



*Guidance on using eReg Lite in REDCap to electronically
maintain study regulatory documents that require signatures*

Table of Contents

BACKGROUND	2
CREATING YOUR EREG LITE PROJECT IN REDCAP	3
PROJECT SETUP.....	3
INSTRUMENT 1: STUDY STAFF	4
INSTRUMENT 2: SIGNATURE/TASK DELEGATION LOG.....	4
INSTRUMENT 3: INDIVIDUAL TRAINING LOG.....	4
INSTRUMENT 4: GROUP TRAINING LOG.....	5
LINKS TO ADDITIONAL RESOURCES.....	6

Background

The purpose of this guidance is to provide study teams tools to help create and maintain important components of regulatory documentation for human research studies so that documents that need evidence of valid signatures can easily be managed (signed, shared, saved, and secured) remotely. The Delegation log and training log are examples of important regulatory documents that support the conduct of the study. These documents require signatures of multiple individuals and may need to be updated many times throughout the life of the study, which is difficult to do when working remotely.

We call this REDCap tool “eReg Lite” since it includes only those regulatory documents that need signatures. It is meant to be used in conjunction with other secure storage methods to store regulatory documents that don’t require signatures, such as the investigator brochure (IB), laboratory certifications and normal ranges, CVs, all approved versions of the study protocol, etc. Note that storage of these documents should follow [BMC](#) and/or [BU](#) policies on information management, privacy and security. (Examples of allowable options include Microsoft Teams/Sharepoint for BU and Box for BMC).

This guidance will walk you through the layout of the eReg Lite REDCap project and the intended use for each of the instruments. The instruments were created based on the [Clinical Research Resources Office](#) (CRRO) Delegation and Training log templates which are available on the CRRO website: <http://www.bumc.bu.edu/crro/tools/>.

Please note that these instruments, just like the MS Word templates noted above, are meant to be edited to match the unique needs of your study. This guidance does recommend specific fields that probably should be edited so that it works for your study. If you have any questions regarding how to make certain technical changes, please contact the BU REDCap Helpdesk at: rchelp@bu.edu.

Note: if you plan to maintain some hardcopy documents with wet signatures then it is a good idea to maintain a signature log of wet signatures. If all of the signatures on your study documentation are going to be electronic then this is not necessary.

If you do not have a REDCap account, you must first complete the REDCap User Agreement survey: <https://redcap.bumc.bu.edu/surveys/?s=RYKEW4N4RX>

If you are new to REDCap, see the end of this document for resources, including links to tutorial videos.

If you have comments or questions about this guidance please contact Mary-Tara Roth at the CRRO (mtroth@bu.edu).

Creating your eReg Lite project in REDCap

1. Sign on to REDCap (<https://redcap.bumc.bu.edu/>)
2. Click “New Project” at the top menu.
 - 2.1 Complete Project title, Purpose (research), PI info, Project notes, etc.)
 - 2.2 At the end of the page, choose “eReg Lite” under “Choose a project template” and press the blue “Create Project” button.
 - 2.2.1 This template provides you with a default layout. **You will have to edit the project to meet your study needs and requirements.**

The screenshot shows the 'Create a new REDCap Project' form. The 'Start project from scratch or begin with a template?' section has the 'Use a template (choose one below)' option selected. The 'Choose a project template' section contains the following table:

select template	Template title (sorted by title)	Template description
<input type="radio"/>	Basic Demography	Contains a single data collection instrument to capture basic demographic information.
<input type="radio"/>	Classic Database	Contains six data entry forms, including forms for demography and baseline data, three monthly data forms, and concludes with a completion data form.
<input type="radio"/>	Longitudinal Database (2 arms)	Contains nine data entry forms (beginning with a demography form) for collecting data on two different arms (Drug A and Drug B) with each arm containing eight different events.
<input type="radio"/>	Multiple Surveys (longitudinal)	Contains three surveys and a data entry form. Includes a pre-screening survey followed by two follow-up surveys, one of which is a questionnaire taken weekly to capture participant information longitudinally over a period of... show more

Project Setup

1. The project is set up as a longitudinal study so that there can be two “Arms.”
 - 1.1 Arm 1: Study Staff
 - 1.1.1 Each record represents one study staff. And per record/study staff, one will complete the following instruments:
 - Study Staff
 - Signature/Task Delegation Log
 - Individual Training Log (if applicable)
 - 1.1.2 A Custom Record Label has been set up so that the records are labeled by the study staff member’s first name and last name, which have the respective variables names [f_name] and [l_name]. (see image below)
 - 1.1.2.1 This setting can be found by going to the Project Setup tab, scroll a little to find the Enable optional modules and customizations section and click Additional Customizations.

1.2 Arm 2: Group Training (NOTE: if this section is not applicable to your study, you may disable the longitudinal feature under Main Projects Settings and delete the Group Training Log instrument).

1.2.1 Each record represents one training of a group of staff members.

1.2.2 A Custom Record Label has been set up so that the records are labeled by the date of the group training, which has the variable name [date_train_group].

Set a Custom Record Label

You may append other data and/or static text to any record name (e.g., Study ID) as the record is displayed on your data collection instruments, such as inside the drop-down lists when choosing a record and at the top of the page after being selected. Simply provide the text you wish to display below, and place any variable names inside square brackets [], after which the data collected for those variables for that record will replace the variable in the text. **NOTE:** Since multiple events are defined for this project (i.e. it is longitudinal), **you must prepend the unique event name to the variable name** in brackets - e.g., [baseline_arm_1][last_name]. Smart Variables can also be used here - e.g., [first-event-name][last_name].

