



NIA IMPACT
COLLABORATORY
TRANSFORMING DEMENTIA CARE

Inclusion, Diversity, and Equity in Pragmatic Clinical Trials



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Housekeeping

- All participants will be muted
- Enter **all questions** in the Zoom **Q&A** or **chat box** and send to All Panelists and Attendees
- Moderator will review questions from chat box and ask them at the end
- Want to continue the discussion? Look for the associated podcast released about 2 weeks after Grand Rounds.
- Visit [impactcollaboratory.org](https://www.impactcollaboratory.org)
- Follow us on Twitter: **@IMPACTcollab1**
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Disclosures as of April 15, 2021:

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Dr. Wilkins receives research support from:

- National Institutes of Health
- Patient-Centered Outcomes Research Institute
- Robert Wood Johnson Foundation
- American College of Radiology and Alzheimer's Association

What is meant by **diversity**?

RACE IS A SOCIOPOLITICAL CONSTRUCT

- **Race:** group a person belongs to (or is perceived to belong to)
 - based on physical attributes – skin color, facial features and hair
 - a socio-political construct; fluid (changes over time)
 - no biological or scientific basis
- **Ethnicity:** group a person belongs to based on culture, language, physical attributes, religion, country of origin
- **Ancestry:** line of descent; usually refers to DNA
- **Culture:** a society's collective thoughts, actions, customs, beliefs, and values



<http://i0.wp.com/panafricanalliance.com/wp-content/uploads/2011/05/RacialDifferences.jpg>

Race



Current Population

World Population by Region in 2020

Population	World Share	Yearly Change	Median Age
Asia: 4,641,054,775	59.5%	0.9%	32
Africa: 1,340,598,147	17.2%	2.5%	20
Europe: 747,636,026	9.6%	0.1%	43
Latin America & Caribbean: 653,962,331	8.4%	0.9%	31
Northern America: 368,869,647	4.7%	0.6%	39
Oceania: 42,677,813	0.5%	1.3%	33

@DrCHWilkins

Changing Population

1950 Population | World Share

Asia: 1,404,909,021 | 55.4%

Europe: 549,328,883 | 21.7%

Africa: 227,794,136 | 9%

Northern America: 172,602,624 | 6.8%

Latin America & Caribbean: 168,820,620
| 6.8%

Oceania: 12,975,865 | 0.5%

Europe's % of World Population

1950: 22%

2020: 9.6%

2050: 7%

2050 Population | World Share

Asia: 5,290,263,118 | 54.3%

Africa: 2,489,275,458 | 25.6%

Latin America & Caribbean: 762,432,366 |
7.8%

Europe: 710,486,313 | 7.3%

Northern America: 425,200,368 | 4.4%

Oceania: 57,376,367 | 0.6%

What is meant by **inclusivity**?

