Bootcamp for New Investigators in Clinical Research

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**

School of Medicine & Health Sciences

THE GEORGE WASHINGTON UNIVERSITY

Enhancing Participant Diversity in COVID-19 Vaccine Trials at GW

David Diemert, MD, FRCP(C)

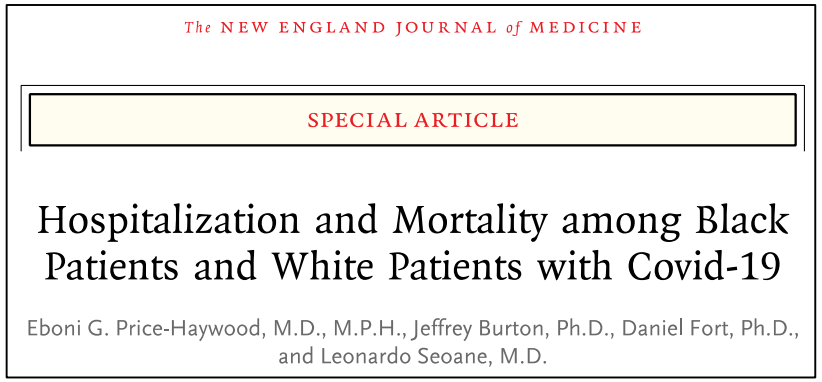
Director, GW Vaccine Research Unit

Professor of Medicine & MITM

Bootcamp on Clinical Research for New Investigators

19 January 2023

COVID-19 Mortality & Morbidity in Underserved Communities

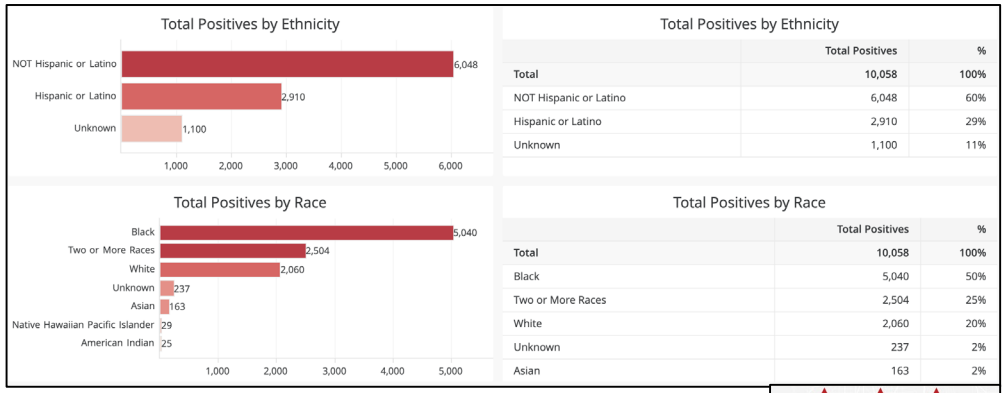


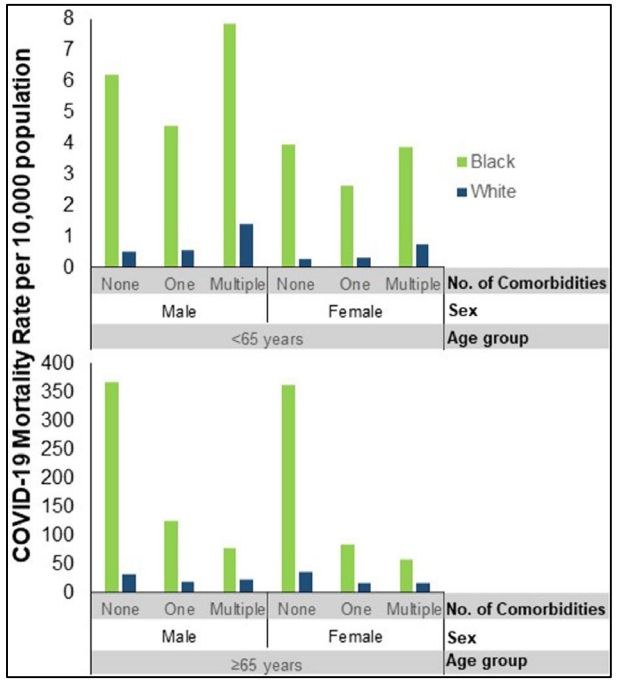
The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

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.





eClinicalMedicine 2021 33DOI: (10.1016/j.eclinm.2021.100761)

USG-Supported COVID-19 Vaccines

GW	moderna	mRNA	EUA: 18 DEC 2020, BLA: 31 JAN 2022
	AstraZeneca	Replication Incompetent Adenovirus (ChAdOx1)	
	janssen (Johnson & Johnson)	Replication Incompetent Adenovirus (Ad26)	EUA: 27 FEB 2021
GW	SANOFI	Adjuvanted protein subunit	
	MERCK iavi	Replication-competent Vesicular Stomatitis Vector (VSV)	
	NOVAVAX	Adjuvanted protein subunit	EUA: 13 JUL 2022
GW	Pfizer	mRNA	EUA: 11 DEC 2020, BLA: 23 AUG 2021

