PEPPER Six-Month Follow-up Surveys
REDCAP Project Guidance
Version 2
2/16/2022

This guidance is designed to help you navigate a REDCap database developed specifically to collect 6-month follow up data for those participants who are not reached by Statix. REDCap is a user-friendly platform designed for data capture for research studies and operations. It is in use by over 3,000 institutions in 127 countries, including most of the institutions participating in PEPPER. If you are unfamiliar with REDCap, you can learn more about it at https://projectredcap.org. The 6-month follow up data is of particular importance to the PEPPER trial, since the study endpoints include all-cause mortality and other significant health outcomes (eg. myocardial infarction).   The "**PEPPER 6-MONTH FOLLOW-UP SURVEYS**" project has been designed to facilitate your ability to efficiently collect and record participant data, and includes functionality like branching logic so it is clear what information is required under specified conditions, and reporting to enable you to efficiently monitor your activity and the status of your patients.

Key Functionality to improve your experience:

- Subject ID#s and key characteristics of patients requiring follow up will be pre-populated throughout the course of the trial by the Clinical Coordinating Center.
- The database will prompt you through the necessary questions required.
- Coordinators will be notified as patients are added. We suggest getting into a routine of checking the database periodically. If you notice any discrepancies, please contact your site-specific liaison.
- A small number of basic reports have been created to assist you in contacting and tracking patients; others will be provided per your specifications upon request.

PROTOCOL FOR PATIENT CONTACT

- **Three attempts should be made** (and documented, as described below) to reach the patient.
  A single attempt means that you have called each number listed by the patient on the contact form. (Example: one attempt is defined by calling the home phone *and* cell phone numbers listed in order to reach the patient.)
- Review the preferred contact days/times listed by the patient on their Contact Form.
- Please allow no more than 3 days to pass before making another attempt to reach the patient.
- If you are unsuccessful in reaching the patient directly, please make attempts in the same manner, to reach the alternate contact (if provided on the Patient Contact Form[1]) to verify mortality status.

Log into this website and be sure to save it under your favorites:

https://redcap.musc.edu/

NetID: _____   Password: _____

If you do not have a netID, have forgotten it, or have forgotten your password, contact Monica baczko@musc.edu.

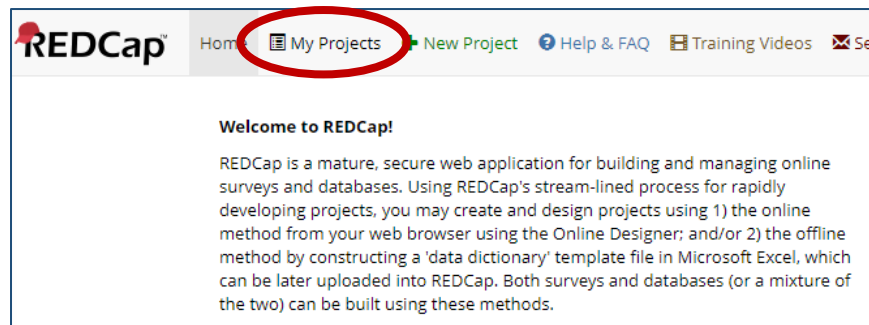[1] Does not apply to patients consented before 11/28/17.

ACCESSING THE PROJECT

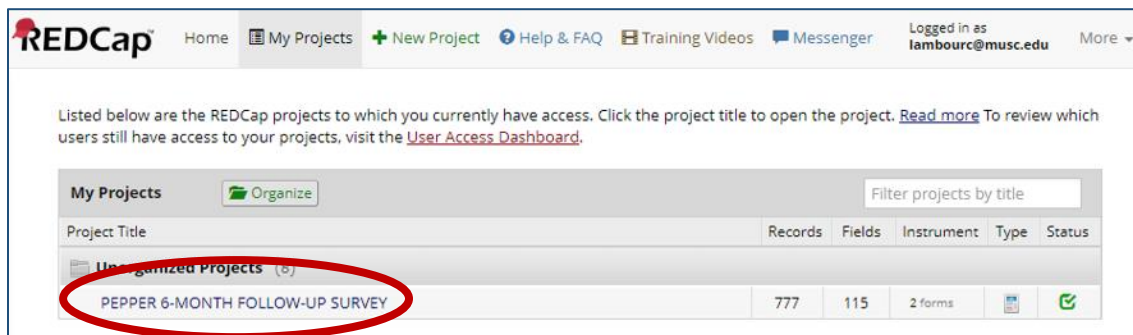1. **Log in as an "MUSC External Affiliate" using your net ID and password**

2. **Click on "My Projects" in upper left hand corner of screen**
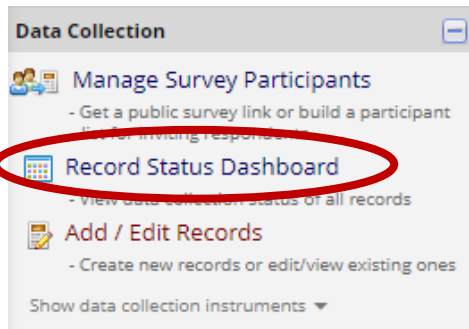   If the project does not appear in Your Projects, contact MUSC.

