UW DIVERSITY IN CLINICAL TRIALS INITIATIVE: DIVERSITY PLAN

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UW DCTI Town Hall

September 4, 2024

Today's Objectives

- Present overview of proposed UW Supplement: Diversity Plan for Clinical Trials
- Respond to questions/solicit feedback on the Diversity Plan and associated guidance

- Future Town Hall: Overview and discussion of resources to support implementation
  - September 20th – Translation/Interpreter Services; Community Engagement

Acknowledgement

- UW Medical School Executive Committee
- Faculty Senate Council on Research
- UW Tacoma
- UW Bothell
- College of Arts & Sciences
- College of Education
- College of Engineering
- School of Nursing
- School of Dentistry
- School of Pharmacy
- School of Social Work
- SOM Dean's Office
- SOM Vice Chairs for Research
- Medical School Executive Committee
- UW IRB Chairs/Vice Chairs
- Fred Hutch IRO
- Seattle Children's
- WCG / Advarra
- UW State Relations
- Office of Research
- Industry sponsors

Acknowledgement

Bierer B.E. et. al., (2021). Achieving Diversity, Inclusion, and Equity in Clinical Research Guidance Document Version 1.2. Cambridge and Boston, MA: Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center).

Multi-Regional Clinical Trials (MRCT) Center Toolkit and User Guide for Achieving Diversity, Inclusion and Equity in Clinical Research.

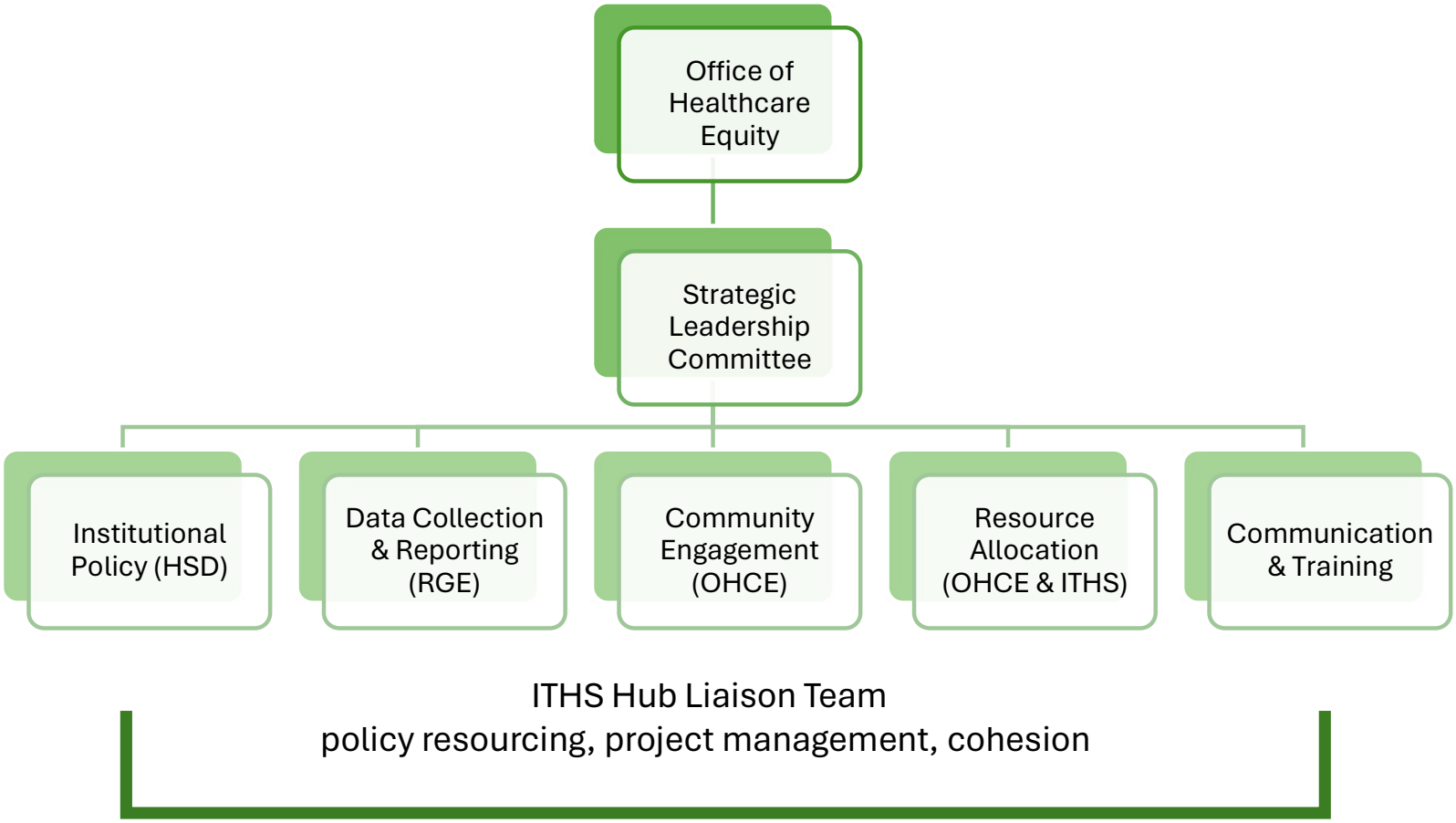
Boston Children's Hospital IRB Policies and Procedures Manual, Informed Consent with Non-English Speakers.