Moderna mRNA COVID-19 Vaccine – Accelerated Clinical Development

NIH National Institute of Allergy and Infectious Diseases

March 16, 2020

News Release

NIH Clinical Trial of Investigational Vaccine for COVID-19 Begins

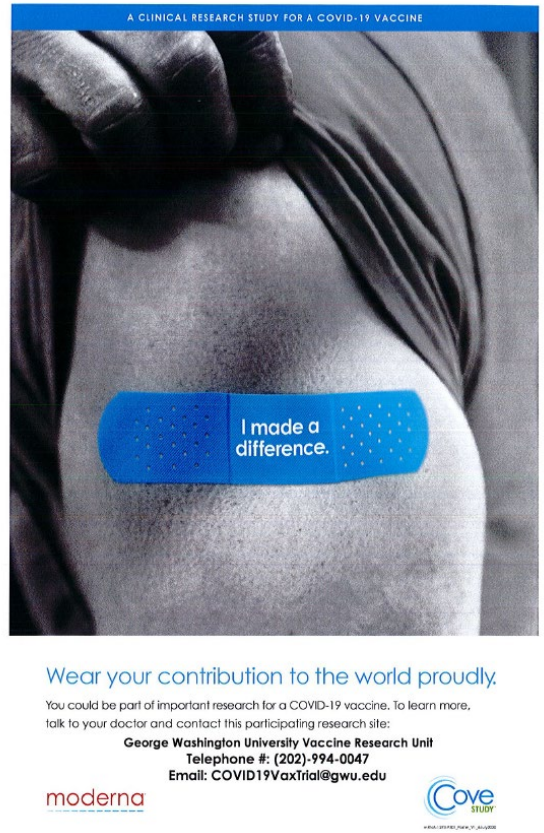
Study Enrolling Seattle-Based Healthy Adult Volunteers

- Trial of vaccine candidate mRNA-1273 will enroll 45 healthy adult volunteers ages 18 to 55 years over approximately 6 weeks

Photo: AP

Moderna Study Enrollment at GW

- 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



Moderna mRNA COVID-19 Phase 3 Trial Demographics

Table 1. Demographic and Clinical Characteristics at Baseline.*

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

Baden et al, NEJM, 30Dec2020

- Leverage Existin
  - Existing CABs
  - SPH & Rodham
  - Community gro
- Legwork!
- Traditional Medi
- Social Media
- Participant amb

The Washington Post
Democracy Dies in Darkness

LOCAL

GWU's covid-19 clinical trial has met one early goal — getting Black and Latino people to join

By Fredrick Kunkle

September 13, 2020 at 8:00 a.m. EDT

Mark M. Spradley, 66, volunteered to be a test subject in George Washington University's clinical trial for a vaccine for the coronavirus. (Sarah L. Voisin/The Washington Post)

Moderna Phase 3 – GW Recruitment Strategies

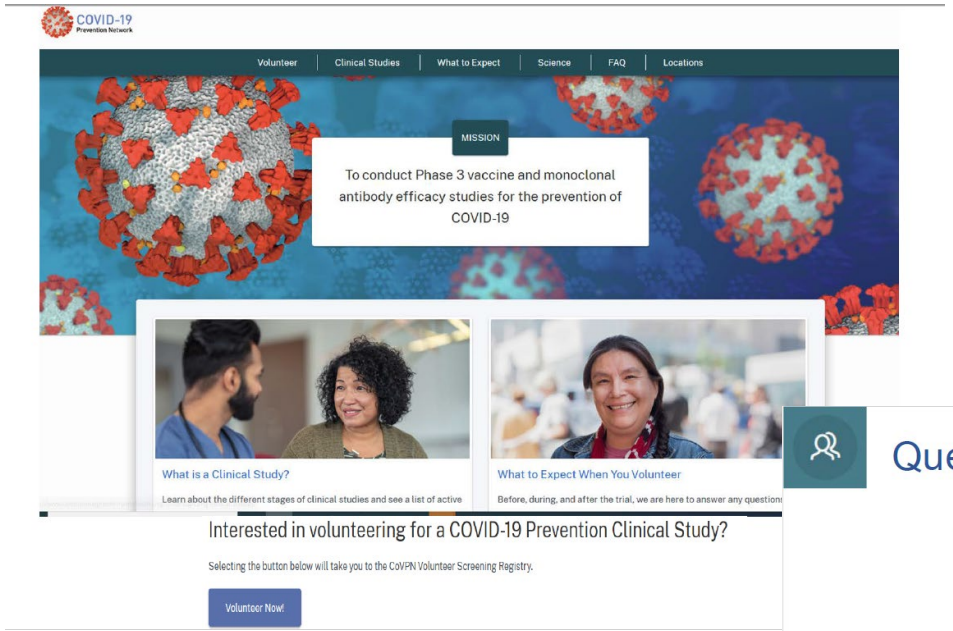
- Websites
  - CoVPN Volunteer Screening Registry
  - NextDoor
  - ResearchMatch
  - PatientWing
  - www.covid19studies.org
- Social Media
  - Facebook, Twitter, Instagram
  - Press Release
  - GW VRU Website
- Traditional Media
  - TV
  - Radio
  - Print

