A Path Towards Thriving

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eConsents and REDCap

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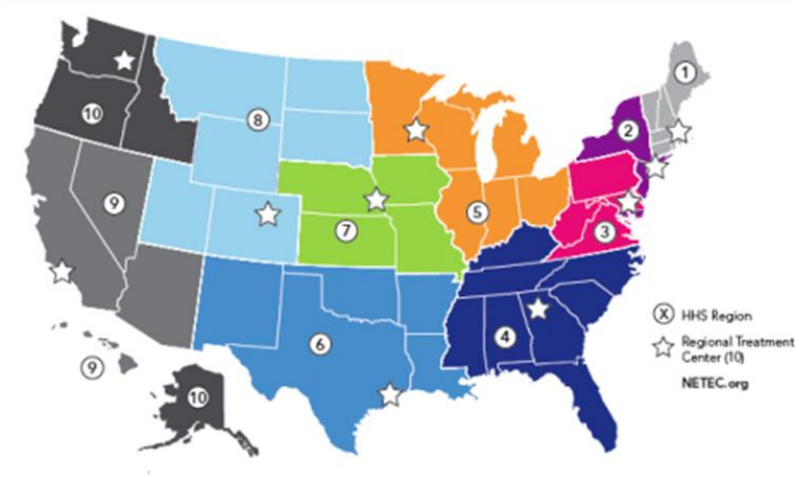
Regional Ebola and Other Special Pathogens Treatment Centers (RESPCT)

1. Massachusetts General Hospital
2. NYC Health & Hospitals Bellevue
3. Johns Hopkins
4. Emory University Hospital
5. University of Minnesota Medical Center
6. University of Texas Medical Galveston
7. University of Nebraska Medical Center
8. Denver Health
9. Cedar-Sinai
10. Providence Sacred Heart Medical Center & Children's Hospital



April 2018 – Spokane Participates in Federal Ebola Exercise

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COVID related Challenges & Solutions

Anticipated challenges

- Face-to-face discussion is limited
- People are very ill
- Language barriers
- Family quarantined
- What goes in the room stays in the room
  - How long does virus survive on paper?
  - Is it enough of a transmission risk?

Plans

- Use traditional paper consent form
- Investigator dons & conducts discussion and gets signature
- Photograph consent form through the unit's video equipment, making sure signatures, version & IRB stamp clearly captured
- Leave the original consent form in the room
- Mail a copy to the participant's home

New Opportunities

- More inclusive
  - reach people who can't easily travel
  - facilitate non-English presentations
- Better comprehension features: links to FAQ, chat bot
- Automate processes: providing a copy and filing

Key Components of Consent Process

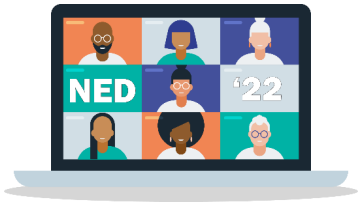
1. Enough information, time and opportunity to decide
2. Processes to facilitate comprehension
3. Required elements presented in the preferred language
4. Competency of participant to make a decision is assessed
5. Decision is voluntary
6. Process is well documented

Components of Electronic Consent

1. Easy to navigate forward, backward, stop and return
2. Include all elements of consent and HIPAA authorization
3. Provides a copy: electronic and paper option at no cost
4. Easily retrievable for monitors and auditors - links need to work for the duration of the study record retention period
5. Documents a valid signature- appropriate controls

Where Can I Find More Information?

- Your organizational policies
- Your IRB policies
- *FDA Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency* www.fda.gov
- Office of Human Research Protections | *Research Guidance on Coronavirus* www.HHS.gov



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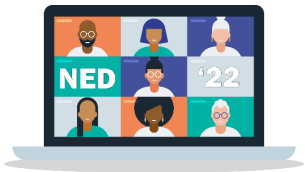
Policies Are Not All the Same

Here are some IRB examples:

- Remote consent approved only during the public emergency
- Allowed only for minimal risk trials /Remote consent for screening only in more than minimal risk trial
- Specifics about the consent form being provided prior to discussion
- Differences in witness requirements
- Contact via a secure mail system
- Teleconference platform must be HIPAA compliant
- Make sure Alexa is deactivated in the home

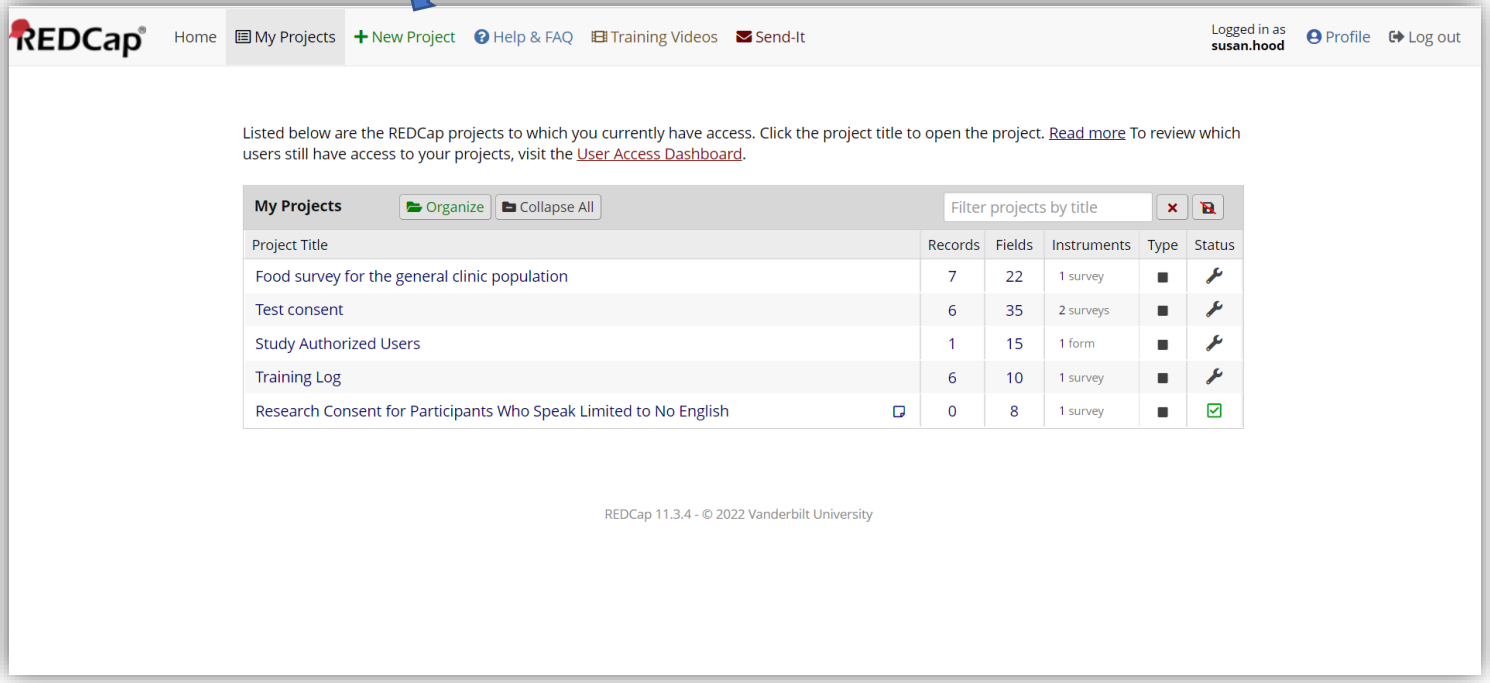


REDCap: Research Electronic Data Capture

- Licensed from Vanderbilt University
- Secure, HIPAA and Part 11 Compliant
- Customizable
- Self Service training modules
- Resources at ITHS:
- RedCap Training Series, RedCap support

REDCap – My Projects List

Create a new project for your consent



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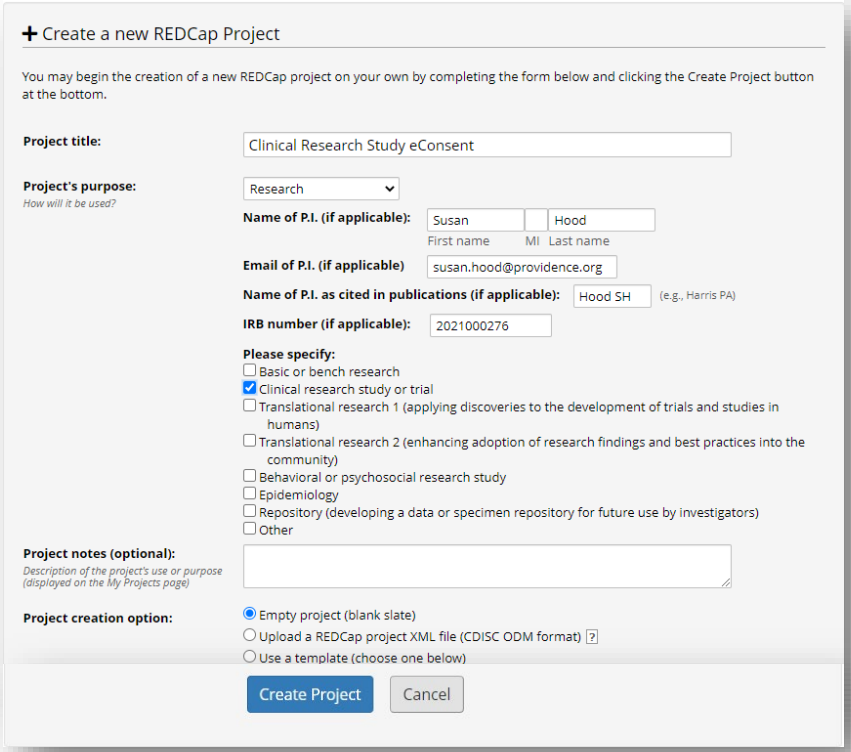
REDCap – Create New Project



