

# Diversity in Clinical Trials Initiative Town Hall: Policy Update, eConsent and other Resources

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November 19, 2025

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# Previous Town Halls and other DCTI Resources

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

## Resources & Information

Resources

+

Timeline

+

Town Halls

+

FAQ

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# Diversity in Clinical Trials Policy Update

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**Maria Savage**, Associate Director of Systems and Initiatives  
Human Subjects Division

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# UW Policy Scope

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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.

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

# UW Policy Exceptions



Phase 1 or earlier trials



Pilot and feasibility studies



Clinical trials involving  
'small populations'

**NEW** - If the available target population is  $\leq 100$ , or the total study cohort enrollment is  $\leq 30$  across all sites, the population may be too small to allow for statistical calculation.

# Human Subjects Division Diversity Plan and Guidance

1. **Enrollment Goals** - age, race, ethnicity, biologic sex, sexual orientation, geographic location, social economic status
2. **Rationale** for current enrollment goals and any exclusions
3. **Strategy** for meeting enrollment goals (e.g., study design, recruitment, and retentional plan):
  - Measures for reducing barriers to participation
  - Plans for participants with Non-English Language Preference
  - Plans for use of eConsent
  - Description of efforts/resources utilized for **community engagement** that informs recruitment strategy
4. **Tracking and reporting** of enrollment data



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 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, Seattle Children's Hospital, or Washington State IRB: **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.

Study Title:

## SETTING ENROLLMENT GOALS

Review [Setting Enrollment Goals](#) in the Diversity in Clinical Trials guidance.

For the purposes of satisfying the Diversity in Clinical Trials policy requirements, this supplement is focused on collecting information about underrepresented populations as defined by RCW 69.78: age, race, biological sex, sexual orientation, geography, and socioeconomic status. The UW IRB does not expect the Diversity Plan to include all underrepresented groups for any particular clinical trial. 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.

The UW acknowledges 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.

1. **Race, ethnicity, and biological sex.** Use the table below to provide a breakdown of enrollment goals with regard to race, ethnicity and biological sex. Specify the goals in terms of percentages.

Note that this table is designed to capture enrollment goals and may not include all the races or sexes that are ultimately enrolled.

Ethnicity	Male	Female
Hispanic or Latino	<input type="text" value="Click or tap here to enter text."/>	<input type="text" value="Click or tap here to enter text."/>
Not Hispanic or Latino	<input type="text" value="Click or tap here to enter text."/>	<input type="text" value="Click or tap here to enter text."/>
Race	Male	Female
American Indian/ Alaska Native	<input type="text" value="Click or tap here to enter text."/>	<input type="text" value="Click or tap here to enter text."/>

Date Posted 12.23.2024

Date Effective 01.01.2026

Version 1.0

SUPPLEMENT Diversity Plan  
for Clinical Trials

Page 1 of 5

# UW Policy – Translation & Interpretation

It is UW policy that:

- When **5% or more of the target population** speaks a primary language other than English:
  - The study must have translations of any written materials to be read by participants (e.g., consent forms, recruitment materials, surveys) available at the outset of the research.
  - There must be resources in place to support their inclusion for the duration of the study.
- When **less than 5% of the target population** speaks a primary language other than English:
  - There must be a plan in place to support their enrollment and participation in the research when they are encountered.



# UW Policy – Community Engagement

Table 1: Spectrum of Community Engagement in Clinical Trials Research, Requirements by Research Lifecycle Stage.

Community Engagement Stage	Plan/Propose	Setup	Implement/Manage	Closeout
<b>Stage 1: Ignore</b> Community is not provided with information or involved in decision-making processes	<b>No community involvement</b> in planning and proposal development	<b>No community input</b> in trial design, setup.	<b>No community oversight</b> or input during trial recruitment and conduct.	<b>No community involvement</b> in data analysis. No follow-up or dissemination of results to the community.
<b>Stage 2: Inform</b> Community is provided with relevant information	<b>Community is informed</b> about plans to conduct the research (e.g., through various media), but input is not sought.	<p><b>Trial design and setup is informed by</b> individuals who are knowledgeable about the community and/or a literature review to reduce barriers and burdens to participation and develop culturally humble recruitment methods.</p> <p><b>Use Interpreter services and translated materials</b> for the <a href="#">inclusion of participants with a non-English language preference</a>.</p>	<p><b>Community is informed</b> about the research procedures through culturally humble recruitment and consent materials.</p> <p><b>Participants may receive updates on trial progress.</b></p>	<p><b>The aggregate results of the trial</b> are shared with participants (e.g., newsletter, email) and posted on CT.gov.</p>
<b>Stage 3: Consult</b> Community is provided with opportunities to offer feedback	<b>Community is informed</b> about plans to conduct the research AND provided with opportunities to offer feedback on the research plan.	<p><b>Community is consulted</b> on trial design, and <u>setup</u>. Trial decisions are made by researchers.</p> <p><b>Use community consultation to:</b></p> <ul style="list-style-type: none"> <li>Identify and reduce barriers and burdens to participation.</li> <li>Develop culturally humble recruitment methods.</li> <li>Identify and address community concerns about the research.</li> </ul>	<p><b>Community is consulted on issues</b> related to trial conduct, including recruitment but has limited involvement.</p> <p><b>Community is informed</b> about the research procedures through culturally humble recruitment and consent materials.</p> <p><b>Participants may receive updates on trial progress.</b></p>	<p><b>Community is consulted on dissemination</b> of results or follow-up plans but has limited input.</p> <p><b>The aggregate results of the trial</b> are shared with participants, posted on CT.gov, the OHCE research results website, AND through additional channels identified in community consultation.</p>