COVID-19 vaccine clinical trial at GW

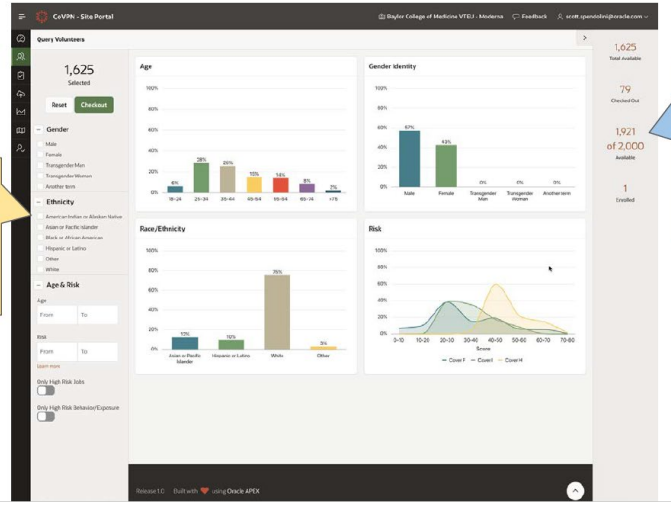
Dr. David Diemert discusses a potential COVID-19 vaccine that will be tested at George Washington University.

Posted July 28, 2020

CoVPN Volunteer Registry



Query Volunteers

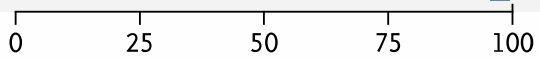


Filter Available Volunteers on:
- Gender
- Ethnicity
- Age
- Risk Scores

View details for:
- Total surveys
- Max # the site can checkout at a time
- # Currently checked out
- # Available for checkout
- # Enrolled

