Diversity in Clinical Trials Initiative Town Hall:

Policy Update, eConsent and other Resources

Carson Simões, Assistant Director of Analytical and Data Services, Office of Research and Graduate Education
Charlie Gregor, Program Director, Institute of Translational Health Sciences
Courtney Howell, REDCap Manager, Institute of Translational Health Sciences
Jennifer Ward, Technology Manager, UW Information Technology
Juliana Garcia, Assistant Director of Community Engagement, Office of Healthcare Equity
Lila Brisk, Research Coordinator, Department of Neurology
Linda Harrison, Regulatory Lead, Clinical Trials Office Research Coordination Center
Maria Savage, Associate Director of Systems and Initiatives, Human Subjects Division

November 19, 2025

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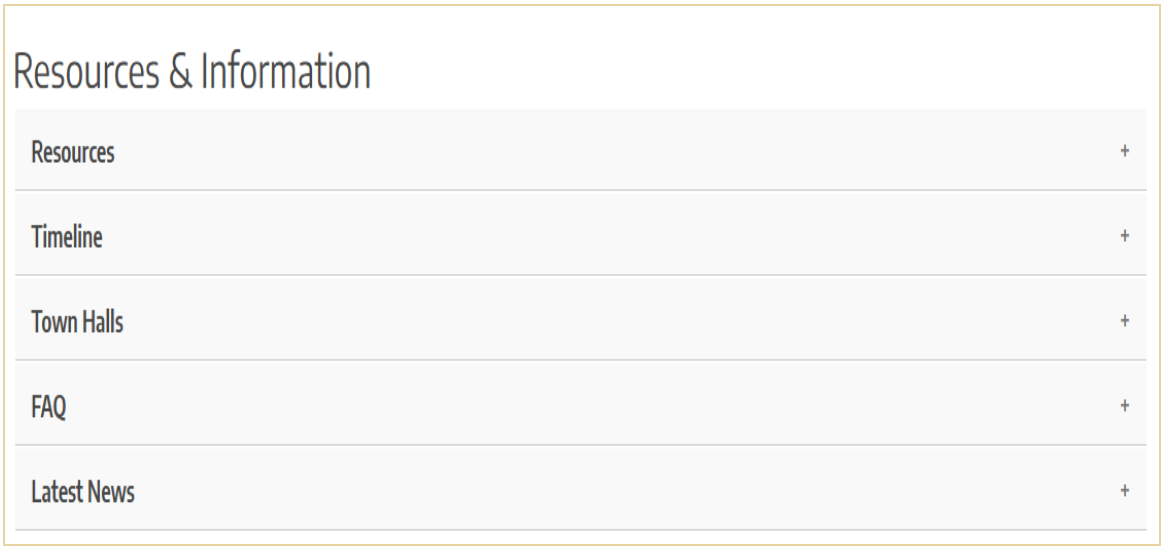
Previous Town Halls and other DCTI Resources

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



Diversity in Clinical Trials Policy Update

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

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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.

- 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

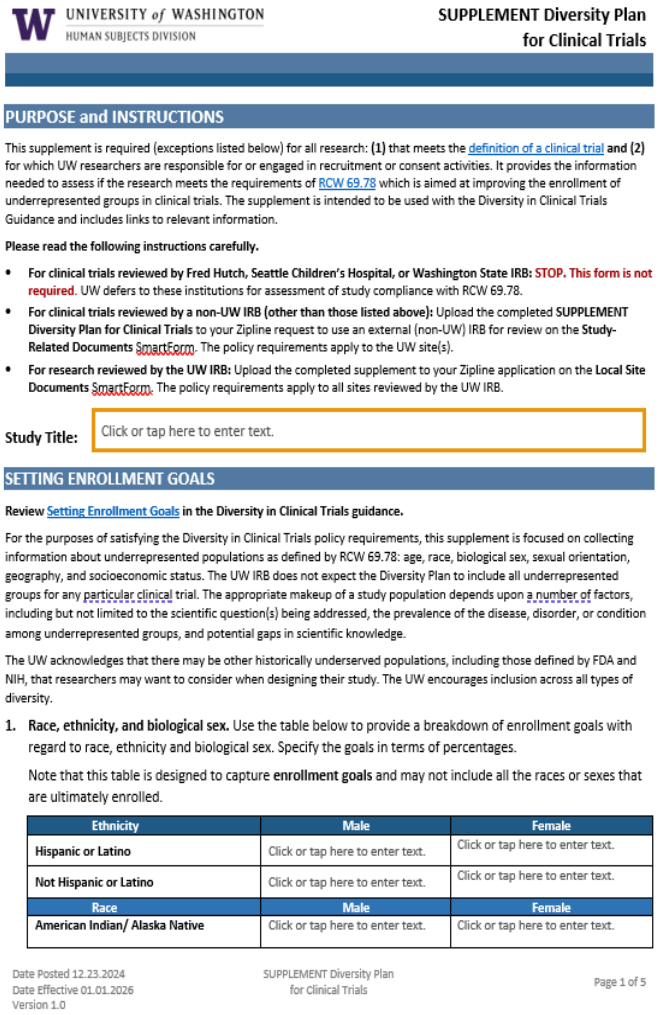
UW Policy Exceptions

- Phase 1 or earlier trials
- Pilot and feasibility studies
- Clinical trials involving ‘small populations’

NEW - If the available target population is ≤100, or the total study cohort enrollment is ≤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



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HUMAN SUBJECTS DIVISION

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: Click or tap here to enter text.

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	Click or tap here to enter text.	Click or tap here to enter text.
Not Hispanic or Latino	Click or tap here to enter text.	Click or tap here to enter text.
Race	**Male**	**Female**
American Indian/ Alaska Native	Click or tap here to enter text.	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
Stage 1: Ignore Community is not provided with information or involved in decision-making processes	**No community involvement** in planning and proposal development	**No community input** in trial design, setup.	**No community oversight** or input during trial recruitment and conduct.	**No community involvement** in data analysis. No follow-up or dissemination of results to the community.
Stage 2: Inform Community is provided with relevant information	**Community is informed** about plans to conduct the research (e.g., through various media), but input is not sought.	**Trial design and setup is informed** by 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. **Use Interpreter services and translated materials** for the inclusion of participants with a non-English language preference.	**Community is informed** about the research procedures through culturally humble recruitment and consent materials. **Participants may receive updates on trial progress.**	**The aggregate results of the trial** are shared with participants (e.g., newsletter, email) and posted on CT.gov.
Stage 3: Consult Community is provided with opportunities to offer feedback	**Community is informed** about plans to conduct the research AND provided with opportunities to offer feedback on the research plan.	**Community is consulted** on trial design, and setup. Trial decisions are made by researchers. **Use community consultation to:** • Identify and reduce barriers and burdens to participation. • Develop culturally humble recruitment methods. • Identify and address community concerns about the research.	**Community is consulted on issues** related to trial conduct, including recruitment but has limited involvement. **Community is informed** about the research procedures through culturally humble recruitment and consent materials. **Participants may receive updates on trial progress.**	**Community is consulted on dissemination** of results or follow-up plans but has limited input. **The aggregate results of the trial are shared** with participants, posted on CT.gov, the OHCE research results website, AND through additional channels identified in community consultation.

UW Policy – eConsent

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

- 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

UW Policy – Tracking & Reporting

- **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

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

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Dashboard: UW Medicine Patient Demographics

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

- The dashboard is available to UW personnel with secured access via UW NetID.

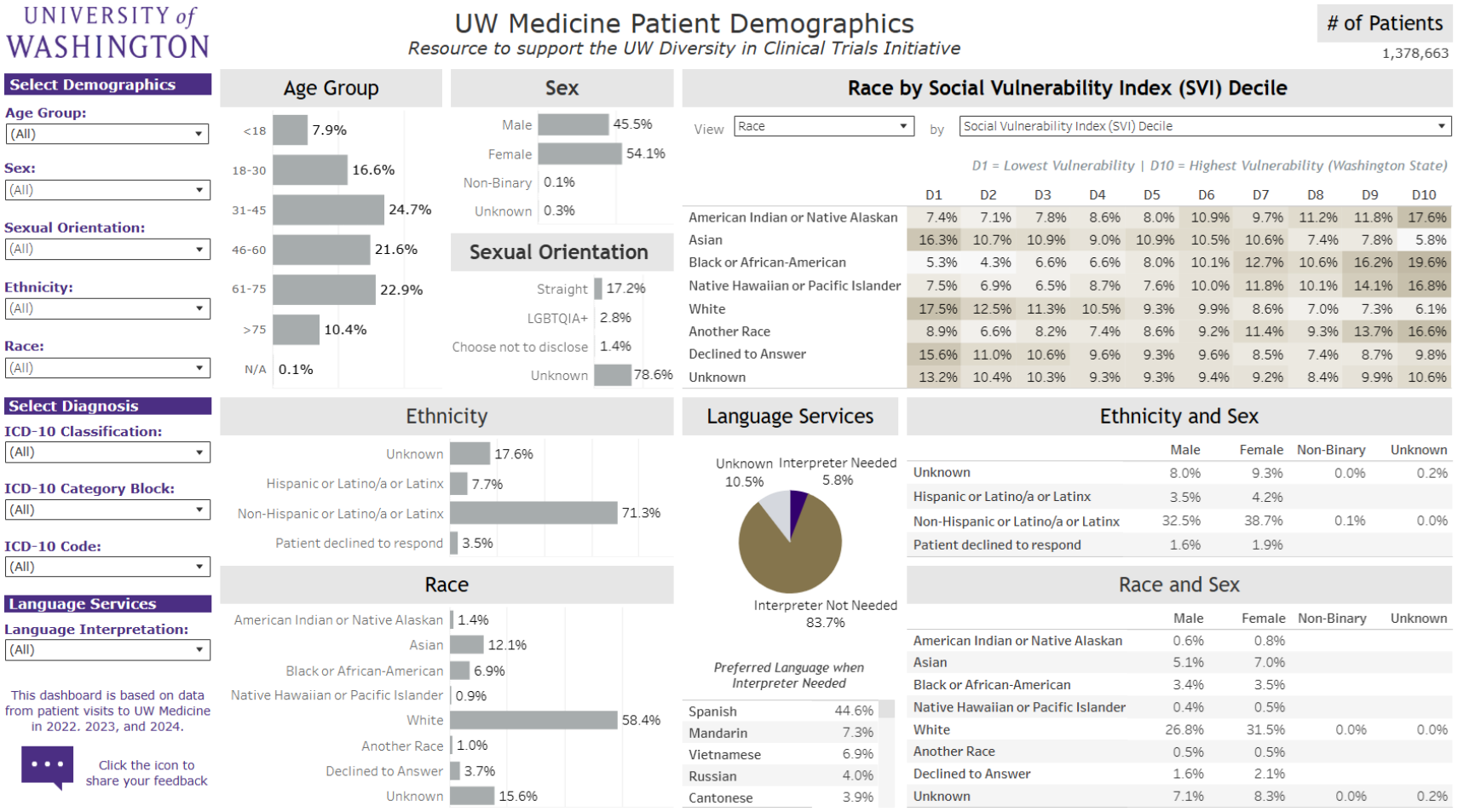
- The dashboard is hosted on the UW's BI Portal (biportal.uw.edu) in the Research subject area.

