September 4 DCTI Town Hall Meeting: Questions & Answers

1. **You mentioned relying on the FDA, NIH, the MRCT and Boston Children's Hospital to help build guidance. Can you speak about why you selected these entities and are you open to other sources, including resources that were created locally?**

   HSD researched and reviewed a variety of resources. At the end of our draft guidance, we cite dozens of source materials. This represents what we chose to use. Many more were reviewed and considered.

   The new WA state law directs us to use "methods recognized by the US FDA" and FDA has published several guidance documents on this topic. Since 2/3 of our clinical trials are FDA-regulated, it makes sense that we would align our approach to theirs. This also could reduce burdens for researchers because Sponsors will be required to comply with FDA's diversity action plan requirements. Mirroring their approach allows researchers to tap into the diversity plan already developed by the Sponsor.

   NIH is a key funder of many UW clinical trials and also has published some useful guidance on this topic.

   The MRCT and Boston's Children's hospital have been working on improving diversity in clinical trials for many years. MRCT in particular has pulled together subject matter experts in this field and conducted their own research and literature review to develop their recommendations and extensive practical resources. We found their approach reasonable, pragmatic and useful and so incorporated many of their ideas into our own policy.

2. **For most industry-sponsored trials, only a few subjects are enrolled per site as part of competitive enrollment. However, the sponsor generally has an established DEI strategy that they already submitted per FDA guidance, applicable to the overall trial. Is there a recommended approach to integrate the strategy the sponsor already submitted or to inform the sponsor of our local site requirements?**

   The HSD approach to using a standalone diversity plan was intended to mirror the FDA guidance to reduce duplication of effort. If a sponsor has developed a diversity action plan for a multi-center trial, the researcher can copy the relevant content into the UW diversity plan and add in any site-specific content. Researchers will likely need to make the sponsor aware of the WA State law during the budgeting and trial negotiation process to provide justification for the likely

increased resource needs (e.g., translation and interpreter service costs, development of culturally sensitive recruitment materials).

3. **Many of the questions in the new diversity plan supplement are open-ended. How will researchers know if their justifications meet HSD criteria for evaluating representation and whether the strategies that they intend to employ to reduce barriers and burdens are adequate?**

   Many of the questions in the diversity plan are open-ended by design to allow maximum flexibility for researchers to respond within the context of their specific clinical trial. There are links in each section to the guidance we've developed, which includes more information for researchers on how to respond. In general, HSD and the IRB will be looking at the diversity planning and asking whether it makes sense in the context of the specific trial and target study population. Has the researcher provided sufficient rationale that is supported by data in the literature, subject matter expertise, etc.? Have they consulted or worked with resource support offices to develop their recruitment strategy?

   HSD recognizes this is a new process for everyone and intends to be flexible and reasonable in our review. For studies overseen by the UW IRB, we intend to gather information at the time of Continuing Review to understand how things are going, what's working/not working for the study and what different strategies might be employed to make improvements.

   We expect this endeavor will be an iterative process that will take many years to refine. Our expectations for ourselves and researchers will be measured accordingly.

4. **Will specific requirements need to be met for small, pilot or rare disease exceptions outlined in the policy? For example, will there be a cap on the number of participants for the study to be considered "small"? Or will researchers be required to provide rationale?**

   We'll consider it and suggestions for how to define it can be sent to hsdinfo@uw.edu.

   Our initial thoughts are that 'small' is often a relative term and needs to be considered within the context of a specific trial and targeted study population(s). If a researcher believes this circumstance applies to their study, they should consult with HSD early in the study design/budgeting process so we can hear their rationale and provide a decision about the applicability of the DCT policy to their clinical trial.

5. **You mention that limits to participants' resources, such as limited access to specific technology, may exempt the clinical trial from specific requirements like e-consent. Will a**

research team's lack of expertise or budget to support translation, interpretation, or other barrier-reducing strategies exempt the study from requirements laid out in the supplement?

In general, no. Historically that has often been the justification for excluding or failing to make efforts to recruit from underrepresented populations. The new WA law does not provide any carve out for this. Researchers who are conducting a clinical trial need to ensure they have the necessary expertise and resources. This is why the policy will only apply to new studies submitted for IRB review one year from publication of the final policy. That should give sufficient time for researchers who are in the early stages of developing their clinical trial protocol to consider and budget for the new requirements. Existing studies are not subject to the new DCT policy.

