REDCap e-Consent

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Outline

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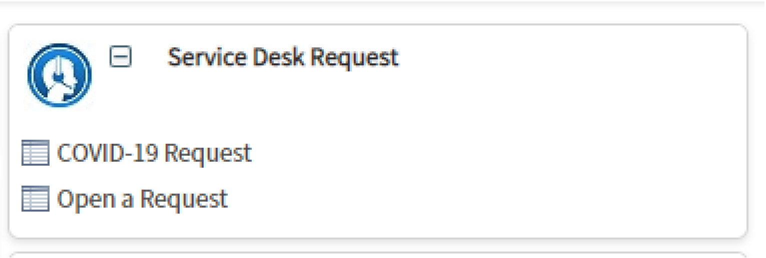
2. REDCap terminology
3. Overview of Setup of REDCap e-Consent
4. In-Person e-Consent vs. Remote e-Consent
5. Method of e-Consent Distribution
6. Updating e-Consent
7. Exempt Research: Information Sheet and HIPAA Authorization Form

1. Quick overview of DocuSign

- Limited access!
- Available for FDA-regulated research studies (drugs/devices studies) that are enrolling COVID-19 patients at BMC
- Process:
  - ICF is sent to participant via email from DocuSign.
  - Participant first must agrees to sign electronically before accessing the form and then signs form
  - Investigator receives email with signed document attached and proceeds to sign the document
  - Copy of fully signed/completed consent form is emailed to both parties
- To get started:
  - Log into ServiceNow's Service Catalog
  - Under Service Desk Requests, click COVID-19 Request
  - Complete the form and check the "Research" checkbox



1. Terminology

Instrument – A data collection tool that can be left as a form or enabled as a survey.

(Data Entry) Form – An instrument in which data can only be entered or collected by a REDCap user. (viewing method)

Survey – An instrument in which a research participant can enter data or answer questions without a REDCap account. Instrument is accessed through a URL. (viewing method)

Record - A record contains all the information for a unique participant. One record may contain many instruments

Record ID – A unique identifier for each record in a project.

Survey Login – A way to increase security on private surveys by requiring participants to enter 1 to 3 specified login credentials in order to begin a survey. The credentials must already exist in the system for the survey login feature to be utilized, either by pulling them from a survey that has already been completed or by entering them on a form.

Online Designer – A way to build and edit instruments through a point-and-click interface.

Data Dictionary – CSV file that holds the architecture of a project. An alternative to the Online Designer for building or editing projects. Mainly use to save the project for future reference or project duplication.

Piping – Allows answers from previous questions to auto-populate or "pipe" into another place in a survey/form.

Action Tags – A method of customizing data entry for individual fields in a survey or form.

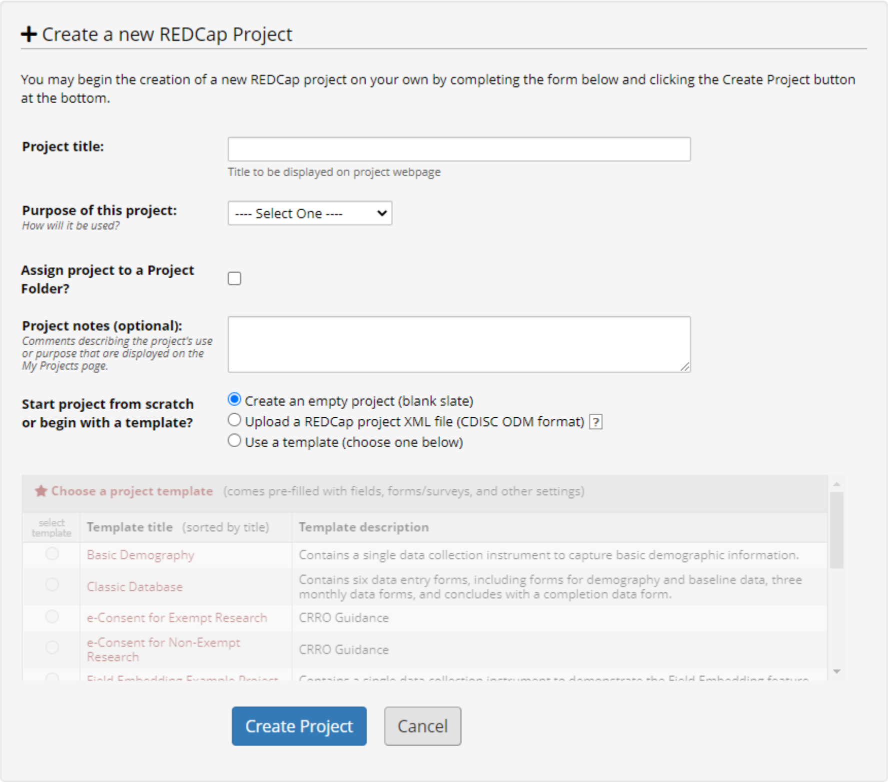
https://healthinstitute.illinois.edu/research-support-translation/redcap/glossary#form