FDA Guidance, Diversity Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies.

FDA Guidance, Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs.

NIH Policy & Guidelines, On the Inclusion of Women and Minorities as Subjects in Clinical Research

Implementation Structure



Background

- 2023 WA State legislature passed 2SHB 1745 Diversity in Clinical Trials (codified in RCW 69.78)
  - Focused on improving diversity in enrolling underrepresented demographic groups in drug/device clinical trials
- Check out past HSD newsletters for more information:
  - April 2, 2024 – Intro to WA State DCT bill
  - May 7, 2024 – DCTI Scope, project Timeline, UW Implementation
  - June 18, 2024 – Draft Policy; Translation & Interpreter Services
  - August 6, 2024 - Community-Based Research Collaboratory
  - August 16, 2024 – Draft Diversity Plan + Guidance

https://www.washington.edu/research/hsd/

Background

- **RCW 69.78.040 Requirements for state entities or hospitals conducting clinical trials.**

Any state entity or hospital that receives funding from the national institutes of health to conduct clinical trials of drugs or medical devices shall:

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.

Clinical Trials at UW CY2023

- **FDA regulated**
  - 65% involve drug/device/biologic with data submitted to FDA
- **Trial Location**
  - 76% UW/Fred Hutch/SCH
  - 92% Puget Sound region
- **IRB of Record**
  - 45% WCG/Advarra
  - 28% UW IRB
  - 15% Fred Hutch/SCH IRB
  - 12% Other IRB

Proposed Scope: UW Policy

All UW clinical trials* where UW employees or agents are responsible for or engaged in recruitment and consent activities should seek to improve enrollment of underrepresented communities applicable to their target condition under study.

Would apply regardless of where the interventions occur

Would apply to UW studies relying on an external IRB

Would be a condition of UW serving as sIRB for multicenter studies

(Diversity plan could be site based or cumulative across all sites)

*NIH definition

Justified Exclusions

PHASE 1 OR EARLIER TRIALS

PILOT AND FEASIBILITY STUDIES

TREATMENTS FOR SMALL POPULATIONS

UW Supplement: Diversity Plan

- Modeled off the FDA Diversity Action Plan in the FDA Draft Guidance for Industry: Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies (June 2024)
- The DCT bill requires use of methods recognized by FDA to identify and recruit members from underrepresented groups

The Plan: Setting Enrollment Goals

SETTING ENROLLMENT GOALS

Review Setting Enrollment Goals in the Diversity in Clinical Trials guidance.