# UW Policy – eConsent

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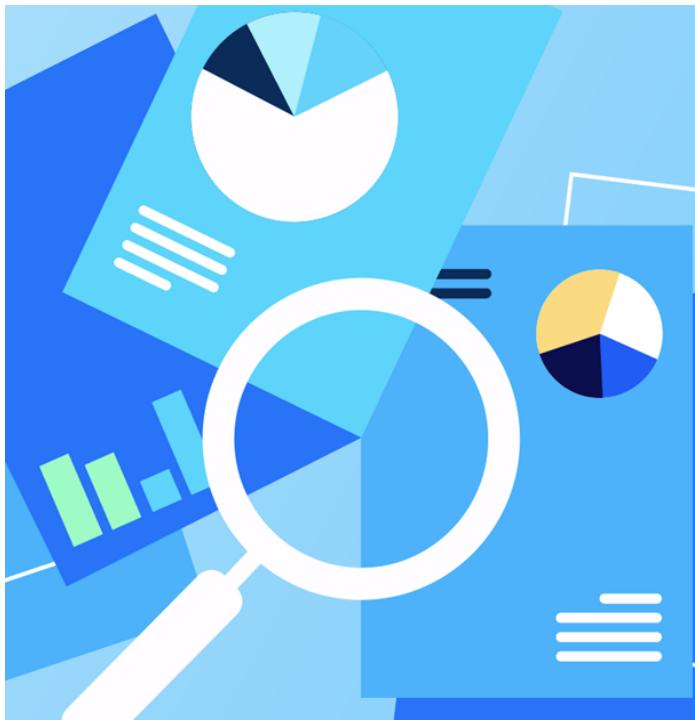
It is UW policy that eConsent must be offered unless a **justified exclusion** based on legitimate study needs (not preference) is documented.

## Acceptable Justifications:

- **Timing of Study Visits:** Consent occurs during in-person clinical visits only (e.g., ER, pre-op).
- **Population Characteristics:** Target population requires in-person interaction (e.g., physical impairment, severe visual impairment).
- **Operational Feasibility:** eConsent adds disproportionate cost/complexity without improving access.

# UW Policy – Tracking & Reporting

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- It is UW policy that all clinical trials requiring the submission of a Diversity Plan Supplement **must provide annual updates on their enrollment targets** for underrepresented groups using the **OnCore Clinical Trial Management System (CTMS)**.
- These studies are **required to be registered** in OnCore CTMS before study approval or authorization to use an external IRB will be granted.
  - Documentation of registration (i.e., email confirmation from CTMS) must be uploaded to Zipline

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# UW Policy – Tracking & Reporting

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- **Clinical trials that already must report into OnCore** (e.g., oncology-related, have UW Medicine billable activities, and/or require Epic activation for orders for subject tracking purposes) **do not need to make any additional reporting nor do study staff need to take any additional training.** These studies follow existing requirements.
- Beginning January 1, 2026, **NEW** clinical trials that are not already required to report in OnCore AND are subject to the UW DCT policy will follow the new OnCore reporting requirements.
- The CTMS Office has **upcoming informational sessions** with more details. Information about Oncore reporting and registration for these sessions may be found on the [CTMS website](#).



Register for **12/11** Intro to OnCore CTMS Webinar

# Demographics Dashboard

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**Carson Simões**, Assistant Director of Analytical and Data Services  
Office of Research and Graduate Education

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# Dashboard: UW Medicine Patient Demographics

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*A resource to support the Diversity in Clinical Trials Initiative*

- A recently-launched web resource that provides demographic data to assist with recruitment planning and completion of the HSD **“SUPPLEMENT Diversity Plan for Clinical Trials”** form.
- Provides demographic distributions of UW Medicine patients from the last few years across age, sex, sexual orientation, ethnicity, and race. Also includes distributions across location-based indices on social vulnerability and area deprivation.
- Filters can help focus on subpopulations of interest to the study.
  - **The dashboard will not return data for fewer than 100 cases.**

# How to Access the Dashboard

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- The dashboard is available to UW personnel with secured access via UW NetID.
- The dashboard is hosted on the UW's BI Portal ([biportal.uw.edu](http://biportal.uw.edu)) in the Research subject area.  
 NOTE: Users must be on campus or connected to the UW network through an active VPN connection (e.g., [Husky OnNet](#))
- The BI Portal contains documentation and guidance on Interpretation, Filters, and Definitions about the dashboard.
- The dashboard has a Feedback icon – please share your feedback to help us continuously improve this resource.

