



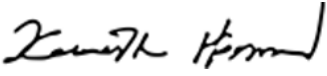

## Standard Operating Procedure: REDCap e-Consenting

SOP Number:	117
Version Number:	3.0
Approved Date:	Dec 4, 2024
Department/System:	Digital Solutions – Data Management /REDCap

### DOCUMENT HISTORY

Version Number:	Summary of Changes Made:	Effective Date
1	New Document	December 16, 2020
2	<ul style="list-style-type: none"> <li>• Branding</li> <li>• Procedural updates</li> </ul>	May 21, 2024
3	<ul style="list-style-type: none"> <li>• Updates to procedures per the Enhanced e-Consent Framework and PDF Snapshot functionality introduced in v14.5.* and updates to resources/links</li> </ul>	December 4, 2024

### APPROVALS

Approver Name	Approver Signature	Date
Kenny Hammond Manager, Research Data Services UBC Faculty of Medicine		Dec 4, 2024
Anastasia Dropol Team Lead, Data Management UBC Faculty of Medicine		Dec 4, 2024

#### 1. PURPOSE



- 1.1. To define the procedure to request and use the UBC Faculty of Medicine (FoM) REDCap to electronically Consent (e-Consent) participants.

## 2. SCOPE

- 2.1. This procedure applies to all FoM Data Management (DM) Team members, Principal Investigators (PI), Project Administrators (PA) and additional identified study/project Team members involved in the set up and use of REDCap for e-Consenting participants.
- 2.2. Electronic Consent (e-Consent) can be used in FoM REDCap projects provided the Research Ethics Board (REB) has approved the use of e-Consent for the project.

## 3. RESPONSIBILITIES

- 3.1. Principal Investigator (PI) and/or Project Administrator (PA) is responsible for enabling the "Enhanced e-Consent Framework and PDF Snapshot" function in the Online Designer page within REDCap to enable e-Consenting functionality on a REDCap survey.
- 3.2. Principal Investigator (PI) and/or Project Administrator (PA) is responsible for ensuring the REDCap project design and data collected is as approved by the REB.
- 3.3. PI and/or PA is responsible for managing User Rights for authorized Project Team members.
- 3.4. FoM DM Team is responsible for providing any ongoing training and support.
- 3.5. The PI and/or PA is responsible for determining which Team members require training, arranging for training, and evaluating whether training objectives have been met

## 4. RELATED SOPS/DOCUMENTS

- 4.1. FoM DM 102 REDCap Project Request
- 4.2. FoM DM 103 REDCap Service Agreement
- 4.3. FoM DM 104 REDCap Project Creation and Initiation
- 4.4. FoM DM 105 REDCap User Accounts
- 4.5. FoM DM REDCap Recommended User Roles

## 5. DEFINITIONS

- 5.1. **Principal Investigator (PI)/Project Lead:** Primary individual in charge of and responsible for the proper conduct of a research project and/or sponsor for non-research projects.



- 5.2. **Project Administrator (PA):** Person responsible for the development of REDCap data instruments and the overall management of the project data.
- 5.3. **Research/Project Team:** Research/project assistants, nurses, data entry and other personnel involved with and granted access to the REDCap project. The Team members report to the PI/Project Lead but are generally directly supervised by the PA.
- 5.4. **FoM Data Management (DM) Team:** Team Lead, Scientific Analyst and other FoM DM individuals responsible for managing projects in REDCap and assisting Research/Project Teams in conducting research studies or projects.
- 5.5. **REDCap Project:** A set of data entry forms, surveys, schedules and other data management tools pertaining to a specific research study or project.
- 5.6. **Electronic consent (e-Consent):** A platform for consenting research subjects either on site or at home using an online consent form rather than traditional paper documentation. Consent forms can be administered through a REDCap survey via computer, mobile phone or tablet.
- 5.7. **Enhanced e-Consent Framework and PDF Snapshot Functionality:** adds two components to a typical REDCap survey:
  - 5.7.1. Before a participant completes the survey, an extra certification page is added to the end of survey that displays an in-line PDF copy of their survey responses in which they will be asked to confirm that all the information in the document is correct.
  - 5.7.2. Upon completion of the survey, a static copy of the survey response is saved as a PDF in the File Repository.
  - 5.7.3. PDF snapshot functionality that can be set-up to daisy-chain forms together (i.e. signed e-Consent survey and counter signature form) based on conditional logic. This is saved as a PDF in the File Repository, in a field (optional) and can also be sent to participants via Alerts & Notifications.

