responsible conduct of research, and help them work with the study coordinator to observe the process of consent/enrollment and data collection. The mentor will also facilitate clinical learning on the multi-system pathology and management of Turner syndrome in a multidisciplinary clinic and foster interdisciplinary interactions with other specialists.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

Dr. Kanakatti Shankar has previously mentored several medical students, residents and pediatric endocrine fellows in both a clinical and research capacity. She has guided and supported several trainees to submit and present abstracts at national conferences. She joined as faculty with Children's National and GWU at the end of 2018, and has established the TS program this past year, is mentoring residents and fellows in the clinic and is enthusiastic to support medical student training on this project. Dr. Clary is the Director of Endocrine and Diabetes Clinical Psychology Services who provides ongoing supervision and mentorship to psychology graduate level externs, predoctoral interns, postdoctoral fellows and new psychology faculty. She has a long track record of mentoring more than 35 students/trainees who provide education, support and treatment to families with type 1 diabetes, type 2 diabetes and a variety of endocrine disorders as well as emotional, attentional and behavioral concerns.

* 13. Do you have or will you obtain IRB approval for this project?

Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected No (Pending)
Faculty Proposal for MD Student Research by Victoria Shanmugam

* **1. Faculty Sponsor**

- **Name:** Victoria Shanmugam
- **Degrees:** MBBS, MRCP, MACP, MACR, CCD
- **Title:** Director of Rheumatology
- **Organization:** GW School of Medicine and Health Sciences
- **Address:** 2300 M Street NW
- **City:** Washington
- **State:** DC
- **Zipcode:** 20037
- **Office Phone:** 202-741-2488
- **Email Address:** vshanmugam@mfa.gwu.edu

* **2. Daily Supervisor**

Name: Derek Jones  
Degrees: PhD  
Title: Post Doctoral Scientist  
Organization: Division of Rheumatology  
Address: 701 Ross Hall, 2300 Eye Street  
City: Washington DC  
State: DC  
Zipcode: 20037

* **3. Project Title (250 character limit)**

Role of Dermcidin and Antimicrobial Peptides in Pathogenesis of Hidradenitis Suppurativa

* **4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.**


* 5. Sponsor's Research Focus:
Yes - Genomics

* 6. Sponsor's translational level
* (Please select ONE)
T2: Translation to Patients

* 7. Hypotheses (200 word limit)
Prior work from our group has demonstrated that HS skin has aberrant expression of antimicrobial peptides (AMPs) which are known to play an important role in the innate immune responses in skin diseases. Based on data from mRNA expression arrays, we hypothesize the AMP Dermcidin is under expressed in HS skin compared to patients without HS.

* 8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).
1. Quantify Dermcidin expression in skin from HS patients and normal control skin Immunohistochemistry will be performed on 20 HS skin specimens and 20 normal control skin specimens collected through the WE-HEAL study. Immunoreactivity will be semiquantitatively assessed by two independent blinded researchers and scored as follows 0= negative, 1= staining in corneal layer, 2=staining in corneal and granular layer. 2. Perform qPCR to assess Dermcidin expression in HS and normal control skin qPCR will be performed on 20 HS skin specimens and 20 normal control skin specimens which are currently stored in the WE-HEAL study biorepository and expression will be compared to the housekeeping gene GAPDH. 3. Quantify other AMPs of interest that are differentially expressed in HS and normal skin.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research
1. Quantify Dermcidin expression in skin from HS patients and normal control skin Immunohistochemistry will be performed on 20 HS skin specimens and 20 normal control skin specimens collected through the WE-HEAL study. Immunoreactivity will be semiquantitatively assessed by two independent blinded researchers and scored as follows 0= negative, 1= staining in corneal layer, 2=staining in corneal and granular layer. 2. Perform qPCR to assess Dermcidin expression in HS and normal control skin qPCR will be performed on 20 HS skin specimens and 20 normal control skin specimens which are currently stored in the WE-HEAL study biorepository and expression will be compared to the housekeeping gene GAPDH. 3. Quantify other AMPs of interest that are differentially expressed in HS and normal skin.

* 10. Describe the student's role in the project (200 word limit)
The successful student for this project will be involved in performing IHC, scoring specimens for analysis, analyzing qPCR results, and assisting with manuscript development and presentation of results. The student will submit an abstract detailing the results from this work at Research Day, and to the Symposium on Hidradenitis Suppurativa Advances.
11. Describe the mentor's role in the project. (200 word limit)
The Mentor will oversee the project and ensure the mentee has adequate support and resources to ensure completion of the primary research during the Gill Scholarship time frame. The mentor will oversee analysis of results, guide the student on abstract submission, poster presentation and assist with manuscript preparation and ultimate submission.

12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

13. Do you have or will you obtain IRB approval for this project? Please note: Students cannot begin a human subjects project without IRB approval.
* (Please select ONE)

Selected Yes

Please provide IRB number and date

* IRB Number: 041408

* IRB Date: 05/28/2019
Faculty Proposal for MD Student Research by Maho Shibata

* 1. Faculty Sponsor

* Name: Maho Shibata
* Degrees: Ph.D.
* Title: Assistant Professor
* Organization: The George Washington University
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* State: DC
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* Office Phone: 202-994-0802
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* 2. Daily Supervisor

Name:
Degrees:
Title:
Organization:
Address:
Apt/Suite:
City:
State:
Zipcode:
Office Phone:
Email Address:

* 3. Project Title (250 character limit)
Prostate cancer patient-derived 3D organoid culture

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.

* 5. Sponsor's Research Focus:
Yes - Anatomy
Yes - Biochemistry
Yes - Cancer
Yes - Surgery
Yes - Endocrinology

* 6. Sponsor's translational level
*(Please select ONE)*
T0/T1: Basic Science Discovery and Initial Translation to Humans

* 7. Hypotheses (200 word limit)
In the United States, both prostate cancer incidence and mortality rates are higher in African American men compared to white men (DeSantis et al., 2016). In addition to socioeconomic factors such as access to care, it is believed that biological differences likely contribute to these health disparities. For example, sequencing studies of prostate tumors have revealed genetic alternations that differ between prostate cancers in African American and Caucasian men (Huang et al., 2017). However, African American samples are not well represented in databases such as The Cancer Genome Atlas (TCGA) (Spratt et al., 2016), and few African American prostate cancer cell culture lines or xenograft models are available, making African American prostate cancers difficult to study. Recent developments in cell culture methodologies, which allow for the growth of cells in 3D culture as “organoids” resembling mini organs, have provided a significant advance for growing prostate cancer cells in culture (Fatehullah et al., 2016), and several prostate cancer organoid lines have recently been generated from patient prostate cancer samples (Gao et al., 2014; Puca et al., 2018). We hypothesize that patient derived organoids can be utilized as a model system for understanding the molecular basis of prostate cancer health disparities.

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
The generation of organoid lines from African American prostate cancers would facilitate research on the molecular basis of racial disparities in prostate cancers. Organoid lines can be generated more rapidly compared to xenograft models, and can also be grafted to generate xenograft models, and used for disease modeling and drug response assays (Lee et al., 2018). Our objective is to generate and characterize organoid lines from prostatectomy tissues from African American and Caucasian prostate cancer patients undergoing surgery at the George Washington University Hospital. We expect that the innovative organoid culture approach proposed for the generation of several organoid culture lines from African American prostate cancers will provide new models for understanding the basic biology and molecular basis for health disparities, and could also be used for high-throughput drug screening in the future to identify better prostate cancer treatments.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research
Overview: To establish a new model system for studying African American prostate tumors, we will generate organoid lines from prostatectomy tissues from African American and Caucasian prostate cancer patients undergoing surgery at the George Washington University Hospital. Dr. Antoun Toubaji (GW, Pathology, GW Biospecimen Repository Core) will identify and isolate tumor regions. We will verify tumor content using adjacent tissue sections. We will enzymatically dissociate fresh tissues and culture cells in organoid culture conditions, with the goal of generating tumor organoid lines that can be passaged and expanded. Based on previous reports, we estimate that we will be able to generate organoid lines from approximately 20% of tumors. We will conduct histopathology and marker analysis to compare organoids to the primary patient tumors. As a control, we will also grow normal organoids from normal regions of the same prostatectomy sample.

