Session 3. Thurs Jan 19, 12-2 pm (virtual)

**Participant recruitment and retention**
- Enhancing participant diversity in Covid-19 Trials  
  David Diemert, MD
- Control populations, Healthy Heroes  
  Dr. Beth Tarini, MD, MS
- Radio outreach to Latinx Communities  
  Dr. Elmer Huerta, MD, MPH

**IRBs and E-consent**
- E-consent and tracking  
  Sarah Ford-Trowell, MPA
- sIRB for multi-site research  
  Almarie Coleman, CIP
- Defining the institutional indemnification parts of consent  
  Alavy Sos, MS

**Breakouts: Institutional solutions to challenges**
Steps to enhance recruitment and retention - Understanding consents and building equity - What is good monitoring? - How to foster social media for communication
- GW: Sarah Ford-Trowell, Richmond Amoako, and Liudmila Tahai
- CNH: Almarie Coleman, Kristin Breslin
Enhancing Participant Diversity in COVID-19 Vaccine Trials at GW

David Diemert, MD, FRCP(C)
Director, GW Vaccine Research Unit
Professor of Medicine & MIIT

Bootcamp on Clinical Research for New Investigators
19 January 2023
COVID-19 Mortality & Morbidity in Underserved Communities

Hospitalization and Mortality among Black Patients and White Patients with Covid-19

Eboni G. Price-Haywood, M.D., M.P.H., Jeffrey Burton, Ph.D., Daniel Fort, Ph.D., and Leonardo Seoane, M.D.
<table>
<thead>
<tr>
<th>Company</th>
<th>Type</th>
<th>EUA &amp; BLA Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderna</td>
<td>mRNA</td>
<td>EUA: 18 Dec 2020, BLA: 31 Jan 2022</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>Replication Incompetent Adenovirus (ChAdOx1)</td>
<td>EUA: 11 Dec 2020, BLA: 23 Aug 2021</td>
</tr>
<tr>
<td>Janssen</td>
<td>Replication Incompetent Adenovirus (Ad26)</td>
<td>EUA: 27 Feb 2021</td>
</tr>
<tr>
<td>Sanofi</td>
<td>Adjuvanted protein subunit</td>
<td>EUA: 13 Jul 2022</td>
</tr>
<tr>
<td>Merck</td>
<td>Replication-competent Vesicular Stomatitis Vector (VSV)</td>
<td>EUA: 13 Jul 2022</td>
</tr>
<tr>
<td>Novavax</td>
<td>Adjuvanted protein subunit</td>
<td>EUA: 13 Jul 2022</td>
</tr>
<tr>
<td>Pfizer</td>
<td>mRNA</td>
<td>EUA: 11 Dec 2020, BLA: 23 Aug 2021</td>
</tr>
</tbody>
</table>
Moderna mRNA COVID-19 Vaccine – Accelerated Clinical Development

Phase 1
May 18: Preliminary Results

Phase 2
1st week of July: Blinded safety post-Vax#1
Mid-July: Blinded safety post-Vax#2

Phase 3
July 27th: Initiation of vaccinations

NIH Clinical Trial of Investigational Vaccine for COVID-19 Begins
Study Enrolling Seattle-Based Healthy Adult Volunteers

Trial of vaccine candidate mRNA-1273 will enroll 45 healthy adult volunteers ages 18 to 55 years over approximately 6 weeks
• First GW ppt enrolled 8/12/2020, last ppt enrolled 10/23/2020

• **349 participants**
  – 51% White, 36% Black, 5% Asian, 8% Other
  – 25% Hispanic
  – 26% > 65 years old, 14% were 18-64 yo and at risk
  – 60% male

