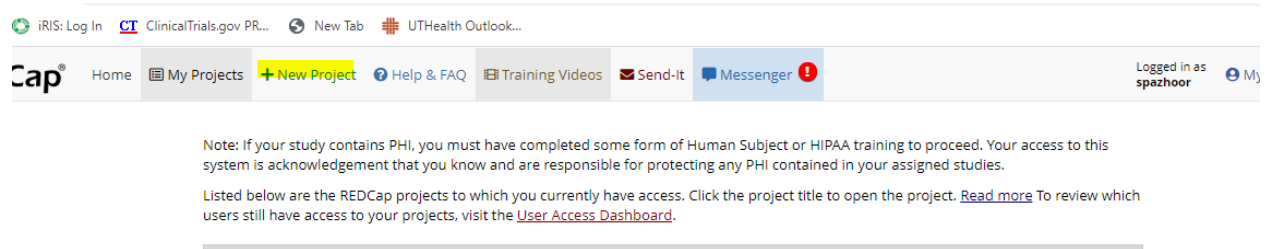# eConsent Using REDCap

1.0 How to set up a project using eConsent template:

Log into REDCap

*If you do not have a REDCap account, log into REDCap using your UT user name and password once-this will create an account for you in REDCap https://redcap.uth.tmc.edu/

Clcik on +New Project(see below)

Fill in following fields

After fillling in the fields, Select the highlighted options.

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2.0 Designing the project

Click on designer(on main page under Project Home and Design)

This will take you to the 3 instruments of the template:

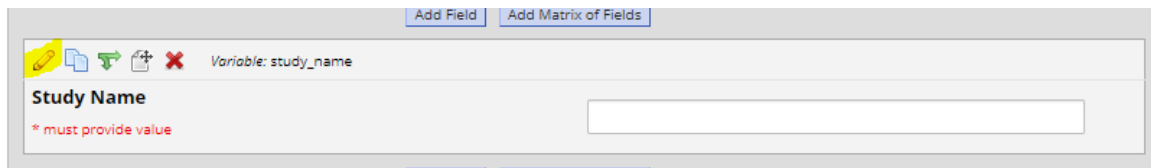You can rename each instrument by clicking on the choose action drop down menu

Click on each instrument to modify if needed

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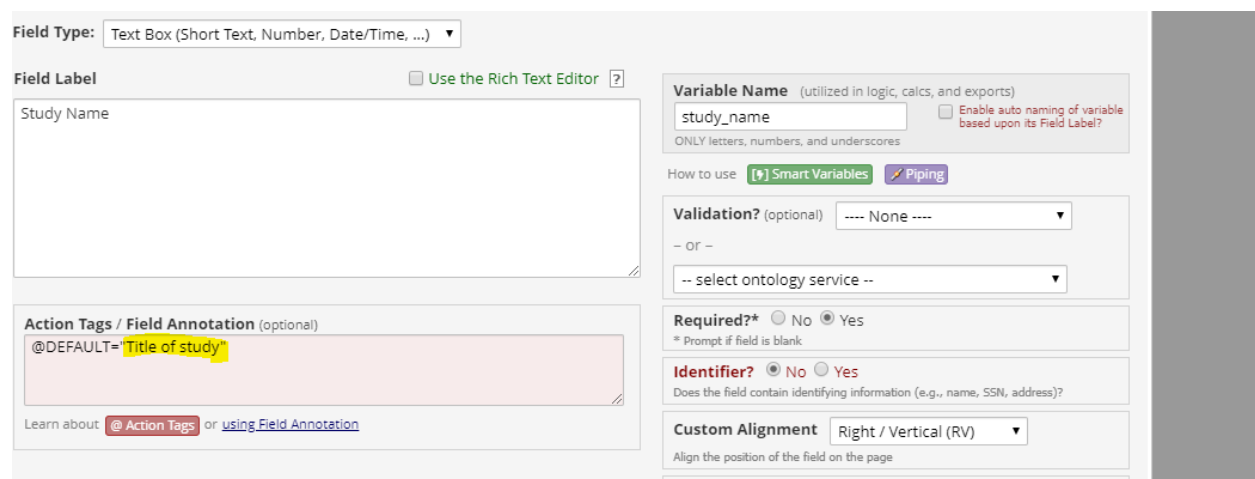## 2.1 STUDY DETAILS INSTRUMENT:

