9/20 Town Hall Questions and Answers

1. **One of the things I think about frequently in recruiting participants from marginalized backgrounds is that the sum of regulatory requirements has made it more difficult and less intuitive for people to participate. How is UW and UW HSD working to revisit things like length and complexity of consents and the process of reconsenting for administrative changes that don't impact the participant? And adding more flexibility like using clinical lab values or conducting research off campus when possible to be able to reach more people? While acknowledging the IRBs and many regulations were formed to increase safety and protection of vulnerable populations, there are now several parts of how we conduct clinical trials that actually impair how we reach, talk about, interact with marginalized populations? For example, the complex legalese and 31 pages in many informed consents can't possibly help increase trust, "being informed", or psychological safety about the research.**

   Answer
   Last year HSD published guidance and consent templates designed to facilitate a participant focused consent process and address issues around the complexity and length of consent forms. You can find information about this in this newsletter: https://www.washington.edu/research/announcements/for-the-record-090523/#a1

2. **Are there any plans to create regulatory relationships with community groups and other local healthcare systems? A large burden they (and we) face is having to go through regulatory approval (IRB, DUA/DTUA) from scratch for each individual study. A different framework with pre-agreed terms around data use and other common aspects of research studies would help reduce these barriers.**

   Answer
   There is not a process for this at this time and we acknowledge this creates barriers for CBOS and other groups. A working group will need to be started to focus on this.
   Agree a working group is needed after we engage with community. Policy will be deferred back to HSD re: regulations working with CBOs
   HSD has established processes in place, to manage IRB review arrangements for collaborative research that could be used to establish IRB review relationships with local clinics and healthcare systems. If you are planning to work with local healthcare systems, please contact HSD about these process at hsdinfo@uw.edu.

3. **Also interested to hear during the Q&A session how WA state legislation and UW work will interact with the FDA guidance that is coming out (which has some wording that sounds like racial essentialism, and we've given feedback about changing this)**

Answer

The WA DCT law directs us to use FDA methods for recruiting from underrepresented groups. This is why the HSD Diversity Plan and Guidance are largely based on the draft FDA Diversity Action Plan Guidance. Since two thirds of UW clinical trials are FDA-regulated, the FDA guidance will apply to a majority of our clinical trials. It is our hope that this will help reduce duplication of effort on the part of sponsors and researchers. We do also draw from other sources such as the Multi-Regional Clinical Trials (MRCT) Center Toolkit and User Guide for Achieving Diversity, Inclusion and Equity in Clinical Research. We recommend watching the recording of the September 4 town hall meeting for an overview of the Diversity Plan and Guidance.

4. **Wondering if strategic initiative(s) focusing on rare cancer types would help promote community engagement further?**

   Answer

   While we don't have plans for initiatives specifically targeting rare cancers or other specific diseases, we're deeply committed to supporting community-driven efforts in this area. Our approach involves collaborating with organizations already focused on rare cancer research and listening to the community to understand their needs and priorities. This collaborative model allows us to leverage existing expertise and ensure our resources are aligned with the community's goals. We believe this strategy will ultimately be more effective in advancing research and support than launching our own separate initiatives.

5. **Another question for HSD: Why are we still using "subject" and not "participant" in the consent templates and in a lot of the language**

   Answer

   HSD is taking a holistic approach to the content in our documents and our website, and we are currently working on developing an inclusive language guide for our office.

6. **Better understanding of the data - what groups are disproportionately affected by certain diseases?**

   Answer

   Our DCTI team is partnering with UW Medicine Research IT to leverage data from Epic and from OnCore to address various aspects of our data needs related to the initiative. One of the areas we're looking into is diagnosis-related data and the extent to which we can include this information with demographic variables in our reporting solutions.

7. **Another huge barrier is lack of transportation for potential subjects who have disabilities that keep them from being able to drive, comfortably use transit or**

participate without out-of-pocket expenses or asking a family member to take time off work to bring them. This is a prominent issue in certain disease groups as a barrier or reason a participant discontinues participation. Is this a consideration to help reduce barriers?

Answer
Absolutely. The HSD Diversity Plan calls for researchers to describe the measures that will be employed to reduce participation burden, enroll, and retain underrepresented groups that are appropriate for the study population. Refer to p16 of HSD's draft diversity in clinical trials guidance for a more detailed discussion on reducing barriers and burdens.

