Diversity in Clinical Trials Initiative Town Hall:
Policy Updates and Resources

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Courtney Howell, REDCap Manager, Research IT
Crystal E Brown, Co-Lead, Recruitment Support Service, Institute of Translational Health Sciences
Jason M Malone, Director, Human Subjects Division
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Michelle Harvey, Research Coordinator, Research Coordination Center, Clinical Trials Office

May 27, 2026
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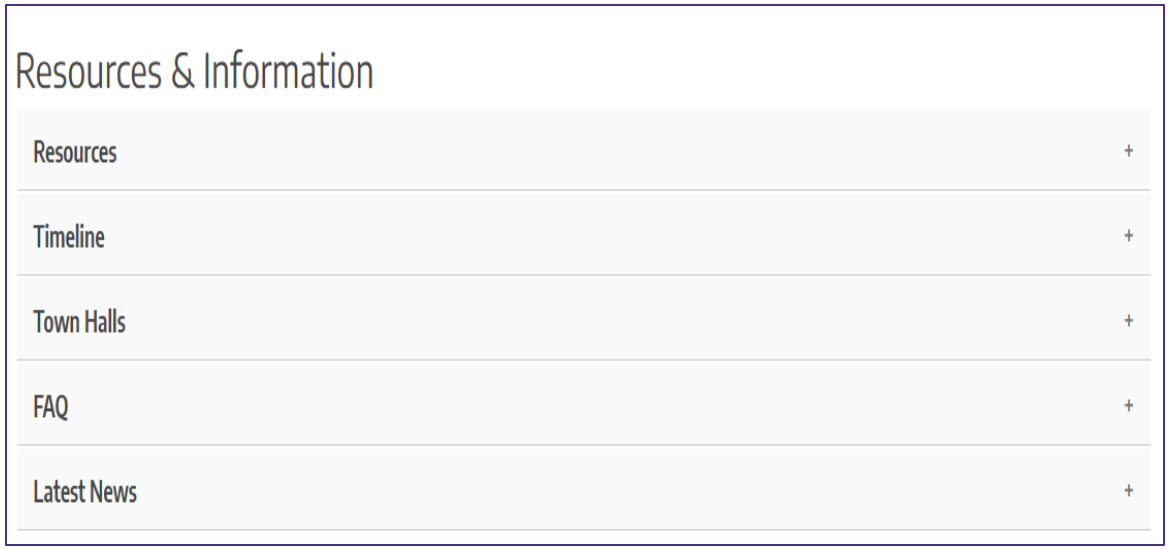
Previous Town Halls and other DCTI Resources

Visit: https://equity.uwmedicine.org/uwm-jedictr/dcti/



Diversity in Clinical Trials Policy Updates

Jason Malone, MPA, CIP, Director
Human Subjects Division

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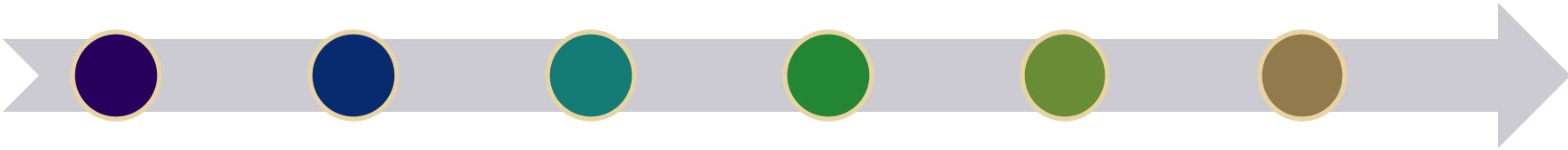
DCTI Timeline



July 23, 2023

+ WA state RCW 69.78 Diversity in Clinical Trials law goes into effect

Aug 16 – Sept 16, 2024

+ HSD Draft Diversity Plan Supplement and Guidance are posted for 30-day public comment period

+ Town Hall Presentation

January 1, 2025

+ HSD posts final guidance and supplement

+ Researchers are given a year to prepare

November 4, 2025

+ Roll out of UW Medicine Patient Demographics Dashboard

+ Announce OnCore reporting requirements for Clinical Trials

January 1, 2026

+ Requirement to submit Diversity in Clinical Trials supplement goes into effect

April 2026

+ Launch of UW REDCap Part 11 and UW Florence eConsent

UW Policy Scope

All new clinical trials (NIH definition) submitted to HSD on/after **January 1, 2026**, where UW employees or agents are responsible for or engaged in recruitment and consent activities.

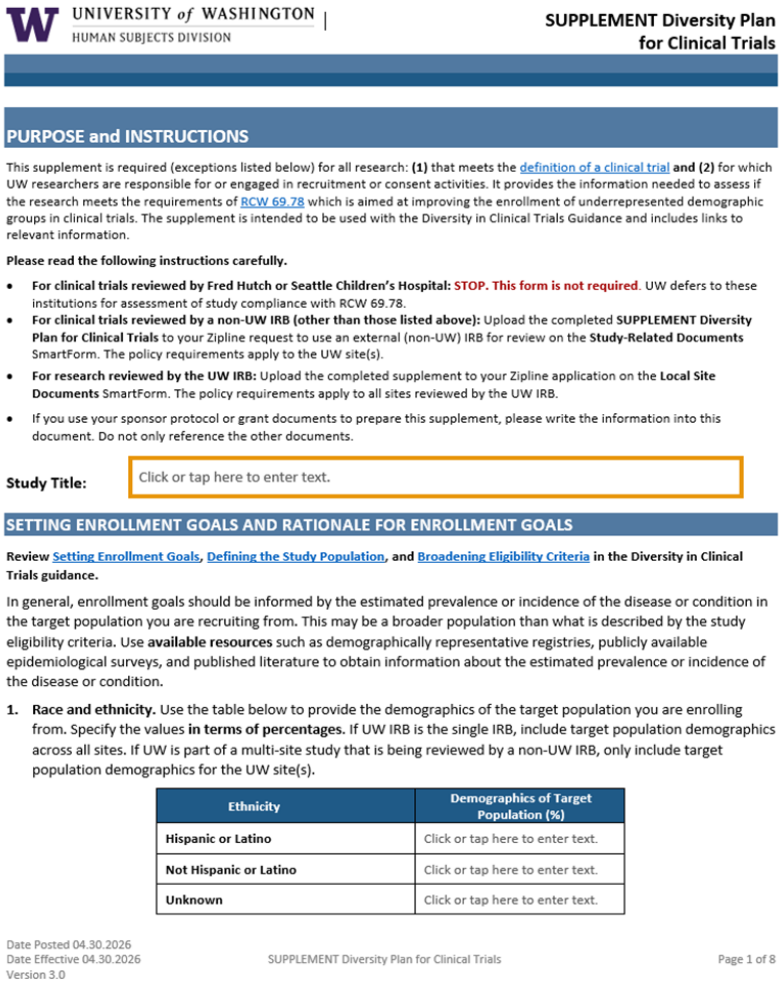
- Applies regardless where the interventions occur
- Applies to UW studies relying on an external IRB
- Will be a condition of the UW serving as sIRB for multicenter studies