Click on study details intrument

2.1.1 Study Name: click on the pencil icon in this filed

Under action tags change the title of study to actual title of study

Ex: @DEFAULT="Title of study" change to @DEFAULT="Blood Draw for Plasma Extraction"

2.1.2 Study IRB Number: Do the same for Study IRB Number field

@DEFAULT="HSC-MS-20-1234"-change the HSC number to actual IRB number

The study name and study IRB number will be automatically generated for every subject

2.1.3 Paper copy of ICF: If for some reason paper copy of ICF was used ,select yes for the question (see below) and upload the paper copy(this is marked yes only if eConsent was not utilized and a paper consent was used under any circumstances by either patient,LAR or person obtaining consent)
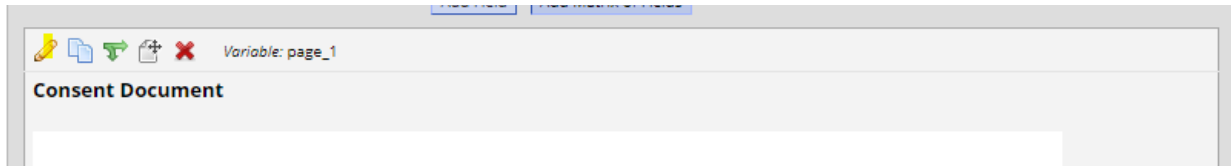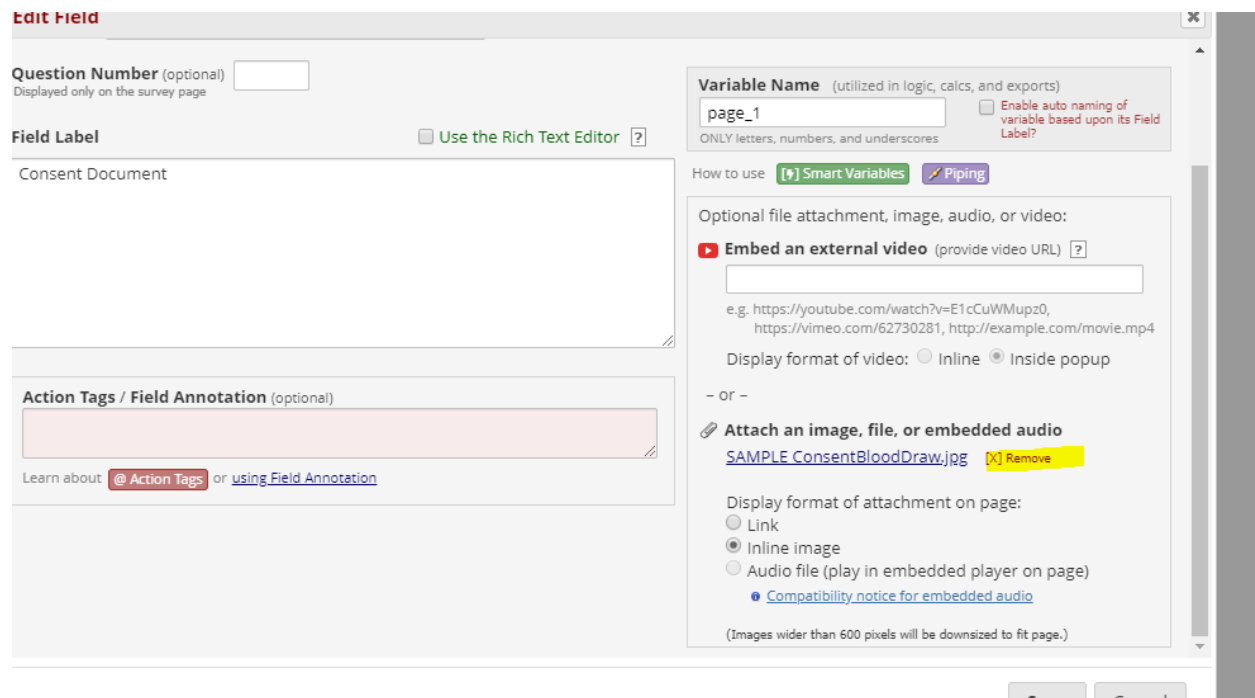
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2.2 CONSENT DOCUMENT INSTRUMENT:

The Patient study ID should be generated automatically form the study details instrument

2.2.1 Uploading a consent document: Convert the consent document to jpeg format.Click on pencil icon

Remove the existing sample consent

Upload new consent and make sure inline image is selected

Save

Repeat the process for each page of the consent(change variable name to page_2,page _3 etc)