2. Overview of Setup of REDCap e-Consent

- Approved e-consent form
- Entry fields for name, signature, and date
- Survey settings
- Consent documentations to consider:
  - Confirmation that a copy of informed consent was given to participant
    - Verbally instruct participant to download a copy of the completed ICF and document this in comment field
    - Automate sending of completed ICF to participant

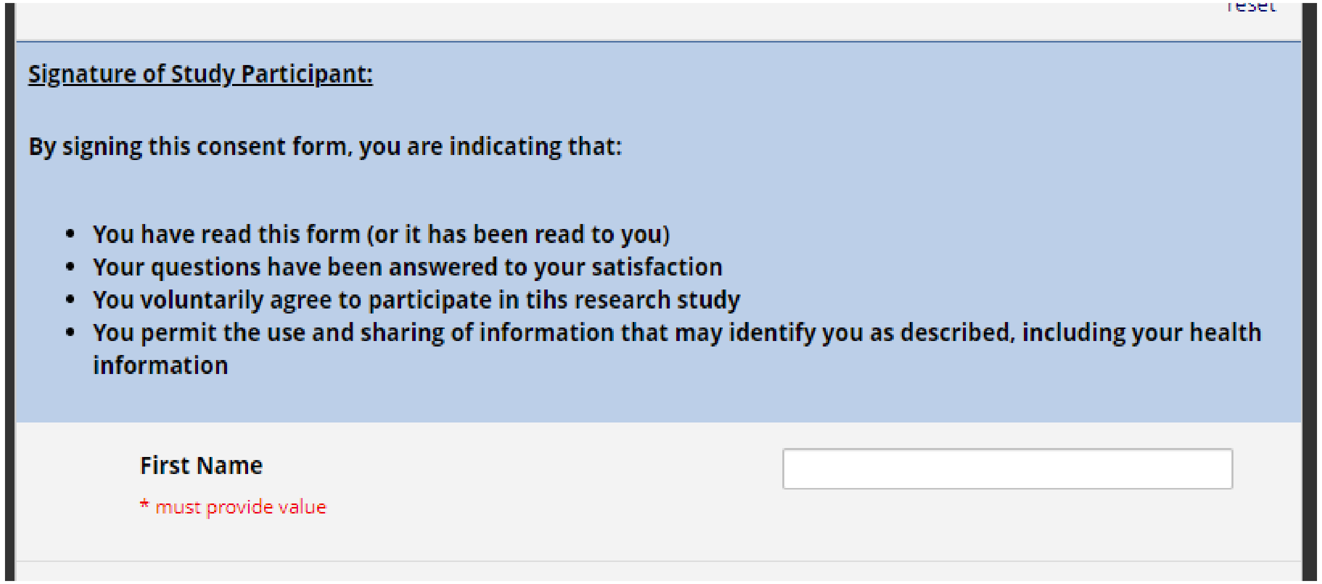
2. Overview of Setup of REDCap e-Consent

1. Create a project in REDCap using the e-Consent template which goes along with the REDCap e-Consent Guidance (“default setup”)



2. Overview of Setup of e-Consent

1. Create a project in REDCap using the e-Consent template (“default setup”)
2. Modify the consent form based on the approved research study:
   i. Convert approved ICF to JPEG files
   ii. Edit default text for REDCap signing language to match approved language in ICF



