Diversity in Clinical Trials: Community Engagement Townhall

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September 20, 2024

UW Medicine

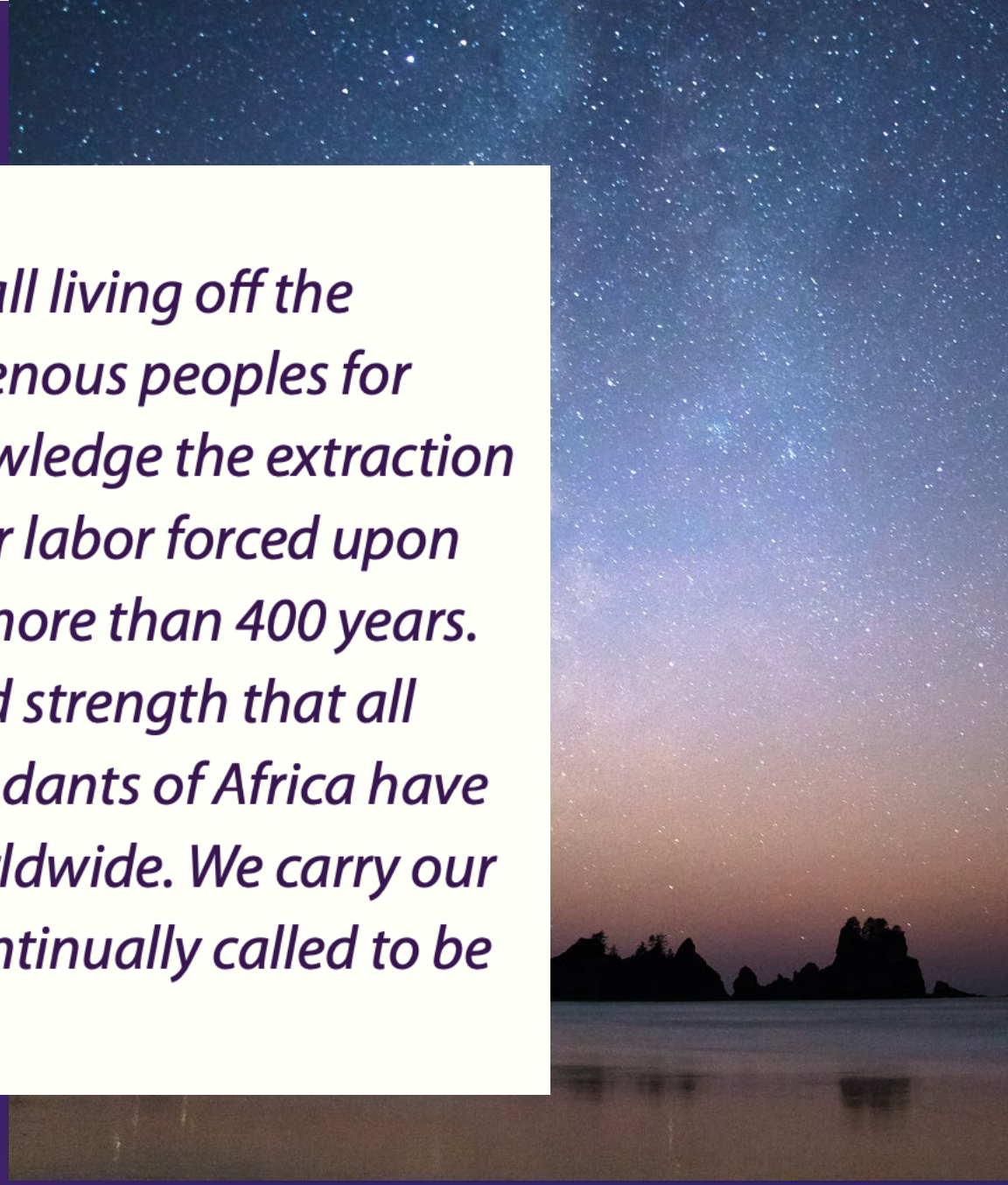
Honoring the land on which the

The University
acknowledges
this land, the la
shared waters
within the Suqu
Muckleshoot n

The Office of H
acknowledges the Duwamish and all
Indigenous peoples of this land.

Land and Labor Acknowledgement:

We acknowledge that we are all living off the taken ancestral lands of Indigenous peoples for thousands of years. We acknowledge the extraction of brilliance, energy and life for labor forced upon people of African descent for more than 400 years. We celebrate the resilience and strength that all Indigenous people and descendants of Africa have shown in this country and worldwide. We carry our ancestors in us, and we are continually called to be better as we lead this work.