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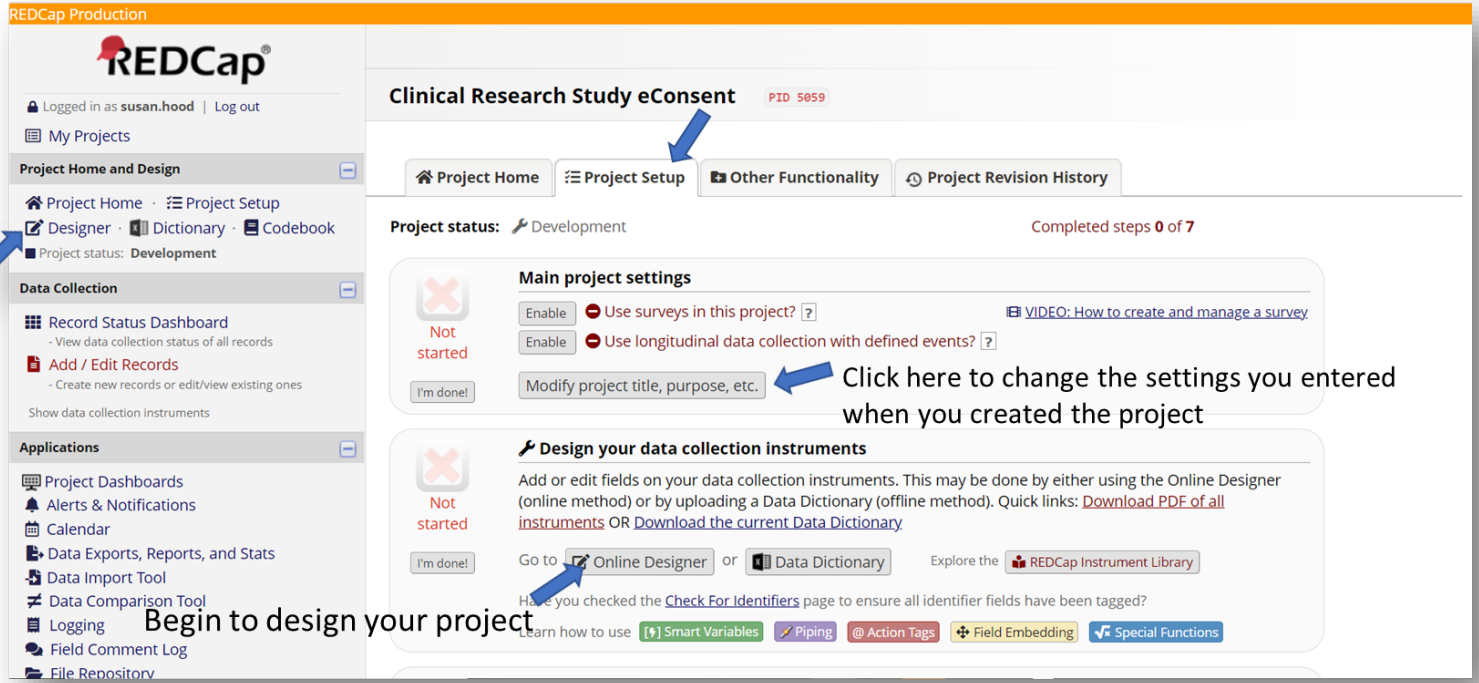
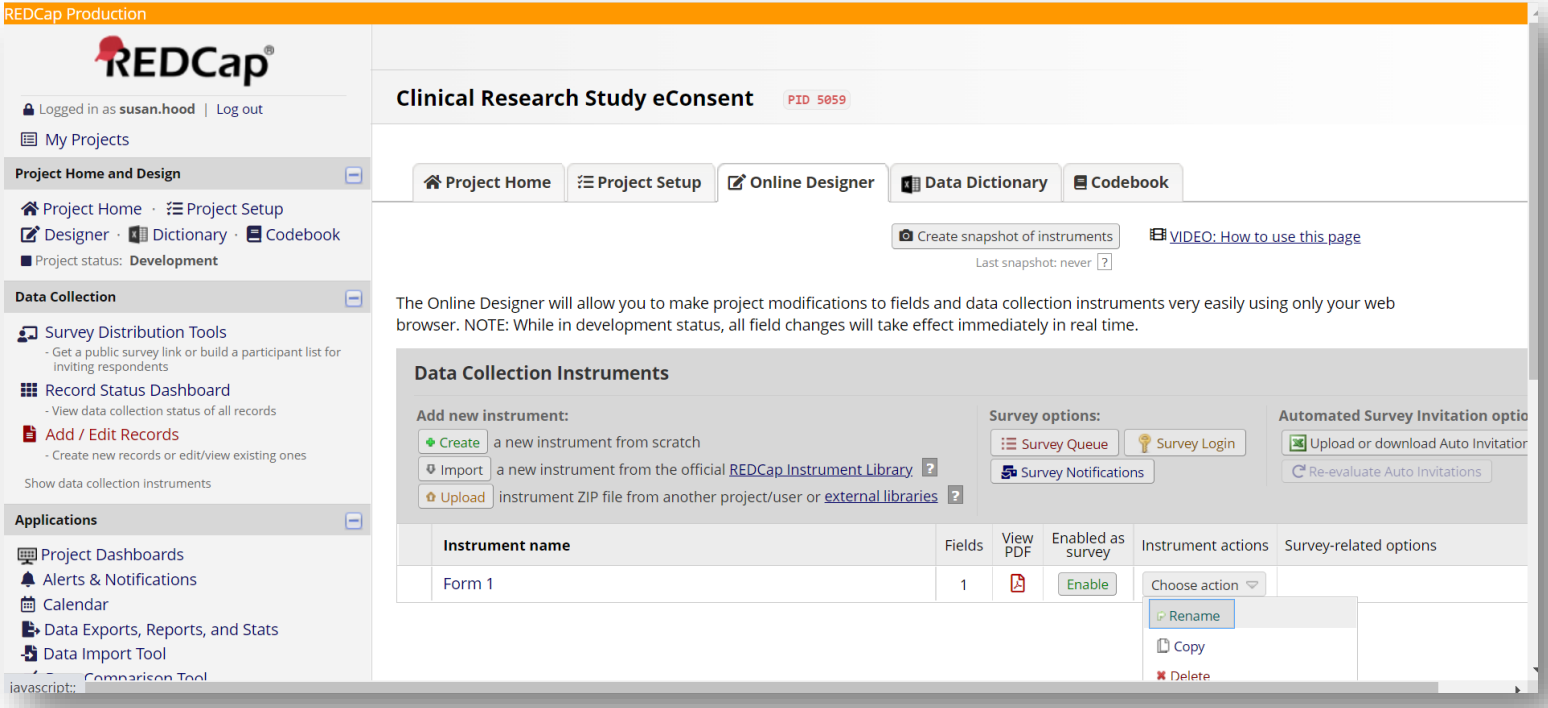
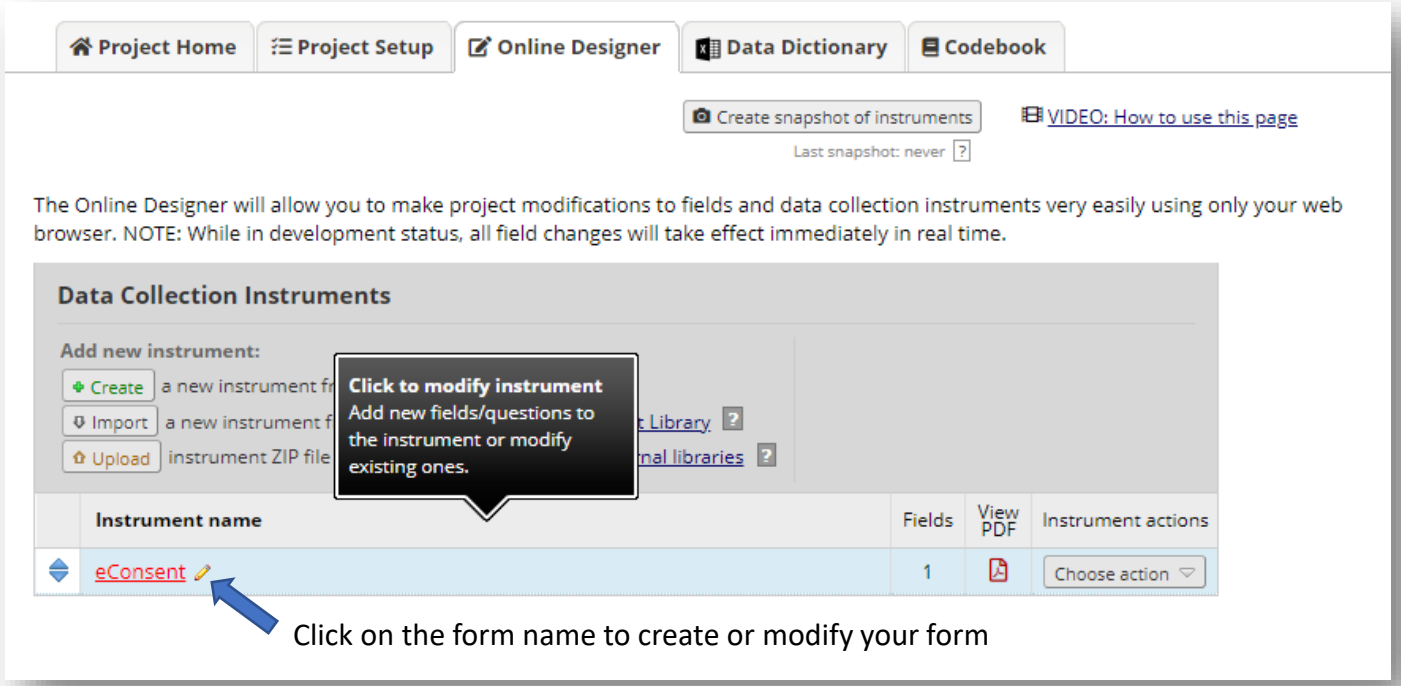
Opening Page of New Project



Project Online Designer Page



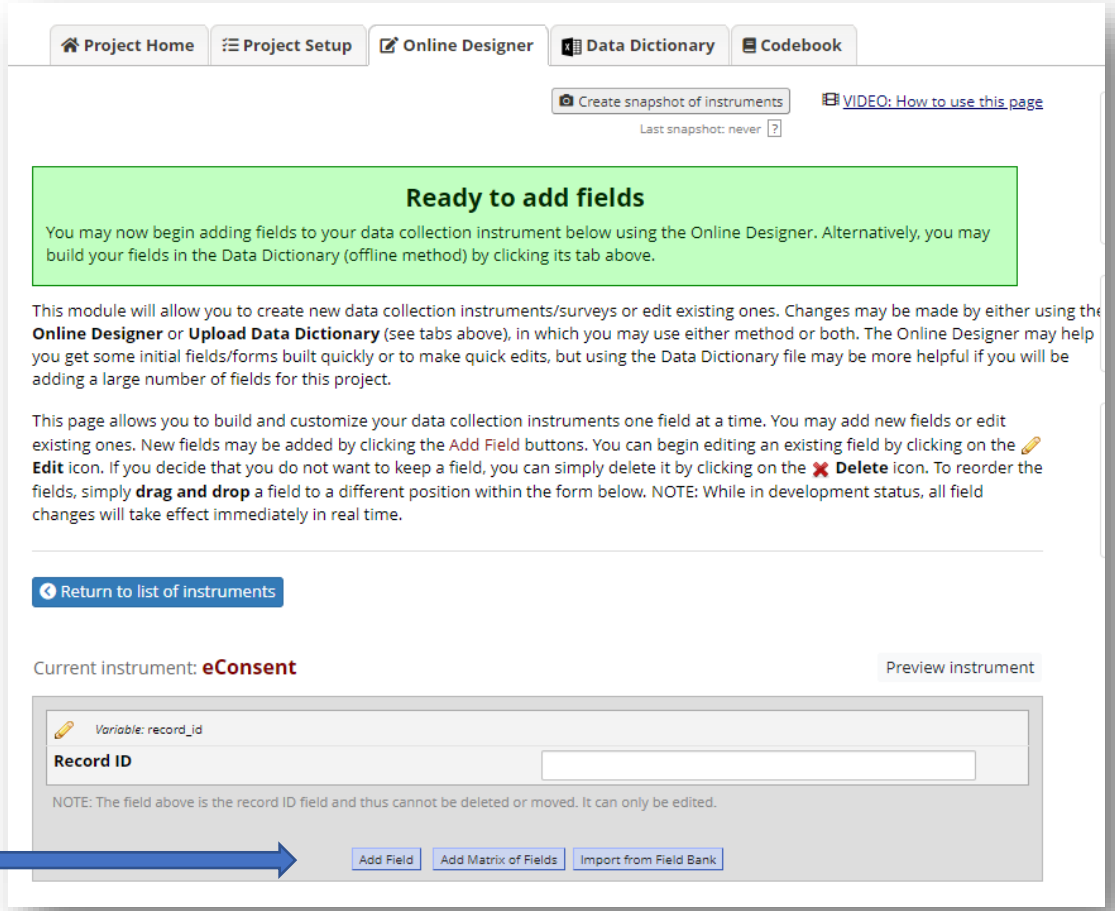
Open Form



Click on the form name to create or modify your form

Add a Field

Click on add field to start adding consent



Select the Field Type

Add New Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the Field Types video (4 min).

Field Type: ---- Select a Type of Field ----

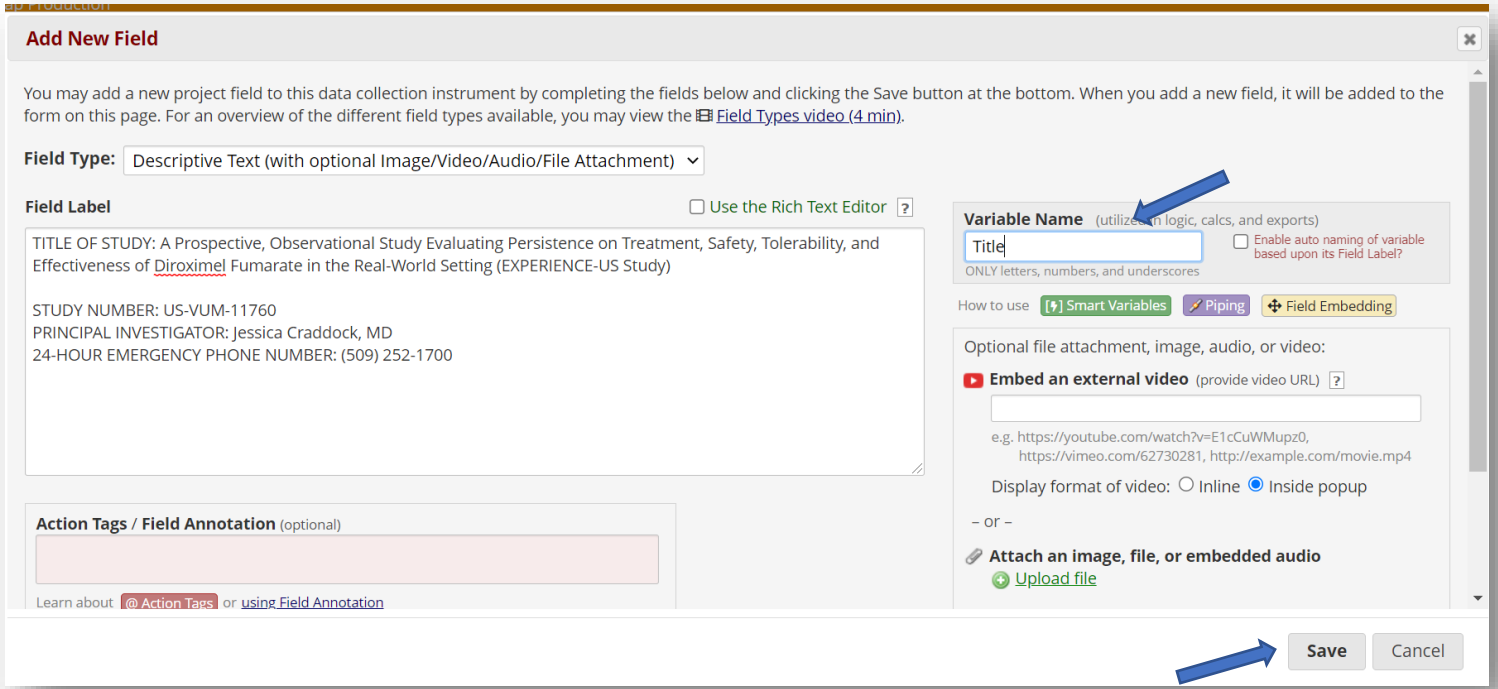
Add New Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the Field Types video (4 min).

Field Type: ---- Select a Type of Field ----

- ---- Select a Type of Field ----
- Text Box (Short Text, Number, Date/Time, ...)
- Notes Box (Paragraph Text)
- Calculated Field
- Multiple Choice - Drop-down List (Single Answer)
- Multiple Choice - Radio Buttons (Single Answer)
- Checkboxes (Multiple Answers)
- Yes - No
- True - False
- Signature (draw signature with mouse or finger)
- File Upload (for users to upload files)
- Slider / Visual Analog Scale
- Descriptive Text (with optional Image/Video/Audio/File Attachment)
- Begin New Section (with optional text)

