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

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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.

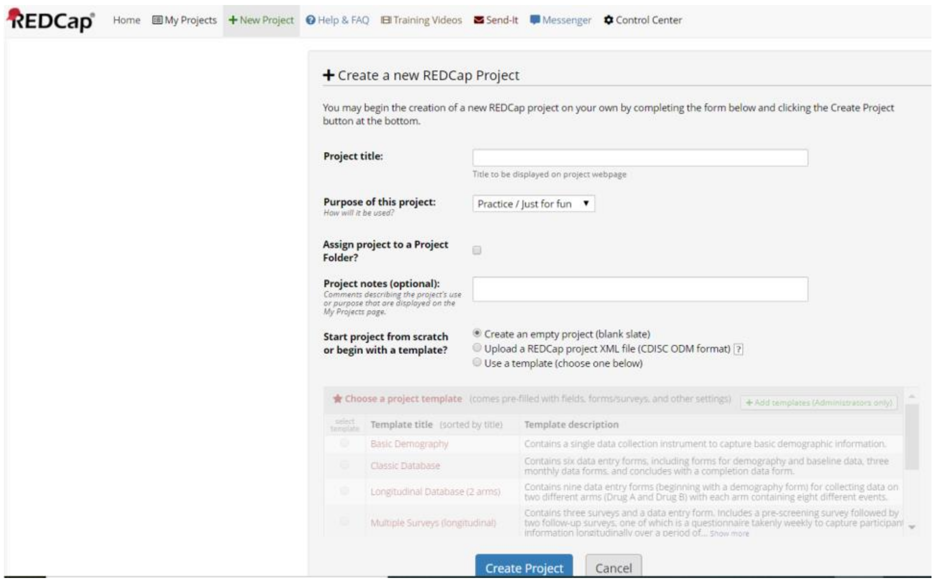
If you do not have a REDCap account, you must first complete the REDCap User Agreement survey: https://redcap.bumc.bu.edu/surveys/?s=RYKEW4N4RX

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.**



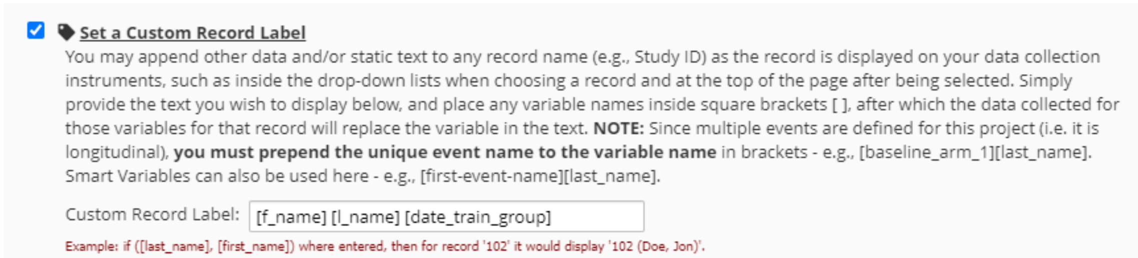
Project Setup

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].