Timeline: We will collect fresh patient samples from the GW Biospecimen Repository in order to culture prostate tumor organoids. The collection of patient tissues will be ongoing, as we estimate the efficiency of organoid line generation to be approximately 20%. Week 1 - Week 4: The student will be involved in the collection of fresh patient prostate tissues from the GW Biorepository. The student will enzymatically dissociate and culture tissues in organoid culture conditions. The cells will be cultured and expanded to generate organoid lines. We estimate that at least 1 patient sample will be available each week. Week 5: Once organoids have grown and sufficient material is available, the student will fix the organoids and section the tissues. Week 6-7: The student will perform histological (hematoxylin and eosin) and immunohistochemical analysis of organoids and tumor tissues from the same patient to assay for luminal (CK8, CK18, Nkx3.1), basal (CK5, CK14, P63), neuroendocrine (synaptophysin) and tumor (AMACR) markers. Week 8: The student will image the stained prostate tumor organoids and control patient tissues. We anticipate that we will be able to culture patient cells from several patients as organoids. As controls we will also culture normal prostate tissues (obtained from the same surgical sample). In the case that organoid lines cannot be generated from the tissues obtained by the student, the student will characterize previously generated organoids in the lab.

10. Describe the student's role in the project (200 word limit)
The student will work with the mentor, laboratory technician, and postdoctoral researcher in the lab to learn laboratory techniques, including sterile technique, media preparation, 3D organoid tissue culture, tissue sectioning and histological and immunohistochemical analysis of tissues. The student will assist in obtaining patient tissues from the Pathology department and will dissociate tissues, grow patient-derived organoids, and characterize the generated organoids though histological and immunohistochemical analysis. The student will participate in weekly lab meetings and journal clubs and present their findings in a lab meeting presentation at the end of the summer.

11. Describe the mentor's role in the project. (200 word limit)
The mentor will supervise the design of the experiments and directly work with the student in the lab. The student will interact with the mentor daily, and will have weekly one-on-one meetings to discuss progress in the research and obtain critical feedback and suggestions. The mentor will also ensure that the student receives the safety and technical lab training necessary for the project, and will provide the supplies, reagents and equipment for the experiments.

12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
I started my lab as a new investigator in the GW Cancer Center in June 2018. We currently have two pre-med undergraduate students in the lab. As a postdoctoral scientist at Columbia University Medical Center, I worked closely with 3 medical residents (5th year Urology residents in their 1-year research year), and 1 oncology fellow in the lab.

13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)
Selected Yes
Please provide IRB number and date

* IRB Number: NCR191204

* IRB Date: April 11, 2019
Faculty Proposal for MD Student Research by Marc Siegel

* 1. Faculty Sponsor

* Name: Marc Siegel
* Degrees: MD
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* City: Washington
* State: DC
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* Email Address: msiegel@mfa.gwu.edu

* 2. Daily Supervisor

Name: Marc Siegel
Degrees:
Title:
Organization:
Address:
Apt/Suite:
City:
State:
Zipcode:
Office Phone:
Email Address:

* 3. Project Title (250 character limit)
Frequency of Low Level HIV Viremia in Patients on Integrase Strand Transfer Inhibitor-Based Antiretroviral Therapy

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.

Lerner A, Frost S, Siegel M. Urban-acquired Leptospirosis in Washington, DC. A Case Report and Review of the Literature. Infectious Diseases in Clinical Practice. 2018 Nov, 26(6); 331-332

* 5. Sponsor's Research Focus:
Yes - Infectious Disease

* 6. Sponsor's translational level
* (Please select ONE)
T2: Translation to Patients

* 7. Hypotheses (200 word limit)
Integrase strand transfer inhibitors (ISTI) are the most virologically active HIV medicines available today. As such, all first line antiretroviral (ARV) therapies are recommended to contain an ISTI. There are multiple ISTI-based options available (Stribild, Genvoya, Triumeq, Biktarvy, Juluca, Dovato) but Biktarvy has become the most widely prescribed regimen. Recently we have noticed an increasing frequency of low level HIV viremia (< 200 copies) in patients recently switched/started on Biktarvy, raising a concern for suboptimal viral suppression with this regimen. Our hypothesis is that when comparing complaint HIV patients on ISTI-based ARV regimens, a greater proportion of those on Biktarvy will have low-level viremia than patients on other ISTI-based ARV regimens

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
The project goal will be to review the electronic medical records of all HIV patients followed at the GW MFA who are compliant on their ISTI-based ARV therapy. These patient charts will be compared based on the specific ISTI-based ARV regimen that the patients are on (Genvoya vs Triumeq vs Biktarvy vs Stribild). In each group of patients we will compare the number of patients with low level viremia (defined as an HIV viral load of < 200 copies/ml) to determine if there is a statistically significant difference in one group versus another. If a difference is discovered, further analysis will occur to determine other factors that might be associated with this difference. There are 1200 HIV patients followed at the MFA of whom 70% are probably on an INSTI-based ARV regimen of who 70% are compliant with their therapy. Therefore an estimated 600 patient charts will be reviewed

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

1. IRB submission (expeditied review) 2. Ask the MFA IT department to provide a list of all patients seen at the MFA with a diagnosis of HIV who have one of Genvoya, Triumeq, Biktarvy or Stribild listed in their medication profile 3. Exclude those patients who have not been seen at the MFA in the last 12 months 4. Exclude patients with reported noncompliance 5. Separate patients into groups based on specific ISTI-based ARV regimen and record demographics of each group (age, sex, race) 6. Review all HIV RNA PCR results from the last 12 months in patients in each group 7. Compare groups to assess difference in frequency of low level viremia 8. If a statistically significant difference is observed, investigate other patient characteristics that might be associated with this
* 10. Describe the student's role in the project (200 word limit)
The student (under my guidance) will be responsible for all aspects of this research project

* 11. Describe the mentor's role in the project. (200 word limit)
I will be overseeing every step of this research project and give any guidance as is needed by the student

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
Andrew Bernstein (currently MSII) has worked with me on a project titled "Weight Change Associated with Switching to Integrase Strand Transfer Inhibitor-based antiretroviral regimens in HIV-positive subjects" that was presented at the ID Week conference this past October and is currently being submitted for publication

* 13. Do you have or will you obtain IRB approval for this project? Please note: Students cannot begin a human subjects project without IRB approval.
* (Please select ONE)
Selected No (Pending)
1. Faculty Sponsor

Name: Neal Sikka
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2. Daily Supervisor

Name: SAME
Degrees: 
Title: 
Organization: 
Address: 
Apt/Suite: 
City: 
State: 
Zipcode: 
Office Phone: 
Email Address: 

3. Project Title (250 character limit)

Effect of immersive Virtual Reality breaks on shift-worker alertness

4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:
Yes - Emergency Medicine

* 6. Sponsor's translational level
* (Please select ONE)
T2: Translation to Patients

* 7. Hypotheses (200 word limit)
Hypothesis: Immersive VR will improve alertness during healthcare provider work hours

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
Plan to Enroll 20 clinicians into the study with 6 shift (3 wild type, 3 VR). Also capture contextual ED volume and business impacting clinician satisfaction and stress. Additionally, capturing biometric information during the shift. Enrollment is starting now (November 2019). The project goals will be to complete data collection and conduct data analysis.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

This project builds on a feasibility study from 18 months ago. Modifications to the protocol should allow for better data collection and improved chance of understanding the impact of the intervention. The IRB is approved and the data collection is starting, so there high chance of reaching the objectives b the end of summer. The impact of VR on alertness goes beyond health care to all type of shift workers. There is little literature in the are of using VR to improve alertness, there is good opportunity to present initial results at a national meeting and write a manuscript for publication.

* 10. Describe the student's role in the project (200 word limit)
The student will assist with enrollment, data analysis and preparing a publication. The student will also participate / exposed to the other health technology projects in the Department and other telehealth related educational activities such as journal club, shadowing, and learning about activities in the department. There are numerous other telehealth related activities that can be matched to the fellow’s interest to ensure a wide exposure to a variety of telehealth programs. Given interest and timing, the student can participate in development of these product lines.

* 11. Describe the mentor's role in the project. (200 word limit)
Dr Sikka has hosted a number of Gill Fellows and focuses his research on the use of telehealth and similar digital tools in health. He leads telehealth and Innovation efforts. He will mentor the student on health innovation, technology implementation, operations, and telehealth as well as supervise all aspects of the research in coordination with our department research coordinator.
* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

Dr Sikka has enjoyed working with numerous Gill and HSP students in the last few years. Each student has had significant hands on exposure to telehealth or technology related project and mentoring. Student with interest in technology, health disparities, health access, telehealth, virtual reality and other innovative solutions at the cross of clinical care and population health will enjoy working with our team and have a high likelihood of having an abstract selected for a regional or national meeting as well as peer reviewed publications. We also have a summer Telehealth Curriculum and journal club that the student will participate in.

* 13. Do you have or will you obtain IRB approval for this project?
   Please note: Students cannot begin a human subjects project without IRB approval.