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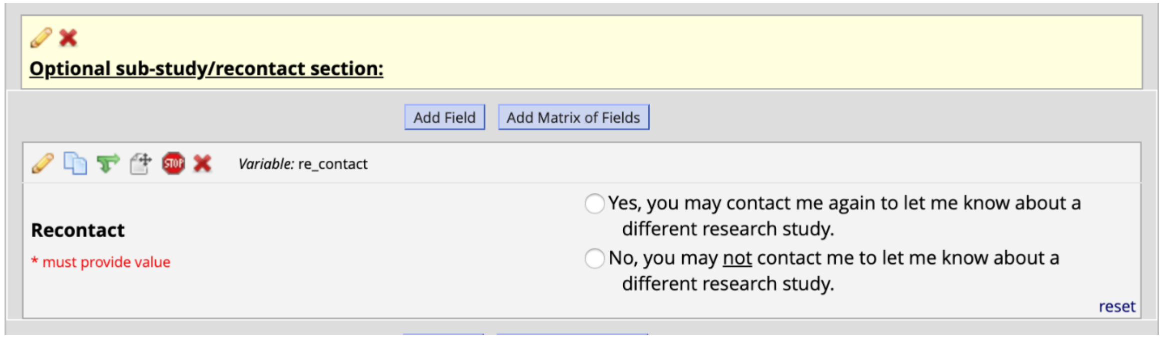

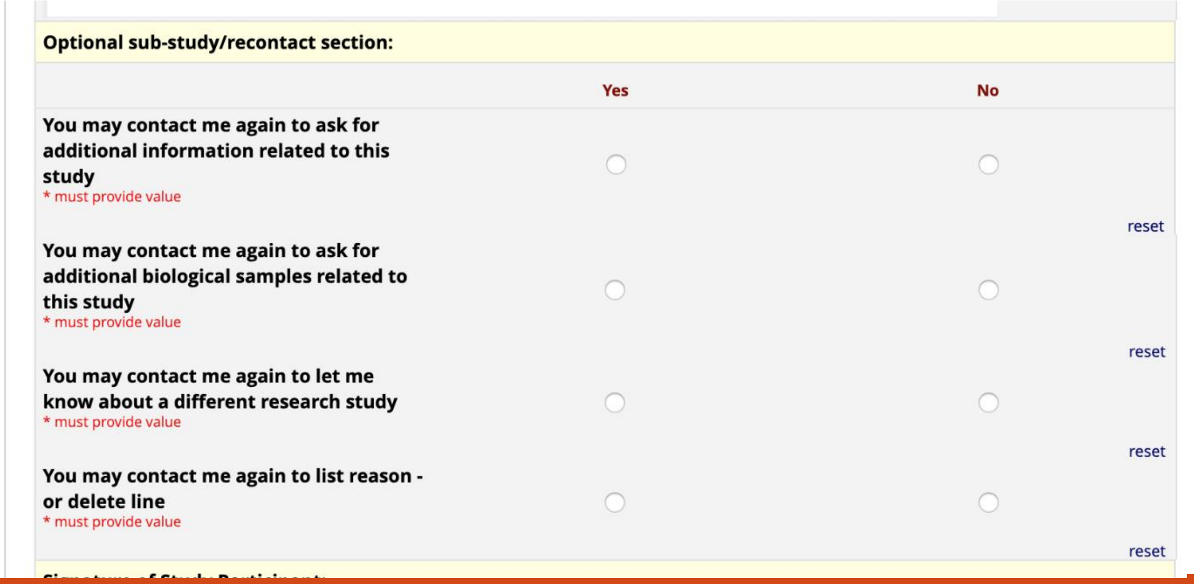

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3. Setup survey settings
   i. Add survey instructions and survey completion text
   ii. Enable option for participants to download a PDF of completed e-Consent at end of survey
   iii. Enable e-Consent framework - this adds two extra things to the survey format:
      - Certification step: Adds extra certification page to end of the survey in which participants will be asked to confirm that all information in the document is correct.
      - Auto-archive step: Completed e-Consent survey will be stored as a PDF in the project’s File Repository.