  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



Bridge Funding & Community Engagement

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

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Bridge Funding: Translation and Interpretation

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

- **Application Currently Open:** 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

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

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

Jennifer Ward, Technology Manager
UW Information Technology
Lila Brisk, Research Coordinator
Department of Neurology

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Docusign eSignatures Introduction

- 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

Docusign Onboarding

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)

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

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

- 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

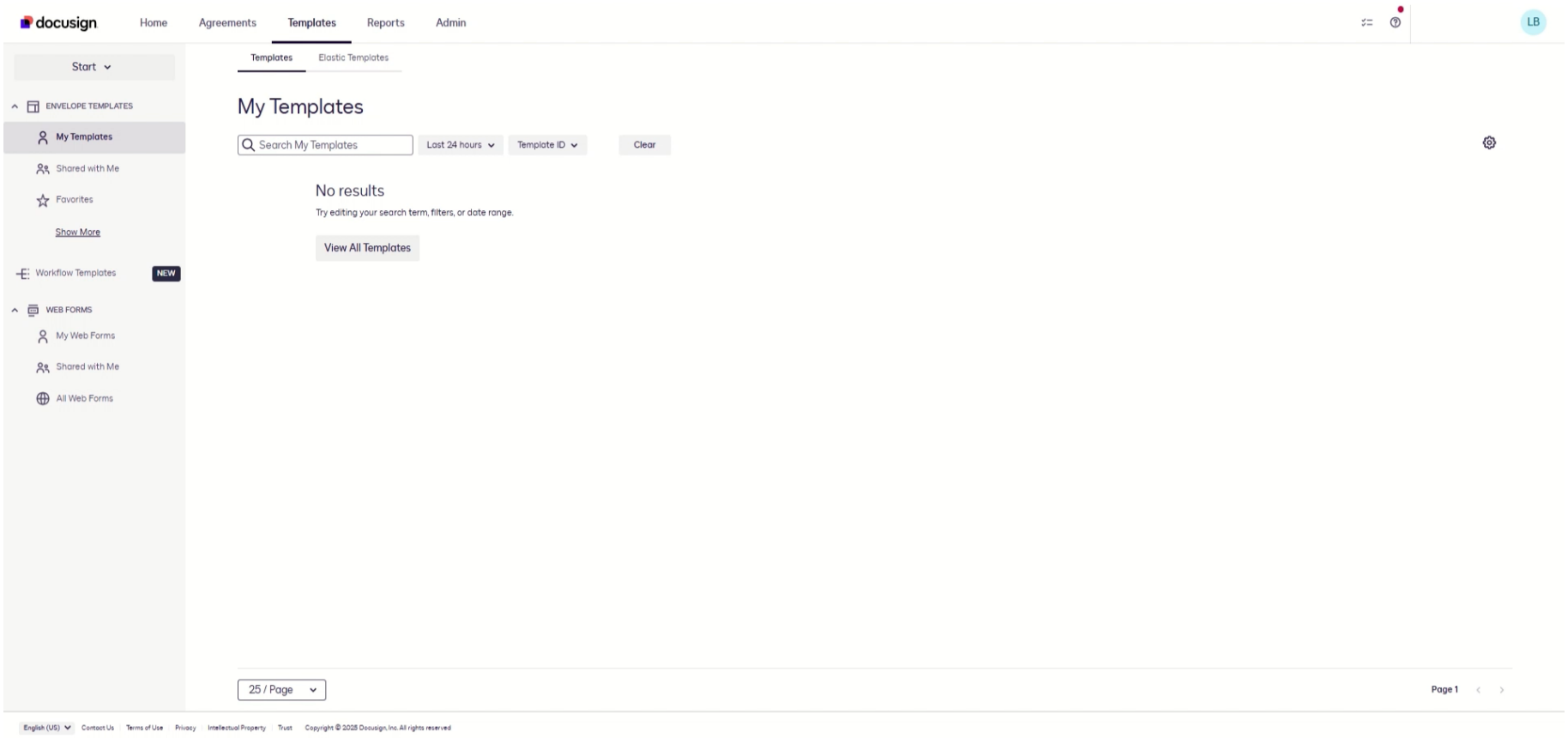
Docusign Features

- 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

- 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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Home
Agreements
Templates
Reports
Admin
LB
Start
ENVELOPE TEMPLATES
My Templates
Shared with Me
Favorites
Show More
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WEB FORMS
My Web Forms
Shared with Me
All Web Forms
Templates
Elastic Templates
My Templates
Search My Templates
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Clear
No results
Try editing your search term, filters, or date range.
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REDCap eConsent

Courtney Howell, REDCap Manager
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.

- With **ImageMagick** integration, REDCap can now render IRB-approved consent PDFs directly, ensuring participants can see exact approved and formatted document.

REDCap®

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Availability and Costs

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 30th
  - Free structure under review, details to be shared in coming months
  - Costs expected to decrease over time as adoption expands