2.3 Informed Consent Documentation instrument

*Repeat steps 2.1.1 and 2.1.2 above for Informed Consent Documentation instrument as well

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3.0 How to change the consent version:

Step 1:

Go to Designer

Upload new version of consent in a new field(leave old consent as is)(repeat steps 2.2)

Click on designer and then click on consent instrument and click on pencil icon of consent version field:

1, eConsent v1-4/20/2020

2, eConsent v2-5/1/2020

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Under action tags change the default number to "2"

This will make sure that the second version is selected and will be hidden on the survey but will automatically appear in the pdf of the signed consent form

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Step 2:

Online designer

Go to survey settings and change to version 2

Step 3:

Branching Logic:(ex if you want the version 1 to pop up)
Click on the green arrows in the consent document field,select Drag-N-Drop Logic Builder and drag consent _version=eConsent v1-date(1) into the box on the right-now every-time version 1 is selected only that version of the consent document will be seen

4.0 User Rights:

4.1For each user make sure the following rights are assigned (make sure owner of project also has all the below mentioned rights):

First, make sure the user has logged into REDCap using their UT user name and password once-this will create an account for the user in REDCap https://redcap.uth.tmc.edu/

Once account has been created, project owner can assign rights to the new user

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Click on user rights, search for user using the user name, and add with custom rights (see below)

This page may be used for granting users access to this project and for managing the user privileges of those users. You may also create roles to which you may assign users (optional). User roles are useful when you will have several users with the same privileges because they allow you to easily add many users to a role in a much faster manner than setting their user privileges individually. Roles are also a nice way to categorize users within a project. In the box below you may add/assign users or create new roles, and the table at the bottom allows you to make modifications to any existing user or role in the project, as well as view a glimpse of their user privileges.

4.2 Customize User rights (for persons obtaining consent):

Click on user rights on the main page left hand side under Applications (see above)

Make sure Edit survey responses are checked (see below)

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Scroll down to make sure Record Locking customization and Locking/Unlocking with E-signature authority are both checked (see below)

4.3 Customize and Manage Locking/E-signatures

Click on customize and manage locking and E-signatures under application in the main page left hand side

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Check "Also display E-signature option on instrument?" (for consent document only)(see below)

4.4 Survey Notifications:

Under Designer which is on the left side of the page under Project Home and design click on survey notifications

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Make sure emails of persons who need to get notification when a consent has been completed by a patient are selected

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HOW TO CONSENT A PATIENT USING ECONSENT:

4.1 In the main project page click on add/edit record

4.2 Click on study details

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NEW Record ID **1**

Data Collection Instrument	Status
Study Details	⊙
English Consent Document HSC-MS-20-1234 (survey)	⊙
Informed Consent Documentation	⊙

4.3 Add all fields and complete the form and click on save and go to next form

Form Status

Complete?	Complete ▼

Save & Exit Form | Save & ... ▼

-- Cancel --

Save & Stay
Save & Go To Next Form
Save & Exit Record
Save & Go To Next Record

4.4 Click on compose survey invitation on drop down menu(survey options)

Actions: 📝 Modify instrument   📄 Download PDF of instrument(s) ▽   📹 VIDEO: Basic data entry

📄 **English Consent Document HSC-MS-20-1234**

Invitation status: ✉   📧 Survey options ▽

📝 Editing existing Record ID **1** (BD001)

Record ID	1
Patient Study ID	BD001
Consent Document	

↪ Open survey

↪ Log out + ↪ Open survey

✉ Compose survey invitation

🖊 Survey Access Code and
▦ QR Code

4.5 Survey invite:

- From email:this should automatically appear depending on who logged into redcap
- To email:you can select this form the drop down menu
- **You can type your invite to the particpant in the box but make sure everything below "please take survey" remains as is

