

May 27 DCTI Town Hall Questions and Answers

- 1. Our concern is for Type 1 Diabetes studies, primarily a non-Hispanic white condition, how are we to recruit ethnic minorities into studies?**

Answer

Having recruitment staff that looks like your patient population is important. Depending on the population you are aiming to recruit, having materials that are easy to read or are translated into relevant languages is also important. Connecting with community partners and community-based organizations that could also provide some recruitment strategies may also be beneficial. The approach should be multifaceted and study-dependent, and the ITHS Recruitment Support Service would be happy to provide individualized recommendations to your team:
<https://www.iths.org/investigators/services/recruitment-support-service/>

- 2. How can we improve inclusion of individuals without health insurance (who need coverage for non-trial follow-up) in clinical trials?**

Answer

This is dependent on the study design and what follow-up is needed. Consider partnering with local organizations to see what resources are available for individuals without insurance or if there are local clinics that they could visit for follow-up. Harborview, for example, has some services to follow-up with patients who are uninsured. The ITHS Recruitment Support Service is a free resource that can provide individualized recommendations to your team:
<https://www.iths.org/investigators/services/recruitment-support-service/>

- 3. If we believe that using interpreters for a clinical trial, rather than native-speaking study coordinators, risks degrading the scientific validity or reliability for our study, is it allowable to limit languages to those we can hire native speakers for?**

Answer

This would need to be evaluated within the specific context of the study. Many interpreters available through UW Medicine contractors are native speakers with professional translating credentials. A study team would need to clearly articulate why use of professional interpreter services would negatively impact the scientific validity of the study but a bilingual study staff would not.

- 4. Does the DCTI apply to healthy volunteer studies?**

Answer

Yes, if the study otherwise meets the criteria for being subject to the DCT policy, then a diversity plan would need to be developed.

- 5. What is the definition of a “clinical trial” that is being used for the DCTI?**

Answer

“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/>. This is the same definition used by the NIH.

- 6. I work for an ongoing clinical trial that began in 2024 and will end around 2029. Do we need to submit a diversity plan?**

Answer

No. The DCTI only applies if the initial application for the study is submitted to HSD on/after January 1, 2026. If you submitted to HSD back in 2024, the policy does not apply.

- 7. How do we address diversity plans for clinical trials that involve a group of people with a rare genetic disease that affects one ethnicity/race? For primarily non-Hispanic white conditions, how do we prove that we tried to recruit the tiny non-white portion of the patient population?**

Answer

There are circumstances in which clinical trials can only be conducted with small populations such that considerations of subgroup differences and/or heterogeneity of treatment effect may not be possible. If the available target population is ≤ 100 , or the total study enrollment is ≤ 30 across all sites, the population may be too small to allow for statistical analysis by subgroup.

The diversity plan supplement allows researchers to articulate the prevalence of the disease or condition in the target population under study by race/ethnicity and then indicate if they plan to enroll along similar lines. The form also solicits the source of information. So, if the condition primarily affects (~95%) White non-Hispanic individuals then it would be reasonable to expect study enrollment would roughly match this. At present there is no penalty for not hitting enrollment targets.

The Human Subjects Division is happy to work with individual study teams to consult on applicability of the policy for a specific study and assist with completing the diversity plan supplement. Requests for consultation can be sent to hsdinfo@uw.edu.

8. How can non-qualifying clinical trials use interpreter services that are attached to clinics?

Answer

Researchers who are undertaking their projects as part of direct healthcare (e.g. they will be charting in the electronic medical record as part of care/research) can utilize clinic- or hospital-based interpreter services.

Research that is being completed separately from direct healthcare will need to provide their own interpreter services.

9. For research teams that are expected to contract their own interpreter services, does UW have pre-approved contracts for vendors?

Answer

Yes, UW Medicine has vetted and contracted vendors for interpreter and translation services. They can be found on our Contracted Vendors for Language Access Services page:

<https://uwnetid.sharepoint.com/sites/uwlaca/SitePages/Contracted%20Vendors.aspx>

Alternatively, interested parties can contact Yvonne Simpson directly for more information: simpsony@uw.edu.

10. Are the Office of Healthcare Equity bridge funding awards a one-time award per PI?

Answer

Preference will be given to first-time applicants. Returning applicants remain eligible and are encouraged to apply, as funding may be available based on program resources. Applicants may apply for multiple award categories as desired, provided they meet the eligibility requirements for each.

11. Is there an opportunity for those of us who have had experience in including Vietnamese- and Mandarin-speaking participants in a previous study to find out challenges and barriers?

