

INSTRUCTIONS FOR USE OF PEPPER E-CONSENT REDCAP PROJECT

This guidance provides specific instructions for the use of the PEPPER eConsent REDCap project for your site. It also includes information about an additional REDCap project “playground” which is a generic copy of the site-specific project that you will use to e-consent patients into PEPPER.

Please read these instructions carefully. We have tried to anticipate questions or problems you encounter, but if this guidance does not adequately answer your questions, please email/call us for additional support¹.

More general instructions for how to incorporate e-consenting into your workflow is available separately.

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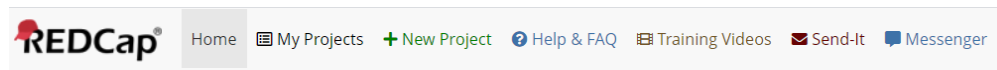
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Field Code Changed

Introduction to REDCap

REDCap is a secure and HIPAA-compliant web application for building and managing online surveys and databases, developed specifically for research purposes by Vanderbilt University. The PEPPER study uses the version of REDCap that is licensed to and managed by the Medical University of South Carolina and is supported by MUSC's Biomedical Informatics Center. Additional information about REDCap can be found at <https://projectredcap.org>. After you have logged in at <https://redcap.musc.edu> additional help is available in [Help & FAQ](#) and [Training Videos](#).



Structure of the PEPPER eConsent Project

The PEPPER eConsent project utilizes the same basic structure and functionality present in the PEPPER 6-Month Follow-Up Survey Project, with the addition of web-based surveys. You will initiate emails sent from within the project to “invite” recruited patients to complete the consenting process, provide their contact information, and complete baseline forms using online surveys, rather than the typical collection of paper instruments in a clinical environment.

Each participant record comprises 4 instruments (5 if your site uses a separate HIPAA form or you are required to also obtain the surgeon's signature). Each one is an electronic version of its paper analog, and is consistent with the structure and layout of the fields in Statix:

1. ***Participant Info: To be completed by COORDINATOR***
This instrument contains minimal information required to identify the patient, including the PEPPER participant ID (assigned during prescreening in Statix), whether the participant is being enrolled based on a hip or knee surgery (used to determine the questions assigned on the baseline form), confirmation of the IRB approval number (required by MUSC's IRB), and whether a separate HIPAA is required for a valid consent (defaulted to “yes” or “no”, as appropriate).
2. ***CONSENT TO BE A RESEARCH SUBJECT***
Developed as an online survey. Specific instructions for patient completion and coordinator counter-signature are detailed below.
3. ***Authorization to Use of Disclose (Release) Health Information that Identifies You for a Research Study***
Developed as an online survey. Specific instructions for patient completion are detailed

below. Note: this instrument is only relevant for a small number of sites so will not be available for all sites.

4. **Contact Information**

Developed as an online survey, for participant completion. Key fields necessary to contact patients at the 1-, 3-, and 6-month follow-ups are required (consistent with those required in Statix).

5. **Baseline Survey**

Developed as an online survey, for participant completion. Key fields are required, consistent with those required in Statix.

Logging in to the PEPPER eConsent Project

Log in to REDCap at <https://redcap.musc.edu> using your MUSC-issued netID. In the **My Projects** view you should see 2 versions of the **PEPPER eConsent** project:

1. **PEPPER eConsent Playground**

This is a generic version of your site-specific project. You are free to use this project as you see fit, in order to become more familiar with the structure, test out the functionality, and practice the steps necessary to guide a patient through the consenting and baseline data collection process.


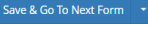


Please do not enter any real patient data in this “playground” project.

2. **PEPPER eConsent–YOUR SITE NAME**

This project must be used to consent all new participants, and to collect their contact information and baseline data. Per MUSC’s IRB, every site has its own iteration of this project, and every iteration contains the site-specific approved ICF (and HIPAA, if appropriate). Other aspects of the project have also been configured to reflect site-specific characteristics.

If you do not have a netID or for any other reason cannot follow the remainder of these instructions, refer to the section below: [Troubleshooting REDCap/eConsent Project Access](#).