Enter the First Section of Consent



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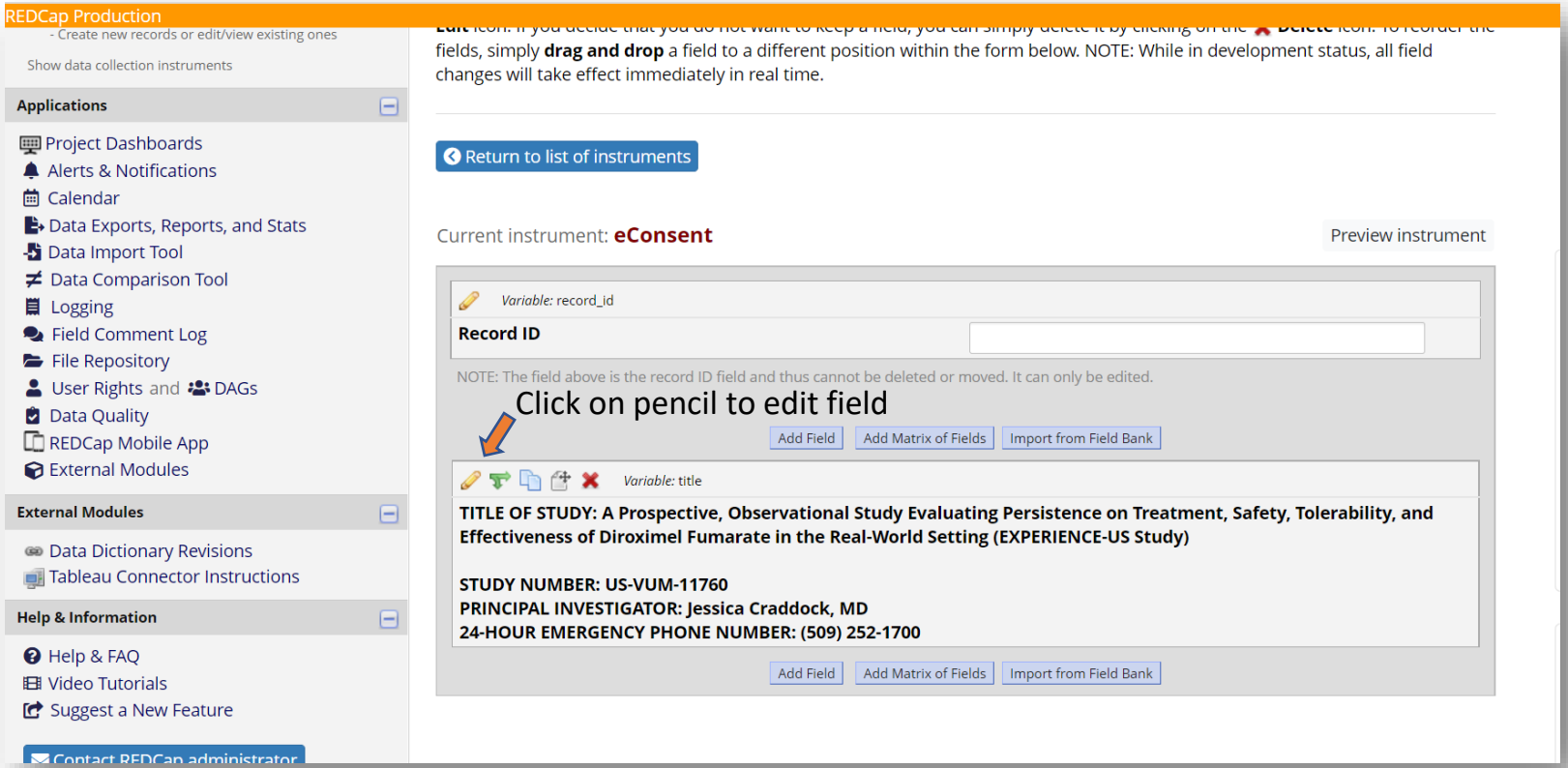
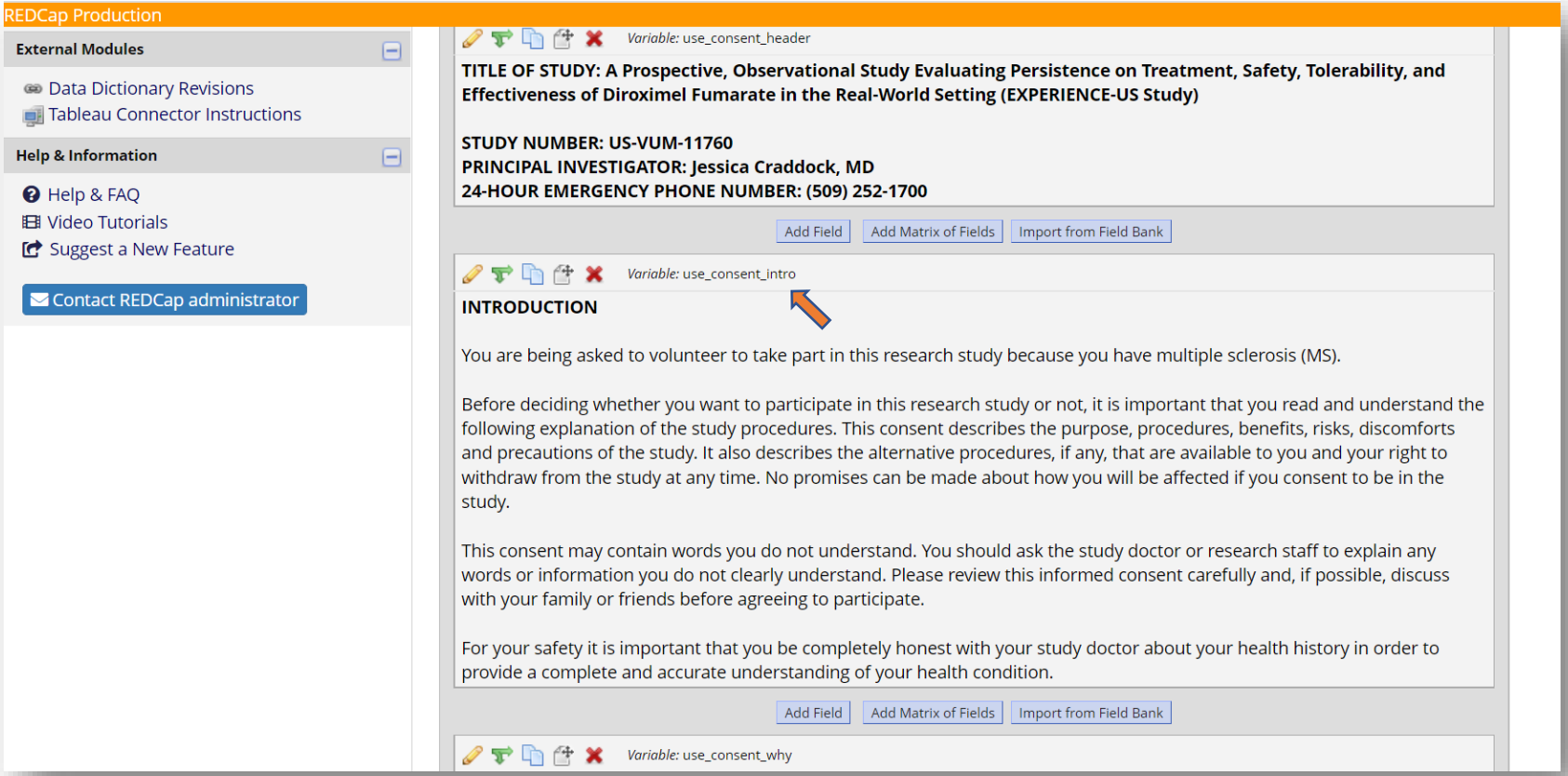
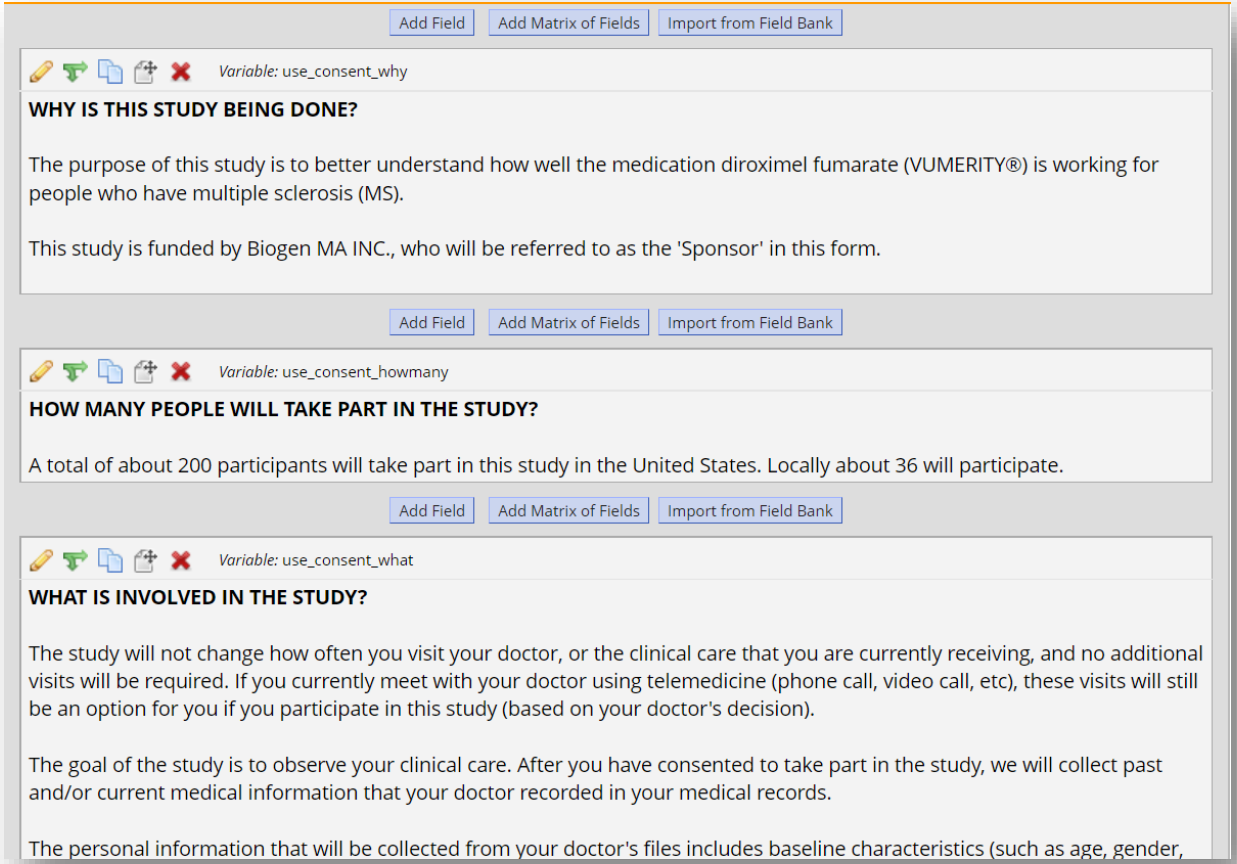
Designer Page with First Field