Acknowledgment of Historical Harms:

Historical injustices have deeply impacted marginalized communities, leaving a lasting legacy of pain and mistrust.

We are committed to addressing systemic inequities and ensuring that all communities have equal access to healthcare and research opportunities.

With a foundation of trust and mutual respect, we can build a more just and equitable healthcare system that values the dignity and well-being of every individual.

We honor the countless individuals who have participated in research and clinical trials, contributing to medical advancements and life changing treatments.

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OFFICE OF HEALTHCARE EQUITY

The Why: Diversity in Clinical Trials

- **Health inequities are pervasive and contribute to increased morbidity and mortality of historically marginalized communities.**
- **Health inequities are costly and account for an estimated $451 Billion in healthcare costs.**
- **There is a lack of diversity in clinical trials.**

We aim to build a new research framework that centers collaboration and partnership with historically minoritized populations for all clinical trial research.

Table 1: Comparing Demographics in Clinical Trials and the United States Population (2020)

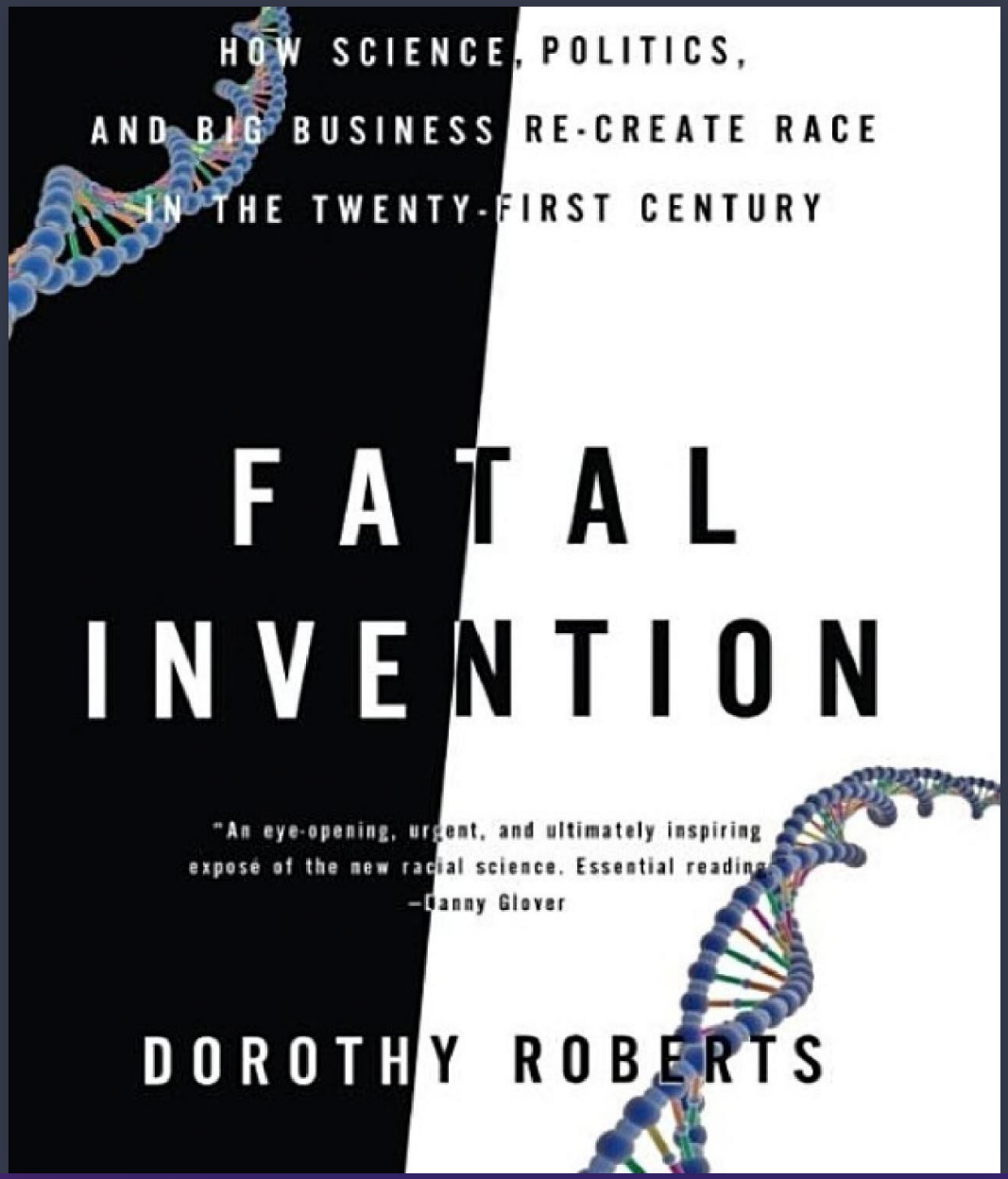
Demographic Groups	Clinical Trial Population	US Census Population
Age 65 and Older	30%	17%
Asian	6%	6%
Black or African American	8%	14%
Hispanic	11%	19%
White	75%	59%
Women	56%	50%