## 6. PROCEDURE

- 6.1. REB-approval for e-Consenting, including all REDCap project design details must be obtained, or at least in the process of obtention, by the Research Team at the time of REDCap e-Consent project request.
- 6.2. e-Consent may be stored in the same project with research data, or in a separate project depending on REB approval (see 'e-Consenting in a separate project: Demo' Project Design Training Materials on the Electronic Data Capture with REDCap section of the Research Technology website). FoM REDCap supports both designs.



### 6.3. e-Consent setup

#### 6.3.1. e-Consent and research data stored in the same REDCap Project

6.3.1.1. Refer to section 6.4.

#### 6.3.2. e-Consent project is separate from the research project:

6.3.2.1. Research project Team requests a new REDCap project (see FoM DM 102 REDCap Project Request).

6.3.2.2. The Research Team must include the word “e-Consent” in the project title.

6.3.2.3. FoM DM Team reviews the project and sends the Research Team a Service Agreement to acknowledge receipt of the new project request. (see FoM DM 103 REDCap Service Agreement).

6.3.2.4. FoM DM Team creates the e-Consent project (see FoM DM 104 REDCap Project Creation and Initiation).

6.3.2.5. PI/PA contacts the FoM DM Team to link projects by the Record ID, and to transfer any requested variables from the e-Consent project to the data project, such as email address, phone number, date of birth, etc. as needed and approved by REB. See ‘e-Consenting in a separate project: Demo’ Project Design Training Materials on the Electronic Data Capture with REDCap section of the Research Technology website.

### 6.4. Enhanced e-Consent Framework and PDF Snapshot functionality

6.4.1. Research Team creates an e-Consent instrument in the REDCap project (*e-Consent 2.0*).

6.4.2. Research Team navigates to the Survey Settings page of the e-Consent form, enables the “e-Consent Framework and PDF Snapshot” function and enables the e-Consent Framework options.

6.4.3. PDF snapshot functionality is activated and defaults to save a PDF after the e-Consent form is signed. This functionality can be further enabled to trigger per specific conditions.

6.4.4. Research teams should make a copy of the signed e-Consent available to participants, either through a download link or an emailed copy.

6.4.5. Instructions for steps 6.4.1 to 6.4.4 can be found on the ‘*e-Consent 2.0*’ Project Design Training Materials on the Electronic Data Capture with REDCap section of the Research Technology website.

## 7. REFERENCE(S)



- 7.1. UBC Office of Research Ethics:  
<https://ethics.research.ubc.ca/sites/ore.ubc.ca/files/documents/E%20consent%20final%20April%2029%20with%20links.pdf>
- 7.2. C&W REB Guidance for Electronic Informed Consent  
<http://www.phsa.ca/researcher/Documents/CW%20Econsent%20Guidance%20May1-2020.doc>
- 7.3. Fraser Health Guidance Notes on the Consent Process  
[https://www.fraserhealth.ca/-/media/Project/FraserHealth/FraserHealth/Health-Professionals/Research-and-Evaluation-Services/Forms-guidance-notes-and-templates/Initial-ethics-submission-forms-and-guidance-notes/2022\\_1018\\_FHGN-Consent-Process.pdf?rev=a1614](https://www.fraserhealth.ca/-/media/Project/FraserHealth/FraserHealth/Health-Professionals/Research-and-Evaluation-Services/Forms-guidance-notes-and-templates/Initial-ethics-submission-forms-and-guidance-notes/2022_1018_FHGN-Consent-Process.pdf?rev=a1614)
- 7.4. BC Cancer Research Ethics Guidance on E-Consent  
<http://www.bccancer.bc.ca/research-ethics-board-site/Documents/Research%20Ethics%20Board/BC%20Cancer%20Research%20Ethics%20Guidance%20on%20E-Consent.07%2009%202020.pdf>
- 7.5. FoM REDCap e-Consent 101:  
[https://rise.articulate.com/share/x24qw7\\_U9dVtIKVRNS3VKtNVCY3\\_aFeW](https://rise.articulate.com/share/x24qw7_U9dVtIKVRNS3VKtNVCY3_aFeW)
- 7.6. REDCap Consortium: e-Consent Framework and PDF Snapshots video  
<https://redcap.link/econsent2vid>
- 7.7. UBC FoM Research Technology website:  
<https://restech.med.ubc.ca>