Naming Variables: Study_Form_section



Continue Building Form



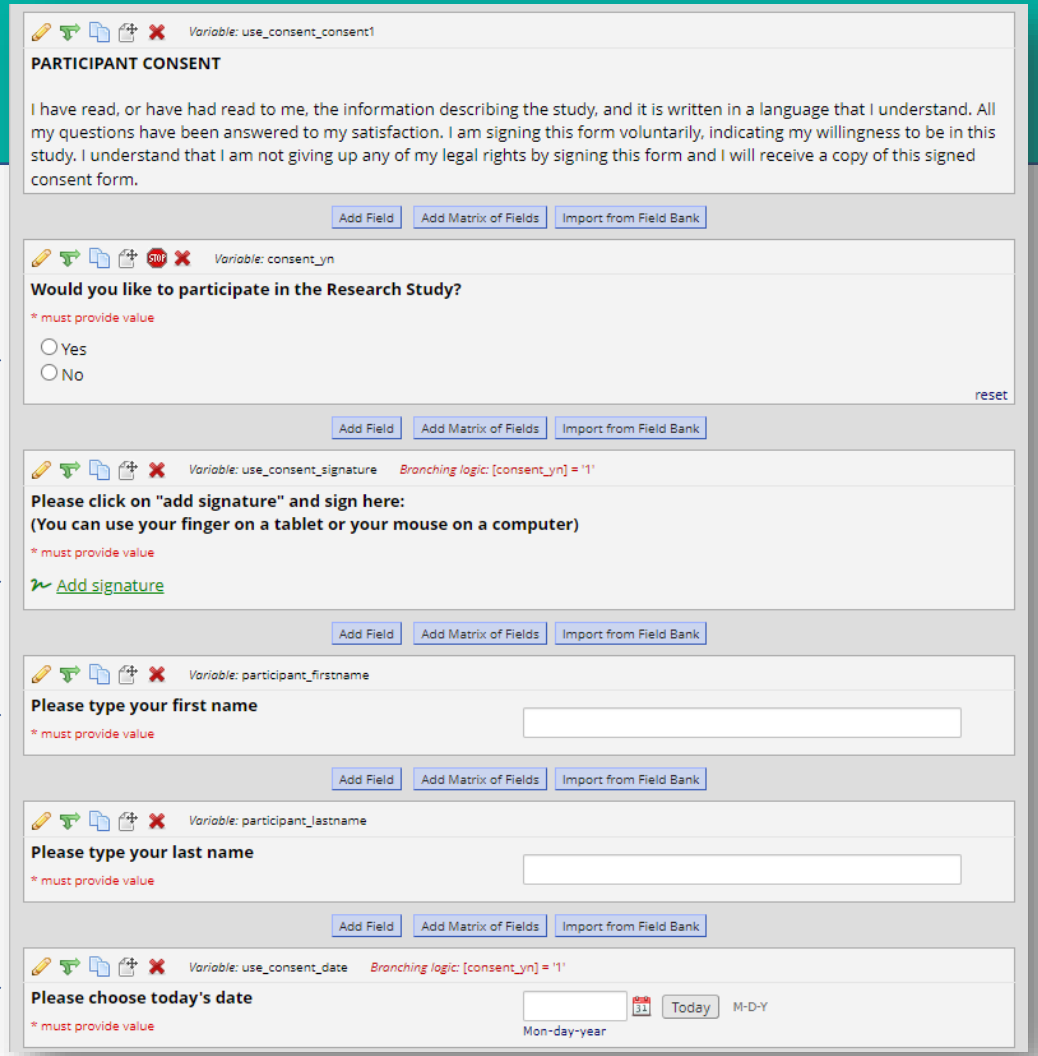
Field Types

Yes-No

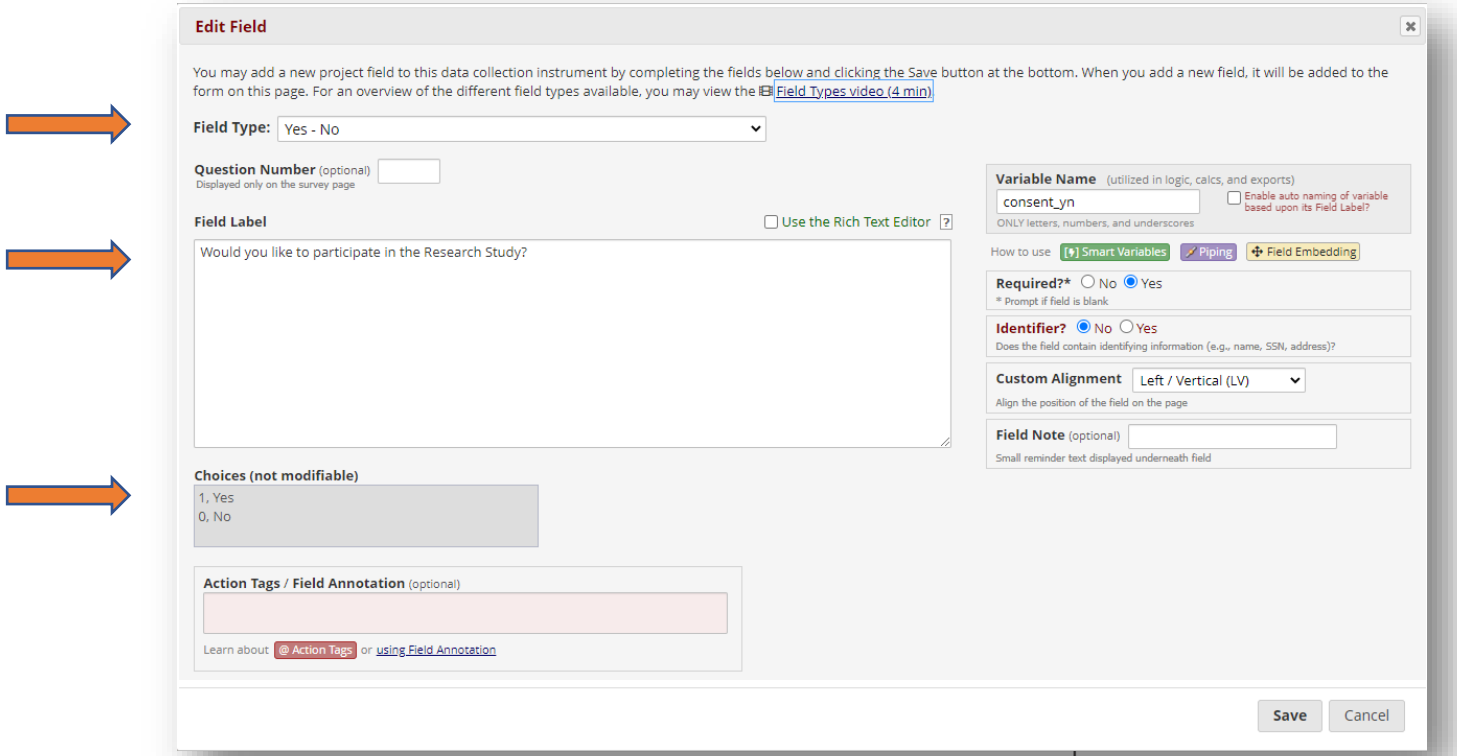
Signature

Text Box

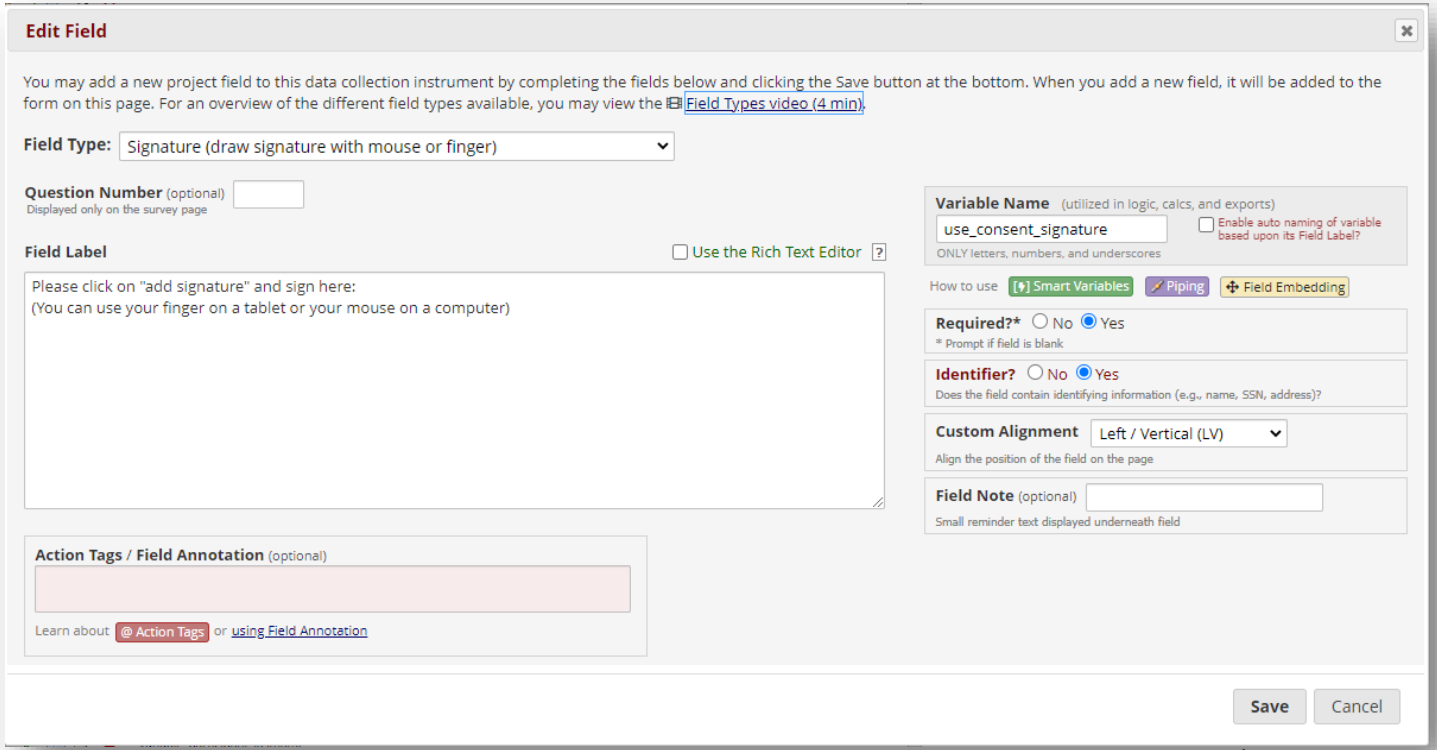
Date



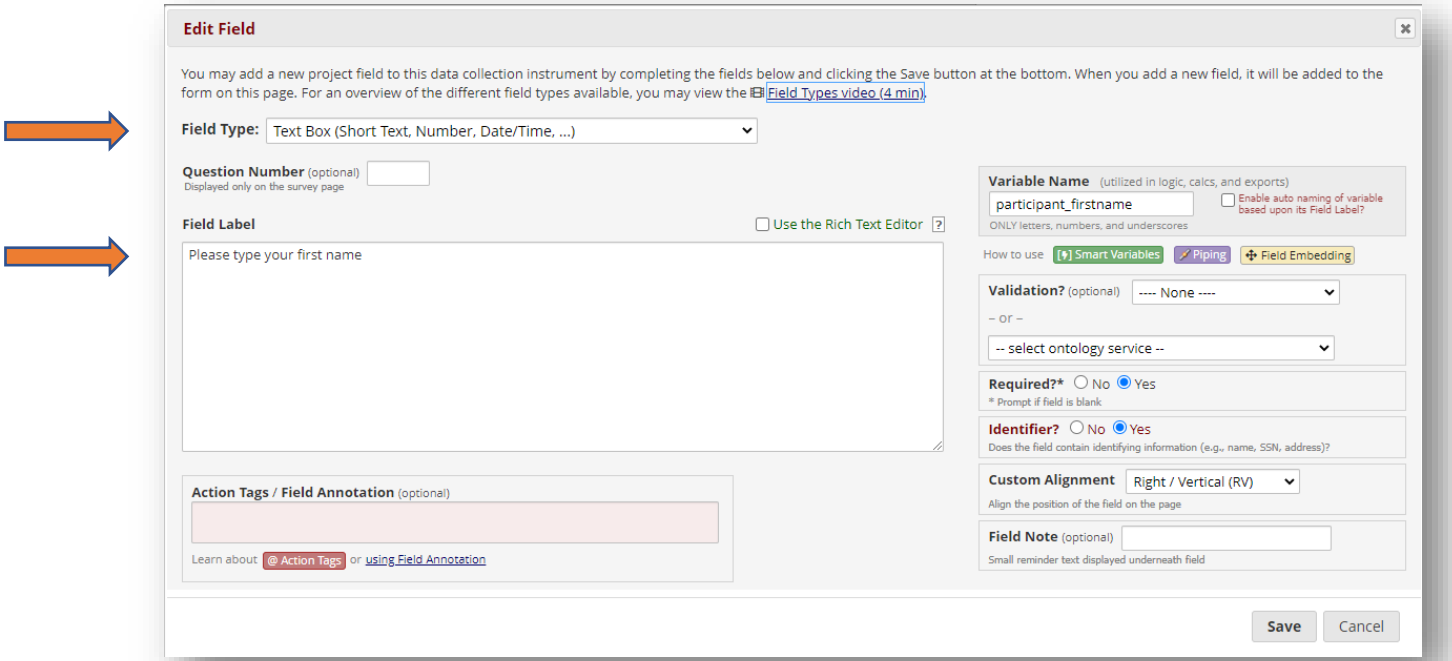
Field Types: Yes-No



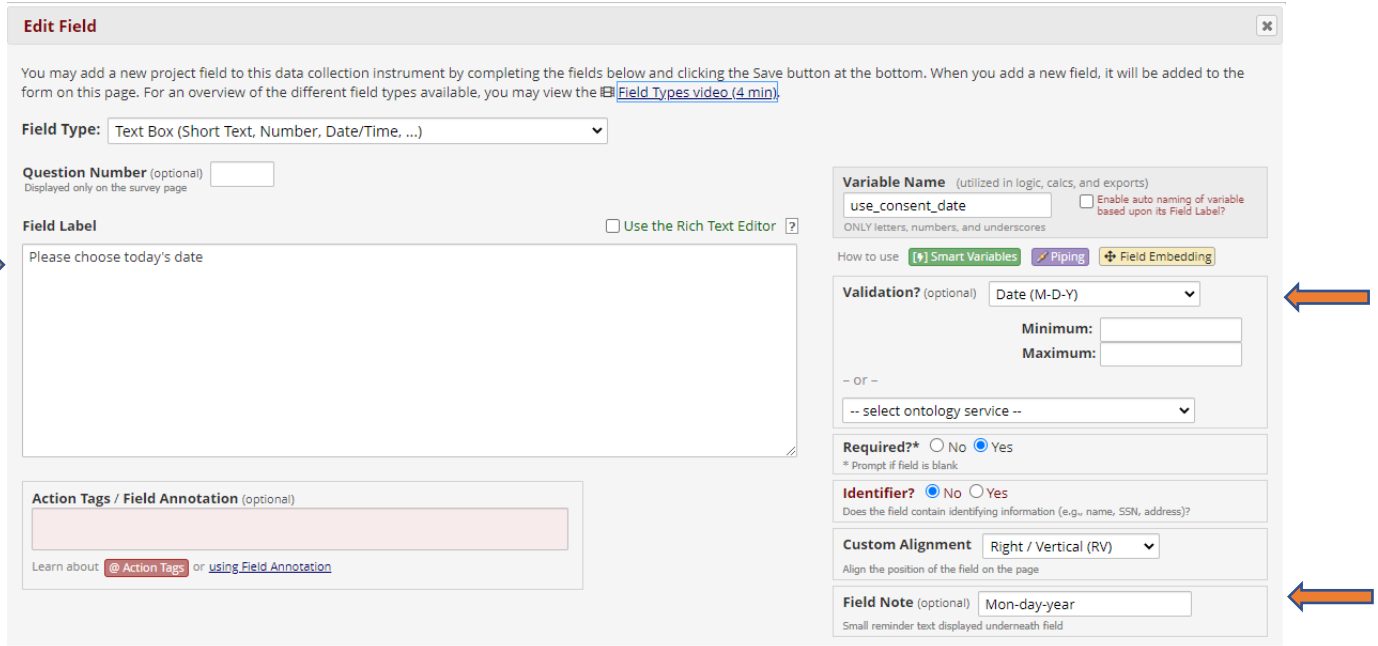
Field Type: Signature

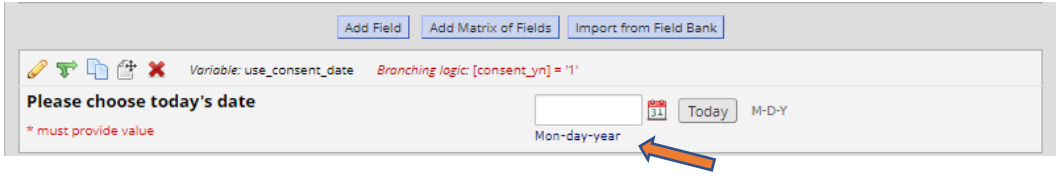


Field Type: Text Box

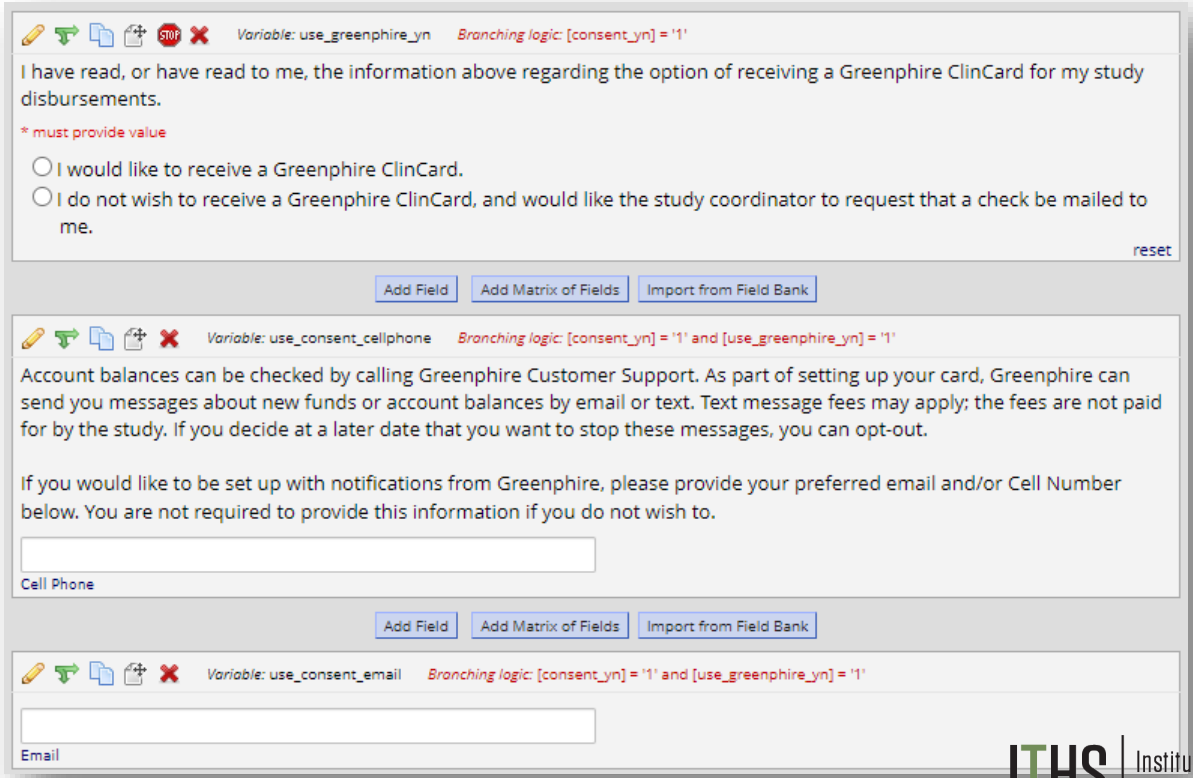


Field Type: Text Box to Capture Date

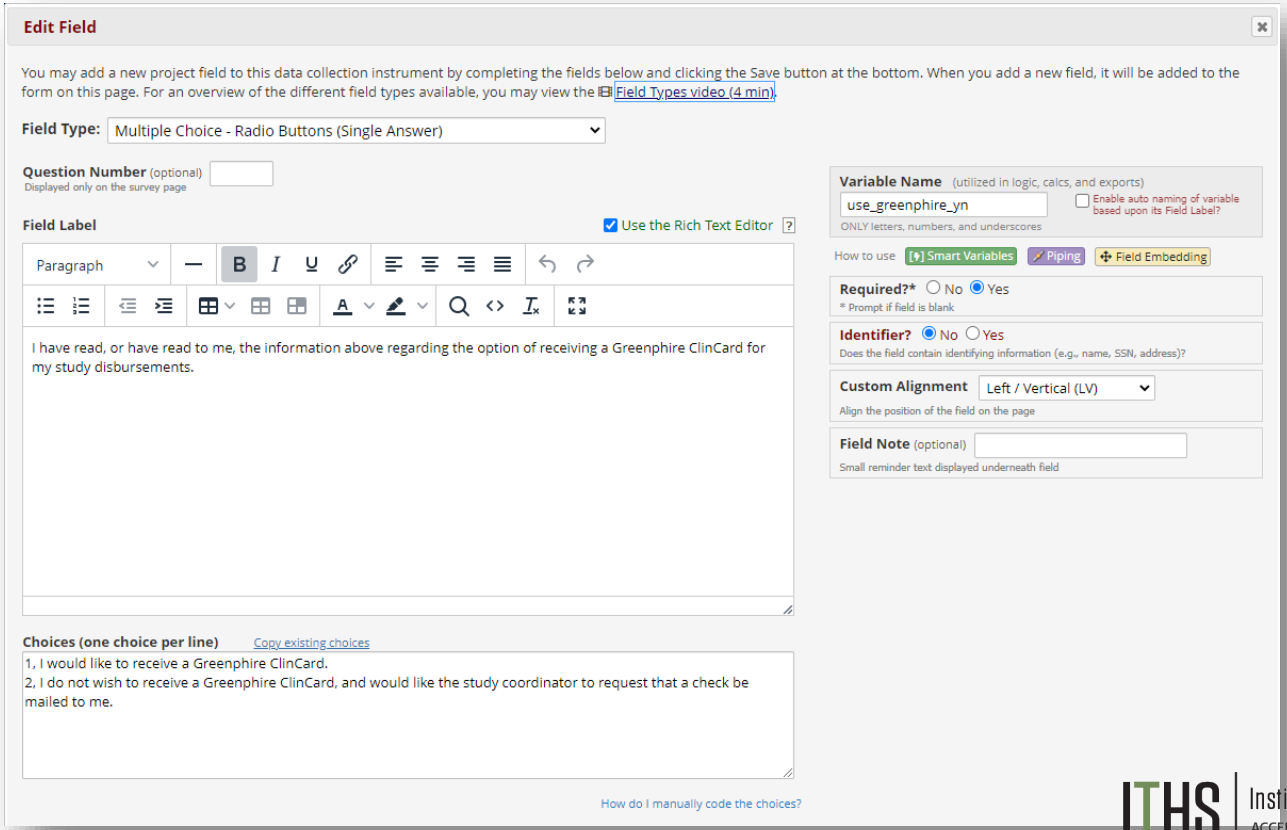




Field Type: Multiple Choice