• <4% lost to follow up after 1 year
# Modena mRNA COVID-19 Phase 3 Trial Demographics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Placebo (N=15,170)</th>
<th>mRNA-1273 (N=15,181)</th>
<th>Total (N=30,351)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex — no. of participants (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>8,062 (53.1)</td>
<td>7,923 (52.2)</td>
<td>15,985 (52.7)</td>
</tr>
<tr>
<td>Female</td>
<td>7,108 (46.9)</td>
<td>7,258 (47.8)</td>
<td>14,366 (47.3)</td>
</tr>
<tr>
<td>Mean age (range) — yr</td>
<td>51.3 (18-95)</td>
<td>51.4 (18-95)</td>
<td>51.4 (18-95)</td>
</tr>
<tr>
<td>Age category and risk for severe Covid-19 — no. of participants (%)‡</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18 to &lt;65 yr, not at risk</td>
<td>8,886 (58.6)</td>
<td>8,888 (58.5)</td>
<td>17,774 (58.6)</td>
</tr>
<tr>
<td>18 to &lt;65 yr, at risk</td>
<td>2,535 (16.7)</td>
<td>2,530 (16.7)</td>
<td>5,065 (16.7)</td>
</tr>
<tr>
<td>≥65 yr</td>
<td>3,749 (24.7)</td>
<td>3,763 (24.8)</td>
<td>7,512 (24.8)</td>
</tr>
<tr>
<td>Hispanic or Latino ethnicity — no. of participants (%)‡</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>3,114 (20.5)</td>
<td>3,121 (20.6)</td>
<td>6,235 (20.5)</td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
<td>11,917 (78.6)</td>
<td>11,918 (78.5)</td>
<td>23,835 (78.5)</td>
</tr>
<tr>
<td>Not reported and unknown</td>
<td>139 (0.9)</td>
<td>142 (0.9)</td>
<td>281 (0.9)</td>
</tr>
<tr>
<td>Race or ethnic group — no. of participants (%)‡</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>11,995 (79.1)</td>
<td>12,029 (79.2)</td>
<td>24,024 (79.2)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>1,527 (10.1)</td>
<td>1,563 (10.3)</td>
<td>3,090 (10.2)</td>
</tr>
<tr>
<td>Asian</td>
<td>731 (4.8)</td>
<td>651 (4.3)</td>
<td>1,382 (4.6)</td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>121 (0.8)</td>
<td>112 (0.7)</td>
<td>233 (0.8)</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>32 (0.2)</td>
<td>35 (0.2)</td>
<td>67 (0.2)</td>
</tr>
<tr>
<td>Multiracial</td>
<td>321 (2.1)</td>
<td>315 (2.1)</td>
<td>636 (2.1)</td>
</tr>
<tr>
<td>Other</td>
<td>316 (2.1)</td>
<td>321 (2.1)</td>
<td>637 (2.1)</td>
</tr>
<tr>
<td>Not reported and unknown</td>
<td>127 (0.8)</td>
<td>155 (1.0)</td>
<td>282 (0.9)</td>
</tr>
</tbody>
</table>

*Baden et al. NLM 2020*
Leverage Existing Partnerships & Relationships
- Existing CABs
- SPH & Rodham
- Community groups, leaders

Legwork!
- Traditional Media
- Social Media
- Participant ambassadors

GWU’s COVID-19 clinical trial has met one early goal — getting Black and Latino people to join.
Moderna Phase 3 – GW Recruitment Strategies

• Websites
  – CoVPN Volunteer Screening Registry
  – NextDoor
  – ResearchMatch
  – PatientWing
  – www.covid19studies.org

• Social Media
  – Facebook, Twitter, Instagram
  – Press Release
  – GW VRU Website

• Traditional Media
  – TV
  – Radio
  – Print
## mRNA-1273 Phase 3 Efficacy

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Placebo (N=14,073)</th>
<th>mRNA-1273 (N=14,134)</th>
<th>Vaccine Efficacy (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All patients</strong></td>
<td>185/14,073</td>
<td>11/14,134</td>
<td>94.1 (89.3–96.8)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥18 to &lt;65 yr</td>
<td>156/10,521</td>
<td>7/10,551</td>
<td>95.6 (90.6–97.9)</td>
</tr>
<tr>
<td>≥65 yr</td>
<td>29/3552</td>
<td>4/3583</td>
<td>86.4 (61.4–95.2)</td>
</tr>
<tr>
<td>Age, risk for severe Covid-19</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18 to &lt;65 yr, not at risk</td>
<td>121/8403</td>
<td>5/8396</td>
<td>95.9 (90.0–98.3)</td>
</tr>
<tr>
<td>18 to &lt;65 yr, at risk</td>
<td>35/2118</td>
<td>2/2155</td>
<td>94.4 (76.9–98.7)</td>
</tr>
<tr>
<td>≥65 yr</td>
<td>29/3552</td>
<td>4/3583</td>
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</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>87/7462</td>
<td>4/7366</td>
<td>95.4 (87.4–98.3)</td>
</tr>
<tr>
<td>Female</td>
<td>98/6611</td>
<td>7/6768</td>
<td>93.1 (85.2–96.8)</td>
</tr>
<tr>
<td>At risk for severe Covid-19</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>43/3167</td>
<td>4/3206</td>
<td>90.9 (74.7–96.7)</td>
</tr>
<tr>
<td>No</td>
<td>142/10,906</td>
<td>7/10,928</td>
<td>95.1 (89.6–97.7)</td>
</tr>
<tr>
<td>Race and ethnic group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>144/8916</td>
<td>10/9023</td>
<td>93.2 (87.1–96.4)</td>
</tr>
<tr>
<td>Communities of color</td>
<td>41/5132</td>
<td>1/5088</td>
<td>97.5 (82.2–99.7)</td>
</tr>
</tbody>
</table>
Become a HEALTHY HERO!

