Electronic Regulatory Binder

Instruction Manual

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I. Introduction to the Electronic Regulatory Binder (eReg binder) Project

The Electronic Regulatory Binder (eReg binder) is a project within REDCap that was developed by Partners Human Research Quality Improvement (QI) Program and Enterprise Research Infrastructure & Services (ERIS). The eReg binder assists sites with the electronic storage and maintenance of regulatory documents for Partners IRB approved protocols. This project is unique in that it contains:

- Data collection instruments that capture required regulatory information similar to what is generally captured in the QI Regulatory Binder for all studies.

- Branching logic that identifies and collects study specific regulatory information, such as laboratory certifications, and FDA forms.

- A report builder for developing site specific reports including delegation of responsibility log, protocol amendment tracking log, and consent version tracking log.

- A calendar for keeping track of due-dates for regulatory documents.

- Ability for the PI to grant different levels of viewing/editing rights for study staff.

General instructions for using this REDCap project to enter and store regulatory information for an IRB approved protocol is enclosed. Review of these instructions is strongly encouraged for first time users. For additional questions and comments related to this project, contact humanresearchqi@partners.org

II. Project Layout (Home Page)

	Left Navigation		Homepage
	Data collection links		Project title
	Applications for managing regulatory documents (e.g. Calendar/Report Builder)*		Intro to Electronic Regulatory Binder project (includes link to instruction manual)
	Built-in links to requirements and QI study management logs (e.g. delegation, protocol version and consent form tracking logs)		Quick summary of tasks*, current users, project statistics and upcoming events
	Site specific reports created using the Report Builder		

* Please note that the options in these areas may be different based on user rights

III. Establish eReg Binder Project for an IRB Approved Protocol

a. *Request New Project*

The eReg binder project is a general template that ***stores and maintains regulatory data for a single IRB approved protocol***. To request a template for an IRB approved protocol:

1. Log-in to REDCap using your Partners username and password
2. Click on the tab titled "Request New Project"
3. Enter a title for the project (e.g. Electronic Regulatory Binder – 0000p000000). Adding the protocol # to the title makes it easy to distinguish between projects.
4. Specify the following information:
   - Project's purpose
   - Requestor's name, department and institution
   - Protocol's IRB status
5. To begin project from the existing template, select the option to **"use a template"**
6. Select the template titled **"Electronic Regulatory Binder"**
7. Click on the "Send Request" button

   You will receive 2 emails after this step. The first email confirms that the request was successfully submitted and the second that the project has been created.
8. Repeat steps 2-7 to request a project for another IRB approved protocol (if applicable)

b. *Open Project*

To open a REDCap project after receiving the email confirmation that the project has been created:

1. Log-in to REDCap using your Partners username and password
2. Under the "My Projects" Tab, click on the applicable eReg Binder project

c. *Manage User Rights (Principal Investigators/Project Managers)*

Principal Investigators/Project Managers can assign different levels of user rights based on staff's delegated tasks. Rights can be granted to access certain applications and/or data collection instruments. **Before data can be entered into project, user rights must be assigned by Principal Investigator/Project Manager.**

1. Open the eReg Binder project

2. Click the application titled "**User Rights**" on the left side of the screen

3. Enter the staff's user name in the "**add new user**" text box

4. Click the "**Add with Custom Rights**" button

5. On the left side of the screen, select the application(s) that apply to the staff. If the default applications do not apply, deselect them. The following table lists applications by delegated task:

Delegated Task	Basic Rights - Applications				
	User Rights	Calendar	Reports & report builder	Create records	Lock/unlock records with e-signature authority
Manage Regulatory Documentation (PI/Project Mgr)	✓	✓	✓	✓	
Sign off on delegated tasks (PI only)					✓
Enter and store regulatory data				✓	
Track due-dates of regulatory documents		✓			

6. On the right side of the screen, assign staff rights to data collection instruments (no access, read only, view/edit)

7. Click the "**Add user**" button to save rights

8. Repeat above steps for additional study staff

d. *Grant Access to External Users*

Access to the eReg Binder project can be granted to external users i.e., employees at other institutions who are listed on the Partners IRB approved protocol as study staff. To request access for external users, Partners Principal Investigators must:

1. Complete the online form "[To Request External User Accounts for REDCap](#)"
2. Click **Submit** at the bottom of the form to confirm the request for external access

IV.   Enter and Store Regulatory Data

Regulatory data is entered and stored in the eReg Binder Project in tandem with IRB reviews to facilitate the retrieval of data and generation of site specific reports.   To ensure the project's accuracy, it's important to enter all reviews (e.g. initial, continuing reviews and amendments) soon after submission and approval.