# A Tour of the BI Portal Dashboard

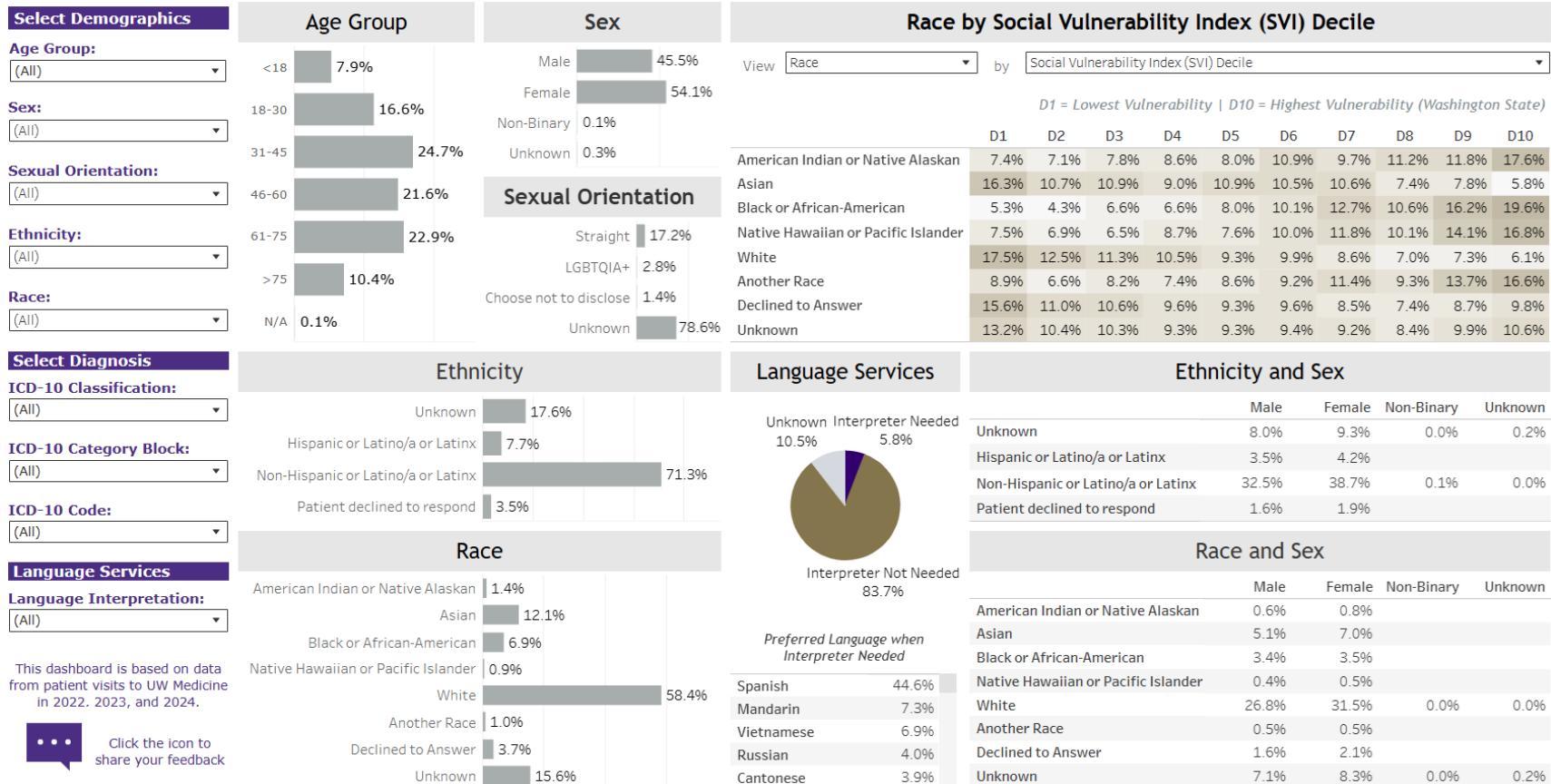
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## UW Medicine Patient Demographics

Resource to support the UW Diversity in Clinical Trials Initiative

# of Patients

1,378,663



# Bridge Funding & Community Engagement

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

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# Bridge Funding: Translation and Interpretation

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Limited proviso funds available to support language access and cultural advocacy project needs

- **Application Currently Open:** [equity.uwmedicine.org/language-access-bridge-funding](http://equity.uwmedicine.org/language-access-bridge-funding)
- **Funding:** up to **\$5,000** awarded, paid directly by the Office of Healthcare Equity. **We cannot** reimburse funds to a grant or project.
- **Eligibility**
  - Lead PI has **primary appointment** at UW
  - Project is a clinical trial
  - IRB approval has been granted
  - Quote for service(s) in next 30 days available to upload, cannot reimburse for service already completed
  - Limited or no grant funding

# Community Engagement

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## Community Based Research Collaboratory (CBRC)

- **Challenge:** Historical exploitation has led to deep mistrust and underrepresentation of marginalized populations in clinical research, fueling systemic healthcare disparities. The CBRC seeks to establish accountability and create a more equitable research environment through transparent, reciprocal partnerships that center community voices.
- **Purpose:** To unite researchers and marginalized communities in transformative partnership, ensuring research is driven by community needs. We aim to establish a foundation of trust and equity to ultimately eliminate health disparities across Washington.

# CBRC Key Activities

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## Establish (connect)

Bi-directional communication between community and researchers



## Educate

Researchers about community engagement



## Advance

Community leadership of research



## Recruit

Participants for clinical trials (research)

# Structure

## Founders Group

Cierra Sisters

Leaders in Women's Health

Tubman Center for Health and Freedom

UTOPIA WA

Pacific Islander Community Association of Washington

African Americans Reach & Teach Health Ministry

Reserved seat for American Indian/Alaska Native-serving CBO

## Governing Board

Aurora Commons

Khmer Community of Seattle King County

Entre Hermanos

Hummingbird Indigenous Family Services

Spokane Marshallese Community Association

Southeast Washington Alliance for Health

PAVE WA

Mujeres in Action

Health Justice Recovery Alliance

**3 seats available** for additional organizations, currently in discussions

# DocuSign eConsent

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**Jennifer Ward**, Technology Manager

UW Information Technology

**Lila Brisk**, Research Coordinator

Department of Neurology

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# Docusign eSignatures Introduction

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- Available to UW faculty and staff at **no cost**
- For research, education, and administrative activities



## Fine Print

- Not FDA Part 11 compliant (REDCap Part 11 Instance and Florence are)
- Use cases for patient-related care are not permitted
- Can be used for HIPAA authorization forms, other use cases for research/administration

Send us your questions

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# Docusign Onboarding

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## **Get approval from UW IRB**

- Specific approval to use eSignatures (Docusign) for consent signature and/or HIPAA authorization signature must be obtained in advance from the UW IRB
- For studies reviewed by an external IRB, approval must be obtained from the external IRB and UW HSD

Source:

<https://www.washington.edu/research/hsd/guidance/consent/econsent/>

# Docusign Onboarding (continued)

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## **Two Docusign roles:**

1. Sender (with or without templates)
2. Delegated Administrator (create templates, manage users)

## **Two paths to sending envelopes:**

1. Sender permissions can be granted by a delegated administrator in your team/unit/department. Ask us if you need help identifying your delegated administrator.
2. If you would like to become the delegated administrator for your team, complete our Become a Delegated Administrator onboarding form.