For the purposes of satisfying the Diversity in Clinical Trials policy requirements, this supplement is focused on collecting information about underrepresented populations as defined by RCW 69.78: age, race, biological sex, sexual orientation, geography, and socioeconomic status. The UW acknowledges that there may be other historically underserved populations, including those defined by FDA and NIH, that researchers may want to consider when designing their study. The UW encourages inclusion across all types of diversity.

1. **Race, ethnicity, and biological sex.** Use the table below to provide a breakdown of enrollment goals with regard to race, ethnicity and biological sex. Specify the goals in terms of percentages.

Ethnicity	Male	Female
Hispanic or Latino	Click or tap here to enter text.	Click or tap here to enter text.
Not Hispanic or Latino	Click or tap here to enter text.	Click or tap here to enter text.
Race	**Male**	**Female**
American Indian/ Alaska Native	Click or tap here to enter text.	Click or tap here to enter text.
Asian	Click or tap here to enter text.	Click or tap here to enter text.
Native Hawaiian or Other Pacific Islander	Click or tap here to enter text.	Click or tap here to enter text.
Black or African American	Click or tap here to enter text.	Click or tap here to enter text.
White	Click or tap here to enter text.	Click or tap here to enter text.

The Plan: Setting Enrollment Goals

2. **Age.** Describe the age range of the target population and provide any enrollment goals for specific age groups in terms of percentages.

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3. **Other determinants of treatment outcomes.** Describe any plans to collect information about sexual orientation, socioeconomic status, and/or geographic location as determinants of treatment outcomes for the clinical trial.

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The Plan: Rationale for Enrollment Goals

RATIONALE FOR ENROLLMENT GOALS

Review Defining the Study Population and Broadening Eligibility Criteria in the Diversity in Clinical Trials guidance.

4. Rationale.

- Provide the basis for the enrollment goals. Include available data on the pathophysiology of the disease or condition in underrepresented groups, including current understanding and available evidence supporting any differences and/or similarities in the disease or condition associated with these groups. Use a plain language description.
- If relevant, describe any differential application or use of currently available prevention, screening or diagnostic strategies and treatments.
- Describe any planned use of data to characterize safety, efficacy, and optimal dosage in these participants.
- Provide justification for any over/under representation based on reasons of science, ethics, and/or safety. In some cases, increased enrollment of certain groups may be needed to reveal important differences.

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The Plan: Rationale for Enrollment Goals

5. **Future research plans.** This question should only be answered if the trial will exclude any groups by age, biological sex, race, sexual orientation, socioeconomic status or geographic region. Briefly describe any other planned trials or studies of safety, effectiveness, and/or dosage (for medical products), and plans for future inclusion of these groups with regard to design, population, endpoints, and geographic locations. If relevant, summarize any differential findings from clinical pharmacology studies that may be associated with certain underrepresented groups.

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6. **Trial design and methodology.** Describe any design and methodological approaches that will be used in this clinical trial to facilitate enrollment of a broader population (e.g. broadening eligibility criteria using enrichment strategies).

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The Plan: Strategies for Meeting Enrollment Goals

STRATEGIES FOR MEETING ENROLLMENT GOALS

7. **Reducing barriers and burdens.** Describe the measures that will be employed to reduce participation burden, enroll, and retain underrepresented groups and explain why the measures are appropriate for the study population.

