UH CRC Research Study Database User Guide

The UH CRC Research Study Database was developed to streamline and standardize the processes required to manage a research project at UH and to improve efficiency. Electronic study start-up forms to help facilitate a faster process and eliminate redundancy, the ability to post enrolling studies on the website, screening and enrollment metrics, electronic tracking of RBNFs, and more are all available within the database.

1. Request access to the “UH CRC Research Study Database” REDCap project by emailing Heather.Tribout@UHhospitals.org. Please provide your department and the names and UH IDs for all personnel needing access to the project for your department.
   - Users will be assigned to a data access group which is the equivalent of their assigned department. This restricts access to only the data that is entered by other users within the same group.

2. Enter your studies into the database by selecting Add / Edit Records in the menu on the left-hand side.
   - The Add / Edit Records page can be accessed directly via this url: https://redcap.uhhospitals.org/redcap/redcap_v8.4.3/DataEntry/record_home.php?pid=510
   - Check the Choose an existing Record ID dropdown menu to make sure your study does not already exist in the database.
If your study is not in the dropdown menu, click Add new record.

REQUIRED FORMS

3. Study Info for UH Website
   - Data from this form will automatically feed to the UH Clinical Trial Finder (https://clinicaltrials.uhospitals.org) when certain conditions are met, so patients and providers can easily find research opportunities.
   - To feed studies to the website, ensure the following conditions:
     ✓ Enrollment Status = “Recruiting: Open to Enrollment”
     ✓ Please post to website = “yes”.
   - When completing the Brief Summary Purpose field, be sure to modify the consent language to be appropriate for the website (i.e., Remove “you are being invited,” and replace with, “The purpose of this study…”)

   - NOTE: The study will not be posted to the website if required fields are not completed, (e.g., IRB number, NCT#, study contact name and phone number)

4. Protocol Information
   - Protocol Information Form contains information necessary to run reports within the database.

5. Study Visit & Billable Protocol Events
   - Enter ALL subjects and their study visits onto this form. Make sure you select the appropriate study from the main dropdown menu first before navigating to this form. (NOTE: only subjects who have signed consent should be entered into this database).
   ✓ This form replaces the current RBNF email or PDF template by having you copy and paste the information you have entered into an email or survey notification to be sent to the ResearchBiller@UHhospitals.org mailbox.
(NOTE: Only studies that require a Coverage Analysis are required to send a notification to ResearchBiller@UHHospitals.org).

✓ A report can be generated from information entered onto this form to act as your study’s enrollment log.

➢ Enter ALL other billable protocol events into this form (ie. SIVs, monitoring visits, audits, etc).

✓ This data can be pulled from REDCap by each department and pasted into a GAIRF to be sent to Grants Accounting to invoice the Sponsor.

6. **Study Contact Info**
   ➢ Contains paragraph boxes so you can easily copy and paste contact information from email signatures directly into the database instead of typing it in.

7. **Drug & Device Info**
   ➢ *NOTE* Fields on this form will not populate until all data is captured on the "Study Info for UH Website" and "Protocol Information" forms. Please complete these forms before entering your drug and device info on this form.

8. **PI Information**
   ➢ ONLY the PI listed on the protocol may complete and sign off on this form.

✓ This form captures COI information, Invention Information, Publication Information, PI Compensation, and Qualifying Status.

**OPTIONAL FORMS & FEATURES**

9. **Protocol Deviation & UAP Reporting**
   ➢ Optional feature that can be used to capture ALL protocol deviations and UAPs for each study.

   ➢ Forms can be routed to the PI for review & signoff *(NOTE: PI must have access to this project to review and sign-off on forms)*.

   ➢ Regulatory Personnel can access the data to pull and submit to the IRB.

10. **AE & SAE Reporting**
    ➢ Optional feature that can be used to capture potential SAEs.
Forms can be routed to the PI for review and signoff (NOTE: PI must have access to this project to review and sign-off on forms).

Regulatory Personnel can access the data to pull and submit to the IRB.

**The following forms are still in development but can be used for data collection and reporting purposes. Please follow the current process for each of these during the IRB submission process:**

### To create a “Screening & Enrollment Log”
1. Select Edit Reports from menu on left-hand side.
2. Select Create New Report
3. Name your report.
   - **STEP 1**: Used to limit who has access to your report.
   - **STEP 2**: in the “-- choose instrument --” dropdown menu, scroll down and select Study Visit & Billable Protocol Events.
   - **STEP 3**: Use the filter to select a certain IRB number (be sure to type this exactly how it appears on the first form in the project).
4. Save Report

### To create a “Protocol Deviation & UAP Log”
1. Select Edit Reports from menu on left-hand side.
2. Select Create New Report
3. Name your report.
   - **STEP 1**: Used to limit who has access to your report.
   - **STEP 2**: in the “-- choose instrument --” dropdown menu, scroll down and select Protocol Deviation & UAP Reporting.
   - **STEP 3**: Use the filter to select a certain IRB number (be sure to type this exactly how it appears on the first form in the project).
4. Save Report

### To create an “AE/SAE Log”
1. Select Edit Reports from menu on left-hand side.
2. Select Create New Report
3. Name your report.
   - **STEP 1**: Used to limit who has access to your report.
STEP 2: in the “-- choose instrument --” dropdown menu, scroll down and select AE & SAE Reporting.

STEP 3: Use the filter to select a certain IRB number (be sure to type this exactly how it appears on the first form in the project).

4. Save Report

General REDCap Tips and Instructions

REDCap Help & FAQs:

REDCap Training Videos:

New UH REDCap Project Request:
https://redcap.uhhospitals.org/redcap/surveys/?s=FM7RM8YHJ7

REDCap User Access Request:
https://redcap.uhhospitals.org/redcap/surveys/?s=KCHECL98KE

*Note: You may only request a new user to one of your own EXISTING projects.

Requesting Access to an existing UH REDCap project:

➢ If you already have a UH REDCap account: contact the departmental personnel who manages the current REDCap project and has access to “User Rights” and request them to add you to the project.

➢ If you do NOT have a UH REDCap account: contact the departmental personnel who manages the current REDCap project and request them to complete the REDCap User Access Request form:

https://redcap.uhhospitals.org/redcap/surveys/?s=KCHECL98KE

For questions/concerns contact: uhredcap@gmail.com or visit: https://redcap.uhhospitals.org/