GW Faculty Proposals for Medical Student Summer Research Projects

Please review this packet of faculty proposals for medical student 2024 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.

Table of Context

Faculty Sponsor Name	Title	Project Title
Randall Burd	Chief, Division of Trauma and Burn Surgery	Comparison of Human Observation with Computer Aided PPE Monitoring in a Multidisciplinary Healthcare Setting
Colleen Cotton	Assistant Professor of Dermatology and Pediatrics	Biologic Therapy in Pediatric Dermatology: Assessing Adherence and Persistence by Drug and Diagnosis
Jennifer Keller	Associate Professor	Perinatal Mental Health and Pregnancy Outcomes
Andrew Meltzer	Professor, Chief of Emergency Department Research Section	Risk Factors Associated with Acute Presentation of Recurrent Abdominal Pain Syndromes in the Emergency Department
Jennifer Klein	Physician	Disparities in maternal health as a predictor of congenital heart disease outcomes in the fetus
Can Yerebakan	MD, PhD Associate Chief, Cardiac Surgery Director, Fellowship Program Cardiac Surgery Director, Quality and Outcomes Cardiac Surgery Professor of Surgery and Pediatrics Cardiovascular Surgery Children's National Hospital, The George Washington University School of Medicine and Health Sciences	Hypoplastic Left Heart Variants with fenestrated surgical atrial septal defect closure
Sinan Turnacioglu	Neurodevelopmental Pediatrician; Assistant Professor of Neurology and Rehabilitation Medicine, Assistant Professor of Pediatrics	Patterns of ADHD medication prescribing in children with congenital heart disease

Brian Reilly	Physician	ABR testing variable outcomes
Anant Vatsayan	Blood and Marrow Transplant/Cellular Therapy Attending, Children's National Hospital; Assistant Professor, Pediatrics, George Washington University School of Medicine and Health Sciences	Predicting Transplant-Associated Thrombotic Microangiopathy in Patients with Sickle Cell Disease
Yves d'Udekem	Professor of Surgery and Pediatrics	Atrioventricular Valve Repair in Single Ventricle Physiology Timing and Outcomes
Shayna Coburn	Associate Professor, Psychologist	Investigating health disparities in screening, diagnosis and treatment of celiac disease among under-represented youth
Allison Mayhew	Director, Pediatric and Adolescent Gynecology	Menstrual Irregularity and Associated Risk Factors for Polycystic Ovarian Syndrome (PCOS) in Patients with Spina Bifida
Jason Triplett	Associate Professor	Role of visual experience in maintenance of visual map alignment in the superior colliculus
Debra Regier	Chief, Genetics and Metabolism	The Children's National Rare Disease Institute is creating an online tool to provide immediate access to rare disease emergency protocols for patients and families with a diagnosed rare disease. The summer project will allow the student to participate in building, launching, and evaluating the program. Specifically, the student will work with outreach to patient and family groups regarding this tool, spend time evaluating the users for the system, and join Dr. Regier in outreach to emergency and primary care providers regarding the tool. We expect that the student will have an understanding of rare disorders, the unique needs of patients and families, the role of educational outcomes research, and the role of communication across disciplines after participating in this

		summer experience.
Michael Whalen	Vice-Chair, Dept of Urology; Associate Professor of Urology; Director, Urologic Oncology	Clinical Outcomes Research in Urologic Oncology
Tim McCaffrey	Professor of Medicine, Director, Division of Genomic Medicine	Neutrophil Activation Test Using RNA Levels (NATURAL Trial) The NATURAL Trial is a prospective, pragmatic trial to evaluate the clinical utility of a blood RNA-based diagnostic to detect intra-abdominal infections.
Irene Zohn	Principal Investigator/Associate Professor	Characterization of a new genetic syndrome causing autism and intellectual disability due to mutations in HECTD1.
William D. Gaillard	Professor of Pediatrics & Neurology	Quantifying structural connectivity signatures of pharmacoresistance in pediatric focal cortical dysplasia-related epilepsy.
Muhammad Rahman	Assistant Professor	Understanding Coping Mechanisms and Peer Support for ADHD on Reddit
David Mendelowitz	Professor	This proposal, based on the role of oxytocin in increasing parasympathetic activity to the heart and improving cardiac function in patients with heart failure, will test if intranasal oxytocin administration blunts the deleterious effects of autonomic imbalance, a distinctive hallmark of HF.
Nobuyuki Ishibashi	Foglia-Hills Professor	Neuroprotection in Congenital Heart Disease (CHD).
Jennifer Webb	Director of Chronic Transfusion Therapy	Iron Removal with Phlebotomy
Maureen E. Lyon	Clinical Psychologist/Prof Peds	Palliative Care Needs of Children with Rare Diseases and their Families
Natasha Shur	Medical Genetics	Non-accidental trauma: The Yield of Genetic Testing Genetics:
Patrick Corr	Assistant Professor & Vice Program Director, Integrative Medicine	The GW Medical Enterprise Annual Well-being Assessment
Leigh A. Frame	Director, Integrative Medicine	Assessing Possible Link Between Mercury Toxicity and Risk of Breast Cancers
Leigh A. Frame	Director, Integrative Med.; Assoc. Dir., Resiliency & Well-being Center	Brain Health & the Microbiome: A Proof-of-Concept Study in Patients with Mild Cognitive Impairment
Briony K Varda	Assistant Professor Urology and Pediatrics	Assessment of bacteriuria and antibiotic resistance patterns among patients presenting for cloacal repair: a retrospective study

Briony K Varda	Assistant Professor Urology and Pediatrics	A multi-institutional analysis of clinical outcomes for patients born with cloacal malformation: Use of the Pediatric Information Health System
Briony K Varda	Assistant Professor Urology and Pediatrics	A qualitative analysis of barriers and facilitators to the execution of a successful institutional testicular torsion care pathway: A focus group study of NSQIP-P sites.

Faculty Proposal for MD Student Research by Randall Burd

* 1. Faculty Sponsor

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Email Address:	

* 3. Project Title (250 character limit)

Comparison of Human Observation with Computer Aided PPE Monitoring in a Multidisciplinary Healthcare Setting

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

Alberto EC, McCarthy KH, Hamilton CA, Shalkevich J, Milestone ZP, Izem R, Fritzeen JL, Marsic I, Sarcevic A, O'Connell KJ, Burd RS. Personal Protective Equipment Adherence of Pediatric Resuscitation Team Members During the COVID-19 Pandemic. Ann Emerg Med. 2021 Nov;78(5):619-627. doi: 10.1016/j.annemergmed.2021.05.022. Epub 2021 May 29. PMID: 34353649; PMCID: PMC8164378.

Gao C, Marsic I, Sarcevic A, Gestrich-Thompson W, Burd RS. Real-time Context-Aware Multimodal Network for Activity and Activity-Stage Recognition from Team Communication in Dynamic Clinical Settings. Proc ACM Interact Mob Wearable Ubiquitous Technol. 2023 Mar;7(1):12. doi: 10.1145/3580798. Epub 2023 Mar 28. PMID: 37719879; PMCID: PMC10501506.

Alberto EC, Mastrianni A, Sullivan TM, McCarthy KH, Milestone ZP, Chung L, Cha N, Mapelli E, Sippel GJ, Marsic I, O'Connell KJ, Sarcevic A, Burd RS. Factors Affecting Peripheral Intravenous Catheter Placement During Pediatric Trauma Resuscitation. J Surg Res. 2023 Mar;283:241-248. doi: 10.1016/j.jss.2022.10.048. Epub 2022 Nov 21. PMID: 36423472; PMCID: PMC9990681.

*** 5. Sponsor's Research Focus:**

Yes - Emergency Medicine
Yes - Surgery

*** 6. Sponsor's translational level**

*** (Please select ONE)**

T3: Translation to Practice

*** 7. Hypotheses (200 word limit)**

Our long-term goal is to reduce workplace-acquired infections in HCWs by improving adherence to appropriate PPE use in settings at high-risk for virus transmission. The overall objectives of this proposal are to design, implement, and test a system (Computer-Aided PPE Nonadherence Monitoring and Detection—CAPPED) that (1) tracks PPE adherence using computer vision and (2) highlights episodes of potential PPE nonadherence on a video-monitoring system, aiding a remote operator in providing real-time alerts to HCWs for nonadherence. This system will be integrated into existing and future remote video-based monitoring systems in EDs, intensive care units, operating rooms, and hospital wards. Our central hypothesis is that continuous monitoring of PPE use by multiple HCWs is a complex, cognitively demanding, and error-prone task unaddressed by current monitoring methods. The rationale for this proposal is that enhanced recognition of PPE nonadherence is a requirement for reducing the risk of transmissible infections in HCWs.

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

The goal of this summer project will be to compare the performance of direct human observation with a computer vision method for monitoring PPE adherence in real-time. Healthcare workers with expertise in monitoring PPE usage will be recruited. Observers will evaluate PPE nonadherence by direct observation in a simulated clinical setting. The type and number of episodes of PPE nonadherence will be varied based findings from preliminary data. We estimate 18 participants will be required for this study. We will evaluate the accuracy of detection of PPE nonadherence and compare it to results obtained using a previously developed computer vision algorithm. The summer student's role on this project will include: 1. Design and conduct of simulation sessions 2. Ground truth analysis of recorded simulation sessions 3. Recruitment and training of study participants 4. Analysis and reporting of final study findings in a peer reviewed journal.

* **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 work is part of an NIH grant supporting a large project related to monitoring PPE nonadherence: https://reporter.nih.gov/search/h2nv2STrqky82fUpG0TnUg/project-details/10585548. This subproject will serve to validate the impact of an AI-based PPE monitoring system in a healthcare setting. If effective, this system will support PPE monitoring in a range of clinical setting that now rely on labor-intensive and less efficient direct human observation. This project will leverage the resources developed in Dr. Burd's laboratory of the past two years of this work.

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

The student will work in collaboration with Dr. Burd's multidisciplinary research team. This study has existing IRB approval and can be begun without delay at the start of the summer. Although the student will participate in all aspects of the study, supervision by experience staff will be available in each step of the study. The student will participate in twice weekly laboratory meetings in which this and other studies are reviewed by our multidisciplinary research team. Although coauthorship and success of the proposed project cannot be guaranteed, it is anticipated that this study will be mostly accomplished over the summer and published in the following year.

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

Dr. Burd will oversee all aspects of this work, as it will be accomplished using funding on an NIH grant that he manages. Dr. Burd will meet twice weekly with the research team to monitor project progress and will ensure that the student has the resources to complete this project.

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

Dr. Burd has had several Gill Fellows and Health Service Scholars over the past 10 years. He has successfully mentored undergraduate students, medical students, graduate students, and junior faculty in research projects.

* **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 have IRB approval to conduct this research already

Faculty Proposal for MD Student Research by Colleen Cotton

* 1. Faculty Sponsor

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* 2. Daily Supervisor

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

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* 3. Project Title (250 character limit)

Biologic Therapy in Pediatric Dermatology: Assessing Adherence and Persistence by Drug and Diagnosis

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

Atherton KM, Shope CN, Andrews LA, Robinson-Pirotte IS, Lee LW, Cotton CH. The Management of Pediatric Hidradenitis Suppurativa Differs Between Dermatologic and Non-Dermatologic Providers: A Retrospective Review. Pediatr Dermatol. 2023 Nov 28. Online ahead of print. PMID: 38018236

Cotton CH, Chen XS, Hussain SH, Lara-Corrales I, Zaenglein AL. Hidradenitis Suppurativa in Pediatric Patients. Pediatrics. 2023 May 1;151(5):e2022061049. PMID: 37102307

Robinson I, Lee L, Cotton C. The Impact of Racial Differences on Treatment Strategies in Hidradenitis Suppurativa: A Retrospective Review. J Drugs Dermatol. 2022 Mar 1;21(3):270-275. PMID: 35254766

* **5. Sponsor's Research Focus:**

Yes - Dermatology

* **6. Sponsor's translational level**

* **(Please select ONE)**

T3: Translation to Practice

* **7. Hypotheses (200 word limit)**

1) Adherence and persistence will be lower than 80%, generally considered the cutoff for optimal therapeutic efficacy. 2) An important factor in decreased adherence and persistence will be insurance authorization. 3) Demographic factors (e.g., age, primary language, zip code) and clinical factors (e.g., diagnosis, comorbidities) will impact adherence and persistence.

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

The student will examine all patients for whom the division of dermatology has prescribed a biologic medication over the last year (n = 523 patients). Primary outcomes will be whether the medication was started and whether the medication was continued for more than three months. Demographic and clinical factors will be evaluated for their relationship with adherence (taking the medication as prescribed) and persistence (time for which the medication was continued).

* **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**

One of our nurse practitioners has designed a clinical dashboard that captures all patients in the dermatology division for whom a biologic was prescribed within the last year. The student will collect information regarding demographics (age, sex, ethnicity, zip code, insurance, primary language), primary diagnosis, drug prescribed, and comorbidities.

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

The student will engage in critical reading/analysis regarding the mechanisms of action of different biologic medications, as well as their use in children and challenges regarding adherence and persistence with these medications. The student will also be involved in creating the statistical analysis plan and designing the data collection instruments in REDCap, and will be the primary individual to identify relevant patients from the biologic clinical dashboard. They will review the medical records for demographic and clinical information, and collect this information in a systematic fashion in REDCap. They will work with the statistician to perform a univariate and multivariable analysis, and will serve as co-first author on the final publication. The student will learn about the entire research process from design of a study to data collection to statistical

analysis to manuscript preparation and submission. The student will work closely with the nurse practitioner regarding quality improvement project design and technical use of the electronic medical record system. There will also be the opportunity to work on other multi-center collaborative projects in multiple fields of pediatric dermatology. Finally, the student will have the opportunity to shadow in dermatology clinic.

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

The mentor will meet with the student on a weekly basis at minimum to review progress on the project and help troubleshoot any difficulties that arise. They will ensure a structured approach for discussing the rationale for the project, discuss possible manuscripts that will come from this project, and will also lead discussions regarding real world implications of this project. The mentor also has six half-days of clinic per week, and will invite the student to participate in clinical patient care at least two half-days per week in the pediatric dermatology clinic. The mentor has extensive experience in retrospective studies, clinical research, and statistical design, and is optimally positioned to guide and train the student on this project.

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

The mentor recently successfully obtained an Emerging Investigator Research Grant to fund a project for a medical student from the Pediatric Dermatology Research Alliance. The period of this grant will be completed by the time the Gill Fellowship begins, ensuring that they have ample time to devote to the applicant. The mentor is also currently working with three other students on various multi-center research projects and has experience managing multiple projects ongoing at the same time. All together, the mentor and other attendings in the dermatology division have mentored dozens of students over the past five years on a variety of clinical research projects that have resulted in multiple 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 No (Pending)

Faculty Proposal for MD Student Research by Jennifer Keller

* 1. Faculty Sponsor

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* 2. Daily Supervisor

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Organization:	
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Zipcode:	
Office Phone:	
Email Address:	

* 3. Project Title (250 character limit)

Perinatal Mental Health and Pregnancy Outcomes

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

Koblyski L, Keller JM, Molock S and Le HN. Preventing Perinatal Suicide: A Substantial Public Health Need. Lancet Public Health 2023; 8: e402.

Margulies S L, Benham J, Liebermann J, Gaba N and Keller, JM. (January 21, 2020) Adverse Events in Obstetrics: Impacts on Providers and Staff of Maternity Care. Cureus 12(1): e6732. doi:10.7759/cureus.6732

* 5. Sponsor's Research Focus:

Yes - Obstetrics/Gynecology

* **6. Sponsor's translational level**

* **(Please select ONE)**

T4: Translation to Population Health

* **7. Hypotheses (200 word limit)**

A growing body of published research links heightened maternal stress and anxiety during pregnancy to an increased risk of adverse outcomes for the pregnant mother herself (preeclampsia, spontaneous abortion and preterm delivery) as well as for her offspring (impaired fetal brain development). Research on the developmental origins of health and disease highlights the vulnerability of the human fetus to a host of potential teratogens, including stress. Research on experimental models has demonstrated a variety of physical and behavioral effects among offspring exposed to prenatal maternal stress. However, these studies cannot tease out the relative effects of the objective stress exposure and the subjective distress in ways that parallel the lived stress experience in humans. (King, Dancause, Turcotte-Tremblay, Veru, & Laplante, 2012). In this study, we will leverage serial, structured mental health assessments of low-resourced, Black and African American pregnant women collected in an ongoing prospective randomized control to trial (the Mommy&Me study), to determine if there is a significant relationship between prenatal maternal mental distress and pregnancy outcome. We hypothesize that elevated maternal stress, anxiety and depression will be significantly associated with increased rates of adverse pregnancy outcomes: namely, preeclampsia, preterm delivery, low-birth weight infants, etc.

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

The student would have several goals and objectives during their summer research time. 1) To relevant pregnancy outcomes of interest, as well as relevant confounders 2) To complete data extraction for relevant outcomes identified above 3) To describe analytic approach to determine relationships of interest, summarize data findings for written and oral presentation The student will also gain practical clinical experience through the following tasks: 1) an analysis of the data collected to this point in the study to determine if there are correlations between stress, anxiety, depression and pregnancy outcomes. 2)To assist in enrolling new participants into the study through reviewing charts for eligibility, approaching eligible patients and explaining the study to them and speaking with interested people in the waiting are of the GW MFA. 3) To gain experience administering mental health questionnaires to enrolled participants as the student will assist the research coordinators in administering the questionnaires when patients present for prenatal visits. 4) The student could also participate in other data analysis/projects with the data that exists if they would like.

* **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 an ongoing PCORI funded, multicenter, randomized controlled trial to investigate the impact of several interventions on pregnancy outcomes and infant development. The study is enrolling Black, under-resourced women at GW MFA, Unity Health Care and Howard University and has a goal of enrolling up to 700 people. Enrollment as of 12/1/23 is around 350, with approximately 120 who have already delivered their babies. The interventions being investigated include the impact of a maternity care specialist (patient navigator), individual therapy, group therapy and peer support groups. As part of the umbrella study, the student would be able to develop additional hypothesis explore relevant pregnancy outcomes in the subset of patients already delivered. a. Project design makes it likely that the objectives will be achieved As on ongoing, active research study with over 300 enrolled participants, and >100 pregnancy outcomes, there is a robust dataset from which to derive new secondary hypotheses b. Project is likely to results in a report of interest to other scholars There is notable increased recognition on the importance of mental health, and especially perinatal mental health, with an emphasis on providing robust, comprehensive mental health assessments in primary care, including perinatal mental health assessments in both obstetrics and pediatrics. This unique dataset is truly multi-disciplinary and at the intersection of psychology, psychiatry, obstetrics and pediatrics. c. Project fulfills discovery/original research This proposal would be an ancillary study of original science as part of an ongoing clinical research trial.

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

The student will play an active role in recruitment, administering questionnaires to participants at several time points during pregnancy and in data collection and analysis. As part of this project, the student will have access to sizeable preliminary data to ask secondary questions of interest regarding perinatal mental health and pregnancy outcomes.