UW Policy Exceptions

- Studies reviewed by Fred Hutch or Seattle Children's
- Phase 1 or earlier trials
- Pilot and feasibility studies
- Clinical trials involving 'small populations'
- Continuation, Follow-on, or Extension Designs

HSD Diversity Plan and Guidance

- Setting **Enrollment Goals** - age, race, ethnicity, sex, sexual orientation, geographic location, socioeconomic status
- **Rationale** for current enrollment goals and any exclusions
- **Strategy** for meeting enrollment goals (e.g., study design, recruitment, and retentional plan, reducing barriers to participation
- Description of efforts/resources utilized for **community engagement** that informs recruitment strategy
- Plan for **collecting and reporting** enrollment data



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SUPPLEMENT Diversity Plan for Clinical Trials

PURPOSE and INSTRUCTIONS

This supplement is required (exceptions listed below) for all research: **(1)** that meets the definition of a clinical trial **and (2)** for which UW researchers are responsible for or engaged in recruitment or consent activities. It provides the information needed to assess if the research meets the requirements of RCW 69.78 which is aimed at improving the enrollment of underrepresented demographic groups in clinical trials. The supplement is intended to be used with the Diversity in Clinical Trials Guidance and includes links to relevant information.

Please read the following instructions carefully.

- **For clinical trials reviewed by Fred Hutch or Seattle Children's Hospital: STOP. This form is not required**. UW defers to these institutions for assessment of study compliance with RCW 69.78.
- **For clinical trials reviewed by a non-UW IRB (other than those listed above):** Upload the completed **SUPPLEMENT Diversity Plan for Clinical Trials** to your Zipline request to use an external (non-UW) IRB for review on the **Study-Related Documents** SmartForm. The policy requirements apply to the UW site(s).
- **For research reviewed by the UW IRB:** Upload the completed supplement to your Zipline application on the **Local Site Documents** SmartForm. The policy requirements apply to all sites reviewed by the UW IRB.
- If you use your sponsor protocol or grant documents to prepare this supplement, please write the information into this document. Do not only reference the other documents.

Study Title: Click or tap here to enter text.

SETTING ENROLLMENT GOALS AND RATIONALE FOR ENROLLMENT GOALS

Review Setting Enrollment Goals, Defining the Study Population, and Broadening Eligibility Criteria in the Diversity in Clinical Trials guidance.

In general, enrollment goals should be informed by the estimated prevalence or incidence of the disease or condition in the target population you are recruiting from. This may be a broader population than what is described by the study eligibility criteria. Use **available resources** such as demographically representative registries, publicly available epidemiological surveys, and published literature to obtain information about the estimated prevalence or incidence of the disease or condition.

1. **Race and ethnicity.** Use the table below to provide the demographics of the target population you are enrolling from. Specify the values **in terms of percentages.** If UW IRB is the single IRB, include target population demographics across all sites. If UW is part of a multi-site study that is being reviewed by a non-UW IRB, only include target population demographics for the UW site(s).

Ethnicity	Demographics of Target Population (%)
Hispanic or Latino	Click or tap here to enter text.
Not Hispanic or Latino	Click or tap here to enter text.
Unknown	Click or tap here to enter text.

Date Posted 04.30.2026
Date Effective 04.30.2026
Version 3.0

SUPPLEMENT Diversity Plan for Clinical Trials

Page 1 of 8

Metrics - Submissions

Since January 1, 2026, policy go-live:

- 110* (assessed) clinical trials submitted to HSD
- 60 required diversity plan
- 56 plans complete