E-Consenting a New Patient into PEPPER

1. Log into REDCap, and select the **PEPPER eConsent–YOUR SITE NAME** project in **My Projects**.
2. On the R side of the screen, select **Add / Edit Records**.
3. Select 
4. Select the grey button to the right of the first instrument **Participant Info: To be completed by COORDINATOR**.
5. Enter the participant ID (assigned during prescreening in Statix), and other information relevant to the study and participant. All fields in this instrument are *required*. Change the Form Status to **Complete** and select .
6. Scroll up to the top of the instrument and select  then .
7. A pop-up window will appear with the title **Send Survey Invitation to Participant "X"**². In the **Compose message** section:
 - a. In the *From:* field, select your email address.
 - b. In the *To:* field, enter the patient's email address.
 - c. In the *Subject:* field, add an appropriate title, eg. "Your PEPPER participation", or similar.
 - d. Send the invitation. You will see a pop-up notification confirming the email invitation was sent, including the patient's email address, and the date and time (see below for an example).



² The ID number in the title is the internal REDCap ID, and not the PEPPER ID entered into the first instrument.

8. Instruct the patient to open the email and select the link. They will see an online survey version of the ICF instrument.
9. Talk the patient through the pages of the consent form, scrolling down towards the bottom of the instrument as you do so, just as you would in an in-person meeting.
10. When you reach the bottom of the form, instruct the participant to complete the fields requiring their first name, last name, signature (not initials), and date. The participant should also respond to a question asking for their consent to future contact for other research³. *The fields used by the coordinator to witness the signature are not visible to the participant. The participant must then submit the survey* (see image below).

The screenshot shows a web form with the following sections:

- Participant first name**: Input field with a red asterisk and "must provide value" below it.
- Participant last name**: Input field with a red asterisk and "must provide value" below it.
- Signature of participant**: Input field with a red asterisk and "must provide value" below it. A green "Add signature" link is visible to the right.
- Date signed**: Input field with a red asterisk and "must provide value" below it. A calendar icon and "Today" button are visible to the right.
- Consent question**: A blue header bar reads "The researcher in charge of this study may want to contact you in the future about other research opportunities. Please initial by your choice below." Below this, the text asks: "The researcher in charge of this study may want to contact you in the future about other research opportunities. Do you agree or disagree to being contacted?" There are two radio buttons: "Yes, I agree to being contacted" and "No, I do not agree to being contacted". A "reset" link is to the right.
- Submit**: A button at the bottom of the form.

11. Upon submission of the ICF, one/more people in your team designated to receive survey submission notifications will receive an email titled **PEPPER e-consent has been completed by XX-XXXX**.
12. When the patient has submitted the ICF:
 - a. Refresh your screen to verify the participant has completed all responses in the ICF;
 - b. **Confirm that all participant responses are complete and accurate.**
 - c. At the top of the instrument, select ;

³ This was added in the event we have another unexpected opportunity to ask for existing participants' willingness to provide additional data (eg. covid-19 sub-study) that is relevant for the success of their surgeries in the PEPPER context. Consistent with HIPAA laws, these data will *not* be shared with others outside of the PEPPER team or existing approved entities.

- d. Then scroll to the bottom of the instrument, and answer the question “*Did the patient complete the ICF completely and correctly?*”

If yes, in the section titled [Signature of PERSON OBTAINING CONSENT](#), add your name, signature, and date to the remaining empty fields.

Please review eligibility criteria and medication contraindications **BEFORE** instructing them to complete the Contact Information and Baseline Survey.

If no, follow the instructions provided in REDCap to create a new record/consent instrument and re-consent the patient.

- e. Change the Form Status to Complete and select [Save & Go To Next Form](#).

If the participant is required to complete a HIPAA, direct the participant to scroll down to the bottom of the survey and provide their name, signature, and date, then Submit their responses.

At the top of the instrument, select [Edit response](#), then scroll down and in the section titled [To be completed by PERSON OBTAINING CONSENT](#) answer the question “*Did the patient complete the HIPAA completely and correctly?*”

If yes, select [Save & Go To Next Form](#) and guide the participant through the Contact Information survey.

If no, follow the instructions provided in REDCap to create a new record and re-consent the patient.