That said, the UW is developing resources to provide support. For example, interpreter services will continue to be provided at no additional cost for research conducted in association with a UW Medicine clinical care visit. The legislature has provided some funding for supporting translations and the UW is looking at how those funds might be utilized for underfunded research.

6. **The policy asks for a description of steps taken to develop a culturally sensitive and inclusive approach to study recruitment and retention. Can you speak more about this requirement?**

Yes, this is a required element of the WA law, so it's included in our UW policy. The bill doesn't define this or provide any details so it's up to each institution for interpretation. However, the law does point us to using "methods recognized by US FDA" and FDA has put out some guidance on this topic. That said, there is some flexibility for the UW to decide what this means in the context of creating meaningful engagement with different underrepresented communities and reducing barriers so that they are interested in participating in research. At our town hall on September 20th, you'll hear from representatives from the Community Engagement working group that are developing resources to support this.

7. **Does the Diversity in Clinical Trials Initiative already have a community engagement group? If not, are there plans to create a group to go out into community to talk about research with the goal of education and not recruitment?**

The Office of Healthcare Equity (OHCE) will be creating a Community Collaboratory to collect resources for the research community.

There are multiple groups focused on community engagement across UW as a whole, including ITHS, and including an initiative across UW 3 campuses:

https://www.washington.edu/community-engagement/community-engagement-working-group/

We are working to identify and pool resources related to Health Science Research and Medicine. Our approach with the Community Collaboratory is still in development, but is taking a much broader lens than recruitment, and really one of meaningful relationship.

Please join our 9/20 town hall to hear more about this effort: https://washington.zoom.us/webinar/register/WN_QXoBxHGsSLqvxef_zIqiJQ#/registration

8. **Is UW partnering with other educational institutions/community partners to learn from progress made in diversity of clinical trials (e.g. the research done by grants such as the American Heart Association with support from Pfizer and Gates Ventures.)?**

   OHCE is actively connecting with national leaders in this work to learn from their experiences in leading this work. There are also several industry funded initiatives that have had success in this space. We would also welcome any additional UW expertise that's aware of or has connections with people who are doing this work nationally! Please connect us!

9. **In trying to make trials more accessible to the community, is there a plan to allow research to be done in neighborhood clinics?**

   It is currently possible to conduct research in neighborhood clinics. This would likely involve consideration of the appropriate IRB review arrangements and the execution of reliance agreements. HSD provides guidance on when the UW can serve as the single IRB reviewing the research. Please contact HSD if you have any questions about this at hsdinfo@uw.edu

   OHCE is in the process of reaching out to groups that come up in the town halls and in our community conversations. We are actively meeting with various groups to inform and build relationships for the work forward.

10. **Can you provide examples of underrepresented groups that are not described in the Diversity in Clinical Trials bill?**

    The diversity plan supplement is focused on collecting information about underrepresented populations as defined by the bill (codified in RCW 69.78): age, race, biological sex, sexual orientation, geography, and socioeconomic status. However, we acknowledge 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. Some examples include prisoners, pregnant people, and people with disabilities.

11. **Most clinical trials are using patient populations that already exist within UW Medicine instead of relying on outside referrals. Will UWM be providing study teams with this demographic information or making it publicly accessible? This isn't data that a study team has readily available to them and we don't have the resources to track or obtain that information.**

    We would like to reiterate that there is not an expectation that each clinical trial must enroll all of the underrepresented groups identified in the Diversity in Clinical Trials bill. The appropriate makeup of a study population depends upon a number of factors, including but not limited to the scientific question(s) being addressed, the prevalence of the disease, disorder, or condition among underrepresented groups, and potential gaps in scientific knowledge.

    As part of this work, the DCTI team is looking into tools and resources available and what additional solutions could be developed to help study teams obtain this information. The UW tools currently available for identifying the distribution of underrepresented groups within the study's target population include:

    - **Leaf.** A self-service, free of charge tool that allows UW investigators affiliated with UW Medicine and who have an AMC account to query the UW Medicine electronic health system (EHS) records. Leaf interacts with live data from the EHS and can generate de-identified data sets in real time.
    - **ITHS Biomedical Informatics.** For researchers not affiliated with UW Medicine, the ITHS Biomedical Informatics team may be able to provide data sets and cohort discovery services. These services may be fee-based but free of charge consultations can be requested.
    - **UW Health Sciences Library.** Librarians are available to assist research teams with identifying underrepresented groups described in publications, preprints, and publicly available databases and registries through the Ask Us portal.