mRNA-1273 Phase 3 Efficacy

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



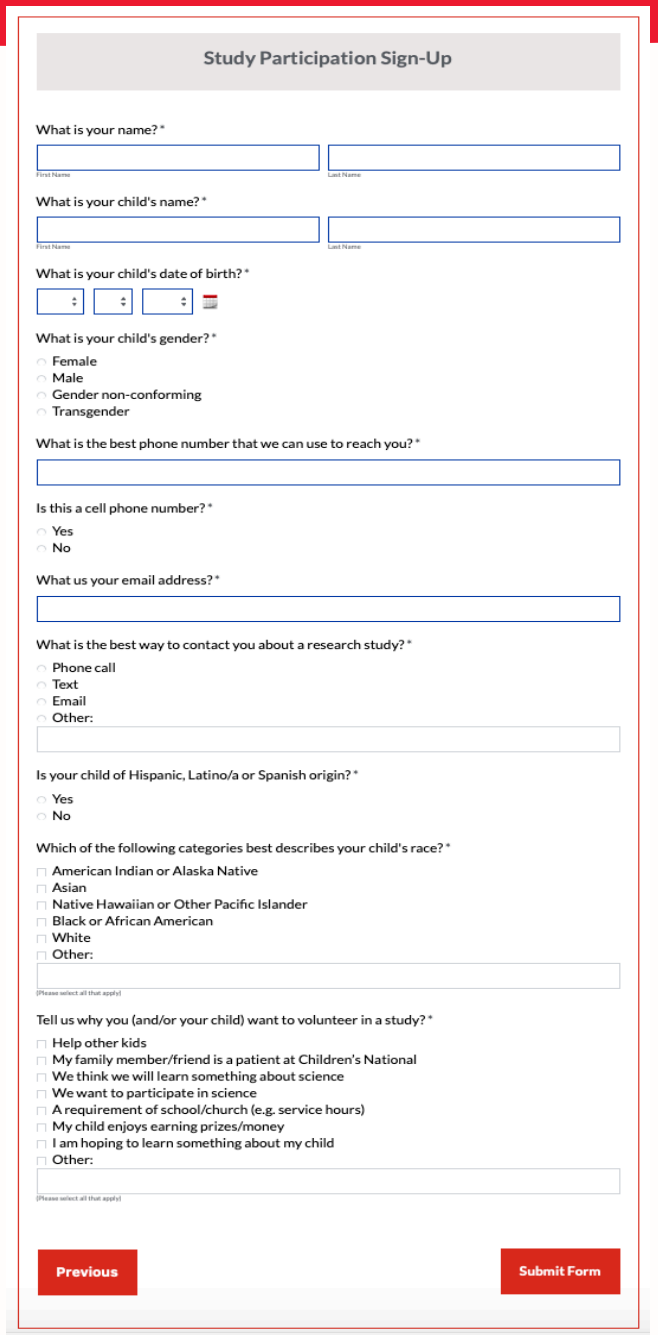
Baden et al, NEJM, 30Dec2020

Children's National

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



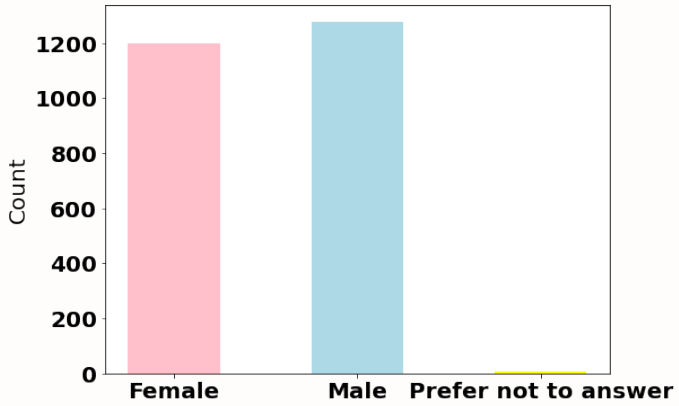
[Healthy Heroes - Clinical Trials | Children's National Hospital (childrensnational.org)]

Healthy Heroes Normal Cohort

Total registrants: 2486

Distribution by age groups

0-1yo	152
2-5yo	975
6-10yo	1058
11-14yo	302
15-18yo	0



Children's National

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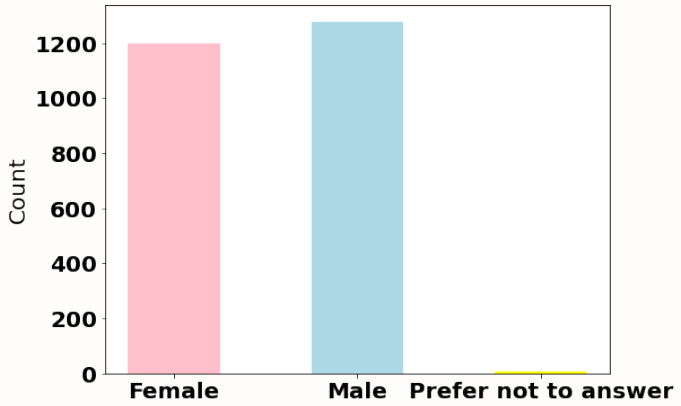
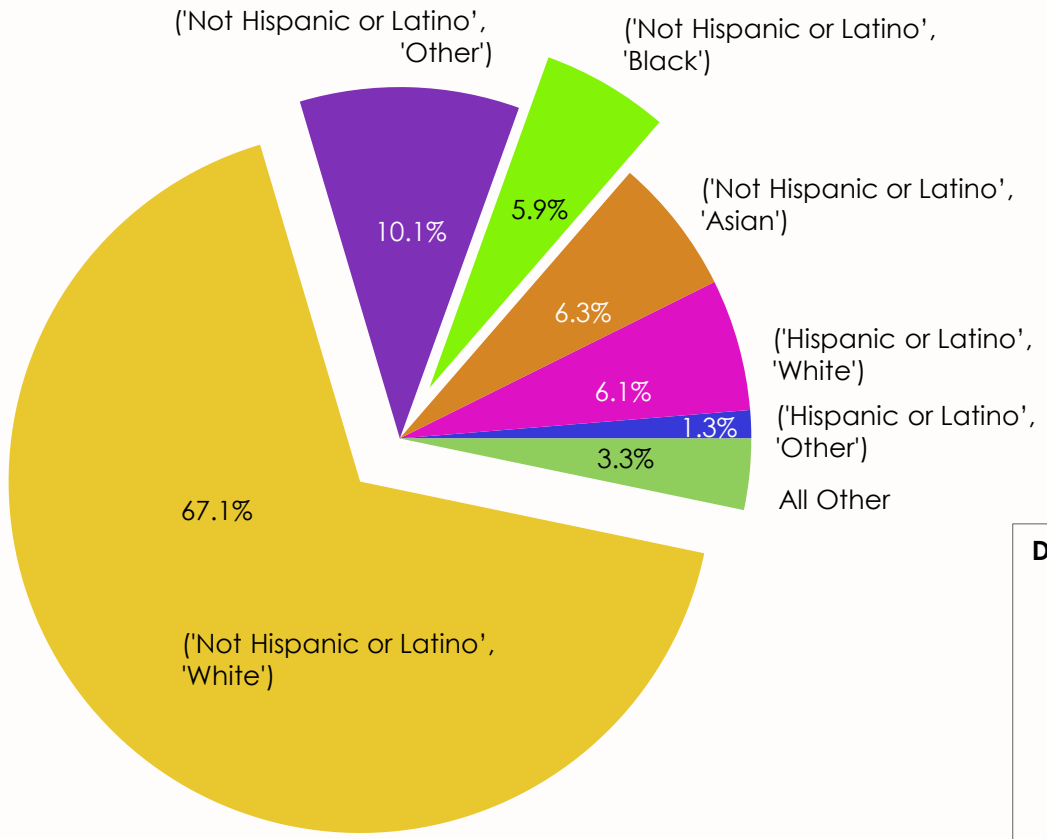