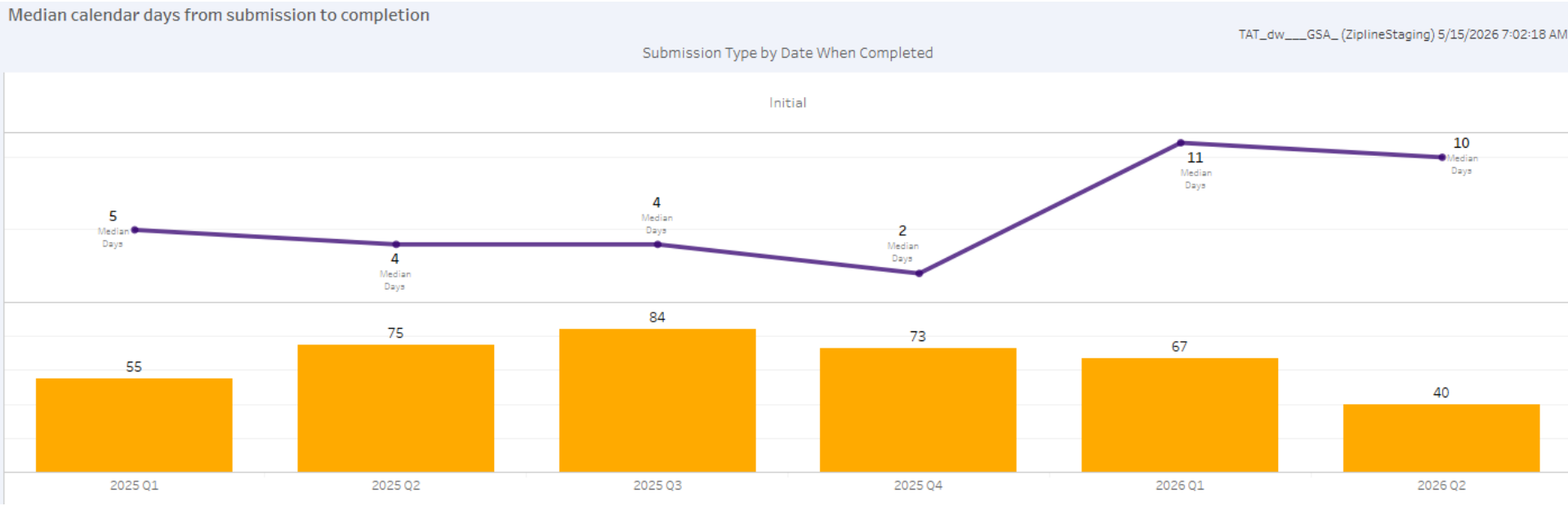
Of the 60 clinical trials that required a plan:

- 83% studies reviewed by external IRB
- 17% studies reviewed by UW IRB

Top submitting departments for studies requiring a plan:

1. 53% - Hematology/Oncology (n = 32)
2. 12% - Allergy & Infectious Diseases (n = 7)
3. 7% - Neurology (n = 4)
4. 7% - Surgery (n = 4)

Metrics – Turnaround Time



Policy Updates

- Two revisions to DCT policy since January 1, 2026 go live
- Updated to clarify edge cases, tighten language, reduce ambiguity
- No new compliance obligations

Policy Updates - Examples

- Policy Exception Clarifications:
  - **Continuation / follow-on / extension trials**
    - Explicitly exempt when enrollment is limited to participants from a prior trial and no new recruitment is possible.
  - **Multi-phase trials under external IRBs**
    - If early phases are exempt (e.g., Phase 1b) but later phases are not, the Diversity Plan must be submitted upfront, covering only the applicable phases.
  - **Pilot & feasibility studies**
    - Clarifies that studies analyzing safety, efficacy, or health outcomes do NOT qualify for this exception.

Policy Updates - Examples

- Addition of examples/language for **justifiable exclusions**:
  - Individuals with Non-English Language Preference
  - eConsent
- Clarification on **OnCore Reporting** Requirements:
  - Limited to domestic enrollment targets
  - UW site(s) only
- Clarification on **sharing aggregate results** with participants

Diversity Supplement Updates

- Clear distinction between target population and planned enrollment
- Structured, decision-guided question flow
- Stronger emphasis on data sources and scientific rationale
- Explicit prompts about sponsor and lead-site constraints
- Clear separation of protocol-level vs. UW site-level strategies
- More explicit, enforceable NELP and community engagement requirements

Community Engagement

Juliana Garcia, PhD, Assistant Director of Community Engagement
Office of Healthcare Equity

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Community Based Research Collaboratory

15 Community-based organizations in collaboration with UW Medicine Office of Healthcare Equity

Collaborating to deepen partnerships between researchers and marginalized communities—creating relationships and building trust

With key activities of establishing (connect), educating, advancing, and recruiting.

Structure & Current Membership

1. Founders Group
2. Governing Board
3. General Members (unlimited)

Founders Group
African Americans Reach & Teach Health Ministry
Cierra Sisters
Leaders in Women's Health
Pacific Islander Community Association of Washington
Tubman Center for Health and Freedom
UTOPIA WA

Governing Board
Afghan Health Initiative
Aurora Commons
Entre Hermanos
Health Justice Recovery Alliance
Hummingbird Indigenous Family Services
Khmer Community of Seattle King County
Mujeres in Action
PAVE WA
Southeast Washington Alliance for Health

General Members

Available for community-based organizations and individuals in the community who want to stay informed, respond to surveys, attend events, share information, volunteer, and may participate in research.

Compensation is provided for participation in activities. These members are not actively participating on a regular basis like the Governing Board and Founders Group member organizations.

CBRC Goals

CBRC Key Goals for FY 25-27

1. **Community Brilliance:** Support community in understanding different ways to engage with clinical trials and researchers (education, webinars).
   - ***Measure 1-1:*** UW Founder and Governing Board have shared language surrounding clinical trials and research, co-developing a plan and curriculum for sharing more broadly with the community.
   - ***Measure 1-2:*** Host **3 Community Conversations**, facilitating conversations about community driven topics, with presentations from UW & Community.

2. **Researcher Competency:** Support researchers in understanding culturally appropriate practices and needs (Research review & feedback, participation in community events).
   - ***Measure 2-1:*** HB1745 Human subject division policy at University of Washington went into effect (1/1/26), do we see an increase in cultural translations of clinical trial materials (consent forms, recruitment guidelines, visit process, etc.)?
   - ***Measure 2-2:*** Establish a baseline of how often researchers are currently working with the community, and at what stage during the research study process are they engaging.
   - ***Measure 2-3:*** Successfully facilitate the presentation of at least 5 research proposals to the community in a way that is relatable, resulting in documented, actionable community feedback for each project.
   - ***Measure 2-4:*** Successfully facilitate at least 50% of researchers requesting CBRC support to join community events.