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

The mentor will help to guide the student and will connect them with the other members of the research team. The team includes the research coordinators onsite that the student would be working with on a daily basis as well as the study leadership team, which meets weekly. The mentor will provide practical guidance on the development and execution of a clinical research trial, including regulatory oversight, study design and methodology. The mentor also will oversee and assist with data collection and guide analysis and interpretation.

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

Dr Keller has sponsored several students for summer research projects and these have resulted in posters, presentations and publications for the students involved. In addition, this multidisciplinary team has incorporated students into the team for research elective and ongoing experiences and recognizes the importance of mentoring and sponsoring students to learn about the research process.

*** 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: NCR213760

* IRB Date: Expires 5/26/24

Faculty Proposal for MD Student Research by Andrew Meltzer

* 1. Faculty Sponsor

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* 2. Daily Supervisor

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* 3. Project Title (250 character limit)

Risk Factors Associated with Acute Presentation of Recurrent Abdominal Pain Syndromes in the Emergency Department

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

Meltzer, A.C., Wargowsky, R.S., Moran, S. et al. Diagnostic accuracy of novel mRNA blood biomarkers of infection to predict outcomes in emergency department patients with undifferentiated abdominal pain. Sci Rep 13, 2297 (2023). https://doi.org/10.1038/s41598-023-29385-3

Meltzer AC, Newton S, Lange J, Hall NC, Vargas NM, Huang Y, Moran S, Ma Y. A randomized control trial of a multiplex gastrointestinal PCR panel versus usual testing to assess antibiotics use for patients with infectious diarrhea in the emergency department. J Am Coll Emerg Physicians Open. 2022 Jan 15;3(1):e12616. doi: 10.1002/emp2.12616. PMID: 35072157; PMCID: PMC8760946.

Meltzer, Andrew C., et al. "Magnetically controlled capsule for assessment of the gastric mucosa in symptomatic patients: a prospective, single-arm, single-center, comparative study." iGIE (2023).

*** 5. Sponsor's Research Focus:**

Yes - Gastroenterology
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)**

Abdominal pain is the most common complaint in the Emergency Department and represents a wide range of conditions from the life-threatening to the benign. Some patients present multiple times to the ED for recurrent and chronic pain. We hypothesize that many of these patients have a psychosocial contribution to their symptoms. For ER patients who meet inclusion criteria, we will perform a validated psychosocial screening tools such as ASSIST and PROMIS-29 to determine how these factors contribute to future healthcare utilization. Long-term goals are to develop targeted interventions to decrease ED revisits in patients with recurrent and chronic pain.

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

Abdominal pain accounts for 15%–34% of all emergency department (ED) visits by super-utilizers (4 or more ED visits per year). ED management of abdominal pain is challenging because patients are at risk of unnecessary radiation exposure due to multiple CAT scans, at risk of repeat opioid exposure due to 35-50% of ED visits receiving opioids, and at risk for moderate to severe depression and other mental health disorders. The purpose of this project is to increase our understanding of who develops chronic recurrent abdominal pain and the ED utilization within this patient population. As a result, we aim to investigate the following: 1. Identify ED patients with undiagnosed disorders of gut-brain interaction. Distinguish them form life-threatening conditions. 2. Assess the impact of undiagnosed abdominal pain on ED utilization and other economic implications 3. Characterize the biopsychosocial features of ED patients with chronic recurrent abdominal pain to guide the development of targeted interventions

*** 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 led by the George Washington University, will enroll subjects across a multi-center network including Duke University and Henry Ford Health with the goal total enrollment of 500 subjects across all sites. Patients eligible to participate include those who present to the ED with undifferentiated abdominal pain. Once the patient is deemed eligible, the study procedures are as follows: 1. The subject will receive an explanation of all study procedures and must sign and date a written Informed Consent Form (ICF) approved by an Institutional Review Board (IRB) 2. The subject will complete a study questionnaire on a tablet device provided by the research team. All study data will be securely kept in electronic data capture system, RedCap. 3. The subject will complete a 30-day follow up survey administered virtually through Redcap. At a fundamental level, our research should help clinicians better understand the context behind the ED presentations of recurrent abdominal pain, hopefully leading to better experience for patients through that shared understanding. We also hope that research such as this will provide the foundation for more prospective interventional research potentially working to test strategies on non-opioid pain management modalities, targeted imaging to the patients who will receive benefit, or better recognize patients with mental health disorders presenting in these atypical ways.

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

Student will spend 20 hours per week in the Emergency Department screening and enrolling patients for primary project and related secondary projects. During this time, the student will be directly involved in collecting patient level data, obtaining informed consent, applying inclusion criteria, in addition to randomization, sample collection and research intervention where applicable. Outside of their time in the ED, student will be mentored in the methodology and ethical conduct of clinical research, in addition to the basics of data management, data analysis, and manuscript preparation. Student will be an integral part of a large ED Research team which includes multiple faculty members and research staff. Weekly team meetings plus additional ad hoc meetings will be held. Gill students from recent years have all gone on to publish in peer-reviewed journals and/or present their data at national conferences.

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

Mentor is a full professor and practicing clinician at GW who also leads a large research portfolio of studies funded by NIH, CDC and industry. The mentor will be available on site and will meet with student individually and in group settings throughout the week. Mentor has ten plus years of experience with students and prioritizes career development of student and providing students with meaningful experiences and not "grunt work."

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

1. Callen Morrison (MS2) 2. Sophia Newton (MS4) 3. Michael Makutonin (MS3) 4. Ben Zollinger (MS4) 5. Kayla Authelet (MS4) - Morrison, Callen, and Babak Sarani. "Which Patients with Biliary Colic Need Gallbladder Removal?." (2023). - Cannabinoid Hyperemesis Syndrome: Survey of Affected Patients (In Submission) - Morrison, Callen (1st author) - Meltzer, Andrew C., Sophia Newton, Joel Lange, Nicole C. Hall, Nataly Montano Vargas, Yihe Huang, Seamus Moran, and Yan Ma. "A randomized control trial of a multiplex gastrointestinal PCR panel versus usual testing to assess antibiotics use for patients with infectious diarrhea in the emergency department." Journal of the American College of Emergency Physicians Open 3, no. 1 (2022): e12616. - Makutonin, Michael, Sophia Newton, Justin Tse, Ali Moghtaderi, Yan Ma, and Andrew C. Meltzer. "Patients with complicated gallstone disease in the emergency department: clinical impact and cost-effectiveness of emergency department disposition decision." Journal of the American College of Emergency Physicians Open 3, no. 5 (2022): e12795.

* **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: NCR213728

* IRB Date: 11/02/2021

Faculty Proposal for MD Student Research by Jennifer Klein

* 1. Faculty Sponsor

* Name:	Jennifer Klein
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* Title:	Physician
* Organization:	Children's National Hospital
* Address:	111 Michigan Avenue NW
* Apt/Suite:	WW 3.0 - Suite 200
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* State:	DC
* Zipcode:	20010
* Office Phone:	(202) 476-2020
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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)

Disparities in maternal health as a predictor of congenital heart disease outcomes in the fetus

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

Klein, J., Ryan, J., Dwivedi, P., Leslie, T., Vyas, A., & Krishnan, A. (2023). Neighborhood location and nutritional resources as a risk factor for congenital heart disease in the fetus. Birth Defects Research, 1–10. https://doi.org/10.1002/bdr2.2231

Klein, J. H., Gourishankar, A., & Krishnan, A. (2022). Development of a national dataset for geospatial analysis of congenital heart disease. Frontiers in Pediatrics, 10. https://doi.org/10.3389/fped.2022.952048

Klein, J., Dwyer, G., Donofrio, M. T., & Krishnan, A. (2022). Geographic distribution of congenital heart disease: A single surgical center experience. The Journal of Pediatrics, 240, 117–121. https://doi.org/10.1016/j.jpeds.2021.08.080

* **5. Sponsor's Research Focus:**

Yes - Pediatrics
Yes - Cardiology

* **6. Sponsor's translational level**

* **(Please select ONE)**

T4: Translation to Population Health

* **7. Hypotheses (200 word limit)**

Maternal health disparities, such as food security, exposure to environmental toxins, and lack of neighborhood resources, influences the health of the fetus and correlates with greater risk of congenital heart disease (CHD) in the fetus and worse outcomes for those infants born with CHD.

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

Congenital heart disease (CHD) is the most common birth defect, affecting 1 in 100 children. It is estimated that up to 70% of cases of CHD are due to modifiable risk factors, such as environmental exposures or the presence of maternal diabetes. However, these risk factors do not exist in a vacuum and are influenced by social determinants of health such as neighborhood resources, maternal access to care, etc. Significant disparities exist in CHD outcomes based upon where a patient lives. This multi-arm study aims to characterize modifiable maternal risk factors that may confer increased risk of CHD on the offspring. This will be done through the application of novel tools such as 1) geospatial analysis of CHD cases to identify “hot spots,” and 2) study of the maternal metabolome as it relates to food security and health. • To characterize the maternal nutritional status and metabolome of mothers whose fetus’ have CHD • To evaluate for the presence of CHD “hot spots” in disadvantaged neighborhoods Ultimately, we hope to develop a maternal risk assessment for CHD in the fetus that can be leveraged to create an intervention that mitigates risk and improves outcomes of CHD.

* **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 multi-arm study involves both a retrospective review of cases of CHD and associated neighborhood characteristics, as well as prospective cohort study that will collect clinical and sociodemographic data and maternal serum for metabolomic analysis from women whose fetuses have CHD. The first objective, evaluating nutritional status and maternal metabolome, is expected to have completed enrollment by Summer 2024. The student will be responsible for data cleaning and management, including query of the electronic medical record to complete data collection. The later part of the summer will then be spent on data analysis and manuscript preparation. The second objective, evaluating for CHD hot spots, will be an ancillary study for which the student will be able to develop a hypothesis, collect data, clean and analyze data, and begin manuscript preparation within the summer months. The student will focus on one of the above objects, to be

jointly selected by the student and mentor and dependent on the student's interests and the research progress by summer 2024.

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

The student will work with the mentor to assist with the above project commensurate with the student's interests and the stage of the project during Summer 2024. Student responsibilities may include background literature review to become familiar with the subject matter, development of a REDCap database, review of patient electronic medical records and information collection to populate the database. The student will assist in data cleaning and preparation for statistical analysis and will have the opportunity to further enhance their skills through writing of scientific reports, posters, and oral presentations.

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

The mentor will be responsible for overseeing the student's progress through regular meetings and teaching sessions throughout the summer both in-person and virtually. The mentor will introduce the student to the field of pediatric and fetal cardiology with the goal of learning how public health tools can be applied to the care of patients. The mentor will guide the student in the development of research skills such as literature review, hypothesis building, data management, data analysis, and manuscript preparation.

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

Prior mentees have assisted with data collection, data cleaning, and manuscript preparation and were included as authors on publications commensurate with their contributions to the project. The mentor has also mentored students on their own student-led projects. List of prior mentees: Julia Ryan (GW Medical Student), Emma Walker (GW Master of Public Health student), Patricia Averill (RN, University of Maryland Master of Public Health student), Ciara Brown (MD, Children's National Pediatric 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 Yes

Please provide IRB number and date

* IRB Number:	STUDY00000587
* IRB Date:	08/23/2023

Faculty Proposal for MD Student Research by Can Yerebakan

* 1. Faculty Sponsor

* Name:	Can Yerebakan
* Degrees:	MD, PhD Associate Chief, Cardiac Surgery Director, Fellowship Program Cardiac Surgery Director, Quality and Outcomes Cardiac Surgery Professor of Surgery and Pediatrics Cardiovascular Surgery Children's National Hospital The George Washington University School of Medicine and Health Sciences
* Title:	Hypoplastic Left Heart Variants with fenestrated surgical atrial septal defect closure
* Organization:	Children's National Hospital
* Address:	111 Michigan Avenue NW
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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)

Hypoplastic Left Heart Variants with fenestrated surgical atrial septal defect closure

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

1) Henmi S, Ryan JA, Mehta R, Haverty MC, Hovis IW, Puente BN, Ozturk M, Desai M, Tongut A, Yerebakan C, d'Udekem Y. A uniform strategy of primary repair of tetralogy of Fallot: Transventricular approach results in low reoperation rate in the first decade. J Thorac Cardiovasc Surg. 2023 Dec;166(6):1731-1738.e3. doi: 10.1016/j.jtcvs.2023.05.036. Epub 2023 Jun 9. PMID: 37301251.

2) Wernovsky G, Ozturk M, Diddle JW, Muñoz R, d'Udekem Y, Yerebakan C. Rapid bilateral pulmonary artery banding: A developmentally based proposal for the management of neonates with hypoplastic left heart. JTCVS Open. 2023 Apr 3;14:398-406. doi: 10.1016/j.xjon.2023.03.009. PMID: 37425468; PMCID: PMC10328842.

3) Ceneri NM, Desai MH, Tongut A, Ozturk M, Ramakrishnan K, Staffa SJ, Zurakowski D, Donofrio MT, Downing T, d'Udekem Y, Jonas RA, Yerebakan C; Children's National Hospital Hybrid Working Group. Hybrid strategy in neonates with ductal-dependent systemic circulation and multiple risk factors. J Thorac Cardiovasc Surg. 2022 Nov;164(5):1291-1303.e6. doi: 10.1016/j.jtcvs.2021.11.103. Epub 2022 Mar 16. Erratum in: J Thorac Cardiovasc Surg. 2023 Jan;165(1):408. PMID: 35577592.

* **5. Sponsor's Research Focus:**

Yes - Pediatrics
Yes - Cardiology
Yes - Surgery

* **6. Sponsor's translational level**

* **(Please select ONE)**

T3: Translation to Practice

* **7. Hypotheses (200 word limit)**

1) We hypothesize, that a fenestrated surgical closure with remaining inter-atrial communication after a biventricular repair in patients with Hypoplastic Left Heart Variants reduces pulmonary hypertensive crises, left heart failure, transition from BV path to SV palliation, and/or mortality. 2) We aim to investigate, if the size of the fenestrated inter-atrial communication has an impact on those outcome variables.

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

Using the Society of Thoracic Surgeons (STS) registry, we will identify all patients with hypoplastic left heart variants that underwent biventricular repair in our center between 2007-2023. We will categorize them in patients with complete atrial septal defect closure and those with fenestrated atrial closure and remaining inter-atrial communication. We aim to evaluate differences in pulmonary hypertensive crises, left heart failure, transition from biventricular path to single ventricular palliation and mortality as outcome variables. Additionally, we will analyze if the size of the fenestrated communication has an impact on our outcome variables.

* **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**

Patients with hypoplastic left heart variants include hypoplastic left heart syndrome with mitral and aortic stenosis, hypoplastic left heart complex, hypoplastic left heart complex with interrupted aortic arch, hypoplastic aortic arch, imbalanced AVSD with hypoplastic arch, double-outlet right ventricle with aortic arch, d-TGA with interrupted aortic arch. Those patients can be eligible for biventricular repair. We hypothesize, that in cases with a restrictive inter-atrial communication, the atrial septal defect should not be closed but a fenestration should remain. We believe, that a postoperatively remaining inter-atrial communication is protective of both pulmonary hypertension and left ventricular decompensation as it functions as a pressure relief valve. In cases of pulmonary hypertensive crisis, it preserves systemic circulation by maintaining left ventricular preload through right-to-left shunting. In situations of left ventricular decompensation, it can reduce left heart/ventricle overload by allowing left-to-right shunting through the remaining inter-atrial communication. In addition, it allows more detailed monitoring of the left atrial pressure by placement of an intracardiac/left atrial line, catheter evaluations of the intracardiac pressures and echocardiographic evaluation of right-to-left versus left-to-right shunting over the ASD. Patients with hypoplastic left heart complex who underwent biventricular reoperation at Children's National Hospital, Washington, DC between 2007 and 2023 will be reviewed. We will categorize the patients as those with closed atrial septal defect and those with fenestrated surgical closure and remaining inter-atrial communication. All available data related to demographics, peri- and postoperative characteristics including complications, early postoperative and discharge echocardiography, outpatient follow-up, last follow-up echocardiography as well as early and late survival will be obtained retrospectively from institutional patient records. The limitations will probably be small-sized cohort, the variety of diagnosis, the variety of morphology, and different type of repair techniques performed according to surgeon preference. The STS CHD database collects extensive data on biventricular repairs. Although other studies have looked at right-to-left mixing in fenestrated closure, there are few studies that have focused on the protective effect for the left sided heart by left-to-right shunting. In this group, although relatively small, we anticipate a high benefit in morbidity and mortality. We thus propose using our retrospective cohort to better understand beneficial factors associated with fenestrated atrial closure in biventricular repairs.

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

The student will work with the Mentor to develop a research database using RedCap. They will review patient electronic medical records and collect information to populate the database. The student will assist in statistical analysis and will have the opportunity to further enhance their skills through scientific reports, posters and oral presentations. This project will also introduce the student to world renowned pediatric cardiac surgeons who are also participating in this research effort.

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

The mentor will be responsible for overseeing the student's progress through regular meetings and teaching sessions throughout the summer. The mentor will guide the student to produce high quality research questions and answers and will aid in enhancing the student's skills in the development scientific publication.

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

A list of students mentored by Dr. Can Yerebakan: Justus Reitz, MD, cardiac surgery fellow, Giessen, Germany; Mahmut Ozturk, MD, cardiac surgery fellow, Siegburg, Germany; Nicolle Ceneri, GW University, United States; Viktoria Kuhn, MD, Obstetrics and Gynakology, Cologne, Germany; Agnieszka Kosiarek, MD, radiology fellow, Zurich, Switzerland; Vanessa Sterzbecher, medical student, Giessen, Germany; Maren Brinken, medical student, Giessen, Germany

* **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: 15566

* IRB Date: 07/01/2021

Faculty Proposal for MD Student Research by Sinan Turnacioglu

* 1. Faculty Sponsor

* Name: Sinan Turnacioglu
* Degrees: M.D.
* Title: Neurodevelopmental Pediatrician; Assistant Professor of Neurology and Rehabilitation Medicine, Assistant Professor of Pediatrics
* Organization: Children's National Hospital
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* Apt/Suite:
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* State: DC
* Zipcode: 20010
* Office Phone: 202-476-4959
* Email Address: sturnaci@childrensnational.org

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* 2. Daily Supervisor

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

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* 3. Project Title (250 character limit)

Patterns of ADHD medication prescribing in children with congenital heart disease

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

McCleery JP, Zitter A, Solórzano R, Turnacioglu S, Miller JS, Ravindran V, Parish-Morris J. Safety and Feasibility of an Immersive Virtual Reality Intervention Program for Teaching Police Interaction Skills to Adolescents and Adults with Autism. Autism Res. 2020 Aug;13(8):1418-1424.