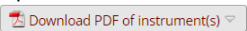
When the ICF/HIPAA are Submitted and Complete

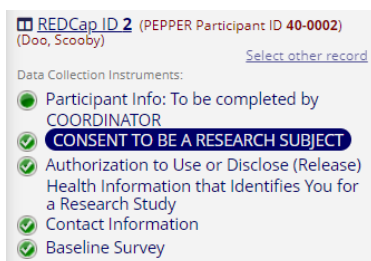
After the participant has submitted the consenting process (ie. ICF, and HIPAA where appropriate) and you have verified these instruments have been completed correctly, you will have to initiate another email invitation for them to complete the Contact Information and Baseline surveys. Follow the steps described above to navigate to the Contact Information instrument and send the participant an email invitation.

At this time, the coordinator may choose to remain on the phone with the patient as they complete the Contact Information survey, and follow the steps above to confirm the validity of the information provided.

When the participant submits the completed Contact Information survey, the Baseline survey will automatically load. Inform the participant that they will need to complete and submit these 2 surveys before closing their browser.

Sending the Participant a Copy of their Completed ICF and HIPAA

1. On the toolbar to the left of the screen, open the participant record using either the Record Status Dashboard or Add / Edit Records.
2. Open the CONSET TO BE A RESEARCH SUBJECT instrument, and select  then [This survey with saved data](#) to download and save the completed consent form. If appropriate, repeat on the HIPAA instrument. Email these documents to the participant.



Reviewing Participant Records

Data is only viewable to the coordinator when the participant has submitted the relevant survey and the coordinator has refreshed the browser. The coordinator must remain on the phone with the participant to ensure these documents are completed correctly and to provide a witness signature/date during the consenting process, and may choose to remain on the phone to provide additional support/direction while the participant completes the Contact Information form and Baseline Survey.

You can review submitted data in several different ways:

1. Review responses within the participant record:
 - a. If you remain on the phone with the participant to provide additional support, you can refresh the relevant instrument in REDCap *after* they submit their responses. If you need to update something on behalf of the participant (eg. an incorrectly entered

street name), see the section below on Updating Information Submitted by the Participant.

- b. If you are still inside the participant’s record, use the participant-specific information in the task bar to select the instrument you want to review.
- c. If you have closed the participant record, use the Record Status Dashboard or Add / Edit Records to locate and open the participant record, then navigate to the appropriate instrument.

Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Dashboard displayed: [Default dashboard] [Create custom dashboard](#)

Displaying record Page 1 of 1: "1" through "45" of 45 records ALL (45) records per page

[Add new record](#)

Displaying: Instrument status only | Lock status only | All status types

REDCap ID	Participant Info: To be completed by COORDINATOR	CONSENT TO BE A RESEARCH SUBJECT	Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study	Contact Information	Baseline Survey
1 PEPPER Participant ID 40-0001 (Doodle, Vankees)	Complete	Complete	Complete	Complete	Complete
2 PEPPER Participant ID 40-0002 (Doo, Scooby)	Complete	Complete	Complete	Complete	Complete
3 PEPPER Participant ID 40-0003 (Baw, Vigi)	Complete	Complete	Complete	Complete	Complete
4 PEPPER Participant ID 40-0004 (Dng, Standy)	Complete	Complete	Complete	Complete	Complete
5 PEPPER Participant ID 40-0005 (Phone, Hong Kong)	Complete	Complete	Complete	Complete	Complete
6 PEPPER Participant ID 40-0006 (pellegrin, Vincent)	Complete	Complete	Complete	Complete	Complete
7 PEPPER Participant ID 40-0007 (Backs, Monica)	Complete	Complete	Complete	Complete	Complete

Add / Edit Records

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, click the button below.

Total records: 45

Choose an existing REDCap ID:

[Add new record](#)

Data Search

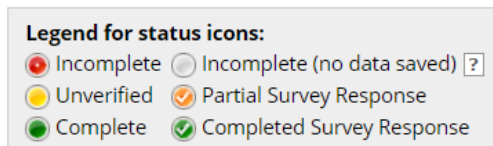
Choose a field to search (excludes multiple choice fields):

Search query
Begin typing to search the project data, then click an item in the list to navigate to that record.