# Using DocuSign

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Regardless of role, your responsibilities are to:

1. Abide by the [Acceptable Use](#) policy
2. Download completed envelopes from DocuSign within 90 days of completion and store them in your team's document repository
3. Complete our [eSignatures Offboarding Request](#) form if you move to another department or leave UW

Questions? Ask us! We're here to help:

<https://it.uw.edu/esig>

# Training and Support

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- Required eSignature training through UW IT
  - Submit an [eSignatures Interest Form](#)
    - Delegated Administrator request
- Electronic Consent: What You Need To Know
  - What is eConsent?
  - How do you document eConsent?
  - What are the differences between DocuSign and REDCap for eConsent?
- HSD Topic-Based Guidance: Consent
  - Choosing between paper vs. eConsent
  - Documentation instructions
  - Best practices

# Docusign Features

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- Envelope templates
  - Delegated administrator permissions required
- Recipient roles
  - PI, research coordinator, participant, witness, etc.
- Signing order
- Required vs. Optional fields
  - Checkbox considerations
- Schedule send
- Individualized messages

# Docusign Use Cases

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- Consenting prior to screening visit
  - More efficient visit flow
- Remote cohorts
  - Higher enrollment
- For those unable to write/sign
  - Provides an additional consent option
  - Must be IRB approved

# Demo

The screenshot shows the DocuSign interface with the following elements:

- Header:** DocuSign logo, Home, Agreements, **Templates** (selected), Reports, Admin.
- Left Sidebar:** Start, ENVELOPE TEMPLATES (My Templates, Shared with Me, Favorites, Show More), WORKFLOW TEMPLATES (Workflow Templates, NEW), WEB FORMS (My Web Forms, Shared with Me, All Web Forms).
- Top Bar:** Templates (selected), Elastic Templates, Search bar (Search My Templates, Last 24 hours, Template ID, Clear), View All Templates button.
- Content Area:** My Templates section with the message "No results" and a sub-instruction "Try editing your search term, filters, or date range."
- Page Bottom:** 25 / Page dropdown, Page 1 of 1, navigation icons.

# REDCap eConsent

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**Courtney Howell**, REDCap Manager  
Institute of Translational Health Sciences

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# REDCap and eConsent Introduction

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- **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 collect consent electronically to support remote participation, improved accessibility across teams and enhanced compliance.
- With **ImageMagick** integration, REDCap can now render IRB-approved consent PDFs directly, ensuring participants can see exact approved and formatted document.

# Availability and Costs

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## ITHS REDCap Instance

- Available to all REDCap users within the WWAMI region and their partners
  - Free to use

## Part 11 REDCap Instance

- 21 CFR Part 11 eConsent will be available starting January 30<sup>th</sup>
  - Free structure under review, details to be shared in coming months
  - Costs expected to decrease over time as adoption expands

# Approvals Required

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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

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- 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)

x :

General

- Introduction to REDCap e-C...
- e-Consent Framework Wo...
- Setting up the e-Consent Fr...
- e-Consent Quick Start Gu...
- Download the e-Consent G...
- REDCap e-Consent Quick S...

### REDCap 307 - Using REDCap for e-Consent

Course Participants Grades Reports Badges More ▾

General

Collapse all

This course covers the following topics:

- What is e-Consent?
- e-Consent at the University of Washington
- Setting up the e-Consent Framework
- How Participants use e-Consent
- How Consents are Stored in REDCap



Access TREE



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# Training, Support and Resources

## eConsent 2.0 Template

+ Create a new REDCap Project

You may begin the creation of a new REDCap project on your own by completing the form below and clicking the 'Create Project' button at the bottom.

**Project title:**

**Project's purpose:**  **How will it be used?**

**Assign project to a Project Folder?**

**Project notes (optional):** Description of the project's use or purpose (displayed on the My Projects page)

**Project creation option:**  Empty project (blank slate)  Upload a REDCap project XML file (CDISC ODM format)   Use a template (choose one below)

select template	Template title (sorted by title)
<input type="radio"/>	Basic Demography
<input type="radio"/>	Classic Database
<input type="radio"/>	CTCAE v4.03 Adverse Events Log
<input checked="" type="radio"/>	e-Consent Template 2.0
<input type="radio"/>	Field Embedding Example Project



# Features

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## 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

# Use Cases

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## Remote Enrollment

- Participants can complete consent forms remotely
- Ideal for rural or geographically dispersed populations

## Multi-Site Study Standardization

- Ensures all sites use the exact same IRB-approved consent
- Eliminates inconsistent formatting or version drift
- Simplifies coordination across sites/institutions

## High-Volume Consenting in Clinical Settings

- Supports rapid consenting in clinics, hospitals or research units
- Can be done with onsite tablets, computers or participant smart devices

# Preview



Inline image of PDF now available to review on attestation page



After submission, eConsent is available in file repository

Displayed below is a read-only copy of your survey responses. Please review it and the options at the bottom.

monitored 24 hours a day and inform participants that they can reach a member of the research team 24 hours a day].