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

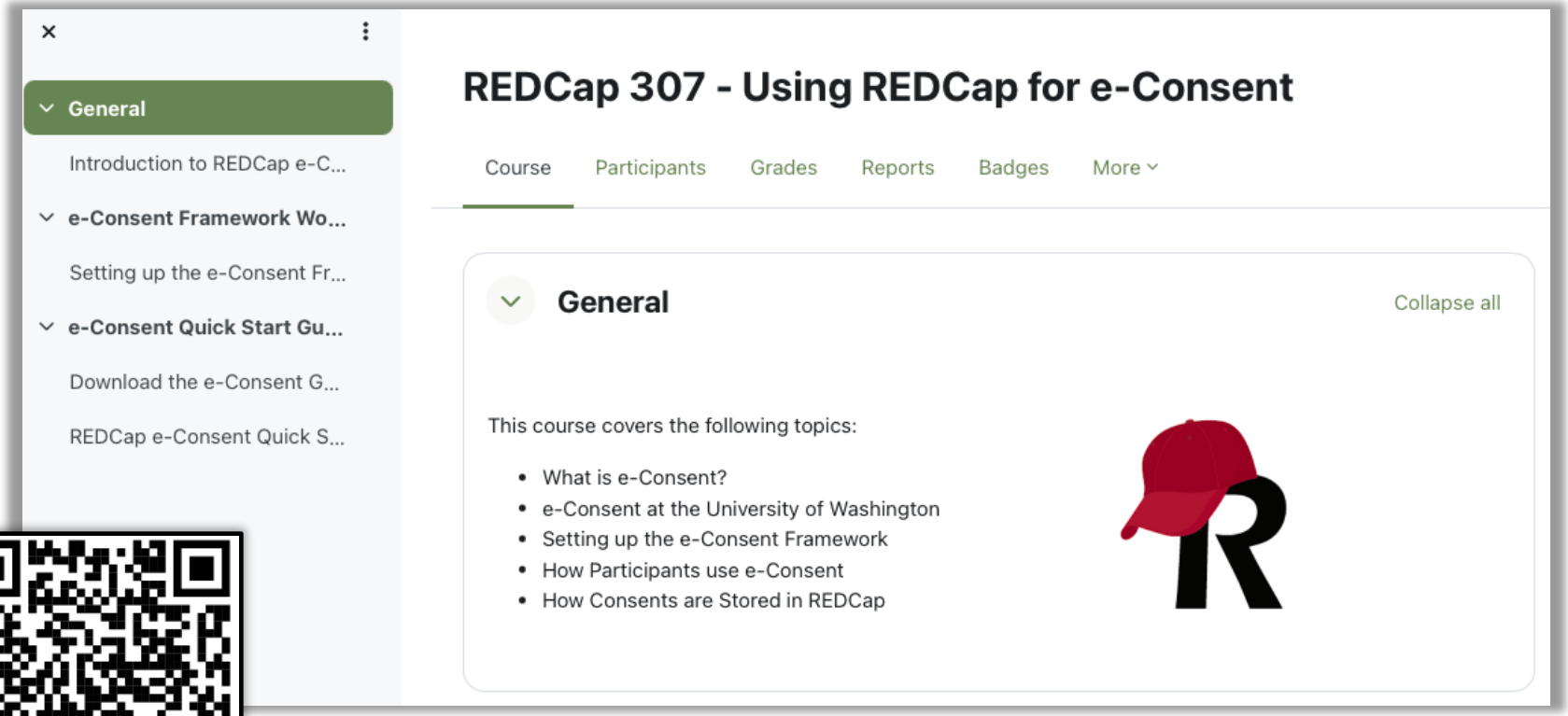
Training, Support and Resources

- 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

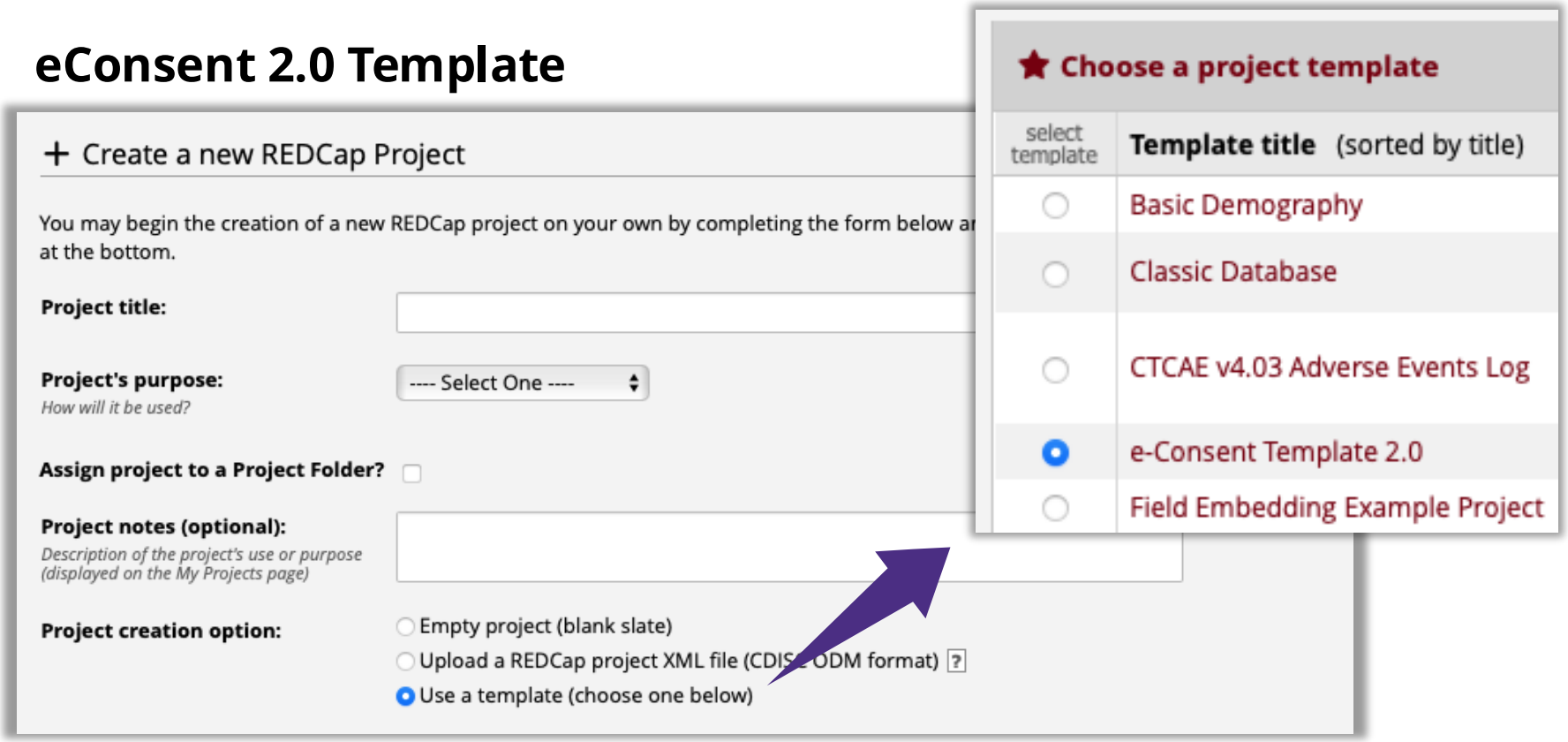
TREE (Translational Research Education Engine)



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

Use Cases

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

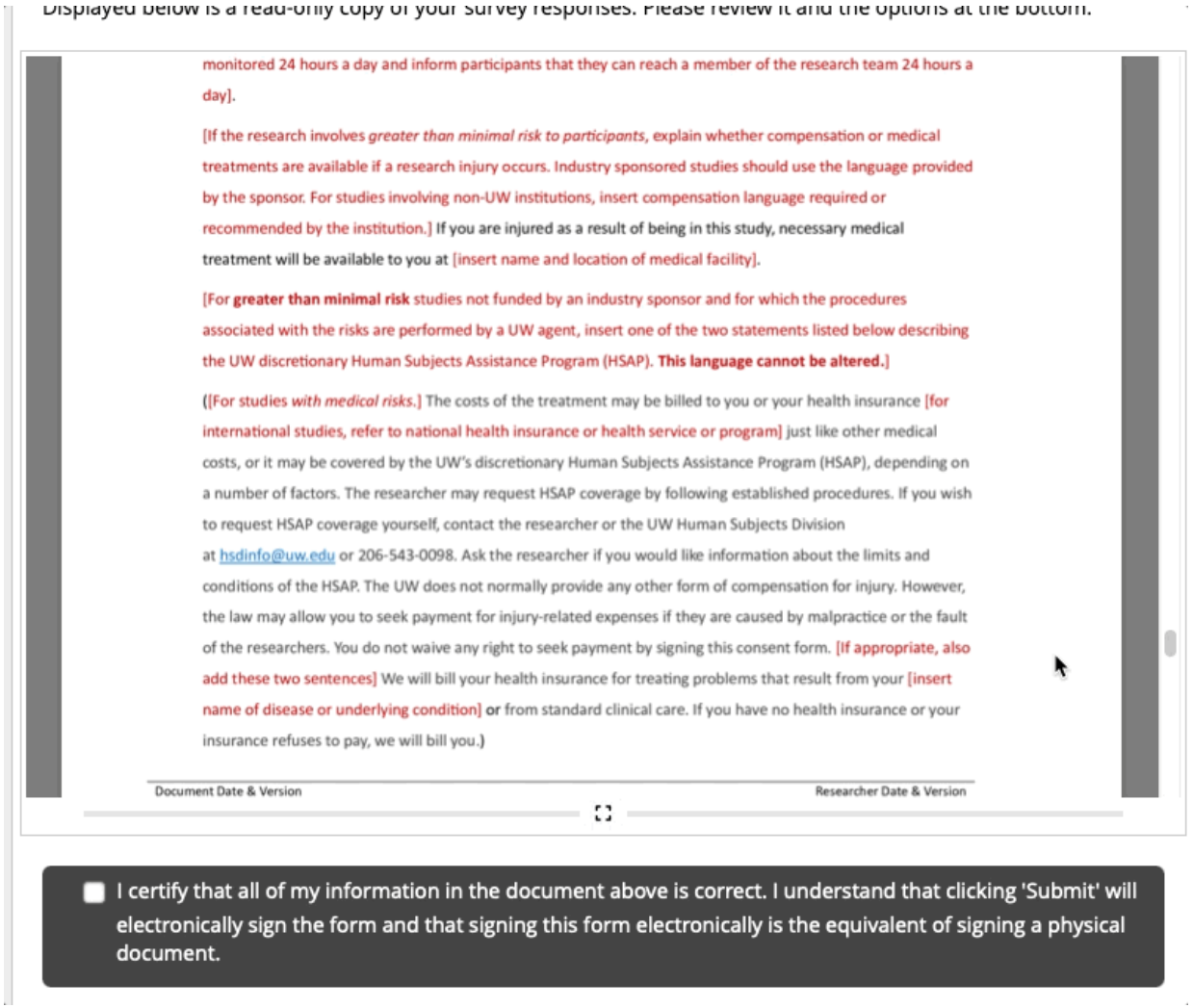
High-Volume Consenting in Clinical Settings

- 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



Florence eConsent

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

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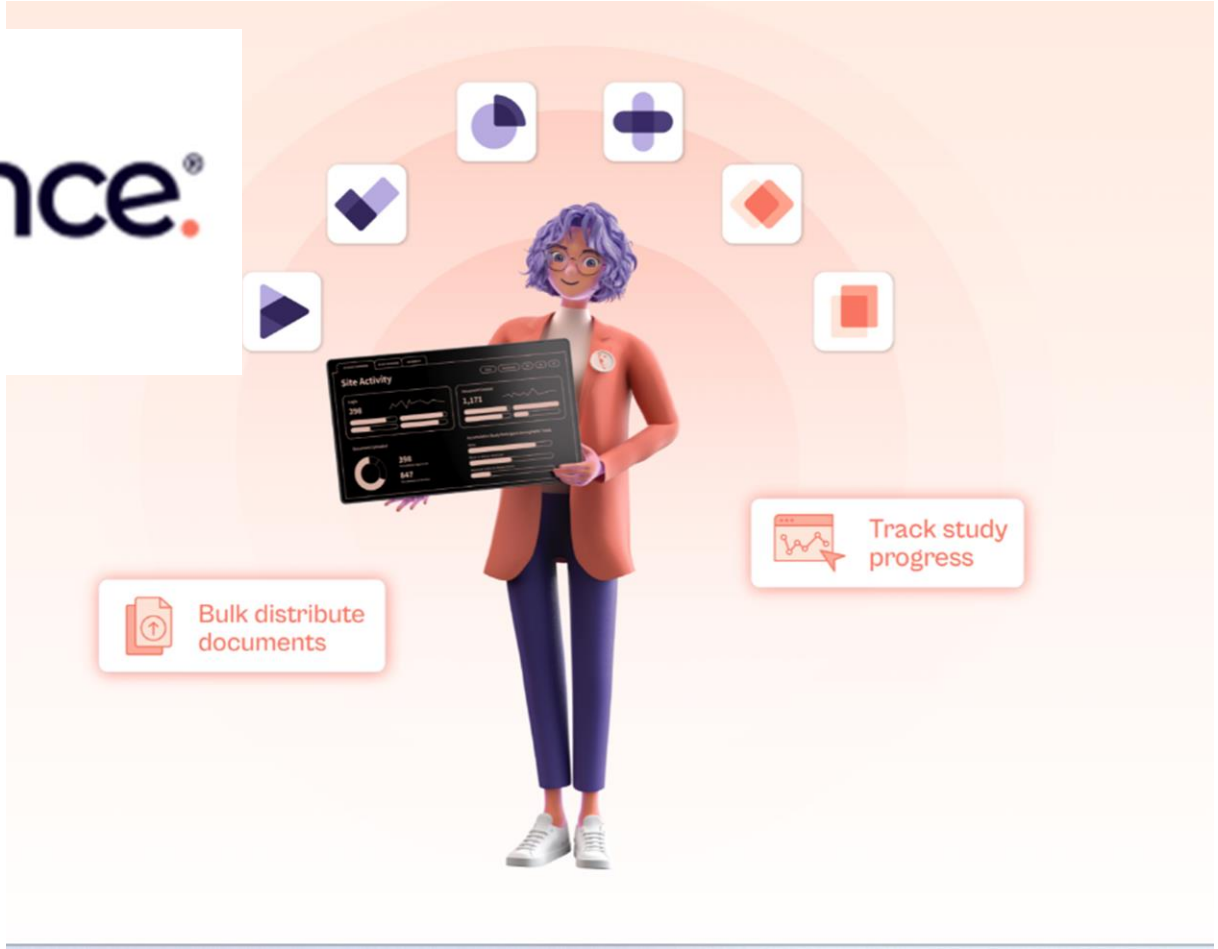
What is “Florence”?

florence.