The eReg Binder project contains 8 data collection instruments (forms), split between two study Arms.   Each time a review is entered into the main "HRC review" form, general information is gathered that facilitates the collection of related regulatory data. Regulatory data is inputted and stored at the same time in the 6 sub-forms linked to a review (Figure 1).
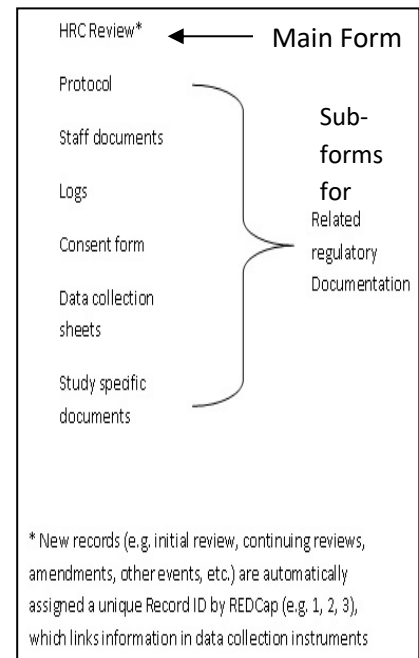
Depending on the HRC review, sub-forms will display certain fields. For example:

Figure 1: Data Collection Instruments (forms)

HRC Review*   ←   Main Form

Protocol

Staff documents

Logs   Sub-forms for Related regulatory Documentation

Consent form

Data collection sheets

Study specific documents

* New records (e.g. initial review, continuing reviews, amendments, other events, etc.) are automatically assigned a unique Record ID by REDCap (e.g. 1, 2, 3), which links information in data collection instruments

If	Fields
Protocol summary was amended	Protocol summary version date, # and copy
Study is funded by an external source (e.g. NIH)	Copy of significant correspondence with sponsor
Written documentation of informed consent	Consent form type, subject population, valid and expiration date
Study involves collection, processing or analysis of specimens	Laboratory name, type, document of qualifications (e.g. CLIA/CAP)

To enter/store regulatory data for an IRB approved protocol:

1. Open the eReg Binder project

2. Click the Add/Edit Records and choose **Arm 1: Protocol**

3. Click the "**Add new record**" button

4. Enter the review information. If you are starting the project, enter the information for the initial IRB review on the **"HRC Review"** form.

5. Identify the form's completion status using the drop down box under **Form Status**

6. Click "**Save and Go to Next form**" to proceed to the sub-form for regulatory data. Note, if the information in the sub-form does not apply to the review, the form will not display the related data entry fields (refer to table in this section's introduction for examples).

7. Repeat steps 5 and 6 to enter/store remaining regulatory data

8. Repeat steps 3-7 for the next HRC review submission (e.g. continuing review/amendment)

To enter study staff information:

1. Open the eReg Binder project

2. Click the **Add/Edit Records** and choose **Arm 2: Staff**

3. Click the "**Add new record**" button on the right side of the screen

4. Enter information for staff member, including their delegation and email address.

5. Repeat steps 2-7 for the next staff member

V. Sign-off on Delegated Tasks (Principal Investigators)

The IRB approved study staff must already be added to the project to sign-off on delegated tasks. If the study staff was not added to the project, refer to the enclosed instructions for entering/storing regulatory data in section IV.

1. Open the eReg Binder project
2. Click the "**Record Status Dashboard**" on the left side of the screen
3. Select Arm 2: Staff and the record that applies to study staff (refer to record list for reviews)
4. Click the data collection instrument titled "**Staff Documents**"
5. Edit/Confirm delegated tasks
6. Check the box to activate e-signature
7. Enter Partners username and password

VI. Develop Reports

The eReg Binder project contains 3 built in reports that approximate QI study management logs for tracking delegation of responsibility, protocol/consent form versions. Additionally, sites can develop reports that query, sort and combine review and regulatory data. These reports can be printed or exported to Excel.

a. Generate QI Study Management Logs

1. Open the eReg Binder project
2. Go to "**Project Bookmarks**" on the left side of screen
3. Select the study management log (e.g. delegation log, consent tracking log, protocol version/amendment tracking log). Note: To view delegated tasks for all study staff, select "All records" from the drop down list

b. *Create Site Specific Reports*

1. Open the applicable eReg Binder project

2. Click the application titled "**Report Builder**" on the left side of screen

3. Enter a name for the report

4. Select the report fields using the field labels in parentheses and (when applicable) any special criteria for field(s).