Answer

Launching in June 2026, the Community Engagement Bridge Funding Award will prioritize UW clinical trial researchers who are seeking to integrate activities focused on community engagement, local context, cultural access, and/or language access as required by the Diversity Plan for Clinical Trials Supplement - UW Research ([see Table 2: Spectrum of Community Engagement in Clinical Trials Research, Examples](#)).

Any UW researcher seeking to improve pathways to health science research and clinical trials for community members are welcome to apply. For more information, visit the Office of Healthcare Equity's Community Engagement website:

<https://equity.uwmedicine.org/community-engagement/>

12. If you're not doing an FDA-regulated study, do you not need to worry about Part 11 compliance?

Answer

Correct. If your study is not FDA-regulated, Part 11 does not apply.

13. Is Florence eConsent part of REDCap?

Answer

No, they are separate products.

14. My understanding is that the REDCap 21 CFR Part 11 instance's quarterly fee would be applicable for the entire trial lifecycle. For oncology trials that frequently have a primary endpoint of overall survival, this fee could easily be upwards of \$24,000 per study. Is there any plan to cap the total cost?

Answer

There is no current plan to cap the total cost, although UW Research IT is trying to minimize the quarterly fees as much as possible. If you are moving your project to "complete" status and want to retain the data within the REDCap system for time, that will be a reduced fee. Right now, the fee is \$2,000/quarter for those with a UW worktag, and \$2,700 for those without a UW worktag. For updates, visit the UW Research IT website: <https://rit.uw.edu/redcap-part-11/>

15. Do participants need to do a training in UW Florence?

Answer

No, only study team members need to complete the training and attestation.

16. Where can people access the Florence Help Desk and Florence training?

Answer

You can access the Florence eConsent training and attestation via the UW Florence Request form: <https://redcap.link/UWFlorence>

Access common inquiries and help articles on the use of Florence eConsent via the Florence Help Desk: <https://florencehealthcare.zendesk.com/hc/en-us/categories/360000220293-eConsent> (Florence login required)

17. Is using eConsent by UW Florence free and eConsent via REDCap \$2000/quarter?

Answer

UW Florence eConsent is available to investigator-initiated studies at no cost. Industry-initiated studies will have a one-time, non-negotiable fee for UW Florence eConsent at the time the study is created. This fee is separate from the UW Florence eBinder fee. For more information, please visit:

<https://clinicaltrials.uwmedicine.org/electronic-regulatory-documents-management-uw-florence/#Fees>

eConsent within the ITHS REDCap instance is available to all REDCap users within the WWAMI region and their partners at no cost. The REDCap 21 CFR Part 11 instance for FDA-regulated studies has a \$2,000 per quarter cost for internal UW studies (with a UW worktag) and \$2,700 per quarter cost for studies external to UW (without a UW worktag). The REDCap Part 11 instance is an electronic data capture system that includes eConsent workflows. REDCap Part 11 is best for those working on an FDA-regulated study who enjoy REDCap's survey distribution system and would like to use it for eConsent and/or plan to use REDCap for its full capabilities.

18. How do you in real time while using the eConsent format? Do you do it over the phone or by Zoom?

Answer

You can use eConsent remotely or in real-time via a computer, tablet, scannable QR code, or a phone call. If you consent participants remotely, this should be built into your consenting SOP. There is no built-in video conferences within UW Florence or REDCap.

Resources

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

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.

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](#).

Community Access & Engagement Bridge Funding

Launching in June 2026, OHCE will offer up to \$10,000 to support community access and engagement needs for UW researchers conducting clinical trials. This funding is intended to support the community engagement activities needed for the Diversity Plan. For more information, visit the [OHCE Community Engagement website](#).

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.

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](#).

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>

REDCap Part 11: <https://rit.uw.edu/redcap-part-11/>

UW Florence request form: <https://redcap.iths.org/surveys/?s=MJXJ4YR7EKPEN4XR>

UW Florence webpage: <https://clinicaltrials.uwmedicine.org/electronic-regulatory-documents-management-uw-florence/>

Florence-provided training: <https://university.florencehc.com/page/course-catalog>

Florence-operated help desk (*Florence login required*):

https://helpdesk.researchbinders.com/?brand_id=671617&locale_id=1&return_to=https%3A%2F%2Fflorencehealthcare.zendesk.com%2Fhc%2Fen-us%2Fcategories%2F360000220293-eConsent×tamp=1781121645

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/>

Submit questions or feedback on the DCTI here:

https://forms.office.com/pages/responsepage.aspx?id=W9229i_wGkSZoBYqxQYL0t9rh5dOdxJPhy_w54kFZjvZURVNLQVdFVkvBVSFU4RDIIUzFRTEpOODIESiQlQCN0PWcu&origin=lprLink