* 5. Sponsor's Research Focus:

Yes - Pediatrics
Yes - Psychiatry
Yes - Cardiology
Yes - Neurology

* **6. Sponsor's translational level**

* **(Please select ONE)**

T3: Translation to Practice

* **7. Hypotheses (200 word limit)**

Despite a higher prevalence of attention deficit hyperactivity disorder in children with congenital heart disease compared to the general population, providers prescribe medications for ADHD at lower rates than what has been reported in children with ADHD who lack a history of congenital heart disease

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

Review records of patients seen through Children's National's Cardiac Neurodevelopmental Outcomes (CANDO) program and associated databases for prescription orders intended for ADHD treatment Describe the frequency of prescribing of stimulant and nonstimulant medications for ADHD in the population of interest Identify associated patient characteristics including age, type of congenital heart disease, co-occurring diagnoses, and race and ethnicity

* **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 with congenital heart disease are at higher risk for ADHD diagnosis than the general pediatric population. However, due to concerns for cardiac side effects of medications used for treatment of ADHD, providers may be less likely to prescribe medications such as stimulants to treat ADHD in this population. Children's National's Cardiac Neurodevelopmental Outcomes (CANDO) program has provided multidisciplinary care for children with congenital heart disease at risk for neurodevelopmental disorders including ADHD for over a decade. The program has also contributed to a growing body of research characterizing the neurodevelopmental profile and the developmental, behavioral, and learning trajectories of this patient population. We seek to describe ADHD medication prescribing patterns in children with congenital heart disease receiving clinical care through the CANDO program at Children's National, and to compare patterns to those observed in the broader pediatric population of children with ADHD. The project will involve review of CANDO program databases and correlation with information from patients' electronic medical records. Relevant data would include type of congenital heart disease, description of neurodevelopmental and psychiatric diagnoses including ADHD, stimulant and nonstimulant medication prescriptions, and demographic information. Familiarity with databases and the electronic medical record system, subsequent database and EMR review, and final analysis of results is expected to occur over an eight week period. This retrospective study is expected to lead to follow up research surveying caregivers of children with CHD regarding

perceptions and preferences regarding ADHD medication prescribing, as well as prospective research evaluating ADHD medication prescribing patterns and neurodevelopmental outcomes.

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

The student will conduct review of CANDO program databases and the electronic medical record to collect data on patients with CHD and ADHD who have been prescribed medication to treat ADHD symptoms. Data in databases and the electronic medical record will be correlated for complete data capture and consistency. The student will further engage in characterization of patients prescribed ADHD medications by documenting the specific type of congenital heart disease, co-occurring neurodevelopmental and psychiatric diagnoses, specific type of ADHD medication prescription, and demographic information. The student will have the opportunity to observe multidisciplinary CANDO clinics to observe clinical care provided by neurology and neurodevelopmental pediatrics and to observe neuropsychological evaluations of these patients.

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

The mentor will support the student with access to the electronic medical record and neuropsychological and other databases relevant to completion of this research project. The mentor will provide instruction on literature review for background information relevant to research goals. The mentor will provide guidance on development of a final research product. Weekly meetings will be scheduled to review progress towards project goals.

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

Previous medical student training has been provided for a project addressing the uses of virtual reality for treatment of anxiety in individuals with autism spectrum disorder and related neurodevelopmental disorders.

*** 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 Brian Reilly

* 1. Faculty Sponsor

* Name:	Brian Reilly
* Degrees:	MD
* Title:	Doctor
* Organization:	Children's National Hospital
* Address:	111 Michigan Ave
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* State:	DC
* Zipcode:	20010
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* Email Address:	breilly@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)

ABR testing variable outcomes

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

Tunkel AE, Gorelik D, Behzadpour HK, et al. Confirmatory Auditory Brainstem Responses Testing Results in Discordant Outcomes: Implications for Timely Care. Laryngoscope. 2023;133(12):3571-3574. doi:10.1002/lary.30670

Bower C, Reilly BK, Richerson J, Hecht JL; COMMITTEE ON PRACTICE & AMBULATORY MEDICINE; SECTION ON OTOLARYNGOLOGY–HEAD AND NECK SURGERY. Hearing Assessment in Infants, Children, and Adolescents: Recommendations Beyond Neonatal Screening. Pediatrics. 2023;152(3):e2023063288. doi:10.1542/peds.2023-063288

Balk SJ, Bochner RE, Ramdhanie MA, Reilly BK; COUNCIL ON ENVIRONMENTAL HEALTH AND CLIMATE CHANGE ; SECTION ON OTOLARYNGOLOGY–HEAD AND NECK SURGERY . Preventing Excessive Noise Exposure in Infants, Children, and Adolescents. Pediatrics. 2023;152(5):e2023063752. doi:10.1542/peds.2023-063752

* **5. Sponsor's Research Focus:**

Yes - Pediatrics
Yes - Surgery

* **6. Sponsor's translational level**

* **(Please select ONE)**

T4: Translation to Population Health

* **7. Hypotheses (200 word limit)**

Auditory Brainstem Response (ABR) tests are used to detect hearing loss and typically conducted in children and infants who cannot undergo traditional hearing tests. ABR testing comes in two forms: screening and diagnostic, which can aid in confirming a hearing loss diagnosis. For this study, we aim to: understand outcomes of ABR testing, including for diagnosis confirmation and intervention development and assessing trends in natural-sleep ABRs.

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

1) Advancing knowledge of outcome measures in pediatric patients undergoing ABR testing as means of ruling or confirming diagnosis, such as hearing loss or autism. 2) Characterize treatment outcomes and complications of ABR testing in pediatric patients at CNH

* **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**

Chart abstraction from population who have undergone ABR at Children's National Hospital. Students will be shown how to: *navigate charts for correct variables and how to record *code dataset for future analysis leading to abstract/manuscript

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

Student will be responsible for data collection from charts and future write-ups

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

Mentor will provide oversight and guidance during the project.

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

The mentor has involved with both Gill Fellows and Health Services Scholars programs for over a decade. Previous students have had projects that cumulated in conference presentations locally and nationally and journal 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: 15769

* IRB Date: 3/14/2021

Faculty Proposal for MD Student Research by Anant Vatsayan

* 1. Faculty Sponsor

* Name:	Anant Vatsayan
* Degrees:	MBBS
* Title:	Blood and Marrow Transplant/Cellular Therapy Attending, Children's National Hospital; Assistant Professor, Pediatrics, George Washington University School of Medicine and Health Sciences
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* 2. Daily Supervisor

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* 3. Project Title (250 character limit)

Predicting Transplant-Associated Thrombotic Microangiopathy in Patients with Sickle Cell Disease

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

Ipe A, Angiolillo A, Jacobsohn D, Cheng J, Bornhorst M, Turner J, Vatsayan A. Case report: Tisagenlecleucel for treatment of relapsed B- acute lymphoblastic leukemia in a patient with CHEK2 mutation. Front Pediatr. 2023 Mar 1;11:1067131. doi: 10.3389/fped.2023.1067131. PMID: 36937957; PMCID: PMC10014590.

McNerney KO, Si Lim SJ, Ishikawa K, Dreyzin A, Vatsayan A, Chen JJ, Baggott C, Prabhu S, Pacenta HL, Philips C, Rossoff J, Stefanski HE, Talano JA, Moskop A, Verneris M, Myers D, Karras NA, Brown P, Bonifant CL, Qayed M, Hermiston M, Satwani P, Krupski C, Keating AK, Baumeister SHC, Fabrizio VA, Chinnabhandar V, Egeler E, Mavroukakis S, Curran KJ, Mackall CL, Laetsch TW, Schultz LM. HLH-like toxicities predict poor survival after the use of tisagenlecleucel in children and young adults with B-ALL. Blood Adv. 2023 Jun 27;7(12):2758-2771. doi: 10.1182/bloodadvances.2022008893. PMID: 36857419; PMCID: PMC10275701.

Diorio C, Vatsayan A, Talleur AC, Annesley C, Jaroscak JJ, Shalabi H, Ombrello AK, Hudspeth M, Maude SL, Gardner RA, Shah NN. Anakinra utilization in refractory pediatric CAR T-cell associated toxicities. Blood Adv. 2022 Jun 14;6(11):3398-3403. doi: 10.1182/bloodadvances.2022006983. PMID: 35395068; PMCID: PMC9198909.

* **5. Sponsor's Research Focus:**

Yes - Pediatrics

* **6. Sponsor's translational level**

* **(Please select ONE)**

T3: Translation to Practice

* **7. Hypotheses (200 word limit)**

Transplant-associated thrombotic microangiopathy (TA-TMA) is a potentially devastating complication of hematopoietic stem cell transplant (HSCT) that leads to formation of microthrombi, resulting in multi-organ dysfunction. Patients with sickle cell disease have endothelial injury at baseline and are thus at higher risk of developing TA-TMA. While overall risk of TA-TMA is about 2% in allogeneic HCT, patients with SCD have 6- fold higher risk (13%). (Schoettler, 2023, Blood Advances) Patients with TA-TMA have 3-fold higher risk of transplant related mortality (TRM) and seven times higher risk of needing renal replacement therapy. (Epperla, 2021, BJH) Predicting who is likely to develop TA-TMA can guide early interventions to prevent this potentially fatal complication and reduce transplant-associated mortality. Pre-HCT markers of endothelial activation (P-selectin, VCAM-1) are elevated in SCD HCT patients. However, these tests are expensive and not widely available. (Schoettler, 2023, Blood Advances) We hypothesize that TA-TMA in patients with SCD HCT can be predicted by the Endothelial activation and stress index (EASIX) score, which is composed of common laboratory values, and has predicted endothelial damage in other allogeneic HCT settings. (Luft, 2020, BMT) EASIX as a prognostic tool for transplant outcomes in SCD has never been described before.

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

Our primary aim is to examine the correlation between EASIX score and development of TA-TMA in patients with SCD who have undergone HCT. Primary outcome will be incidence of TA-TMA. Secondary outcomes will be incidence of endothelial injury syndromes (acute and chronic graft versus host disease, graft failure, veno-occlusive disease, TRM, and overall survival in the year following transplant. In addition to EASIX scores, we will also example covariates that indicate higher severity of sickle cell disease, including frequent hospitalizations, need for more disease-modifying therapies, and lower baseline performance status. An aim at the end of a summer project will be to compile this data into an abstract for conference presentation, with a longer-term goal of completing a manuscript.

*** 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 mechanism of TA-TMA is a complex feedback loop between endothelial damage, inflammation, and complement activation as a result of stem cell transplant and the associated conditioning therapies. Patients with sickle cell disease, who at baseline have endothelial damage and often renal injury, due to abnormal red cell structure are at higher risk for microangiopathy complications. However, TA-TMA is relatively rare and has a range of symptom severity. At this time, we do not have a way of predicting who will develop severe symptoms. Importantly, we do have therapies targeting the complement cascade in TA-TMA, and early identification of patients at high risk of organ dysfunction will allow us to initiate these sooner in a targeted population. This will be a retrospective chart review that aims to examine pre-transplant characteristics and peri-transplant laboratory values that differentiate patients who go on to develop TA-TMA from those who do not. We will include patients (<21 years) with SCD undergoing HCT from matched related and alternative donors at Children's National Hospital from January 2014- December 2023. A total of 150 patients will be included in the study. We will gather the following information from day of admission for HCT: indication for transplant for SCD, performance status, disease-modifying therapies prior to transplant, hospitalization rate in year prior to transplant. We will also collect laboratory values including complete blood counts, %Hgb S, Cr, and LDH daily between admission and transplant (while receiving conditioning regimen), and weekly for the month following transplant. EASIX scores will be calculated at each of these timepoints. We will examine the EASIX score as a predictor of TA-TMA in univariate analysis as well as in a multivariate analysis including baseline factors associated with sickle cell disease severity. This would be a novel application of the EASIX score and could impact our approach to peri-transplant monitoring. Furthermore, the descriptive data gathered for this project, which will include one of the largest cohorts of sickle cell transplant patients nationally, will in itself be an important addition to the literature. This project will allow the student to learn about clinical manifestations of sickle cell disease as well as stem cell transplant complications. They will also be guided in performing basic statistical analysis. Children's National take care of one of the largest sickle cell populations nationally and as such we have a uniquely large data set for sickle cell transplant patients. The results of this analysis will provide important guidance on clinical management and may lead to multi-center collaborative studies to further develop predictive models of TA-TMA. Timeline: Data gathering and quality assurance is expected to take about 3-4 weeks, with 4-5 weeks dedicated to data analyses. The student will meet with both mentors weekly to go over progress. Dr. Dreyzin will be available to meet multiple times throughout the week as needed to discuss an day to day questions.

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

The student will be involved in data collection, analysis, and presentation. They will help to design a data collection tool and will implement it to complete a chart review as described above. They will work together with mentors as well as biostatistician support as needed, to complete an analysis of the data. They will then write an abstract describing the results for submission to the American Society of Pediatric Hematology/Oncology conference. If desired, they will also have the opportunity to spend some time in the BMT clinic interacting with patients who are being evaluated for bone marrow transplant. The clinical experience can be tailored to students' interest.

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

We will prepare the IRB prior to the beginning of the summer. We will then orient the student to basics of sickle cell disease and transplant complications. We will provide EMR training to the student and work together to develop a data collection tool. We will continue to meet regularly as we gather, interpret, and analyze data. Mentor will ensure that the result of the study is presented by the student at a national or international pediatric hematology/oncology (ASPHO) or blood and marrow transplant conference (PTCTC). Mentor will guide the student write and submit the manuscript for publication in a peer reviewed journal.

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

Dr. Vatsayan has worked with several GW medical students clinically as well as on research projects. Recent projects include: Abraham Ipe, as a 4th year medical student, completed a clinical rotation in BMT as well as a case report, which was presented as a poster at The American Society of Pediatric Hematology/Oncology and published in Frontiers in Pediatric Oncology. Florence Yan, MS3, also completed a case report which is currently in submission, and is working with another medical student, Angela Sarkisian, MS2, on a retrospective study to investigate the PICU admission after different types of donor hematopoietic cell transplantation at Children's National Hospital.

* **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 Yves d'Udekem

* 1. Faculty Sponsor

* Name:	Yves d'Udekem
* Degrees:	MD, PhD
* Title:	Professor of Surgery and Pediatrics
* Organization:	Children's National Hospital
* Address:	111 Michigan Ave. NW
* Apt/Suite:	Suite W3-402
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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)

Atrioventricular Valve Repair in Single Ventricle Physiology – Timing and Outcomes

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

Henmi S, Ryan JA, Mehta R, Haverty MC, Hovis IW, Puente BN, Ozturk M, Desai M, Tongut A, Yerebakan C, d'Udekem Y. A uniform strategy of primary repair of tetralogy of Fallot: Transventricular approach results in low reoperation rate in the first decade. J Thorac Cardiovasc Surg. 2023 Jun 9: S0022-5223(23)00461-0. doi: 10.1016/j.jtcvs.2023.05.036

d'Udekem Y, Kisamori E, Ishigami S, Konstantinov IE. Aortic valve-sparing procedure in the pediatric population. Ann Cardiothorac Surg. 2023 May 31;12(3):253-258. doi: 10.21037/acs-2023-avs1-0029

Schlapbach LJ, Gibbons KS, Horton SB, Johnson K, Long DA, Buckley DHF, Erickson S, Festa M, d'Udekem Y, Alphonso N, Winlaw DS, Delzoppo C, van Loon K, Jones M, Young PJ, Butt W, Schibler A; NITRIC Study Group, the Australian and New Zealand Intensive Care Society Clinical Trials Group (ANZICS CTG), and the ANZICS Paediatric Study Group (PSG). Effect of Nitric Oxide via Cardiopulmonary Bypass on Ventilator-Free Days in Young Children Undergoing Congenital Heart Disease Surgery: The NITRIC Randomized Clinical Trial. JAMA. 2022 Jul 5;328(1):38-47. doi: 10.1001/jama.2022.9376

* **5. Sponsor's Research Focus:**

Yes - Cardiology
Yes - Surgery

* **6. Sponsor's translational level**

* **(Please select ONE)**

T3: Translation to Practice

* **7. Hypotheses (200 word limit)**

1) The outcomes of patients with single ventricle who undergo atrioventricular valve (AVV) repair during interstage are more likely better than those who undergo AVV repair simultaneously at staged palliation. 2) Patients with single ventricle and decreased ventricle function who undergo AVV repair have a higher mortality compared to those who require AVV repair with a good ventricle function.

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

We will identify all single-ventricle patients that underwent AVV surgery by using the STS CHD data. We will evaluate our surgical experience of AVV regurgitation in patients with single ventricle physiology. Additionally, we will analyze factors associated with poor outcomes within the cases according to their time of reoperation.

* **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 patients with staged-single-ventricle palliation who underwent AVV reoperation at Children's National Medical Center, Washington, DC between 2010 and 2023 will be reviewed. We will categorize the patients as; those that had a AVV repair at interstage as a separate surgery and those had a AVV repair during a staged palliation (Glenn or Fontan) as a simultaneous surgery. All available data related to demographics, peri and postoperative characteristics including complications, early postoperative and discharge echocardiography, outpatient follow-up, last follow-up echocardiography as well as early and late survival will be obtained retrospectively from institutional patient records. The limitations will probably be small-sized cohort, the variety of diagnosis, the variety of morphology, and different type of repair techniques performed according to surgeon preference. The STS CHD database collects extensive data on univentricular staged

palliation. Although other studies have looked at over all outcomes of staged palliation, there are few studies that have focused on AVV repair in univentricular patients. This group, although relatively small, we anticipate will have a high morbidity and mortality. We thus propose using the STS CHD database to better understand modifiable and non-modifiable risk factors associated with survival or reoperation following AVV repair in single ventricle.

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

The student will work with the Mentor to develop a research database using RedCap. They will review patient electronic medical records and collect information to populate the database. The student will assist in statistical analysis and will have the opportunity to further enhance their skills through scientific reports, posters and oral presentations. This project will also introduce the student to world renowned pediatric cardiac surgeons who are also participating in this research effort.

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

The mentor will be responsible for overseeing the student's progress through regular meetings and teaching sessions throughout the summer. The mentor will guide the student to produce high quality research questions and answers and will aid in enhancing the student's skills in the development scientific publication.

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

Justus Reitz, MD, cardiac surgery fellow, Giessen, Germany; Mahmut Ozturk, MD, cardiac surgery fellow, Giessen, Germany; Dr David Glineur, MD, PhD, Consultant Cardiac Surgeon, Cliniques Universitaires, St-Luc, Belgium Dr Parla Astarci, MD, Consultant Cardiac Surgeon, Cliniques Universitaires St-Luc, Belgium Dr Nelson Alphonso, M.S., FRCS, FRCSI, Consultant Cardiac Surgeon, Head of the department of paediatric cardiac surgery, Alderhey Hospital, Liverpool, UK Dr Lyubomyr Bohuta, MD, Consultant Cardiac Surgeon, Head of department of paediatric cardiac surgery, Children's Cardiac Centre, Kyiv, Ukraine Dr Ajay Iyengar, MBBS, PhD student, trainee in the cardio-thoracic surgery program of the RACS.

