November 19 DCTI Town Hall Questions and Answers

1. **What eConsent options are available to UW researchers to meet DCTI requirements?**

   Answer

   The UW REDCap 21 CFR Part 11 Instance and UW Florence are FDA compliant eConsent platforms. Both platforms are expected to be available around January 30, 2026. The UW REDCap ITHS instance and UW Docusign are not FDA compliant but are available now.

Service	FDA Part 11 Compliant	Available
UW Docusign	No	Now
UW Florence	Yes	January 30, 2026
UW REDCap ITHS Instance	No	Now
UW REDCap Part 11 Instance	Yes	January 30, 2026

2. **How do eConsent forms record subject answers to yes or no questions?**

   Answer

   Most eConsent forms will use a checkbox feature to record answers to yes or no questions. It is important to highlight these fields to participants when going over the consent process to ensure they are not missed, as these checkbox fields are optional.

   In REDCap you can make certain questions "required." On the eConsent attestation page, participants are required to select "I attest" for a valid eConsent and for the workflow to be complete.

3. **What patient health information do these eConsent platforms obtain?**

   Answer

   Research teams should refer to what the IRB stipulates as required.

   Docusign: The full name and email address of research participants is required to send the document for signing. No other patient health information (PHI) is required. This information is inputted by research staff in the "recipients" section of an agreement.

   REDCap: REDCap does not technically require any information. However, for best practices, first and last names are highly recommended for verification purposes.

   Florence: The user's identifier is associated with an email address, and they will also be required to select a code that will identify them to the researcher. This can be decided by the researcher and the participant and does not need to be related to any PHI.

4. **What is the consent process like when eConsent is used? Are PIs/research coordinators sitting down with the potential participant in real-time (whether in person or on Zoom) and having an informed consent discussion and Q&As?**

   Answer

   You can use eConsent for fully remote participants, in which case you walk through the eConsent form with them via Zoom or a phone call, making sure to leave time for questions. Ideally, coordinators should send a copy of the Informed Consent Form document ahead of time, so participants have a chance to review in advance. Once the consent discussion is complete, research staff can send the participant a link to the eConsent form.

   The process is similar for in-person participants, although research coordinators may use a physical consent form to reference (in addition to the eConsent platform) for their informed consent discussions. After explaining the form and leaving sufficient time for questions, the research coordinator can send the participant a link to the eConsent form and walk through the signing process in person.

5. **Can a parent consent and child assent have one code number?**

   Answer

   Florence: You can group a research participant with other signers associated with them, such as a parent. Each signer would need a unique identifier.

   REDCap: You can house a child assent under the record ID of the parent. You can have multiple email addresses or signatures under one record ID. Consider taking the free Translational Research Education Engine training course for support on setting up multi-signatures in REDCap eConsent 2.0.

   Docusign: You can create a new role for a child assent on a parental consent form, similar to the way you could add a witness. Please refer to the November 19 Town Hall recording (39:55 – 42:40) for a Docusign demo.

6. **Part 11 compliant Docusign seems to be a more common industry standard for sites. Will this be considered in the future?**

   Answer

   For the initial launch of the policy and supporting research, we have only explored Florence and the REDCap Part 11 solutions.

7. **Will there be a cost only for use of a REDCap Part 11-compliant eConsent module, or also for the use of the REDCap ITHS instance for eConsent for non-Part 11-compliant studies?**

   Answer

   The existing ITHS REDCap instance is free for all users in the WWAMI region. There will be a cost associated with the REDCap 21 CFR Part 11 instance. The cost is not yet confirmed but should be announced in the coming months.

8. **Will the REDCap platform be presented in the non-English language with process instructions in the same language as the document?**

   Answer

   Although translated non-English language consent forms can be used in the REDCap Part 11or ITHS instance, REDCap does not do any translating. Consent forms or instruments need to be translated by study teams. Study teams can translate specific process instructions within the Multi Language Management feature within REDCap. The Multi Language Management feature can be found under the application section within the project.

   There are some .ini files available that translate process aspects such as "submit this" or "critical error" that can be shared with investigators. However, these are community translations and should be reviewed by official translators. These are available in limited languages. Please reach out to redcaphelp@uw.edu for a link to the repository with these files.