3. In-Person vs. Remote e-Consent

- In-Person e-Consent Form:
  - Study teams need to create 1 instrument
  - Participant and Study Personnel signature section exist on the same instrument
- Remote e-Consent Form
  - Study teams need to create 2 instruments
  - Participant e-Consent and Study Personnel e-Consent forms are two separate instruments
  - The 2 e-Consents are linked by the same Record ID

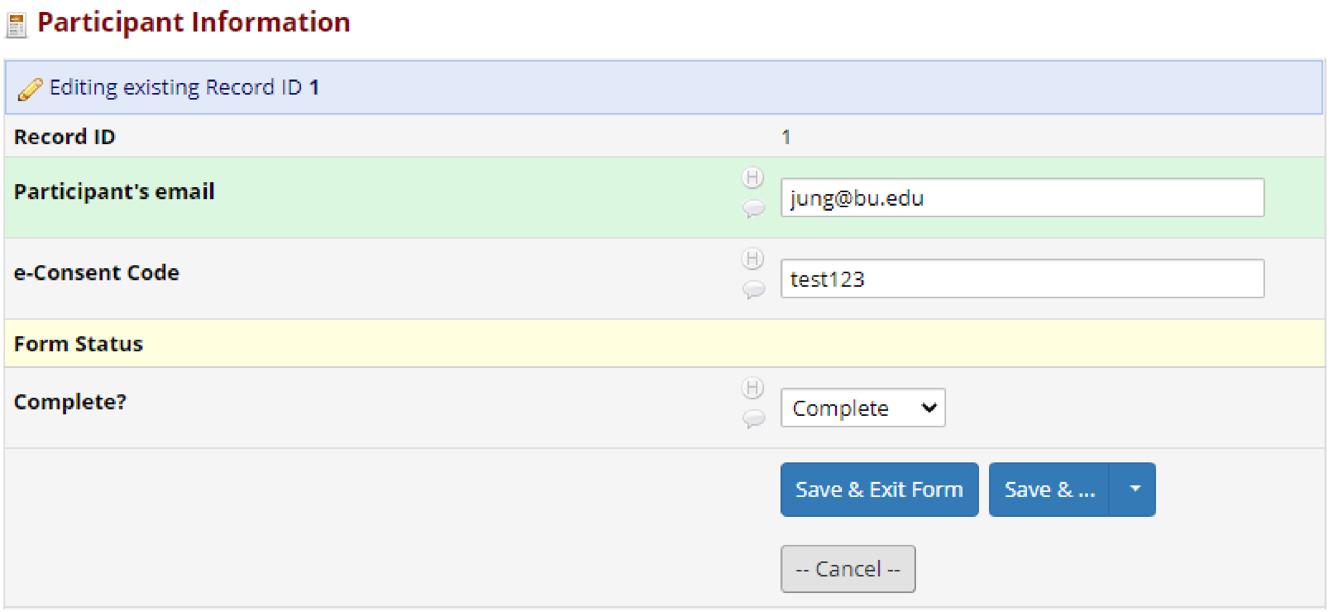
4. Method of e-Consent Distribution

- E-mail
  - Enable module to designate an email field for sending survey invitations
  - Invitation can be automated
  - Use Survey Login for added security (e-mail alone is not a secure form of communication)
- Twilio
  - Survey as webpage – survey URL provided by SMS (similar to invitation via email)
  - Study teams must submit this form to enable Twilio in their REDCap project: https://redcap.bumc.bu.edu/surveys/?s=HJPXWCME7H
- Hospital patient communication portal
- Video conference chat