Examples:

- *Holding recruitment events in non-clinical, but trusted locations (e.g., community centers, places of worship, cultural festivals etc.) to connect with populations who may have limited or no internet access.*
- *Using online/social media strategies to recruit participants for whom a traditional referral center is not accessible.*
- *Providing cultural humility and competency training for clinical investigators and research staff.*
- *Allowing flexibility in study visit windows (e.g., after work hours or weekends).*
- *Using secure electronic communication or digital health technology tools to replace site visits.*
- *Sending mobile medical professionals to participants and/or using labs and imaging facilities local to the participant.*
- *Providing reimbursement for expenses incurred due to trial participation (e.g., travel, parking, and childcare).*
- *Remaining engaged with communities after the conclusion of the research and sharing trial updates to continue to strengthen bi-directional relationships with communities.*

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The Plan: Strategies for Meeting Enrollment Goals

8. **Participants with Limited English Proficiency (LEP).**

Plans for inclusion of participants with limited English proficiency. It is a **UW Policy** that all clinical trials that require submission of a SUPPLEMENT Diversity Plan for Clinical Trials must have resources in place to include prospective participants with limited English Proficiency (LEP) **unless** there is compelling justification for their exclusion (e.g., based on reasons of science or safety).

- Describe plans for inclusion of participants with LEP.
- Describe the prevalence of languages spoken other than English within the target study population.
- Explain whether there are plans to exclude any participants on the basis of language and provide justification for any exclusions.

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Explain in which languages written materials will be available at the outset of the research.

Describe the interpreter services that will be available to participants and for which languages.

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Translation Policy

It is a **UW Policy** that:

- When 5% or more of the target population (as defined above) speaks a primary language other than English:
  - The study must have translations of any written materials to be read by participants (e.g., consent forms, recruitment materials, surveys) available at the outset of the research
  - There must be resources in place to support their inclusion for the duration of the study.
- When less than 5% of the target population (as defined above) speaks a primary language other than English:
  - There must be a plan in place to support their enrollment and participation in the research when they are encountered.
  - The UW provides services and resources for translation and interpretation as described in the guidance.

Short Form Policy - Revised

- In response to updated FDA guidance and the WA DCT law, HSD is revising our policy for using short form consent when enrolling individuals with LEP
- Some of the more significant changes include:
  - Prospective IRB approval to use the short form method is now required for all greater than minimal risk and FDA-regulated studies
  - Study participants must be provided an IRB-approved translated consent form at the participant's next study visit or within 60 days, whichever occurs first
  - Researchers must notify the IRB of use of the short form consent process and provide a translated consent form as a modification in Zipline within 2 weeks
  - In most instances, the required impartial witness must be proficient in the language of the oral consent presentation

The Plan: Strategies for Meeting Enrollment Goals

9. **Use of e-consent**. Electronic consent allows participants to read and sign necessary forms remotely instead of travelling to a clinical trial site. It is a **UW Policy** that e-consent must be made available as an option for all clinical trials that require submission of a SUPPLEMENT Diversity Plan for Clinical Trials unless it presents a barrier to participation. Indicate if e-consent will be available to research participants.

   ☐ **Yes**
   ☐ **No –** Explain why e-consent is not appropriate for the study population.

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10. **Community engagement and cultural sensitivity**. Explain what steps the research team or study sponsor has taken to develop a culturally sensitive and inclusive approach to study recruitment and retention.

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The Plan: Enrollment Data Collection & Reporting

ENROLLMENT DATA COLLECTION AND REPORTING

11. **Enrollment metrics and corresponding actions.** Describe plans for tracking enrollment of underrepresented groups.