Data Source(s): FDA 2020 Drug Trial Snapshots, U.S. Census Bureau Quick Facts (2020)

We are not promoting racial essentialism

What does that mean?

- We are not promoting the use if race as a biologic variable.
- There are not differential effects on drug metabolism and device needs by race, but rather the Social Determinants of Health affect how people have access to drugs and devices and access to experimental therapies.
- Historically marginalized communities need to have compensation for participating in trials



HSB 1745, Section 8

- **If at any time the University of Washington receives funding from the NIH to conduct clinical trials of drugs or medical devices, the University of Washington shall adopt a policy concerning the identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials of drugs and medical devices. This policy must include requirements to:**
- (1) Adopt a **policy** concerning the identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials. This policy must include requirements that investigators who are conducting clinical trials collaborate with community-based organizations and use methods recognized by the United States food and drug administration to identify and recruit such persons to participate in those clinical trials;
- (2) **Provide information** to trial participants in ***languages*** other than English;
- (3) **Provide translation services** or bilingual staff for trial screening;
- (4) **Provide culturally specific recruitment materials** alongside general enrollment materials; and
- (5) **Provide electronic consent** when not prohibited by the granting entity or federal regulations.

PCORI: 4 Equity Guiding Principles

•Inclusion:

Beyond representation – intentional invitations & welcoming environments

Equitable Partnerships:

Mutual benefit, respect, co-creation, transparency

Trust & Trustworthiness:

Earned, not presumed. Center the perspective of those with least power.

Accountability:

Practices and processes to uphold Equity & Inclusion values in action

Thank you to the many members of the UW Research community that have embraced principles of Community Engagement in their research practices!

Shoutout to ITHS Community Engagement Program and Fred Hutch Office of Community Outreach & Engagement

Our intent will be to ensure our research community has access to best practices regarding Community Engagement, while always challenging ourselves to do better.

THE SPECTRUM OF COMMUNITY ENGAGEMENT TO OWNERSHIP

Facilitating Power

STANCE TOWARDS COMMUNITY	0 IGNORE	1 INFORM	2 CONSULT	3 INVOLVE	4 COLLABORATE	5 DEFER TO
IMPACT	**Marginalization**	**Placation**	**Tokenization**	**Voice**	**Delegated Power**	**Community Ownership**
COMMUNITY ENGAGEMENT GOALS	Deny access to decision-making processes	Provide the community with relevant information	Gather input from the community	Ensure community needs and assets are integrated into process & inform planning	Ensure community capacity to play a leadership role in implementation of decisions	Foster democratic participation and equity through community-driven decision-making; Bridge divide between community & governance
MESSAGE TO COMMUNITY	***Your voice, needs & interests do not matter***	***We will keep you informed***	***We care what you think***	***You are making us think, (and therefore act) differently about the issue***	***Your leadership and expertise are critical to how we address the issue***	***It's time to unlock collective power and capacity for transformative solutions***
ACTIVITIES	Closed door meeting Misinformation Systematic	Fact sheets Open Houses Presentations Billboards Videos	Public Comment Focus Groups Community Forums Surveys	Community organizing & advocacy House meetings Interactive workshops Polling Community forums	MOU's with Community-based organizations Community organizing Citizen advisory committees Open Planning Forums with Citizen Polling	Community-driven planning Consensus building Participatory action research Participatory budgeting Cooperatives

Facilitating Power, 2021

Foundations

- **Demonstrating respect** for communities and community members, including by **compensating them** for their time, *particularly* when we're working with low-income, BIPOC, and other marginalized groups. It is unreasonable (and inequitable!) to ask community members to invest substantial time, effort, and expertise in community improvement efforts without being paid.