Children’s National Hospital is looking for kids ages 0-18 to volunteer as control subjects in clinical trials to help our researchers advance pediatric medicine.

LEARN MORE
Rationale

• Observational and intervention projects often require comparisons of observations with otherwise similar and “healthy” individuals.

• Finding a diverse group “healthy” controls can be time consuming and difficult

• A ready cohort of individuals willing to participate in research studies could enhance research efficiency and reduce costs
Healthy Heroes Cohort

Healthy Heroes - Clinical Trials | Children's National Hospital (childrensnational.org)
Healthy Heroes Normal Cohort

Total registrants: 2486

Distribution by age groups

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Count</th>
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<tbody>
<tr>
<td>0-1yo</td>
<td>152</td>
</tr>
<tr>
<td>2-5yo</td>
<td>975</td>
</tr>
<tr>
<td>6-10yo</td>
<td>1058</td>
</tr>
<tr>
<td>11-14yo</td>
<td>302</td>
</tr>
<tr>
<td>15-18yo</td>
<td>0</td>
</tr>
</tbody>
</table>

DMV Demographics

- 45% White
- 25% Black
- 10% Asian
- 0% Islander
- 0% Native/Other
- 4% Two+
- 16% Hispanic

https://censusreporter.org

- ('Hispanic or Latino', 'White') 6.1%
- ('Hispanic or Latino', 'Not Hispanic or Latino') 6.3%
- ('Not Hispanic or Latino', 'White') 67.1%
- ('Not Hispanic or Latino', 'Other') 10.1%
Healthy Heroes Normal Cohort

Total registrants: 2486

Distribution by age groups

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https://censusreporter.org
CONTACTS

• Dr. Lisa Guay-Woodford
  lguaywoo@childrensnational.org

• Dr. Beth Tarini
  btarini@childrensnational.org

• Jasmine Jaber
  jjaber@childrensnational.org
Session 3:
Participant recruitment and retention

Radio outreach to Latinx communities
In order to recruit and retain volunteers in clinical trials...
We need to inform and educate them...
How can we convince people that participating in clinical trials is important?
I am convinced that coherent, consistent, media-based, public education programs need to be created
An ethnically-sensitive, culturally-relevant, media-based community outreach program was progressively developed since 1989 following four basic principles:
Radio outreach to Latinx communities

- Radio has been a powerful public health tool
- Started December 4, 1989
- The “Community Clinic of the Air” is broadcast daily in the DC and South Florida Metro areas
Our Media Principles...

1. Use the media CONSISTENTLY
2. Develop COMPREHENSIVE health education programs
3. Use ALL MEDIA CHANNELS available TO the community
4. Be a TRUSTED MESSENGER
Creation of the Cancer Preventorium
PREVENTORIUM

NOUN: 1. An institution for the prevention and early detection of chronic diseases or for medically supervised patient education. 2. A resort for maintenance of health, especially for people without evident illness.