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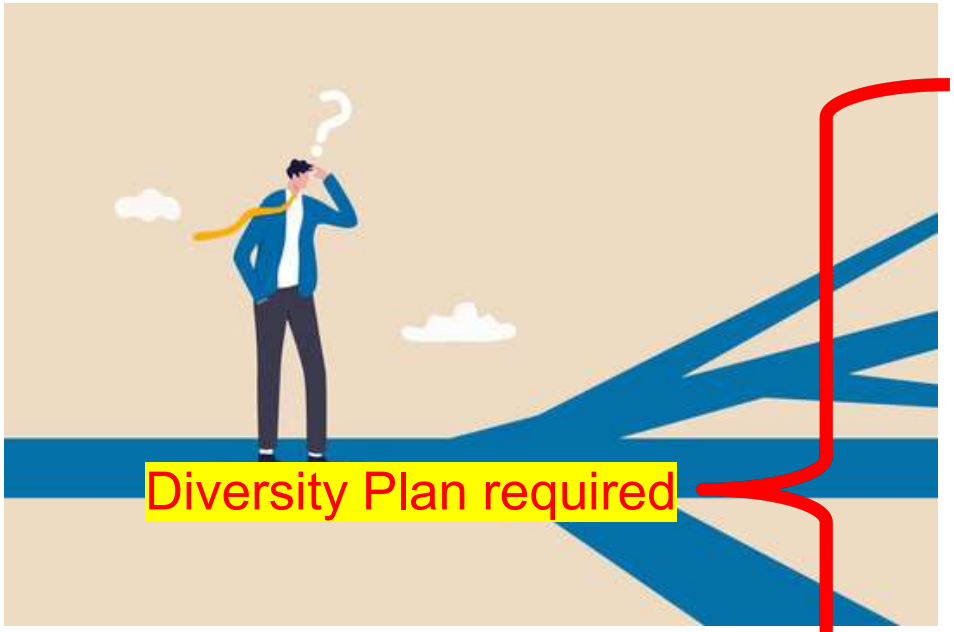
IRB Review: Four Pathways



- Cooperative Partners (e.g., Fred Hutch, Seattle Children's)
- UW IRB Review
- Commercial IRBs (e.g., Advarra, WCG)
- Other external IRBs (e.g., Johns Hopkins, Vanderbilt, Duke)

UW IRB Review

- UW researchers submit a completed *Supplement: Diversity Plan for Clinical Trials* as part of their initial application
- Reviewed by the IRB

Commercial IRBs

- Not subject to the requirements of the RCW 69.78
- However, Advarra and WCG have agreed to review the UW Diversity Plan
- UW researchers would submit a copy to HSD as part of authorization process
- UW researchers would include the plan with their application to the commercial IRB

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Other External IRBs

- Primarily other academic institutions (outside WA State)
- Not subject to the requirements of the RCW 69.78
- Unlikely to review the UW Diversity Plan
- UW researchers would submit a copy of the UW Diversity Plan to HSD for evaluation during authorization process
  - **NOT** an IRB review of the plan
- UW researchers would be directed to incorporate elements of their plan into their application for review by the external IRB

Compliance

- Focus on education and support vs. penalty
- **UW IRB reviewed studies** - Collect information at time of continuing review regarding:
  - Status of target enrollment goals
  - Possible reasons for under-enrollment
  - Proposed strategies for improvement
- **Externally reviewed studies** – Collect information via annual survey
- Data collected will inform HSD and the University of common issues/challenges researchers face and inform future policy, guidance, education, and resource support.

Implementation Timeline

- Researchers submitting an initial application to the IRB one year from date new policies/guidance posted would be required to have a diversity plan
  - January 2026
- Existing studies are not subject to the new policy

Our Request

- Draft *SUPPLEMENT Diversity Plan for Clinical Trials* and associated guidance
- Please send any additional comments or questions to hsdinfo@uw.edu
- Deadline for feedback is Monday, **September 16th, 2024**