- **Earning the trust** of communities and community members, including by **meeting them where they are** and in the spaces they already gather, by being present in the community long-term and building lasting relationships, by respecting and building from the assets of particular communities and community members, and by **ensuring community members are driving the agenda** and that we are supporting them instead of vice versa.

PCORI's Foundational Expectations for Partnership in Research

Resources in development

- Working with Tri-Campus effort focused on Community Engagement for Research Initiatives
- Working with ITHS and Fred Hutch OCOE
- Developing aggregate site for resources as directly related to Community Engagement in Health Research and Clinical Trials
- Advocating for resources to fund community
- **Development of Community Based Research Collaboratory**

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#1972930

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We want to connect explicitly with Researchers who are doing Community Engagement Work. Who should we connect with? Please share names/emails (including yourselves!)

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Slido results

- Becertain@uw.edu
- Dr. Janet England and her ID group (englundgroup@seattlechildrens.org)
- Anna Wald in Allergy Inf. Disease worked with Lummi tribe on. CoVID
- Nina Kim, hyangkim@uw.edu Rachel Bender Ignacio, rbi@uw.edu Louis Shackleford, lshackel@fredhutch.org
- We have a newly established community advisory board related to treatment for substance use disorders. You can reach out to Sharon Garrett ghungus@uw.edu if you want to talk more.
- Pedro Goicochea (Pedro.goicochea@icloud.com)
- Ro Yoon, Kim Louis, Allysson Angeldekao, Rachel Bender Ignacio at the Seattle Vaccine Trials Unit and UW Positive Research
- Virology Research Clinic (vrc@uw.edu)
- School of Social Work - multiple researchers
- Jolene Olvera: olverj@uw.edu -- Engaging AI/AN communities to assess barriers to reaching radiation treatment
- Anthony Floyd (asfloyd@uw.edu)
- Gail Broder at FHCC HVTN and her team. HVTU at Cabrini medical tower
- Community Outreach Consultations for EFIC studies - traumaresearch@uw.edu
- steelejl@uw.edu
- nfranko@uw.edu - family medicine research on substance use
- Laura Hennessy (hennessy@uw.edu)

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What are the resources related to Community Engagement that you need?

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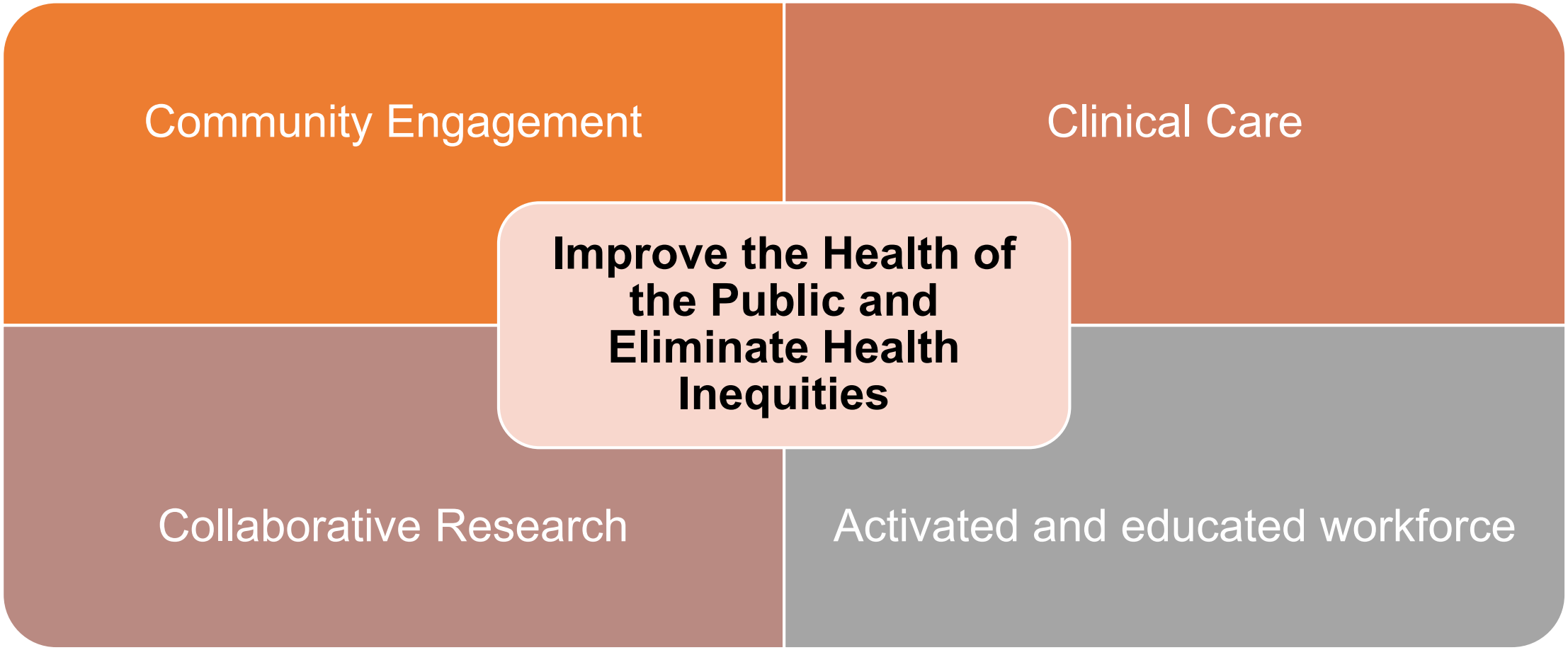
Slido results