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CLINICAL TRIALS OFFICE

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)

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 3rd party accessibility software used by participants**

Additional points

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

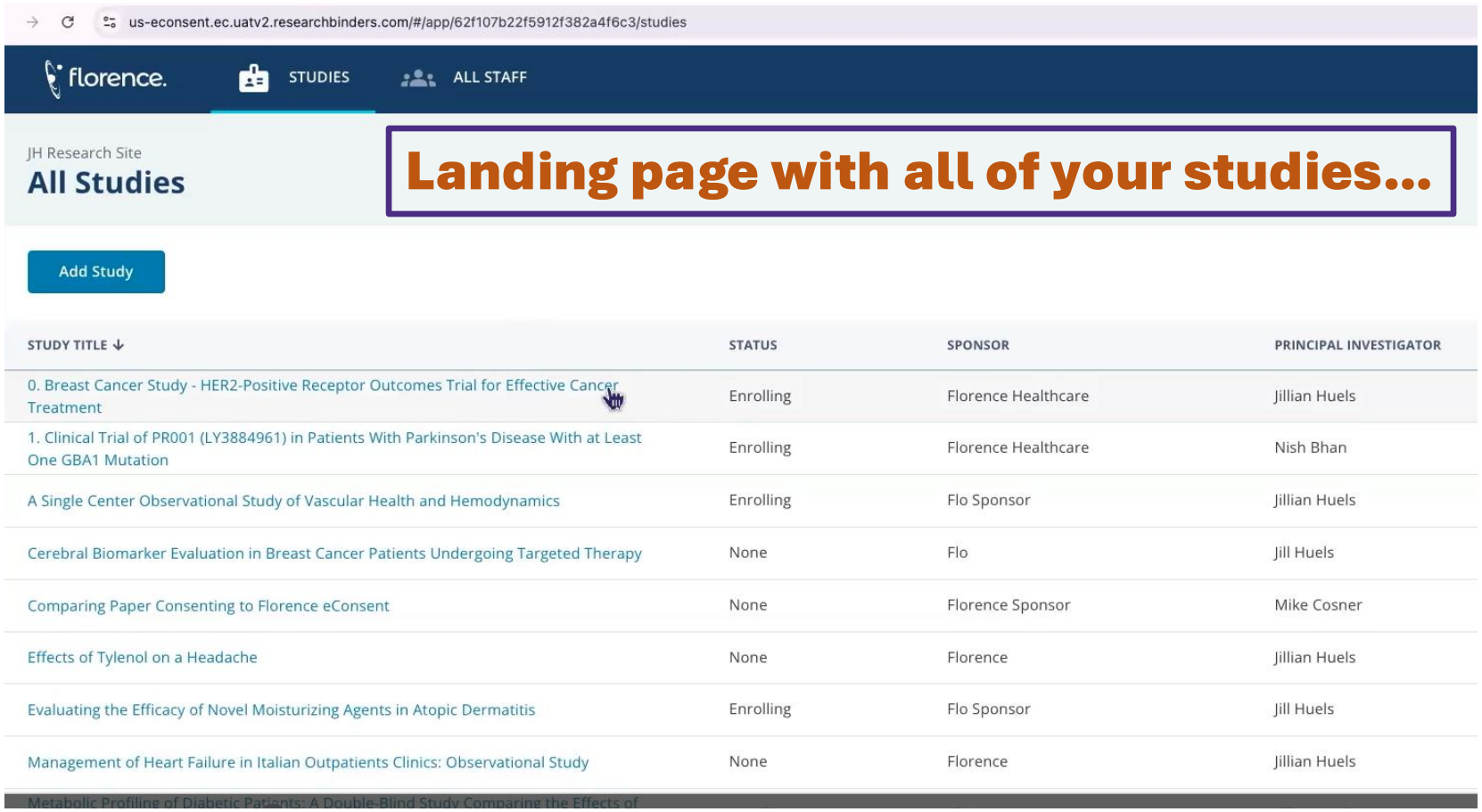
Transparency: Tracks outstanding tasks and organizes the files

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…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All Studies
Landing page with all of your studies...
Add Study
STUDY TITLE
STATUS
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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
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Jill Huels
Management of Heart Failure in Italian Outpatients Clinics: Observational Study
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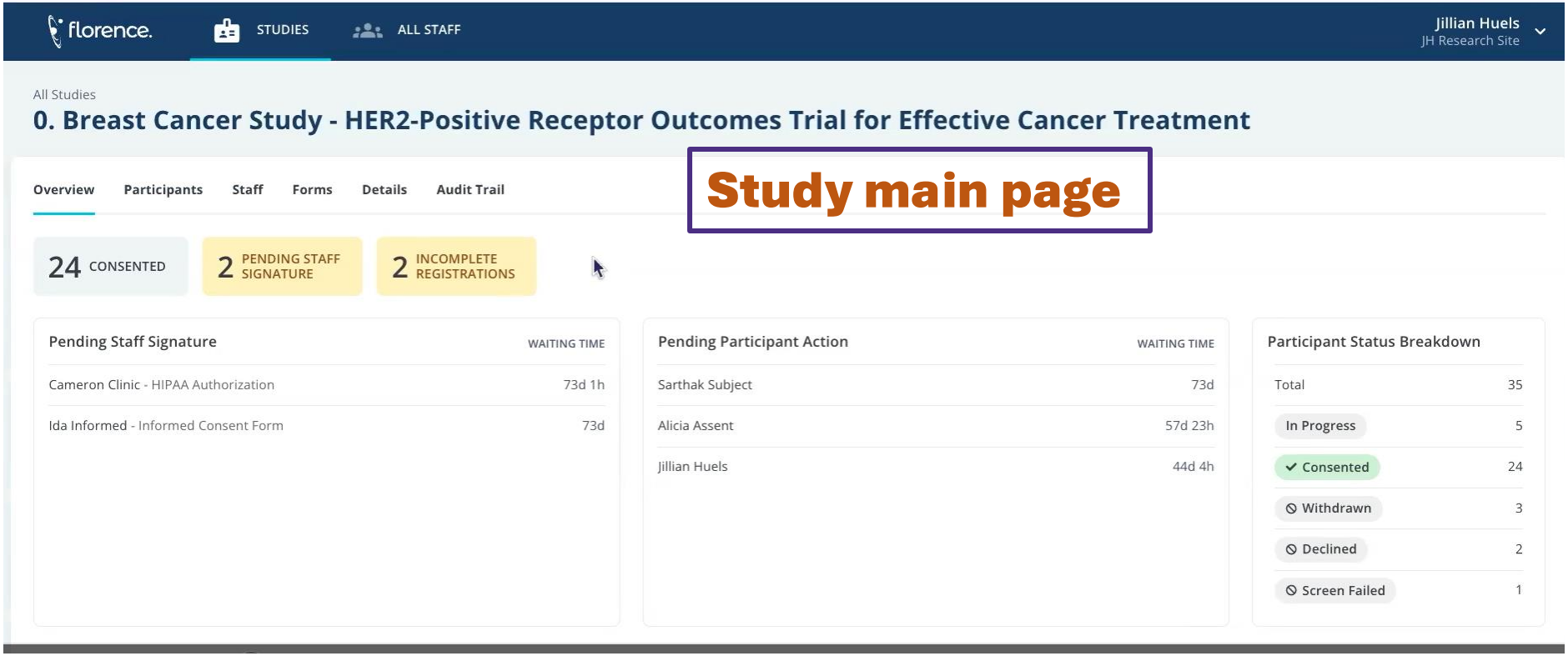
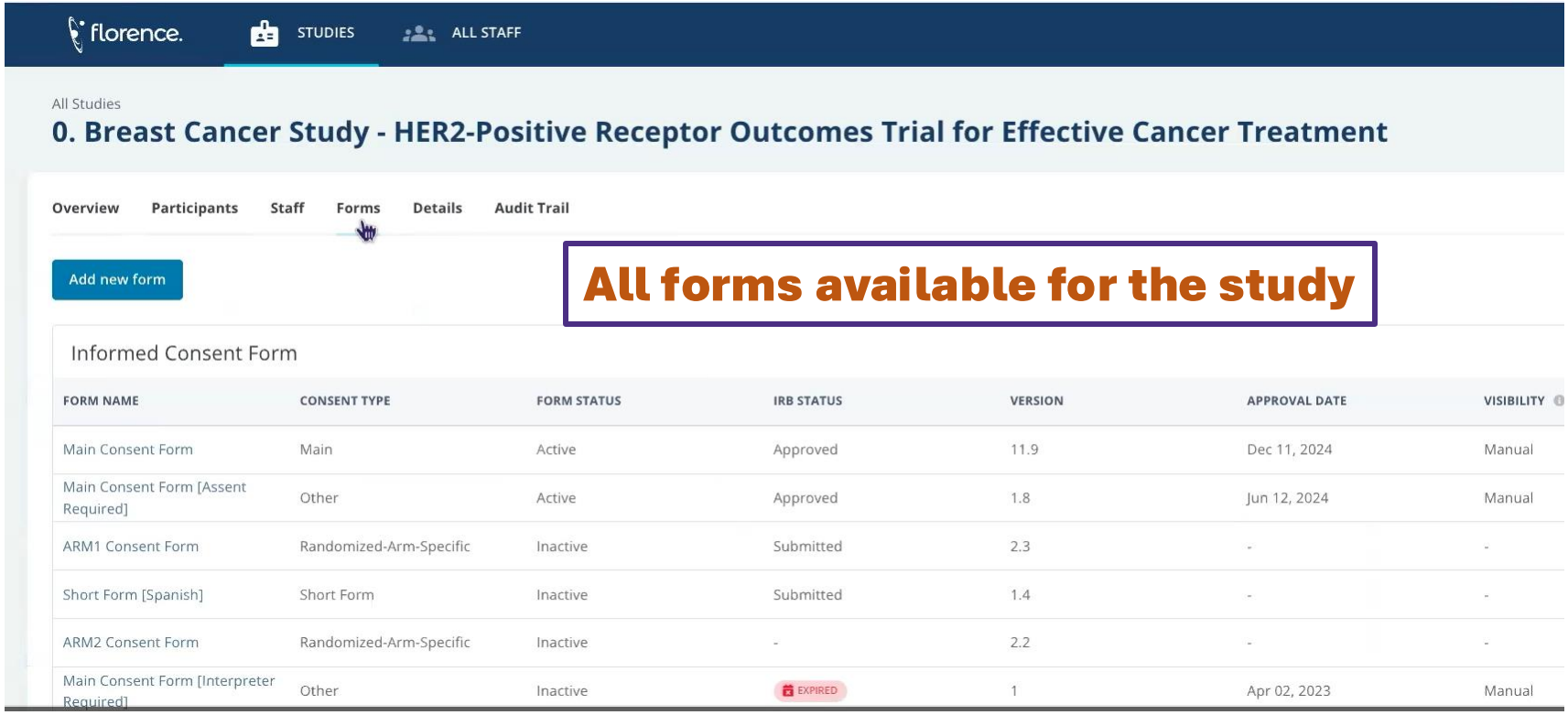
Florence
Jillian Huels