CBRC Resources for Researchers

Research Consultations

The **Community Based Research Collaboratory (CBRC)** consultation service supports researchers by:

- Building **bi-directional communication** between community and research teams
- Offering **education and guidance** on best practices for community engagement
- Supporting **community leadership** within research processes
- Helping create **equitable recruitment pathways** for participation in clinical trials

Support activities might include:

- an opportunity to present study results and receive feedback for dissemination
- community input on an upcoming grant submission
- community support with cultural translations of materials
- an opportunity to meet with community members and learn about their current areas of need
- best practices and tips on being in and sharing with community
- community support with recruitment logistics

Additional Researcher Resources

Currently Available

Language Access Bridge Funding

- Limited proviso funds available to support language access and cultural advocacy project needs
- Up to $5,000 available for UW Clinical Trial Researchers
- Application currently open
- Learn more here using the QR code below or link in the chat

Language Access Bridge Funding Website

Launching in June!

Community Access & Engagement Bridge Funding

- Limited proviso funds available to support community access and engagement project needs
- Up to $10,000 available for UW clinical trial researchers
- Application will open in June
- Be on the lookout at our website, QR code below & link in the chat

OHCE Community Engagement Website

UW Florence eConsent

Linda Harrison, Regulatory Lead
Research Coordination Center, Clinical Trials Office

Michelle Harvey, Research Coordinator
Research Coordination Center, Clinical Trials Office

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UW Florence eConsent Introduction

- “UW Florence eConsent” refers to the University of Washington instance of the Florence eConsent system.
- Florence eConsent is a secure, 21 CFR Part 11 and HIPAA compliant electronic informed consent platform that allows participants to read and sign informed consent documents remotely.
- It is designed to be simple to use for remote consent processes and mimics the look and flow of paper informed consent.

Key Features

- On-site workflows for in-person electronic consent
- Multiple-signatures
- Signing order
- Automatic vs Manual send
- Save signed forms from eConsent to eBinders

Availability and Costs

- Available to **investigator-initiated studies** at no cost.
- **Industry-initiated studies** will be assessed a one-time, non-negotiable fee **at the time the study is created.**
  - We recommend study teams wait until contracts are finalized and IRB approval is granted before submitting a new study request.
  - This fee is separate from the UW Florence eBinder fee.

UW INDUSTRY INITIATED STUDIES (Not inclusive of F&A)

UW Florence eBinders	UW Florence eConsent
$2,336	$2,544

Using UW Florence eConsent

To get started:

Projects involving human subjects must obtain IRB approval to use UW Florence eConsent for electronic consent and/or HIPAA authorization prior to use.

Study team members must complete the Florence eConsent for End Users training and UW Florence Attestation for eConsent.

eConsent Project Set Up

Study Team

Submit UW Florence Request Form

→ UW Florence eConsent New Study Request Form

→ UW Florence eConsent Study Access Form

UW Florence Team

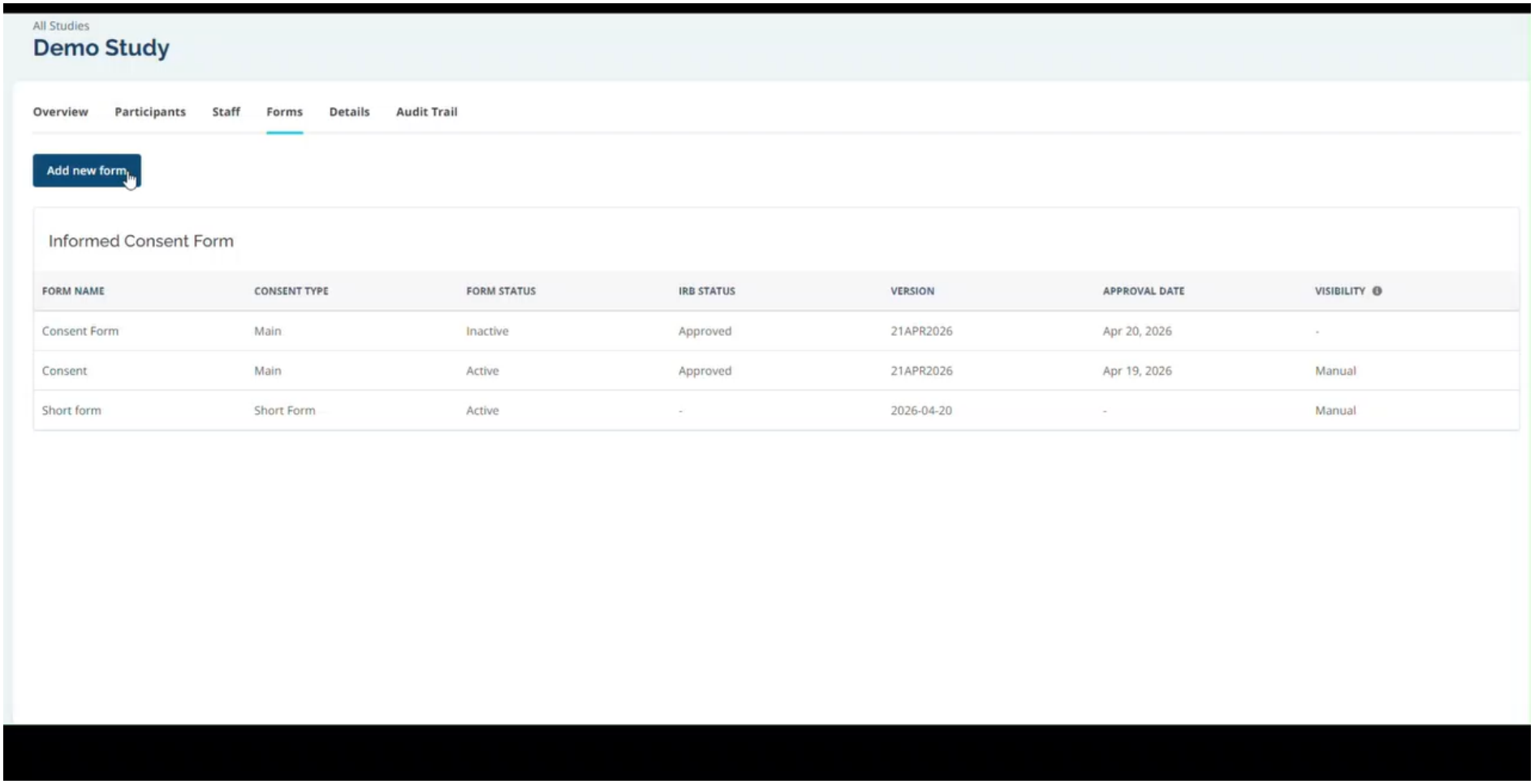
- Create study in eConsent environment
- Verify training & attestation are complete
- Add user(s) to the study → user(s) will receive a notification from Florence that they have been added to a New eConsent project

