eConsent Framework: New Build Self-Evaluation Checklist

This Self-Evaluation Checklist is intended to supplement the instructions for the REDCap eConsent framework found in the ***Yale REDCap Frequently Asked Question Library.*** Note: If the IRB has approved a waiver of documentation of consent or categorized your study as exempt and signatures are not required by other regulations (e.g. FERPA), you are not required to use the eConsent framework.

This checklist can be used to evaluate whether a project has followed the technical instructions for building a new eConsent. This document is not intended to be a stand-alone resource for building an eConsent project nor is it designed to assess the quality of the process (i.e. eConsent administration).

Note: This checklist is for eConsent built using ***FAQ: eConsent Build PDF Upload (v2.0, 3/24/25)***.

REGULATORY CONSIDERATIONS

INSTITUTIONAL REVIEW BOARD (IRB)

- ☐ The protocol permits the collection of IP addresses (automatically collected).
- ☐ The eConsent uploaded PDF is consistent with the current IRB-approved, stamped document.
- ☐ *If applicable:* The survey invitation message that accompanies the eConsent has been approved and reviewed by the IRB.
- ☐ *If applicable*: FDA-regulated research that is subject to 21 CFR Part 11 regulations has eConsents built on the validated REDCap (*https://redcapynh-p11.ynhh.org/*) and not the standard REDCap.
- ☐ For remote consenting procedures, the study has defined how they will verify the identity of the person(s) signing.

DESIGN

PROJECT SETUP

- ☐ eConsent is a stand-alone project (i.e. not an instrument within another data collection project).
- ☐ The Project Title includes word 'eConsent'.
- ☐ The eConsent form is enabled as a survey in form design.
- ☐ There are no embedded fields.

☐ The rich text editor was not used.

☐ User rights are assigned:

- ☐ Research staff responsible for consent have File Repository access.
- ☐ Research staff who need to download the consent PDF have 'full' data export rights to the eConsent form(s).
- ☐ For projects on 21 CFR Part 11 REDCap: Never allow users permission for deletion or renaming of records. Exceptions may apply only if the study has established a formal written procedure for documenting 'Record Deletion/ Renaming.'

INSTRUMENT DESIGN

☐ The eConsent contains separate forms that include:

- ☐ 1st Instrument: Participant Contact Information
- ☐ Participant Consent Instrument
- ☐ Person Obtaining Consent Instrument
- ☐ *If applicable*: Other study-specific forms for signatures (e.g. parent, adolescent).

Participant Consent Instrument:

☐ The consent version number is **NOT** included in the instrument name, if one instrument will be used for multiple versions of the consent.

☐ If the consent process occurs in-person/onsite, instructions are present along the top for staff to open the form as survey.

☐ Consent instruments contain 1 descriptive field to display the consent form.

☐ The descriptive field used for the eConsent document is maintained as a placeholder (e.g. no in-line images).

☐ If the Consent document includes questions that require a response from the participant, those questions are included verbatim as REDCap fields.

☐ Data-entry fields utilize the action tag @READONLY-FORM to prevent completion as a data entry form instead of a survey.

☐ The following fields are tagged as identifiers, and they are marked as required:

- ☐ Participant First Name
- ☐ Participant Last Name
- ☐ Participant Signature
- ☐ Participant Signature Date

Person Obtaining Consent Instrument:

☐ Instructions are present along the top for staff to open the form as survey.

☐ A descriptive field is present showing the participant first and last name, and date/time of participant's completed consent. These values are piped from the participant consent form.

☐ The following fields are tagged as identifiers and marked as required:

- ☐ Person Obtaining Consent First Name
- ☐ Person Obtaining Consent Last Name
- ☐ Person Obtaining Consent Signature
- ☐ Person Obtaining Consent Signature Date

☐ Data-entry fields utilize the action tag @READONLY-FORM to prevent completion as a data entry form instead of an e-Consent survey.

All Other Study Specific Instruments:

☐ Fields that contain HIPAA identifying information are tagged as identifiers.

☐ Data-entry fields utilize the action tag @READONLY-FORM to prevent completion as a data entry form instead of an e-Consent survey.

eConsent Framework

☐ '**eConsent Framework**' is enabled for Participant Consent and Person Obtaining Consent surveys (and any other study-specific instruments for signatures, if applicable).