9. **Can you expand on what Florence participant access training means? Do patients need to do training before they can sign eConsent forms?**

   Answer

   Participants will need to know how to create a Florence account, navigate the website, and locate the consent documents. The UW Clinical Trials Office is in contact with the Florence vendor to learn about available trainings options and additional support mechanisms.

   There is no participant training needed to use REDCap or Docusign, but research teams should walk through the system with participants at least once and highlight key areas such as checkboxes or the submit button.

10. **If patients need training to use Florence, is it available in multiple languages for them?**

    Answer

    Right now, Spanish is the only non-English option. An interpreter will need to assist with other languages.

11. **Will there be costs associated with Florence for industry-sponsored research? What about non-interventional studies?**

    Answer

    For Florence, the cost is for industry-initiated (not PI-developed) studies. This applies to non-interventional studies as well. Basically, if you have an industry sponsor with a negotiable budget, there is a charge. There is no cost for investigator-initiated studies in Florence, despite the funding sources.

12. **Is there a lag between the time participants complete training and them being "added" to the system or creating an account in Florence?**

    Answer

    Once the participant verifies the email associated with the account, they should be able to access it. Right now, we do not have much information about the training process itself. Research coordinators may need to walk participants through, or it may have a self-guided tour for participants to become familiar with using the system. We are still pending these details from the Florence vendor.

13. **How do we request access to the Florence eConsent tool?**

    Answer

    Once UW finalizes their contract to use eConsent, the UW Clinical Trials Office will send an announcement to alert the community. The Clinical Trials Office's Florence webpage will also be updated with eConsent news.

14. **Can you confirm that the DCTI policy only applies to new (and not ongoing) studies?**

    Answer

    Yes, the policy applies only to new studies submitted to the UW Human Subjects Division as of January 1, 2026.

15. Are there examples of previously approved Diversity Plans for reference?

Answer

No. We do not have examples of the completed Diversity Plan for Clinical Trials Supplement form at this time. However, the Human Subject Division Diversity in Clinical Trials Guidance does include a few cases studies illustrating diversity efforts that have been successfully integrated into clinical research designs and links to additional case studies on the Multi-Regional Clinical Trials Center website about achieving diversity in clinical trials.

16. What is the coordination of plans between UW and Fred Hutch?

Answer

The UW Human Subjects Division had regular meetings with Fred Hutch and Seattle Children's leading up to the initial publication of the Human Subjects Division's Diversity in Clinical Trials Guidance and the related supplement to discuss the implications of UW's policy requirements. We have coordinated about how to handle research involving UW that is submitted to Fred Hutch and Seattle Children's for IRB review, and on some related issues, such as requirements for the use of the Short Form Consent Process for the unanticipated enrollment of participants with a non-English language preference.

17. How would this apply to foreign recharge centers (like UW-Kenya) with foreign staff hired by UW?

Answer

The UW Diversity in Clinical Trials policy applies to clinical trials when UW employees or agents are responsible for or engaged in recruitment and consent activities. It is often the case that these foreign staff are responsible for recruitment and consent, but it is not always clear when they should be considered UW employees or agents. This can vary depending on contractual arrangements. Please email hsdinfo@uw.edu if you have questions about whether work conducted by foreign staff is subject to the Diversity in Clinical Trials policy.

18. Are there any conflicts with the Washington State law and NIH policies?

Answer

The DCTI requirements align with an August 15, 2025, policy statement from the NIH that reinforces the priority item "Promoting research focused on scientifically valid, measurable health outcomes." It states that:

“NIH will continue to support research that advances the health of all Americans, regardless of their age, race, ethnicity, sex, sexual orientation, or other characteristics. To conduct meaningful biomedical research, scientists must consider both individual and external factors that influence health outcomes, guided by the needs of the specific research question…”

https://www.nih.gov/about-nih/nih-director/statements/advancing-nihs-mission-through-unified-strategy

19. How do these rules apply to studies that enroll patients in EFIC trials?

Answer

EFIC trials are clinical trials conducted under an Exception to the Informed Consent requirement. These investigations involve people who have a life-threatening medical condition that necessitates urgent intervention for which available treatments are unproven or unsatisfactory, and who, because of their condition (e.g., traumatic brain injury) cannot provide informed consent. The research must have the prospect of direct benefit to the patient and must involve an investigational product that, to be effective, must be administered before informed consent can be obtained. These studies will face some unique challenges or constraints in applying some of the requirements of the Diversity in Clinical Trials policy.