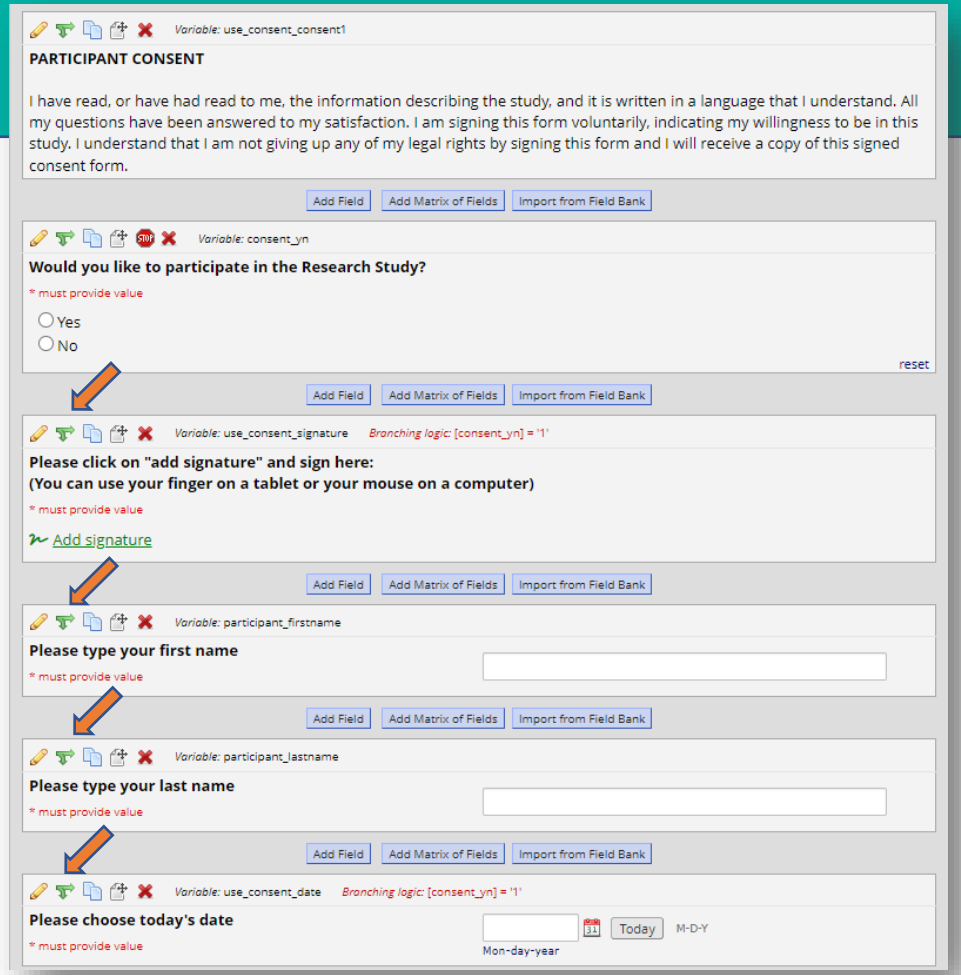


Field Type: Multiple Choice

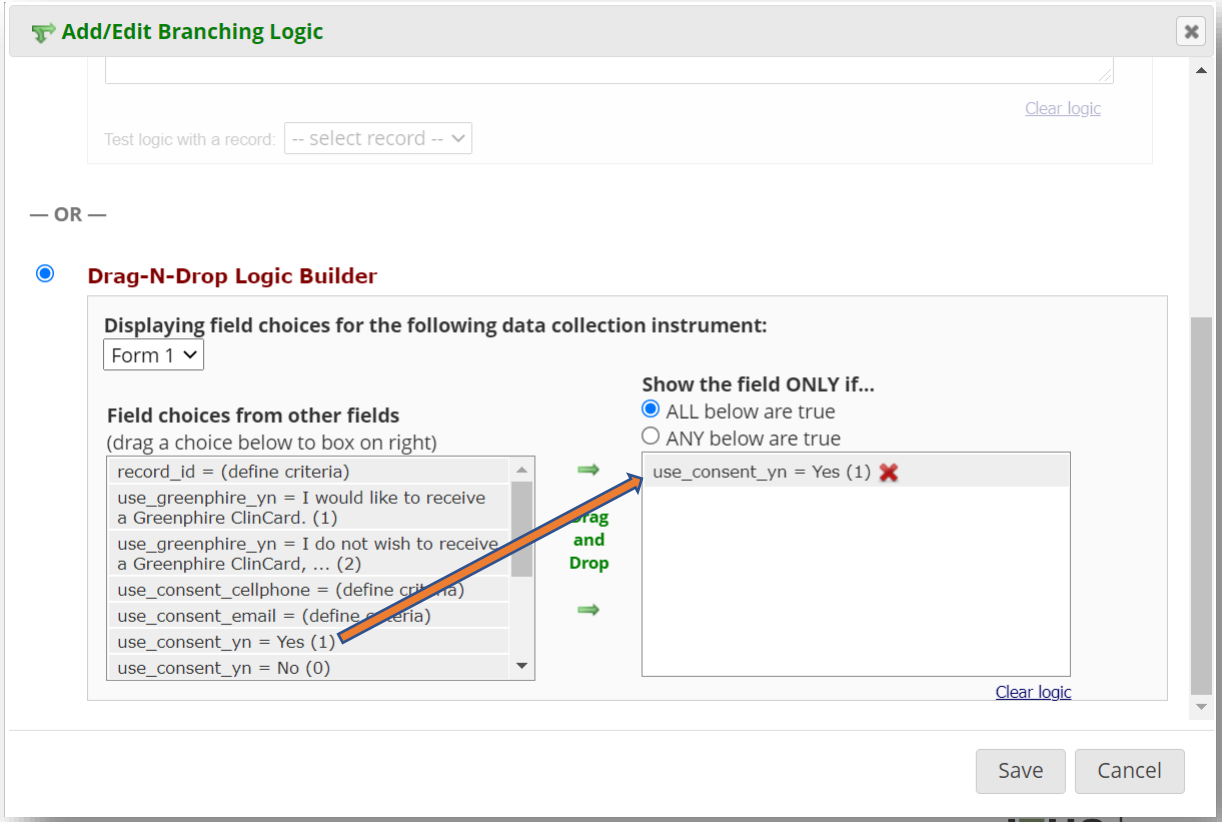


Branching Logic

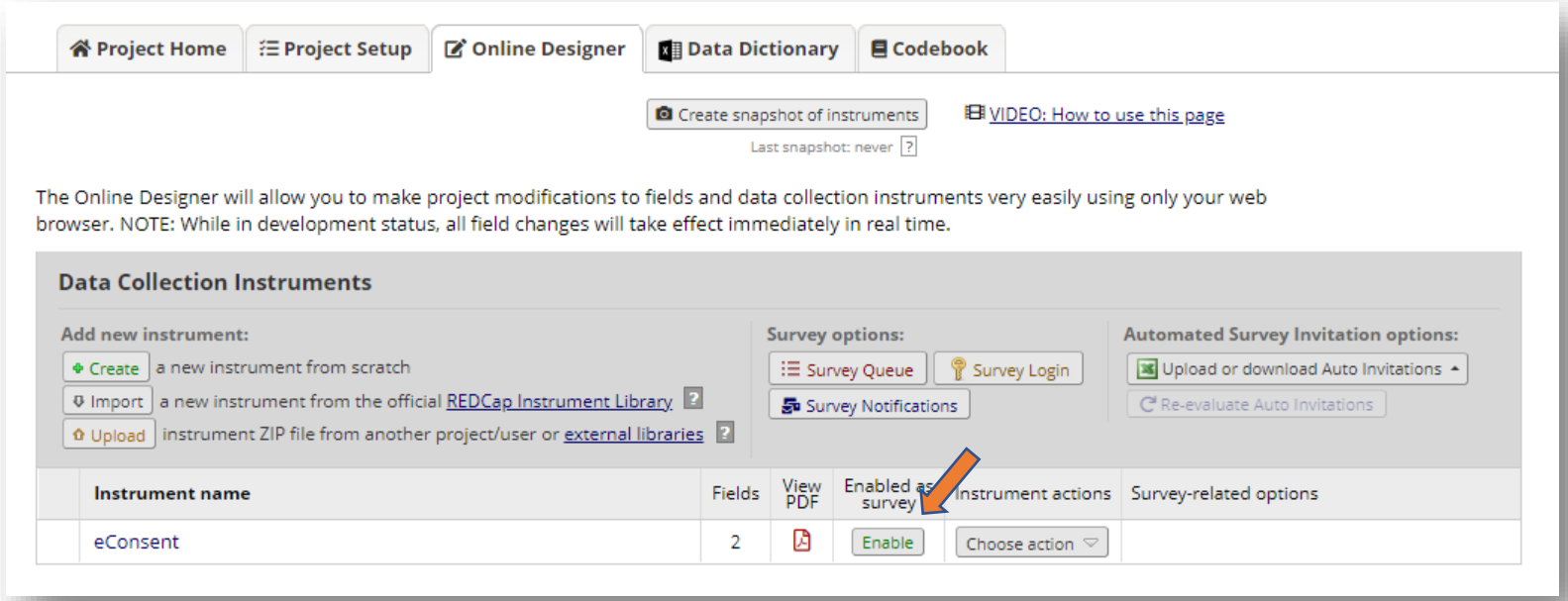
We only want this section to show up if the patient wants to participate in the study



Branching Logic



Enable Consent Form as Survey



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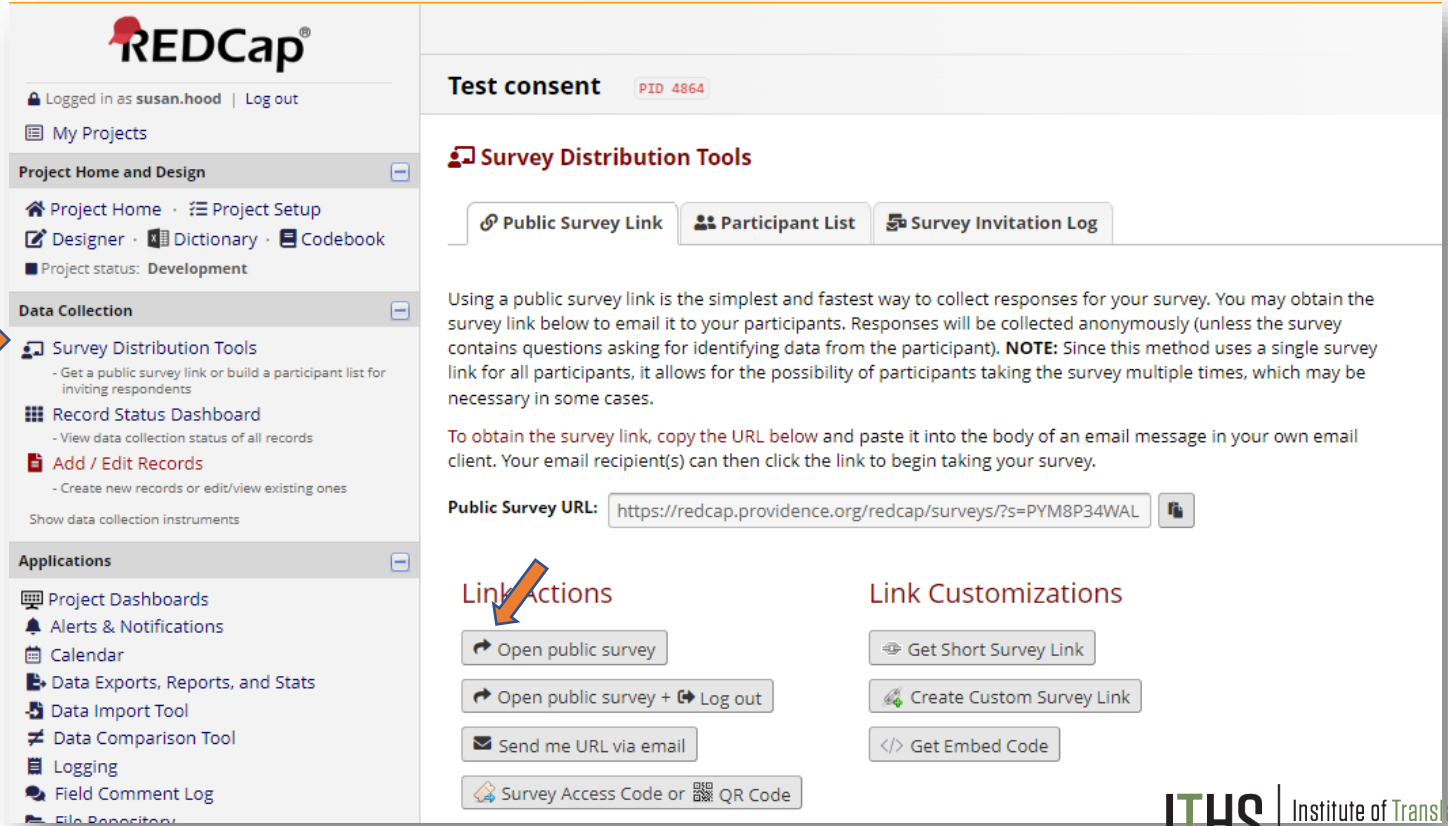
Open a Public Survey



Participant view of eConsent

Providence

Resize font:

Research Study Consent Form

Please read the following consent and decide if you would like to participate in this study.