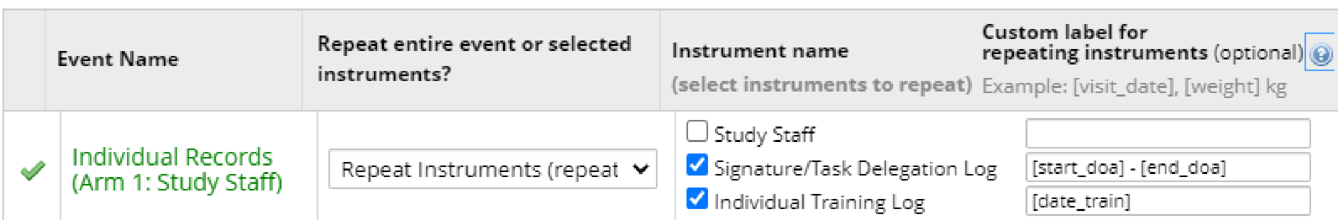


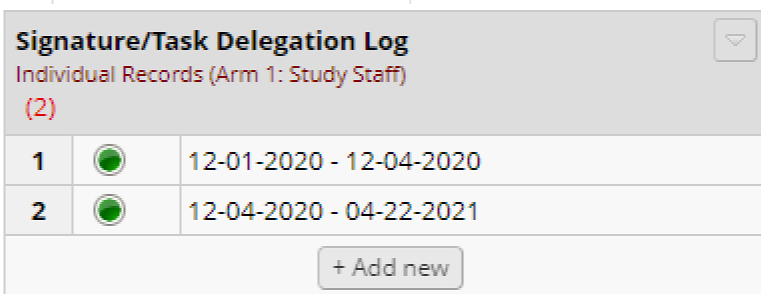
Instrument 1: Study Staff

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

1. 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.
2. And each instance of the delegation log has been given a custom label: start date – end date of the delegated role.

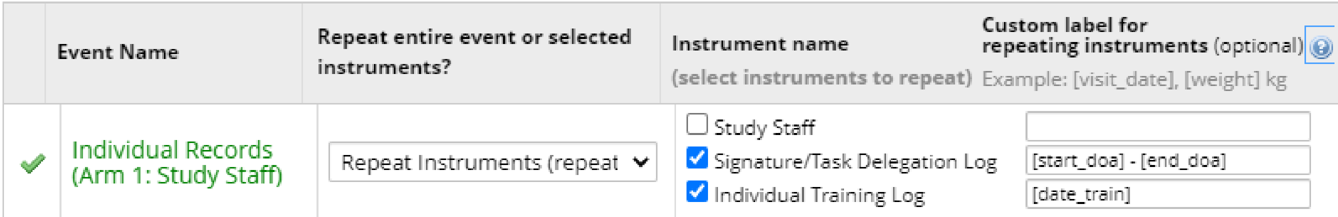


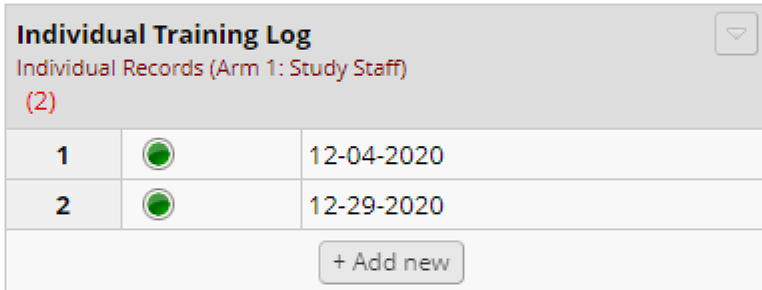


3. The Role on study and Delegated study tasks field lists default roles and study tasks. These fields can/should be edited to meet the study needs.

Instrument 3: Individual Training Log

1. 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.
2. And each instance of the training log has been given a custom label: date of training.