* **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: Pro00015566
* IRB Date: 07/01/2021

Faculty Proposal for MD Student Research by Shayna Coburn

* 1. Faculty Sponsor

* Name:	Shayna Coburn
* Degrees:	PhD
* Title:	Associate Professor, Psychologist
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* 2. Daily Supervisor

Name:	Shayna Coburn
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* 3. Project Title (250 character limit)

Investigating health disparities in screening, diagnosis and treatment of celiac disease among under-represented youth

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

Sady, M., Coburn, S., Kramer, Z., Streisand R., & Kahn, I. (2023) Associations between executive functioning and adherence in pediatric celiac disease, Children's Health Care, DOI: 10.1080/02739615.2023.2259291

Coburn, S., Germone, M., McGarva, J., & Taft, T. (2022). Psychological considerations for food intolerance. Invited manuscript for special issue, “Psychogastroenterology,” L. Keefer (ed.), Gastroenterology Clinics of North America, 51(4): 753-764. Doi: 10.1016/j.gtc.2022.07.003.

Wright, C.D.*, Germone, M.M., Kimmons, R., Germone, M.M., & Coburn, S. (2022). Twitter trends for celiac disease and the gluten-free diet: A cross-sectional descriptive analysis. JMIR Infodemiology, doi 10.2196/37924.

*** 5. Sponsor's Research Focus:**

Yes - Gastroenterology
Yes - Psychiatry

*** 6. Sponsor's translational level**

*** (Please select ONE)**

T3: Translation to Practice

*** 7. Hypotheses (200 word limit)**

It is hypothesized that the rates of screening and referral to tertiary care for celiac disease differs based on social determinants of health (e.g., race, ethnicity, spoken language, neighborhood, etc.), such that youth from a historically under-represented background receive fewer screening tests and referrals for celiac disease.

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

1. Identify barriers to accessing screening, diagnosis, and/or treatment in children from historically underrepresented backgrounds with potential OR diagnosed celiac disease a. Discussion/interviews with primary care, community-based practices b. Queries of CNH medical records for referrals c. Interviews/surveys with patients from target backgrounds 2. Identify potential solutions to mitigate barriers and improve access to healthcare and food resources.

*** 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 Celiac Disease Clinic at Children's National Hospital offers a comprehensive treatment service to youth with celiac disease. However, it has been observed that the patients attending the clinic comprise an over-representation of White, suburban, and privately insured patients. The current project aims to identify the extent to which disparities may exist throughout the process of screening, diagnosis, and referral to the clinic. The proposed project will use stakeholder engagement techniques to identify biases, institutional and environmental barriers, and other challenges that may contribute to health disparities for celiac disease treatment. These findings will inform future quality improvement initiatives and guidance for addressing disparities and improving access to care.

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

The student will assist with developing the proposal for the project and planning data collection. Based on the student's experience and interest, they may contribute to IRB and grant applications, conducting interviews, and analyzing data using qualitative and quantitative methods. The student will be provided with all necessary training.

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

Dr. Coburn has extensive research experience and a record of grant funding in behavioral science in celiac disease. She will meet weekly with the student throughout the project to guide them through their training goals and related activities. Dr. Coburn will ensure appropriate training for specific assigned tasks such as navigating the IRB regulatory process, conducting interviews, designing surveys, and/or analyzing data.

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

Dr. Coburn has previously mentored several medical students in research projects, including a REACH student, Rebecca Trillo, from 2021-2023. Students have been invited to join Dr. Coburn's research lab and work collaboratively with her team, as well as work on personal projects of their own interest.

* **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)
Selected No (Not Required)

Please specify why it is not required.

The first portion of the project will be considered a quality improvement initiative whereby initial clinic data and information-gathering from clinicians will be completed. Based on the findings of the first portion of the project, IRB approval for human subjects research may be secured as needed to pursue additional aims to investigate patient experiences and impact.

Faculty Proposal for MD Student Research by Allison Mayhew

* 1. Faculty Sponsor

* Name:	Allison Mayhew
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* 2. Daily Supervisor

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Email Address:	snaroji@childrensnational.org

* 3. Project Title (250 character limit)

Menstrual Irregularity and Associated Risk Factors for Polycystic Ovarian Syndrome (PCOS) in Patients with Spina Bifida

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

Mayhew AC and Gomez-Lobo V. Fertility Options for the Transgender and Gender Nonbinary Patient. The Journal of Clinical Endocrinology and Metabolism. 2020 October; 105(10): 3335-3345.

Jacobs SE, Tiusaba L, Al-Shamaileh T, Bokova E, Russell TL, Ho CP, Varda BK, Pohl HG, Mayhew AC, Gomez-Lobo V, Feng C, Badillo AT, Levitt MA. Fetal and Newborn Management of Cloacal Malformations. Children. 2022 June; 9(6): 888.

Nashed LM, Mayhew A, Gomez-Lobo V, Lawlor C. Dicer1 Mutation Detected in an Infant Guides Accurate Diagnosis of Auto-Amputated Embryonal Rhabdomyosarcoma. Journal of Pediatric and Adolescent Gynecology. 2021 December; 34 (6): 865-868.

*** 5. Sponsor's Research Focus:**

Yes - Pediatrics
Yes - Obstetrics/Gynecology

*** 6. Sponsor's translational level**

*** (Please select ONE)**

T2: Translation to Patients

*** 7. Hypotheses (200 word limit)**

Spina bifida is a neural tube defect that results in damage to the spinal cord and nerves. Spina bifida has a wide range of disease severity depending on the size and location of the spinal lesion. Some common effects include hydrocephalus, tethered spinal cord, physical and mobility disability, cognitive impairment, and bowel and urinary incontinence. Little is known regarding the impact of spina bifida on gynecologic and reproductive outcomes. Some data suggests that those with spina bifida may progress through puberty earlier than age-matched peers. Clinical experience has demonstrated that after puberty, periods may remain irregular and may be associated with metabolic derangements consistent with Polycystic Ovarian Syndrome in this population, however, little has been published on this relationship. We aim to better characterize the prevalence of menstrual irregularity and hormonal derangements in patients with Spina Bifida and hypothesize that there will be a higher prevalence of irregular periods, elevated testosterone levels, elevated DHEAS levels, and increased metabolic concerns in this population.

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

Our team has a database of 129 female patients with spina bifida who are age 11 and older. Initial project goals will include a retrospective chart review to assess for documentation of menarche, menstrual frequency, and hormone lab results. In those patients without gynecologic documentation, project goals will include completion of a patient survey to assess gynecologic function and, if qualified, prospective completion and review of hormone lab results in select patients. We anticipate this project will provide sufficient data for submission of a scientific abstract to the North American Society of Pediatric and Adolescent Gynecology Annual Meeting and research article publication in the Journal of Pediatric and Adolescent Gynecology.

*** 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 utilizing a known patient database. Medical charts will be reviewed to assess for gynecologic data such as age of menarche, menstrual frequency, length of menses, and use of hormonal medications to alter menstrual function. Medical charts will additionally be reviewed for laboratory data including testosterone level, DHEAS level, hemoglobin A1C, and other hormonal and metabolic parameters. Patients who have not had an encounter with the gynecology team or documentation of gynecologic function will be provided with a survey to assess for gynecologic function. If menstrual irregularity is noted on this survey, prospective data will be gathered on testosterone level, DHEAS level, hemoglobin A1C, and other hormonal and metabolic parameters. We anticipate that retrospective data collection will take 1-2 weeks. Prospective data collection will take 4-6 weeks. Data analysis and completion of scientific work (abstract and research publication) will take 1-2 months. The majority of this project will be completed during the summer session, however, continued work toward a research abstract and publication may extend beyond the summer session. Prospective data collection will be completed with the assistance of a Pediatric and Adolescent Gynecology Clinical Fellow in addition to a Gynecology Research Coordinator. Statistical analysis and support will be provided by the Children's National Division of Colorectal and Pelvic Reconstructive Surgery.

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

The student will complete data collection for the retrospective chart review. The student will work closely with the clinical fellow and research coordinator for prospective data collection and review. The student will complete data analysis and prepare data for a scientific abstract and scientific journal publication.

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

The mentor will provide one-on-one support for data collection, analysis, and preparation of the scientific abstract and journal publication. In conjunction with the Colorectal Surgery and Urology collaborative teams, the mentor will provide learning opportunities for all summer research students to better understand research design, analysis, and publication. The mentor will provide opportunities for clinical shadowing to deepen the student's understanding of the research project and patient population. Additionally, the mentor will include the student in all Pediatric and Adolescent Gynecology didactics and education sessions to increase their understanding and exposure to Pediatric and Adolescent Gynecology.

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

Our Pediatric Gynecology team at Children's has two full-time faculty members, three part-time faculty members, and three clinical fellows. We routinely have OB/GYN resident and medical student rotators and work collaboratively within the Colorectal Surgery, Urology, Endocrinology and Hematology/Oncology Divisions at Children's. As a result, our team works with a variety of learners throughout the year and we routinely mentor learners in research projects as small as case reports and as large as multi-center prospective research studies. The faculty sponsor for this project currently mentors two fellows on QI and prospective research protocols for ovarian torsion and additionally mentors an OB/GYN resident on a retrospective multi-center project focusing on patients with cloacal malformation. Our collaborative Gynecology, Urology, and Colorectal Surgery team has previously hosted summer medical students and has a robust curriculum for research education, statistical support, and clinical shadowing opportunities.

*** 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 Jason Triplett

* 1. Faculty Sponsor

* Name:	Jason Triplett
* Degrees:	PhD
* Title:	Associate 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)

Role of visual experience in maintenance of visual map alignment in the superior colliculus

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

Johnson KO, Harel L, Triplett JW. Post-synaptic NMDA receptor expression is required for visual corticocollicular projection refinement in the mouse superior colliculus. Journal of Neuroscience 2023 Feb 22;43(8):1310-20.

Russell AL, Dixon KG, Triplett JW. Diverse modes of binocular interactions in the mouse superior colliculus. Journal of Neurophysiology 2022 Apr;127(4):913-927.

Su J, Sabbagh U, Liang Y, Olejníková L, Dixon KG, Russell AL, Chen J, Pan YA, Triplett JW, Fox MA. A cell-ECM mechanism for connecting the ipsilateral eye to the brain. Proceedings of the National Academy of Science USA 2021 Oct 19;118(42):e2104343118.

* **5. Sponsor's Research Focus:**

Yes - Ophthalmology
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 the etiology of sensory dysfunction in NDDs, precluding the development of effective therapies. To bridge this gap, we previously investigated visual circuit organization and function in a model of fragile X syndrome (FXS). We found deficits in visual function in the superior colliculus (SC), a critical midbrain nucleus. Intriguingly, our preliminary data suggests that inputs to the SC from the primary visual cortex (V1) develop normally in FXS mice but then degrade after the onset of visual experience. These data raise the exciting possibility that sensory experience is required for the maintenance of circuitry and could also be exploited to rescue deficits observed in FXS mice. To test this possibility, we will deprive FXS and control mice of visual experience for different time periods and observe impacts on SC circuitry using neural tracing approaches.

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

Goal: To determine the impact of visual deprivation on SC circuit organization in control and FXS mice. Objectives: 1) Learn surgical techniques to block visual experience via eyelid suture in mice at postnatal day 11 (P11). 2) Learn neural tracing techniques. 3) Learn tissue processing, microscopic imaging, and quantitative image analysis. 4) Trace projections from V1 to the SC in sham and sutured groups. 5) Process tissue, image, and analyze data.

* **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 techniques and analyses that are well-established in the Triplett lab and, thus, have a high probability of success. First, mice will undergo a surgical procedure to permanently deprive visual experience via eyelid suture. Second, after recovery for two weeks, mice will undergo a second surgical procedure to trace neuronal projections from V1 to the SC. Third, after allowing one week for dye diffusion, mice will be euthanized via intracardial perfusion, and the brain will be extracted. Brains will be fixed overnight, sectioned and mounted onto glass slides for fluorescent microscopy. Images of termination zones of labeled axons will be acquired and quantified using image analysis software. To achieve sufficient statistical power, an N of at least 9 will be required for each group. Importantly, 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 that will be of broad interest to the neuroscience community. Timeline: After a brief period of training to learn the techniques (2-3 weeks), we expect that the experiments outlined will take approximately 1.5 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 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 or Health Services Scholars. (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 used.

Faculty Proposal for MD Student Research by Debra Regier

* 1. Faculty Sponsor

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* Title:	Chief, Genetics and Metabolism
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* 2. Daily Supervisor

Name:	Debra Regier/Tiffany Swaringer
Degrees:	MD PhD
Title:	Chief, genetics and metabolism
Organization:	Children's National
Address:	
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City:	
State:	
Zipcode:	
Office Phone:	
Email Address:	

* 3. Project Title (250 character limit)

The Children's National Rare Disease Institute is creating a online tool to provide immediate access to rare disease emergency protocols for patients and families with a diagnosed rare disease. The summer project will allow the student to participate in building, launching, and evaluating the program. Specifically, the student will work with outreach to patient and family groups regarding this tool, spend time evaluating the users for the system, and join Dr. Regier in outreach to emergency and primary care providers regarding the tool. We expect that the student will have an understanding of rare disorders, the unique needs of patients and families, the role of educational outcomes research, and the role of communication across disciplines after participating in this summer experience.

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

Bosfield K, Albert J, Cheng N, Swaringer T, Cusmano-Ozog K, Regier DS. Optimization of the biochemical genetics laboratory rotation using a multidesign approach to curriculum. Genet Med. 2023 Feb;25(2):100340. doi: 10.1016/j.gim.2022.11.008. Epub 2022 Dec 9. PMID: 36484781.

Cohen AJ, Shur N, Starin D, MacLeod E, Roshan Lal T, Leon E, Regier DS. Pediatric medical genetics house call: Telemedicine for the next generation of patients and providers. Am J Med Genet C Semin Med Genet. 2021 Mar;187(1):55-63. doi: 10.1002/ajmg.c.31882. Epub 2021 Jan 11. PMID: 33427371.

Regier DS, Smith WE, Byers HM. Medical genetics education in the midst of the COVID-19 pandemic: Shared resources. Am J Med Genet A. 2020 Jun;182(6):1302-1308. doi: 10.1002/ajmg.a.61595. Epub 2020 Apr 23. PMID: 32323908; PMCID: PMC7264783.

*** 5. Sponsor's Research Focus:**

Yes - Pediatrics
Yes - Biochemistry

*** 6. Sponsor's translational level**

*** (Please select ONE)**

T2: Translation to Patients

*** 7. Hypotheses (200 word limit)**

Patients and families with rare disorders are at a unique risk for receiving treatments that may be standard of practice, but harmful in their specific circumstance. Thus, the creation of a online tool to support the decision-making provider at the time of their decision making is crucial for the safety of rare disease patients.

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

The project will require that the student achieve the following: 1. Co-author 10 (or more) rare disease entries in the online system (RareCap). 2. Work with Dr. Regier to create one-page summaries of how RareCap will support each group to distribute to the NORD rare disease family groups with their disorder's QR code and an "invitation" to RareCap. 3. Co-author one publication on the creation of RareCap with the full team. 4. Attend rare disease clinic with Dr. Regier or another rare disease provider each week to a) obtain patient experience, and b) obtain family feedback on the RareCap system (through our QI proposal to improve patient input for rare disease tools).

*** 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 student will join the Rare Disease Education team at the Reasearch and Innovation campus for the first 4 weeks of the experience. This will allow them to work directly with all members of the team and join the team in the rare disease clinic. -During the in-person time, they will work directly with a physician on the team to co-author a rare disease entry, of their interest (or based on a patient seen in the clinic). -In weeks 3-5, the student will work with Dr. Regier to contact the NORD family groups with one-page summaries of the RareCap program and inviting them to join the collaborative. -We are able to accommodate remote work during the second half of the rotation, as needed by the student. This will be accommodated using telemedicine visits for the patient interaction component and using virtual meetings with Dr. Regier.

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

The student will co-author 10 or more rare disease entries, create the template and disease-specific flyers for the rare disease family groups, and directly discuss with families their comments and needs from an online tool. We expect that the last 3 weeks of the summer will be spent in preparing a manuscript for the team on the inception, development, and launching of the RareCap program. This will be done in collaboration with the full RareCap team, both at Vanderbilt and Children's national.

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

Dr. Regier is the PI of the RareCap program. This system has already rolled out to a small number of patient diagnoses, but by summer will be ready for a broader launch to additional family groups. Dr. Regier is known in rare disease research for her approach to educational outcomes and creation of tools and devices to improve patient care and outcomes.

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

Dr. Regier teaches across the George Washington University School of Medicine. She has mentored undergraduate, medical, and graduate students in both basic sciences and, most recently, in educational outcome measurements.

* **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 patient component is part of the current QI project to incorporate the "patient voice" in the tools built for educational purposes in the rare disease institute.

Faculty Proposal for MD Student Research by Michael Whalen, MD

* 1. Faculty Sponsor

* Name:	Michael Whalen, MD
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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)

Clinical Outcomes Research in Urologic Oncology: 1. Prostate MRI, urinary exosomes, and pre-malignant biopsy pathology and prostate cancer detection rates; 2. Novel applications of Artificial Intelligence (AI) and Google Trends analysis in Urology patient and provider informational awareness

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

Antar RM, Farag CM, Xu V, Drouaud A, Gordan O, Whalen MJ. Evaluating the Baseline Hemoglobin, Albumin, Lymphocyte, and Platelet (HALP) Score in the United States Adult Population and Comorbidities: An Analysis of the NHANES. Front. Nutr. 2023 May; Volume 10. doi: 10.3389/fnut.2023.1206958.

Impact of Minimally Invasive Approach to Radical Cystectomy on Perioperative Outcomes in Patients with Preoperative Malnutrition. Cyrus P. Adams-Mardi, Andrew Sparks, Michael Whalen. Cancer and Nutrition, 2023 Apr 26;1-6.

HALP is a Significant Biomarker Surrogate for Nutritional Status to Predict Overall Survival in Patients Post Radical Cystectomy. Christian Farag, Sinan Akosman, Jennica Luu, Shawn Haji-Momenian, Michael Whalen. Urology Practice, 2023. 10(3): 262-269.

* **5. Sponsor's Research Focus:**

Yes - Cancer
Yes - Radiology
Yes - Surgery

* **6. Sponsor's translational level**

* **(Please select ONE)**

T2: Translation to Patients

* **7. Hypotheses (200 word limit)**

There is a growing number of pelvic MRI studies being performed for prostate cancer diagnosis, especially in the wake of level 1 evidence demonstrating the superior performance of prostate biopsy performed with MRI-guidance compared to traditional (non-targeted) systematic biopsy (PRECISION and PROMIS clinical trials). There are also many novel biomarker tests commercially available for prostate cancer risk-stratification prior to prostate biopsy, such as 4K score blood test and ExoDX urine exosome mRNA test. The interrelationship between MRI and these tests as biomarkers for aggressive prostate cancer has yet to be fully elucidated. It is a specific aim of this research project to determine the performance characteristics of prostate MRI vs. biomarkers with regards to diagnostic accuracy in a practical clinical setting. While ExoDX has been validated for prediction of high-grade prostate cancer for patients with elevated PSA levels, other potential applications of this biomarker, such as early detection of disease progression during a period of active surveillance, or even detection of biochemical recurrence after definitive prostate radiotherapy have not been widely explored and represent exciting novel frontiers. Another project utilizing the growing prostate MRI REDCap database (GW IRB #041723) involves examining the presence of specific non-neoplastic pathologic entities on prostate biopsy to elucidate the natural history of these conditions. Such conditions include chronic and acute inflammation “prostatitis,” as well as the putatively pre-malignant lesions: 1. High-grade intraepithelial neoplasia (HG-PIN) and 2. Atypical small acinar proliferation (ASAP). Previous studies done in the pre-MRI sextant-biopsy (i.e. 6 cores of tissue) era having suggested that multifocal HG-PIN and ASAP are associated with an increased risk of prostate cancer detection on subsequent biopsy performed 6-12mos later (40-60% risk), suggesting that these pathologic entities are pre-cancerous lesions. The rate of subsequent cancer detection in the era of prostate MRI fusion biopsy, which offers increased diagnostic accuracy and often samples >20 cores of tissue, is not clear. This project seeks to utilize the GW prostate MRI database to elucidate this question with potential for direct positive clinical impact.