Custom Record Label:

Example: if ([last_name], [first_name]) where entered, then for record '102' it would display '102 (Doe, Jon)'.

Instrument 1: Study Staff

1. This instrument is to add basic information about the study staff: first name, last name, degree, and email. Additional fields can be added if necessary.

Instrument 2: Signature/Task Delegation Log

- This is set up as a repeating instrument, which is a setting under Enable optional modules and customizations, so that the log can be updated for that specific staff if their role has changed.
- And each instance of the delegation log has been given a custom label: start date – end date of the delegated role.

Event Name	Repeat entire event or selected instruments?	Instrument name (select instruments to repeat)	Custom label for repeating instruments (optional)
<input checked="" type="checkbox"/> Individual Records (Arm 1: Study Staff)	Repeat Instruments (repeat)	<input type="checkbox"/> Study Staff <input checked="" type="checkbox"/> Signature/Task Delegation Log <input checked="" type="checkbox"/> Individual Training Log	<input type="text"/> <input type="text" value="[start_doa] - [end_doa]"/> <input type="text" value="[date_train]"/>

Signature/Task Delegation Log (2)

1	<input checked="" type="radio"/>	12-01-2020 - 12-04-2020
2	<input checked="" type="radio"/>	12-04-2020 - 04-22-2021

3. The Role on study and Delegated study tasks field lists default roles and study tasks. These fields can/should be edited to meet the study needs.

Instrument 3: Individual Training Log

- This instrument is set up as a repeating instrument, which is a setting under Enable optional modules and customizations, so that multiple trainings can be entered for specific study staff members.
- And each instance of the training log has been given a custom label: date of training.

Event Name	Repeat entire event or selected instruments?	Instrument name (select instruments to repeat)	Custom label for repeating instruments (optional) Example: [visit_date], [weight] kg
✓ Individual Records (Arm 1: Study Staff)	Repeat Instruments (repeat ▾)	<input type="checkbox"/> Study Staff <input checked="" type="checkbox"/> Signature/Task Delegation Log <input checked="" type="checkbox"/> Individual Training Log	<input type="text"/> <input type="text" value="[start_doa] - [end_doa]"/> <input type="text" value="[date_train]"/>

Individual Training Log		
Individual Records (Arm 1: Study Staff)		
(2)		
1		12-04-2020
2		12-29-2020
+ Add new		

3. The Training Topics field lists default topics. This field can/should be edited to meet the study needs.

Instrument 4: Group Training Log

1. As mentioned in the Project Setup section, this instrument is intended to document training of groups of staff members.
2. The Names of Trainees field is set up a checkbox and lists study staff name placeholders. You should go into the Online Designer and edit the checkbox options (Study Staff #) accordingly.

Names of Trainees	<input type="checkbox"/> Study Staff 1 <input type="checkbox"/> Study Staff 2 <input type="checkbox"/> Study Staff 3
--------------------------	--

3. The Training Topics field lists default topics. This field can/should be edited to meet the study needs.

Optional setting: Alerts & Notifications

1. One alert has been set up so that one can be notified when a PI sign off is required for the delegation log.
2. This setting can be found on the left hand side menu, under Applications, look for Alerts & Notifications.
3. It is set up so that when the delegation log form is saved as “Incomplete” ([signaturetask_delegation_log_complete]=1), an email will be sent to the designated recipient, the PI and any other staff member that wants to get the notification. You will specify this in the “Email to” section (see image at step 5).

STEP 1: Triggering the Alert

- A) How will this alert be triggered?
- When a record is saved on a specific form/survey*
 - When a record is saved on a specific form/survey with conditional logic*
 - Using conditional logic during a data import or data entry

B) Trigger the alert...

when "Signature/Task Delegation Log" [Any event] is saved with any form status (excludes data imports)

while the following logic is true:

[signaturetask_delegation_log_complete]=1

(e.g., [enrollment_arm_1][age] > 30 and [enrollment_arm_1][sex] = "1")

[How to use 'stop logic' to disable a scheduled alert](#)

Ensure logic is still true before sending notification? [?](#)

* The alert will not be re-triggered if the form/survey is saved again, unless it is set to send Every time in Step 2 below

4. There are additional settings regarding the alert schedule, which you can modify to fit the study needs.

5. The subject line and message should be edited accordingly as well.

STEP 3: Message Settings

Email From: * must provide value Display name (optional) jung@bu.edu

Email To: * must provide value mtroth@bu.edu
[+ Show more options](#) Or manually enter emails: jane@example.com; john@mysite.org

Subject: * must provide value REDCap: Delegation log PI sign off required

Message: * must provide value

Prevent piping of data for Identifier fields [?](#)

Paragraph **B** *I*

A delegation record was completed for study staff [f_name] [l_name] (record id: [record_id]). Please review and complete the following:

1. Review and confirm that the [f_name] [l_name] has been delegated with the appropriate tasks.
2. Complete PI Approval section (initials and date).

In the subject or message, you may use [Piping](#) and [Smart Variables](#)
Example: Hi [first_name]! Please complete this survey: [survey-link:followup_survey]

[Add attachments](#)

Links to additional resources

Please visit the [CRRO website](#) if you would like to refer to the MS Word regulatory document templates.

Resources for REDCap:

- [REDCap FAQ](#)
- [REDCap Training Videos](#)
- BU REDCap email support: rchelp@bu.edu

- See the “mini-series” within the [Clinical Research Seminars](#) on using REDCap:
 - Oct., Nov, and Dec. 2020: <http://www.bumc.bu.edu/crrro/training-education/past-seminars/>