Our proposed definition
The Preventorium has two main goals:

✓ To find and treat early asymptomatic conditions (cancer, diabetes, high blood pressure)

✓ To find and manage risk factors for those chronic conditions
Preventorium Model

Use of media by a trusted professional

Culturally and ethnically sensitive messages

Registration and data collection

Personalized follow-up

Navigation

Tools

Revisit for continuous care

Interventions
- Link to primary care services
- Genetic testing
- Clinical trials enrollment
- Lifestyle interventions
The Washington Cancer Institute at MedStar Washington Hospital Center

Cancer Preventorium

✓ Date Started: July 27, 1994

✓ Patients Seen (as of 2/28/20): 38,172
GENDER:

Male: 12,052 (31%)
Female: 26,120 (69%)
Patients seen at the GW Cancer Preventorium
September 3, 2020 to January 12, 2023

Total 851

Male: 420 (49%)
Female: 377 (45%)
Returns: 54 (6%)
I still consider good information to be the best medicine

Michael E. DeBakey, MD
Inventor, Surgeon, Educator,
(1908–2008)
Knowledge exists in two forms -lifeless, stored in books- and alive in the consciousness of men.

The second form... is the essential one.

Albert Einstein
The Ivory Tower of Science
eConsent and Tracking

Sarah Ford-Trowell
Sr. Manager of Regulatory and Compliance
GWU MFA
INTRODUCTION

What are eConsents?

BENEFITS OF USING eCONSENTS

Why eConsents are helping clinical research

STORING eCONSENTS

How to store your eConsent

THANKS!
01. Introduction

What are eConsents?
An electronic Informed Consent (eIC) refers to an interactive online-based Informed Consent application that facilitates interactions over time and enables a personalized approach, adapted to research participants’ needs.

- In a research, it has shown that using eConsent illustrates to
- Increase participant adherence to the study requirements and retention,
- Reduced drop-out rates and
- Increased protocol adherence

Ultimately this aids the participants in benefiting from the trial treatment, which may be potentially lifesaving.
Benefits of Using eConsent

Why using eConsents can transform your research
Why Participants Prefer eConsents

- Simplifies the study enrollment experience
- Reduces the complexity of consent forms
- Supports participant diversity related to location, finances, or family and work demands
- Provides flexibility for participants to discuss their consent decision with loved ones, caregivers, or friends
- Enables easy outreach to site teams, in some cases
eConsent Eases the Burden on Staff

- Expands the geographic range of recruitment efforts
- Facilitates better discussions between staff and participants
- Lessens site staff burden
- Improves tracking, oversight and compliance
03. Storage

How best to store your eConsents
• The e-IC must be secure with restricted access and include suitable methods to ensure confidentiality regarding the patient’s identity.

• It recommends that the subject’s information within the system must be encrypted unless it is precisely documented.

• The e-IC process should incorporate procedures to ensure that electronic documents can be archived appropriately and that all versions can be retrieved easily.

• The system should also have audit trail capability.
More information is provided on the Resources Page in the Lookbook, or reach out to me @strowell@mfa.gwu.edu if you have any further questions or want more information.
Single IRB Overview
What is Single IRB?

• **Single IRB (sIRB):** An IRB defined by the NIH as the single IRB of record that has been designated to conduct human subjects protections review for all participating sites of a multi-site study based on the NIH Policy on the Use of a Single IRB of Record for Multi-Site Research.

• **IRB of Record:** Sometimes called the **Reviewing IRB.** The IRB which assumes review and oversight responsibilities for human subjects research on behalf of one or more institution(s); the delegated or relied upon IRB.

• **Relying IRB:** An institution which has ceded IRB oversight to another IRB.
Why Single IRB?

- **NIH Single IRB Policy**: Requires domestic awardees and domestic sites conducting NIH-funded multisite research to be overseen by a single IRB.

- **2018 Revised “Common Rule”**: Requires single IRB review for federally funded multisite human research

- Reduces administrative burden on the local IRB committee and staff;
- Improves study activation timelines to allow innovative therapies to reach patients in a timelier manner; and
- Enables institutions to expand their portfolio of clinical trials, generating more revenue to further the research mission.
More Definitions

- **Local Context**: The characteristics of the setting where the research will be conducted, including institutional policies and procedures, local law, institutional resources, and community and subject population.

- **Local Context Review**: IRB review of local context issues pertaining to a research protocol prior to releasing it to an external IRB of record or accepting the review of a single IRB.

- **IRB Authorization Agreement (IAA)**: Also called a **Reliance Agreement**; A formal, written document that assigns the responsibility for the review of human subjects protections required under a Federal Wide Assurance (FWA) to a designated IRB. The agreement can designate responsibility for the review of a single protocol, multiple protocols, or an entire research program.
IRB REVIEW

- Institutional Resource Review
- Monitoring Compliance with Local, State Laws
- HIPAA and data sharing agreements (DUA, BAA)
- Grants and Contracts
- Ancillary Reviews (IDS, COI, Coverage Analysis, etc.)
- Review of PI & Staff Training

Each participating site’s institution retains responsibility for ancillary and institutional reviews and verifications

*Slide adapted with permission from Megan K. Singleton (JHU IRB)
Who decides which IRB will be the sIRB?