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

Required]	Other	Inactive	EXPIRED	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	EXPIRED	3	Apr 11, 2023	Manual
Short Form [English]	Short Form	Inactive	Submitted	1	-	-

HIPAA Authorization

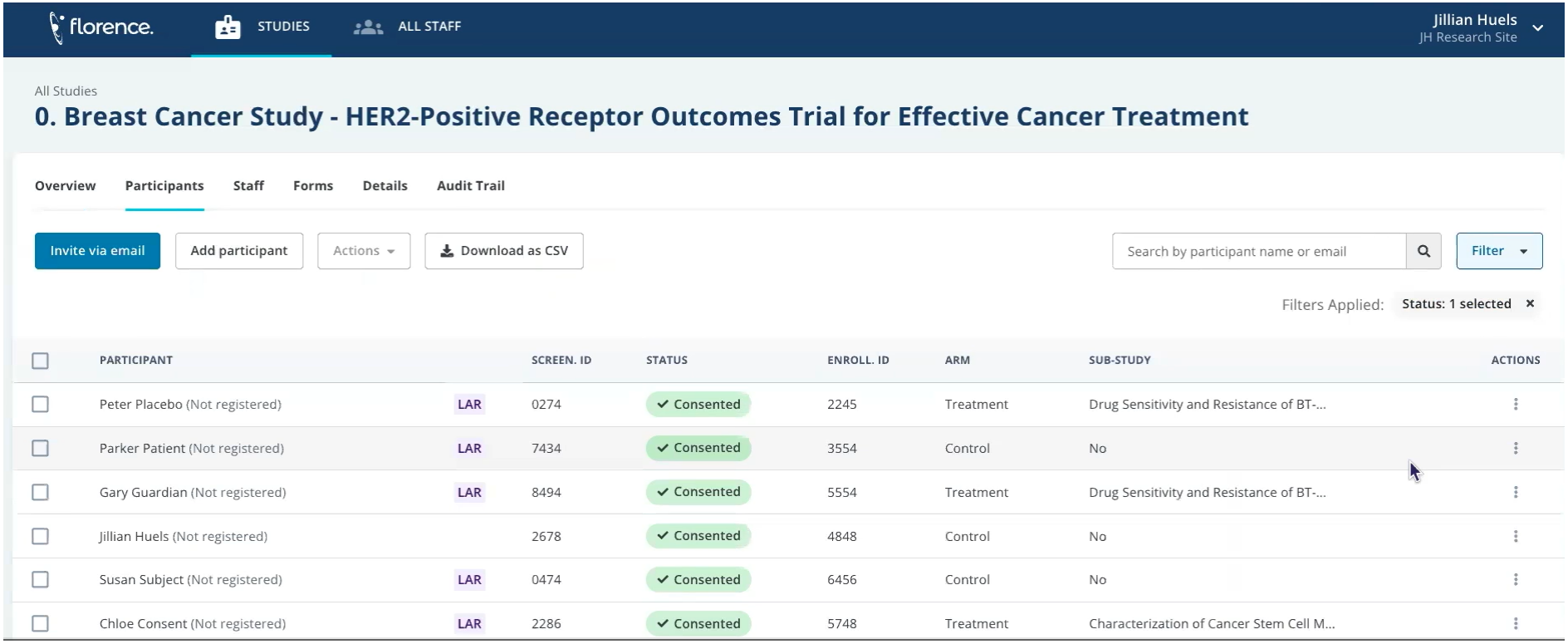
FORM NAME	FORM STATUS	IRB STATUS	VERSION	APPROVAL DATE	VISIBILITY
HIPAA Authorization Form	Active	Approved	1	Jun 01, 2023	Manual