Recruitment Continuum

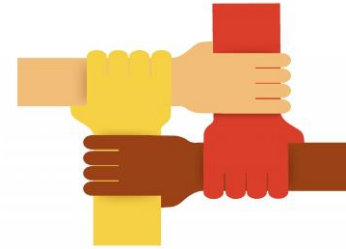
Awareness Campaign



Tailored Recruitment Materials



Culturally congruent staff



Results to Community & Providers



Community Partners



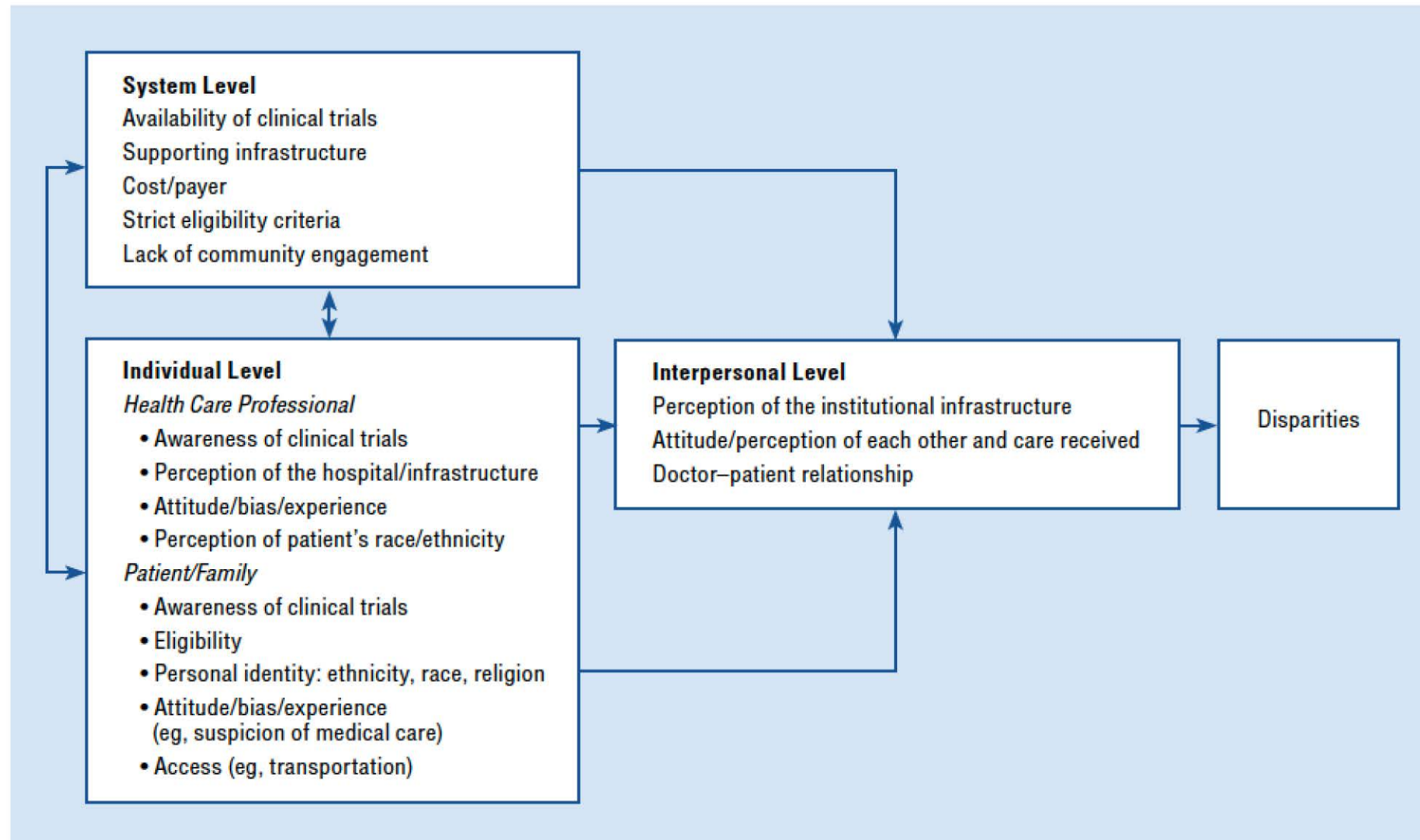
Consent forms in multiple languages



MyCap in translated versions



Factors contributing to lack of diversity in clinical trials



Study-level Barriers to Recruiting Racial and Ethnic Groups Historically Excluded

Investigators

- Limited knowledge/experience recruiting diverse groups
- Few, if any, minority researchers
- Little to no experience working with community orgs
- Ineffective communication strategies
- Lack of cultural humility

Study-level barriers

- budgets inadequate for recruitment
- no expertise to culturally adapt tailor documents
- lack of culturally congruent research staff
- No bilingual staff or access to language services



**RARE DISEASES
HAVE MET THEIR MATCH**

researchmatch.org
Difficult diseases have met their match.

By participating in clinical research you can play an active role in healthcare and contribute to medical research.

1. LOG ON
Visit the web site at www.researchmatch.org to learn more about this opportunity.

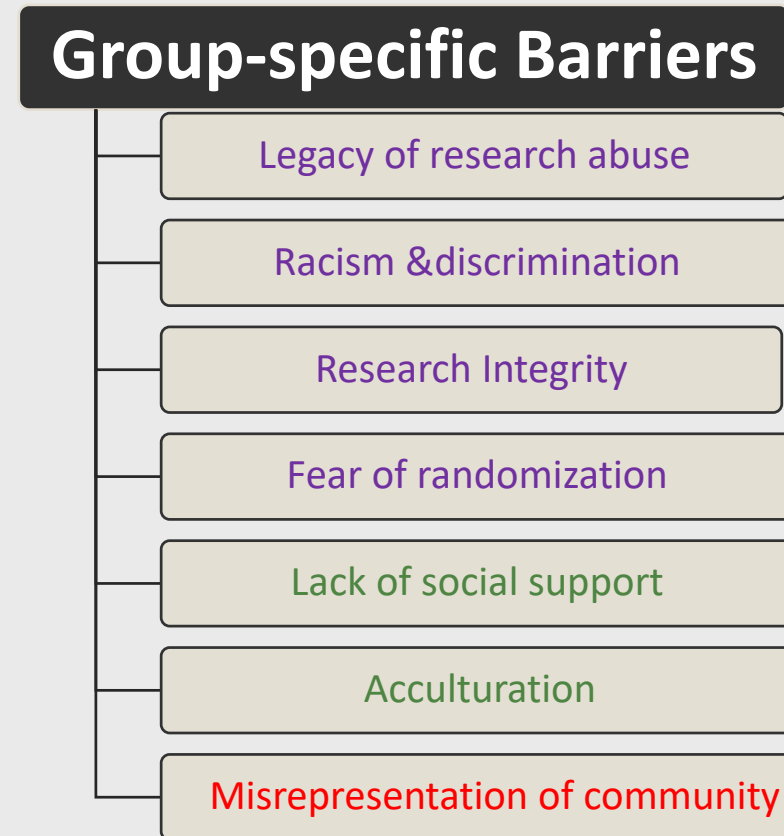
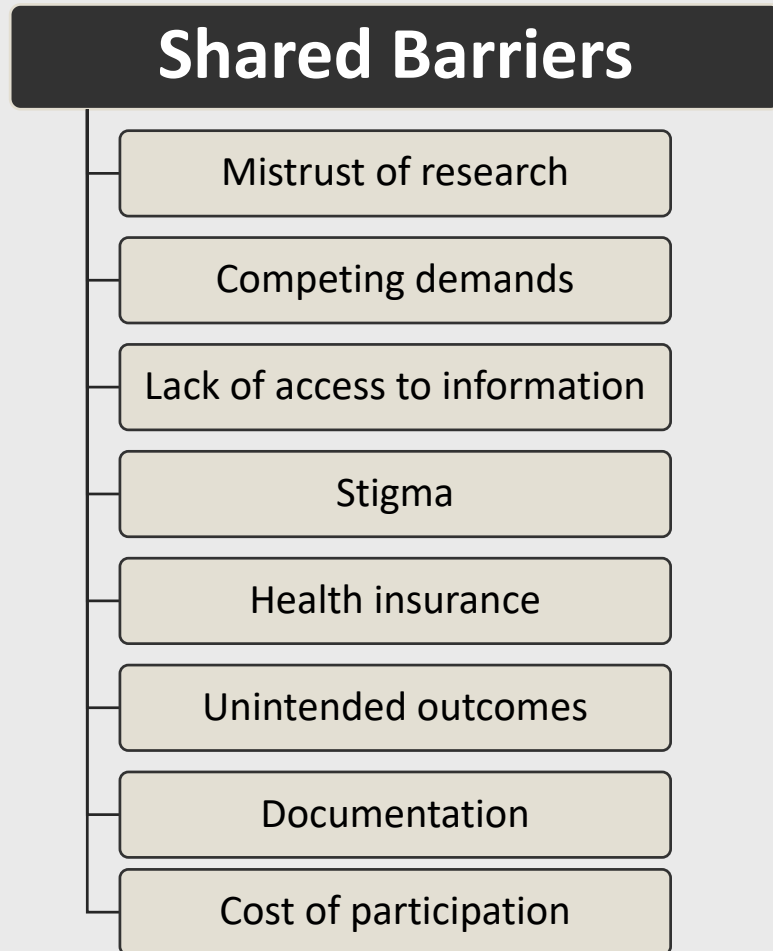
2. REGISTER
Create an online profile and fill in your contact and health information.