eConsent study access and permissions

- Access levels are based on roles and designed to be SIMPLE in Florence eConsent.
- **UW Florence eConsent Study Access Form**
  - Add new users to an existing eConsent study
  - Modify a user's access
  - Remove a user who no longer needs access to an eConsent study
  - Remove user from UW Florence eConsent environments.

What if I need to add someone to my eConsent study?

Submit UW Florence Request form →UW Florence eConsent Study Access Form



florence

Michelle Test

Welcome, Michelle!

You have **1 study** that needs attention.

View tasks

Your studies

Demo Study
Participating as: Participant
CONSENTED

Michelle Practice Study
Participating as: Participant
CONSENTED

LindaHarrisonPracticeStudy
Participating as: Participant
DECLINED

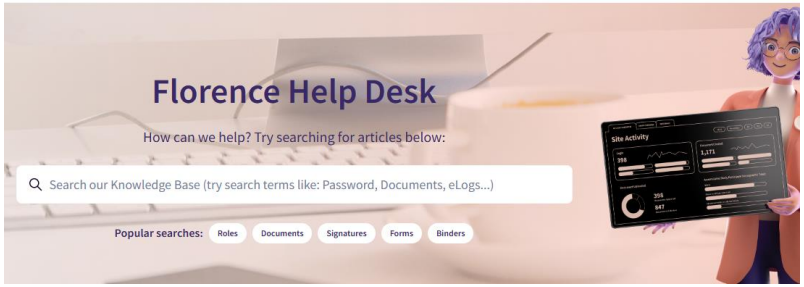
Michelle UAT Study 001
Participating as: Participant
CONSENTED

Before you join a study, it is important to fully understand the details.

- Consider the commitment level, procedures, and timeframe.
- Understand the risks and potential benefits.
- Reach out to the research team if you have questions.

Support and Resources

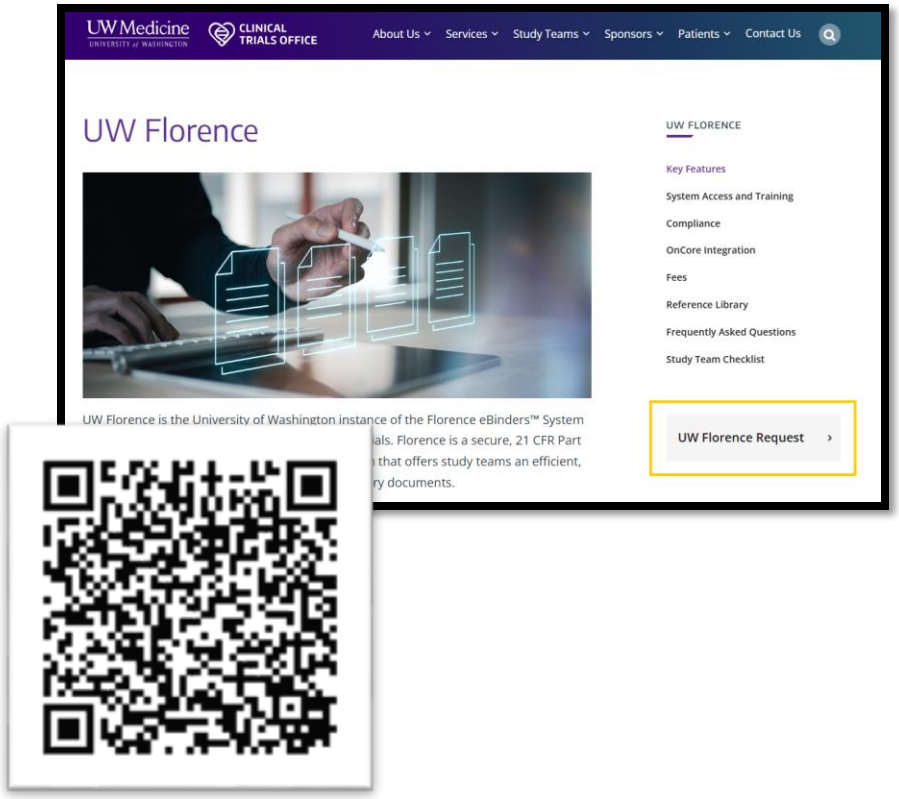
- Florence Help Desk (Florence login required) access common inquiries and help articles on the use of Florence eConsent.
- Florence-provided training Course Catalog.
- UW Florence Team is available for assistance UW Florence Request Form.



UW Florence Request Form

One form for all things UW Florence!

Submit UW Florence requests and questions here: https://redcap.link/UWFlorence



REDCap eConsent

Courtney Howell, REDCap Manager
Research IT and the Institute of Translational Health Sciences

Adam Mahama, Lead REDCap Administrator
Research IT and the Institute of Translational Health Sciences

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REDCap and eConsent Introduction

- **REDCap (Research Electronic Data Capture)** is a secure, web-based application designed for building and managing online surveys, databases and research workflows.