   * (Please select ONE)
     Selected Yes

   Please provide IRB number and date
   * IRB Number: 051818
   * IRB Date: 6/21/19
Faculty Proposal for MD Student Research by James Simon

* 1. Faculty Sponsor

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* 2. Daily Supervisor

Name: Dr. Rachel Rubin
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State: DC
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* 3. Project Title (250 character limit)

Treatment of Clitoral Adhesions for the Treatment of Clitoral Phimosis in Women. Outcomes and Satisfaction Rates

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


5. Sponsor's Research Focus:
Yes - Obstetrics/Gynecology

6. Sponsor's translational level
• (Please select ONE)
T3: Translation to Practice

7. Hypotheses (200 word limit)
We hypothesize that women who have the symptomatic adhesions of their clitoral hood treated experience relief and a high level of satisfaction at low risk after an in-office procedure.

8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).

Little is known about the clitoris and its pathology. Few medical providers ever examine the clitoris or ask patients about its function in their sexual pleasure. Our initial published data shows a 23% prevalence of clitoral adhesions in patients presenting to a sexual medicine practice for any reason. Our goal is to establish whether or not patients were helped by an in-office procedure to remove symptomatic clitoral adhesions and assess the clinical outcomes and risks. We also hope to understand the underlying risk factors behind women who develop clitoral adhesions and how to prevent the tissue from re-adhering. The medical student will review about fifty medical charts of our patients who underwent lysis of clitoral adhesion procedures for the treatment of clitoral adhesions. She may also work with several other experts in the field to combine data to evaluate larger groups of women. After collecting and analyzing data from patient charts, a survey will be conducted to be sent to patients who underwent the procedure. Our main goal of this project is to gather information about outcomes and satisfaction after undergoing the procedure. This information will come from the anonymous survey answers from the patients.

9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.

Selection criteria include:
• The project design makes it likely that the objectives will be achieved
• The project is likely to result in a report of interest to other scholars
• The project fulfills discovery/original research

This research involves a retrospective chart review of patients who underwent lysis of clitoral adhesion procedures to treat clitoral adhesions. The student will also create a web-based survey to evaluate outcomes. This project is easily completeable in a few short weeks, and the data collected is of great significance to the sexual medicine community as well as the OB/GYN and Urology fields. Clitoral adhesions are not well understood, or adequately researched. This is an exciting project that has big implications for future research and changes of practice management for Women’s Health providers.

10. Describe the student's role in the project (200 word limit)
The medical student will do a retrospective chart review of patients who underwent a lysis of clitoral adhesions procedure due to clitoral adhesions. After compiling all relevant information, survey questions will be constructed to be sent to patients who underwent the procedure. After receiving completed surveys from patients, the medical student will analyze the answers and compile the data for evaluation. The medical student will write up the findings from the information already known from the patient charts and from the patient survey answers to formulate conclusions about the effectiveness of the lysis procedure from patient outcomes and what further research needs to be conducted in learning more about prevention and treatment of clitoral adhesions. This data will quickly be turned into a publication or multiple publications that will be submitted to the peer reviewed literature.

11. Describe the mentor's role in the project. (200 word limit)

The student will have an enriching research experience as well as clinical shadowing experience with experts in the field of sexual health. This is ideal for any student interested in women’s health, obgyn and urology. The mentor will oversee the retrospective chart review, constructing of survey questions, and analysis of patient survey answers. The mentor will have daily interaction as well as check-in with the medical student to answer questions and give guidance for next steps of the project. This data will quickly be turned into a publication or multiple publications that will be submitted to the peer reviewed literature.

12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

The senior investigator has trained multiple medical students, interns, residents, research fellows and postdoctoral fellows. There are not current or anticipated other summer student research fellows. No current or past Gill fellows.

13. Do you have or will you obtain IRB approval for this project?

Please note: Students cannot begin a human subjects project without IRB approval.

(Please select ONE)

Selected No (Not Required)

Please specify why it is not required.

Blinded, retrospective, de-identified chart review
Faculty Proposal for MD Student Research by Mary Ann Stepp

* 1. Faculty Sponsor

* Name: Mary Ann Stepp
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* 2. Daily Supervisor

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* 3. Project Title (250 character limit)
Conditioned media from Mitomycin C treated human corneal fibroblasts alters extracellular matrix secretion by human corneal fibroblasts.

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:
Yes - Anatomy

* 6. Sponsor's translational level
* (Please select ONE)
T0/T1: Basic Science Discovery and Initial Translation to Humans

* 7. Hypotheses (200 word limit)
We hypothesize that treating human corneal epithelial cells with media secreted by human corneal fibroblasts transiently treated with mitomycin C will alter matrix secretion by corneal epithelial cells.

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
Treat human corneal epithelial cells in vitro with media secreted by control and human corneal fibroblasts transiently treated with mitomycin C. Determine whether treatment alters matrix secretion and deposition by epithelial cells by doing Western blots, staining of cells to visualize ECM proteins, and doing QPCR on RNA isolated from treated cells.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

Injuries to the cornea cause pain and discomfort and reduce the quality of life for patients. Recurrent corneal erosions are particularly difficult to treat. The Stepp lab has published several papers describing how the drug mitomycin C reduces the frequency of corneal erosions in vivo in a mouse model. Studies in vitro suggest that MMC helps improve adhesion of epithelial cells to their underlying substrate. The proposed studies will provide further evidence to allow us to determine how MMC works in vivo to help reduce corneal erosions and help them heal. 1. Culture human corneal fibroblasts and treat transiently (2 hr) with MMC. Remove media, wash cells and add fresh media. After 48-72hr, remove media, count cells, freeze media. 2. Add control and MMC treated CM to human corneal epithelial cells in vitro and allow cells to grow for several days. 3. Remove media and a) extract cell monolayers to perform Western blots to quantify laminins and collagens produced by the cells, b) fix cells and perform immunofluorescence to localize ECM proteins, c) Isolate RNA and perform QPCR to quantify mRNAs for ECM proteins. The cells for these studies are available in the lab. The Stepp Lab has experience and equipment needed allow the student to carry out the proposed experiments. It will take 1-3 weeks to generate the conditioned media and cells needed to perform the quantitative part of the work. The remaining time will be spent doing the Western blots, staining and imaging cells, and doing QPCR.

* 10. Describe the student's role in the project (200 word limit)
The student will learn how to do cell culture, how to design the experimental protocol, and carry out the quantitative assessment of extracellular matrix expression by corneal epithelial cells.
11. Describe the mentor's role in the project. (200 word limit)

The mentor will work with the student to design the experiment, oversee the experimental design, and make sure the resources needed are available to allow the project to be completed within the time available. She will assist the student in preparing a presentation describing the results.

12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

Marcus Brown, M.D. GWU BS in Biological Sciences, 1999–2001. Received MD degree from Georgetown Medical School in 2006. Kristen Losicco, M.D. Got her BS in Biological Sciences at GWU and was a Howard Hughes Undergraduate Research Fellow, 2002–2005. Received M.D. 2010 from Wake Forrest University. Adith Sekarin, M.D. Summer 2005 high school student intern and summers of 2006 and 2007. Received MD from GWU Medical School 2014. Lamise Rajjoub, M.D., Summer research assistant in 2007 and was awarded a GILL FELLOWSHIP to work in the lab during the summer of 2008. Dr. Rajjoub graduated from GWUMC with the MD degree May 2011. Anjana Sekarin, M.D. Summer 2008. She graduated last year and is now a resident physician at Mount Sinai Hospital in NYC. Brianna Kyne B.S. Summers of 2013-2015. Currently a 4nd year medical student at U. of MD. Brianna is considering returning to GWU next year as an OB/GYN resident.

13. Do you have or will you obtain IRB approval for this project?  
Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected No (Not Required)

Please specify why it is not required.

Studies use cultured cells only.
Faculty Proposal for MD Student Research by Kathleen Thoma

* 1. Faculty Sponsor

* Name: Kathleen Thoma
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* 2. Daily Supervisor

Name: (same as above)

Degrees:
Title:
Organization:
Address:
Apt/Suite:
City:
State:
Zipcode:
Office Phone:
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* 3. Project Title (250 character limit)

The importance of qualitative research in the health sciences: Coding, analyzing and interpreting qualitative data about the lived experiences of low income, urban young adults living with HIV/AIDS.

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:
Yes - Infectious Disease

* 6. Sponsor's translational level
* (Please select ONE)
T0/T1: Basic Science Discovery and Initial Translation to Humans

* 7. Hypotheses (200 word limit)
Understanding the nuances of a population's lived experiences and coping skills enhances medical practice. The qualitative research method generates in-depth, narrative data that is important for understanding patient behavior at a deep level. The lived experiences and coping skills of low income, urban young adults living with HIV/AIDS are dependent on Bronfenbrenner's Ecological Model of Human Development and the concept of Resilience.