3. PARTICIPATE
Wait to be contacted by researchers who think you may be a good match for their study.

FIND YOUR MATCH. JOIN IN THE FIGHT.

ResearchMatch is a not-for-profit effort that brings together researchers and people who are willing to learn more about research studies via a secure and convenient online web portal.

Barriers to clinical trial participation among African American, Hispanic/Latinx, Asian American, and Pacific Islander groups



African American

Asian

Pacific
Islander

Guiding Principles for Successful Trial Recruitment

- Set accrual goals
 - based on evidence of recruitment feasibility, not solely patient counts
- Be transparent about potential risks/adverse events
- Minimize participant burden
- Offer compensation that reflects the true costs of participation (e.g., time-off work, transportation, childcare)
- Set an appropriate budget for recruitment and retention
- Employ a diverse, experienced team
- Share results/return value to participants and community

Strategies to Enhance Minority Recruitment

1. Embed researchers with expertise in minority health and health disparities into research teams
2. Integrate the perspectives of individuals from marginalized groups in the study design and planning
3. Train research teams in cultural humility and effective communications
4. Partner with trusted community organizations
5. Hire individuals with experience working in communities
6. Support an asset-based, community-led approach to recruitment

Hire individuals with experience working in communities

- Specifically, hire individuals with experience working in communities that you want to recruit from
- Preferably individuals from marginalized communities as study coordinators/recruitment staff
- Prioritize individuals who are bilingual and bicultural



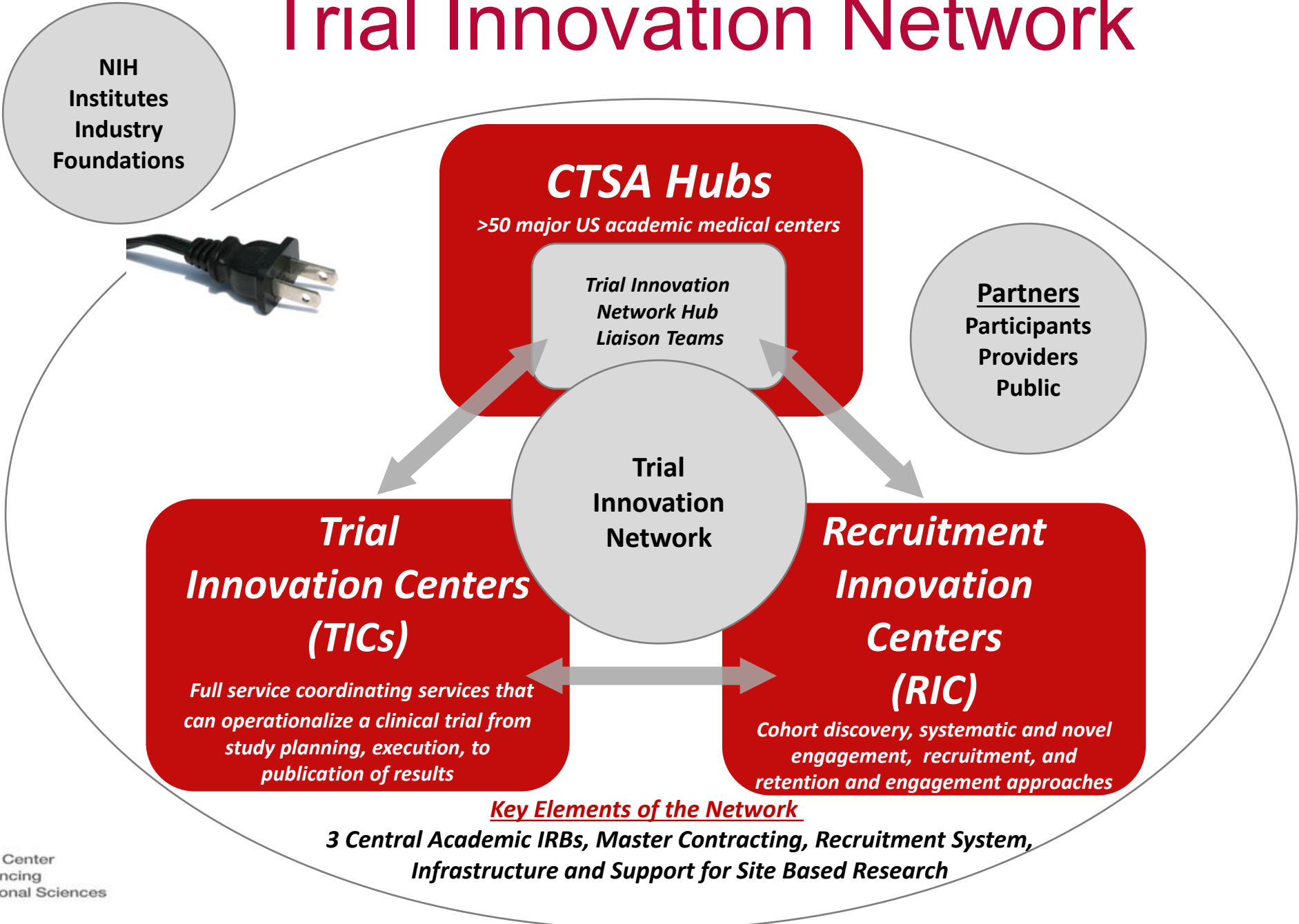
Support an asset-based community-led approach to recruitment and retention