12. **What is the expectation for accounting for socioeconomic diversity and representation? Will our local entities be involved in a process to more efficiently and accurately collect this data so that we can target numbers and actively identify these patients? Sexuality and socioeconomic status could be a challenge to identify depending on the type of study conducted.**

    We are working with a team in UWM to identify data collected in Epic that could be candidates to summarize demographic information that may not be easily represented by one variable or that reflect complex demographic categorizations. In some cases, these may be variables that are being considered by the UWM team and not yet being collected within Epic.

Our goal is to gather the thoughts and perspectives from experts and community partnerships to help assess these cases and inform decisions when we are defining and implementing them into data collection processes.

Even when a study does not have enrollment goals that focus on socioeconomic status and sexual orientation, it is still important to consider barriers to participation to ensure that underrepresented groups have access to the trial. For example, for patients with low income, access could be improved by addressing economic challenges to participation in research. This might include allowing for study visits outside of work hours, reducing travel by conducting study procedure remotely when possible, providing adequate compensation for participation, and other methods described in the guidance under, "Reducing Participation Barriers and Burdens."

13. **Will UW be providing data on what the language populations are for the hospital and specific clinics? Research teams and clinicians rarely have this information.**

    Data on language populations across UW Medicine available via the UW Language Access website (NetID required): https://uwnetid.sharepoint.com/sites/uwlaca/SitePages/Language-of-Care-Data.aspx?source=https%3A%2F%2Fuwnetid.sharepoint.com%2Fsites%2Fuwlaca%2FSitePages%2FForms%2FByAuthor.aspx

14. **Is e-consent required for all studies, even when consent will happen in-person?**

    The default assumption is that e-consent should be an 'option' for participants where it makes sense to reduce burdens for individuals who might not otherwise be able to participate. Researchers should be able to give individuals the option to consent electronically if they wish. However, we recognize where there may be studies or populations where that doesn't make sense. In those cases, the researcher can articulate this in the diversity plan supplement for the IRB to consider.

15. **Is HSD requiring a specific e-consent tool or, for example, can a research team use a tool provided by a sponsor or coordinating center?**

    The UW currently supports two e-consent tools, REDCap and DocuSign. HSD will consider and approve other e-consent methods but there are some additional requirements for attestation about the security of the system and compliance with state and federal e-signature laws. In general, it has not been a problem to review/approve other e-consent tools.

16. **Does the UW/ITHS have any resources available to clinical trial teams to help with creating e-consents?**

Guidance and resources for researchers planning to use e-consent:

- HSD Tutorial: Electronic Consent: What You Need to Know
- HSD guidance: Approvable methods for obtaining electronic signatures
- HSD guidance: UW e-Signature Tools
- ITHS webpage: Using REDCAP to consent research participants
- The ITHS Research Coordination Center (RCC) is a pool of research coordinators that can support research, including REDCAp build support, on an hourly basis. Please contact the RCC to learn more at ithsrcc@uw.edu.

17. **There is some concern that the 2-week turnaround time for translated consent forms, following the use of the short form, is too short. Can you speak to the justification for 2-weeks?**

    We feel it is important that study participants with limited English proficiency that are consented via the short-form process should have access to the same information as any other participant, in a language that is understandable to them. The consent form is a useful tool for participants to refer back to for information associated with upcoming study procedures and associated risks. We agree with FDA that these individuals should be provided a translated copy of the full consent form in their preferred language. Two weeks was chosen because we feel that provides sufficient time for a researcher to obtain a translation and submit it to the IRB for review/approval.

    In the town hall coming up on September 20th you'll hear more about the translation services the UW is standing up to support this but basically, rapid translation will be available and easy to request. Researchers will be able to send an email request with a translation company already contracted with UW. For more common languages like Spanish, rapid turnaround on translation could be 1-2 business days. For more rare languages, it could take 3-5 business days. Once the researcher has the translated consent form back, they can submit a modification in Zipline solely for approval of the translated consent form. That submission process takes about 15 minutes. This means that from the time of initial email request to the translation company to submission to the IRB approval, a researcher could accomplish this within a matter of days but certainly within 2 weeks. Once received, HSD is committed to reviewing and approving a clean mod with just a translation request within 1-2 business days. After that, the researcher would need to provide a copy of the translated consent form to the participant. This could be accomplished by email or a physical copy provided at their next visit.