The UW Human Subjects Division will be meeting with some representatives from the Department of Emergency Medicine to better understand the unique challenges and constraints faced by EFIC studies in the application of the Diversity in Clinical Trials policy requirements and will consider what aspects of the guidance require clarification in light of these discussions.

20. **Should investigators interpret the UW Diversity in Clinical Trials policy, and specifically the Stage 3 requirements in the Community Engagement rubric, as creating additional obligations for EFIC studies beyond what the FDA requires for community consultation and public disclosure?**

    Answer

    The policy requires studies that are subject to the Diversity in Clinical Trials policy to comply at minimum with all Stage 2 requirements. EFIC studies are listed as an example of studies that may need to go beyond Stage 2 requirements; however, they are not required under the UW Diversity in Clinical Trials policy to apply all the level 3 requirements listed in the rubric. They would not be expected to go beyond what is required by federal regulations after Stage 2 requirements are met. The Human Subjects Division plans to clarify this in the Diversity in Clinical Trials guidance.

21. **For the new DCTI policy, can you clarify if this applies only to NIH-sponsored clinical trials or all clinical trials?**

    Answer

    The UW DCTI policy applies to all studies that meet the definition of a clinical trial regardless of funding source. We use this definition of a clinical trial:

    "A research study that prospectively assigns one or more human subjects to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

    https://www.washington.edu/research/glossary/clinical-trial/

22. **It looks like there is no requirement to follow the DCTI policy for the development of specimen repositories. Is this correct?**

    Answer

    The policy applies to studies that meet the definition of a clinical trial and do not meet one or more of the policy exceptions outlined in the Diversity in Clinical Trials guidance. Specimen repositories would generally be excluded. If you have questions about the applicability of the policy to your study, please contact the UW Human Subjects Division (hsdinfo@uw.edu).

23. What support will the University supply in terms of translation services?

Answer

UW Medicine holds contracts with various vendors providing translation, transcription, and interpretation services. UW Medicine's Information Technology has braille transcription and embossing resources. Investigators should plan to reserve these services in advance. Please visit UW Medicine Language Access & Cultural Advocacy to learn more about these resources. If you have any questions, feel free to contact Yvonne Simpson (simpsony@uw.edu) or UW Language Access (uwlaca@uw.edu).

The Office of Healthcare Equity is also currently providing bridge funding for language access needs—such as document translation, interpreter services, and communication access real-time translation (CART) services—that will help researchers more effectively recruit and engage underserved populations in clinical trials.

24. Will UW provide any support to investigators for any mechanisms like community outreach?

Answer

The Office of Healthcare Equity is actively collaborating with local community-based organizations to support investigators. The Community-Based Research Collaboratory (CBRC) includes 15 diverse organizations partnering with us to strengthen researcher-community engagement. Together, we participate in community events, host informational tables, gather insights on community perceptions of clinical trials, and create opportunities for feedback on research projects. A core offering and goal for the CBRC is explicitly to build more channels to connect our UW researchers with the community, in ways that approach them with respect and deep cultural humility. If you have any questions about collaborating opportunities, feel free to reach out to Juliana Garcia, Assistant Director of Community Engagement, at garcia00@uw.edu, or you can also contact us at ohce@uw.edu.

25. **The requirement to use the bridge funds within 30 days seems limiting. Can you expand on examples of using bridge funding for interpreters?**

Answer

We allow researchers to submit a quote for anticipated services, ensuring they have an estimate from a vendor and understand potential costs. This approach enables us to approve funding within the 30-day window while recognizing that actual invoicing typically occurs after the service is provided. In other words, we can commit funds based on the estimate, even if the final invoice comes later. We do need to ensure all services are completed within the billing cycle by June 2026, pending future funding availability. We want to award the funds to those that will use them and not inadvertently hold funds in a way that prevents others from using them.