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

There are n=1295 patients who have completed prostate MRI studies at GW since 2015-present. 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. One component of this project is updating the n=100 patients that have undergone MRI and prostate cancer treatment since the last iteration of this project. The remainder of the time will be spent in conducting original analysis of the data for 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. Another goal of the project will be to draft an IRB for collection of ExoDX urine samples in the post-radiation setting in collaboration with the company Exosome Diagnostics. Another aspect of the project will be to build on the work already made by existing Urology Interest Group research students to expand the scope of investigation of ChatGPT and Google Trends analyses in patient and provider informational awareness.

*** 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/analysis of published journal articles in the domain of prostate cancer, prostate MRI, ASAP, HGPIN, and urinary exosomes. 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 and GW School of Medicine & Health Sciences biostatisticians. The student will also work very closely with other student members of the Urology Interest Group/Research Collaboration who have done research projects with Dr. Whalen in the past, and therefore serve as an excellent resource for guidance, mentorship, and troubleshooting of research methods. The student will also work closely with a Urology resident mentor to provide clinical context and relevance for the research hypotheses. Further projects using these databases will be possible based on the student's own intellectual curiosity and motivation to develop original ideas/hypotheses for investigation. There will also be opportunity and expectation to contribute to the growing IRB-approved Retrospective and Longitudinal Database of Genitourinary Cancer, as well as the prostate cancer MRI database and bladder cancer "Bluelight cystoscopy database" based on the clinical and surgical experience of the GW Urology physicians. These databases may be queried to answer many clinically relevant and potentially practice-changing questions using data extracted from real patient encounters in the Urology department at GW. Depending on the student's interests, time will be spent performing literature review and drafting the introduction and discussion of the manuscript. The student 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 2024. 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. The student 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. There will be opportunity for statistical analysis of the data alongside the professional statisticians as well. The student will work closely with the biostatisticians/senior student mentors to understand the REDCap prostate MRI 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 or Health Services Scholars. (200 word limit)**

I have worked with over 40 students and Urology residents since 2018. Medical students have been involved with published manuscripts in peer-reviewed journals, as well as authorship of review articles and book chapters. Students have presented at numerous local, regional, and even national research meetings and society conferences. I serve as Research Coordinator for the Urology Department. I was awarded the “Outstanding Clinical Instruction” award (“Teacher of the Year”) by the Urology residents in June, 2019. Summer 2023: 4 students: -Ryan Antar (Health Services Scholarship): investigation of patients with stage cT2-4N0M0 bladder cancer who underwent partial cystectomy from 2006-2019 to examine trends in the use of neoadjuvant chemotherapy over time, as well as the impact of neoadjuvant chemotherapy on patient overall survival. -Vincent Xu (Gill Fellow): investigation of metastatic bladder cancer patients (i.e. cM1) who undergo radical cystectomy as a non-palliative surgery, which is known as “cytoreductive cystectomy” (CC -Faozia Pio (ASCO scholarship): Insurance status and primary treatment modality for cT1-4N1-3M0 bladder cancer (does insurance impact what patients get radical cystectomy vs. chemo/radiation in setting of clinical node positive disease) -Andeulazia Murdock (Health Services Scholarship): Investigation of interrelationship between prostate MRI and blood- and urine-based biomarker tests

*** 13. Do you have or will you obtain IRB approval for this project?**
<u>Please note:</u> 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: exp 7/19/2024

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
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* Zipcode: 20037
* Office Phone: 202-994-8919
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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)

Neutrophil Activation Test Using RNA Levels (NATURAL Trial) The NATURAL Trial is a prospective, pragmatic trial to evaluate the clinical utility of a blood RNA-based diagnostic to detect intra-abdominal infections. In short, the True Bearing Diagnostics neutrophil activation test (TruNAV) detects 6 RNA transcripts in whole blood that are highly responsive to the presence of internal infections caused by biofilm infections, typical bacterial infections, and viral infections. Published data on appendicitis, diverticulitis, and other infections, including COVID-19, suggest a high degree of sensitivity. The NATURAL Trial is a multicenter trial that will include The George Washington University Medical Center, and about 5 other sites with a total enrollment target of 500 patients. Enrollment would occur at any clinic where there is a presentation of abdominal pain with a potentially infectious etiology in which there is CT and other standard clinical diagnostic evaluation. The project design is a prospective, pragmatic, observational study. Patients with suspected intra-abdominal infections (IAIs), such as appendicitis, diverticulitis, acute cholecystitis, pancreatitis, peritonitis, pyelonephritis, and abscess are candidates for this study. This is a broad category of patients that are defined by the suspicion of an internal infection, usually requiring

some type of advanced imaging analysis such as CT scan or ultrasound. All participants will be consented for this observational, minimal-risk study prior to venipuncture. The results will determine the sensitivity and specificity of the RNA biomarkers in relation to the clinical diagnosis of the presence or absence of an IAI, based on CT scans.

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

Chawla, L.S., Toma, I., Davison, D., Vaziri, K., Lee, J., Lucas, R., et al., Acute appendicitis: transcript profiling of blood identifies promising biomarkers and potential underlying processes, BMC Med Genomics 9(1) (2016) 40.

Wargodsky, R., Dela Cruz, P., LaFleur, J., Yamane, D., Kim, J.S., Benjenk, I., et al., RNA Sequencing in COVID-19 patients identifies neutrophil activation biomarkers as a promising diagnostic platform for infections, PloS one 17(1) (2022) e0261679.

Meltzer, A.C., Wargowsky, R.S., Moran, S., Jordan, T., Toma, I., Jepson, T., et al., Diagnostic accuracy of novel mRNA blood biomarkers of infection to predict outcomes in emergency department patients with undifferentiated abdominal pain, Scientific Reports 13(1) (2023) 2297.

* **5. Sponsor's Research Focus:**

Yes - Genomics
Yes - Infectious Disease

* **6. Sponsor's translational level**

* **(Please select ONE)**

T3: Translation to Practice

* **7. Hypotheses (200 word limit)**

A genomic-derived panel of 6 RNA biomarkers present in stabilized whole blood will provide diagnostic information about the presence of bacterial, biofilm, and viral infections in the abdomen. We hypothesize that biomarkers will be 95% sensitive with a high (>90%) negative predictive value for IAI.

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

To validate a novel RNA fingerprint in ED patients with suspected IAIs. We aim to determine the accuracy of a novel RNA biomarker for diagnosis of IAI in patients suspected of having IAI. Subgroup analysis will analyse RNA biomarker for multiple types of actual and suspected IAIs (appendicitis, diverticulitis, acute cholecystitis, pancreatitis, peritonitis, pyelonephritis, and abscess.) Subjects: Approximately 500 ED patients with acute abdominal pain that receive CT diagnosis will be enrolled. Data analysis: The 500 coded blood samples will be analyzed by droplet digital PCR (ddPCR) for 6 RNA biomarkers that report the activation state of the white blood cells, and their levels will expressed as a percentage of a normative transcript (ACTB). The levels of the TruNAV biomarkers, compared to predetermined thresholds, will be indicative of the type and degree of internal infection. The ddPCR method is implemented on a diagnostic platform that is FDA-cleared for certain genetic tests and has an EUA for the quantification of the SARS-CoV2 RNA virus (BioRAD). The TruNAV results are compared to the clinically defined presence or absence of IAI to determine the agreement between the two diagnoses.

*** 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 design is a prospective, pragmatic, observational study. The current study will be sponsored by True Bearing Diagnostics, Inc., and performed at 5 or more academic medical centers, including The George Washington University Medical Center. Patients with suspected intra-abdominal infections (IAIs), such as appendicitis, diverticulitis, acute cholecystitis, pancreatitis, peritonitis, pyelonephritis, and abscess are candidates for this study. This is a broad category of patients that are defined by the suspicion of an internal infection, usually requiring some type of advanced imaging analysis such as CT scan or ultrasound. All participants will be consented for this observational, minimal-risk study prior to venipuncture. Ultimately, we will calculate the sensitivity and specificity of the RNA biomarkers in relation to the clinical diagnosis of the presence or absence of an IAI, based on CT scans, the current standard of care for diagnosis of IAI.

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

The student can be involved in all phases of the research, from patient screening, consenting, blood sampling, clinical and lab data collection, and ddPCR quantitation of the biomarkers.

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

The mentor will oversee all aspects of the trial and be available on a daily basis for discussion.

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

Kevin Jaatinen, Tristan Jordan, Jennifer Goldman, Zachary Falk.

*** 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

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* 2. Daily Supervisor

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City:	Washington
State:	DC
Zipcode:	20012
Office Phone:	202-476-2106
Email Address:	eoxman@childrensnational.org

* 3. Project Title (250 character limit)

Characterization of a new genetic syndrome causing autism and intellectual disability due to mutations in HECTD1

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

Cechinel LR, Batabyal RA, Freishtat RJ, Zohn IE. Parental obesity-induced changes in developmental programming. Front Cell Dev Biol. 2022 Oct 7;10:918080. doi: 10.3389/fcell.2022.918080. PMID: 36274855; PMCID: PMC9585252.

Leon E, Nde C, Ray RS, Preciado D, Zohn IE. ALDH1A2-related disorder: A new genetic syndrome due to alteration of the retinoic acid pathway. Am J Med Genet A. 2023 Jan;191(1):90-99. doi: 10.1002/ajmg.a.62991. Epub 2022 Oct 19. PMID: 36263470; PMCID: PMC9805811.

Yitsege G, Stokes BA, Sabatino JA, Sugrue KF, Banyai G, Paronett EM, Karpinski BA, Maynard TM, LaMantia AS, Zohn IE. Variations in maternal vitamin A intake modifies phenotypes in a mouse model of 22q11.2 deletion syndrome. Birth Defects Res. 2020 Oct;112(16):1194-1208. doi: 10.1002/bdr2.1709. Epub 2020 May 20. PMID: 32431076; PMCID: PMC7586978.

*** 5. Sponsor's Research Focus:**

Yes - Genomics
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)**

Over 20 years ago, Dr. Zohn was involved in a large-scale mouse ENU mutagenesis screen to identify new candidates for human disorders, where she discovered a mutation in the ubiquitin ligase encoding gene, Hectd1. Since its discovery, studies by the Zohn lab and others established that HECTD1 plays pleiotropic roles, regulating heart, placental, and neural development. However, HECTD1 has not yet been implicated in human disease. To address this gap, Dr. Zohn recently joined the Matchmaker Exchange to connect with clinicians who identified variants of unknown significance (VUS) in the human HECTD1 gene in their patients. Through this exchange, we are building a cohort of patients with HECTD1 VUS. The predominant phenotypes include microcephaly, epilepsy, heterotopias, developmental delay, autism, and ADHD. Experiments will characterize neuronal defects in Hectd1 mutant mice by testing the hypothesis that Hectd1 is required for normal brain development and architecture via the regulation of neural migration and outgrowth.

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

PROJECT GOAL: TO CHARACTERIZE THE BRAIN DEFICITS IN ADULT HECTD1 MUTANT MOUSE MODELS. The Zohn laboratory generated a conditional mouse model to characterize abnormal brain development with a mutation of HECTD1. Our preliminary histological analysis revealed abnormal cortical and corpus callous development in adult Hectd1 conditional mutant mice. Based on these initial findings, we hypothesize that Hectd1 is required for neural migration and outgrowth. Experiments will characterize the neuronal deficits in Hectd1 mutant mice using a combination of histological, neuronal, and cortical layer-specific markers.

*** 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**

Sectioned brains will be subjected to immunohistochemistry with a variety of markers of neuronal subtypes and migration. Images will be acquired by fluorescent microscopy and analyzed in IMAGEJ to quantitate cortical layers, cell proliferation and migration. Figures and graphs of results will be generated and included in publications.

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

The student will be trained in histological and microscopy techniques. They will section mouse brains, perform immunohistochemistry, and acquire and analyze images. Finally, the student will prepare figures and present results.

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

The mentor will oversee the training of the student as well as the scientific progress of the project.

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

While my laboratory has trained >20 students using this training model, we have trained 3 medical students over the years. One was a Gill Fellow (Bryce Winrow) , another a Health Services Scholar (Omowunmi Oluwo), and the third was a medical student at Meharry Medical School (Kevin Mcfadgen).

* **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 are working with mouse tissues and we currently have IACUC approval for the project.

Faculty Proposal for MD Student Research by William D. Gaillard

* 1. Faculty Sponsor

* Name:	William D. Gaillard
* Degrees:	MD
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* 2. Daily Supervisor

Name:	Nathan T. Cohen
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State:	District Of Columbia
Zipcode:	20010
Office Phone:	2024762120
Email Address:	ncohen@childrensnational.org

* 3. Project Title (250 character limit)

Quantifying structural connectivity signatures of pharmacoresistance in pediatric focal cortical dysplasia-related epilepsy

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

Cohen NT, Chang P, You X, Zhang A, Havens KA, Oluigbo CO, Whitehead MT, Gholipour T, Gaillard WD. Prevalence and Risk Factors for Pharmacoresistance in Children With Focal Cortical Dysplasia-Related Epilepsy. Neurology. 2022 Aug 19;10.1212/WNL.0000000000201033. doi:10.1212/WNL.0000000000201033. Online ahead of print. PMID: 35985831

Cohen NT, You X, Krishnamurthy M, Sepeta LN, Zhang A, Oluigbo C, Whitehead MT, Gholipour T, Baldeweg T, Wagstyl K, Adler S, Gaillard WD, Multi-centre Epilepsy Lesion Detection (MELD) Project. Networks underlie temporal onset of dysplasia-related epilepsy- a MELD study. Ann Neurol. 2022 Jun 20. doi: 10.1002/ana.26442. Online ahead of print. Ann Neurol. 2022. PMID: 35726354

Cohen NT, Chang P, Gholipour T, Oluigbo C, Vezina LG, Xie H, Zhang A, Gaillard WD. Limbic network co-localization predicts pharmacoresistance in dysplasia-related epilepsy. Ann Clin Transl Neurol. 2023 Sep 12. doi: 10.1002/acn3.51892. Online ahead of print.

* **5. Sponsor's Research Focus:**

Yes - Neurology

* **6. Sponsor's translational level**

* **(Please select ONE)**

T2: Translation to Patients

* **7. Hypotheses (200 word limit)**

Hypothesis 1: Focal cortical dysplasia patients with pharmacoresistant epilepsy have increased global hemispheric structural connectivity ipsilateral to the lesion as compared to healthy controls. Hypothesis 2: FCD patients with pharmacoresistant epilepsy have increased perilesional (within 2 cm) local connectivity compared to healthy controls.

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

Focal cortical dysplasia (FCD) is the most frequent etiology of surgically treatable pharmacoresistant (PRE) epilepsy in children. Using functional connectivity analysis of resting state functional MRI, we found that FCD patients with PRE have mutual functional network alterations compared to healthy controls (Xie et al., AES 2023). Many patients also have structural diffusion weighted imaging/diffusion tensor imaging (DWI/DTI) studies which would allow for quantitative analysis of structural connectivity alterations in FCD patients with PRE. The goal of this study is to identify global and local signatures of pharmacoresistance by investigating DWI/DTI connectivity alterations in 90 FCD patients with PRE compared to healthy controls.

* **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**

Weeks 1-2: Student will conduct background reading and receive orientation to computational imaging software Weeks 3-4: Student will process 40 FCD patient DWI/DTI MRIs and begin quantitative analysis. Age-matched normal DWI/DTI will be obtained from the publicly available NIH Pediatric MRI Data Repository. Weeks 5-6: Quantitative data analysis of global and local structural connectivity differences will be completed. Manuscript will be drafted. Weeks 7-8: The final segment will be spent creating abstract for submission to national meeting (American Academy of Neurology or American Epilepsy Society) and preparing manuscript for final

submission. Our program already has a series of >90 pediatric patients with pharmacoresistant FCD-related epilepsy who have confirmed FCD pathology. These patients all had high-resolution, preoperative epilepsy protocol MRI. These include diffusion weighted images. Through our prior studies, we have already manually segmented the FCD lesions on MRI. Therefore, this study is achievable in the summer timeframe. The primary outcome of the study is to demonstrate DTI-based structural connectivity differences in patients with FCD-related pharmacoresistant epilepsy as compared to controls. We will also be able to evaluate if there are local DWI/DTI-based structural connectivity differences in FCD PRE patients compared to controls. Team: Co-mentor: William D. Gaillard, MD: Professor of Pediatrics and Neurology at GWU; Associate Director of Children's Research Institute Center for Neuroscience Research at Children's National Hospital; Chief of Neurology, Epilepsy and Neurophysiology at Children's National Hospital. Past President American Epilepsy Society. Co-mentor: Nathan T. Cohen, MD: Assistant Professor of Pediatrics and Neurology at GWU; Investigator, Center for Neuroscience Research at Children's National Hospital; Attending Epileptologist and Child Neurologist, Children's National Hospital. Consultant: Hua Xie, PhD: Assistant Professor of Neurology (Research) at GWU; Computational Scientist Consultant: Venkata Sita Priyanka Illapani, MS: Research Staff at Center for Neuroscience Research at Children's National; Computational Scientist

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

The Gill Fellow will gain experience in quantitative neuroimaging of pediatric epilepsy by performing a focused, mentored project that is expected to be completed in the timeframe. The student will participate in weekly epilepsy imaging laboratory meetings at the Center for Neuroscience Research at Children's National Hospital to include didactic lectures related to pediatric epilepsy, epilepsy neuroimaging and surgery. They will have guided readings and exposure to ongoing discussions about study design, the ethical conduct of research, advanced data and statistical analytic techniques as well as exposure to grantsmanship and collaborative research efforts. The fellow will have the opportunity to attend pediatric epilepsy clinics with Dr. Gaillard or Dr. Cohen and to participate in weekly surgical epilepsy conferences at the Children's National Comprehensive Pediatric Epilepsy Program to put their research into context. Additionally, it is expected that this project will yield at minimum a first author abstract at a national meeting, and expect authorship on a derivative publication.