- Anonymous Diverse staff who can make the participants comfortable
- Anonymous Training Not all research is for patients who interact with UW system, how do we support those who need guidance from us but may not use our regular services. Policy changes? New offices dedicated to helping these individuals?
- Anonymous Protocol templates.
- Anonymous queer, trans, etc outreach
- Anonymous Repository of contacts from different group leadership. If someone already has contacts at a Tribe or a particular community, we need to share those and share the "warm hand off" so it's a connection made with trust
- Anonymous event planning support; writing and editing support to create materials written in plain/lay language
- Anonymous Resources of where and how to recruit along with translations.
- Anonymous Prevalence of common diagnoses under study in marginalized populations
- Anonymous Funding, translation, interpretation, UW policies and adherence, cultural sensitivity, networking of groups interested or barriers to certain groups
- Anonymous Funding
- Anonymous Resources surrounding hiring
- Anonymous Potential collaborators interested jn a similar question
- Anonymous Accurate translations
- Anonymous Interpreted documents Funding Transportation for participants
- Anonymous Funding and training
- Anonymous Translation services
- Anonymous Dedicating funding and easier paths to compensation.
- Anonymous Funding for FTE to coordinate boards, surveys, community events.
- Anonymous More time—grant turnaround time makes this exceptionally difficult to do meaningfully
- Anonymous Participant reimbursement
- Anonymous $$$, it takes staff to do this work and many grants do not include adequate resources
- Anonymous Translation and interpreter services
- Anonymous Funding
- Anonymous Funding and approaches to letter meet with community
- Anonymous Funding for Community Advisory Board compensation for providing feedback in focus groups or in reviewing protocol drafts etc
- Anonymous Training, relationships and funding
- Anonymous More flexible institutional polices for partner compensation
- Anonymous Funding

UW Office of Healthcare Equity and UW JEDI Center for Transformational Research



Community Engagement: Nothing about Us Without Us!

Started meeting with CBOs Sept 2023

Use AAMC/PCORI toolkits **to further engage communities**

No funding for CBOs: Grant submitted

-Listening sessions

-Community engagement

-Development of CBRC

-Partnership with Andy Hill Foundation

Future: Community Engagement Charter

-MOU agreements

-Funding for integrating Community in Diversity of Clinical Trials

-Adding CBO individual to DCT Steering Committee

--**Develop partnerships with UW Researchers who are engaging community**

Community-Based Research Collaboratory (CBRC)

Designing a Community-Based Research Collaboratory to Increase Diversity in Clinical Trials

Develop Community Advisory Board

- Meet monthly with CBOs
- Need external CBO funding
  - Wrote a grant with Tubman Health
- 9/23-present

Continue listening sessions

- CBOs
  - Community
- Researchers
- Policy makers (Human Subjects)
- SWOT analyses
- 7/24-12/24