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
The goal of this project is to teach medical students how to code, analyze and interpret a large, qualitative database that contains in-depth interviews from a group of low income, urban young adults living with HIV/AIDS. The ultimate measurable objective is for the student to develop a manuscript in collaboration with the mentor and submit it for publication as one of the authors.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

In 2015, I conducted in-depth interviews with 16 low income, young adults living with HIV/AIDS in order to investigate their lived experiences, coping skills, challenges and support system while at the University of Florida. I am still analyzing the database and preparing manuscripts. Breakdown of student activities: Over summer 2020, the student will learn about qualitative research and will assist with coding, analyzing and interpreting the qualitative database described above based on a research question that they design. The student will meet on a weekly basis via web conferencing with the mentor (Dr. Thoma) for in-depth guidance, direction and collaboration. Student will initially review provided literature about coding, analyzing and interpreting qualitative data and will write a short paper about the topic in order to demonstrate their knowledge before they begin coding the database. Student will develop a research question and short data analysis plan based on the interview database. Student will code and analyze the interview data based on their research question (this will include developing a code book). Student will interpret the interview data by developing sub-themes, conceptual categories and trends regarding their research question. Depending on their progress, student will develop a manuscript for publication based on their analysis of the interview data in collaboration with Dr. Thoma.
* 10. Describe the student's role in the project (200 word limit)
As described above, the student will learn about qualitative research and will code, analyze and interpret a large, qualitative database that contains in-depth interviews from a group of low income, urban young adults living with HIV/AIDS based on a research question that they design with the assistance of the mentor. Depending on the student's progress, s/he will prepare a manuscript for publication with the assistance and collaboration of the mentor.

* 11. Describe the mentor's role in the project. (200 word limit)
The mentor (Dr. Thoma) will meet once a week (or more as required) with the student via web conferencing in order to provide in-depth direction and guidance each step of the way. Dr. Thoma will provide literature about coding, analyzing and interpreting qualitative data to the student along with instruction about the process. Dr. Thoma will review the student's coding/analysis work and will provide guidance. Depending on the student's progress, Dr. Thoma will guide the student on writing a manuscript for publication (this will done in collaboration). Note: this project will take place virtually because Dr. Thoma lives out of state. Most of the meetings will take place via web conferencing. There might be several in-person meetings if Dr. Thoma's and the student's location and schedule allow it.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
In the Spring 2019 and Fall 2019 semesters, I mentored doctoral students from the Translational Health Sciences PhD Program at GW on this project during which they assisted with the coding, analysis and interpretation of this database. While at the University of Florida, I mentored a medical student on her student research project (designing the study, preparing the IRB application, etc.).

* 13. Do you have or will you obtain IRB approval for this project? Please note: Students cannot begin a human subjects project without IRB approval.
* (Please select ONE)

Selected Yes
Selected No (Not Required)

Please provide IRB number and date
* IRB Number: UFJ 2014-112 & UNF 602785-1
* IRB Date: 7/3/14 & 7/30/14

Please specify why it is not required.
This project was approved by the University of Florida IRB and the University of North Florida IRB (I can provide the IRB approval letters if you need them). After the data collection portion ended, the database was de-identified and all identifiable links between the participants and the data had been severed, I was notified that continuing IRB approval was not required since the only activity remaining was analysis of the data (I can provide the closure letters).
Faculty Proposal for MD Student Research by Laura L Tosi

* 1. Faculty Sponsor

* Name: Laura L Tosi
* Degrees: MD
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* 2. Daily Supervisor

Name: Susan Knoblach
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* 3. Project Title (250 character limit)
Association of Genetic Markers for Hip Geometry and Measures of Bone Quality and Muscle Strength in Young Adult Individuals

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:

Yes - Anatomy
Yes - Genomics
Yes - Pediatrics

* 6. Sponsor's translational level

* (Please select ONE)

T0/T1: Basic Science Discovery and Initial Translation to Humans

* 7. Hypotheses (200 word limit)

This is a validation study and not a hypothesis-driven study. Using large scale GWAS meta-analysis, two recent papers (Baird et al and Hsu et al; see Citations) have identified several genetic variants associated with hip geometry, a predictor of hip fracture risk. The genetic determinants of fracture risk are not well described, and whether commonly used clinical risk factors for fracture are causal is not known. The Bone Health Program has access to DNA from 2 cohorts of young adults with bone quality and muscle strength phenotypes. We plan to assess whether the most common genetic variants identified by Baird et al and Hsu et al are also associated with variation in bone quality and strength phenotypes in our study cohorts.

* 8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).

The goal of this project is to determine whether the genetic variants identified by Baird et al in the GWAS meta-analysis “Identification of Novel Loci Associated With Hip Shape: A Meta-Analysis of Genome wide Association Studies” and Hsu et al in “Meta-Analysis of Genomewide Association Studies Reveals Genetic Variants for Hip Bone Geometry” are also associated with variation in bone quality and muscle strength phenotypes in our 2 study cohorts. Genotype/phenotype associations for the study variants will be identified using Applied Biosystems Taqman Allelic Discrimination Assays and the Applied Biosystems QuantStudio 7 Flex Real-Time PCR System under the supervision of Dr. Susan Knoblach. Once completed, results will be analyzed in partnership with our statistician, Heather Gordish-Dressman PhD. An abstract for George Washington University Research Day, Children’s National Research Week and the Orthopaedic Research Society must be completed before the end of the summer.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.

Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research
This research project is designed to be a guided exploration of the genetic underpinnings of musculoskeletal growth and development, and is intended to cover a wide variety of musculoskeletal health topics ranging from basic bench science to clinical expertise and surgical management. Training will include hands-on instruction from the lab team about proper lab practices, the best ways to handle DNA for optimal results, and general guidelines for bench research. After completing our orientation program, the student’s time will be divided equally between 1) performing DNA genotyping, organizing and doing back end research on the genes we are interested in, and 2) shadowing Dr. Tosi, her Bone Health team, and her orthopaedic colleagues in the clinic and operating room. The student will be expected to attend all genetic research conferences held over the summer at Children’s. The current system we use for PCR analysis only allows for one plate to be run at a time and involves significant prep and scheduling. These lab tasks will require the student to be organized and diligent about their lab work to make sure all samples can be run during our 8 week program. A smaller portion of time will be devoted to organizing and analyzing the resulting data. There will also be time set aside for the student to perform database searches to look for relevant work relating to his/her genes of interest. Additional time will be devoted to shadowing in the Children’s National Orthopaedic Clinic and operating room, so the student can interact with patients followed in our Bone Health Program as well as other orthopaedic specialties. This clinical and OR exposure is designed to assist the student in making a well thought out career decision about whether to pursue orthopaedics. The student will be expected to attend all Orthopaedic teaching conferences as well as the weekly case conference. The student is required to write an abstract summarizing their work for the Orthopaedic Research Society annual meeting, GW Research Week, and Children’s National Research Week.

*10. Describe the student's role in the project (200 word limit)*

As described throughout this proposal, the student will receive significant guidance and mentoring throughout the project, however the student is expected to take charge of the project and make sure that he/she completes all necessary steps. The student will learn the basics of performing genotyping. The student will perform genotyping with Realtime PCR and then work with our statistician to explore Hardy-Weinberg Equilibrium, data stratification, and analysis of covariance (ANCOVA) as part of the data analysis plan. The student will be required to attend all research conferences held in the Research Center for Genetic Medicine. Dr. Susan Knoblach, PhD will oversee supervision and training in the laboratory. In addition, the student will be required to attend Dr. Tosi’s weekly Orthopaedic Bone Health Clinic so that he/she can develop a better appreciation of the clinical impact of genetic variation on skeletal health and disease. The student will have the opportunity to observe in the Orthopaedic Operating Room. The student will be required to submit an abstract to the Orthopaedic Research Society, GW Research Day and Children’s National Research Week and prepare a poster or podium presentation if accepted. This project is supported by the Bone Health Program Research Fund.

*11. Describe the mentor's role in the project. (200 word limit)*

During the course of the project, Dr. Tosi and Dr. Knoblach will be available to guide the student and answer questions regarding the purpose of the research and proper conduct of laboratory work. Dr. Tosi will guide the brainstorming and initial planning phases of the investigation and Dr. Knoblach and her laboratory staff will provide hands on training and guidance on the use of the sequencing technologies and other equipment used. Dr Heather Gordish-Dressman (Statistics) maintains the phenotype data for our study cohorts and will assist in data analysis. Drs Tosi and Knoblach, as well as their research teams, will assist in drafting the project abstract, poster, and hopefully manuscript for publication. For the clinical and OR shadowing component of the program, Dr. Tosi’s Bone Health team will ensure that the student is introduced to experiences that emphasize the role of genetic variation and bone metabolism on musculoskeletal health.