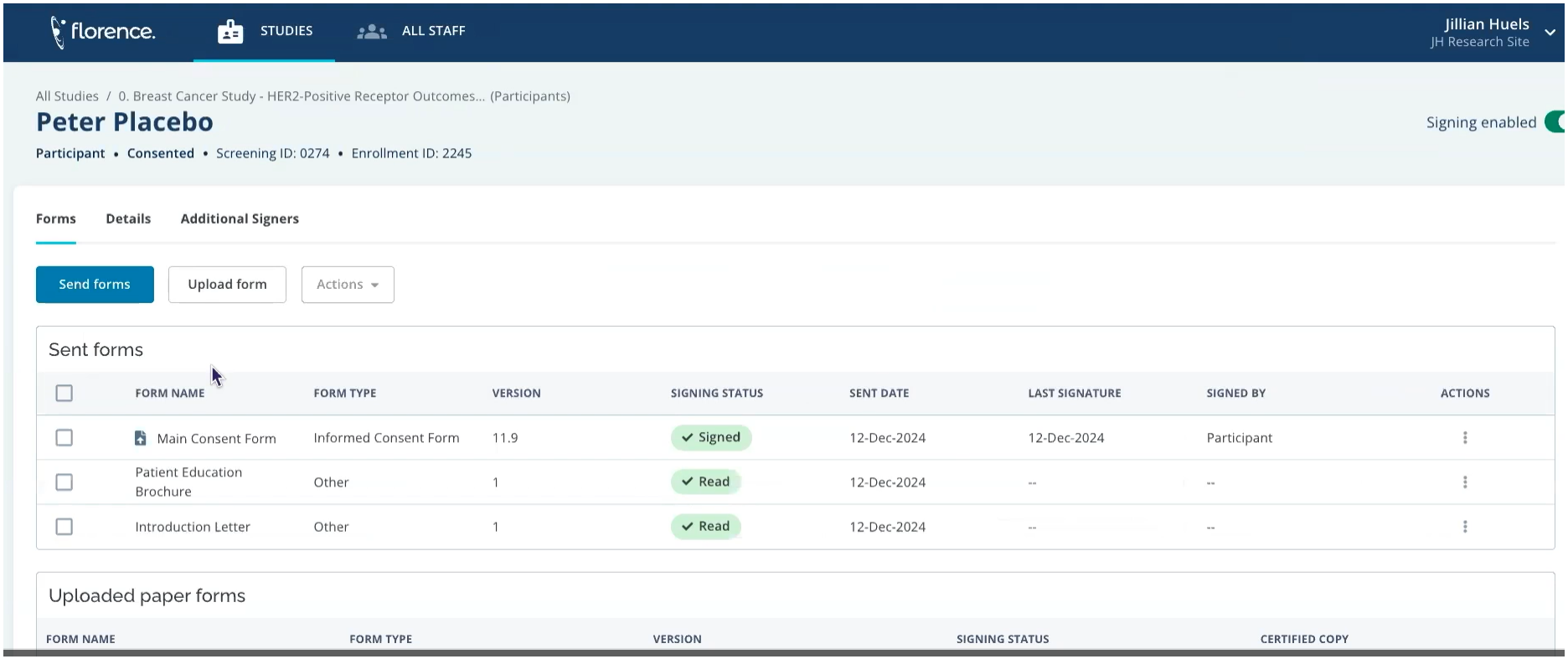
Other

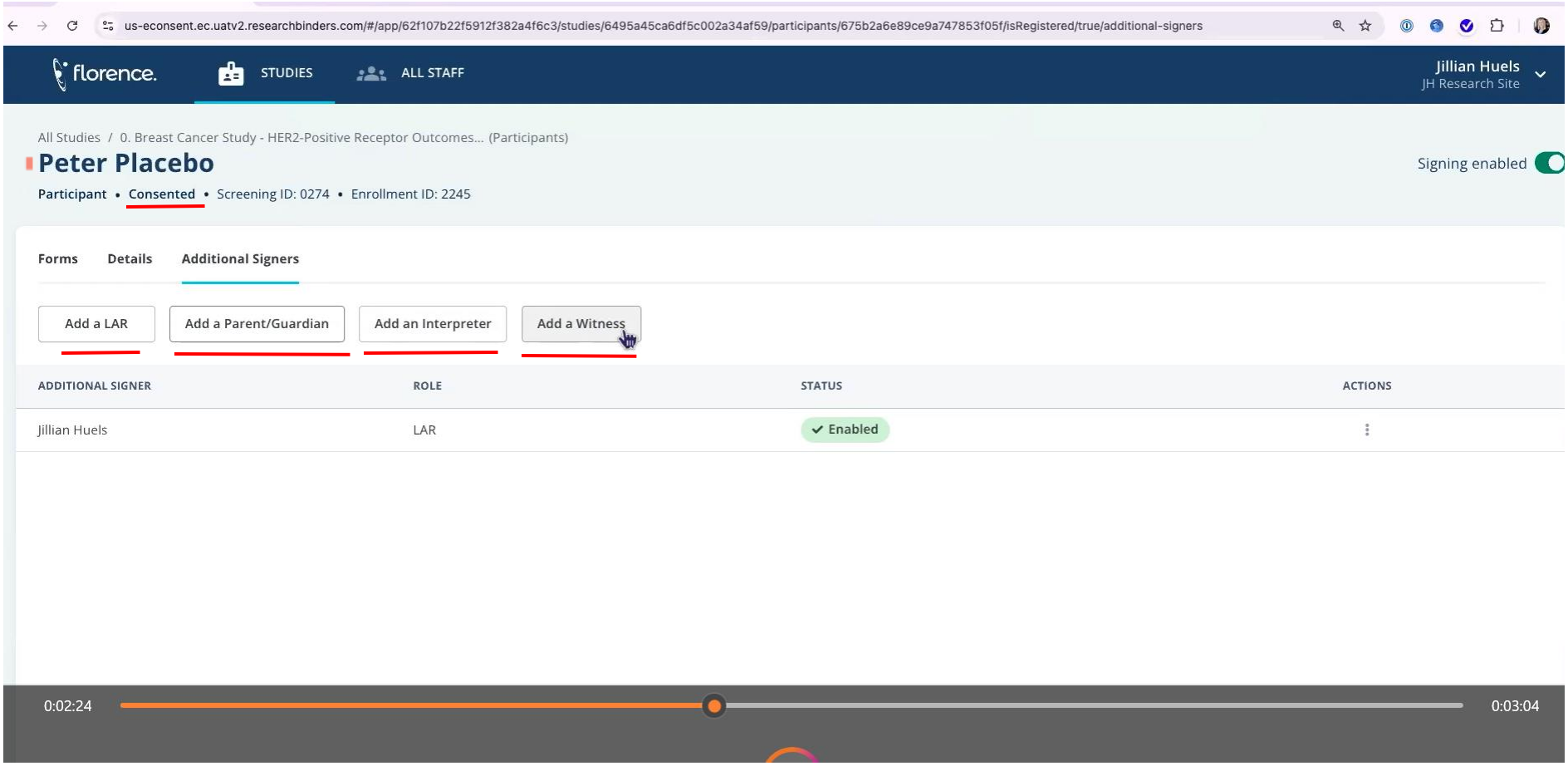
FORM NAME	FORM STATUS	IRB STATUS	VERSION	APPROVAL DATE	VISIBILITY
Consent Checklist	Active	-	1	-	Manual
Drug Diary Template	Active	Approved	1	Mar 01, 2024	Manual
Participant Post-Test	Inactive	Approved	1	-	-
Participant Pre-Test	Inactive	EXPIRED	1	-	Manual
Quality of Life Questionnaire	Active	Approved	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