- Prepare/support community – emphasize co-learning
- Community capacity building

TABLE 1 | WAI-Milwaukee Asset-Based Community Development (ABCD) Approach, examples of community activities and current outcomes.

Panel A: Core Aspects of ABCD Approach	Panel B: Examples of Activities	Panel C: Outcomes
<p>Community assessment</p> <ul style="list-style-type: none"> • Identify the community and their assets • Identify key community stakeholders • Address the community needs and wants 	<p>Outreach & Education</p> <ul style="list-style-type: none"> • Breaking the Silence Annual Breakfast and Community Workshops • The “Amazing Grace” Chorus Family Support Program • Annual Faith-Based ADRD Initiatives 	<p>Stigma Reduction</p> <p>Increased community awareness of ADRD</p>
<p>Community engagement (WAI-Milwaukee becoming part of community “social fabric”)</p> <ul style="list-style-type: none"> • Invest time in the community • Provide resources identified by the community • Address barriers through service 	<p>Coordination of Medical & Social Services Milwaukee Health Services Center & Clinic Network Development</p> <p>Culturally inclusive professional training</p>	<p>Increased access of community members to comprehensive care and support services</p>
<p>Community involvement</p> <ul style="list-style-type: none"> • Recognize community members as experts • Validate community members’ perspectives • Build relationships between community members, researchers, and health professionals • Community members provide counsel to WAI-Milwaukee and researchers 	<p>Community Advisory Board development and sustenance</p>	<p>Academic-community partnership in initiatives</p> <p>Increased community awareness of importance of research</p> <p>Increased African-American participation in research</p>