3. **Select "PEPPER 6-MONTH FOLLOW UP SURVEY"**

ENTERING PATIENT CONTACT AND OUTCOMES DATA

1. **ACCESS PATIENTS in one of three different ways:**

    a. *In the Project Menu bar, on the left side of the screen, select "Record Status Dashboard"*

    This will take you to the pre-populated list of patients who require follow up. Use the REDCap internal ID to select the patient.
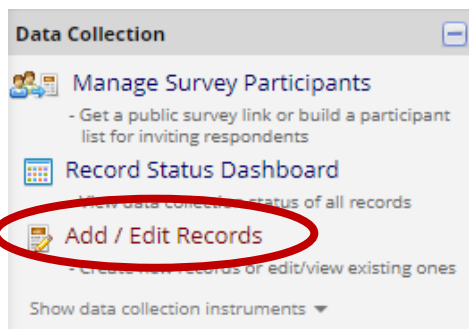

    Blank buttons indicate that no data has been entered;

    RED buttons indicate incomplete data;

    YELLOW indicates unverified data;

    GREEN indicates complete data.
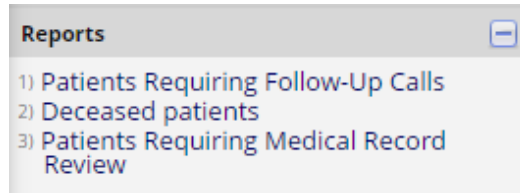
    b. *In the Project Menu bar, select "Add/Edit Records"*

Choose an existing patient by selecting a specific record.

Total records: **777**	
Choose an existing Record ID	-- select record -- ▼

c. *In the Project Menu bar, run a report (**Reports** section).*

Reports ⊟

1) Patients Requiring Follow-Up Calls
2) Deceased patients
3) Patients Requiring Medical Record Review

Select the record you want to update from within the reported data, using the REDCap internal ID.

REDCap internal ID

Record ID record_id	Data Access Group redcap_data_access_group	PEPPER Patient ID pid
10001 (PEPPER Patient ID 40-0002)	PRACTICE	40-0002
10002 (PEPPER Patient ID 40-0003)	PRACTICE	40-0003
10003 (PEPPER Patient ID 40-0004)	PRACTICE	40-0004
10004 (PEPPER Patient ID 40-0005)	PRACTICE	40-0005
10005 (PEPPER Patient ID 40-0006)	PRACTICE	40-0006
10006 (PEPPER Patient ID 40-0007)	PRACTICE	40-0007

Each participant has a *Patient Contact Log* and a *Six-Month Followup Survey*

2. PATIENT CONTACT LOG

If the patient is contacted:

- Mark accordingly in Patient Contact Log
  Enter patient-reported outcomes data. *See 3. Six-Month Followup Survey*

If the patient is not contacted:

- Make 3 documented attempts to reach the patient. Use the Notes fields to document your activity and any relevant information.
- If an alternate contact is listed on the PEPPER Contact Form, make 3 attempts to reach the alternate contact.
- If no contact is made with the patient or alternate contact, **you must complete a review of the patient's medical record** available at your institution
  - *REMINDER: Only look at events within the 6 months following their surgery, as they are related to Reported Events (PE/DVT, transfusion, MI, hemorrhagic event, reoperation, fatal event, sepsis/infection of surgical site, aspiration of joint)*
- When the EMR review is completed, enter the date of review and if any reportable AE's were discovered.

- o If YES → submit appropriate AE form
- o If NO → perform internet search for obituary and copy/paste link into appropriate field

3. SIX-MONTH FOLLOWUP SURVEY

- Start entering data; required questions will populate based on patient responses.
- The appropriate survey will automatically populate based on days since surgery
  - o if within 236 days of surgery, patients will complete the full survey
  - o if beyond 236 days of surgery, patients will complete an abbreviated 12-question instrument

When all appropriate data has been entered, save the form as "Complete" at the bottom of the screen, this will turn the radio button green, and will signal the follow up is finished for the patient.

## SUGGESTED INTRODUCTION WHEN SPEAKING WITH PATIENTS

"*Hello Mr/Ms/Mrs/Dr* [PATIENT NAME], *my name is* [CALLER NAME] *and I am calling from Dr.* [SURGEON NAME]'*s office in regards to the* [LATERALITY] [JOINT] *replacement you had on* [DATE]. *I'd like to ask you a few questions about your recovery after your operation."*

It is important to mention the surgeon and the specific operation in the event that the patient has had multiple surgeries/joint replacements.

When leaving voicemails, please only mention that you are calling from their surgeon's office and are requesting a callback. **You should not leave any protected health information regarding surgery, study participation, etc. in a voicemail.**

PROJECT REPORTING

One of REDCap's strengths is its user-friendly reporting function. During the process of project development, we generated three reports that we think will be helpful during the process of contacting patients and recording this data, as well as their outcomes data. Within the limitations of the data, these can be amended and/or additional reports developed to your specifications, upon request.
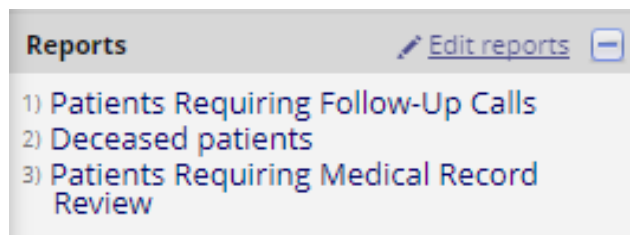
Clinical Coordinating Unit Contact Information

Contact us with any questions or requests

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