Thank you!

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

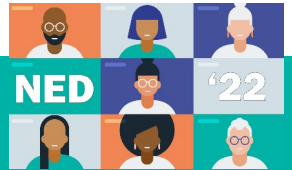
TITLE OF STUDY: A Prospective, Observational Study Evaluating Persistence on Treatment, Safety, Tolerability, and Effectiveness of Diroximel Fumarate in the Real-World Setting (EXPERIENCE-US Study)

STUDY NUMBER: US-VUM-11760
PRINCIPAL INVESTIGATOR: Jessica Craddock, MD
24-HOUR EMERGENCY PHONE NUMBER: (509) 252-1700

INTRODUCTION

You are being asked to volunteer to take part in this research study because you have multiple sclerosis (MS).

Before deciding whether you want to participate in this research study or not, it is important that you read and understand the following explanation of the study procedures. This consent describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative procedures, if any, that are available to you and your right to withdraw from the study at any time. No



Participant view of eConsent

Would you like to participate in the study?

* must provide value

- (•) Yes
- ( ) No

reset

Signature of participant — Add signature

Please type your full name

Please choose today's date — Today M-D-Y

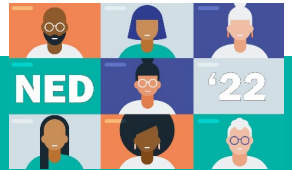
Mon-day-year

Signature of person obtaining consent — Add signature

Typed name of person obtaining consent

Please choose date — Today M-D-Y

Submit



Participant view of eConsent

- It is necessary for your safety.
- You do not follow instructions.
- You do not meet the conditions of the study.
- The study is closed for any reason.

PARTICIPANT CONSENT

I have read, or have had read to me, the information describing the study, and it is written in a language that I understand. All my questions have been answered to my satisfaction. I am signing this form voluntarily, indicating my willingness to be in this study. I understand that I am not giving up any of my legal rights by signing this form and I will receive a copy of this signed consent form.

Would you like to participate in the study?

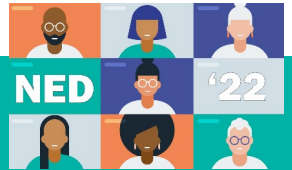
* must provide value

- ○ Yes
- ◉ No

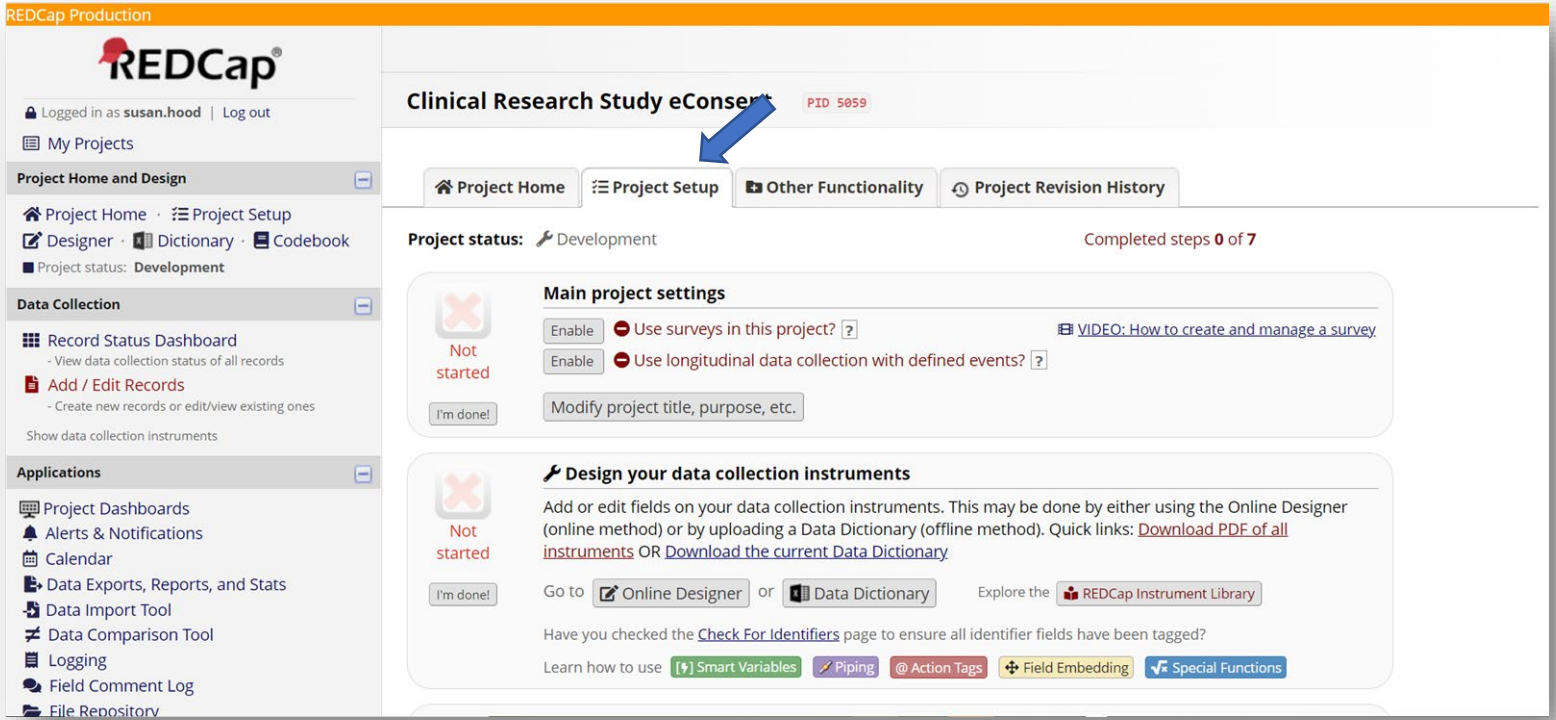
reset

Thank you for considering the Experience Research Study

Submit



Move Project Into Production



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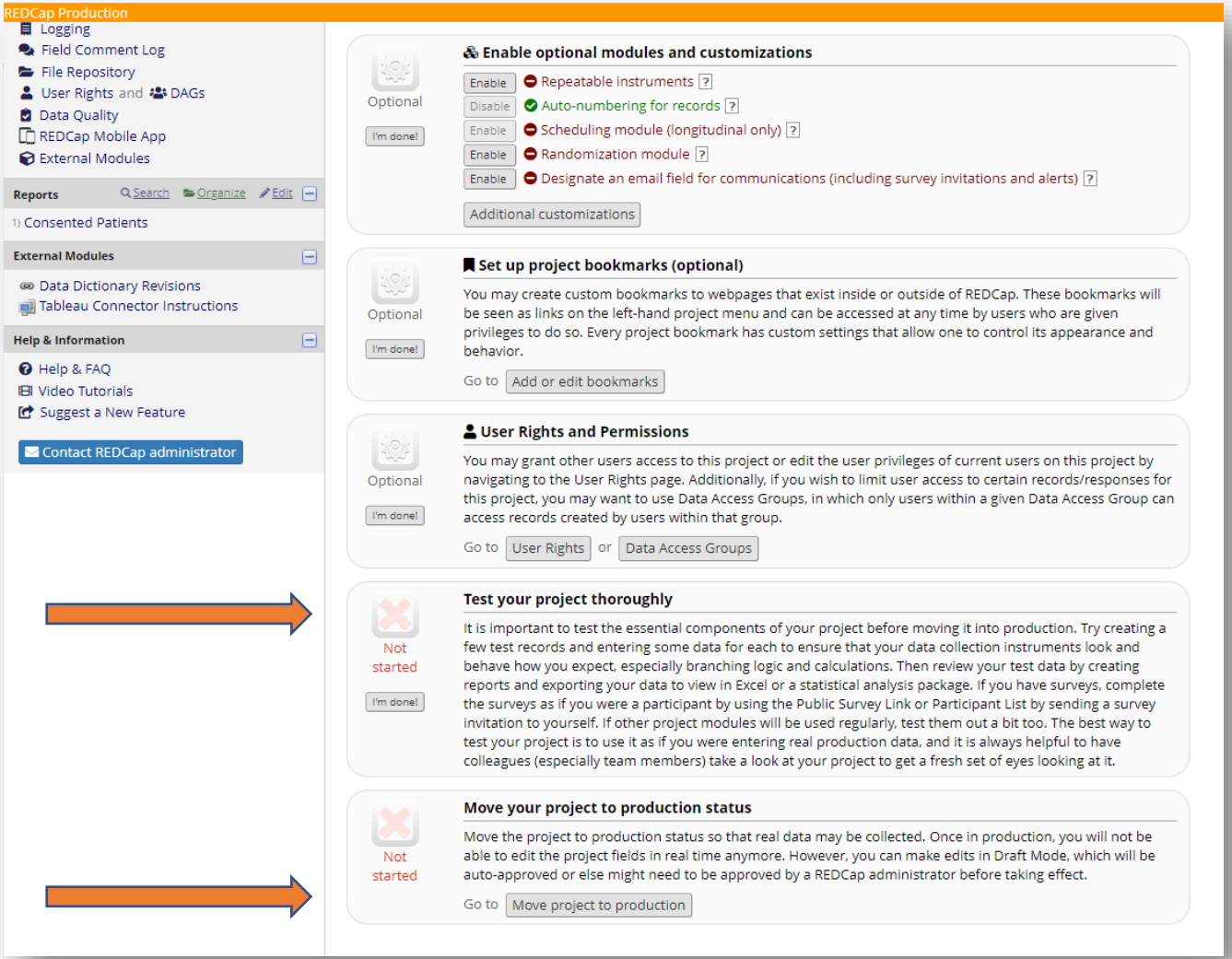
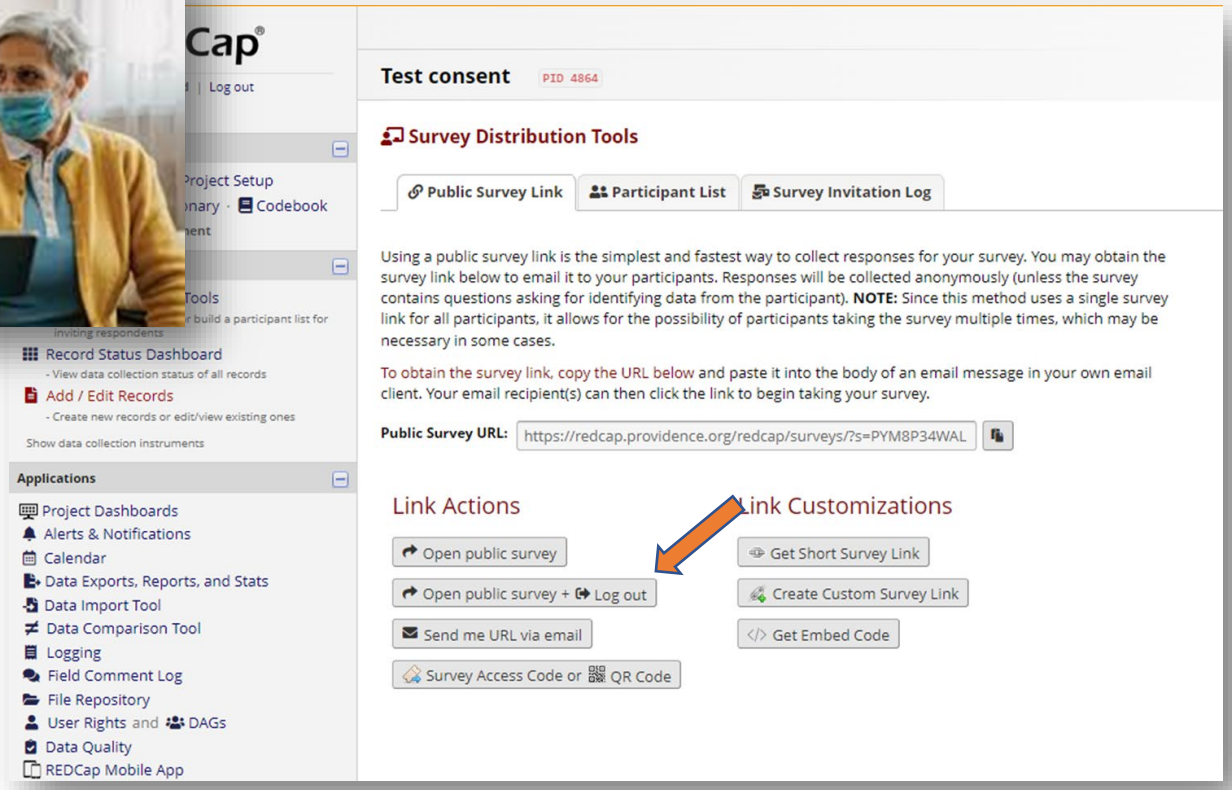


Signing the eConsent Form in Person



Signing Consent Remotely-Sending Email or Text

REDCap

Logged in as **susan.hood** | Log out

My Projects

Project Home and Design

Project Home · Project Setup
Designer · Dictionary · Codebook
Project status: **Development**

Data Collection

Survey Distribution Tools
- Get a public survey link or build a participant list for inviting respondents

Record Status Dashboard
- View data collection status of all records

Add / Edit Records
- Create new records or edit/view existing ones

Show data collection instruments

Applications

Project Dashboards
Alerts & Notifications
Calendar
Data Exports, Reports, and Stats
Data Import Tool
Data Comparison Tool
Logging
Field Comment Log
File Repository
User Rights and DAGs
Data Quality
REDCap Mobile App

Test consent PID 4864

Survey Distribution Tools

Public Survey Link | Participant List | Survey Invitation Log

Using a public survey link is the simplest and fastest way to collect responses for your survey. You may obtain the survey link below to email it to your participants. Responses will be collected anonymously (unless the survey contains questions asking for identifying data from the participant). **NOTE:** Since this method uses a single survey link for all participants, it allows for the possibility of participants taking the survey multiple times, which may be necessary in some cases.