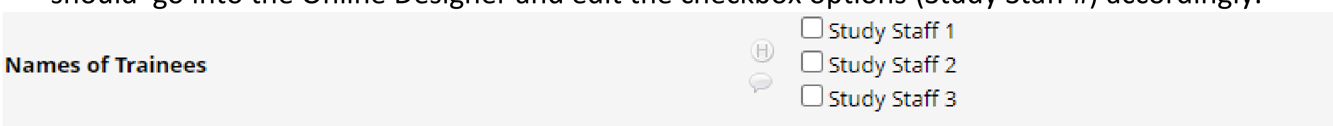




3. The Training Topics field lists default topics. This field can/should be edited to meet the study needs.

Instrument 4: Group Training Log

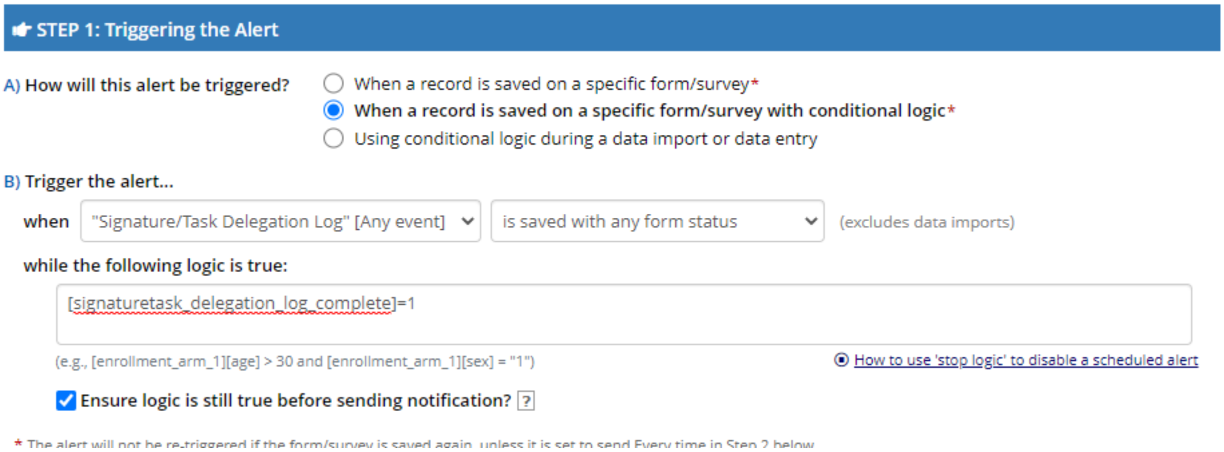
1. As mentioned in the Project Setup section, this instrument is intended to document training of groups of staff members.
2. The Names of Trainees field is set up a checkbox and lists study staff name placeholders. You should go into the Online Designer and edit the checkbox options (Study Staff #)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



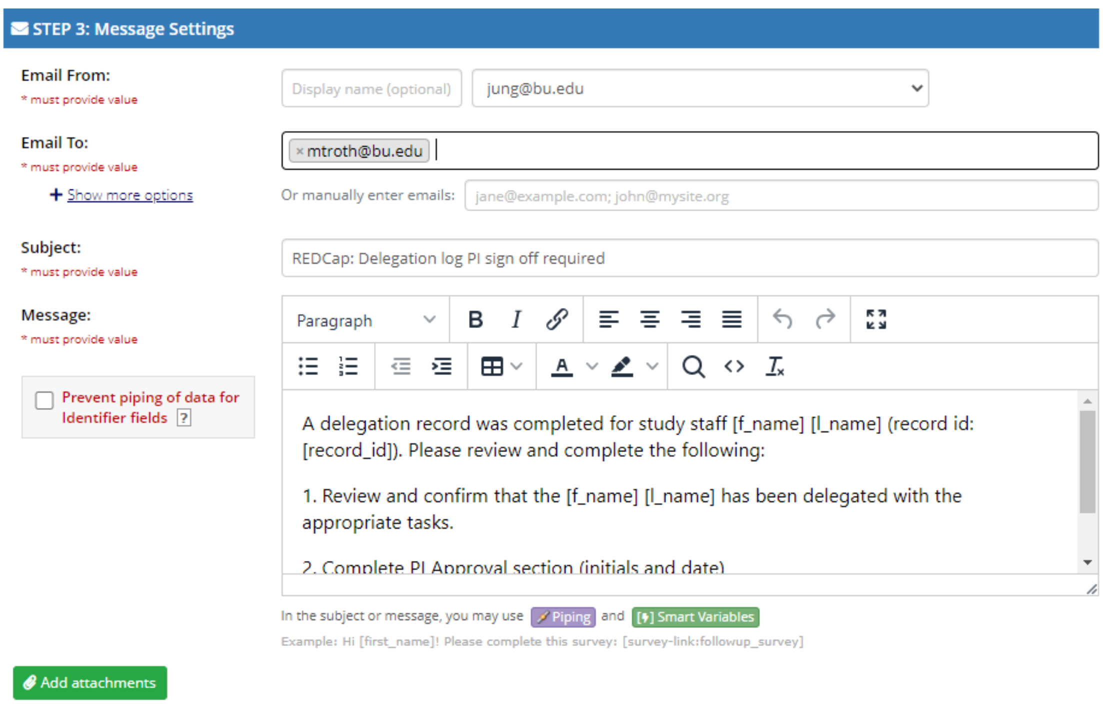
3. The Training Topics field lists default topics. This field can/should be edited to meet the study needs.

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).



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.



Links to additional resources

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

<u>Resources for REDCap</u>:

- 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/crro/training-education/past-seminars/