[If the research involves *greater than minimal risk to participants*, explain whether compensation or medical treatments are available if a research injury occurs. Industry sponsored studies should use the language provided by the sponsor. For studies involving non-UW institutions, insert compensation language required or recommended by the institution.] If you are injured as a result of being in this study, necessary medical treatment will be available to you at [insert name and location of medical facility].

[For *greater than minimal risk* studies not funded by an industry sponsor and for which the procedures associated with the risks are performed by a UW agent, insert one of the two statements listed below describing the UW discretionary Human Subjects Assistance Program (HSAP). **This language cannot be altered.**]

([For studies with *medical risks*.] The costs of the treatment may be billed to you or your health insurance [for international studies, refer to national health insurance or health service or program] just like other medical costs, or it may be covered by the UW's discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. The researcher may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, contact the researcher or the UW Human Subjects Division at [hsdinfo@uw.edu](mailto:hsdinfo@uw.edu) or 206-543-0098. Ask the researcher if you would like information about the limits and conditions of the HSAP. The UW does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form. [If appropriate, also add these two sentences] We will bill your health insurance for treating problems that result from your [insert name of disease or underlying condition] or from standard clinical care. If you have no health insurance or your insurance refuses to pay, we will bill you.)

Document Date & Version

Researcher Date & Version



I certify that all of my information in the document above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.

# Florence eConsent

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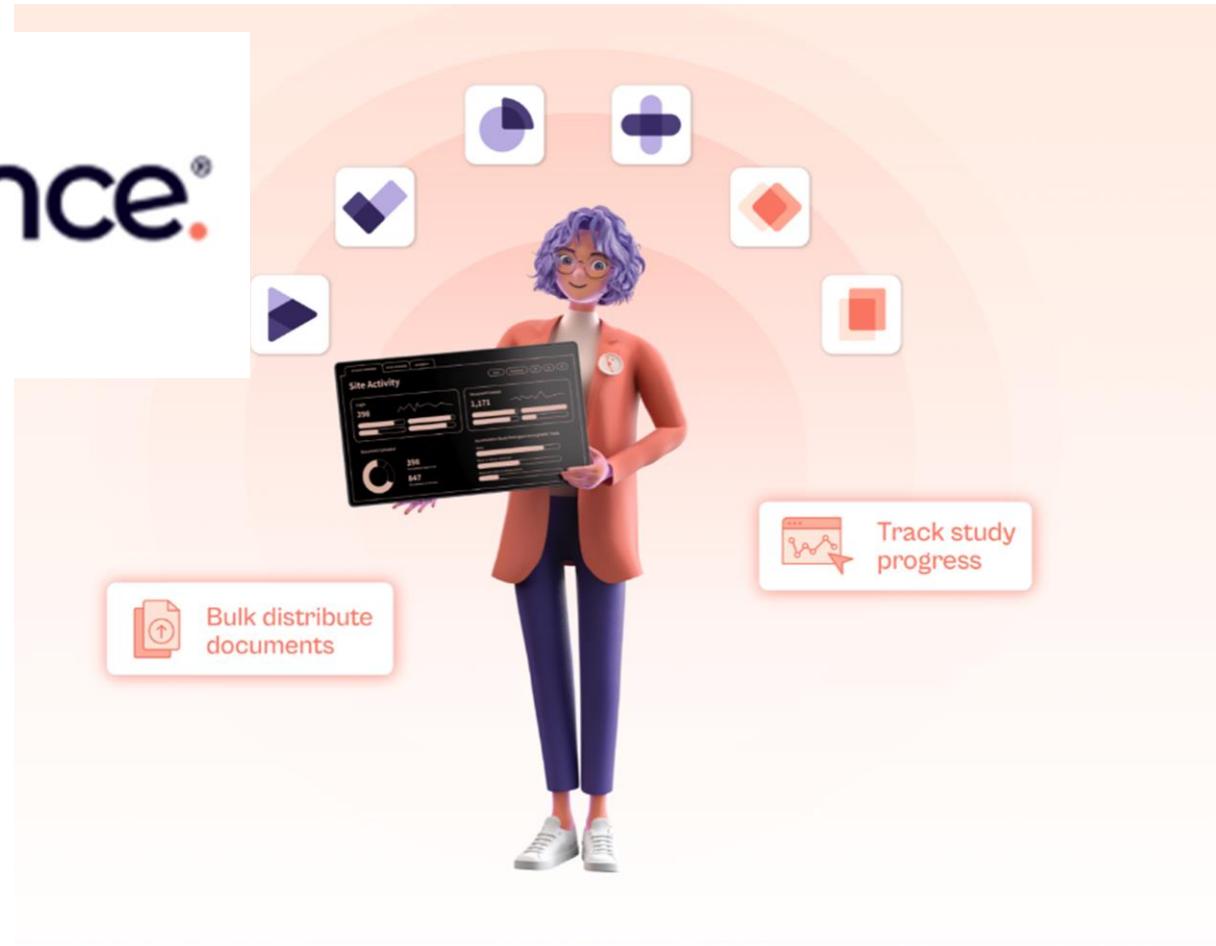
**Linda Harrison**, Regulatory Lead  
Clinical Trials Office, Research Coordination Center

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# What is “Florence”?