Trial Innovation Network



Key Elements of the Network

3 Central Academic IRBs, Master Contracting, Recruitment System, Infrastructure and Support for Site Based Research

Trial Innovation Network

NIH
I
Fo

Duke Clinical Research Institute

UNIVERSITY OF UTAH HEALTH CARE

Ford

VANDERBILT UNIVERSITY MEDICAL CENTER

Benjamin

Dean

JOHNS HOPKINS MEDICINE

Tufts Medical Center

CTSA Clinical & Translational Science Awards

Bernard

Hanley

Selker

NIH National Institute on Aging

NIH NLM

Harris

VANDERBILT UNIVERSITY MEDICAL CENTER

WILKINS

MEHARRY MEDICAL COLLEGE

NIH National Center for Advancing Translational Sciences

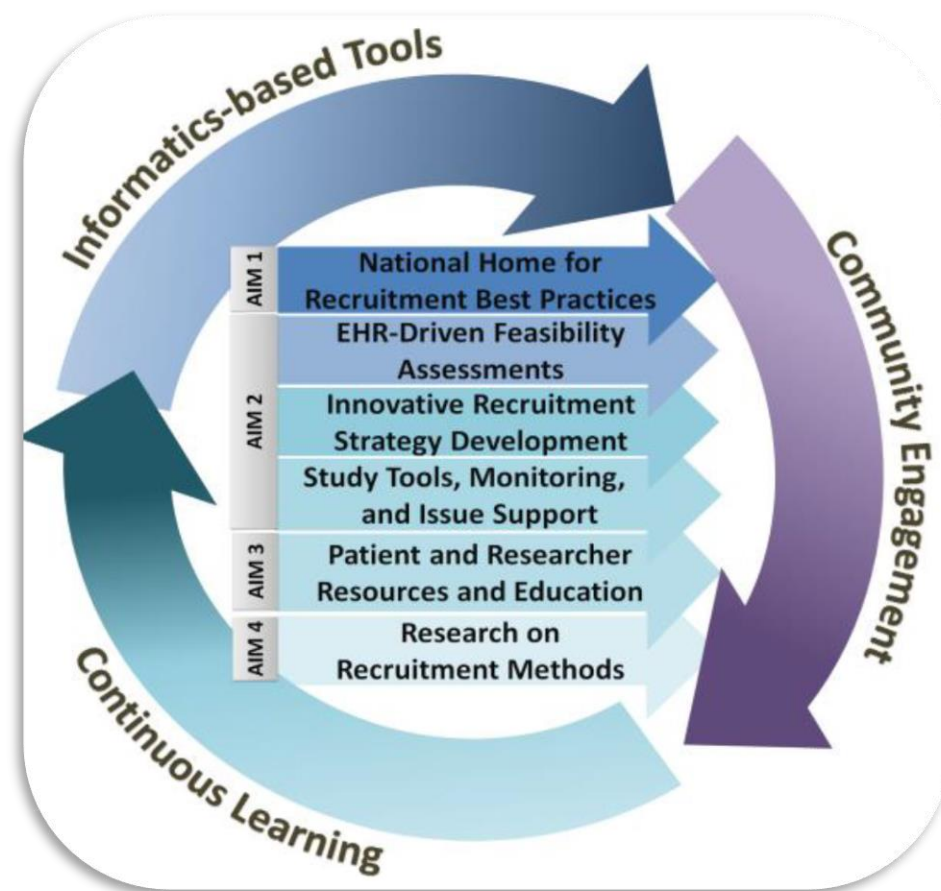
NIH

Central Academic IRBs, Master Contracting, Recruitment System, Infrastructure and Support for Site Based Research

Vision and purpose

Our goal is to positively impact human health by **improving participant enrollment and retention in multi-center clinical trials.**

Achieving this goal will require sophisticated **informatics-based recruitment tools** and **novel engagement approaches** to accelerate recruitment and retention.



Recruitment Continuum: Example COVID Vaccine Trials

National Campaign



Tailored Recruitment Materials



Culturally congruent staff



Results to Community & Providers



Community Partners



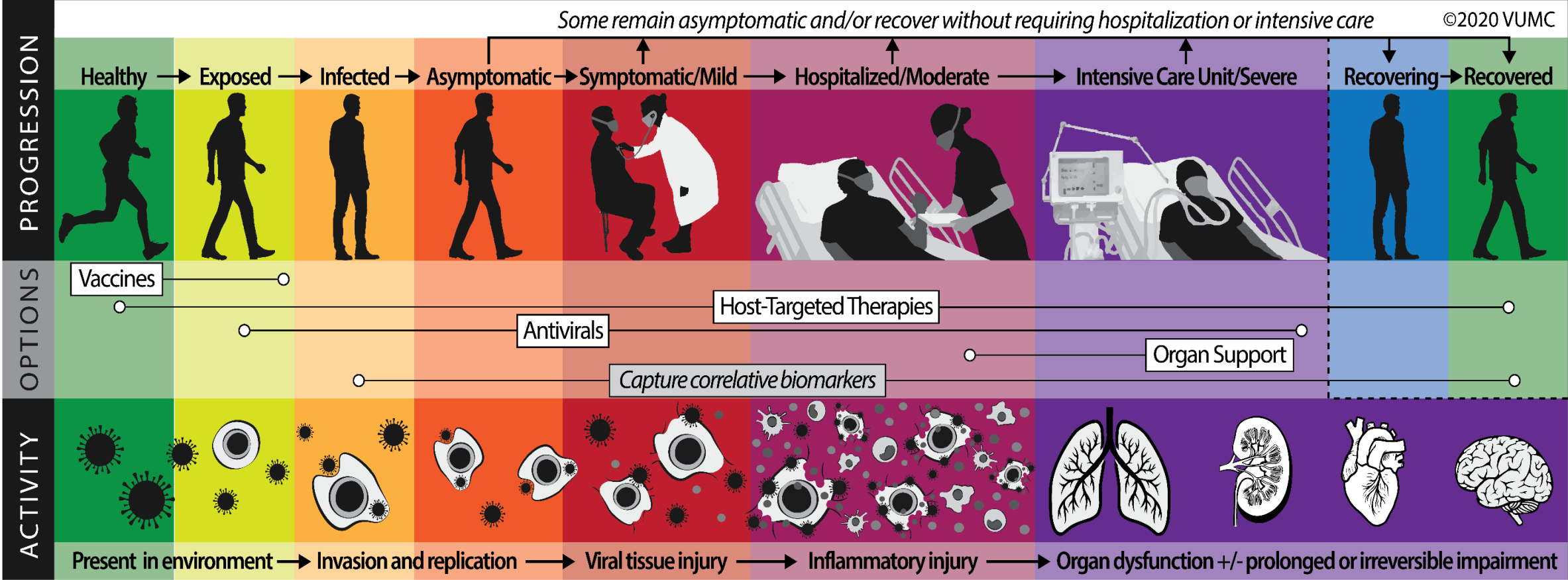
Consent forms in multiple languages



MyCap in translated versions



COVID lifespan progression



Comprehensive Approaches to Minority Recruitment

Goal: Address study-specific and common barriers

Common Barriers

Scientist –level barriers

- Limited experience recruiting minorities
- Lack relationships with community orgs
- Few, if any, minority researchers

Participant-level barriers

- Perceived harms, fear, mistrust
- Costs, transportation, access, convenience
- Info unavailable in preferred language

Study-level barriers

- Budgets inadequate for recruitment
- No expertise to culturally tailor documents
- Lack of culturally congruent research staff

Study-Specific Barriers

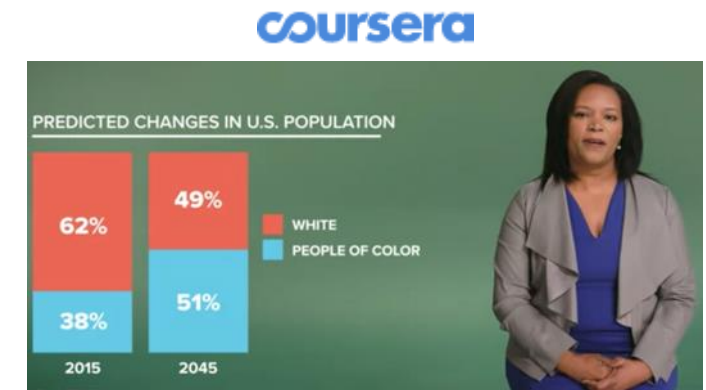
- Misinformation about COVID-19
- Concerns re safety of COVID-19 tests, treatments, vaccines
- Limited access to testing and care
- Fears related to government involvement
 - Contact tracing
 - Information being shared w/ law enforcement
- Stigma related to COVID-19
- Lack of dedicated staff to support recruitment
- No information/resources for family and household members involved in decision making
- Study materials not available in multiple languages
- Minimal/no involvement of trusted leaders/community orgs

Heller et al. Strategies addressing barriers to clinical trial enrollment of underrepresented populations: a systematic review. *Contemp Clin Trials*. 2014;39(2):169-182.