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- Send invite

Leave page

4.6 Participant will now get the email to sign consent

Once patient completes the form make sure they click on add signature and sign the form click on date and time and click on next page
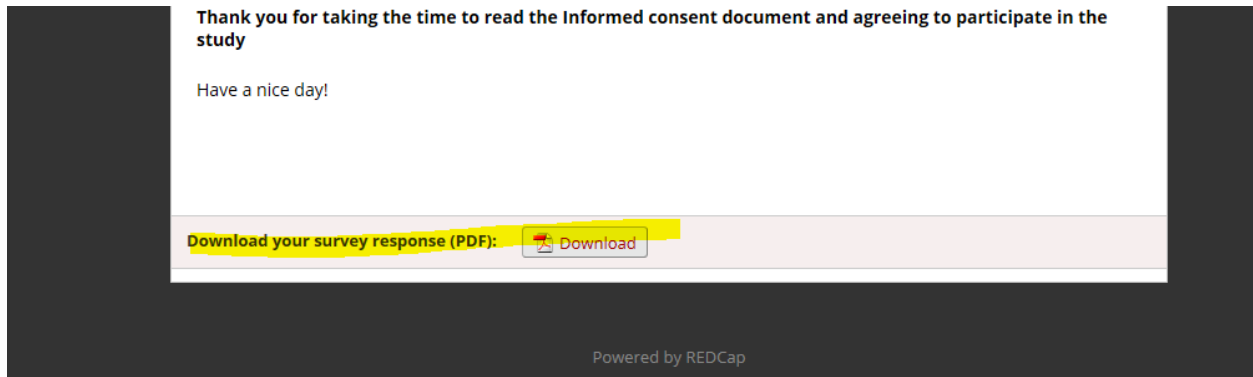
4.7 Patient will be asked to certify that everything they have entered is correct and then submit

4.8 The patient can then chose to download the consent with their responses here(please note this will not have the signature of the person obtaining consent)

Thank you for taking the time to read the Informed consent document and agreeing to participate in the study

Have a nice day!

Download your survey response (PDF):   📄 Download

Powered by REDCap

4.9 Once the patient submits the consent the person obtaining consent will get an email notification
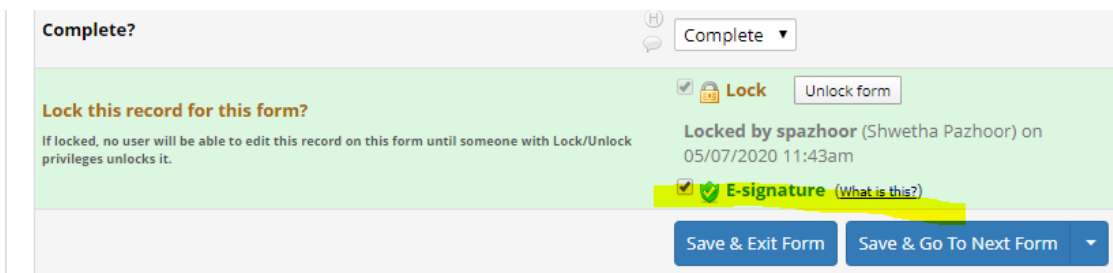
5.0 Person obtaining Consent

5.1 Click on the link and sign into redcap-this will take you to the signed consent form-check the form and click on lock at the bottom of the page
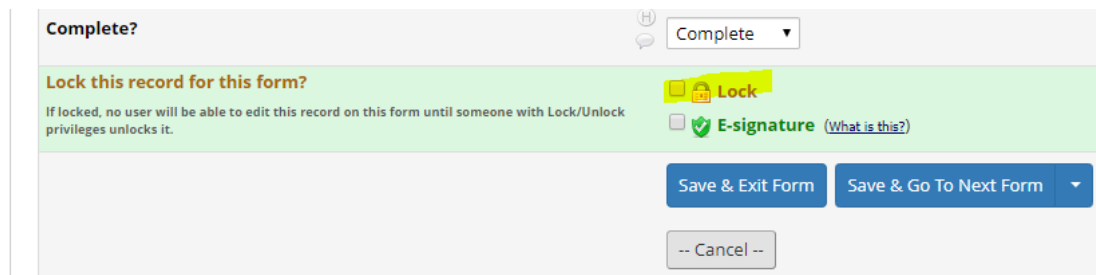
Then ok and close

5.2 Go back to bottom of page and click on E-signature

5.3 Save and go to next form

You will have to log in to REDCap again(to confirm your e-signature)

6.0 Complete Informed Consent documentation form

Once all three forms are complete it will appear green like this:

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Click on record status dashboard to see the list of all your patients

7.0 Click on the consent instrument and download pdf instrument drop down menu to download the signed ICF

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******************************STOP HERE******************************

9.0 Moving your project t to production:

Once you have tested your project and are ready to move into production go to the project set up page

Scroll to the bottom of the page and click on move to production

Once the project is in production you have to enter in =to draft mode to make any changes and submit for approval.