Upcoming DCTI Town Hall 9/20

9/20 2 pm-3:30 pm
Topic: Community Engagement and Language Services

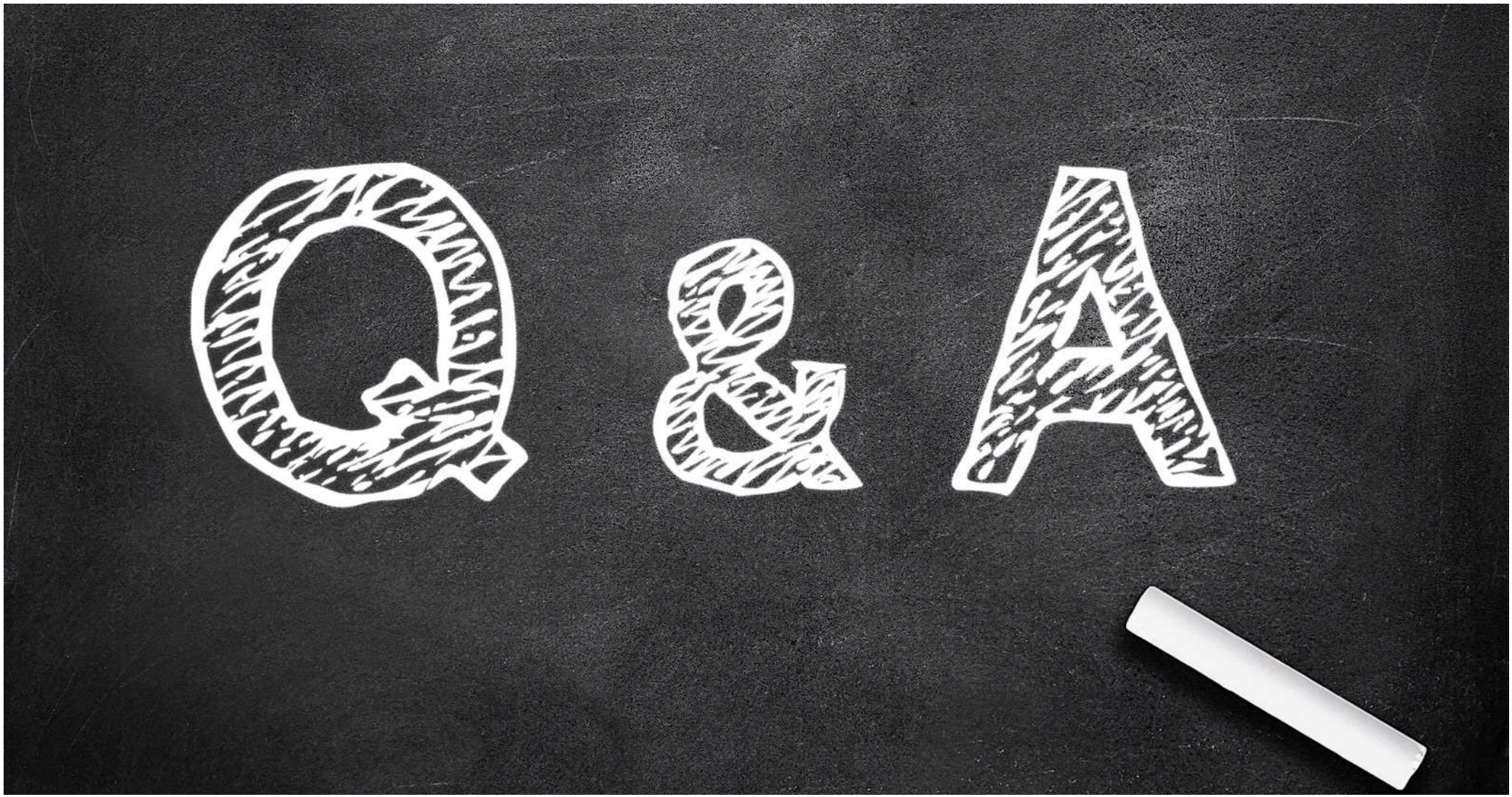
Panelists:
Aric Ho, Associate Director at the Office of Healthcare Equity

Yvonne Simpson, Senior Director of Language Access and Cultural Advocacy at UW Medicine

Moderated by **Charlie Gregor, MPH,** Manager of Hub Liaison Team, Institute of Translational Health Sciences

Recording will be available after

Register here:
https://washington.zoom.us/webinar/register/WN_QXoBxHGsSLqvxef_zlqiJQ


Q & A