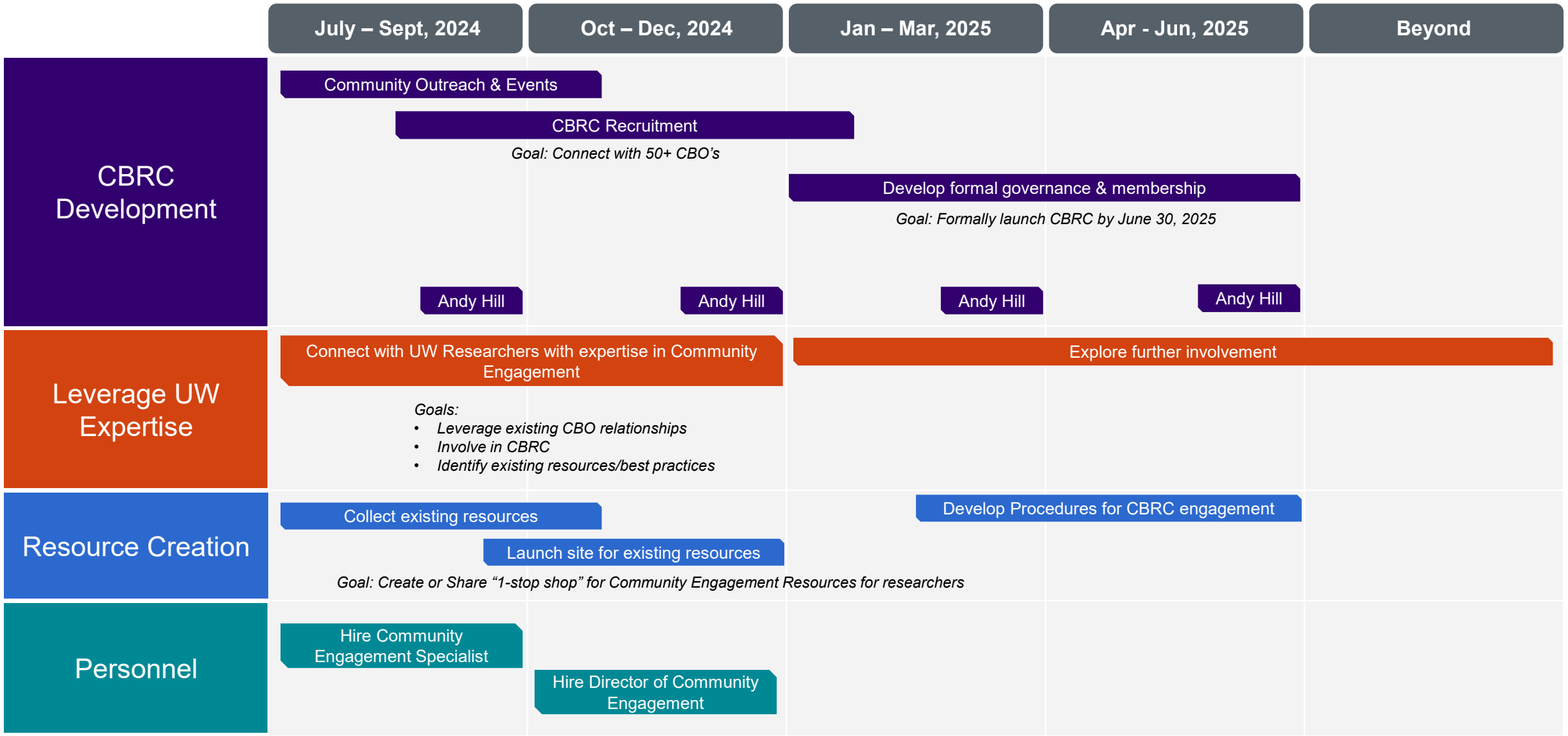
Develop Research Collaboratory

- Develop plan for implementation
- CBPR-principles
- Finalize plan for collaboratory
- Develop metrics and analysis plan
- FY 2025-FY2026

Assessment of Implementation

- Phase assessment
- Metrics
- PRISM (RE-AIM) evaluation
- Annual Reporting
- Sustainability
- FY 2025-Beyond

Diversity in Clinical Trials Initiative - Community Engagement



QUESTIONS?

Language Access & Cultural Advocacy UW Medicine

YVONNE SIMPSON, SENIOR DIRECTOR

simpsony@uw.edu

Sharepoint Link: Resources for Clinical Trials

UW Medicine

Agenda

- Equitable Service
- Language Access Services
- Grant Writing
- Translation/Interpretation Bridge Funding

Equitable Services for Communities

Terms

- **Limited English Proficiency (LEP):** defined by US Census; person who self-identifies as speaking English "less than well"
- **Threshold language**: language spoken by >5% of surrounding population
- **Languages of Lesser Demand/Lower Diffusion**: languages spoken by a relatively small number of speakers
- **Meaningful communication**: receptive and expressive communication that meets the individual's needs
- **Equitable access**: fair and reasonable so that all have the same opportunity to participate at the same level