DMV Demographics

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

https://censusreporter.org

Children's National

CONTACTS

- Dr. Lisa Guay-Woodford
  lguaywoo@childrensnational.org
- Dr. Beth Tarini
  btarini@childrensnational.org
- Jasmine Jaber
  jjaber@childrensnational.org

Bootcamp on Clinical Research for New Investigators

Session 3:
Participant recruitment and retention

Radio outreach to Latinx communities

Washington, DC
January 19, 2023

Elmer E. Huerta, MD, MPH

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


VIDENZA
PODER
PODER
DELL

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.

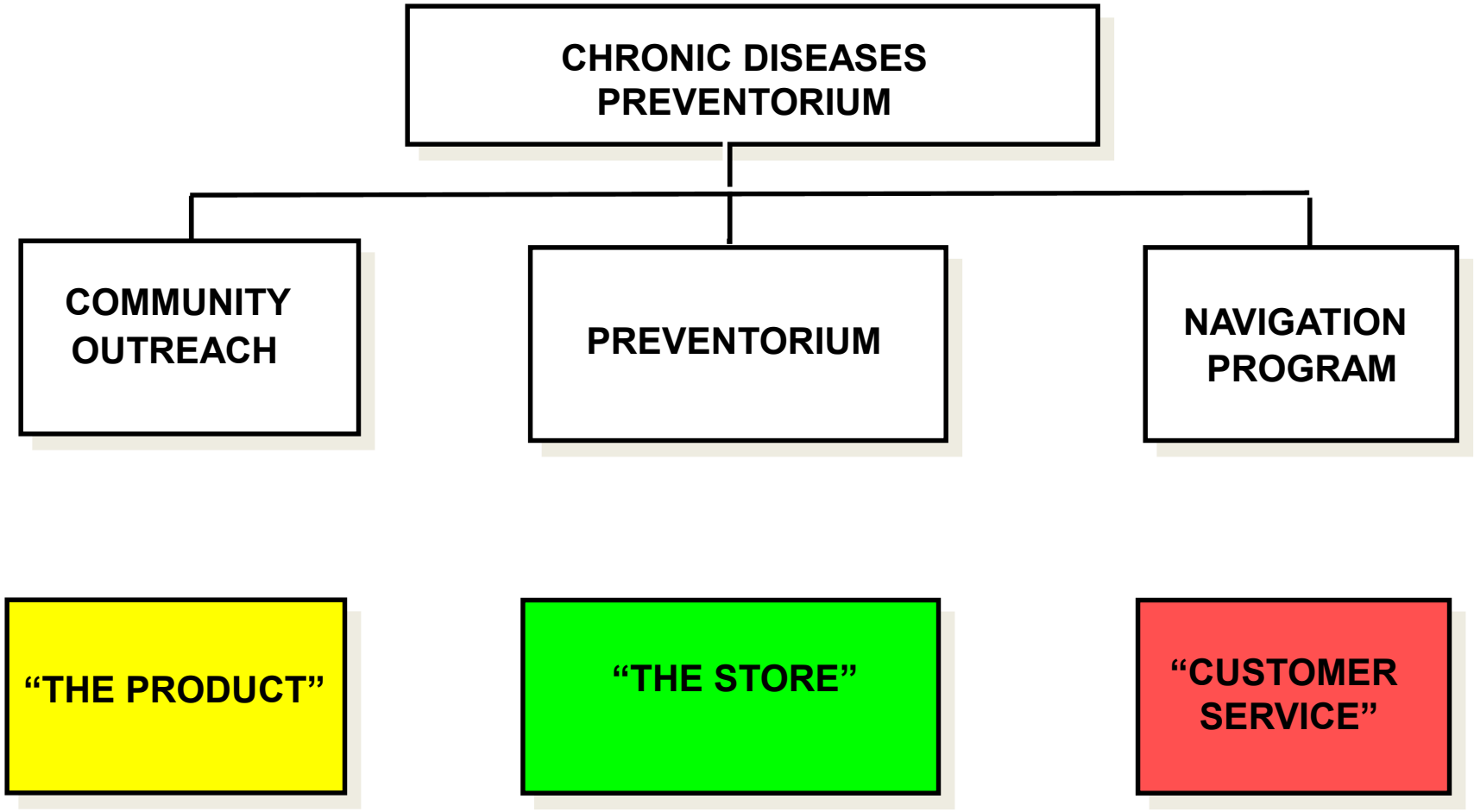
Our proposed definition

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

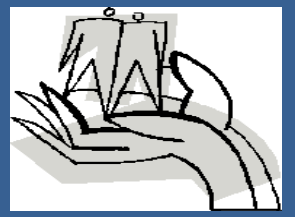