To obtain the survey link, copy the URL below and paste it into the body of an email message in your own email client. Your email recipient(s) can then click the link to begin taking your survey.

Public Survey URL: https://redcap.providence.org/redcap/surveys/?s=PYM8P34WAL

Link Actions

- Open public survey
- Open public survey + Log out
- Send me URL via email
- Survey Access Code or QR Code

Link Customizations

- Get Short Survey Link
- Create Custom Survey Link
- Get Embed Code

Research Study Consent Form - Message (HTML)

File | Message | Insert | Options | Format Text | Review | Help | Acrobat | Tell me

Paste | Basic Text | Names | Include | Tags | Dictate | Sensitivity | Immersive Reader | View Templates

Clipboard | Voice | Sensitivity | Immersive | My Templates

Send

To: Hood, Susan C;

Cc:

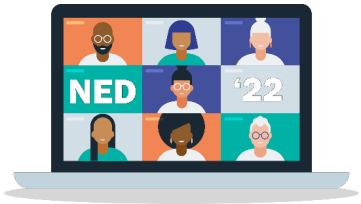
Subject: Research Study Consent Form

The link below will take you to the consent form for the Clinical Research Study. Please review the form prior to our call on Thursday. Please do not sign the consent form until after you have spoken with me .

https://redcap.providence.org/redcap/surveys/?s=PYM8P34WAL

Susan Hood, PhD, CCRC
Clinical Research Coordinator
Providence Medical Research Center
105 W 8th Avenue
Suite 250E
Spokane, WA 99204
O 509-474-4224
F 509-474-4325
susan.hood@providence.org

Providence



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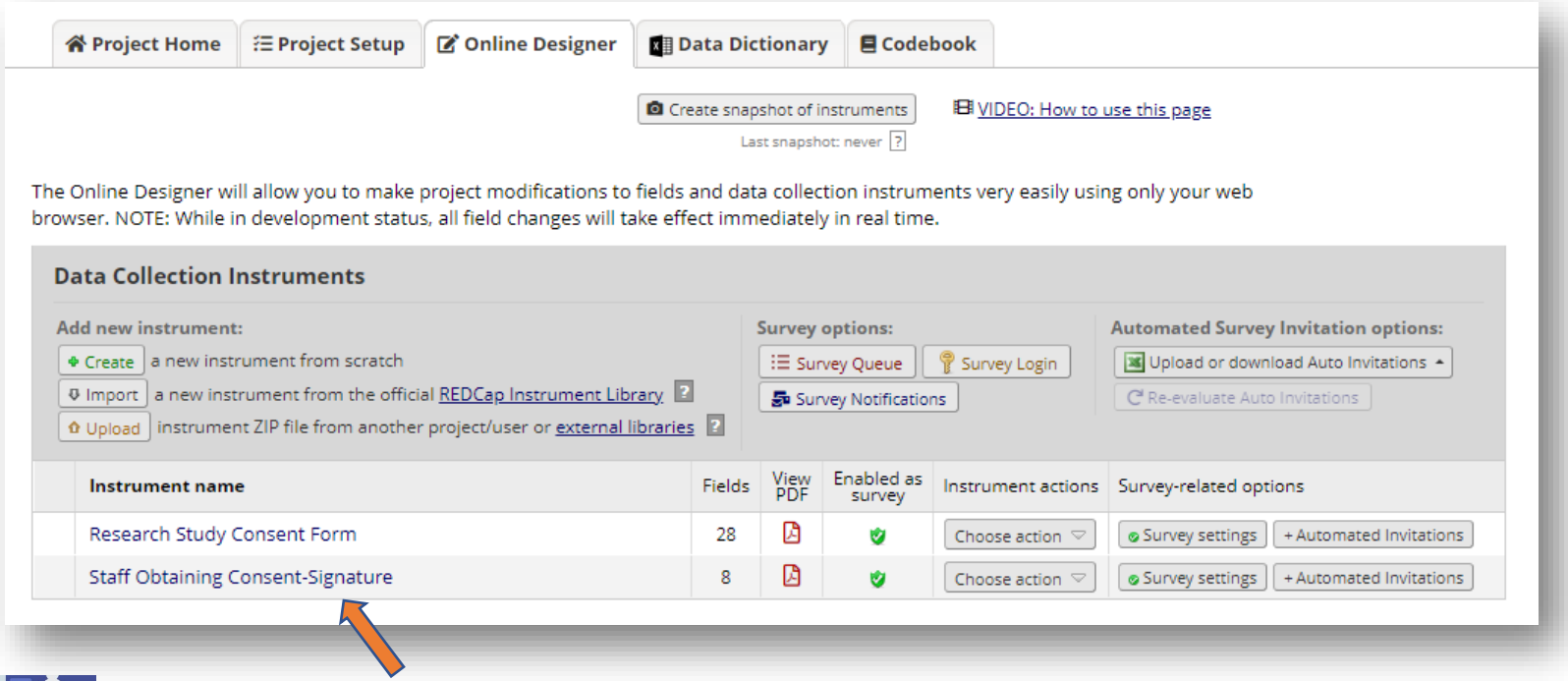
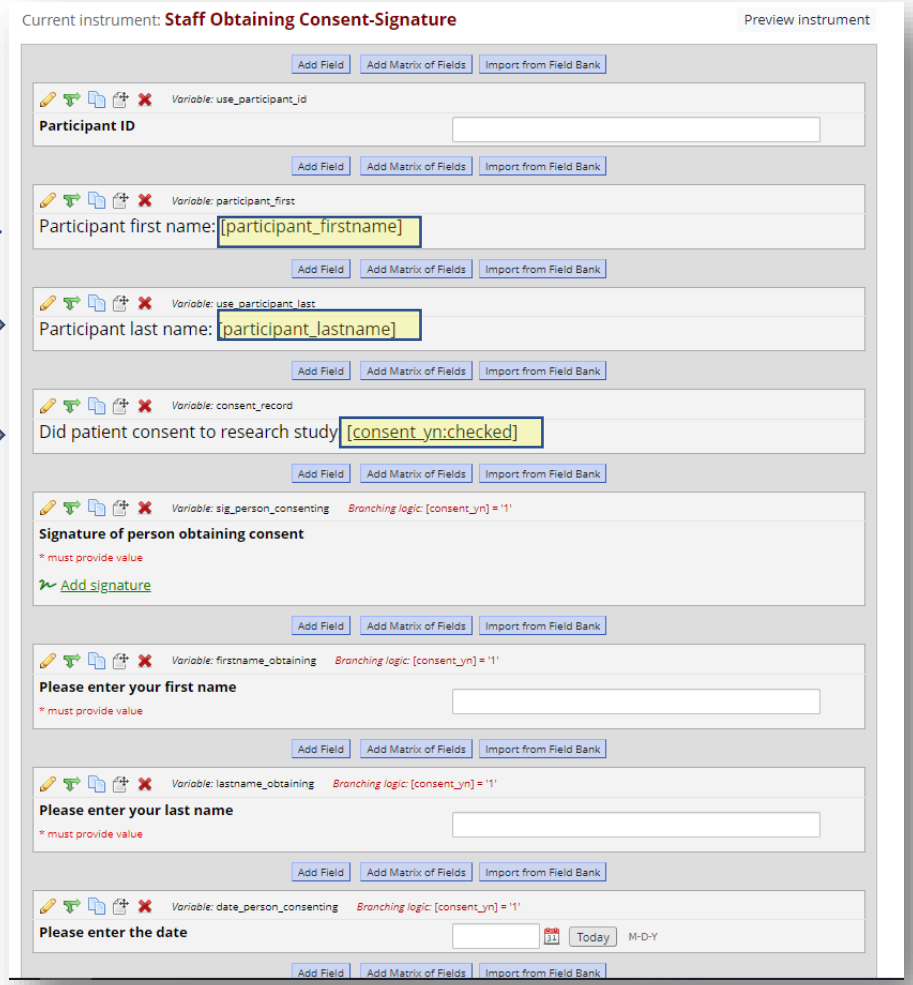
Signing Consent Remotely
Staff Signs Separately



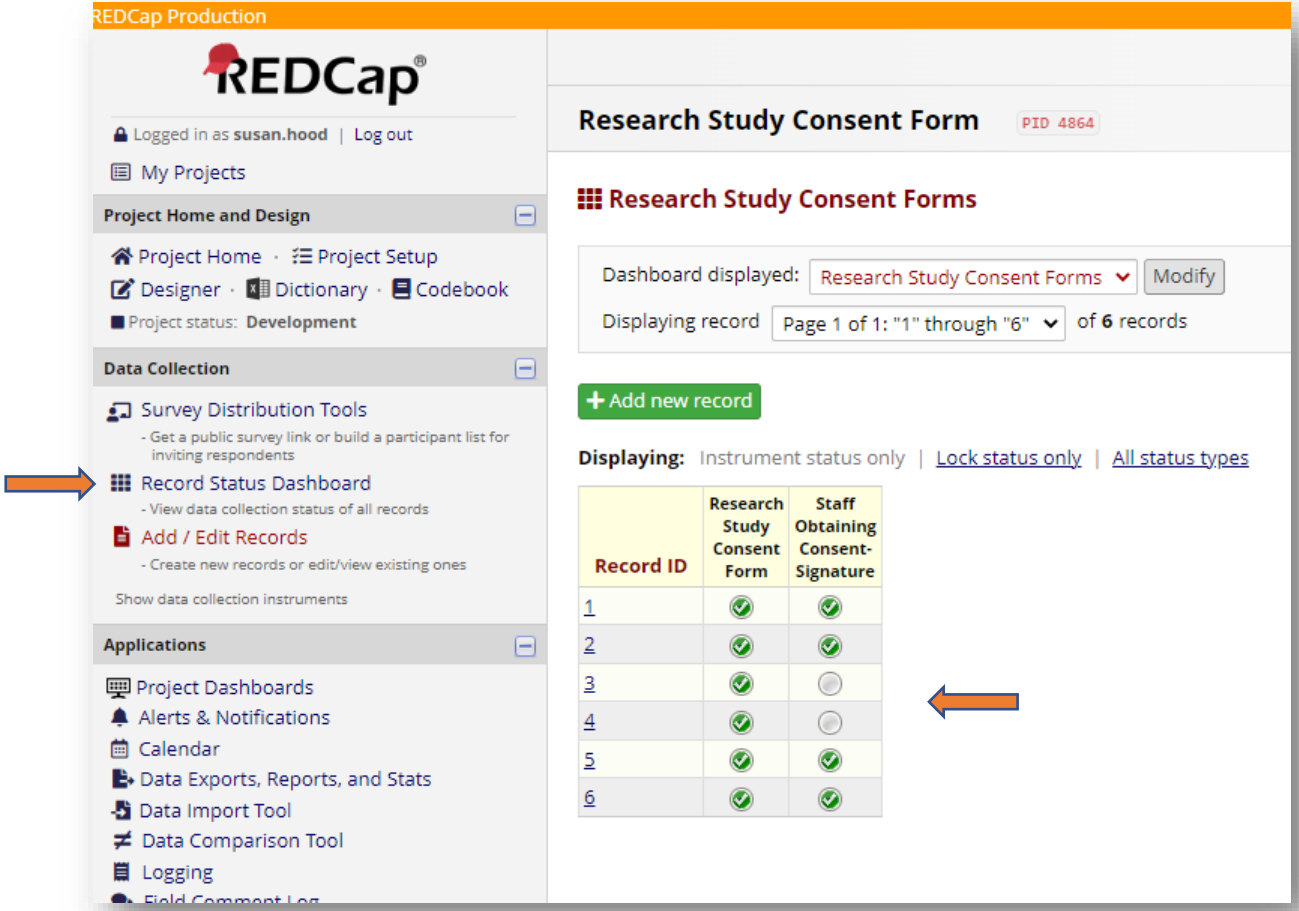
Signing Consent Remotely
Staff Signs Separately

Piping is used here to bring information in from the consent form the participant filled out.