Schmotzer GL. Barriers and facilitators to participation of minorities in clinical trials. *Ethn Dis*. 2012;22:226–30

Enabling Minority Recruitment

- **Identify** sites with capacity to recruit minorities
 - Contact sites with higher % minorities
 - Questions on site selection to determine interest/capacity
 - Prior experience recruiting minorities, bilingual staff
- **Support** facilities in minority recruitment
 - Training in minority recruitment
 - Culturally tailored recruitment materials
 - Information to address fears related to radiation



Enabling Minority Recruitment (cont)

- **Increase** pipeline of referrals to COVID-19 research sites
 - Identify primary care and community champions
 - Professional and community-focused orgs, National Med Assoc, Assoc
- **Create** awareness of study
 - National campaign; using tailored messaging
- **Partner** with trusted community organizations
 - Engage through trusted community organizations
 - Support families in decision making and study participation



COVID-19 - Library of Recruitment Materials

Join the fight against the COVID-19 pandemic. Become a part of the VUMC Research Registry.

- Our world-renowned researchers are focusing on finding ways to prevent, diagnose and treat COVID-19. **We can't do it without you!**
- People who work in healthcare* are at the highest risk. This is because of the critical role they serve in supporting the care of our COVID-19 patients.
- **Register now** if you would like to be contacted about COVID-19 research studies at VUMC.

*Working in a clinical area in a supportive role or in a direct patient care role for our patients who have or may have COVID-19.

To Register: Complete a short online survey so VUMC researchers may contact you about COVID-19 research studies that could be right for you.

Contact: Email: research.support.services@vumc.org Hotline: 615-322-7343

Join the fight against the COVID-19 pandemic. Become a part of the VUMC Research Registry.

- Our world-renowned researchers are focusing on finding ways to prevent, diagnose and treat COVID-19. **We can't do it without you!**
- People who have tested positive or think they've had COVID-19 can help us answer the most important research questions as quickly as possible.
- Essential workers are at higher risk for getting COVID-19. This is because the critical role they serve in keeping our communities up and running.
- **Register now** if you would like to be contacted about COVID-19 research studies at Vanderbilt University Medical Center (VUMC).

To Register: Complete a short online survey so VUMC researchers may contact you about COVID-19 research studies that could be right for you.

Contact: Email: research.support.services@vumc.org Hotline: 615-322-7343

VANDERBILT UNIVERSITY MEDICAL CENTER

If you join the VUMC COVID-19 research registry, you are not obligated to take part in a research study. You will not be enrolled in any studies without your consent. Becoming a part of this registry does not guarantee that you will be able to join a study. Taking part in this research registry will not affect any future care for you at Vanderbilt University Medical Center.

VANDERBILT UNIVERSITY MEDICAL CENTER

If you join the VUMC COVID-19 research registry, you are not obligated to take part in a research study. You will not be enrolled in any studies without your consent. Becoming a part of this registry does not guarantee that you will be able to join a study. Taking part in this research registry will not affect any future care for you at Vanderbilt University Medical Center.

What is the COVID CSSC-004 study?

- This study will test whether a transfusion of plasma that has antibodies from persons who have recovered from COVID-19 is a good treatment for patients with early COVID-19 illness.
- Before you get the infusion, the blood bank will test the plasma for other infectious diseases.

Helpful Definitions:

- **Antibodies** are part of the body's immune system.
- **Plasma** is the liquid portion of the blood.

What's involved?

- One plasma infusion. A computer will assign you by chance to get either plasma with COVID antibodies or plasma without COVID antibodies.
- Up to 5 in person visits over 90 days
- Medical history
- Physical exam
- Blood tests
- Daily log of symptoms

Can I join?

You may be able to join if you:

- Are 18 years of age or older
- Tested positive with SARS-CoV-2 virus within the past 6 days or less
- Have had any COVID symptoms within the past 6 days or less:
 - cough
 - shortness of breath
 - fever
 - chills
 - muscle pain
 - headache
 - sore throat
 - new loss of taste or smell

Will I be compensated?

Yes, you will be compensated up to \$200 for study participation.

Taking part in this study is completely voluntary.

Your blood could save lives.

JOIN THE FIGHT AGAINST COVID-19

Have you tested positive for COVID-19 and recovered?

You may be able to join our research study to test if antibodies in your blood could help others recover faster.

Contact us today to see if you can join. Together we can make a difference.

Study Contact Name
Study Contact Phone
Study Contact Email

COVID CSSC-004 Research Study

Have you been diagnosed with COVID-19 illness, but are not in the hospital?

Join us in our fight against the virus, SARS-CoV-2, which causes COVID-19 illness.

What is the study about? This study will test whether a transfusion of plasma that has antibodies from persons who have recovered from COVID-19 is a good treatment option for patients with early COVID-19 illness.