5. Select the order of results

6. Click the **Save Report** button

VII. Additional Features

a. *Send study staff a survey invite to provide a signature for their study delegation(s)*

1. Using REDCa's Automated Survey Invitation feature, study staff can be sent a survey invite to sign off on their delegated tasks. These can be set or altered by going to the Online Designer page and selecting Automated Invitations:

2. On the Automated Invitation page, the user can edit the following settings:

3. To ensure the survey invitation gets sent out when expected, conditional logic needs to be provided. In the example below, the logic provided refers to a checkbox on the Study Staff instrument being checked off. When that box is checked and the record is saved, the survey invitation gets sent out immediately.

b. *Automatic notifications to Principal Investigator*

Using the Email Notification plugin, IRB approved staff members can receive an email when it is time to log into REDCap and sign off on delegated tasks. To properly set up:

1. Click on the Email Notification link on the left under Project Bookmarks

2. Provide information for the following fields: Title, Logic, To, From, Subject, and Body

3.   Click Save Configuration at the bottom of the screen.

c. *Track Due Dates of Regulatory Documents*

The eReg Binder project has a "calendar alert" feature that allows users to track the due dates of regulatory documents. Once a calendar alert is established, the due date is visible from the eReg Binder Calendar application.   Due dates occurring in a week are also visible from the Project Home page. Any dates in the next few months can be viewed from the calendar itself. To establish a calendar alert:

1.   On the left side of the screen, click on the Project Bookmark titled Calendar Alert
2.   Enter a unique title for the alert (e.g. IRB Expiration Date)
3.   Select the data collection form containing the date (e.g. HRC Review)
4.   Select the date field (e.g. IRB Expiration Date)
5.   Select the time field, if applicable
6.   Add any notes that you would like to appear next to the date in the calendar
7.   Click the option to enable the alert.   This option can be modified at any time during the project.
8.   Click "Save Configuration" at the top of the form to save the alert.   To delete the alert click the red "X" in the upper right of the form. Please note, only dates in records that have a "Complete" status will be transferred to the Calendar application.
9.   To view dates by month or year, click on the application titled "**Calendar**" on the left side of screen. To ensure that regulatory documents are current, the calendar should be viewed often (possibly at the start of every month). To view calendar dates in the upcoming week, go to the "**Upcoming Calendar Events**" section at the bottom of the Project Home page.
10. To create an alert for another date field, click on "Add another calendar trigger" at the top of the form and repeat steps 2-9 (if applicable).

d. *Display Status of All Regulatory Documents*

The Record Status Dashboard provides a snapshot of regulatory documentation by HRC reviews.

1. Open the eReg Binder project

2. Click on the Record Status Dashboard under "Data Collection" on the left side of screen

3. To view/edit regulatory documentation, click the buttons adjacent to the HRC review

e. Search for Regulatory Data

1. Open the eReg Binder project

2. Click on the data collection instrument containing the regulatory data on the left side of screen

3. Select field to search using the field labels in parentheses

4. Enter specific criteria in search query text box

f. Access to Requirements/Additional Resources

Links to federal regulations, institutional policies and Good Clinical Practice guidelines are available under **Project Bookmarks** in the left navigation area. Also included are links to webpages that provide additional tools and resources for maintaining regulatory documents. Some of the links included with this project are:

Links
21 CFR 312
21 CFR 812
Enterprise Research Infrastructure & Services (ERIS)
Good Clinical Practice (GCP) Guidelines
Partners QI Program
PHRC Recordkeeping and Record Retention Requirements
REDCap Knowledge Base Help & FAQ

g. Connecting to other REDCap Projects

Connections can be established to other REDCap Projects that gather data reported to the IRB.

For example, links can be established to other projects that collect information on subject

enrollment, protocol deviations and adverse events for the IRB approved protocol. To create a link to another REDCap project:

1. Open the eReg Binder project
2. On the home page, click the tab titled "Project Setup"
3. Scroll down to the section "Set up project bookmarks"
4. Click on "Add or Edit Bookmarks"
5. Scroll to the end of the bookmark list
6. Enter the REDCap Project's name and url address
7. Use the drop down box next to the url address to change simple link to redcap project
8. Specify if you want the project to be available to all or select users
9. Click the "Add" button to the right of the project's name to add the REDCap project to the bookmark list

h. *Delete REDCap Project*

1. *If the project is in development status*, click the tab titled "Other Functionality" on the Project Homepage then click on the "Delete the project" button. *If the project has moved to production*, send the request to delete the project to edcsupport@partners.org