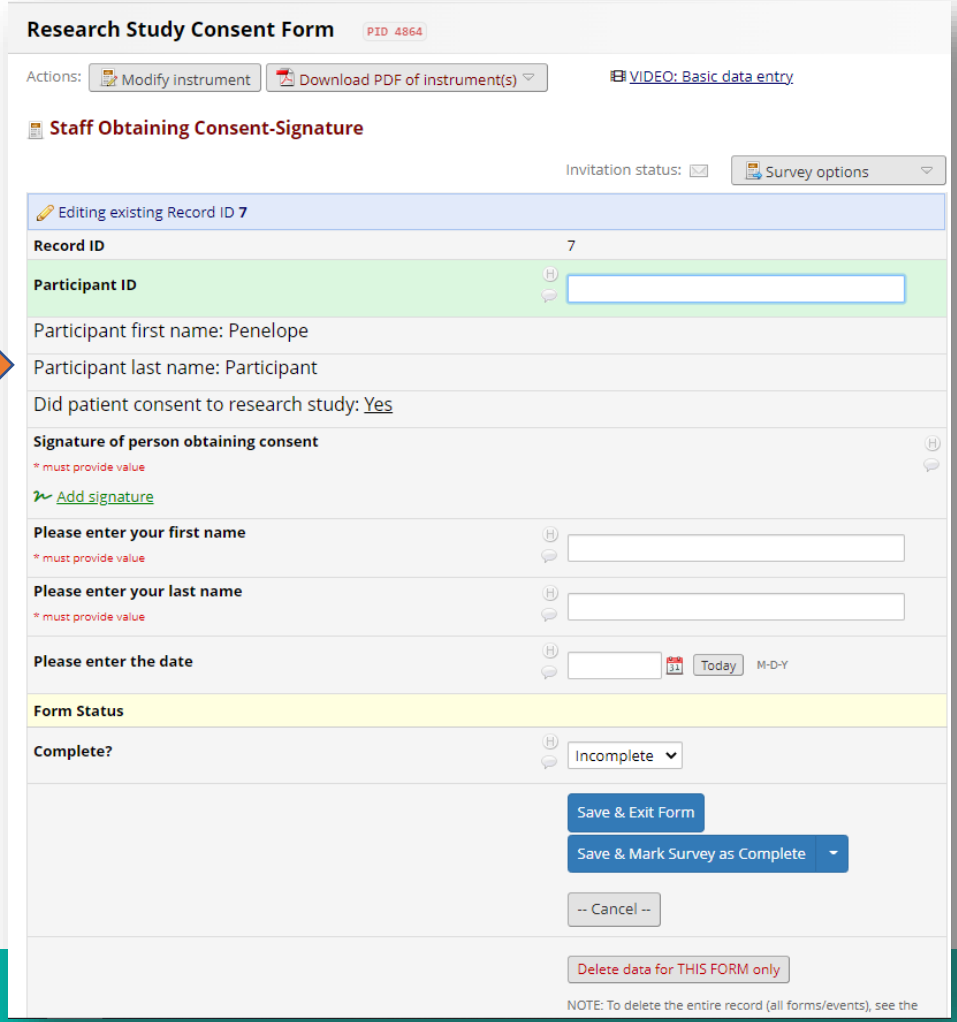


Staff Signs Separately

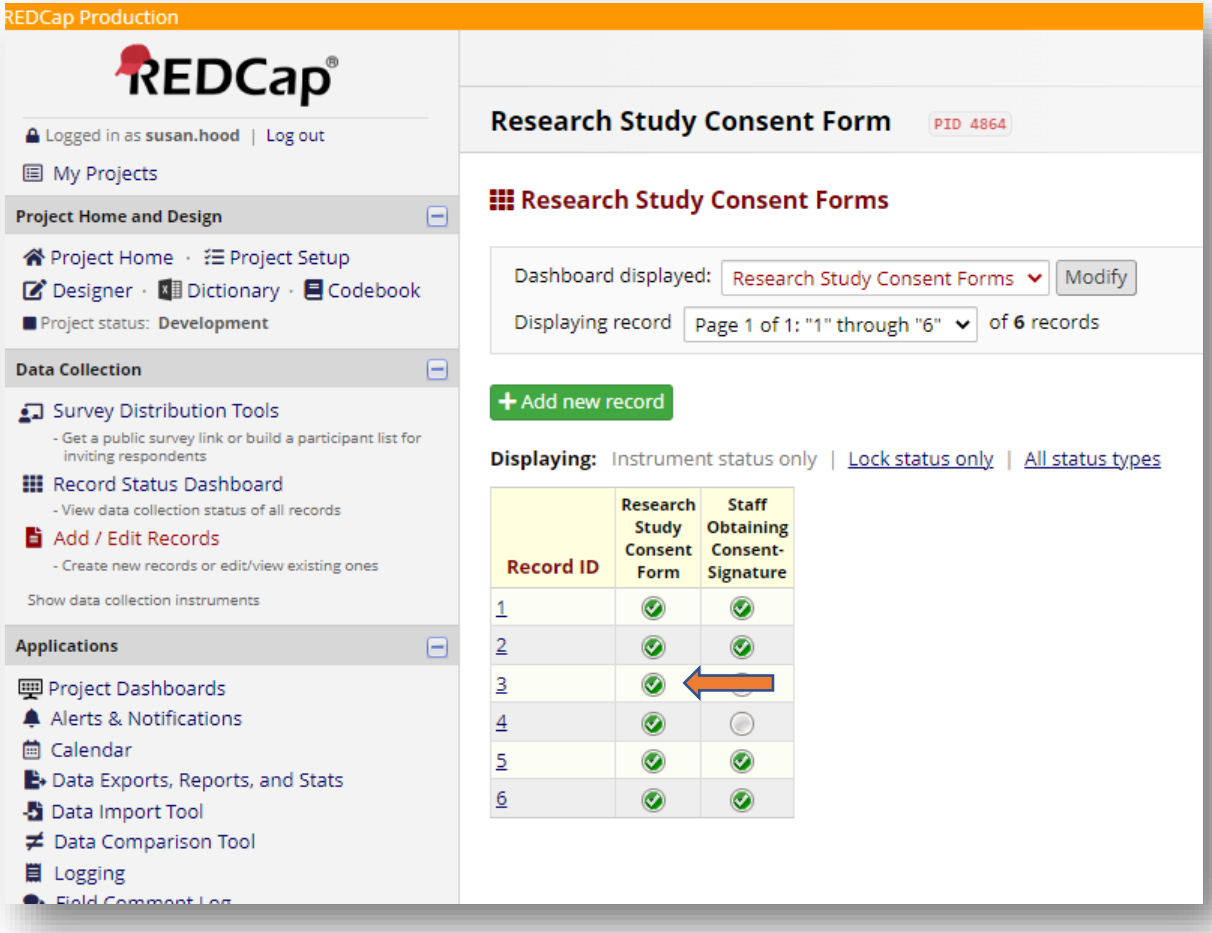
Staff can access the form to sign through the Record Status Dashboard



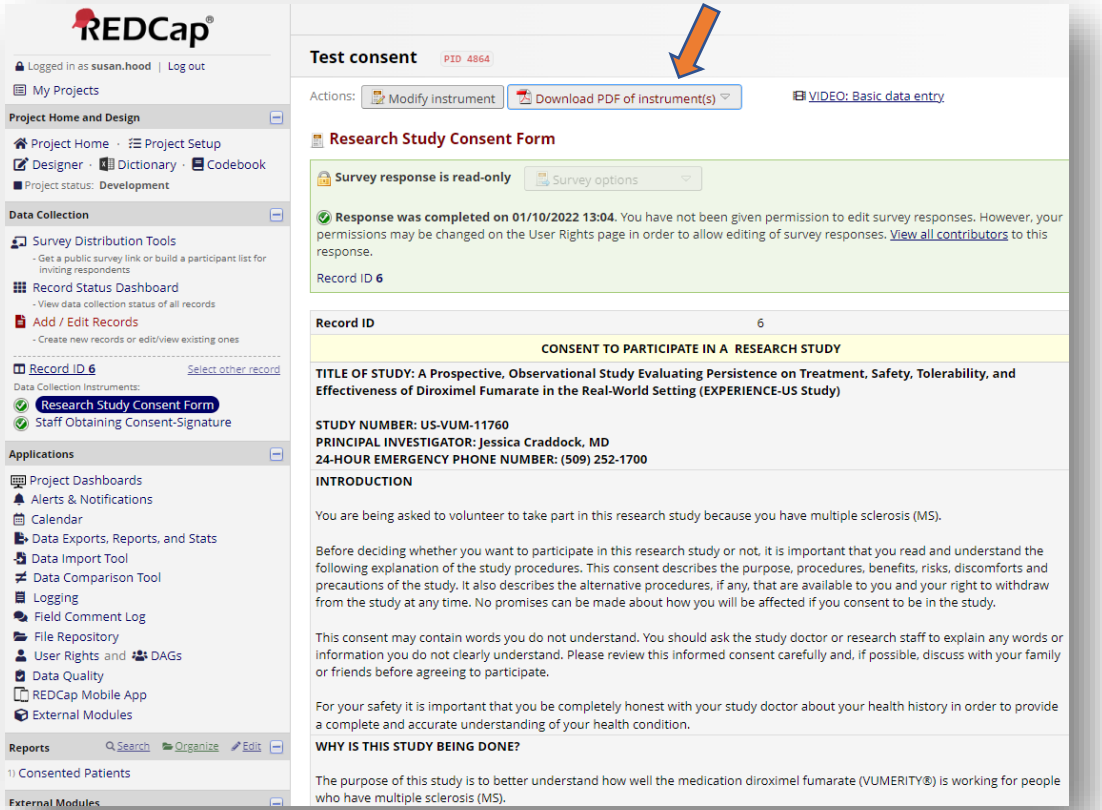
Staff Signs Separately



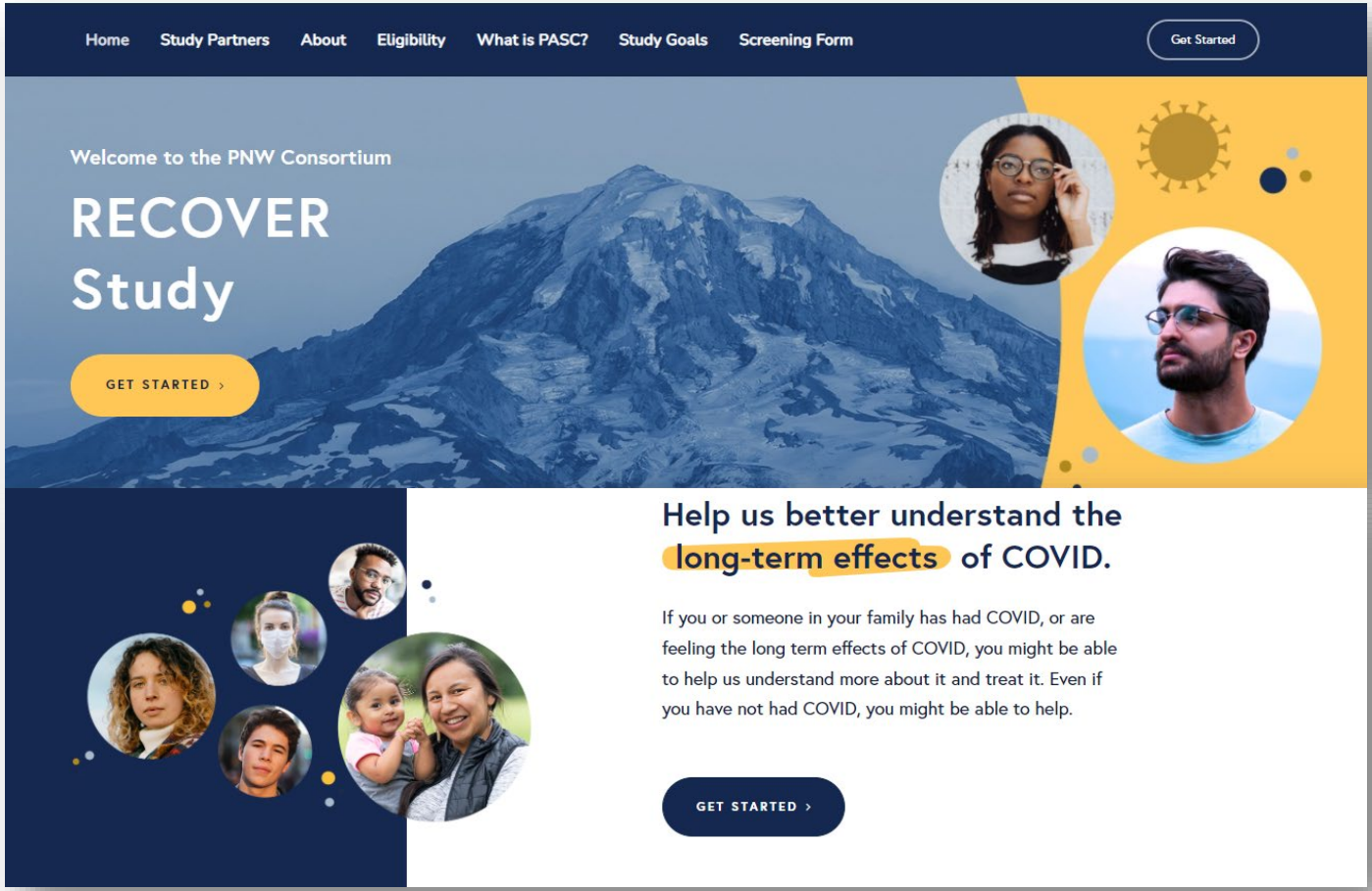
Download PDF of Consent



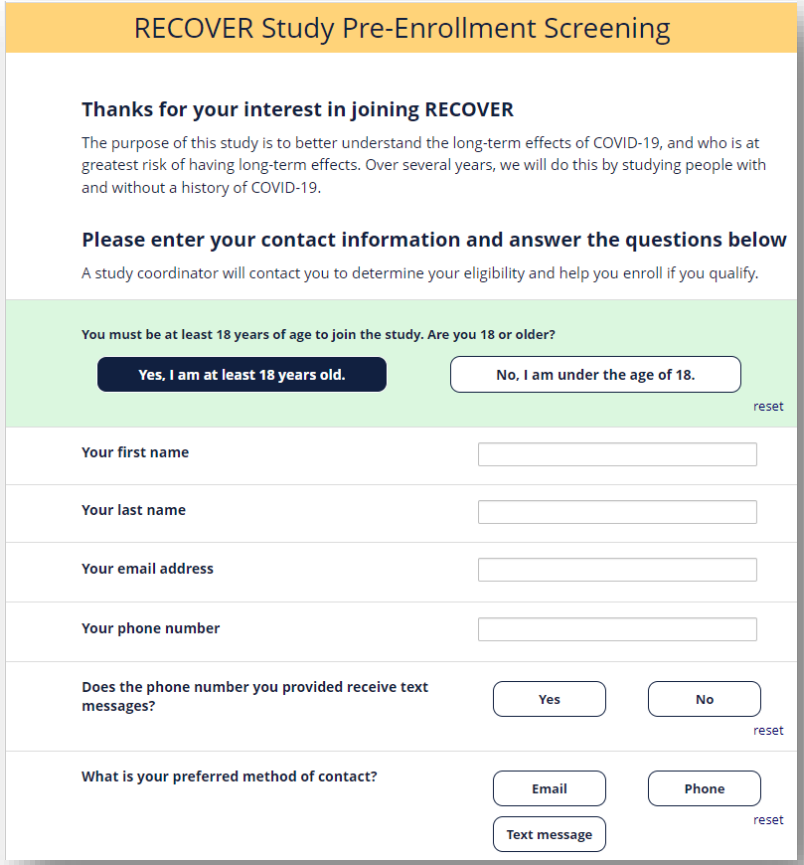
Download PDF of Consent



RECOVER Research Study Website



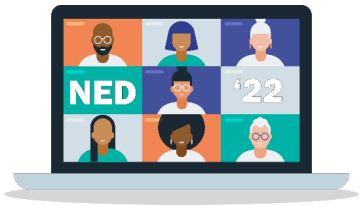
RECOVER Research Study Screening Form



RECOVER Research Study Consent Form

REDCap Training Resources

- ITHS Online Training Courses
  https://www.iths.org/investigators/services/bmi/redcap/curriculum/
- REDCap Training Videos (within the app) or online
  https://projectredcap.org/resources/videos/



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Questions?