Regulations/Guidance

- FDA Informed Consent Guidance (sections V.3 through V.9)
  - LEP
  - Limited literacy and numeracy in any English
  - Communication Disabilities (including but not limited to hearing, vision, speech production, information processing, etc.)
- Title VI of the 1964 Civil Rights Act
- Centers for Medicare & Medicaid
- Section 1557 (Non-Discrimination) of Affordable Care Act
- Americans with Disabilities Act

- *The right thing is to provide access so all have equitable opportunity*

UW Medicine Language Data

Top10 spoken languages YTD:

English, Spanish, Mandarin, Vietnamese, Amharic, Russian, Somali, Tigrinya, Korean, Cantonese

Demographic Data Sources

- US Census
- State/County demographic data
- UW, Fred Hutch, or other facility EHR

Language Access Services

Types of Language Access

- Document Translation
- Interpretation
- Braille Transcription
- Auxiliary Devices

Document Translation

Document Translation

- UW Medicine has contracted vendors for document translation
  - Researchers will work directly with translation vendors
- Types of services include: human translation, human + machine translation, secondary review of translations, audio transcription, back translations, voice recording, formatting, and related services
- Clinical Trials researchers are not required to UW contracted vendors. They may use any service that meets FDA guidelines by a qualified translator, including:
  - Qualified bilingual research team member
  - Qualified community member
  - Other vendors of their choosing

Planning Considerations

- Plain Language (5th-6th grade) whenever possible; definitions
- Consent forms and related materials (letters, surveys, informational forms, etc.)
  - *What information should the participant receive to ensure that the communication they get is equitable with English speakers?*
- Rewrites
- Back translations to English (if required by study)
- Psychometric validation of tools in another language (if required)
- Dual Language Forms (required for EHR inclusion)

Can I use AI and machine translation?

AI and Machine Translation

- The FDA recommends the use of a qualified individual (human)
- Federal regulations and guidelines regarding use of AI
- UW Language Access AI Considerations

AI in language access

- Affordable Care Act Section 1557 (non-discrimination clause)
  - Requires a qualified human review machine translation if an entity uses machine translation for text that is critical to the:
    - rights, benefits, or meaningful access of a limited English proficient individual;
    - when accuracy is essential; or
    - when the source documents or materials contain complex, non-literal or technical language.
  - *"It required covered entities to take reasonable steps to provide meaningful access to each LEP individual eligible to be served in covered entities' health programs and activities."*

UW Medicine Guidance on use of Generative AI

email: GenAIatUWM@uw.edu

Can UW Medicine employees and researchers use publicly available AI-related tools to assist in their job? **Yes**

- Users must not share any of the following data with these tools:
  - UW Medicine patient data or clinical data of any kind, including deidentified patient data
  - Personally identifiable information
  - Proprietary UW Medicine data
  - Intellectual property of any kind
- Users must not:
  - Use information derived from the tools to inform clinical care
  - Rely on information derived from the tools without validation
  - Disseminate content generated by the tools without careful review
  - Utilize programming code from an external LLM without code undergoing additional security review as described below
  - Leverage the tools for automating workflow

Interpretation

Interpretation

- UW Medicine has contracted vendors for interpretation
- Telephonic, video, in-person
- Clinical Trials researchers are not required to UW contracted vendors. They may use any service that meets FDA guidelines by a qualified translator, including:
  - Qualified bilingual research team member
  - Qualified community member
  - Other vendors of their choosing

Accessing Interpreters

- Research conversations occurring in tandem with direct patient care may piggy-back on the interpreter already obtained for care
  - Outcome: no additional fee for research team
  - Reasoning: continuity of interpretation for patient and interpreter
  - Caveat regarding in-person interpreters: an in-person interpreter may not be available to extend their time with a researcher if scheduled elsewhere for patient care

Accessing Interpreters

- Research conversations not occurring in relation to direct patient care will need to be paid for out of the research budget
  - Phone calls, meetings outside UW facilities, visiting in-patients who are not already connected to an interpreter for direct patient care, etc.
- Researchers will work with UW Language Access to identify a name for their study that can be invoiced for interpreter use
  - Confidentiality: for purposes of invoicing, instead of "Mpox in BIPOC Elders", consider non-specific name "The Simpson Study"
- Documentation: caller name, project name, patient name/MRN
  - Required for healthcare provision
  - For research *only*, can opt to not provide patient name/MRN