*12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)*
The summer of 2020 will mark the 16th anniversary of our Children’s National Bone Health Summer Research Program. We have hosted one or more Gill Fellows each year, as well as a number of Health Service Scholarship students. We have strived to provide an intensive lab experience focused on exploring genetic markers of musculoskeletal health, while also providing exposure to orthopaedic clinical and surgical practice, particularly in the areas of rare bone disease as well as metabolic bone disease. Besides submitting an abstract and poster to GW Research Day, our students are required to submit an abstract to the Orthopaedic Research Society and Children’s National Research Week. Over the past 15 years nearly all of the student projects have been accepted as posters or podium presentations and the students have had the opportunity to present their work on a local and national level. In addition, several of our students have won awards for their work, most recently Mohamed Al-Amoodi, who won 2nd place at 2018 American College of Physicians conference.

* 13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected Yes

Please provide IRB number and date

* IRB Number: Pro00006645, Pro00003972

* IRB Date: 10/29/2019 (Date Approved), 2/4/2015 (Date Approved, Review Exempt)
Faculty Proposal for MD Student Research by Jason Triplett

* 1. Faculty Sponsor

* Name: Jason Triplett
* Degrees: PhD
* Title: Associate Professor
* Organization: Children's National Medical Center
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* Zipcode: 20010
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* 2. Daily Supervisor

Name:
Degrees:
Title:
Organization:
Address:
Apt/Suite:
City:
State:
Zipcode:
Office Phone:
Email Address:

* 3. Project Title (250 character limit)
Sensory circuit disruption in fragile X syndrome

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


Drayson LE and Triplett JW. A Chrnb3-Cre BAC transgenic mouse line for manipulation of gene expression in retinal ganglion cells. Genesis 2019 Sep;57(9):e23305.
5. Sponsor's Research Focus:
Yes - Ophthalmology
Yes - Pediatrics
Yes - Neurology

6. Sponsor's translational level
(Please select ONE)
T0/T1: Basic Science Discovery and Initial Translation to Humans

7. Hypotheses (200 word limit)
Sensory dysfunction is a common co-morbid condition with many neurodevelopmental disorders (NDDs), presenting an attractive therapeutic target that could have reverberating impacts on many aspects NDDs. However, there is a significant gap in our understanding of sensory dysfunction in NDDs at the circuit level is poor, precluding the development of effective therapies. To bridge this gap, we previously investigated visual circuit function in a model of fragile X syndrome (FXS) and found sub-circuit-specific deficits in visual function in the superior colliculus (SC), a critical midbrain nucleus. We hypothesize that the disorganization and/or dysfunction of descending inputs from the visual cortex (V1) underlies the visual deficits we observed. We will test this hypothesis using a combination of cutting-edge viral, in vivo electrophysiological, and optogenetic approaches in genetically-modified mice.

8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
1) To characterize the function of neurons in V1 of FXS mice. The receptive field properties of neurons will be determined and compared with littermate control animals. 2) To determine the role of V1 neurons in the disruption of visual circuit function in the SC of FXS mice. Neurons in V1 will be selectively silenced and the receptive field properties of neurons in the SC of FXS mice and littermate controls will be determined. For each objective, at least 70 visually-responsive neurons from at least 10 mice in each group will be characterized in order to establish statistical significance. Importantly, the collection of these data is feasible in the time frame proposed and would represent a complete publishable unit of potentially high impact.

9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

These experiments will leverage cutting-edge in vivo electrophysiological, optogenetic, and viral expression techniques in genetically-modified mouse models. Briefly, for Objective (1), high density silicon multi-electrodes will be placed in the SC and neuronal signals acquired while a battery of visual stimuli is presented. Receptive field properties will be determined post hoc using custom software. For Objective (2), light-activatable ion channels will be selectively expressed in inhibitory neurons in V1 using adeno-associated viruses (AAVs). Following this, the receptive field properties of neurons in the SC will be determined as in Objective (1) while simultaneously silencing V1 by shining blue light on the cortex. Importantly, the techniques and analyses to be utilized are well-established in the Triplett lab and, thus, have a high probability of success. Further, all mouse lines and reagents are present in the laboratory, reducing any potential delays in the performance of experiments. These experiments represent original, cutting-edge investigations and are likely to yield high-impact results. Finally, this novel investigation is likely to yield high-impact results that will be of broad interest to the neuroscience community. Timeline: After a brief
period of training to master the techniques (1-2 weeks), we expect that the experiments outlined will take approximately 2 months to complete, including the collection and analyses of all data. The preparation of a manuscript is expected to take another month.

* 10. Describe the student's role in the project (200 word limit)
Student will be trained in and perform all experimental techniques, collect and analyze data, interpret results in collaboration with mentor, and present the findings in written/oral/poster format as appropriate.

* 11. Describe the mentor's role in the project. (200 word limit)
The mentor or oversee the training of the student in experimental techniques, meet regularly with the student to discuss results and troubleshoot experiments, and aid in the preparation of data for dissemination to the community as a paper, talk, and/or poster. Importantly, the Triplett lab is relatively small, allowing for frequent interactions between the mentor and all members of the lab.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
I have previously mentored one Gill fellow in the lab (Mohib Khan).

* 13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)
Selected No (Not Required)

Please specify why it is not required.
Human subjects are not utilized in this study.
**Faculty Proposal for MD Student Research by Lisa Tuchman**

* 1. Faculty Sponsor

<table>
<thead>
<tr>
<th>* Name:</th>
<th>Lisa Tuchman</th>
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</thead>
<tbody>
<tr>
<td>* Degrees:</td>
<td>MD, MPH</td>
</tr>
<tr>
<td>* Title:</td>
<td>Division Chief, Adolescent and Young Adult Medicine</td>
</tr>
<tr>
<td>* Organization:</td>
<td>Children's National Hospital</td>
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<td>* Address:</td>
<td>111 Michigan Ave NW</td>
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<tr>
<td>* Apt/Suite:</td>
<td>3.5 WW Suite 400</td>
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<td>* City:</td>
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<td>* Zipcode:</td>
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<tr>
<td>* Office Phone:</td>
<td>202-476-6481</td>
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<tr>
<td>* Email Address:</td>
<td><a href="mailto:ltuchman@childrensnational.org">ltuchman@childrensnational.org</a></td>
</tr>
</tbody>
</table>

* 2. Daily Supervisor

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| Office Phone: | 202476-6481 |
| Email Address: | nramsey2@childrensnational.org |

* 3. Project Title (250 character limit)

Predictors of Early etonogestrel birth control implant (Nexplanon) Discontinuation in Adolescents ages 12-22 years.

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:
Yes - Pediatrics
Yes - Obstetrics/Gynecology

* 6. Sponsor's translational level
* (Please select ONE)
T3: Translation to Practice

* 7. Hypotheses (200 word limit)
Population: Adolescent females ages 12-22 years seen in the Adolescent Health Center at Children’s National. Hypothesis 1: The presence of pre-insertion abnormal uterine bleeding is associated with early termination of the etonogestrel implant. Hypothesis 2: Among, the subset of patients with pre-insertion abnormal uterine bleeding the most common cause of early termination of etonogestrel implant is post-insertion abnormal uterine bleeding.

* 8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).
Aims: 1. To describe the use of the etonogestrel birth control implant (descriptive data including number of users, demographics, abnormal uterine bleeding, time to cessation/removal, weight/BMI, vital signs, history of STIs, pregnancies, number of sexual partners, etc.). 2. To predict continuation patterns for etonogestrel birth control implant based on pre-insertion contraception history, menstrual pattern, lipids, BMI, previous pregnancy (descriptive data including number of users, demographics, abnormal uterine bleeding, time to cessation/removal, weight/BMI, vital signs, STIs, pregnancies, number of sexual partners, etc.). 3. To predict continuation patterns for Nexplanon based on pre-insertion contraception history, menstrual pattern, lipids, BMI, previous pregnancy.