**Make sure you state in your IRB application your method of e-Consent distribution and get appropriate IRB approval

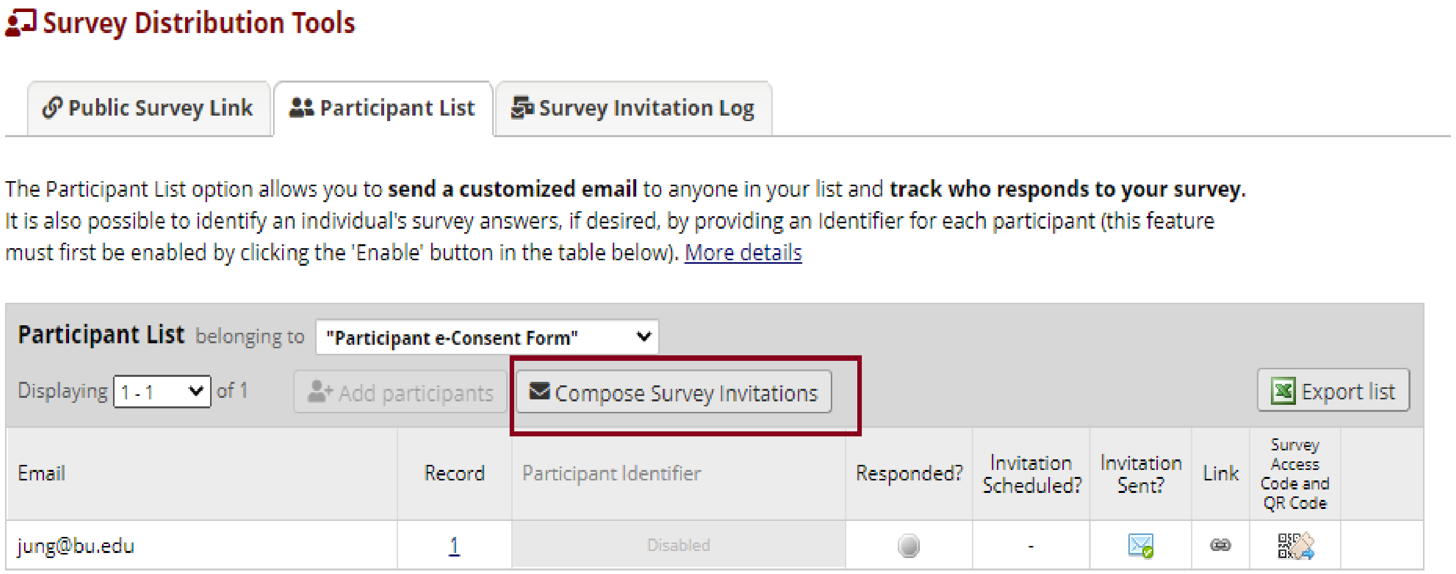
4. Method of e-Consent Distribution

- Utilizing Survey Login
  1. Create a “Participant Information” instrument to enter participant’s email and e-Consent code
     i. Study staff can create a (easy) unique code