2. Review their data in a report. There are 4 reports pre-designed and available for you to use to review your participants' data.
 - a. **PEPPER e-consent participants (PRO0005374, ICF v.XXXX)** lists all participants by PEPPER ID with their ICF signature and date.
 - b. **Survey completion status** lists all participants by PEPPER ID with the status of each instrument.
 - c. **Pts with missing contact information** lists participants with one or more missing *required* variables in the Contact Form. If participants attempt to submit without completing all required fields, they will be prompted to provide the missing data, and all existing data will be saved. But these fields are the minimum required in order for Statix to reach out to them during the follow-up windows, so if the participant fails to provide these, please reach out to collect this information.
 - d. **Baseline data, all participants** lists all baseline responses. For more detailed review, use the *Data Exports, Reports, and Stats* tool to export the instrument to Excel (contact Carol for additional information).

There may be other reports available to you, if you have requested a specific report type to assist in managing/monitoring e-consent participants and their data, or if the CCC has created on in the process of testing/monitoring.

3. Review the completion status of instruments and participant records by reviewing the Record Status Dashboard. Each instrument is represented by a colored dot; each color represents a different status according to the following legend.



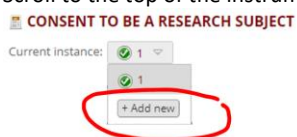
Troubleshooting: Consent/Data Collection

Patient fails to complete the ICF/HIPAA correctly

The IRB does not permit coordinators to edit information provided by participants on the ICF or HIPAA forms.

Instead, follow the instructions below to initiate a new consent instrument/survey:

1. Select **Save and Stay to remain on the incomplete consent**;
2. If you are reminded that some fields are required, select **"Okay"**;
3. Scroll to the top of the instrument and generate a new instance of the consent;

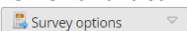



4. Re-consent the patient following the instructions provided above.

Patient fails to complete all surveys

By default, the submission of an instrument will automatically result in the participant viewing the next survey in sequence. I.e. ICF → HIPAA → Contact Information → Baseline Survey.

If the participant closes the survey/browser window and requires a new invitation, you can initiate a new email and survey link in any instrument *that has not already been submitted* by selecting

 and composing a survey invitation as described above under [E-Consenting a New Patient into PEPPER](#), item 6.

If the participant has *partially* completed a survey before submission and missing field need to be completed, you cannot resend the same survey. Instead, contact the participant by phone and talk them through the remaining items, then add their responses. Select  at the top of the relevant instrument in the participant record to complete missing fields. Make sure you **SAVE** the instrument before navigating to a different instrument or closing the record.

Information Submitted by Participants is Incorrect/Inaccurate

Incorrect or inaccurate information on the Contact Information survey or Baseline Survey *may* be corrected by the coordinators if: 1. the participant has agreed to your changing the information; *or* the participant is unable to complete the Contact Information or Baseline Survey themselves (eg. navigating the survey using a mouse is challenging, or they are unable to clearly read each question) and you are reading the questions to the participant and entering their responses in real time.

Each time you made a change to a non-empty field you will be required to provide a reason for the change and this data becomes part of the audit trail.

Troubleshooting: REDCap/eConsent Project Access.

If you cannot access the PEPPER eConsent project in REDCap, answer these questions and follow the appropriate steps below:

Q1. *Do you have an MUSC netID?* If yes, go to Q2, else...

NetIDs are issued directly from MUSC at our request, in an email titled "MUSC External Affiliate NetID Information", and have the format *abc123*, where *abc* are the first 2 letters of your first name and the first letter of your last name, and *123* is a 3-digit number, eg. Monica's netID is mob200.

Q2. *Have you set up your netID password?* If yes, go to Q3, else...

If you still have the notification email with your netID assignment, you can follow the link in that email to set up your password.

Q3. *Have you forgotten your netID password?* If no, go to Q4, else...

Call 843-792-9700 and say that you are an external affiliate and have forgotten your netID password, and ask for a password reset to be sent to you.

Q4. *Have you registered to use REDCap at MUSC?* If yes, go to Q5, else...

Your netID allows you to pass MUSC's security firewall and gives you access to certain tools, but you must still register for REDCap use at redcap.musc.edu so that we can give you permission to access the eConsent project. Once you have registered, send us an email letting us know.

Q5. *Can you log in to REDCap but, but are unable to see the **PEPPER eConsent** project in **My Projects**?*

Send an email to Carol, Laura, and/or Monica (email addresses on page 1) and we will give you access to both the **PEPPER eConsent Playground**, and your site specific project.