Florence is a commercial “site enablement platform” product intended to support various aspects of clinical research operations



Florence Healthcare offers sponsors and sites a suite of clinical trial management tools

UW currently has a contract to use eBinders (an electronic regulatory filing system)



Track study progress

**By the end of January 2026,  
UW researchers will be able to use  
the eConsent product for clinical trials**

# Key Considerations

Similarities to eBinders include:

- ↳ **No cost for investigator-initiated studies, regardless of funding source**
- ↗ **Institutional technical support is limited**
- ↳ **Access is within the Florence platform, SSO (UWNet ID)**
- ↳ **Fully compliant with 21 CFR Part 11**

# Key Considerations

## Differences from eBinders:

- ☛ **Not customizable, i.e. format, roles, integration with other platforms**
- ☛ **Spanish language version is available**
- ☛ **Training is required for participant access**
- ☛ **Florence will have materials available for IRB submissions**
- ☛ **Compatible with most 3<sup>rd</sup> party accessibility software used by participants**

# Additional points

**Storage: eConsent will be able to store the forms, even scanned paper docs**

**Transparency: Tracks outstanding tasks and organizes the files**

**Allows Monitor/Auditor access**

**Includes special workflows for LARs, interpreters and assent**

**Prevents premature signing of a consent form with a “read only” toggle**

# Glimpse into the platform...

→ ⌂ us-econsent.ec.uatv2.researchbinders.com/#/app/62f107b22f5912f382a4f6c3/studies

  STUDIES  ALL STAFF

JH Research Site  
**All Studies**

## Landing page with all of your studies...

[Add Study](#)

STUDY TITLE ↓	STATUS	SPONSOR	PRINCIPAL INVESTIGATOR
0. Breast Cancer Study - HER2-Positive Receptor Outcomes Trial for Effective Cancer Treatment 	Enrolling	Florence Healthcare	Jillian Huels
1. Clinical Trial of PR001 (LY3884961) in Patients With Parkinson's Disease With at Least One GBA1 Mutation	Enrolling	Florence Healthcare	Nish Bhan
A Single Center Observational Study of Vascular Health and Hemodynamics	Enrolling	Flo Sponsor	Jillian Huels
Cerebral Biomarker Evaluation in Breast Cancer Patients Undergoing Targeted Therapy	None	Flo	Jill Huels
Comparing Paper Consenting to Florence eConsent	None	Florence Sponsor	Mike Cosner
Effects of Tylenol on a Headache	None	Florence	Jillian Huels
Evaluating the Efficacy of Novel Moisturizing Agents in Atopic Dermatitis	Enrolling	Flo Sponsor	Jill Huels
Management of Heart Failure in Italian Outpatients Clinics: Observational Study	None	Florence	Jillian Huels
Metabolic Profiling of Diabetic Patients: A Double-Blind Study Comparing the Effects of			



All Studies

## 0. Breast Cancer Study - HER2-Positive Receptor Outcomes Trial for Effective Cancer Treatment

[Overview](#) [Participants](#) [Staff](#) [Forms](#) [Details](#) [Audit Trail](#)

24 CONSENTED

2 PENDING STAFF SIGNATURE

2 INCOMPLETE REGISTRATIONS

### Study main page

#### Pending Staff Signature

WAITING TIME

Cameron Clinic - HIPAA Authorization

73d 1h

Ida Informed - Informed Consent Form

73d

#### Pending Participant Action

WAITING TIME

Sarthak Subject

73d

Alicia Assent

57d 23h

Jillian Huels

44d 4h

#### Participant Status Breakdown

Total 35

In Progress 5

Consented 24

Withdrawn 3

Declined 2

Screen Failed 1

  STUDIES  ALL STAFF

All Studies

## 0. Breast Cancer Study - HER2-Positive Receptor Outcomes Trial for Effective Cancer Treatment

Overview Participants Staff Forms Details Audit Trail 

[Add new form](#)

**All forms available for the study**

Informed Consent Form

FORM NAME	CONSENT TYPE	FORM STATUS	IRB STATUS	VERSION	APPROVAL DATE	VISIBILITY 
Main Consent Form	Main	Active	Approved	11.9	Dec 11, 2024	Manual
Main Consent Form [Assent Required]	Other	Active	Approved	1.8	Jun 12, 2024	Manual
ARM1 Consent Form	Randomized-Arm-Specific	Inactive	Submitted	2.3	-	-
Short Form [Spanish]	Short Form	Inactive	Submitted	1.4	-	-
ARM2 Consent Form	Randomized-Arm-Specific	Inactive	-	2.2	-	-
Main Consent Form [Interpreter Required]	Other	Inactive	 EXPIRED	1	Apr 02, 2023	Manual

## Informed Consent Form

FORM NAME	CONSENT TYPE	FORM STATUS	IRB STATUS	VERSION	APPROVAL DATE	VISIBILITY ⓘ
Main Consent Form	Main	Active	Approved	11.9	Dec 11, 2024	Manual
Main Consent Form [Assent Required]	Other	Active	Approved	1.8	Jun 12, 2024	Manual
ARM1 Consent Form	Randomized-Arm-Specific	Inactive	Submitted	2.3	-	-
Short Form [Spanish]	Short Form	Inactive	Submitted	1.4	-	-
ARM2 Consent Form	Randomized-Arm-Specific	Inactive	-	2.2	-	-
Main Consent Form [Interpreter Required]	Other	Inactive	<span>EXPIRED</span>	1	Apr 02, 2023	Manual

Required]	Other	Inactive	<span>EXPIRED</span>	1	Apr 02, 2023	Manual
ARM3 Consent Form	Randomized-Arm-Specific	Active	Approved	1	May 09, 2023	Manual
Sub-Study Consent Form	Sub-Study	Inactive	<span>EXPIRED</span>	3	Apr 11, 2023	Manual
Short Form [English]	Short Form	Inactive	Submitted	1	-	-
<b>HIPAA Authorization</b>						
FORM NAME	FORM STATUS	IRB STATUS	VERSION	APPROVAL DATE	VISIBILITY	
HIPAA Authorization Form	Active	Approved	1	Jun 01, 2023	Manual	
<b>Other</b>						
FORM NAME	FORM STATUS	IRB STATUS	VERSION	APPROVAL DATE	VISIBILITY	
Consent Checklist	Active	-	1	-	Manual	
Drug Diary Template	Active	Approved	1	Mar 01, 2024	Manual	
Participant Post-Test	Inactive	Approved	1	-	-	
Participant Pre-Test	Inactive	<span>EXPIRED</span>	1	-	Manual	
Quality of Life Questionnaire	Active	Approved	2	Jun 14, 2023	Manual	