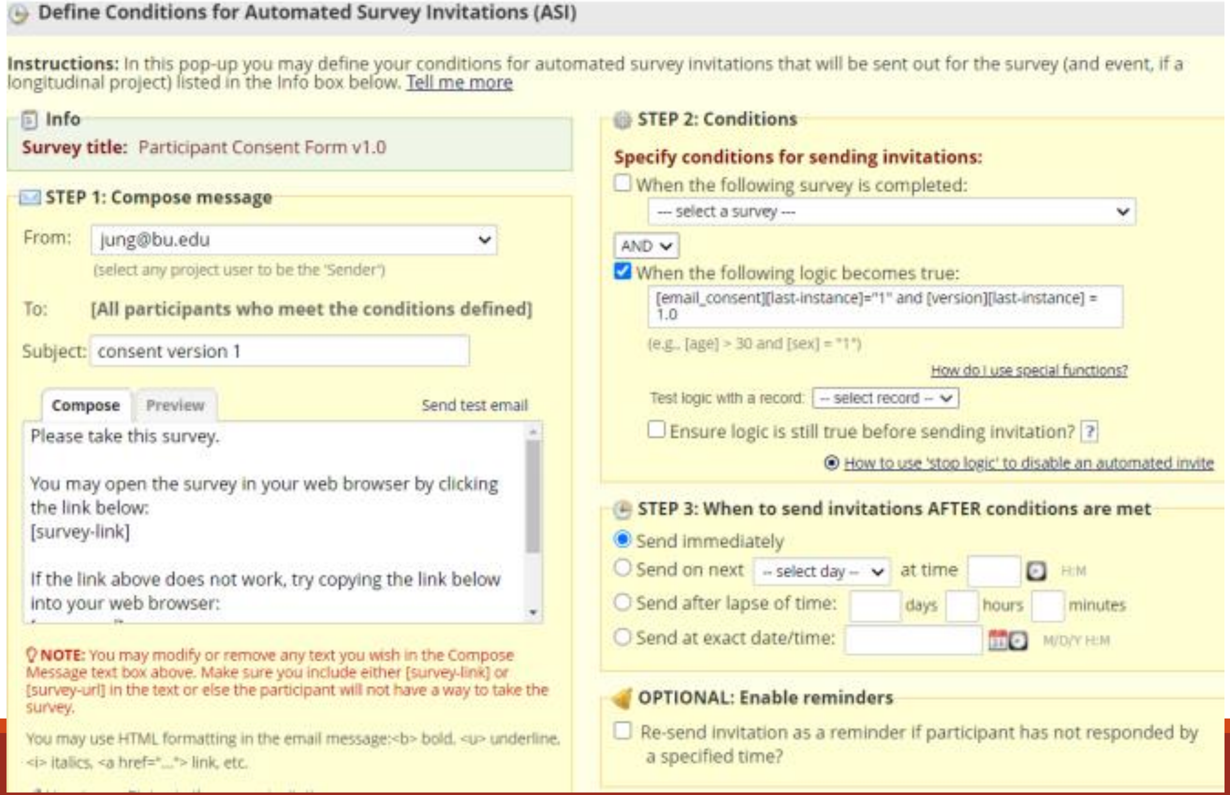
4. Method of e-Consent Distribution

- Utilizing Survey Login
  - Create a “Participant Information” instrument to enter participant’s email and e-Consent code
    - Study staff can create a (easy) unique code
- Manually send survey invitation



4. Method of e-Consent Distribution

- Automated Survey Invitation
  - study teams can specify conditions for sending invitation
    - create a Yes/No field where staff will confirm whether or not to email the consent survey and specify which e-consent instrument version to email to the participant

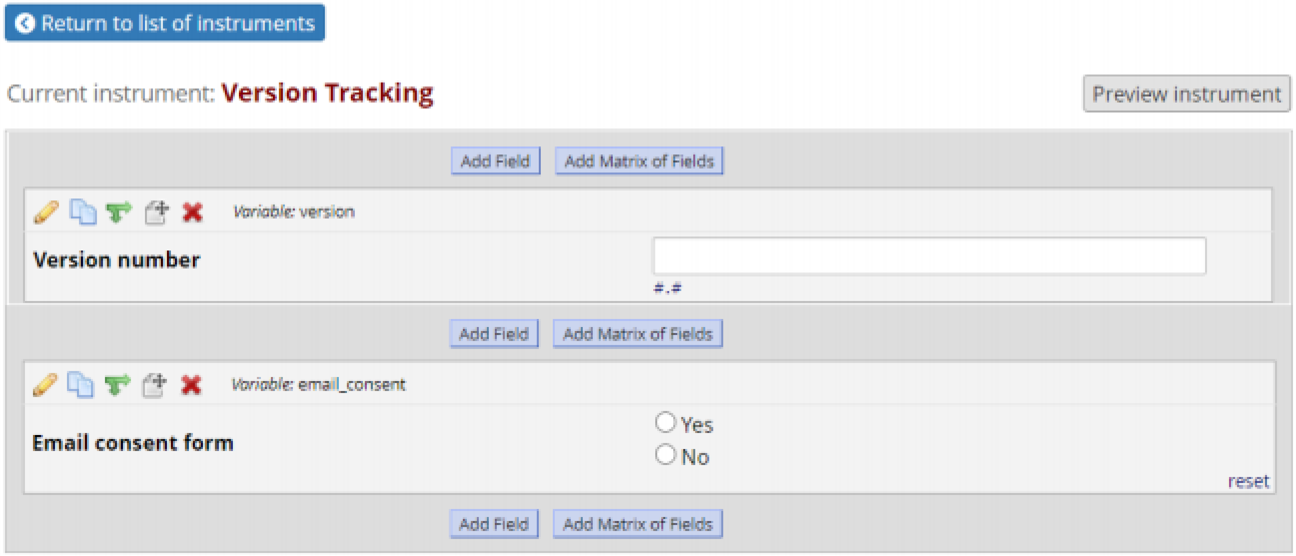


5. Updating e-Consent

- Are you utilizing an Automated Survey Invitation feature?
  - Then you need to carefully think about what exactly you should set as your conditional field that will trigger this invitation
  - So our recommendation is that you utilize a Version Tracking instrument
- If you are not utilizing ASI, then you don’t have to worry about this step
  - You can select which instrument to email to the participant via Survey Distribution Tool

5. Updating e-Consent

- Version tracking instrument
  - Use this to keep track of informed consent versions
  - Create a Yes/No field in this instrument to set up the Automated Survey Invitation trigger
  - Create a ICF version field to specify which ICF version you are going to email out
  - Make a repeatable instrument



Define Conditions for Automated Survey Invitations (ASI)

Instructions: In this pop-up you may define your conditions for automated survey invitations that will be sent out for the survey (and event, if a longitudinal project) listed in the Info box below. Tell me more

Info

Survey title: Participant Consent Form v1.0

STEP 1: Compose message

From: jung@bu.edu

(select any project user to be the 'Sender')

To: **[All participants who meet the conditions defined]**

Subject: consent version 1

Compose | Preview | Send test email

Please take this survey.