- The **eConsent** feature in REDCap allows teams to collection consent electronically to support remote participation, improved accessibility across teams and enhanced compliance.

REDCap®

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Availability and Costs

ITHS REDCap Instance

- Available to <u>all</u> REDCap users within the WWAMI region and their partners
  - **Free** to use

Part 11 REDCap Instance

- Quarterly costs to users within the WWAMI region
  - Costs may decrease over time as adoption expands

Part 11 Pricing & Service Structure

Service and Payment Structure

- To support Part 11 Validation projects, UW RIT applies quarterly service fees

+ $2,000 per quarter, *UW internal studies (with a UW worktag)*

+ $2,700 per quarter, *Studies external to UW (without a UW worktag)*

Additional Cost Considerations

- Custom development, advanced consultation, excessive AWS usage, or extended support beyond standard Part 11 services may incur additional fees.

Part 11 Pricing & Service Structure

Why is there a charge?

- Supports FDA-regulated research requiring higher compliance standards
- Greater technical oversight than standard REDCap
- Involved documentation and administrative support
- Reflects additional infrastructure needed for a validated environment

Part 11 RIT Website

Infrastructure

- REDCap Part 11 is AWS native
- Built from scratch with 21 CFR Part 11 in mind
- Highly available, Secure, Resilient to disaster
- Ability to right-size resources to maximize benefits
- Integrated with UW Med ITS cloud security and instance patching workflows

Governance

- AMC and UW netIDs only
- Multi Factor authentication required
- Strict requirements on usage
  - SOP and training required for access
- API Usage reviewed on a case-by-case basis
- Rigorous validation process, not just for eConsent

Approvals Required

Projects involving human subjects must obtain IRB approval for eConsent use

Research teams are responsible for confirming IRB compliance prior to enabling within REDCap

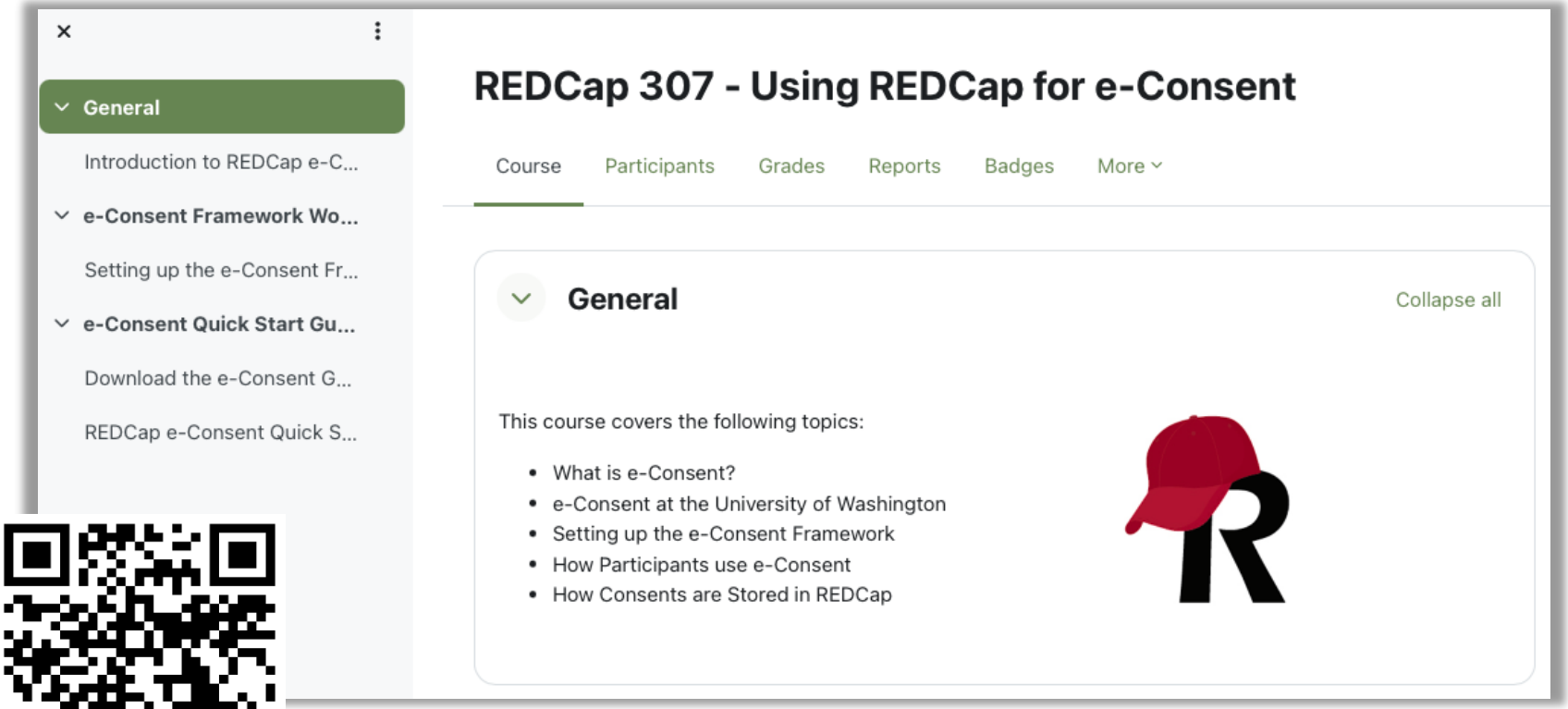
Training, Support and Resources

- Comprehensive training and resources that are provided:
  - Template guide to be enabled within new REDCap projects
  - Tip Sheet on Electronic Consent Setup
  - Self-paced course

- REDCap administrators available for assistance with project specific compliance as paid consult support