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Self-Evaluation Checklist

For every eConsent that is enabled check the following eConsent Edit Settings

☐ '**Allow eConsent responses to be edited by users?**' is disabled and not checked. (REQUIRED)

☐ In the eConsent settings, '**First name field**' is mapped to the participant's first name field for the Participant Consent Form and for the Person Obtaining Consent Form.

☐ In the eConsent settings, '**Last name field**' is mapped to the participant's last name field for the Participant Consent Form and for the Person Obtaining Consent Form.

☐ *If applicable*: '**Date of birth**' is left blank unless specified in study protocol. *Note: Yale HRPP discourages collection of DOB in consent instrument.*

☐ If utilizing different consent types (e.g. parent, child), each consent survey is labeled in the **'Custom tag/category for PDF footer'** in **Additional setting**.

☐ Participant signature and other fields for participant initials are selected under the '**Force signature fields to be erased if participant clicks precious page's'** setting.

☐ **eConsent version** in eConsent Framework Options is unique to the REDCap upload version and appends the IRB consent version (e.g. RC1.0_032425) to prevent misalignment from IRB-approved document versioning.

☐ Consent documents are uploaded to the Participant Consent survey within the eConsent Framework. NOT the Person Obtaining Consent survey.

QUALITY CONTROL:

After reviewing the design, thoroughly test the content, appearance and functionality of your project. This includes asking others to enter data and testing each consent scenario that may be encountered in your study. For example, if participants will be consented on Zoom, test this scenario; if using smart phones or tablet, test with these devices.

Please refer to the ***FAQ: eConsent Administration*** to familiarize yourself with the process for administering REDCap consent.

IMPORTANT: Remember eConsent must be administered as a survey. Enter test data by opening in survey mode (click the survey link or using the '**Log Out + Open Survey**' option).

eCONSENT REVIEW/TESTING eCONSENT SURVEY

- ☐ Uploaded PDF is clear and legible while in survey mode on electronic devices that will be used for consenting.
- ☐ Uploaded PDF is paginated correctly.
- ☐ The consent version is consistent in all locations.
- ☐ There is a warning to open the eConsent form as a survey.
  - ☐ For in-person consent, the warning is on Participant and Person Obtaining Consent Forms
  - ☐ For remote consent, the warning is on the Person Obtaining Consent Forms.
  - ☐ These warning fields utilize the @HIDDEN-PDF and @HIDDEN-SURVEY Action Tags to prevent them from appearing in the consent documentation.
- ☐ eConsent certification is active and functional: After the participant completes the consent fields and selects 'next page' they are presented with a PDF display of their completed consent form and a checkbox to review and certify the PDF.
- ☐ The PDF that is shown to the participant for certification displays their signature and all field, images, and pages. *This PDF is their consent form and will be saved as shown in the File Repository.*
- ☐ If back button is selected, signature field(s) are erased and must be re-entered.
- ☐ The data entry form locks (cannot be edited) after the eConsent certification is completed.
- ☐ *If applicable*: For remote consenting, the procedure for verifying participant's identity works, per protocol.

FILE REPOSITORY REVIEW/TESTING

- ☐ Research staff responsible for consent have File Repository and/or download access (i.e. User Rights are assigned).
- ☐ Within the File Repository → PDF Snapshot Archive folder, each signed form (including person obtaining consent form) appears in the PDF Snapshot Archive folder.

Download the PDF(s) from the File Repository's PDF Survey Archive folder and verify the following:

- ☐ Participant's first and last name display in the form and footer of Participant Consent Form.
- ☐ Participant's first and last name display in the form and footer of Person Obtaining Consent Form.
- ☐ *If applicable*: Participant's first and last name display in the form and footer of other study-specific signature forms.
- ☐ All fields, images, signatures, date/times and pages are visible and correctly displayed in the PDF.

ADDITIONAL REQUIREMENTS (ADD STUDY SPECIFIC REQUIREMENTS HERE)

- ☐
- ☐
- ☐
- ☐
- ☐

Version	Effective Date	Section	Page	Description/Rational
3.0	03/24/25	*Intro*	1	Non-substantive editorial revisions.
3.0	03/24/25	*Participant Consent Instrument*	2	Added check for presence of consent version.
3.0	03/24/25	*Participant Consent Instrument*	3	Removed check for completion of survey date/time from participant and person obtaining consent form.
3.0	03/24/25	*Person obtaining consent instrument*	3	Removed consent version. Added clarification that participant information descriptive field is in Person Obtaining Consent form.
3.0	03/24/25	*eConsent Framework*	4	Added clarification that Consent document is uploaded to Participant consent survey.