Preventorium Model



Preventorium Model

Use od media by a trusted professional

Preventorium

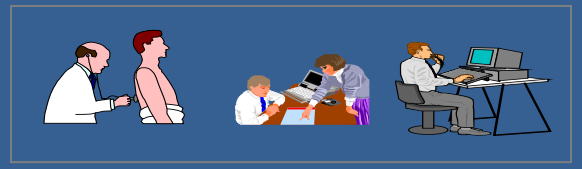


Navigation

Personalized follow up

Registration and data collection

Tools



Interventions

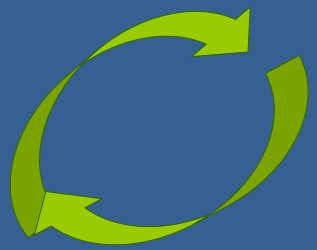
Link to primary care services

Genetic testing

Clinical trials enrollment

Lifestyle interventions

Culturally and ethnically sensitive messages



Revisit for continuous care

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

The Washington Cancer Institute at
MedStar Washington Hospital Center

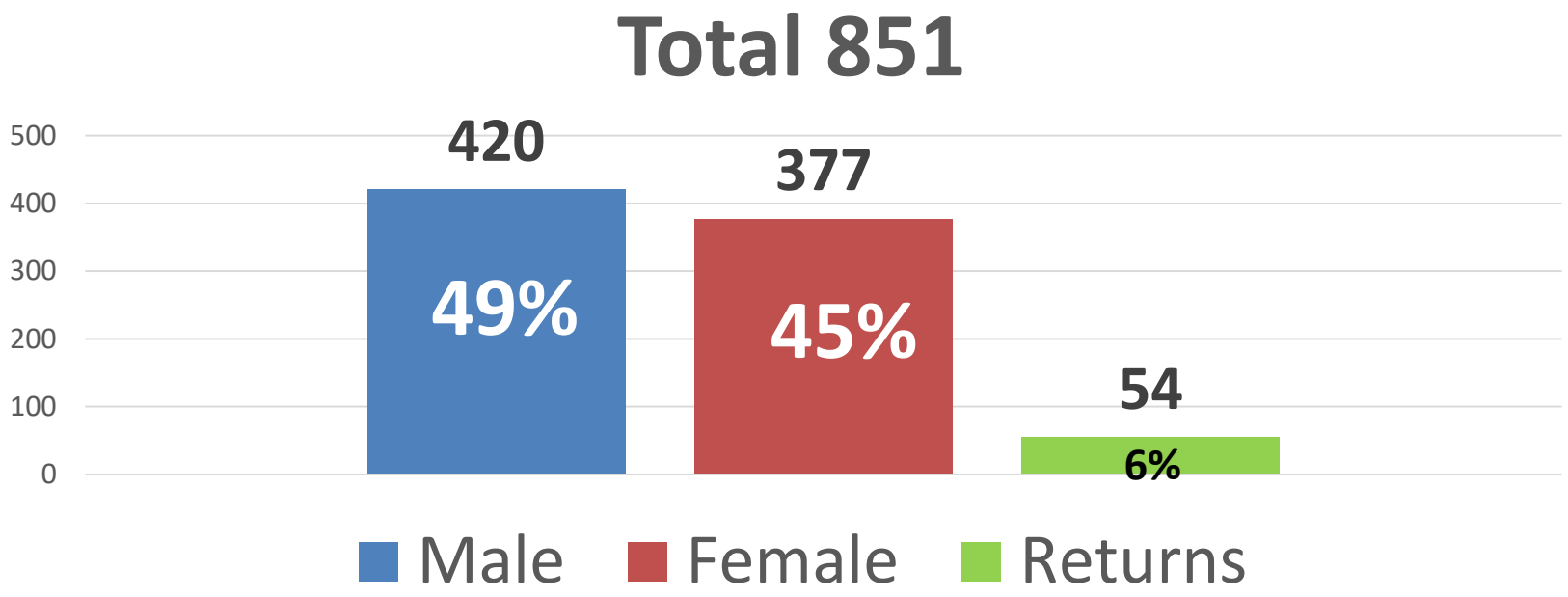
Cancer Preventorium

GENDER:

Male: 12,052 (31%)

Female: 26,120 (69%)

Patients seen at the GW Cancer Preventorium
September 3, 2020 to January 12, 2023