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
  * The project design makes it likely that the objectives will be achieved
  * The project is likely to result in a report of interest to other scholars
  * The project fulfills discovery/original research

This will be a retrospective cohort study. IRB approval has already been obtained at Children's National. A chart review will describe adolescents ages 12-22 years who received etonogestrel birth control implant at Children’s National Hospital between Jan 1, 2014 and Jan 1, 2019 (n = 453). Additional data regarding pre and post insertion variables including demographics, history of menstrual bleeding, menarche, weight/BMI, BP, lipids, CBC, history of STIs, history of pregnancy, number of sexual partners and reproductive health history. Time to discontinuation will be documented as will documented reasons for early discontinuation. Data will be abstracted and entered into RedCAP. All data abstracted from the EMR will be de-identified and stored in an encrypted database to ensure patient confidentiality. Analysis of Hypothesis 1: Analysis of predictors of early discontinuation will be performed with a time to event analysis using a Cox Proportional Hazard Model up to a maximum of three years post implant insertion. Significance will be demonstrated with 95% CI of the Hazard Ratio excluding the null hypothesis. Analysis of Hypothesis 2: Chi-squared analysis will be used to determine association between post-insertion AUB and early termination of Nexplanon among the subgroup with pre-insertion DUB. Significance will be demonstrated with a two-sided alpha of 0.05.
* 10. Describe the student's role in the project (200 word limit)
Following completing CITI training and being added to the existing IRB protocol, the student will be involved in data collection, analysis, and manuscript writing. The student will have the opportunity to generate their own hypotheses if motivated to look at the dataset differently. The student will join a high functioning research team and have access to all learning opportunities at Children's National and the Children's Research Institute which includes Adolescent and Young Adult Division-level meetings and educational sessions, hospital level lectures such as Grand Rounds, as well other research lecture series. We have welcomed many students to our team in the past and prioritize matching experience with students’ interests and long-term goals.

* 11. Describe the mentor's role in the project. (200 word limit)
The mentor is the PI of the project and oversees all aspects of the project and facilitate the student's involvement in the project. The mentor will work 1:1 with the student, meet at least weekly with the student, and invite the student to integrate into our Division and establish relationships with multiple multidisciplinary members of our team.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
We are experienced working with learners of all levels in our Division both clinically and academically. We have worked with multiple medical students over the years. Dr. Tuchman has mentored 4 Gill Fellows and 2 Health Services Research GWU students in the past 10 years. One GWU student was awarded a prestigious National AOA mentored research award for her work. We have worked with medical students from Howard, GWU, and Dr. Tuchman was Research mentor for 2 hosted medical students (2014 and 2019) from Emory School of Medicine on a Discovery Research Project. One recent Health Services Research GWU student presented a platform at a national pediatric meeting. Many students have earned authorship on abstracts with few motivated students earring authorship on manuscripts.

* 13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.
* (Please select ONE)

Selected Yes

Please provide IRB number and date

* IRB Number: Pro00012732

* IRB Date: 8-6-2019
Faculty Proposal for MD Student Research by Robert W. Turner II

* 1. Faculty Sponsor

* Name: Robert W. Turner II
* Degrees: Ph.D. Medical Sociology
* Title: Assistant Professor
* Organization: SMHS, Department of Clinical Research & Leadership
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* Office Phone: (202) 994-1728
* Email Address: rwturner124@gwu.edu

* 2. Daily Supervisor

Name: Leslie Davidson
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* 3. Project Title (250 character limit)

Black Male Dementia Caregiver Burden: Stress-related Cognitive Dysfunction, and physiological and psychosocial measures

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.


* 5. Sponsor's Research Focus:
Yes - Geriatrics
Yes - Psychiatry
Yes - Neurology

* 6. Sponsor's translational level
* (Please select ONE)
T4: Translation to Population Health

* 7. Hypotheses (200 word limit)
The findings from this research project are designed to have significant scientific, clinical, and policy relevance. First, the findings will provide important new information to advance the science of brain health through enhanced understanding of caregiver burden (CB), while also advancing the science of physiological and psychological stress among Black American men. Although research on cognitive function in dementia caregivers has been previously established, a limited number of studies directly compared caregivers of a Person With Dementia (PWD) and a control group using more than two cognitive measures. This research project will advance a more comprehensive scientific understanding of CB, and differences in cognition among Black American men providing care for a person with dementia. Second, these scientific advances will have a significant clinical impact by improving our ability to target and deliver interventions to improve brain health care for these men. Furthermore, our study of black American male CB will enable interventions that better address sociocultural and biobehavioral needs of primary caregivers. Third, these findings may have a significant impact on policy to address the attitudinal, behavioral, social, and psychological vulnerabilities of male dementia caregivers.

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
This study seeks to examine the impact of dementia CB on cognitive function and physiological health of adult Black American males. We will replicate previous research designed to evaluate whether the stress of being the primary caregiver of a person with dementia produces cognitive dysfunction. Methods used the original study will be applied to a population of 40 black American male dementia caregivers and compared to group of 40 non-caregiving black American men (n=80). Participants will be generally healthy men, 45–85 years of age, and recruited from the Washington DC metropolitan area. The control subjects will be recruited to match the mean age of the caregivers. Participants will fill out a self-reported questionnaires that measures stress, depression, fatigue, personality, self-efficacy, mindfulness, and sleep quality. We will also measure Neuroticism and Salivary cortisol. Additionally, two tasks will be used to focus on attention and executive function, domains believed most likely to be altered by stress, the Stroop Color and Word Test46 and the Attention Network Task (ANT)

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research
Research Question: What is the effect of dementia caregiving stress on cognitive function in adult black American males? An emerging area of public health concern for policy makers, caregivers and families, and health service workers, is the growing number of older adults with Alzheimer’s disease and related dementia (ADRD). The number of older black Americans with ADRD who will require some type of care is projected to triple in the upcoming decade. It is estimated that as much as 90% of care for mentally or physically impaired adults is provided informally, mitigating an otherwise significant financial strain on the healthcare system. This study seeks to examine the impact of dementia CB on cognitive function and physiological health of adult Black American males. Current caregiving literature tends to describe gender and racial differences in caregiving superficially. Research that addresses the psychosocial and physiological complexities of adult black American men as primary caregivers of a PWD is lacking. Understanding cognitive and physiological effects of CB will be essential in determining support measures and treatment options for black American men as primary caregivers of a PWD. Drawing on the NIA Health Disparities Research Framework, this research project seeks to address these specific Aims: Research Aim 1) Examine which aspects of cognitive performance are affected by caregiver status and stress. Research Aim 2) Investigate which stress-related physiological and self-rated psychological measures may mediate the caregiver effect on cognitive performance. Data from the Stroop conflict condition time, the ANT incongruent non-cued condition RT, and the correctly recalled words on the CERAD delayed recall will used to analyze cognitive performance. If the primary cognitive test measure is significantly different between groups, the other measures from the test (Stroop non-conflict condition and interference difference score, ANT cued and congruent conditions, and CERAD immediate recall) will also be examined to ascertain the specific cognitive component causing the stress-related decline. Other measures to be analyzed include demographic information, PSS, CESD-10, GPSE, the SF-36 Fatigue, PSQI, Neuroticism, mindfulness-current moment, mindfulness-non-judgmental, and salivary cortisol concentrations (am and pm). Analyses will be performed using Stata/IC v15.0 (StataCorp LP, College Station, TX). Variables will be inspected for normality, and Shapiro-Wilk testing will be done. T-test will be done for initial group comparisons. Education would be included in further analyses only if there are significant group differences. ANCOVA will be used to cognitive function group differences with age and age-squared, if significant, (the latter to allow for accelerated declines over the wide age range in this study) entered as covariates. The interaction between age and caregiving status will be included in the ANCOVA. Since a separate analysis will be performed for each of the 3 cognitive measures, a conservative overall Bonferonni correction will be applied. If the ANCOVA for cognitive function is significant for group, a simple mediation analysis will be done. The potential mediators will be evaluated in a regression, only entering caregiver group, age, and the single mediator being evaluated.

10. Describe the student's role in the project (200 word limit)

The Survey Research Assistant is responsible for the comprehensive collection and distribution of reliable black male dementia caregiver burden data related to cognitive dysfunction, and physiological and psychosocial measures of stress. These data are primarily collected through self-rated questionnaires (electronic or printed) and a range of cognitive tests to be used extensively by the research team for empirical analysis, manuscript development, grant applications, and health policy interventions.