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

Dr. Gaillard's research focuses on using advanced imaging to study epilepsy and its impact on the developing brain. He is an international expert in pediatric neuroimaging having chaired international committees on the imaging of pediatric epilepsy and guided numerous studies in structural and functional neuroimaging. His work showed the utility of epilepsy-specific image protocols in the evaluation of children and infants with epilepsy, demonstrate the superiority of MRI to CT, and yielding diagnosis in over a quarter of infants. As an expert in functional imaging, conducted the first functional MRI-based cognitive studies in children, and used fMRI to map cognitive networks in children. He pioneered the use of fMRI for the noninvasive determination of language dominance for planning epilepsy surgery. Additionally, his lab has developed and applied advanced analytic methods to functional imaging to identify patterns of language network reorganization in pediatric epilepsies. Dr. Cohen's interests include using functional imaging to explore networks underlying pediatric epilepsies and their comorbidities, with a focus on focal cortical dysplasia-related epilepsy. He has expertise in structural and functional imaging techniques and advanced analyses of imaging data. His research has led to key discoveries such as the redefinition of pharmacoresistance in FCD-related epilepsy, the functional

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

Dr. Gaillard has mentored 19 prior Gill Fellows and numerous trainees. Most recently, Dr. Gaillard and Dr. Cohen co-mentored Kara Hom in summer 2023. During her time in the lab, she performed studies to evaluate artificial intelligence-based algorithm effectiveness in segmenting pre- and postoperative structural MRI. This work yielded an abstract to be submitted for the American Academy of Neurology National Meeting and she has prepared her findings into a draft manuscript. Additionally, she performed a study looking at the effectiveness of stereoEEG-guided reoperations which will be presented at the national American Epilepsy Society Meeting in Orlando, FL this December. She is a co-author on a manuscript related to this sEEG study. We have also co-mentored a prior GW METEOR Student, Phat Chang in Summer 2022. His summer work, “Focal to Bilateral Tonic-Clonic Seizures are a Marker of Pharmacoresistance in Focal Cortical Dysplasia-Related Epilepsy,” was presented at the American Epilepsy Society Meeting in Nashville, TN in 2022. Additionally, this work led to a first-author manuscript, “Focal to bilateral tonic-clonic seizures predict pharmacoresistance in focal cortical dysplasia-related epilepsy” (Chang et al., Epilepsia 2023) and co-authorship on another manuscript, “ Limbic network co-localization predicts pharmacoresistance in dysplasia-related epilepsy,” (Cohen et al., Ann

* **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: Pro00000106

* IRB Date: 1/9/11

Faculty Proposal for MD Student Research by Muhammad Rahman

* 1. Faculty Sponsor

* Name:	Muhammad Rahman
* Degrees:	Ph.D
* Title:	Assistant Professor
* Organization:	Children's National Hospital
* Address:	1 Inventa Pl, 4th floor
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* State:	MD
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* Office Phone:	240-531-6587
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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)

Understanding Coping Mechanisms and Peer Support for ADHD on Reddit

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

a) Rahman, M. M. (2023). AI for ADHD: Opportunities and Challenges. Journal of Attention Disorders, 27(8), 797-799.

b) Giorgi, S., Guntuku, S. C., Himelein-Wachowiak, M., Kwarteng, A., Hwang, S., Rahman, M., & Curtis, B. (2022, May). Twitter Corpus of the# BlackLivesMatter Movement and Counter Protests: 2013 to 2021. In Proceedings of the International AAAI Conference on Web and Social Media (Vol. 16, pp. 1228-1235).

c) Himelein-Wachowiak, M., Giorgi, S., Devoto, A., Rahman, M., Ungar, L., Schwartz, H. A., ... & Curtis, B. (2021). Bots and misinformation spread on social media: Implications for COVID-19. Journal of Medical Internet Research, 23(5), e26933.

* **5. Sponsor's Research Focus:**

Yes - Pediatrics
Yes - Psychiatry

* **6. Sponsor's translational level**

* **(Please select ONE)**

T4: Translation to Population Health

* **7. Hypotheses (200 word limit)**

We hypothesize that individuals sharing their experiences with ADHD on Reddit employ specific coping mechanisms and engage in peer support discussions. These coping mechanisms, including sharing personal strategies and seeking advice, contribute to improved self-management of ADHD symptoms and reduced stress. The presence of such mechanisms within the Reddit community is associated with enhanced well-being and self-reported improvements in daily functioning among individuals with ADHD. A qualitative analysis of the Reddit data will be conducted to identify these coping mechanisms and provide measurable insights into their impact on the mental health and symptom management of individuals with ADHD.

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

This summer project aims to investigate the coping mechanisms and the impact of peer support within the ADHD Reddit community using the pre-collected Reddit data. The measurable objectives include conducting qualitative analysis of the Reddit data, identifying common coping strategies, assessing the role of peer support, and summarizing the findings for potential application in clinical or community settings.

* **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**

Data Analysis Approach: Given that the data has already been collected, the primary focus of this research project will be on the qualitative analysis of the Reddit dataset. Qualitative Analysis: The qualitative analysis approach will involve in-depth examination of the textual data, focusing on the narratives, themes, and patterns within the Reddit discussions. Data Preparation: The pre-collected Reddit dataset, comprising posts, comments, and interactions from individuals with ADHD, will be organized and cleaned to ensure that it is ready for analysis. Coping Mechanisms Identification: Researchers will categorize and identify coping mechanisms and strategies used by individuals to manage their ADHD symptoms and challenges. Coping strategies may include time management techniques, mindfulness practices, lifestyle adjustments, and medication management. Peer Support Assessment: A specific emphasis will be placed on the assessment of peer support within the Reddit community. This will involve identifying posts or comments where individuals seek support, share their experiences, and provide guidance to others.

Narrative Analysis: Narrative analysis will be employed to provide context and depth to the coping mechanisms and peer support experiences. This analysis will allow for a better understanding of the personal stories and journeys of individuals with ADHD and the practical application of coping strategies. Data Interpretation: Following the coding and analysis of the data, the research team will interpret the identified coping mechanisms and peer support dynamics. The analysis will also consider variations in experiences and their potential impact on the well-being and self-management of individuals with ADHD. Expected Outcomes and Applications: The research findings are expected to provide a comprehensive understanding of how individuals with ADHD engage in coping mechanisms and peer support discussions on Reddit. This knowledge will enable potential applications in clinical and community settings, such as the development of enhanced support interventions, the promotion of mental health, community building, and research guidance. Tasks and Timeline: The timeline will be adjusted as follows: 1. Data Analysis (4 weeks): o Qualitatively analyze the pre-collected Reddit data to identify common coping mechanisms used by individuals with ADHD. 2. Peer Support Assessment (2 weeks): o Examine how individuals with ADHD on Reddit provide and receive peer support. 3. Findings Summarization (2 weeks): o Summarize the research findings regarding coping mechanisms and the role of peer support for individuals with ADHD.

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

The student researchers will actively participate in the data analysis phase during this 8-week summer project including data cleaning. Their responsibilities include identifying and categorizing coping mechanisms and assessing the role of peer support within the Reddit discussions. This project offers medical students a unique opportunity to gain a deeper understanding of the practical aspects of coping with ADHD and the significance of peer support in managing the condition. It is also expected that they will prepare an abstract for national conference presentation and participation in manuscripts will be encouraged, depending on their interests.

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

The mentor will play a central role in the student researchers' journey, offering continuous guidance and expertise during the summer project. They will provide comprehensive training in qualitative analysis techniques, ensuring that the students are well-prepared for the data analysis phase. Moreover, the mentor will actively oversee the data analysis process, offering valuable insights into the coping mechanisms employed by individuals with ADHD and assessing the significance of peer support within the Reddit dataset. Their role extends to facilitating the summarization of research findings, guiding students in exploring potential applications in clinical and community settings, coordinating the development of abstracts for submission to local and international conferences, and assisting in manuscript preparation for publication. Additionally, the mentor will support students in future research engagements at Children’s National Research Institute, fostering their continued growth in the field of mental health research.

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

Dr. Rahman has had extensive experience mentoring with a diverse group of professionals, including NIH postbaccalaureate fellows, masters students, undergraduate students and interns, several of whom have now progressed to pursue MD degrees in medical schools. Presently, Dr. Rahman continues to engage in research activities alongside a postdoctoral researcher and a pediatric resident, focusing on AI and Data Science research.

* **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.

Ethical considerations are crucial for the responsible use of data collected from Reddit. As we are not involving human subjects, traditional IRB approval is not required. However, to maintain ethical standards and adhere to Reddit's terms of service and guidelines, it is imperative to ensure that all necessary approvals and permissions for the data's research usage will be obtained.

Faculty Proposal for MD Student Research by David Mendelowitz

* 1. Faculty Sponsor

* Name:	David Mendelowitz
* Degrees:	PhD
* Title:	Professor
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* Zipcode:	20037
* Office Phone:	2029943466
* Email Address:	dmendel@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)

This proposal, based on the role of oxytocin in increasing parasympathetic activity to the heart and improving cardiac function in patients with heart failure, will test if intranasal oxytocin administration blunts the deleterious effects of autonomic imbalance, a distinctive hallmark of HF. Study Objectives: Primary Objective: This study will explore if oxytocin added to standard of care medical treatment will improve clinical outcomes regarding symptomatic improvement and markers of heart failure including dyspnea, exercise tolerance, quality of life, and systolic function. Protocol Outline: We will test our hypothesis with a randomized double blinded cross-over study. Patients will self-administer either oxytocin nasal spray (BID, 40IU/ml), or sterile water spray, for 3 months, followed by 3 months of the spray not used initially. We anticipate that self-administered intranasal oxytocin treatment will improve standard clinical outcomes and indices of heart failure. Currently, we aim to enroll twenty subjects that have recently been diagnosed with moderate heart failure (HF, NYHA II-III patients and those with LVEF <45%) in this FDA approved randomized double-blinded controlled trial. This study will be conducted in collaboration with Dr. Vivek Jain and TBD cardiologists.

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

Outcomes of hypothalamic oxytocin neuron-driven cardioprotection after acute myocardial infarction. Schunke KJ, Rodriguez J, Dyavanapalli J, Schloen J, Wang X, Escobar J, Kowalik G, Cheung EC, Ribeiro C, Russo R, Alber BR, Dergacheva O, Chen SW, Murillo-Berlioz AE, Lee KB, Trachiotis G, Entcheva E, Brantner CA, Mendelowitz D, Kay MW. Basic Res Cardiol. 2023 Oct 6;118(1):43. doi: 10.1007/s00395-023-01013-1. PMID: 37801130

Intranasal oxytocin increases respiratory rate and reduces obstructive event duration and oxygen desaturation in obstructive sleep apnea patients: a randomized double blinded placebo controlled study. Jain V, Kimbro S, Kowalik G, Milojevic I, Maritza Dowling N, Hunley AL, Hauser K, Andrade DC, Del Rio R, Kay MW, Mendelowitz D. Sleep Med. 2020 Oct;74:242-247. doi: 10.1016/j.sleep.2020.05.034. Epub 2020 Jun 5. PMID: 32862007

Hypothalamic Oxytocin Neuron Activation Attenuates Intermittent Hypoxia-Induced Hypertension and Cardiac Dysfunction in an Animal Model of Sleep Apnea. Rodriguez J, Escobar JB, Cheung EC, Kowalik G, Russo R, Dyavanapalli J, Alber BR, Harral G, Gill A, Melkie M, Jain V, Schunke KJ, Mendelowitz D, Kay MW. Hypertension. 2023 Apr;80(4):882-894. doi: 10.1161/HYPERTENSIONAHA.122.20149. Epub 2023 Feb 16. PMID: 36794581

* **5. Sponsor's Research Focus:**

Yes - Pharmacology
Yes - Cardiology
Yes - Pulmonology

* **6. Sponsor's translational level**

* **(Please select ONE)**

T2: Translation to Patients

* **7. Hypotheses (200 word limit)**

Based on our previous work and Preliminary Data, we propose that chronic selective activation of PVN OXT neurons, as well as IN OXT, restores parasympathetic activity to the heart, markedly improves autonomic balance, cardiac function, exercise tolerance and survival, and diminishes respiratory dysfunction in HF.

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

We will test our hypothesis with a randomized double blinded cross-over study. Patients will self-administer either oxytocin nasal spray (BID, 40IU/ml), or sterile water spray, for 3 months, followed by 3 months of the spray not used initially. We anticipate that self-administered intranasal oxytocin treatment will improve standard clinical outcomes and indices of heart failure. Currently, we aim to enroll twenty subjects that have recently been diagnosed with moderate heart failure (HF, NYHA II-III patients and those with LVEF <40 %) in this FDA approved randomized double-blinded controlled trial. Subjects will be randomized by the pharmacy to be administered either 40 IU of oxytocin twice daily or placebo (sterile water spray, twice daily) for the initial 3 month period. In the second 3 month period, the subjects will crossover between treatment and the placebo group. For example, if a subject is randomized to receive placebo for the first 3 months, upon completion of this 3 month period, the subject will now self-administer oxytocin for

the next 3 months. If a subject is randomized to receive oxytocin for the first 3 months of the trial, then he or she will receive placebo for the final 3 months.

* **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**

: All participants will undergo assessment of clinical status (blood pressure heart rate, volume status), functional class (NYHA class , Minnesota living with heart failure (MLWHF), six minute walk test , transthoracic echocardiogram with tissue doppler and strain measures, serum chemistry including N-terminal pro-BNP, Troponin T, Galectin 3 , norepinephrine, c-reactive protein, complete metabolic panel,electrocardiogram (EKG) at baseline and at six months. In addition, those with an implantable cardiac defibrillator will undergo assessment of arrythmia burden (PVC burden, non sustained or sustained ventricular arrythmia and atrial fibrillation) both at baseline and at six months. The outcomes measured will be analyzed using standard statistical analysis.

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

Student will participate in all aspects of this project, as best as possible.

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

Mentor will supervise project, to the best of his ability.

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

Previous research trainees who are clinicians: Ryan Bateman, currently resident, Emergency Department, Thomas Jefferson University; Whitmey Wolaver, currently resident, Anesthesiology, VCU Health System; Kerry (Philbin) Sadler, currently Family Physician, Naval Hospital Jacksonville; Sunit Baxi, currently internist, University of Maryland Medical Center Midtown Campus and Sinai Hospital of Baltimore; Chris Stephens, currently Associate Professor, Department of Anesthesiology, Program Director, Trauma Anesthesiology Fellowship, McGovern Medical School, University of Texas; Cory Evans, currently trauma surgeon at Regional One Health and assistant professor in the department of surgery at Univ. of Tenn. Health Science Center. Previous Graduate Student Trainees: Robert Neff III, 2004, currently at Johnson and Johnson, Scientist, (Pain & Related Disorders), Kathy Griffioen, 2007, currently adjunct Assistant Professor, Liberty University, Julie Frank, 2011, currently scientist, FDA, Amanda Woerman, 2013, currently Assistant Professor at University of Massachusetts Amherst, Chris Gorini, 2012, currently Research Director at Spinal Research Foundation, Ramon Pinol, 2012, currently post-doctoral fellow, NIH, Heather Jameson, 2015, currently Research Scientist, Massachusetts General Hospital, Harvard Medical School.

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

* **(Please select ONE)**

Selected No (Pending)

Faculty Proposal for MD Student Research by Nobuyuki Ishibashi

* 1. Faculty Sponsor

* Name:	Nobuyuki Ishibashi
* Degrees:	MD
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* Address:	111 Michigan Avenue, NW
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* Office Phone:	202-476-2388
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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)

Neuroprotection in Congenital Heart Disease (CHD)

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

Sarkislali K, Kobayashi K, Saric N, Maeda T, Henmi S, Somaa FA, Bansal A, Tu SC, Leonetti C, Hsu C, Li J, Vyas P, Kawasawa YI, Tu TW, Wang PC, Hanley PJ, Hashimoto-Torii K, Frank JA, Jonas RA, Ishibashi N. Mesenchymal stromal cell delivery via cardiopulmonary bypass provides neuroprotection in a juvenile porcine surgical model. J Am Coll Cardiol Basic Trans Science. Sep 06, 2023. Epublished DOI: 10.1016/j.jacbts.2023.07.002

Saric N, Hashimoto-Torii K, Jevtovic-Todorovic V, Ishibashi N. Non-apoptotic caspases in neural development and in anesthesia-induced neurotoxicity. Trends Neurosci. 2022 Jun;45(6):446-458.DOI: 10.1016/j.tins.2022.03.007. Epub 2022 Apr 28.

Dhari Z, Leonetti C, Lin S, Prince A, Howick J, Zurakowski D, Wang PC, Jonas RA, Ishibashi N. Impact of Cardiopulmonary Bypass on Neurogenesis and Cortical Maturation. Ann Neurol. 2021 Vol. 90 Issue 6 Pages 913-926. doi: 10.1002/ana.26235.

*** 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)**

Significant neurological delay is emerging as one the most important current challenges for children with congenital heart disease (CHD), yet few treatment options are currently available. We proposed the use of cardiopulmonary bypass (CPB) as a cell delivery system in infants with CHD for improving the neurological impairments in CHD. Our work has demonstrated the efficacy and utility of this approach and, most notably, the development of a phase 1 clinical trial termed “MeDCaP”. However, the mechanisms underlying the therapeutic action of BM-MSCs still remain largely unknown. Exosomes are a class of extracellular vesicles loaded with bioactive molecules such as microRNAs (miRNAs). Exosomes derived from BM-MSCs (BM-MSCexo) can play a major role in the effects on surrounding cells and tissues and elicit favorable responses in various diseases. The overarching goal of this proposal is to establish detailed molecular signatures at single cell resolution. We will then use those molecular signatures as roadmaps to identify novel molecular entities within the BM-MSCexo. The studies will test our central hypothesis that specific exosomal cargo constituents from BM-MSCs promote repair and regenerative processes, both through neural progenitors and regulatory T cells, thereby improving neurological outcomes and post-operative course.

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

The overarching goal of this proposal is to establish detailed molecular signatures at single cell resolution. We will then use those molecular signatures as roadmaps to identify novel molecular entities within the BM-MSCexo. We have established a pipeline for post-cell delivery integrated transcriptomic analysis of exosomal miRNAs from BM-MSCs and host tissue mRNA. These approaches involve bioinformatic classification of the most abundant exosomal miRNA species, target transcript prediction and finally dataset overlapping with host tissue differentially expressed transcripts. To retroactively identify key exosomal bioactive molecules, we will determine the transcriptional and chromatin landscape of three specific cell populations: 1) SVZ neural stem and progenitor cells (NSPCs); 2) WM oligodendrocytes (OLs); and 3) regulatory T cells (Tregs). Three specific goals are: Aim 1. Define detailed molecular signatures of therapeutic efficacy of BM-MSCs on SVZ NSPCs; Aim 2. Define detailed molecular signatures of therapeutic efficacy of BM-MSCs on WM OLs; and Aim 3. Define detailed molecular signatures of therapeutic efficacy of BM-MSCs on Tregs.