18. **Does the requirement for a 2-week turnaround time for translated consent form following the use of the short form apply when the research is reviewed by an external (non-UW) IRB?**

The proposed policy is to apply this requirement regardless of which IRB is conducting the review and the UW site would have access to all of the same translation resources regardless of which IRB does the review. We will review the feedback we receive and will make a final decision after the public comment period which concludes on September 16.

19. **Will HSD require back translation of consent forms? If not, how does HSD verify the accuracy of translation into another language?**

    Back translation is the process of translating a text back to its original language after it has been translated into another language. Some IRBs ask researchers to provide back translations to check the accuracy of a translated consent form by comparing it to the original English version. HSD does not currently require back translation and has no plans to require this in the future. Instead, we focus on the qualifications of the translator. When research involves more than minimal risk, we require an attestation by the translator or translation company that the translation is true, accurate, and complete. That said, for clinical trials reviewed by an external non-UW IRB, it will be important to know if the reviewing IRB requires back translations in order to plan and budget accordingly.

20. **Is the diversity plan supplement required only when HSD is the IRB of record or does this also need to be submitted with a request to rely on an external IRB for review?**

    The supplement will be required to be submitted as part of the IRB application when a clinical trial will be reviewed by the UW IRB. It will also need to be submitted as part of the request for reliance when a clinical trial will be reviewed by an external IRB, such as a commercial IRB (e.g. Advarra and WCG IRB) or other non-UW IRB (primarily IRBs at other academic institutions). The only exception is when the research will be reviewed by either the Seattle Children's Hospital IRB or the Fred Hutchinson Cancer Center IRB because these two institutions are developing their own policies and procedures to comply with the new WA State diversity in clinical trials requirements.

21. **Do the Diversity in Clinical Trials policies and guidance that were presented at the town hall meeting apply only to clinical trials reviewed by the UW IRB or do they apply to all UW clinical trials?**

    The policies and guidance apply to all UW clinical trials where UW employees or agents are responsible for or engaged in recruitment and consent activities. They apply:

    - regardless of where the interventions take place;
    - to studies reviewed by an external non-UW IRB; **and**
    - as a condition of the UW IRB agreeing to review on behalf of non-UW institutions and individuals.

There are 3 categories of research that have been identified as exceptions to the requirement for a diversity plan. These include phase 1 or earlier trials, pilot and feasibility studies, and treatment for small populations.

When the research is reviewed by Advarra or WCG IRB, they will review the diversity plan supplement and apply the policies and guidance presented today. When the research will be reviewed by another external IRB HSD's Reliance Team will assess the diversity plan when it is submitted with the request to use an external IRB. Researchers must then incorporate the plan information into the external IRB's application materials.

22. **When the diversity plan supplement is reviewed by Advarra or WCG IRB, will there be additional costs associated with this review or will this be covered by the standard IRB review fee for industry-sponsored trials?**

    HSD is confirming with Advarra and WCG that the review of the diversity plan will be covered by the standard fee for IRB review. We will provide an update when we have more information.

23. **Can you update us on how tools like Epic and OnCore will be used and if there will be guidance and / or standards for researchers to reference when documenting race and other demographics?**

    The tracking of enrollment and demographic data happens at many levels. Researchers use methods and tools that support capturing the data they need to meet the aims of their study. Sponsors may have specific requirements for how data is tracked and reported. Our goal is to identify a solution that meets the DCTI objectives and continues to support these various scenarios without introducing duplicative work for studies that track and report these types of data.

    A working group is assessing how the data and processes of current systems like Epic and OnCore can be leveraged to support the collection and reporting of information in support of the DCTI. A component of this includes specifying how demographic variables are defined and operationalized within the system.

    The outcome of this work will include documentation of the demographic variables and their definitions, the possible categories within a variable, and supporting references as appropriate.

24. **When studies are acting as a subcontractor under a larger study the funding is often defined for us, so it might not be within the local sites ability to define resource availability. What can**

UW researchers do in this situation to ensure that they have adequate resources in place to support inclusion of underrepresented groups?

If the UW researcher is engaged in the screening, recruitment, or enrolling research participants for a clinical trial, they are subject to the new policy. Researchers are encouraged to consider all the costs associated with the requirements of the diversity plan and to ensure subaward budgets and other fiscal agreements cover the full cost of the research.

During the Town Hall on Friday, September 20, DCTI will share about funding that is specifically earmarked to support researchers with translation and interpretation during the initial years of this initiative.