All Studies

## 0. Breast Cancer Study - HER2-Positive Receptor Outcomes Trial for Ef

Overview Participants Staff Forms Details Audit Trail



Add new form

### Informed Consent Form

FORM NAME	CONSENT TYPE	FORM STATUS	IRB STATUS	VER

# Participant Management page



STUDIES



ALL STAFF

Jillian Huels  
JH Research Site

All Studies

## 0. Breast Cancer Study - HER2-Positive Receptor Outcomes Trial for Effective Cancer Treatment

[Overview](#) [Participants](#) [Staff](#) [Forms](#) [Details](#) [Audit Trail](#)[Invite via email](#)[Add participant](#)[Actions](#) ▾[Download as CSV](#)

Search by participant name or email



Filter ▾

Filters Applied: Status: 1 selected [x](#)

<input type="checkbox"/>	PARTICIPANT	SCREEN. ID	STATUS	ENROLL. ID	ARM	SUB-STUDY	ACTIONS
<input type="checkbox"/>	Peter Placebo (Not registered)	LAR	✓ Consented	2245	Treatment	Drug Sensitivity and Resistance of BT...	⋮
<input type="checkbox"/>	Parker Patient (Not registered)	LAR	✓ Consented	3554	Control	No	⋮
<input type="checkbox"/>	Gary Guardian (Not registered)	LAR	✓ Consented	5554	Treatment	Drug Sensitivity and Resistance of BT...	⋮
<input type="checkbox"/>	Jillian Huels (Not registered)		✓ Consented	4848	Control	No	⋮
<input type="checkbox"/>	Susan Subject (Not registered)	LAR	✓ Consented	6456	Control	No	⋮
<input type="checkbox"/>	Chloe Consent (Not registered)	LAR	✓ Consented	5748	Treatment	Characterization of Cancer Stem Cell M...	⋮

All Studies / 0. Breast Cancer Study - HER2-Positive Receptor Outcomes... (Participants)

**Peter Placebo**

Participant • Consented • Screening ID: 0274 • Enrollment ID: 2245

Signing enabled

[Forms](#) [Details](#) [Additional Signers](#)[Send forms](#)[Upload form](#)[Actions ▾](#)

## Sent forms

<input type="checkbox"/>	FORM NAME	FORM TYPE	VERSION	SIGNING STATUS	SENT DATE	LAST SIGNATURE	SIGNED BY	ACTIONS
<input type="checkbox"/>	Main Consent Form	Informed Consent Form	11.9	<span>✓ Signed</span>	12-Dec-2024	12-Dec-2024	Participant	⋮
<input type="checkbox"/>	Patient Education Brochure	Other	1	<span>✓ Read</span>	12-Dec-2024	--	--	⋮
<input type="checkbox"/>	Introduction Letter	Other	1	<span>✓ Read</span>	12-Dec-2024	--	--	⋮

## Uploaded paper forms

FORM NAME	FORM TYPE	VERSION	SIGNING STATUS	CERTIFIED COPY
-----------	-----------	---------	----------------	----------------

us-econsent.ec.uatv2.researchbinders.com/#/app/62f107b22f5912f382a4f6c3/studies/6495a45ca6df5c002a34af59/participants/675b2a6e89ce9a747853f05f/isRegistered/true/additional-signers

  STUDIES  ALL STAFF Jillian Huels JH Research Site

All Studies / 0. Breast Cancer Study - HER2-Positive Receptor Outcomes... (Participants)

## Peter Placebo

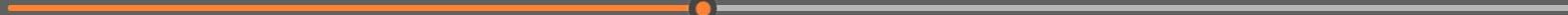
Participant • Consented • Screening ID: 0274 • Enrollment ID: 2245

**Signing enabled** 

**Forms** **Details** **Additional Signers**

[Add a LAR](#) [Add a Parent/Guardian](#) [Add an Interpreter](#) [Add a Witness](#) 

ADDITIONAL SIGNER	ROLE	STATUS	ACTIONS
Jillian Huels	LAR	 Enabled	

0:02:24  0:03:04

## Additional signers

The screenshot shows a web browser window for the Florence eConsent platform. The URL in the address bar is <https://us-econsent.ec.uatv2.researchbinders.com/#/app/62f107b22f5912f382a4f6c3/studies/6495a45ca6df5c002a34af59/participants/675b2a6e89ce9a747853f05f/isRegistered/true/additional-signers>. The main page displays a participant profile for "Peter Placebo" with status "Consented". Below the profile, there are tabs for "Forms", "Details", and "Additional Signers", with "Additional Signers" being the active tab. Under "Additional Signers", there is a table with one row showing "Jillian Huels" as an LAR. A modal dialog box titled "Add a Parent/Guardian" is open in the center. The dialog contains the following text: "A Parent/Guardian will receive all of the forms sent to this participant and will be able to sign those forms on behalf of the participant." It includes fields for "Email \*", "Language" (set to "English"), and "Role" (set to "Parent/Guardian 1"). At the bottom of the dialog are "Cancel" and "Send Invitation" buttons.