8. **The most prevalent issues I see in recruiting marginalized communities are the requirements of a study schedule. The folks who: regularly seek medical care, can take time off of work to come in during business hours (or are retired), are not primary caregivers, etc. are generally not from marginalized groups, which results in a heavy self-selection bias.I would love to have resources to address these issues, but they seem so ubiquitous with the clinical trial model that it is hard to imagine solutions.**

   Answer
   As part of best practice, we encourage equitable compensation for time given to research and reimbursement. There is not a lot of standardization regarding compensation and this needs to be developed and included in budget for research. Perhaps there can be a group that can come together to create standards.

9. **Do the DCTI rules also apply to transcription?**

   Answer
   Yes, a live person needs to review transcription. So, for example, should a team choose to utilize auto-transcription for a Zoom meeting, it is necessary that a live person review the transcription (ideally in real time) to catch any meaningful errors**.**

10. **Does the bill specify a number of languages that studies need to provide interpretation/translation for?**

    Answer
    It does not. The guidance comes from federal guidelines around providing translation for languages that meet the 5% threshold. At this time in our area that is Spanish, so the recommendation is to plan to translate all materials in Spanish. Beyond that, research teams can determine which languages they need services for depending on which communities are being recruited from.

11. **What about studies that involve other states? Some other U.S. states have passed laws prohibiting DEI-type projects. Does UW have advice for that issue and navigating that?**

Answer

The UW Diversity in Clinical Trials policy and its associated requirements apply regardless of where the research is being conducted. While the new WA State law aims to improve enrollment of underrepresented groups, the requirements to consider equitable selection of participants under federal regulations (45 CFR 46 and 21 CFR 56) and the ethical principles of the Belmont Report have existed for decades and apply across the US. If there is a specific state or local law that a researcher believes may impact the conduct of the research and specifically the implementation of their diversity plan they should contact the Human Subjects Division (hsdinfo@uw.edu) for consultation.

12. Do you provide Spanish interpreters at no cost for researchers to include Spanish speaking patients in their studies?

Answer

Accessing professional interpretation services in any language has associated fees. See the UW Language Access site (NetID required) for more information. Research-related conversations that occur in tandem with direct healthcare provision may utilize the same interpreter as the healthcare team, with no additional cost to the researcher. The purpose of this decision is continuity of conversation for the patient. However, research teams will be responsible for covering the costs of conversations occurring outside of direct health care (phone calls, community visits, appointments specific to the research, etc.)

13. When will fees for translation services be available?

Answer

Information about currently contracted vendor fees can be found on the UW Language Access site (NetID required)

14. Will recruitment resources/community engagement resources have fees?

Answer

The answer to this broad question really depends on the source and types of those resources. As a part of the DCTI, we are not planning on standing up new resources that have fees associated with them for researchers. We would prioritize any money being exchanged to be directed towards community organizations.
Many of the resources that we are collating are already available, free of charge.

15. **Is UW requiring specific source information be used when establishing the language threshold of their prospective study population if the study is not conducted in King County or is remote and not limited to a geographic area?**

    Answer

    There is no requirement to use a specific information source when establishing the language threshold of study population. However, the expectation is that it should be as accurate and reliable as possible.

16. **You mention FDA guidance for identifying or selecting an interpreter. For studies not following FDA guidance, does UW have guidance for selecting language services?**

    Answer

    At the September 4 Town Hall, HSD Director Jason Malone discussed use of an interpreter in the context of new FDA guidance on consent and the short form consent process. We do provide some considerations for working with interpreters in the section of HSDs consent guidance that discusses comprehension barriers. Friends and family members aren't going to be the best option when there is a need to communicate complicated medical information, and due to potential privacy concerns. It's important that the interpreter is appropriately qualified, in terms of certifications, experience, familiarity with research-related vocabulary in English and the target language, to ensure that information about the research is accurately conveyed to the participant.

    UW Medicine follows guidance from the Non-discrimination clause (section 1557) of Affordable Care Act, directives by the Centers for Medicaid and Medicare (CMS), and our hospital accrediting body, The Joint Commission, in addition to others regarding language access. Details about those regulations and their implications can be found at: https://uwnetid.sharepoint.com/sites/uwlaca/SitePages/Regulations.aspx (NetID required). In brief, as a recipient of federal funds, UW Medicine must take reasonable steps to provide meaningful access to healthcare conversations including ensuring that those who are providing services in languages other than English are qualified to do so. UW Medicine recognizes qualified services to include: state or national medical interpreter certification, staff bilingual assessment through vendor contracted with UW, and qualification assessments administered by interpreter/translator vendors contracted with UW Medicine.