Training, Support and Resources

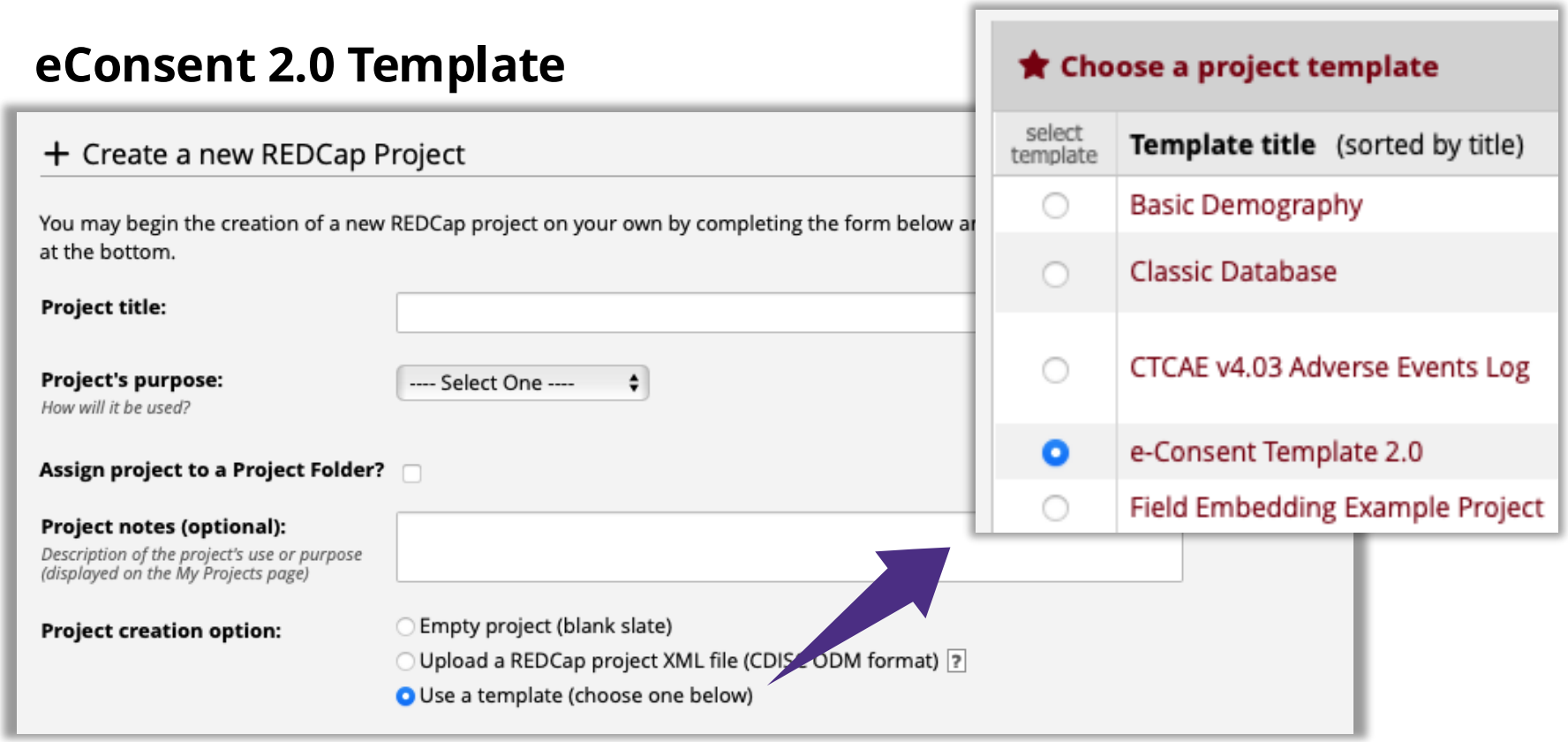
TREE (Translational Research Education Engine)



Access TREE

Training, Support and Resources

eConsent 2.0 Template



Features

Key Capabilities

- Upload IRB-approved consent PDFs directly – no manual reformatting
- Integrated ImageMagick rendering for accurate, compliant presentation
- Speeds up setup and reduces versioning errors
- Provides logging and audit trails
- ReConsent, tracks versions and timestamps