What's involved?

- One plasma infusion
- Physical exam
- Up to 5 study visits*
- Blood tests
- Medical history
- Daily symptom log

*You may be compensated up to \$200 for study participation

Can I join? You may be able to join if you:

- Are 18 years of age or older
- Tested positive for SARS-CoV-2 virus within the past 6 days or less
- Have had any COVID symptoms within the past 6 days or less (cough, shortness of breath, fever, chills, muscle pain, headache, sore throat, new loss of taste of smell, neurological changes, or new skin rash)

Learn More Or visit our website at CovidPlasmaTrial@jhmi.edu

Contact Us CovidPlasmaTrial@jhmi.edu

Logo Placeholder
Principal Investigator: David Sullivan, MD
Proposed Number: 1802447902
ClinicalTrials.gov: NCT04373460

COVID-19

En estos tiempos de COVID-19, vemos la importancia de la investigación clínica y cómo sigue siendo una prioridad. En Vanderbilt Institute for Clinical and Translational Research (VICTR), usamos nuestros conocimientos para encontrar maneras de prevenir, diagnosticar y tratar el COVID-19.

Hacemos esto mediante nuestro compromiso de:

- **Colaborar con las instituciones de todo el país.** VICTR trabaja con instituciones académicas, centros médicos y agencias del Gobierno de toda la nación en investigaciones clínicas diseñadas para entender y tratar mejor el COVID-19.
- **Investigar estrategias nuevas de prevención y tratamiento.** VICTR colabora con expertos en enfermedades infecciosas y desarrollo de medicamentos para crear nuevas estrategias para afrontar la pandemia.

Lo que debe saber hoy

Estamos trabajando de manera activa en proyectos de investigación para aprender más sobre las mejores maneras de diagnosticar, tratar y prevenir la enfermedad del COVID-19.

En este momento, estamos buscando personas que tengan o hayan tenido un caso confirmado o sospechado de la enfermedad del COVID-19 y que quieran participar en estudios de investigación.

Haga clic en el botón de abajo para completar una breve encuesta, y podríamos comunicarnos con usted por un estudio de investigación o varios.

Quiero que se comuniquen conmigo por estudios del COVID-19

eConsent



eConsent has addressed the problems of:

- How to continue doing research studies during a pandemic?
- How to do studies with COVID-19+ participants and keep everyone safe, preserve PPE, and reach LARs, parents, translators, etc., when everyone is remote?

YouTube Channel for eConsent education videos: https://www.youtube.com/playlist?list=PLiMIsWK5xzDsjG_slun3JTDJxIzVWOIR2

Recent publication: [REDCap based model for electronic consent](#)

MyCap

The image displays four sequential screenshots of the MyCap mobile application interface. Each screenshot shows a survey question with a 'Next' button and 'Skip'/'Cancel' options at the bottom.

- Screenshot 1 (4 of 27):** Question: "Have you started taking any new medications that you have not yet reported to the study team?" Options: Yes, No (selected).
- Screenshot 2 (6 of 27):** Question: "Have you been to the hospital since your COVID-19 test?" Options: Yes, No (selected).
- Screenshot 3 (10 of 27):** Question: "Check the COVID-19 symptoms you are experiencing." Checklist items: Cough (checked), Fever, Shortness of breath (checked), Chest pain, Abdominal pain (checked), Nausea or vomiting.
- Screenshot 4 (27 of 27):** Question: "Would you like us to call you regarding any aspect of this study?" Options: Yes, No (selected).

MyCap provides the ability to collect valuable data in the outpatient, post-discharge, and recovery contexts such as:

- Medication changes
- New hospitalization
- Symptoms
- Need for follow-up

Soon to be available in Spanish
And Portuguese!

ResearchMatch

¿En qué consiste ResearchMatch??

ResearchMatch es una plataforma útil en línea, gratis, segura y confidencial creada por instituciones académicas de todo el país que desean incluirlo en su misión de ayudar a que los estudios mejoren la salud en el futuro. ResearchMatch funciona al enviarle información por correo electrónico acerca de estudios que pueden ser adecuados para usted. [\[Preguntas frecuentes\]](#)

¿Por qué se necesita ResearchMatch?

Muchos estudios finalizan antes de tiempo porque no hay suficientes voluntarios para el estudio. Al mismo tiempo, las personas buscan estudios para participar, pero puede ser difícil encontrarlos. En consecuencia, las preguntas claves que pueden afectar la salud comunitaria quedan sin respuesta.

¿Es ResearchMatch para mí?

Cualquier persona que viva en los Estados Unidos, incluyendo Puerto Rico, puede unirse a ResearchMatch. Son bienvenidas personas de todas las edades y orígenes. Un padre de familia, tutor legal o guardián puede registrar a un menor de 18 años, o bien, registrar a un adulto que no pueda unirse por cuenta propia.

Son numerosos los estudios que necesitan voluntarios saludables así como aquellos que presentan todo tipo de condiciones médicas. ResearchMatch es una plataforma que pone en contacto a personas con los estudios de investigación que puedan resultar una combinación para ellos, por medio de una herramienta segura en línea para establecer coincidencias. Siempre tiene la opción de decidir qué estudios pueden interesarle. Si se une a ResearchMatch, no se le exige que participe en un estudio. ¡Usted siempre tiene la decisión!

¿Cómo funciona ResearchMatch?