17. **Are all clinical trials included in the scope of this initiative subject to the Affordable Care Act, the ADA, and other regulations you shared about today?**

    Answer

All clinical trials are included in the scope of federal civil rights laws, such as title VI of the 1965 Civil Rights Act and the ADA, as those are applicable to all persons in public arenas (including state institutions such as UW). Some regulations, such as the Affordable Care Act, CMS, and Joint Commission regulations are specific to the arena of direct provision of healthcare.

18. Will participants undergoing screening, but not yet enrolled, be required to have a medical record number?

    Answer

    No. When requested, that demographic field can be left blank.

19. **Are in-person interpreters available to researchers outside the UW Medicine clinics?**

    Answer

    Yes, to the extent that UW Language Access & cultural Advocacy (UW LACA) can assist the researcher to contract a freelance interpreter for the language/location/date/time requested. They cannot be guaranteed. UW Medicine staff interpreters are not available for research work off site.

20. **Are UW tablets for video access to interpreters available to research teams outside of UW Medicine (UWM) clinics? If so, is there a cost?**

    Answer

    No. The UW tablets are specific for the provision of direct healthcare at a UWM site. Should a researcher have a specific need for video interpretation that cannot be address otherwise (e.g. extensive work with the Deaf population outside UWM facilities), UW LACA can discuss the possibility of assisting the researcher obtain their own (sub)contract with a video vendor for their research's express use.

21. **An often-asked question is whether we should consider increasing stipends, compensation for time, and reimbursement– specifically for missed work, transportation costs, childcare. What are your thoughts?**

    Answer

    Equitable compensation for time given to research and reimbursement for expenses incurred in order to participate is encouraged. Researchers should consider the costs to individuals for participating in the research (including lost opportunity costs such as missed work) and do so in the context of the particular population they are recruiting from. In some instances, input from the targeted community early in the study design

and budgeting process may be beneficial in informed appropriate compensation and reimbursement amounts.

22. Sometimes researchers hear that increasing stipend, compensation for time, and reimbursement are coercive or constitute an undue influence. Could you share HSD's position on increasing incentives?

Answer

Payments are considered to be unduly influential when they cloud someone's judgment while they consider unreasonable choices. For example, a payment would be unduly influential if it caused potential participants to not adequately consider the risks, discomforts and burdens of participating in research. Unfortunately, there isn't a fixed standard for determining when a payment becomes unduly influential.

In recent years ethicists have argued that IRB emphasis on concerns about undue influence has led to unnecessarily conservative limitations on the size of incentives. For the purpose of increasing representation in clinical trials, we would instead like to emphasize the need to reduce financial barriers to participation in research. It's not unduly influential to reimburse participants for expenses incurred due to participation in research, such as travel, parking, meals, lodging, and childcare costs. It is not unduly influential to provide compensation that appropriately offsets the time and burdens of research participation because for many people participating in research means forgoing other sources of income. We encourage researchers to be thoughtful about payment to participants and consider that underpaying could mean asking some participants to assume a burden to participate in the research.

We recommend reviewing HSD's guidance on participant payment where differences between coercion, undue influence and mere influence, as well as reimbursement, compensation, incentives, and types of payment are discussed.

23. Can you speak more about programming code from an external LLM code undergoing additional security review? Who would provide this security review?

Answer

We recommend connecting with the UW Generative AI (GenAI) task Force as they are building recommendations based on the LLM Workgroup sponsored by Dr. Tim Dellit: GenAIatUWM@uw.edu https://huddle.uwmedicine.org/wp-content/uploads/2024/02/UW-Medicine-LLM-Interim-Guidance-Generative-AI.pdf

Links shared:
https://huddle.uwmedicine.org/wp-content/uploads/2024/02/UW-Medicine-LLM-Interim-Guidance-Generative-AI.pdf

https://uwnetid.sharepoint.com/sites/uwlaca/SitePages/Language-Access-Resources-for-Clinical-Trials-Research.aspx
https://www.iths.org/dcti/

Fatal Invention
https://www.goodreads.com/book/show/10055524-fatal-invention

PCORI: 4 Equity Guiding Principles
https://www.pcori.org/sites/default/files/Equity-and-Inclusion-Guiding-Engagement-Principles.pdf

PCORI's Foundational Expectations for Partnership in Research
https://www.pcori.org/resources/pcoris-foundational-expectations-partnerships-research

Spectrum of Community Engagement to Ownership
https://movementstrategy.org/wp-content/uploads/2021/08/The-Spectrum-of-Community-Engagement-to-Ownership.pdf

HSD guidance on translation/interpretation:
https://www.washington.edu/research/hsd/guidance/consent/#8a

HSD payment guidance: https://www.washington.edu/research/hsd/guidance/subject-payment/