Funds are limited and tied to a specific budget cycle, which means we cannot carry over funds from one cycle to the next for future projects. To ensure equitable access, the application will remain open until funds are fully allocated or through May 2026, whichever comes first. The 30-day usage requirement is intended to support immediate needs for ongoing studies rather than long-term planning. For example, teams can use bridge funding to cover interpreter costs for participant visits already scheduled, urgent consent processes, or rapid enrollment activities where language access is critical. If you have any questions, feel free to reach out to Juliana Garcia, Assistant Director of Community Engagement, at garcia00@uw.edu, or you can also contact us at ohce@uw.edu. We are happy to help you navigate this process!

26. **Does the UW Medicine Patient Demographics dashboard include patients enrolled in clinical trials at Fred Hutch?**

Answer

The current dashboard includes individuals who have had an encounter or visit in the UW Medicine system. This is independent of if they have been a participant in a clinical trial. Future dashboard developments intend to include clinical trials where the University of Washington is the holder of funds, which would include cancer-related clinical trials.

Resources

Below you will find a comprehensive list of resources to assist with completing the Diversity Supplement and establishing recruitment goals.

UW Medicine Patient Demographics Dashboard

UW Medicine Patient Demographics Dashboard. A free, self-service tool available to anyone with a UW NetID. The dashboard provides aggregated demographic data from EPIC and OnCore Clinical Trials Management System about the UW Medicine patient population. It is designed to help researchers align their enrollment goals with the requirements of the UW Diversity in Clinical Trials policy and provide a data-driven foundation for setting realistic and inclusive recruitment targets based on the populations served by UW Medicine. Users must be on campus or connected to the UW network through an active VPN connection to access the tool.

UW Health Sciences Library

UW Health Sciences Library. Librarians are available to assist research teams with identifying underrepresented groups described in PubMed and the ClinicalTrials.gov registry. For clinical trials and studies subject to the DCTI requirements, submit your interest via this DCTI Library Intake form. The librarians can assist with non-clinical trial research via the Ask Us feature.

Recruitment Support Service

The ITHS Recruitment Support Service provides a free consultation service to investigators, focusing on pre-award and study development, study design, implementation strategy, recruitment and retention planning, and budget development to help researchers attain their enrollment goals. **Researchers and their teams are encouraged to contact the ITHS Recruitment Support Service early and preferably in the proposal or grant development phase** to discuss and develop recruitment strategies.

Translation and Interpretation Services

UW Medicine Language Access and Cultural Advocacy has many resources for UW researchers and can provide consultation when you are planning your research study and writing the proposal. These resources are available to all UW researchers, even when the study is not taking place at UW Medicine or Harborview. Interpretation services can be accessed anywhere telephone service or video conferencing are available. You can contact them directly at uwlaca@uw.edu.

Language Access Bridge Funding

The Office of Healthcare Equity (OHCE) offers up to $5,000 to support language access needs for UW researchers conducting clinical trials. Funding is intended for real-time language access needs (within 30 days). OHCE will submit payment for the desired support services for approved applications. Researchers are required to submit an initial quote for support needs during the application process. Awardees will be contacted within 2 weeks to move forward with gathering final documents and submitting payment. For more information, visit Language Access Bridge Funding.

Electronic Consent Tools

Human Subjects Division Guidance:
https://www.washington.edu/research/hsd/guidance/consent/econsent/

Docusign: https://it.uw.edu/esig

Docusign interest form: https://it.uw.edu/uware/esignatures/

Docusign help form:
https://uwconnect.uw.edu/sp?id=sc_cat_item&sys_id=916c087f1b3b9114cc990dc0604bcb44

REDCap: http://redcap.iths.org

REDCap training service, TREE: https://ithstree.org/login

Florence: https://clinicaltrials.uwmedicine.org/electronic-regulatory-documents-management-uw-florence/

Additional Resources

Find information, updates, and resources related to the DCTI and its implementation efforts on its comprehensive resource hub: https://equity.uwmedicine.org/uwm-jedictr/dcti/

For more information about clinical trials at the University of Washington, visit https://clinicaltrials.uwmedicine.org/announcements/

Register for the **January 14, 2026** informational session on OnCore reporting of enrollment data for studies subject to the DCTI: https://washington.zoom.us/meeting/register/kFdMyLO4TiyEOOTFZqw23w#/registration