11. Describe the mentor's role in the project. (200 word limit)

The MD summer student with work with a team of researchers responsible for the comprehensive collection and distribution of reliable black male dementia caregiver burden data related to cognitive dysfunction, and physiological and psychosocial measures of stress. These data are primarily collected through self-rated questionnaires (electronic or printed) and a range of cognitive tests to be used extensively by the research team for empirical analysis, manuscript development, grant applications, and health policy interventions. The cross-sectional data will be collected using a multi-method approach that consists of cognitive function and stress-related physiological and psychological measures, and in-depth interviews. RESPONSIBILITIES include: • Collect and code data regarding caregiver burden and cognitive function • Analyze qualitative and qualitative health data • Assist Survey Research Coordinator and PI with participant recruitment • Conduct field research and phone or in-person interviews with dementia caregivers and non-caregiver to gather stress-related physiological and self-rated psychological information • Provide frequent updates on progress and/or issues to Survey Research Coordinator, Principle Investigator (PI), and Mentors • Achieve and maintain CITI certifications in social & behavioral research, and other required certifications • Conduct cognitive tests, and salivary cortisol collection
Dr. Robert Freishtat, Chief of Emergency Medicine - My role on the administrative supplement to the project “Black Male Dementia Caregiver Burden: Stress-related Cognitive Dysfunction, and physiological and psychosocial measures” is as a mentor to Dr. Robert W. Turner II. I will oversee the analysis of the salivary cortisol data as a biomarker for human aging and will oversee Dr. Turner’s career development and mentoring. I will provide Dr. Turner with the lab space and personnel (research technician) needed to analyze the salivary cortisol data and I will meet with him regularly to help him gain a comprehensive understanding of the experimental protocols, as well as how to interpret human aging biomarkers. Additionally, I will contribute to all scientific presentations and manuscripts required to complete the work. I have the expertise and motivation necessary to be a mentor on the proposed project. I am a Pediatric Emergency Medicine physician with master-level training in epidemiology/biostatistics. My research has been continuously funded by the National Institutes of Health since 2003 starting with a K12 award and continuing to include K23 and multiple R01/21 grants. I have >15 years of experience working on pediatric disorders in several cohort studies.

* 13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected No (Pending)
Faculty Proposal for MD Student Research by Michael Whalen

1. Faculty Sponsor

* Name: Michael Whalen
* Degrees: MD
* Title: Assistant Professor of Urology/Urologic Oncology
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* Email Address: mjw2117@gmail.com

2. Daily Supervisor

Name: Michael Whalen
Degrees: MD
Title: Assistant Professor of Urology/Urologic Oncology
Organization: GW MFA
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City: Washington
State: DC
Zipcode: 20037
Office Phone: 4134416197
Email Address: mjw2117@gmail.com

3. Project Title (250 character limit)
Clinical Outcomes Research in Urologic Oncology

4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.

i. Trends in the use of Neoadjuvant Chemotherapy for Bladder Cancer with Non-Urothelial and Variant Histology: An analysis of the National Cancer Database (NCDB). Campbell Grant, Andrew Sparks, Richard Amdur, Michael Whalen (accepted for publication Indian Journal of Urology, 6/2019)


5. Sponsor’s Research Focus:
Yes - Cancer
Yes - Surgery

6. Sponsor’s translational level
*(Please select ONE)*
T3: Translation to Practice

7. Hypotheses (200 word limit)
Testicular cancer is the second most common malignancy in young men. Radical orchectomy is often curative, but depending on histologic risk factors, up to 50% of patients may suffer relapse of the disease in the retroperitoneum while on surveillance after surgery. Adjuvant retroperitoneal lymph node dissection (RPLND) surgery is a morbid procedure that involves a long midline incision, several day hospital stay, and prolonged recovery. Growing experience with robotic surgery has been applied to RPLND with small series showing favorable outcomes. The present study seeks to query the American College of Surgeons National Surgical Quality Improvement Project (ACS-NSQIP) database to compare perioperative characteristics and outcomes for open vs. robotic RPLND, along with trends over time 2007-2017. Another project involves examining pelvic MRI features for prostate cancer detection. Prostate biopsy performed with MRI-guidance compared to traditional (non-targeted) systematic biopsy has been shown to be more accurate. There are many novel biomarker tests commercially available for prostate cancer risk-stratification tools, such as 4K score and tissue-based tests (Oncotype DX and Decipher). The interrelationship between MRI and these protein-based blood tests as biomarkers for aggressive prostate cancer will be examined in collaboration with the Radiology department as part of a novel "Radiomics" initiative.

8. Project goals and measurable objectives (e.g. number of patient records, assays completed) (200 word limit).

...
We have access to the NSQIP database for the robotic RPLND project, through the department of general surgery. The database will be queried for stage I testicular cancer patients from 2007-2017 to compare outcomes for robotic vs. open surgery, as well as trends over time. There are n=600 patients who have completed prostate MRI studies at GW since 2015. A primary objective of the project is population of the relevant clinical, demographic, pathologic, perioperative, and cancer outcomes information of these patients who have undergone treatment for their prostate cancer diagnosis. This number of patients is certainly feasible for data-entry during a summer research project. The remainder of the time will be spent in conducting original analysis of the data and also publication as well as Urology Department Quality Improvement, which will have direct and meaningful impact on the delivery of patient care. Findings generated from this project will likely also generate protocol revisions for the ordering and interpretation of prostate MRI studies. The tangible goal will be drafting one or two abstracts for submission to the Society of Urologic Oncology annual meeting and the American Urological Association annual meeting. These abstracts will culminate in manuscripts to be submitted for publication.

9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.

Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

This research project is designed to provide exposure to clinical outcomes research within the field of Urology and Urologic Oncology. The student will engage in critical reading/analytics of published journal articles in the domains of prostate cancer and testicular cancer. These will serve as a model for subsequent design and implementation of a retrospective research project utilizing our single-institutional prostate MRI database and the NSQIP database. The research experience will teach the student how patient clinico-pathologic variables can be assessed with basic statistical methods to derive correlations with multiple clinically relevant study endpoints. The student will gain exposure to these statistical methods as well as work closely the Medical Faculty Associates biostatisticians, Andrew Sparks and Richard Amdur. There will also be opportunity and expectation to contribute to the growing IRB-approved Retrospective and Longitudinal Database of Genitourinary Cancer based on the clinical and surgical experience of the GW Urology physicians. Depending on the student's interests, time will be spent performing literature review and drafting the introduction and discussion of the manuscript. He/She will also spend time with data entry to input information from the electronic medical record into the database. This work will be supplemented by weekly meetings for troubleshooting and discussion of interesting aspects of prostate cancer diagnosis and treatment. The expectation will be that one or more abstracts are generated to be submitted to our national Urologic Oncology meetings: Society of Urologic Oncology, Genitourinary American Society of Clinical Oncology, American Urological Association. The deadline for the initial submission is late summer 2020. The project will last for the summer, with opportunity to extend participation during the academic year.

10. Describe the student's role in the project (200 word limit)

The student will take the lead with literature search and drafting the project manuscript with the guidance of the Urology residents and attending supervisor. He/She will be responsible for coordination with the biostatistician and assist with interpretation of the statistical results. The goal of the project is for the student not only to learn about outcomes research, but to make a meaningful contribution to the field of Urologic Oncology. He/She will also be responsible for populating the growing prostate MRI database using the REDcap interface and collaborating with the Radiology department to expand this database. There will be opportunity for statistical analysis of the data alongside the MFA professional statisticians as well. The student will work closely with the biostatisticians to understand the NSQIP dataset, including organization, statistical analysis, analysis of outcomes of interest (i.e. surgical complications and success rates) and presentation of data in a clear, concise, and meaningful format. There will be ample opportunity for shadowing experiences in the outpatient clinic and the operating room to gain further exposure to clinical Urology. The student will also participate in weekly Urology Grand Rounds and resident didactic sessions to supplement their growing Urologic fund of knowledge.

11. Describe the mentor's role in the project. (200 word limit)

The mentor will provide ample opportunity for discussion of the rationale for the project and the potential ideas for publication arising from the database. The mentor will schedule regular weekly research meetings to assess the student's progress and troubleshoot any questions. The mentor will also invite the student to participate in clinical patient care. One half-day per week will be spent shadowing in the Urology clinic and another day will be spent in the operating room. These mentorship experiences will provide student exposure to the field of Urology and to provide clinical context for the database work. The mentor will also attend regular meetings between the student and the statisticians. The mentor has significant experience in outcomes research as well as basic statistical methods, so is well-equipped to be able to guide the student's interest and success with the project.

12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

- I have worked with Akshay Reddy during the summer 2019, which has been a fruitful collaboration resulting in three abstracts, including one recently accepted to be presented at the GU American Society of Clinical Oncology national meeting in San Francisco in February 2020. We are still working closely. - I am thankful to have worked with a student during the Gill Fellowship program Summer 2018, Christina Darwish. - During fellowship at Mount Sinai and Yale, I also was responsible for coordinating resident research activities. - I am currently the Research Coordinator for the Urology Department, helping to oversee and trouble shoot the various research and quality improvement projects in which the Urology residents are engaged. - Dr. Campbell Grant, chief resident in Urology, and I worked a project with the National Cancer Database in 2017, which has been accepted for publication in the Indian Journal of Urology. - I have served as a medical student mentor in the Clinical Apprenticeship Program since 2017, and have had four students thus far.

13. Do you have or will you obtain IRB approval for this project?

Please note: Students cannot begin a human subjects project without IRB approval.