rence. STUDIES ALL STAFF

es / 0. Breast Cancer Study - HER2-Positive Receptor Outcomes... (Part  
**Peter Placebo**  
Patient • Consented • Screening ID: 0274 • Enrollment ID: 2245

Details Additional Signers

forms Upload form Actions ▾

forms

FORM NAME	FORM TYPE	VERS
Main Consent Form	Informed Consent Form	11.9
Patient Education Brochure	Other	1
Introduction Letter	Other	1

added paper forms

NAME	FORM TYPE

### Send forms to Peter Placebo

**Study:** 0. Breast Cancer Study - HER2-Positive Receptor Outcomes Trial for Effective Cancer Treatment

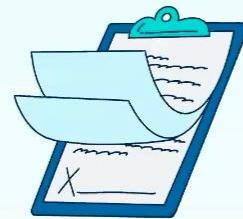
**Selected forms will be sent to the participant's LAR.**

Active Forms (not sent)	SIGNATURE	SIGNED BY
<input type="checkbox"/> ARM2 Consent Form (version 2.1)	2024	Participant
<input type="checkbox"/> ARM1 Consent Form (version 2.2)		..
<input type="checkbox"/> Comprehension Quiz (version 1)		..
<input type="checkbox"/> ARM3 Consent Form (version 1)		
<input type="checkbox"/> Quality of Life Questionnaire (version 2)		
<input type="checkbox"/> Drug Diary Template (version 1)		
<input type="checkbox"/> Main Consent Form [Assent Required] (version 1.8)		
<input type="checkbox"/> Consent Checklist (version 1)		

# Participant's Portal View

florence.

Jillian Huels



#### Your studies



0. Breast Cancer Study - HER2-Positive Receptor Outcomes Trial for Effective Cancer Treatment

CONSENTED

# Welcome, Jillian!

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

[View tasks](#)

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

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

→ G us-econsent.ec.uatv2.researchbinders.com/participants/#/tasks

 florence.

[Back to Home](#)

## 0. Breast Cancer Study - HER2-Positive Receptor Outcomes Trial for Effective Cancer Treatment

**Site:**  
JH Research Site

**This study requires the following tasks:**

- 1 Read forms**
  - Number of forms: 1
  - Total pages: 2
- 2 Sign forms**

 You will need your account password to sign each document.

**View tasks** 

1 View → 2 Sign

## Informed Consent Form



Download

2 of 2

### ***TO BE FILLED OUT BY SUBJECT ONLY***

Please print your name, sign, and date below if you agree to be in this research study, and any optional studies you initialed above. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

---

Name of Subject

---

Signature of Subject/LAR (18 or older and able to consent)

### ***TO BE FILLED OUT BY STUDY TEAM ONLY***

---

Name of Person Conducting Informed Consent Discussion

**Informed Consent Form**

Consent and Authorization

Consent and HIPAA Authorization  
I opt to participate in an

Yes  No

**Before moving to the next document...**

Enter your account password and enter your information for verification.

Password  
*Enter in your password*

Participant Date of Birth (DDMMYYYY)

**Submit this form**

**Cancel**

**TO BE FILLED OUT BY SUBJECT ONLY**

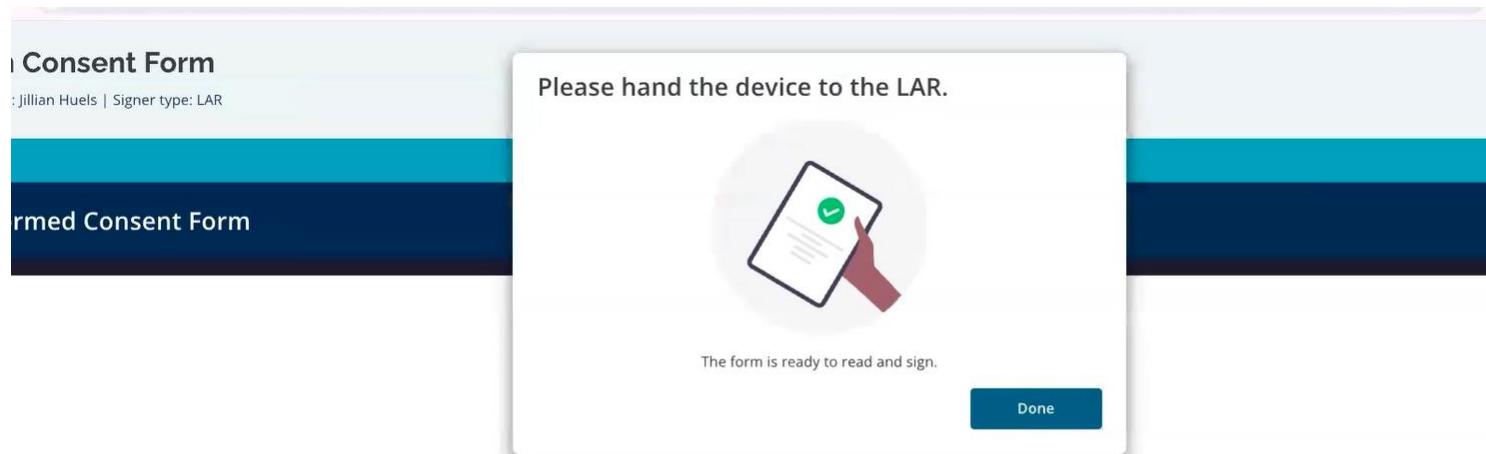
Please print your name, sign, and date below if you agree to be in this research study, and any optional studies you initialed above. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

Jillian Huels

Name of Subject

## On-site eConsent process with device

### Can also upload scanned PDF consent forms if participant prefers paper document



#### You Are Being Asked to Be in a Research Study Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you ag

# eConsent Summary

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

# Q&A

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