*** 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**

Based on student's interest and discussion with mentor team, the student will perform studies using either bioinformatics approach or cellular/molecular assays based on following time frame. Time frame is designed based on our previous experience with Gill fellows to complete the projects from the beginning. Cell population of interest or target genes in summer 2024 will be discussed and selected according to progress of ongoing studies. Sample time frame for cellular/molecular assays Week 1: Preparation: cryostat training for the large animal brain section and RNA probe optimization Week 2: RNAscope in situ hybridization of the first cell population and image acquisition with a direct mentor Week 3: Data quantification using imaging software Week 4: Data analysis using statistical software and optimization for 2nd study Week 5: RNAscope in situ hybridization of the second population based on the results of the first studies Week 6: Data quantification using imaging software Week 7: Data analysis using statistical software Week 8: Presentation at the lab meeting and development of poster draft for presentation at meetings The proposed project will identify endogenous signals that act as pathological mediators during CPB and mine exosomal contents that contribute to the disease-modifying effects of BM-MSCs.

*** 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 determine detailed molecular signatures of therapeutic efficacy of BM-MSCs, the student role will be focused on bioinformatics analysis or cellular/molecular assays 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 Yves d'Udekem, 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 animal brain. Daily supervisor - Drs. Saric, Prasad, Henmi, Furuta, Khoshneviszadeh, and Ates (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 or Health Services Scholars. (200 word limit)**

The current and previous medical students training by my mentor team are listed below: Sonali Kumar (2013 W.T. Gill Summer Fellow) David Kim (2014 W.T. Gill Summer Fellow) Angeline Pham (2015 W.T. Gill Summer Fellow) Soraiya Thura (2015 AATS Summar Scholarship) Vincent Parenti (2016 W.T. Gill Summer Fellow) Joel Rosenberg (2018 Foglia-Hills Summer Fellow) James F. Howick (2018 Foglia-Hills Summer Fellow) Nisha Kapani (2018 W.T. Gill Summer Fellow) Naeha Haridasa (2019 W.T. Gill Summer Fellow) Casey Briggs (2019 Foglia-Hills Summer Fellow) Tessa Higgins (2020 Foglia-Hills Summer Fellow) Alice Chen (2021 W.T. Gill Summer Fellow) Christopher M. Liu (2021 Foglia-Hills Summer Fellow) Julia Ryan, M.S., B.S. (2022 Foglia-Hills Summer Fellow) Stephen Xu, B.S. (2022 W.T. Gill Summer Fellow) Christina Tolete, B.S. (2023 W.T. Gill Summer Fellow) Previous summer students at the Ishibashi laboratory performed oral and poster presentations at multiple regional and national conferences as the first author. Their work was included in our peer reviewed publications. Previous fellows obtained authorship for their contributions including publications at J Am Heart Assoc. 2017, Ann Thorac Surg. 2020, JTCVS open 2021, Cardiol Young 2022, and Ann Thorac Surg. 2022.

* **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: Pro00011914
* IRB Date: 12/5/2019

Faculty Proposal for MD Student Research by Jennifer Webb

*** 1. Faculty Sponsor**

* Name:	Jennifer Webb
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* Title:	Director of Chronic Transfusion Therapy
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* Zipcode:	20010
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* Email Address:	jwebb@childrensnational.org

*** 2. Daily Supervisor**

Name:	Jennifer Webb
Degrees:	MD, MSCE
Title:	Director of Chronic Transfusion Therapy
Organization:	Children's National Hospital
Address:	111 Michigan Ave, NW
Apt/Suite:	4th Floor, West Wing, Room 605
City:	Washington
State:	D.C.
Zipcode:	20010
Office Phone:	202-476-2800
Email Address:	jwebb@childrensnational.org

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

Iron Removal with Phlebotomy

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

Webb J. AABB Educational Session Speaker. “Pediatric Therapeutic Phlebotomy.” AABB Annual (Virtual) Meeting 2021.

*** 5. Sponsor's Research Focus:**

Yes - Pediatrics

*** 6. Sponsor's translational level**

*** (Please select ONE)**

T3: Translation to Practice

*** 7. Hypotheses (200 word limit)**

In adults, mathematical modeling has allowed us to estimate duration of therapeutic phlebotomy required to achieve normal body iron stores in patients with iron overload. This model has not been applied to pediatric patients. We hypothesize that rate of linear growth will decrease the duration of required therapeutic phlebotomy to achieve normal body iron stores in pediatric patients.

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

Cerner is assisting with data abstraction; however, data will need to be aligned for 67 individual charts. Additional data abstraction for clinical care elements will need to be performed; however, the relevant timeframes for each subject chart have already been identified. Preliminary analysis on duration of phlebotomy and effectiveness of iron stores to be measured and presented to inform practices around counseling patients/families and providers on need for iron overload screening.

*** 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 is a retrospective review of patients with secondary iron overload due to repeated transfusions during a period of prior oncologic treatment or treatment with bone marrow transplant. Our goal is to model the volumes of iron removal (cc/kg or % of total blood volume) to calculate the number of phlebotomies required to achieve normal iron stores as measured by liver iron concentration and ferritin. A mathematical model has been created for adult patients with iron overload conditions; however, the fit of this model has not been applied to pediatric patients where linear growth is likely to impact iron mobilization. Our goal is to create a similar mathematical model for pediatric patients so that we can predict the number of phlebotomies needed to better counsel patients and families. We will use this data to inform current clinical practice around monitoring and follow up of patients with secondary iron overload in our Long Term Follow Up Oncology clinic.

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

The student's role will be to review laboratory data abstracted from Cerner and align in a common dataset. Additional data abstraction will be required for clinical elements. Preliminary descriptive statistics to be presented to Hematology/Oncology/BMT service. Student will review of current practices around screening for iron overload in patients and align with evidence-based recommendations, as well as recommendations specific to our patient population.

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

The mentor has worked with previous students to submit the project to the IRB and create the data collection forms. A literature review has been performed to inform critical data elements. The data request has been made of Cerner/EHR. The names and dates of all included subjects have been extrapolated from clinical records. The mentor will work with the summer student to complete the data abstraction and begin preliminary analysis of the data. The mentor will connect the student with formal statistical support for additional analysis.

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

Our team has hosted multiple students over the years, either through the Gill Program or as Special Category volunteers. These students have worked on data collection tools, data abstraction, consenting of patients, analysis of data and presentations to the division. These have resulted in abstracts and poster publications. Students have had an opportunity to observe in our Hematology/Oncology clinics to understand first-hand the impact of our therapies.

*** 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: 00000619

* IRB Date: 6/21/2023

Faculty Proposal for MD Student Research by Maureen E. Lyon

* 1. Faculty Sponsor

* Name:	Maureen E. Lyon
* Degrees:	PhD
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* Organization:	Children's National Hospital
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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)

Palliative Care Needs of Children with Rare Diseases and their Families Pediatric patients with rare genetic and metabolic diseases typically experience high severe disability and high mortality. Taken together rare diseases comprise a significant proportion of patients at tertiary medical centers. For children with cancer and HIV, pediatric advance care planning (pACP) improved communication and spiritual and emotional well-being for children and their families. pACP is a key component of pediatric palliative care is a person-centered decision-making process which involves reflection, understanding and discussion about goals of care and future medical choices before a medical crisis. Families also have in common the likelihood of being asked to make complex medical decisions for their child. These children are a heterogeneous group often with co-morbidities, resulting in their exclusion from research, thereby creating a health disparity. Available research lacks scientific rigor. Few empirically validated interventions exist to address these issues. There is an urgent need for interventions to ease the suffering of these families, a goal of palliative care. The objectives are (1) to close a gap in the knowledge of the palliative care needs of families caring for a heterogeneous group of children with rare diseases, who are unable

to participate in shared medical decision-making; 40 and (2) to test a pACP intervention which may empower families by providing some control in a low-control situation. Student will have access to baseline data. Or can test hypotheses noted below.

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

Lyon ME, Wiener L. Special Issue: Psychosocial Considerations for Children and Adolescents Living with a Rare Disease. Children (Basel). 2022 Jul 21;9(7):1099. doi: 10.3390/children9071099. PMID: 35884083; PMCID: PMC9322344.

Needle JS, Friebert S, Thompkins JD, Grossoehme DH, Baker JN, Jiang J, Wang J, Lyon ME. Effect of the Family-Centered Advance Care Planning for Teens with Cancer Intervention on Sustainability of Congruence About End-of-Life Treatment Preferences: A Randomized Clinical Trial. JAMA Netw Open. 2022 Jul 1;5(7):e2220696. doi: 10.1001/jamanetworkopen.2022.20696. PMID: 35819787; PMCID: PMC9277499.

Sandquist M, Davenport T, Monaco J, Lyon ME. The Transition to Adulthood for Youth Living with Rare Diseases. Children May 2022; 9(5):710. DOI:10.3390/children9050710 PMID: 35626888; PMCID: PMC9139297.

* **5. Sponsor's Research Focus:**

Yes - Pediatrics
Yes - Cancer
Yes - Psychiatry

* **6. Sponsor's translational level**

* **(Please select ONE)**

T3: Translation to Practice

* **7. Hypotheses (200 word limit)**

AIM. To evaluate process outcomes with respect to satisfaction with study participation. H: FACE-Rare families will report significantly greater satisfaction, compared to controls. H: FACE-Rare families will report significantly greater quality of communication, compared to controls.

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

N=21 family caregivers

* **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**

Study design is a pilot randomized clinical trial. Results of the primary aim have been analyzed. However, there are significant variables that have not been examined in the data base that provide the opportunity for independent/original research. Participants underwent randomization and data collection are complete. The project is of great interest to other scholars, as indicated by its funding by the National Insitute of Health/National Insitute of Nursing Research. The project fulfills discovery/original research and is hyothesis based.

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

Student would be responsible for completing human subjects training so could be added to IRBear at Children's Nation. Student would need to complete raining in the use of the REDCap data base. All data are de-identified. Student would meet with the research team on a weekly basis and fully participate as time of student permits. Student would access the data base to complete the project, after submitting a concept sheet which the preceptor, Dr. Lyon, approves. Intent would be for student to present findings at GW and Children's National's Research Week and consider for submission of an abstract to the Pediatric Academic Societies annual meeting. If findings are meaningful support would be provided for publication of study results with student as first author.

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

Dr. Lyon will meet weekly with the student. Dr. Lyon will oversee the development of the concept sheet, data analysis, interpretation and presentation of results as noted above.

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

1. Jessie Sun Honey, Rising 2nd Year Medical Student GWU School of Medicine & Health Sciences. Project entitled Tell me how you feel: An examination of adolescent oncology patients and their families' uses of emotionally valent and salient words in discussing end-of-care as a predictor of congruence. Role: Formal Primary Mentor on her Summer Health Services Scholarship 2022. Abstract accepted as Oral Presentation 2023 Pediatric Academic Societies Meeting. Palliative Care. Monday, May 1, 2023. 9 a.m. Oral Presentation. Tell Me How You Feel: An Examination of Adolescent Oncology Patients and Their Families' Use of Emotionally Valent and Salient Words in Discussing End-of-Life Care 2. Schreiner, Kate, MD. 1st year medical student, George Washington School of Medicine and Health Sciences. "Living life as if I never had cancer": a study of the meaning of living well in adolescents with cancer. Manuscript published based on her research project: Schreiner, K., Grossoehme, D.H., Friebert, S., Baker, J.N., Needle, J., & Lyon, M.E. "Living as if I never had cancer": A study of the meaning of living well in adolescents and young adults who have experienced cancer." Pediatric Blood & Cancer. First published: 19 July 2020. 2020;67(10):1-8. Role: Health Services Scholar Mentor (2019-2020).

*** 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: 8808

* IRB Date: 8/21/2023

Faculty Proposal for MD Student Research by Natasha Shur

* 1. Faculty Sponsor

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* 2. Daily Supervisor

Name:	Natasha Shur
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Organization:	
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Zipcode:	
Office Phone:	
Email Address:	

* 3. Project Title (250 character limit)

Non-accidental trauma: The Yield of Genetic Testing Genetics: Molecular Classification and Testing Background: Due to broadening molecular classification, the question of what genetic testing needs to be performed in suspected child abuse cases has raised some confusion with different Institutions using different panels. As previously mentioned, most experts cite that 90 % of all OI cases, particularly the milder forms (OI types I and IV) are autosomal dominant disorders due to mutations in type I collagen with changes in COL1A1 and COL1A2. However, , there are also many new genes and types that have been classified. In terms of genetic testing options, many different OI panels and even bone fragility panels are available. The plethora of options can be overwhelming, but this process can be simplified by considering a stepwise approach to genetic testing including the following: 1) Whether genetic testing is indicated in the first place (benefits versus risk) 2) If genetic testing is indicated, what genes are in the differential for a clinical presentation of unexplained fractures. 3) How to provide proper pre-test counseling to families regarding methodology of testing, timing of tests, and potential results 4) How to interpret the tests when they return Goal: Review 200 cases of suspected NAI where genetic testing was

done and do chart review. Report: Yield of testing, number of variants that returned Conclusion: Publish paper on this topic and how we handle this testing to date

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

1. Currently, writing Kleinman chapter on Osteogenesis Imperfecta for international text book and skeletal dysplasia chapter

2. Shur N, Summerlin ML, Robin NH, Moreno-Mendelson A, Shalaby-Rana E, Hinds T. Genetic consultations in cases of unexplained fractures and haemorrhage: an evidence-based approach. Curr Opin Pediatr. 2021 Feb 1;33(1):3-18. doi: 10.1097/MOP.0000000000000986. PMID: 33337606. 2. Shur N, Summerlin ML, Robin NH, Moreno-Mendelson A, Shalaby-Rana E, Hinds T. Genetic consultations in cases of unexplained fractures and haemorrhage: an evidence-based approach. Curr Opin Pediatr. 2021 Feb 1;33(1):3-18. doi: 10.1097/MOP.0000000000000986. PMID: 33337606. Copy

3. Shur N, Carey JC. Genetic differentials of child abuse: Is your case rare or real? Am J Med Genet C Semin Med Genet. 2015 Dec;169(4):281-8. doi: 10.1002/ajmg.c.31464. Epub 2015 Oct 29. PMID: 26513547.

* **5. Sponsor's Research Focus:**

Yes - Genomics
Yes - Pediatrics

* **6. Sponsor's translational level**

* **(Please select ONE)**

T4: Translation to Population Health

* **7. Hypotheses (200 word limit)**

Hypothesis: 1. In cases when multidisciplinary teams make diagnoses of child abuse, genetic yield of testing remains very low. Our hypothesis is that likely < 1 percent of patients will have a positive result. 2. We hypothesize that variants will account for about 5% of genetic testing and discuss how these variants can be solved

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

Child abuse is a major public health concern that can explain a proportion of fractures in children. Osteogenesis imperfecta (OI) is the most common inherited syndrome that predisposes to skeletal fractures. Our goal is to retrospective analysis of data from clinical, laboratory, and radiographic information from children evaluated for child abuse in which molecular testing for COL1A1 and COL1A2 genes was conducted. A total of > 200 patients will be retrospectively analyzed. The goal of the medical student will be to perform chart review and help publish the results of the finding with some recommendations for a standard genetic testing approach based on 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**

Retrospective chart review will be done There are very limited studies done on this previously, and none have as robust numbers in a diverse center like our own The student will also be able to work in molecular genetics These numbers will be published in a child abuse or pediatrics issue

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

The student will have the opportunity to work with medical genetics, child protection, and laboratory medicine in a multiidisciplinary team The student will have opportunity to be a co-author on the publication

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

I will be helping oversee all aspects of the project including study design, review, authorship and helping the student with learning how to write and publish

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

I have worked with students for fifteen years, and many of those students have successfully completed publications and other activities.

* **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 Patrick Corr

* 1. Faculty Sponsor

* Name: Patrick Corr
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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 GW Medical Enterprise Annual Well-being Assessment

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

Hands, J.M., Corr, P.G., & Frame, L.A. (2023). Clarifying the role of Vitamin D in the development, prevention, and treatment of type 2 diabetes mellitus: A narrative review. International Journal of Environmental Research and Public Health, 20(12); 6187. Doi: 10.3390/ijerph20126187

Corr, P.G., Aly, R. & Artino, A. (In Press). Survey Research for Health Professionals. In E. Rees, A. Ledger, & K. Walker (Eds.) Starting Research in Clinical Education (pp. ??-??). Wiley Education Services.

Corr, P.G., Siglin, M, Frame, L.A., Dyer, K., Powell, C., Dawson, D. & Warren, A. (2022). Common academic stress points and mental health concerns among pre-health and health science students. In L. Schwartz & R. Ganjoo (Eds.) Handbook of Research on Developing Competencies for Pre-Health Professional Students, Advisors, and Programs (pp. 98-120). IGI Global. https://doi.org/10.4018/978-1-6684-5969-0.ch006

* **5. Sponsor's Research Focus:**

* **6. Sponsor's translational level**

* **(Please select ONE)**

T3: Translation to Practice

* **7. Hypotheses (200 word limit)**

Over the last four years, burnout and mental health concerns among clinicians and the broader healthcare workforce has been on the rise. The GW Resiliency and Well-being Center (R&WC) was developed in response to the this ongoing need and SMHS' commitment to providing meaningful and impactful support to the Medical Enterprise. In order to best serve the community, the R&WC developed an annual well-being assessment to identify baseline well-being across the community and changes in well-being overtime. This year, we seek to do a comparative analysis of existing data (from 2022-23) and data we will collect in 2023-24.

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

Goal: The assist in adjusting and disseminating the annual Medical Enterprise Well-being Assessment alongside Dr. Corr with the GW Resiliency & Well-being Center (R&WC). Upon survey closure, assist in data analysis including basic descriptive statistics, comparative analyses, and thematic analysis. The survey is disseminated widely and receives approximately 750 unique responses from across the Medical Faculty Associates, SMHS, and the GW University Hospital. This survey is used to benchmark employee well-being and identify possible interventions to support members of the community. We anticipate the results of this study will: 1) improve interventions available to the Medical Enterprise and 2) lead to peer-reviewed publications and/or professional presentations.

* **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**

Half of the data is extent, so analysis of 2022-23 data can begin immediately. The 2023-24 assessment is slated for dissemination in late-October. Depending on when a student researcher joins the team, there may be opportunity to assist in review and design of this instrument.

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

The medical student will be the primary driver of this research: pulling the data, organizing the data, assisting with data analysis, developing an outline for the manuscript, writing the manuscript, and integrating with the research team (PI and data scientist). As such, they will develop independent research capabilities. They will have access to the research team for assistance and mentoring throughout the process.

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

Dr. Corr has mentored multiple medical and health sciences students over the years and is a recognized expert in survey design and data analysis. He will support students as they develop independent research skills, can provide training on methods, and guide the student through the research and dissemination process.