(Please select ONE)

Selected Yes

Please provide IRB number and date

- IRB Number: 041723
- IRB Date: 8/7/2019
Faculty Proposal for MD Student Research by David Yamane

* 1. Faculty Sponsor

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<tr>
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<tr>
<td>Name</td>
<td>David Yamane</td>
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<td>Degrees</td>
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<td>Title</td>
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* 2. Daily Supervisor

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<tr>
<td>Name</td>
<td>Ghazhi Rizvi</td>
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<td>Email Address</td>
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* 3. Project Title (250 character limit)
Thromboelastogram (TEG) in Medical bleeding

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.
5. Sponsor's Research Focus:
Yes - Anesthesiology
Yes - Emergency Medicine

6. Sponsor's translational level
* (Please select ONE)
T2: Translation to Patients

7. Hypotheses (200 word limit)
thromboelastogram (TEG) is utilized often in surgery and trauma as a real time measure of the clotting properties of whole blood to guide blood component resuscitation. abnormalities in the TEG are utilized to decide the need for FFP, platelets, and/or cryoprecipitate. The use of TEG however has never been evaluated in the medical patients with bleeding disorders such as GI bleeding. Our hypothesis is that patients with GI bleeds admitted to the ICU who undergo TEG will have more appropriate blood component resuscitations and have improved outcomes.

8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
The goals of the project will be for the student to gain experience with the research process, including: data collection, data management, data analysis, abstract writing, and manuscript writing. the student will be responsible for chart review of ~200 patients. the student will be responsible for drafting the abstract and submission to the Society of Critical Care Medicine, (abstract deadline in august)

9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.

Selection criteria include:

- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

The project will be a retrospective review of all patients with a GI bleed admitted to the ICU over a 1 year period and compare those patients who underwent a TEG vs those who did not, baseline demographics of the patients will be collected, as well as blood product usage (packed red cells, fresh frozen plasma, and platelets). the first 4 weeks of the study will be dedicated to data collection. the next 2 week will be dedicated to data analysis with our statistician. and the final 2 weeks will be dedicated to abstract writing and submission, as well as drafting of the manuscript.

10. Describe the student's role in the project (200 word limit)
The student's primary role will be data collection over the first month. the next two weeks the student will meet with the teams statistician to go over data analysis and data management. the final two weeks, the student will be responsible for drafting the first draft of the abstract. as well as drafting the background and methods of the final manuscript.

11. Describe the mentor's role in the project. (200 word limit)
The mentor will directly oversee the student. The mentor will meet with the student at least weekly and keep in contact with the student electronically at least three times a week. The mentor will help the student to arrange the meeting with the statistician and oversee that meeting. The mentor will direct the student in the abstract drafting process and assist the student in revision to the abstract. The mentor will directly oversee the manuscript drafting and assist the student in revisions.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)

I have participated in this process last year with a gill fellow who successfully published an abstract at SCCM that was the winner of an award to be presented in February. Also, last year outside the Gill process I supervised, 3 MS1s, an MS3, and 2 MS2s over the summer. All of which were successful in getting an abstract at SCCM.

* 13. Do you have or will you obtain IRB approval for this project?

**Please note:** Students cannot begin a human subjects project without IRB approval.

* (Please select ONE)

Selected No (Pending)
Faculty Proposal for MD Student Research by Irene Zohn

* 1. Faculty Sponsor

* Name: Irene Zohn
* Degrees: PhD
* Title: Principal Investigator, Associate Professor
* Organization: CNMC
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* Zipcode: 20010
* Office Phone: 2024762106
* Email Address: izohn@cnmc.org

* 2. Daily Supervisor

Name: Linda Leatherbury
Degrees: MD
Title: Professor of Pediatrics, Cardiologist
Organization: CNMC
Address: 111 Michigan AVE NW
Apt/Suite: 
City: Washington
State: DC
Zipcode: 20010
Office Phone: 
Email Address: LLLeather@childrensnational.org

* 3. Project Title (250 character limit)
Mechanisms underlying maternal diet as a modifier of Congenital Heart Defects in 22q11.2 Deletion syndrome

* 4. Up to three faculty publications (within the last three years). Projects without recent publications are unlikely to be filled.
Sugrue KF, Zohn IE. (2019) Reduced maternal Vitamin A Status Increases the Incidence of Normal Aortic Arch Variants. Genesis. 57(7-8):e23326, PMID:31299141

* 5. Sponsor's Research Focus:
Yes - Cardiology

* 6. Sponsor's translational level
* (Please select ONE)
T0/T1: Basic Science Discovery and Initial Translation to Humans

* 7. Hypotheses (200 word limit)
Reduced Dgcr8 gene dosage in 22q11DS creates a bottleneck in miRNA processing, impacting Vitamin A buffering, thus sensitizing the embryo to genetic and environmental perturbations.

* 8. Project goals and measureable objectives (e.g. number of patient records, assays completed) (200 word limit).
The aim of the proposed project is to establish the impact of increased maternal Vitamin A intake (within recommended levels during pregnancy) on CHDs in the LgDel mouse model of 22q11DS. Hypothesis: Increased maternal Vitamin A intake will have a strong modifier effect on the incidence and severity of aortic arch and the outflow tract in LgDel embryos. Our preliminary analyses demonstrate significant pharyngeal arch arteries defects in LgDel embryos but not WT littermates from dams fed a Vitamin A supplemented diet. Proposed experiments will evaluate the impact on development of the mature aortic arch and the outflow tract in 20 embryos to detect a significant effect (p<0.01) and increased severity with a significance level of p<0.05 (Chi2 test).

* 9. Overall design of the research project (500 word limit). Please describe time frame and breakdown of activities.
Selection criteria include:
- The project design makes it likely that the objectives will be achieved
- The project is likely to result in a report of interest to other scholars
- The project fulfills discovery/original research

The spectrum of aortic arch abnormalities will be evaluated in LgDel with increased maternal Vitamin A intake. For these experiments, WT females will be fed either 10 IU (Vitamin A, similar to normal chow) or 16 IU (elevated Vitamin A) diets beginning at weaning for 3 weeks. The aortic arch of E17.5 fetuses will be visualized by intracardiac injection of an India ink/gelatin solution. The aortic arch will be photographed using a light microscope and phenotypes diagnosed by Drs. Leatherbury and Zohn along with the fellow. Preliminary experiments indicate that the 4th and 6th PAA are most impacted in LgDel embryos from dams fed altered Vitamin A diets and analysis will focus on the branches of the aortic arch that arise from the 4th and 6th PAA. These include: the aortic arch between the left common carotid and the left subclavian artery, the right subclavian artery, the pulmonary arteries and the ductus arteriosus. We expect a spectrum of aortic arch malformations with increased incidence and severity as Vitamin A content of the diet is increased. For example, the incidence of less severe anomalies such as coarctation of the aortic arch will be reduced as severe phenotypes such as complete interruption of the aortic arch will become more common. We expect the incidence of aortic arch abnormalities to be fewer than PAA defects since there is some recovery and compensation during subsequent development. Assessment of OFT defects. The incidence and severity of OFT alignment defects will also be scored in hearts of E17.5 fetuses. OFT will initially be examined in whole mount to visualize the relative orientation of the roots of the aortic arch and pulmonary artery which should cross in a properly formed outflow tract. TOF occurs when these vessels do not fully rotate during development resulting in the aortic arch overlying the ventricle septum along with a VSD. The presence or absence of CHDs will be assessed in whole mount views of dissected hearts (OA and DORV) and by histological analysis
(OA, DORV and VSDs. We expect a spectrum of OFT defects with increased incidence and severity as Vitamin A content of the diet is increased. The incidence of VSDs should increase as well as OA and the most severe DORV and potentially PTA as the most severe malformations.

* 10. Describe the student's role in the project (200 word limit)
Embryos will be collected and genotyped prior to the rotation to maximize data collection. The student will inject ink into the ventricles and analyze aortic arch and outflow tract alignment defects. Phenotypes will be scored, documented and figures generated for publication.

* 11. Describe the mentor's role in the project. (200 word limit)
The mentor will teach student the experimental approaches needed for the project as well provide guidance in scoring and data analysis.

* 12. Describe the current and previous medical student training by your mentor team. Indicate any Gill Fellows. (200 word limit)
Dr. Zohn has mentored 2 medical students: Kevin Mcfadgen, Omowunmi Oluwo. Ms Oluwo was a GWU student. Dr. Leatherbury has mentored countless medical students and cardiac fellows during her 30 year career as a researcher and cardiologist.

* 13. Do you have or will you obtain IRB approval for this project?
Please note: Students cannot begin a human subjects project without IRB approval.
* (Please select ONE)
Selected No (Not Required)

Please specify why it is not required.
no human subjects - IACUC approval has been obtained.