You may open the survey in your web browser by clicking the link below:
[survey-link]

If the link above does not work, try copying the link below into your web browser:

NOTE: You may modify or remove any text you wish in the Compose Message text box above. Make sure you include either [survey-link] or [survey-url] in the text or else the participant will not have a way to take the survey.

You may use HTML formatting in the email message:<b> bold, <u> underline, <i> italics, <a href="..."> link, etc.

How to use Piping in the survey invitation

STEP 2: Conditions

Specify conditions for sending invitations:

- [ ] When the following survey is completed:

--- select a survey ---

AND

- [x] When the following logic becomes true:

[email_consent][last-instance]="1" and [version][last-instance] = 1.0

(e.g., [age] > 30 and [sex] = "1")

How do I use special functions?

Test logic with a record: -- select record --

- [ ] Ensure logic is still true before sending invitation? ?

How to use 'stop logic' to disable an automated invite

STEP 3: When to send invitations AFTER conditions are met

- (•) Send immediately
- ( ) Send on next -- select day -- at time H:M
- ( ) Send after lapse of time: days hours minutes
- ( ) Send at exact date/time: M/D/Y H:M

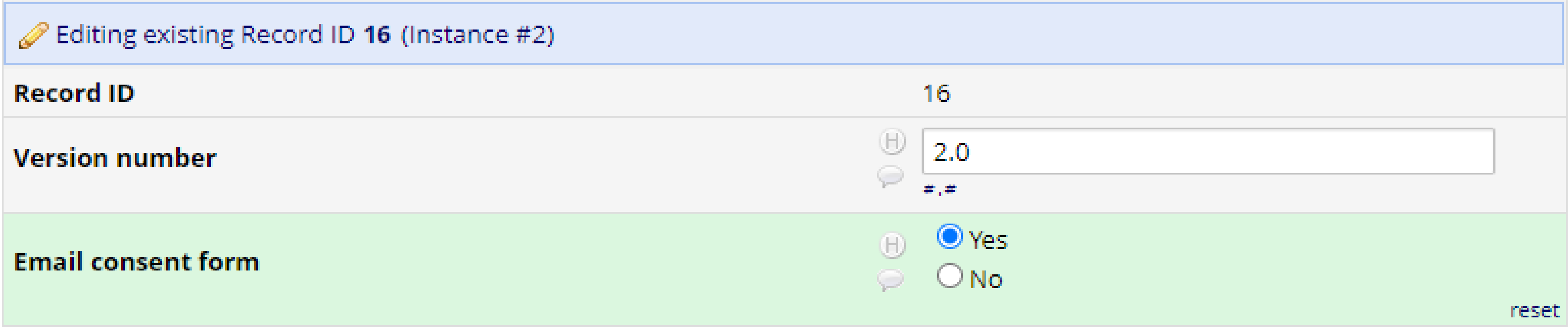
OPTIONAL: Enable reminders

- [ ] Re-send invitation as a reminder if participant has not responded by a specified time?

5. Updating e-Consent

- Create a NEW e-consent survey for your updated (newly approved) informed consent form
  - Simple method: create a copy of the Participant e-Consent survey and Study Personnel e-Consent survey and updates the fields accordingly

- Fill out the Version Tracking instrument (if re-consenting, you will utilize that repeatable instrument feature and create a new instance of the Version Tracking instrument)



6. Exempt Research: Information Sheet and HIPAA Authorization Form

- Also applies to Non-Exempt Research that have a waiver of documentation
- Utilize the Template available in REDCap: “e-Consent for Exempt Research”
- Survey format option:
  - Use JPEG image of the Information sheet and HIPAA Authorization Form <u>OR</u>
  - Copy and paste text directly onto REDCap fields

Questions?