• The federal department or agency supporting or conducting the research selects the IRB that will serve in this capacity.

OR

• The lead institution proposes the sIRB, and this is subject to the acceptance of the Federal department or agency supporting the research.
## Role and Responsibilities of sIRB vs. Principal Investigator and IRB Liaison

<table>
<thead>
<tr>
<th>sIRB</th>
<th>PI and IRB Liaison</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary</strong></td>
<td></td>
</tr>
<tr>
<td>Initial Review of Protocol</td>
<td>Request Reliance Agreement for Relying Sites</td>
</tr>
<tr>
<td>Review of Local Investigator</td>
<td>Develop Communication Plan (plan for communication with collaborators across the life span of the study)</td>
</tr>
<tr>
<td>Overall Protocol Modifications</td>
<td>Provide information to IRBs at institutions relying on the single IRB</td>
</tr>
<tr>
<td>Annual/Continuing Review Approval of Study Wide ICP’s Reportable Events Study Closeout</td>
<td>Provide Site Investigators with IRB policies of the sIRB (i.e., reporting unanticipated problems, noncompliance, etc.)</td>
</tr>
<tr>
<td></td>
<td>Provide relying site study teams with IRB approved versions of all study documents</td>
</tr>
<tr>
<td></td>
<td>Prepare and submit IRB application on behalf of all sites, including initial review, local amendments, personnel updates, local reportable events, etc.</td>
</tr>
</tbody>
</table>

| **Secondary** | | |
| Review of Additional Sites | Notify Site Investigators of all Reviewing IRB determinations and communications, including those for initial review, continuing review, amendments, and reportable events |
| Annual/Continuing Review of Additional Sites Reportable Events at Additional Sites Site Specific Modifications Change of Relying PI Approval of Site-Specific Recruitment Documents Audit (as requested) Site Closeout New Reliance Agreements | Promptly report to the site investigator/designee on relying study team’s relevant information including, any UPIRTSOs, research-related subject injuries, significant subject complaints, etc. |
| | Follow up with relying study teams for continuing reviews. Report absence of information and lapses in approval, as appropriate |
| | Participate in audits, as required |
| | Follow all requirements of the relying institution regarding cede review |

Resource: SMART IRB
RESOURCES:

Children’s National:

• Research Navigator: https://cnmc.sharepoint.com/sites/research/SitePages/Research-Navigator-Resources.aspx


George Washington University:

• Training Assistance: https://humanresearch.gwu.edu/training-assistance

• Research Tools: https://humanresearch.gwu.edu/research-tools
sIRB Contacts

Children’s National:
Almarie Coleman – ascoleman@childrensnational.org
or reliance@childrensnational.org

George Washington University:
Lacey Maddox – ohrirb@gwu.edu
Required Parts of Informed Consent

Alavy Sos
Executive Director, Research Regulatory Affairs
Background

- Informed Consent ≠ document
- Ongoing process from recruitment to study completion
- Required by federal agencies under the “common rule” (OHRP, FDA, DoD, etc.)
- Consent form is a “method” of documenting consent
- IRB may waive requirements:
  - To obtain informed consent, or
  - For documenting consent
Elements of Informed Consent

• Statement that the study involves research
• Description of risks and discomforts
• Possible benefits
• Alternatives
• Confidentiality (not just HIPAA)
Elements of Informed Consent, cont’d.

- Compensation, if applicable
- Treatment for injury, if applicable
- Research team’s contact information
- Statement the study is voluntary
- Additional statement for research with identifiable information or identifiable specimens
- Additional elements here:
CNH Consent Form Template

- “Key Information”
- HIPAA Authorization Language
- Research-related injury
- Confidentiality
Key Takeaways

• Informed Consent is ongoing, not just a document
• 9 minimum elements of informed consent
• IRB has authority to grant waivers
• Children’s National and GW have different, required consent templates
Questions?

- Alavy Sos: asos@childrensnational.org
- CNH IRB office contact: ophs@childrensnational.org