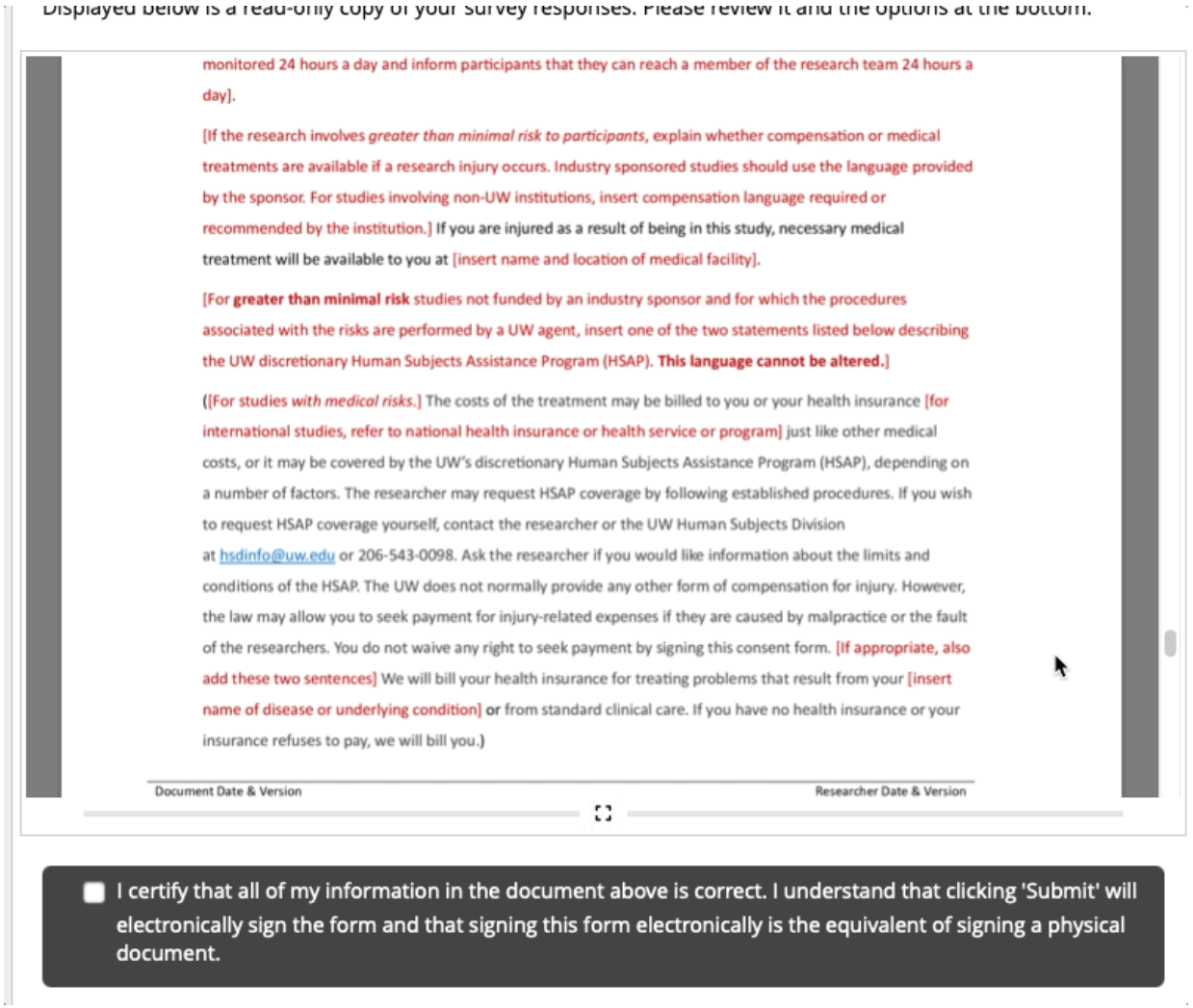
Strategic Value

- Simplifies eConsent rollout for study teams
- Promotes participant-friendly digital workflows
- Enhances regulatory compliance with 21 CFR Part 11 standards

Preview

Inline image of PDF now available to review on attestation page

After submission, eConsent is available in file repository



eConsent Summary

Service	FDA Part 11 Compliant	Available	Cost Associated
REDCap ITHS Instance	No	Now	No
Docusign*	No	Now	No
UW Florence	Yes	Now	Investigator-initiated: No Industry-initiated: Yes
REDCap Part 11 Instance	Yes	Now	Yes

* not discussed today. See November 19, 2025 Town Hall: https://equity.uwmedicine.org/uwm-jedictr/dcti/

Recruitment Support Service

Crystal E Brown, MD, MA Recruitment Support Service Co-Lead
Institute of Translational Health Sciences

Assistant Professor, Division of Pulmonary, Critical Care, and Sleep Medicine
Adjunct Assistant Professor, Bioethics and Humanities
University of Washington

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ITHS Recruitment Support Service

ITHS developed a Recruitment Support Service (RSS) to provide **strategic, project-specific recruitment advice**, along with a repository of tools and resources to help research teams meet enrollment goals.

The goal of the RSS is to ensure that clinical investigators **meet their recruitment goals** both for rate of enrollments and total study enrollment.

ITHS adapted the RSS to align with **DCTI and WA HB 1745 goals**, providing pre-award consults and resources to improve clinical trial representation.

RSS Approach

- Consult team has **interdisciplinary expertise to best support research teams:**
  - Physician Researcher
  - Bioethicist
  - Associate Director of Systems & Initiatives
  - UW HSD IRB Operations Staff
  - Community Engagement
  - Research Coordinator
  - Program Manager

RSS Consult

One-hour session with study team and RSS members

Includes introductions, study overview, Q&A, and discussion

Goal: develop recruitment and retention strategies to improve clinical trial representation.

Post-Consult

One-on-one work with the investigator, as applicable

Additional research & soft connections to ITHS and other resources

Post-Consult Follow-Up Data Collection

REDCAP **SURVEY**
(2 WEEKS AFTER CONSULT)

FOLLOW-UP **INTERVIEW**
(2 WEEKS POST-SURVEY)

Survey Results To Date

Satisfaction

- 100% of survey respondents **approved of the consult recommendations**

Feasibility

- 67% of respondents **intend to use the consult recommendations** 'almost every time'
  - 33% intend to use the recommendations 'occasionally'

Use

- 100% of respondents agree that **using the consult recommendations will save their research team time**

n = 4 respondents

Post-Consult Interview Findings

*"**I would 100% recommend RSS to investigators**, especially those who are new to research."*

*"**I wish I contacted RSS earlier**, when I was developing my proposal."*

*"I appreciated the **range of options**. I opted for strategies that did not require IRB modifications."*

*"We **recruited additional participants** after our RSS consult."*

*"The recommendations were **helpful and feasible**."*

n = 6 interviews

Interview Themes

Discovering RSS through being **connected to ITHS** (personally or via colleague/mentor)

Seek RSS in **early stages** of project

Some recommendations out of **budget**

Post-consult summary materials very useful

FREQUENTLY ASKED QUESTIONS

How much does it cost to use RSS?

Your 1 hour consult with RSS is **FREE**!

How do I set up a conslt?

Scan the QR Code! Click the link that says “click to request a consultation”.

ITHS | Institute of Translational Health Sciences

ACCELERATING RESEARCH. IMPROVING HEALTH.

Visit: https://www.iths.org/investigators/services/recruitment-support-service/

Q&A

Additional questions or feedback?

Fill out this form: