

How to Use the MUSC eConsent Project Template in REDCap

Who Can Use the Template

The REDCap MUSC eConsent Project Template is a database to be used by those who have approval from the IRB to collect the consent and HIPAA documents for their study electronically, and who choose to use REDCap for that process.

The database contains 3 data collection instruments, one to create the record, one for the study consent, and the third one to create the study HIPAA/Notice of Privacy document. Note that since records are created in the project prior to obtaining consent, the possibility exists that the database will contain completed participant records as well as incomplete records for those cases where consent was not obtained.

How to Use the Template

When using this template, please follow the steps below. If you are new to REDCap and unfamiliar with the basic terminology and features, there are short tutorial videos provided on the REDCap site under the 'Training Resources' tab to help you. "Detailed Overview," "Data Entry Overview" and "Online Designer" are 3 videos that cover much of the basics you will need. If you have a specific question you can submit a ticket for assistance by clicking 'Contact a REDCap administrator' from any REDCap project and completing the survey. Also, as is true for any study database, be sure to test your eConsent database thoroughly while it is in development status, and move it from development to production before collecting actual study data.

Help Is Available

If you need to meet with someone to discuss your project, we offer a one-hour consultation which you can request from the SPARC Request system located at <https://sparc.musc.edu>. Once on the SPARC site select the green SCTR button on the left side of the screen and then the REDCap consultation service for research.

This standard operating procedure document has been uploaded into the first field in the Participant Information Form of the eConsent template and is also available from the Research Toolkit accessible from https://academicdepartments.musc.edu/sctr/tools_links/toolkit_setup.html.

Using the MUSC eConsent Project Template

STEP 1: Create a study folder in REDCap to group your study's databases/projects

A. Create the study folder

- Once on the REDCap site, click "My Projects"
- Click the "Organize" button above the project listing
- Enter the name of your study in the text field displayed
- Click "Add"
- Customize the folder and save

B. Assign study projects to the folder

- To assign an existing project to this folder
 - From the "My Projects" page click the "Organize" button
 - Select the study's folder from the dropdown menu
(Step 2: Assign Projects to Folders)
 - Place a check next to each project assigned to this study folder
- To assign a new project to this folder check the box provided on the "Create New Project" screen

STEP 2: Access and customize the eConsent project template for your study

A. Download the eConsent project template

- Click "New Project"
- Fill in the fields *and* assign the project to its study folder
- Select "Use a template"
- Select "MUSC eConsent Project Template" from the menu
- Click "Create Project"

B. Review the pre-defined settings and set user rights

Settings defined on the Project Setup page:

- Surveys are enabled
- Auto-numbering is enabled

Settings defined on the Online Designer page:

- The Consent and HIPAA documents have been enabled as surveys
- The Survey Queue has been set up to display the HIPAA document when 2 conditions are met: (1) the answer to the HIPAA question in the first instrument is "yes" and (2) the consent document has been submitted. The document will automatically appear once the consent is submitted.

B. Review the pre-defined settings and set user rights (*continued*)

User Rights – Survey Setting

In order to complete the signature-related sections of the consent the person consenting will need to have ‘Edit Survey Responses’ rights so they can log into the database after the consent has been submitted and enter their data under their own netid.

To enable this feature from their user rights page:

- Check the ‘Edit survey responses’ box associated with the consent form
- Click ‘Save Changes’

C. Customize the 3 data collection instruments

From the Project Setup page, click on “Online Designer” to customize the data collection instruments

Edit each of the 3 instruments as follows:

- For Instrument #1 - Participant Information
This instrument consists of 2 required fields and contains a copy of the instructions for this project.
Customize as follows:
 - Edit the eIRB PRO# field by entering your study’s PRO# as the choice for the radio button
 - Return to the list of instruments
- For Instrument #2 – MUSC Consent to be a Research Subject
This instrument consists of descriptive text field placeholders for the consent document, 4 required fields to capture the first and last name, signature and signature date of the participant, 3 fields to capture the full name, signature and signature date of the person consenting and text that will appear only when the signature and date fields associated with both the person being consented and the person consenting are completed. That text states that all signatures are associated with the specific study PRO# which is piped in from the first form, and must appear prior to printing any copies of the consent.
Customize as follows:
 - Save your IRB approved stamped consent document as a JPEG
 - Make sure you have a descriptive text field in the consent instrument for each page of your document so you can upload one page per field– the template provides for 6 pages
 - If your consent has more than 6 pages, copy “consent_p6” make sure the variable field name of the new field is “consent_p7.” Repeat the process if you require more fields.
 - If your consent has less than 6 pages, delete the excess descriptive text fields starting with “consent_p6”
 - Upload the first page of the consent document into the first descriptive text field and select “inline image” for display type

C. **Customize the 3 data collection instruments (*continued*)**

- Repeat the process for each subsequent page
- When the entire document has been uploaded review the form to verify that the pages are in correct sequence and each has the correct IRB approval stamp
- Return to the list of instruments

- For Instrument #3 – Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study (HIPAA)

This instrument consists of descriptive text field placeholders for the HIPAA document including the 'Notice of Privacy Practices', 3 required fields to capture the first and last name, signature and signature date for the participant, 4 fields to capture LAR information if applicable and text that will appear only when the participant signature and date fields are completed. The text states that all signatures are associated with the specific study PRO# that is piped in from the first form. This statement must appear prior to printing any copies of the consent.

Customize as follows:

- Save your IRB approved stamped HIPAA document as a JPEG
- Make sure you have a descriptive text field for:
 - Each page of your HIPAA document so you can upload the document one page per field. These descriptive text fields are to appear before the signatures (3 fields are provided)
 - Each page of the "Notice of Privacy Practices" so you can upload the document one page per field. These descriptive text fields are to appear after the signatures (3 fields are provided)

(See consent instrument instructions above to add or delete descriptive text fields)

- Upload the first page of the HIPAA document into the first descriptive text field and select "inline image" for display type
- Repeat the process for each subsequent page including the "Notice of Privacy Practices"
- When each document has been uploaded review each form to verify that the pages are in correct sequence and each has the correct IRB approval stamp
- Delete LAR-related fields if not appropriate for your study
- Return to the list of instruments

STEP 3: Using your eConsent project to consent a participant – Direct Data Entry by Participant

A. **Create the participant record**

- Select 'Add/Edit Records'
- Click 'Add new record' button to open record home page
- Click the gray icon associated with the Participant Information form

- Select the Study PRO# radio button in the first *data collection* field
- A. **Create the participant record (*continued*)**
- Select response for 'Will a HIPAA document need to be signed....?'
 - Select 'Complete' for form status
 - Save and continue to the next form to access the consent
- B. **Open record-specific consent form as a survey**
From the consent form of the participant record created above:
- Click on the "Survey Options" menu in the upper right corner
 - Select the option to ***log out of the database and open survey***
 - Once the form opens as a survey in a new tab:
 - Close the database tab
 - Ensure that only the survey is accessible
 - Review the consent document with the prospective participant
 - If the prospective participant elects to be a subject for the study they will:
 - Print their name in the text box provided
 - Sign their name in the signature field
 - Click "Today" for the date field
 - 'Submit' the survey to register the consent document into the record and trigger the HIPAA form if applicable
- C. **Open record-specific HIPAA as a survey (if applicable)**
By default the HIPAA survey will open automatically
- Review the HIPAA document with the prospective participant
 - If the prospective participant agrees to the terms in the HIPAA document they will:
 - Sign their name in the signature field
 - Click "Today" for the date field
 - 'Submit' the survey to register the HIPAA document into the record
 - The statement: "The above signatures are in association with study: [PRO# entered in the first form appears here]" will now appear at the bottom of the form "
 - Close out the survey

STEP 4: Using your eConsent project to consent a participant – Entry by Person Obtaining Consent
Once the consent survey and HIPAA (if applicable) have been submitted the person obtaining consent will:

- A. **Complete the consent form**
- Log back into the eConsent project
 - Select "Add/Edit Records"
 - Access the current prospective participant's record home page
 - Click on the consent form icon

- Click “Edit Survey Responses” to activate the page
- A. **Complete the consent form (*continued*)**
- Print name in the text box provided
 - Sign name in the signature field
 - Click “Today” for the date field
 - The statement: “The above signatures are in association with study: [PRO# entered in the first form appears here]” will now appear at the bottom of the form
 - Save the record
- B. **Print a PDF version of signed documents (OPTIONAL)**
- Return to prospective participant’s record home page
 - Click on “download PDF of instruments(s)” menu at top of page
 - Select “this data entry form with saved data” to create the PDF
 - Print the document
 - Repeat process to print HIPAA for participant if needed

Note: To mimic the process of modifying data on a hardcopy that includes a line through the original data element and entering the new data with initials and a date, use the Field Comment Log when editing data elements in the eConsent project. [For information on the Field Comment Log see “Data Resolution Workflow” under the “Help & FAQ” tab in REDCap].

STEP 5: Creating an Amended eConsent REDCap Project for the study

- A. **To mitigate the possibility of using an outdated consent, archive the obsolete database**
- Storing the data with other study documents (Optional)
If you choose to store the data from the obsolete consent database with other study data, you can export the report created in the project template and download a PDF of all records. These steps must be carried out prior to archiving.
 - To archive:
 - From the ‘Project Home’ page of the existing eConsent project, select the ‘Other Functionality’ tab
 - Click ‘Archive the Project’ to remove it from the ‘My Projects’ list and take it offline
 - Click ‘Archive the Project’ on the popup screen
- B. **Create a new eConsent REDCap project**
- Follow the process outlined above in STEP 2 to create an eConsent project and assign to the study folder

B. **Create a new eConsent REDCap project (*continued*)**

- Reminder: The Survey Queue has been set up to display the HIPAA document when 2 conditions are met: (1) the answer to the HIPAA question in the first instrument is “yes” and (2) the consent document has been submitted. The document will automatically appear once the consent is submitted.
- Since the obsolete eConsent REDCap project has been archived, there should now only be one eConsent database in your REDCap study folder.