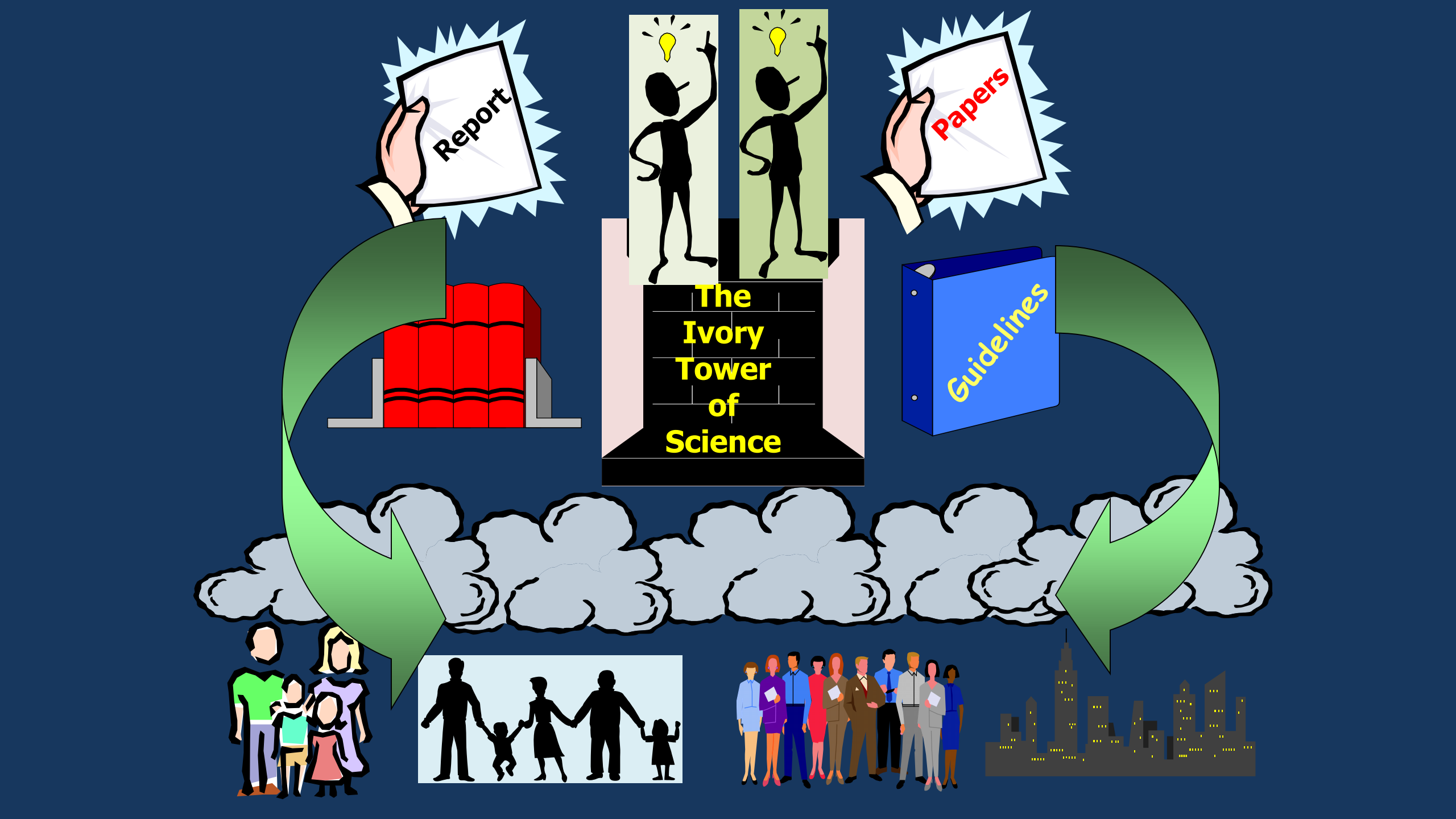
I still consider good information to be the best medicine

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


Report
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Guidelines

eConsent and Tracking

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

ENTER

GW Office of Clinical Research

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01.

Introduction

What are eConsents?

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

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02. 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

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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

01

02

03

04

01
02
03
04

03.

Storage

How best to store your eConsents

HOW 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.

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04.

Thanks!

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

Children's National

Single IRB Overview

January 19, 2023 | Almarie S. Coleman, CIP | Reliance Manager | OPHS

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.*

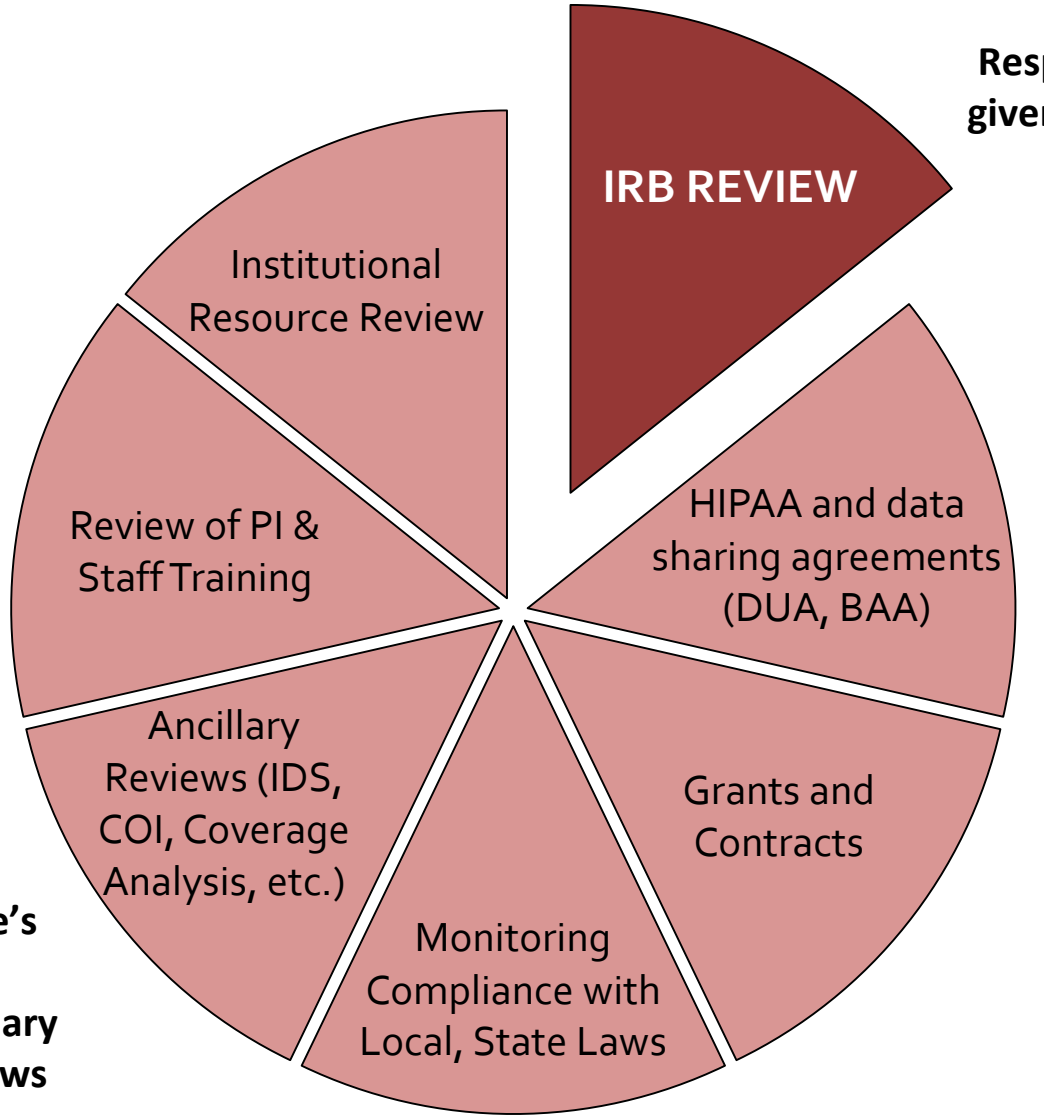
More Definitions

- **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.

Responsibilities given to the sIRB



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

*Slide adapted with permission from Megan K. Singleton (JHU IRB)

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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

	sIRB	PI and IRB Liaison
Primary	Initial Review of Protocol Review of Local Investigator Overall Protocol Modifications Annual/Continuing Review Approval of Study Wide ICF's Reportable Events Study Closeout	Request Reliance Agreement for Relying Sites
		Develop Communication Plan (plan for communication with collaborators across the life span of the study)
		Provide information to IRBs at institutions relying on the single IRB
		Provide Site Investigators with IRB policies of the sIRB (i.e., reporting unanticipated problems, noncompliance, etc.)
		Provide relying site study teams with IRB approved versions of all study documents
		Prepare and submit IRB application on behalf of all sites, including initial review, local amendments, personnel updates, local reportable events, etc.
Secondary	Review of Additional Sites 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	Notify Site Investigators of all Reviewing IRB determinations and communications, including those for initial review, continuing review, amendments, and reportable events
		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 ceded review.

Resource: SMART IRB

RESOURCES:

Children's National:

- Research Navigator: https://cnmc.sharepoint.com/sites/research/SitePages/Research-Navigator-Resources.aspx
- Single IRB Guidance Document: https://cnhirb.huronresearchsuite.com/IRB/sd/Doc/0/D7PC5BVU6C8UOM44NGE9CLIG00/Single%20IRB%20Guidance%20Document%20v3.pdf

George Washington University:

- Training Assistance: https://humanresearch.gwu.edu/training-assistance
- Research Tools: https://humanresearch.gwu.edu/research-tools

Children's National

sIRB Contacts

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

George Washington University:
Lacey Maddox – ohrirb@gwu.edu

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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:

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116

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

Children's National