



eConsent in REDCap

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August 7, 2025

Purpose

The IRB has put out guidance for eConsent: <https://www.hrpo.pitt.edu/econsent-guidance>

- The e-Signature must be linked to the person signing the e-Consent form. This can be done using any of the following methods:
 - The research team observes the signature either in person or using video, and documents this in the research notes or by recording the session with the agreement of the research participant.
 - Using the participant's full name and date of birth combined with one or more security questions, such as mother's maiden name, participant's place of birth, or name of participant's high school.
 - Providing the research participant with a personalized link to the document.
- When necessary, research participants may be asked to show their identification documentation during a videoconference. Scanning or photographing of identification documents should occur only when it would be required in an in-person consent process.
- If other methods to verify signature are being considered, contact Askirb@pitt.edu.
- **Note: Clicking an icon absent any identity validation does not meet the definition of an e-signature.**
It is an acceptable consent process when the protocol is IRB approved with a waiver to document informed consent.

Topics Covered

- Live building of a simple eConsent
- Distributing consent without Survey Distribution Tools
- Handling changes in consent documents
- Collecting additional signatures (LAR, impartial witness, others)
- ReConsent

Live Build Basic eConsent

Goals:

Create surveys

Add signature, date, and required fields

PDF of consent in Descriptive Field

Notifications

Multi-Signature Consent Module

Surveys and Form

- Participant Information (survey, optional)
- Consent (survey)
- Study Team consent (survey)
- Signed Consent Copy (form)
- Optional
 - Study Team Enter (must include email of participant)
 - Triggers alert for consent to participant

Signature, Date/Time, and Other Required Fields

- Signature and Date/Time of Participant
- Signature and Date/Time of Study Personnel
- Must be separate surveys

PDF of Consent

- PDF of Consent in Descriptive Field
 - Inline
 - Cannot be copied and pasted

Notifications

- Survey Distribution Tools (add email or cell phone number)
 - Twilio
 - Mosio
 - PDF of consent cannot be texted, must be email
- Alert to Study Personnel
- PDF copy of consent with signatures sent to the participant

Multi-Signature Module

We now require a form to be completed to enable a module on your REDCap project.

Created and managed by third-parties

Please complete the following form and we will enable the module on your project:

<https://redcap.link/REDCapAssistanceRequest>

Sending a Consent Survey Without Survey Distribution Tools

Goals:

New Form Addition
Avoids Auto Numbering

New Form

- Study Team Enter
- Must include email
- Cannot email a participant with an email that was not entered yet

Changes in Consent Documents



When Changes Are Needed

- New risk information
- Protocol updates
- Regulatory or IRB-required changes

Managing Versions in REDCap

- New Descriptive Field
 - PDF of new Consent
- Old consent branching logic
 - [date]<'2025-08-05' and [pers_sig_date_v2]<'2025-08-05' (the date of your change in consent)
- New Consent branching logic
 - [date]>'2025-08-04' (the date of your change in consent)
- Tips
 - Date must be in YY-MM-DD format
 - First survey or form must include a date

LAR, Impartial Witness, and Other Third Signatures

Extra Survey

- Participant Information (must be form to capture emails)
- Participant Consent
- Third Signature
- Study Personnel Signature
- Signed Consent Copy

- Must go in an order (Third Party and Study Personnel)
- Shows all three signatures



Add a third instrument to merge

Multi-Signature Module

Configure Module: Multi Signature Consent

Project: Third Signature Consent

Settings

Values

Hide this module from non-admins in the list of enabled modules on this project:

1. Instruments to Merge

1. Form:

* must provide value

2. Instruments to Merge

3. Instruments to Merge

2. Form:

* must provide value

3. Form:

* must provide value

File Field

This is where the PDF will be saved in the record and it must be a file-upload field:

* must provide value

study_doctors_consent

compl_consent - Complete

[participant_consent_form]=2' AND
[impartial_witness_consent]=2' AND
[study_doctors_consent]=2'

Update Logic

When this logic is true and one of the above forms is saved, then create the PDF. This logic should not be true until all forms are complete AND should not remain true after the PDF has been generated or else it might lead to multiple PDFs being created on each SAVE event.

e.g. [coordinator_signature]<>"" AND [dest_file_field]=""

* must provide value

ReConsent



Two Events

- Consent and Reconsent
- Must have alert for each event
- Branching logic
- Old consent
 - [event-name]='consent_arm_1'
- New Consent
 - [event-name]='reconsent_arm_1'
- Saves old consent in first event



REDCap is used at over 7500 institutions across 160 countries.

**Please complete the survey, so we
can improve for support**



How to request assistance from the REDCap support team

- Submit support tickets via to hs.appsupport@hs.pitt.edu
OR “Contact the REDCap Administrator” on the left side of every project
- Specific eConsent Assistance
 - <https://redcap.link/PitteConsentREDCapAssistance>
- Things HSIT CANNOT do:
 - Accept Gmail or similar email address for account requests. Must be a work email
 - Add users to projects: the admin or owner of the project will need to add you
- **We CAN help with pretty much anything else**

Best Practices for Submitting a Ticket

- Include the REDCap PID (red number right next to the title of your project)
- Send screenshots for error messages
- If submitting a question for someone else on your study team, please include their name and username
- HSIT- Research Application Support (Jan-June 30, 2025) ticket stats
 - 3,883
 - Average working hour response time of 2.64 hours
- **Bottom line: We get a ton of tickets but will get to your ticket quickly as possible**



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Questions?

hs.appsupport@pitt.edu