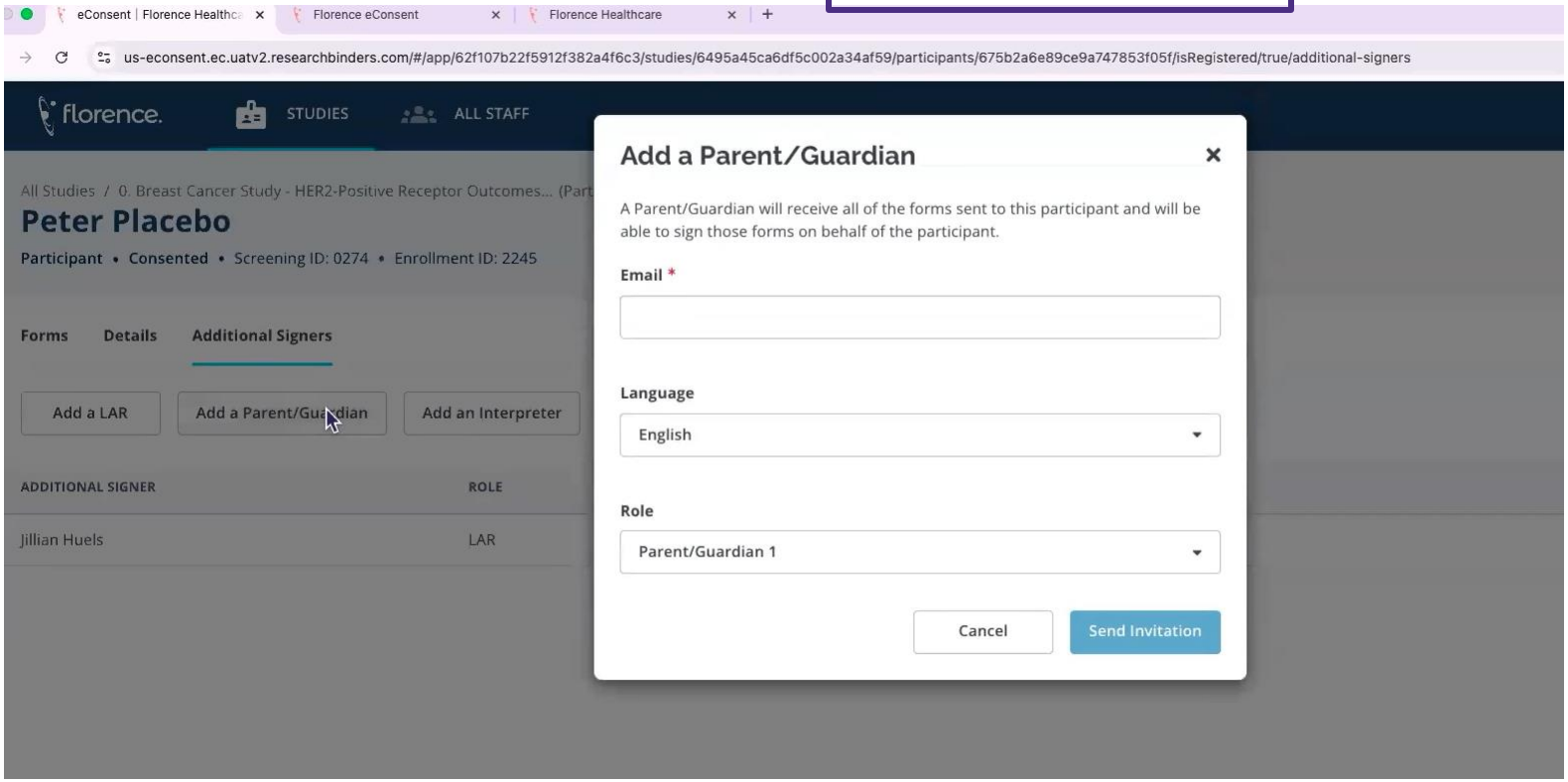
Participant Management page

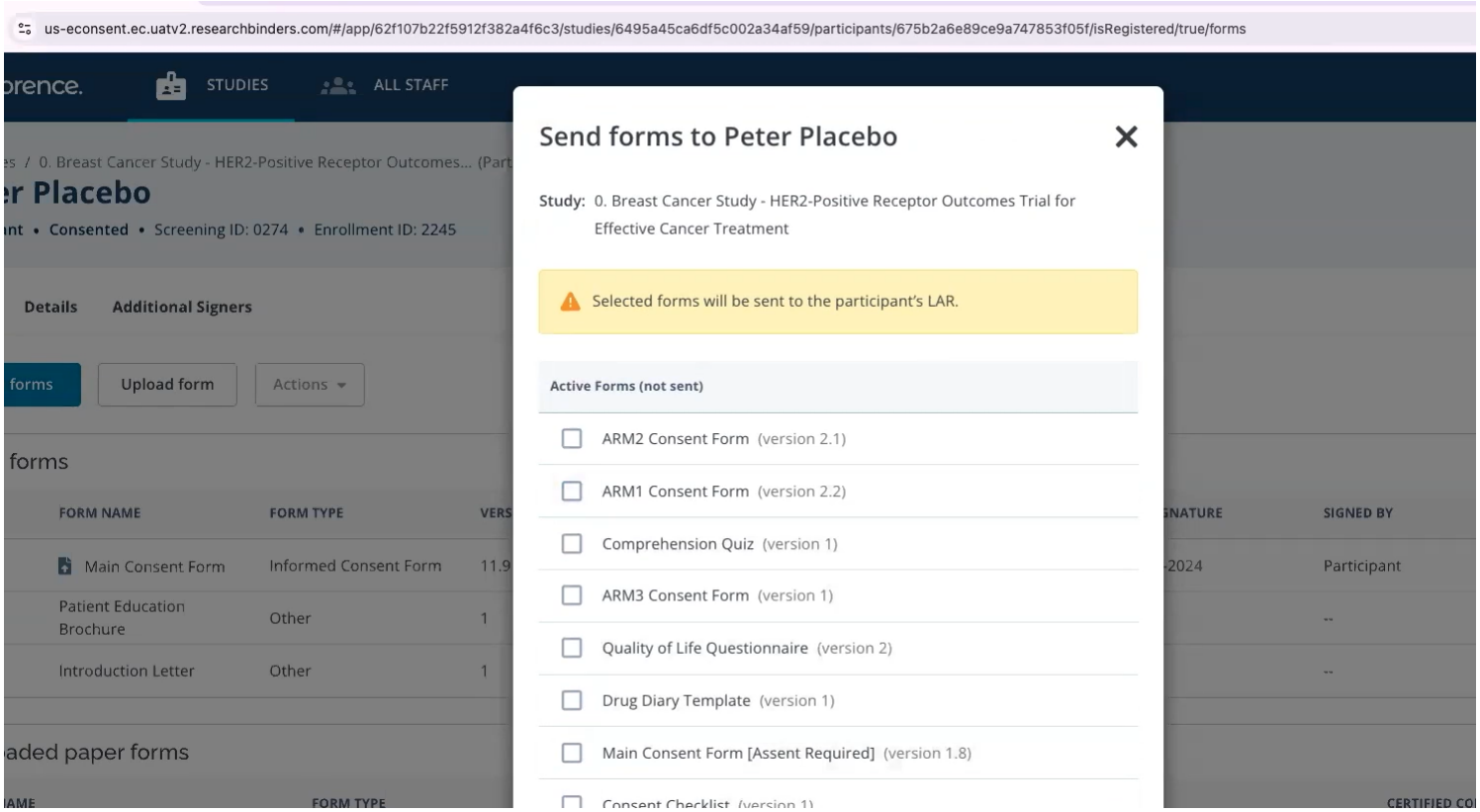




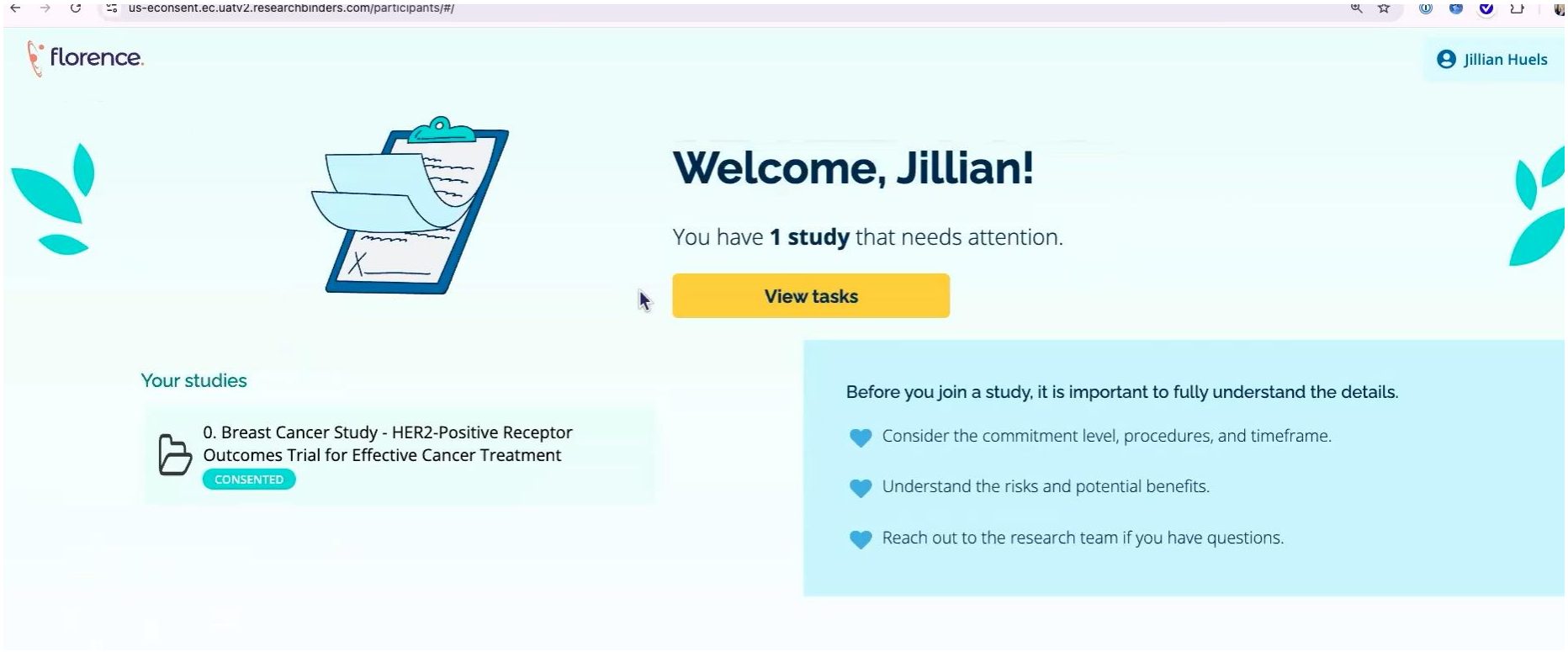


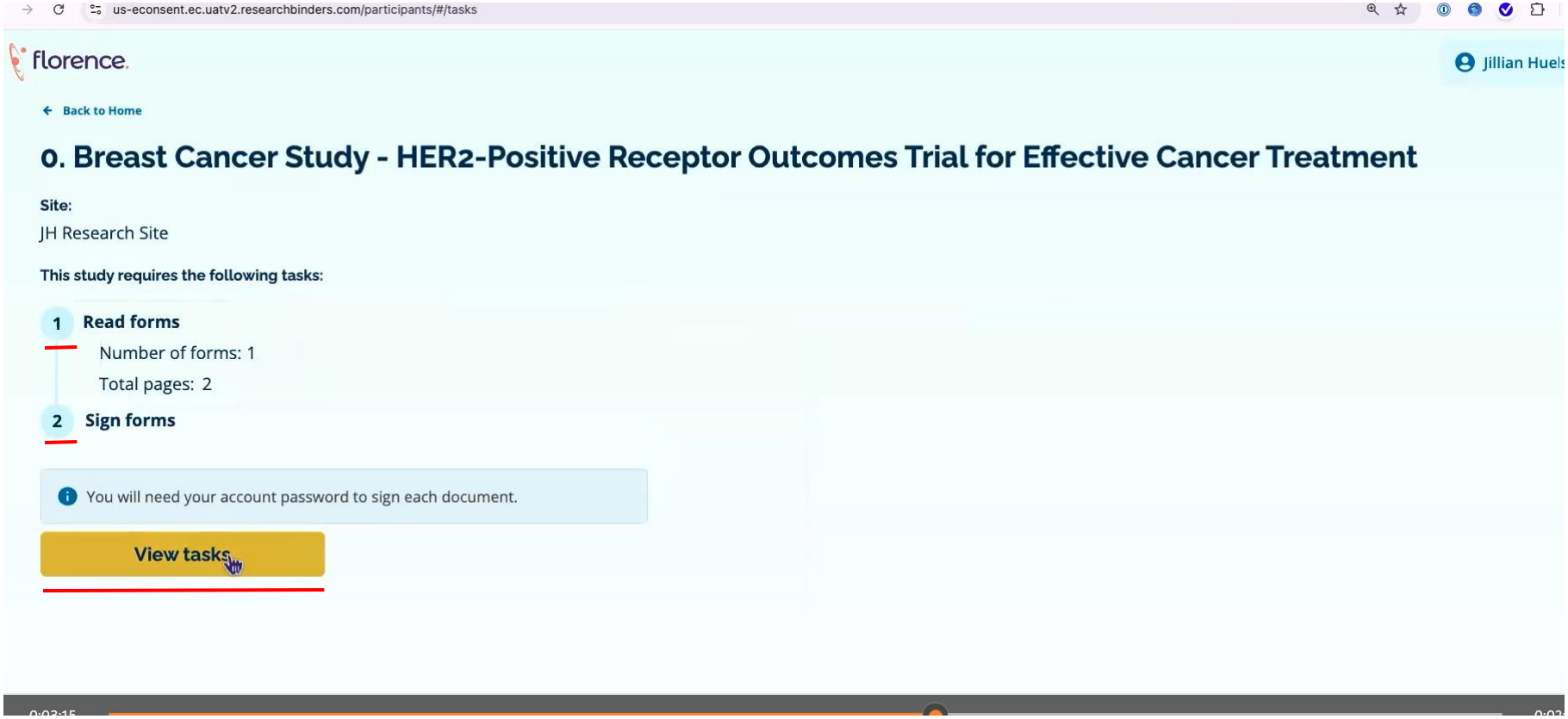
Additional signers

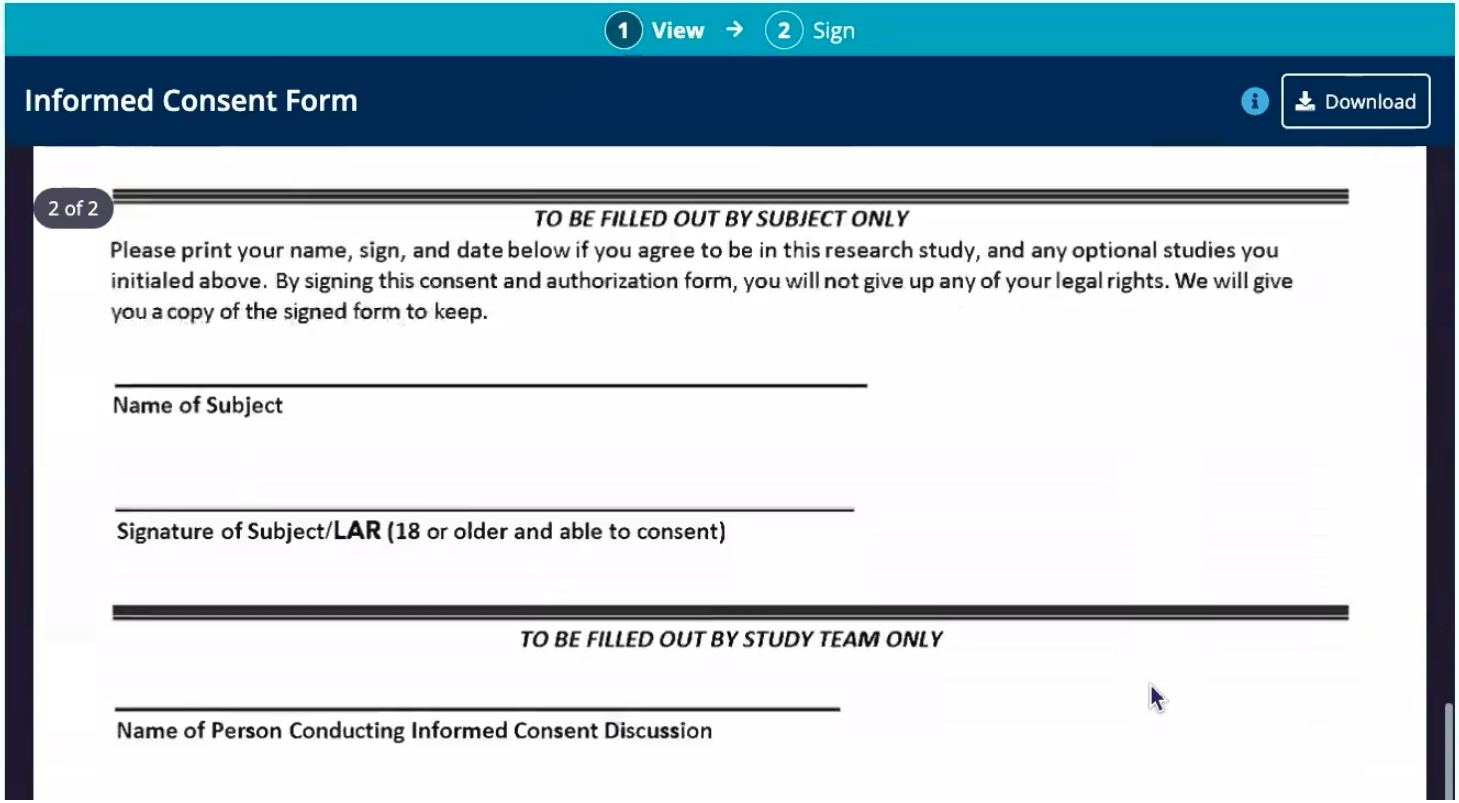


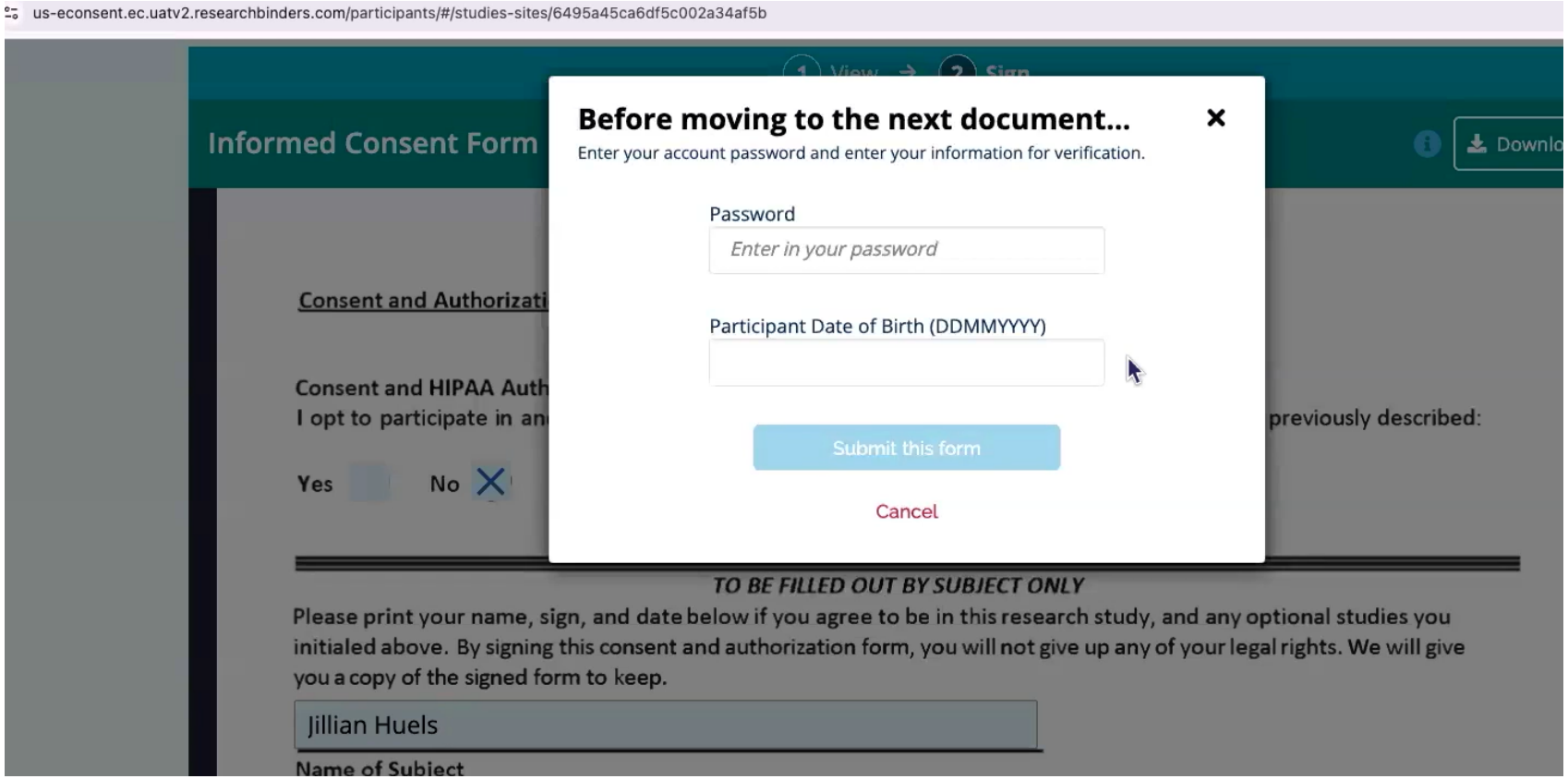

us-econsent.ec.uatv2.researchbinders.com/#/app/62f107b22f5912f382a4f6c3/studies/6495a45ca6df5c002a34af59/participants/675b2a6e89ce9a747853f05f/isRegistered/true/forms
STUDIES
ALL STAFF
Send forms to Peter Placebo
Study: 0. Breast Cancer Study - HER2-Positive Receptor Outcomes Trial for Effective Cancer Treatment
Selected forms will be sent to the participant's LAR.
Active Forms (not sent)
ARM2 Consent Form (version 2.1)
ARM1 Consent Form (version 2.2)
Comprehension Quiz (version 1)
ARM3 Consent Form (version 1)
Quality of Life Questionnaire (version 2)
Drug Diary Template (version 1)
Main Consent Form [Assent Required] (version 1.8)
Details
Additional Signers
Upload form