Accessing Interpreters

- Video: available 24/7 from tablets at UW
  - Not all languages available by video 24/7; system will connect with audio interpreter on same device
- Telephonic: available 24/7
  - Telephonic interpretation available through any phone on Earth
  - Not every language on the planet available on-demand; UW Language Access will offer assistance for pre-scheduling, as available
- In-person: available by pre-schedule; limited languages available; researchers will be responsible for paying in-person interpreter minimums (e.g. 2 hour minimum for agency) and/or hours plus benefit rates (UW staff interpreters)

Short Form Consents

- FDA requires bilingual "witness" to sign short form consents
  - Training of UW staff/agency interpreters re: clinical trials
  - Video vendor unable to sign consents
  - Telephone vendor – may agree to sign if interpreter pre-scheduled
- FDA allows signing by qualified bilingual person (bilingual research staff, participant companion, community member, etc.) FDA does not require the bilingual witness be a certified interpreter.

Auxiliary Devices

Auxiliary Devices/Services

Americans with Disabilities Act requires accommodations such as:

- Braille Transcription (UW IT – no charge for UW staff)
- Voice amplifiers for hard of hearing
- High contrast or large font text for visual impairment
- Accessible web content, pdfs, and other text
  - UW Access Technology Center (UW staff) for support

- Socio-economic access (devices, wifi, travel, etc.)

Grant Writing for Language Access

Budget & Grant Writing

- Cost and considerations
- Fee Examples
- Completion Time
- UW Medicine will hold RFQQ for new contracts in 2026

Continued planning for language access

Details to be Finalized

- Streamlined process for invoicing for interpretation services
- Simplified process to utilize contracted telephonic interpretation for short form consents
- Collaboration with Fred Hutch
- Bridge Funding Application Process

FAQs

- **Q:** When do I need to get an interpreter to talk with participants/surrogate decision makers?
- **A:** Participants who have self-identified as preferring a language other than English for participation in the trial must be provided an interpreter. This includes conversations regarding all components of their trial participation (recruitment, information, education, consent, appointments, treatments, follow-up, etc.).

FAQs

- **Q**: My research is outside UW and the research staff is not employed by or otherwise connected to UW, but because of our IRB we are beholden to HB1745. How do we get interpretation or translation?
- **A**: Consult with UW Medicine Language Access & Cultural Advocacy at uwlaca@uw.edu. If the research project is based out of another healthcare organization, or the research staff are employees of another healthcare organization, there are likely resources available through those facilities. Otherwise, UW Medicine Language Access will be happy to help you determine where to get these resources.

FAQs

- **Q**: My research is not funded at all or has very limited funding that does not cover language access. How do I get services?
- **A**: Translation and interpretation are professional skills and are not generally available for free. There is some funding from the state earmarked for translation and interpretation. This bridge funding is available for just a few years to help researchers initially comply with HB1745 while research teams consider long-terms plans for compliance..

Translation/Interpretation Bridge Funding

Translation/Interpretation Bridge Funding

- Limited funds will be made available by proviso funding
- Estimated Rolling Application Window
  - October 2025-March 2029
  - (Funding note ends in June 2029)
- Application process and criteria still under development
  - Initial draft will likely be up to $5000 available for each award
  - Up to 5 awards a month (pending budget availability)

Questions?

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What topics would you like covered in future town halls?

ⓘ Start presenting to display the poll results on this slide.

Slido results

- Anonymous OP/PQ requirements research groups needs to implement to develop part 11 complaint redcap projects
- Anonymous Strategies to emphasize the importance of this to our teammates
- Anonymous e-consent options
- Anonymous The role of AI to augment in language translation and interpretation? Are there regulations or guidelines we need to consider?
- Anonymous logistics on implementing e-consent
- Anonymous Creative ideas or resources to help researcher integrate into low-income or marginalized communities not necessarily in different languages.
- Anonymous Econsent training

WE WANT TO HEAR FROM YOU!

- More questions?
- Visit our contact form at the QR code, or available on the website

CONTACT US

The Case: Diversity in Clinical Trials Washington Legislature House Bill 1745

- The United States food and drug administration has evaluated demographic profiles of people participating in clinical trials for approved drugs and found that some groups, especially ethnic and racial groups, are not always well represented in clinical trials. Diversity in clinical trials is necessary to effectively determine how race, gender, and age impact how a person metabolizes a drug.

- **The lack of diversity in clinical trials compounds access to treatment disparities and limits our understanding of the impacts of studied interventions and conditions across the population.**

- "Underrepresented community" or "underrepresented demographic group" means a community or demographic group that is more likely to be historically marginalized and less likely to be included in research and clinical trials represented by race, sex, sexual orientation, socioeconomic status, age, and geographic location.