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

Dr. Corr has published with multiple medical students in the past, with much of this work beginning in 2020. Each year, Dr. Corr provides research mentorship to approximately three medical students and has published in peer-reviewed research journals with six medical 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 Leigh A. Frame

* 1. Faculty Sponsor

* Name:	Leigh A. Frame
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* 2. Daily Supervisor

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* 3. Project Title (250 character limit)

Assessing Possible Link Between Mercury Toxicity and Risk of Breast Cancers

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

Hands JM, Corr PG, Frame LA. Clarifying the Heterogeneity in Response to Vitamin D in the Development, Prevention, and Treatment of Type 2 Diabetes Mellitus: A Narrative Review. Int J Environ Res Public Health. 2023;20(12):6187. Published 2023 Jun 20. doi:10.3390/ijerph20126187

Frame LA, Costa E, Jackson SA. Current explorations of nutrition and the gut microbiome: a comprehensive evaluation of the review literature. Nutr Rev. 2020;78(10):798-812. doi:10.1093/nutrit/nuz106

Dunn M, Mirda D, Whalen MJ, Kogan M. An integrative active surveillance of prostate cancer. Explore (NY). 2022;18(4):483-487. doi:10.1016/j.explore.2021.04.005

* **5. Sponsor's Research Focus:**

Yes - Gastroenterology
Yes - Genomics
Yes - Biochemistry

* **6. Sponsor's translational level**

* **(Please select ONE)**

T0/T1: Basic Science Discovery and Initial Translation to Humans

* **7. Hypotheses (200 word limit)**

• Previous research suggests a possible link between mercury toxicity and increased risk of breast cancer. • Mercury has no biological role in the human body and prolonged exposure to either organic (e.g., from consuming seafood) or inorganic (e.g., dental amalgam fillings or accidental environmental exposure) sources cause gradual accumulation in fatty tissues and other organs. • While case reports have linked breast cancer and elevated mercury, this issue has not been systematically studied. • The recent Quicksilver Scientific® Mercury Tri-Test® can assess mercury in urine, blood, and hair at the same time and is the only test capable of measuring both organic and inorganic mercury levels.

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

• The average level of mercury in this patient population is higher compared to expected CDC recommended average of 0.833 ng/mL. • This study is not designed to establish a causative relationship or assess the possible mercury toxicity treatment impact on breast cancer outcomes. • This pilot will lay the foundation for a larger trial, including determining sufficient power to assess a possible causative relationship.

* **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**

An observational pilot study to evaluate the prevalence of elevated mercury (inorganic and organic) in patients identifying as female with a history of breast cancer.

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

The student will interact with participants and liaise with the MFA Cancer Center. Tasks will include communication/recruitment, informed consent process, data collection, etc. If interested/able, the student may be involved in any (or all) of the following as well: data analysis, poster design, manuscript writing, and study design/grant writing for the larger follow-up study. They will have access to the research team for assistance and mentoring throughout the process.

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

Drs. Frame and Kogan conducted a micro-pilot of this study with 19 participants. The aim is now to expand this to 40 participants, a full pilot that will warrant publication. Both have extensive experience in clinical, translational research such as this. Dr. Kogan is the PI of this study.

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

Dr. Frame is currently working with a number of medical students on various projects including a Brain Health & Microbiome Study, an intervention related to gut microbiome patient education and behavior change, several comprehensive/scoping reviews, and one outcome research project. Learn more on her lab website: https://framecorrlab.smhs.gwu.edu/

*** 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: NCR203067

* IRB Date: June 24, 2021

Faculty Proposal for MD Student Research by Leigh A. Frame

* 1. Faculty Sponsor

* Name: Leigh A. Frame
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* 2. Daily Supervisor

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

Brain Health & the Microbiome: A Proof-of-Concept Study in Patients with Mild Cognitive Impairment

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

Frame LA, Costa E, Jackson SA. Current Explorations of Nutrition and the Gut Microbiome: A Systematic Evaluation of the Review Literature. Nutrition Reviews. 2020. DOI: https://doi.org/10.1093/nutrit/nuz106

Leonard H, Jackson SA, Frame LA. From Patient to Laboratory: Challenges in Developing Standardized Measurements for the Microbiome. SAGE Research Methods. 2020. DOI: https://dx.doi.org/10.4135/9781529726602

Hands JM, Corr PG, Frame LA. Clarifying the role of vitamin D in the development, prevention, and treatment of type 2 diabetes mellitus: A narrative review. Int J Environ Res Public Health. 2023. DOI: https://doi.org/10.3390/ijerph20126187

* **5. Sponsor's Research Focus:**

Yes - Gastroenterology
Yes - Geriatrics
Yes - Neurology

* **6. Sponsor's translational level**

* **(Please select ONE)**

T2: Translation to Patients

* **7. Hypotheses (200 word limit)**

This proof-of-concept study will examine the gut microbiomes of three groups in the hopes of identifying a dose-response relationship: 1) Alzheimer's disease (eAD), 2) mild cognitive impairment (MCI), and 3) healthy controls (HC). Microbiome testing will be conducted at baseline (2 consecutive samples to be integrated into a single EzBiome report). Subjects will receive their EzBiome reports and be advised to consider implementing the suggested, tailored lifestyle changes. This will be repeated at 3- and 6-month time points, as this will allow for the lifestyle feedback to be iterative (they can implement something and see how it affects their microbiome for additional motivation and/or modification). All changes implemented by the subjects while participating in the study will be documented including dietary pattern analysis with DietID. MCI outcome measures will include BOCA scores, PROMIS 29 assessment, and caregiver report of symptoms; participants will answer questions and will be assisted by their caregivers as needed. Additional measures that are part of standard of care (such as inflammation, e.g. CRP) will also be collected. These will likely be unavailable for the healthy controls but may inform future research.

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

Sampling at 0-, 3-, & 6-months for 90 subjects Specific Aim 1 To compare the gut microbiomes of patients with early Alzheimer’s disease (eAD), mild cognitive impairment (MCI), and healthy controls (HC) using diversity as well as genus, species, and strain level differences in composition and function. Hypothesis 1 Gut microbiome diversity will exhibit a dose-response relationship among subjects with eAD, MCI, and HC. Hypothesis 2 Gut microbiome composition will exhibit a dose-response relationship among subjects with eAD, MCI, and HC. Hypothesis 3 Gut microbiome function will exhibit a dose-response relationship among subjects with eAD, MCI, and HC. Specific Aim 2 To document microbiome changes following lifestyle changes in subjects with eAD, MCI, and HC.

* **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 foundation-funded research study, we will partner with a cutting-edge microbiome innovation and discovery platform, EzBiome, to collect pilot data on the gut microbiome alterations in MCI at a greater depth and precision than has previously been conducted to our knowledge. The ability to obtain such detailed and high-fidelity information is a unique opportunity. This alone will advance the field of gut microbiome research and, potentially, care in patients with MCI/AD. It will also make it possible to obtain larger grant funding to reproduce these findings in more robust and diverse cohorts, allowing for generalizability and, hopefully, immediate application to personalized and precision medicine. In addition to the higher resolution of the gut microbiome composition (genus, species, and strain). The EzBiome platforms allows us to begin to explore functional analysis with shotgun metagenomics—singularly a major advantage over 16S rRNA. This means that we can move away from simply cataloging who is there and begin to investigate what roles they are playing. This functional understanding is necessary to translate this into the clinic be that in the form of a microbiome therapeutic, lifestyle intervention, or a multi-modal approach (most likely). With analysis of each sample, EzBiome issues a report, which includes personalized, actionable advice about basic actions to improve gut health including lifestyle measures such as diet as well as probiotics if relevant. EzBiome does not sell, market, or endorse any specific probiotic products; instead, they recommend the introduction of keystone species or species/strains with known probiotic activity and health benefits. This report will be provided to each subject in this proposed proof-of-concept study. Implementation of such actionable advice by each subject will be monitored and correlated with the findings. While this study may be underpowered to determine the effect of such interventions, it will certainly lay the groundwork for the evidence-based design of a study to investigate such interventions and will serve as the pilot data necessary to fund intensive interventional studies.

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

There is the opportunity for the student to be intimately involved in the enrollment/consent, data collection, data analysis, developing an outline for the manuscript, writing portions of the manuscript, and integrating with the research team, which can be customized to fit the skills, needs, and availability of the student. They will have access to the research team for assistance and mentoring throughout the process.

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

Dr. Frame is the PI for this research study and its grant funding. She has worked with many students on this and similar projects in the past. She has a supportive approach that allows the students to get their hands messy and even struggle through the process to some extent, as this leads to the most robust learning. Through her years of experience, she has developed an approach to conducting such clinical research with relative ease even with novice researchers.

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

Dr. Frame is currently working with a number of medical students on various projects including this study, an intervention related to gut microbiome patient education and behavior change, several comprehensive/scoping reviews, and one outcome research project. Learn more on her lab website: https://framecorrlab.smhs.gwu.edu/

*** 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: NCR234792
* IRB Date: 07/27/2024

Faculty Proposal for MD Student Research by Briony K Varda

* 1. Faculty Sponsor

* Name:	Briony K Varda
* Degrees:	MD, MPH
* Title:	Assistant Professor Urology and Pediatrics
* Organization:	Children's National
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* 2. Daily Supervisor

Name:	Butool Hisam
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Zipcode:	
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* 3. Project Title (250 character limit)

Assessment of bacteriuria and antibiotic resistance patterns among patients presenting for cloacal repair: a retrospective study

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

Davis M, Mohan S, Russell T, Feng C, Badillo A, Levitt M, Ho CP, Pohl HG, Varda BK. A prospective cohort study of assisted bladder emptying following primary cloacal repair: The Children's National experience. J Pediatr Urol. 2023 Mar 21:S1477-5131(23)00100-6.

3. Al-Shamaileh T, Tiusaba L, Jacobs SE, Russell TL, Bokova E, Pohl HG, Varda BK, Ho C, Feng C, Badillo A, Levitt MA. Cloacal Malformation with Associated Urethral Atresia. European J Pediatr Surg Rep. 2023 Jan;11(1):e1-e4. doi: 10.1055/s-0043-1761206. eCollection 2023 Jan.

4. Jacobs SE, Tiusaba L, Bokova E, Al-Shamaileh T, Russell TL, Varda BK, Feng C, Badillo AT, Levitt MA. Where Is the Vagina? A Rectal Stricture after a Presumed Cloacal Repair Turns Out to be the Mobilized Vagina and a Missed High Rectovaginal Fistula. European J Pediatr Surg Rep. 2022 Jan;10(1):e145-e147.

* **5. Sponsor's Research Focus:**

Yes - Pediatrics
Yes - Infectious Disease
Yes - Surgery

* **6. Sponsor's translational level**

* **(Please select ONE)**

T3: Translation to Practice

* **7. Hypotheses (200 word limit)**

A cloacal malformation arise from failure of separation of the urinary tract, vagina and rectum during fetal development. These patient often have significant comorbidities and inherently are hospitalized after delivery which could allow for bacterial colonization with hospital acquired resistant bacteria. At the very least, by having the rectum in continuity with the urinary tract, they are likely to have bacterial colonization of the urinary tract. We hypothesize that patients presenting for primary cloacal repair have a higher rate of bacteriuria and bacterial resistance than patients presenting for other urologic procedures.

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

The aim of this project is to collect urinalysis and urine culture data for 40 patients undergoing cloacal reconstruction and 40 female patients undergoing ureteral reimplant. The exposure will be surgery type: cloacal reconstruction vs. ureteral reimplant. The outcome will be presence of bacteriuria (>50k of a single-isolated organism) at the time of surgery, and the rate of bacterial resistance. We aim to adjust for prior degree of hospitalization, number of prior surgeries, and prior antibiotic exposure as well the complexity of the cloacal malformation. I do not anticipate data collection consuming more than 10 days of the research block.

* **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 fall we will write a proposal expanding an existing IRB to include collection of urinalysis and urine culture data. Baseline clinical and patient data has previously been collected on all cloacal patients from the parent project. Additional data urinalysis and culture data will need to be collected on the control group (reimplant patients). Some of this data will be automatically pulled from the childrens EMR using administrative codes so the student will only be doing a fraction of chart review needed for this project. Data collection will be completed after the first 10 days of the summer session, assuming a 6 hour work days. Once collected, we will then clean the data and

quality check. Once the final dataset is generated we will be able to conduction descriptive statistics and likely unadjusted logistic regression. This should result in an abstract by summer's end.

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

The student will perform limited chart review, conduct data analysis with the support of Dr Varda and a biostatistician. The student will write an abstract and present at a national meeting the next academic year. The student will contribute to a manuscript. If the student would like to extend their experience, they may then participate in a QI project aimed at antibiotic stewardship in the cloacal population.

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

Provide didactics and research materials surrounding quantitative analysis. Mentor the student towards writing an abstract and presenting it at a national meeting, as well as co-authoring a manuscript. Dr. Varda holds a weekly research meeting during which 30 minutes are devoted to research didactics to helps student further their clinical research skillset and better understand health services research. During the research meeting, Dr. Varda also has team members present "Works-in-progress" to elicit feedback and also learn how to present research at various phases of execution. For quantitative research projects, Dr. Varda teaches the student how to organize research data and work with a biostatistician to ensure there is a high quality statistical analysis. Dr. Varda will also facilitate clinical shadowing experiences as desired, both in clinic, telemedicine and the operating room.

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

Dr. Varda has mentored formally mentor nine GW Medical students. 8/9 of these students participated in Summer research. All 8 received summer funding with either the Gill award, the Health Services award, or the Fourcroy award. Of the students, all have submitted a research abstract to a national meeting with acceptance. All students are currently in various phases of writing / submitting / revising / publishing manuscripts related to their research work. Projects have completed using qualitative methods and quantitative methods. Through this experience I have learned that large retrospective data collection is not the most effective use of a student's summer, and I know try to have a project set up for a student to enter and progress it forward (not start from scratch). In addition to students, Dr. Varda also mentors a Colorectal Fellow and a Urology Fellow, who participate in research meetings and are able to guide students on projects if additional help is needed.

* **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 Briony K Varda

* 1. Faculty Sponsor

* Name:	Briony K Varda
* Degrees:	MD, MPH
* Title:	Assistant Professor Urology and Pediatrics
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* 2. Daily Supervisor

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State:	DC
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Email Address:	bvarda@childrensnational.org

* 3. Project Title (250 character limit)

1) A qualitative analysis of barriers and facilitators to the execution of a successful institutional testicular torsion care pathway: A focus group study of NSQIP-P sites.

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

Davis M, Mohan S, Russell T, Feng C, Badillo A, Levitt M, Ho CP, Pohl HG, Varda BK. A prospective cohort study of assisted bladder emptying following primary cloacal repair: The Children's National experience. J Pediatr Urol. 2023 Mar 21:S1477-5131(23)00100-6.

4. Jacobs SE, Tiusaba L, Bokova E, Al-Shamaileh T, Russell TL, Varda BK, Feng C, Badillo AT, Levitt MA. Where Is the Vagina? A Rectal Stricture after a Presumed Cloacal Repair Turns Out to be the Mobilized Vagina and a Missed High Rectovaginal Fistula. European J Pediatr Surg Rep. 2022 Jan;10(1):e145-e147.

Lee T, Varda BK, Venna A, McCarthy I, Logvinenko T, Nelson CP. Changes in Clinical Presentation and Renal Outcomes among Children with Febrile Urinary Tract Infection: 2005 vs 2015. J Urol. 2021 Jun;205(6):1764-1769.

*** 5. Sponsor's Research Focus:**

Yes - Pediatrics
Yes - Surgery

*** 6. Sponsor's translational level**

*** (Please select ONE)**

T3: Translation to Practice

*** 7. Hypotheses (200 word limit)**

The time from when a patient arrives in the ED with scrotal pain to surgery for testicular detorsion is a metric of quality used by NSQIP institutions. We hypothesize that common themes exist surrounding barriers and facilitators to time to surgery, and that themes may converge or diverge depending on institutions own performance in testicular torsion management.

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

Conduct multidisciplinary institutional-based focus groups of stakeholders within NSQIP-P institutions to elucidate perceived facilitators and barriers to optimal testicular torsion management. Sample: There are currently 29 participating sites in the collaborative. Purposeful sampling based on time from arrival to procedure start will be conducted. Snowball sampling will used within institutions to identify additional institutional stakeholders. The team will aim to recruit 2 – 3 focus groups per quartile of time, for a total of 8 – 12 focus groups. The focus groups will include 3 – 5 stakeholders from the same NSQIP-P institution. This amounts to 18 – 60 total participants. Urology or Pediatric surgery stakeholders will be approached to participate in the focus groups. They will be asked to provide contact information for additional institutional stakeholders (e.g., ED clinicians, anesthesia, nursing, quality leadership, surgeon champions, SCRs, and/or radiologists). Recruitment Strategy Leverage NSQIP-P CRC/RA network to identify Urologist or Pediatric surgeons involved in torsion 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**

Qualitative study using semi-structured interviews to facilitate discussion within focus groups made up of NSQIP-P institutional stakeholders aiming to elucidate perceived facilitators and barriers to optimal evaluation and management of testicular torsion. A framework approach will be used for thematic analysis. The project proposal and focus group question guide is being formalized by the Urology advisory committe (sub-committee on testicular torsion) currently. This Winter and Spring we will be recruiting and performing focus groups. We aim to have this completed by the Summer 2024 when we will start analyzing the focus group responses and

developing themes surrounding our objective. This analytic process is enhanced by having a research team member who is not directly involved in clinical care and may provide an "outsider perspective". We hope to have the focus groups analyzed by the end of the Summer with abstract creation for the Fall. Completion of a manuscript will be after the Summer and the student may need to work on this over the next year (though with the understanding that they have limited bandwidth).

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

The student will help with critical analysis of focus groups interviews during research team meetings. They will receive training in qualitative analysis by Dr. Varda and learn from example provided by other expert members of the research team. They may be able to attend focus groups if still on-going during the summer. The student will write a research abstract and ideally present at a national academic meeting. They will be asked to contribute to manuscript writing and editing.

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

Provide didactics and research materials surrounding qualitative analysis. Mentor the student towards writing an abstract and presenting it at a national meeting, as well as co-authoring a manuscript. Dr. Varda holds a weekly research meeting during which 30 minutes are devoted to research didactics to helps student further their clinical research skillset and better understand health services research. During the research meeting, Dr. Varda also has team members present "Works-in-progress" to elicit feedback and also learn how to present research at various phases of execution. For quantitative research projects, Dr. Varda teaches the student how to organize research data and work with a biostatistician to ensure there is a high quality statistical analysis. Dr. Varda will also facilitate clinical shadowing experiences as desired, both in clinic, telemedicine and the operating room.

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

Dr. Varda has mentored formally mentor nine GW Medical students. 8/9 of these students participated in Summer research. All 8 received summer funding with either the Gill award, the Health Services award, or the Fourcroy award. Of the students, all have submitted a research abstract to a national meeting with acceptance. All students are currently in various phases of writing / submitting / revising / publishing manuscripts related to their research work. Projects have completed using qualitative methods and quantitative methods. Through this experience I have learned that large retrospective data collection is not the most effective use of a student's summer, and I know try to have a project set up for a student to enter and progress it forward (not start from scratch). In addition to students, Dr. Varda also mentors a Colorectal Fellow and a Urology Fellow, who participate in research meetings and are able to guide students on projects if additional help is needed.

*** 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 a quality improvement project and participants are clinical providers not patients