Actions
FORM NAME
FORM TYPE
Main Consent Form
Informed Consent Form
Patient Education Brochure
Other
Introduction Letter
Other
Participant

Participant's Portal View



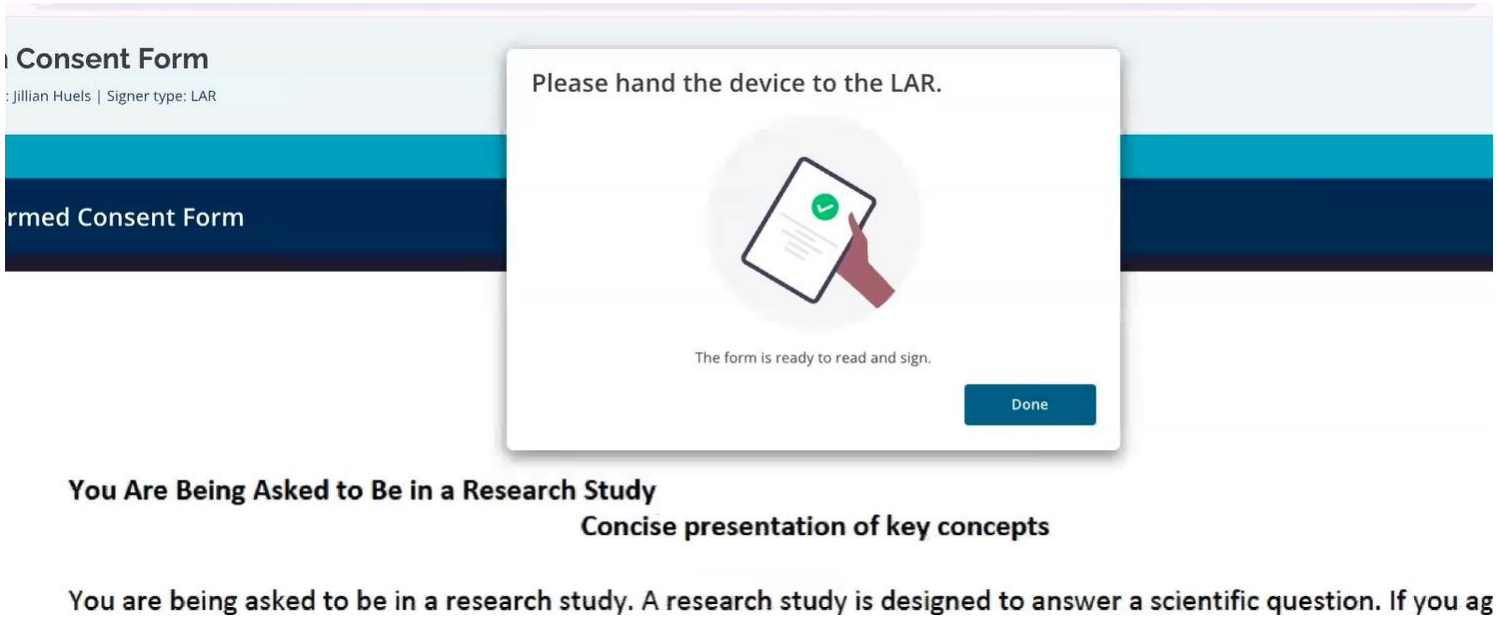

us-econsent.ec.uatv2.researchbinders.com/participants/#/tasks
florence.
Jillian Huels
Back to Home
0. Breast Cancer Study - HER2-Positive Receptor Outcomes Trial for Effective Cancer Treatment
Site:
JH Research Site
This study requires the following tasks:
1 Read forms
Number of forms: 1
Total pages: 2
2 Sign forms
You will need your account password to sign each document.
View tasks




us-econsent.ec.uatv2.researchbinders.com/participants/#/studies-sites/6495a45ca6df5c002a34af5b
Informed Consent Form
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
Consent and HIPAA Auth
I opt to participate in an
previously described:
Yes
No
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



eConsent Summary

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