ÚNASE AHORA MISMO ACERCA DE INVESTIGADORES RED ENSAYOS RESULTADOS CONTÁCTENOS INICIE SESIÓN

research match.org

En este momento, dispone de:

voluntarios	investigadores	estudios	instituciones	publicaciones
146,308	8,599	774	176	454

[mas estadísticas](#)

In English

¡Por medio de la investigación, usted se convierte en parte de la solución!

Los descubrimientos médicos no serían posibles sin voluntarios como **usted**. ¡Los investigadores necesitan su ayuda! La investigación sobre la salud cambia la vida de las personas a diario. Sin embargo, muchos estudios finalizan antes de tiempo porque no hay suficientes voluntarios. Nuestra plataforma le ayuda a encontrar el estudio de investigación que más se ajuste a sus necesidades. Los investigadores necesitan tanto personas saludables como personas que padezcan todo tipo de condiciones médicas. ¡Cualquier persona puede ser candidata para estas investigaciones!

Algunas partes de Researchmatch.org no se pudieron traducir al español en esta ocasión por razones técnicas. Pedimos disculpas por el inconveniente y agradecemos su paciencia.

Únase ahora mismo

- Supports recruitment of people that speak English or Spanish
- Matches Spanish recruitment messages with people selecting Spanish language
- Offers Volunteer support, education, and engagement in Spanish

Community Engagement Studios

Guidance from CESs regarding clinical trial recruitment to date:

1. **Be aware of exclusion criteria** that limits participation.
2. **Remove systemic barriers** to participation (adding non-traditional times for study visits, transportation/stipends)
3. **Develop culturally tailored and translated** study materials being carefully not to pander.
4. **Partner** with respected community (national and local) organizations / contacts
5. **Train** study staff (e.g. cultural humility and bias) *Hire study staff **representative of community**.
6. **Disseminate** results in real time - full transparency to continue to establish and gain trust.



Continuum of Community Engagement in Research



Faster Together: Training Recruiters to Better Engage Minorities

- Training Recruiters- The Art of Recruitment
 - Course design, syllabus and curriculum created.
 - Course content created.
 - Filming of lessons and supporting materials finalized.
 - [Example](#) (3min 40")
 - Training in Coursera

FasterTogether: Mass Open Online Course for Enhancing Minority Recruitment in Clinical Trials

courseera



Faster Together, Enhancing the Recruitment of Minorities in Clinical Trials

Vanderbilt University

COURSE

★★★★☆ 4.9 (7)

Beginner

<https://www.coursera.org/learn/recruitment-minorities-clinical-trials>



100% online

Start instantly and learn at your own schedule.



Flexible deadlines

Reset deadlines in accordance to your schedule.



Beginner Level

Course launch: April 1, 2019

National Center for Advancing Translational Sciences, National Institutes of Health (U24TR001579), PIs: Wilkins and Harris

Videos

Importance of Increasing Minority Recruitment in Clinical Trials



LOW PARTICIPATION IN RESEARCH LIMITS:

- Ability to understand differences in effectiveness of treatments across populations
- Discovery of new drugs and devices
- Healthcare delivery
- Scientific knowledge

Save Note Discuss Download



English

Lecture Video mp4

Subtitles (English) WebVTT

Transcript (English) txt

Module 1 Slides odf

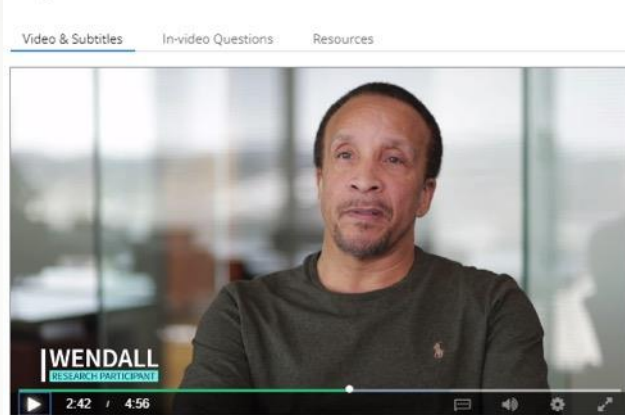
[Help Us Translate](#)

0:09 Clinical trials are an incredible part of healthcare. Clinical trial recruitment is a challenge. In five clinical trials either ex

improve health and safety. We have already found that almost one in five participants, or completed

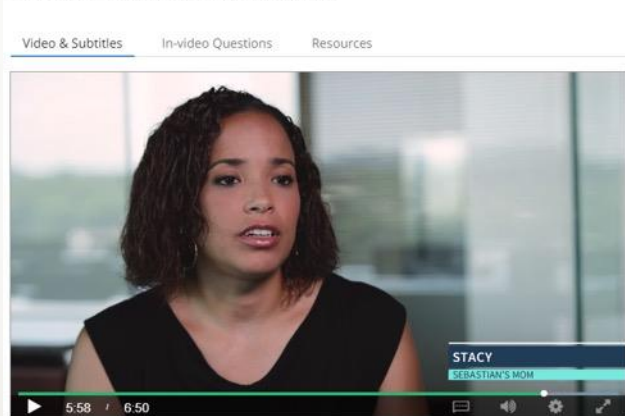
Interviews with Research Participants

Impact of Historical Abuses in Research



“I used to hear horror stories literally from my grandparents, starting with Tuskegee about what happened, and what was done, and wasn’t told to our community. So there has been mistrust for years.”

Person-centered Retention



“I have never heard back from any of the studies my son has been involved in, and...I would love to see what came of it... That’s also another reason why a lot of minorities don’t want to do the studies is because they never hear the results.”

Consuelo H. Wilkins, MD, MSCI
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