





## Standard Operating Procedure: REDCap e-Consenting

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### DOCUMENT HISTORY

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1	New Document	December 16, 2020

### APPROVALS

Approver Name	Approver Signature	Date
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#### 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 either on site or off-site

#### 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 Research REDCap projects provided the Research Ethics Board (REB) has approved the use of e-consent for the project.

### 3. RESPONSIBILITIES

- 3.1. The FoM Research DM Team is responsible for enabling the "Auto-Archiver + e-Consent Framework" function in the Survey Settings page within REDCap, upon request. This enables 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 Research DM 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 Research DM 102 REDCap Project Request
- 4.2. FoM Research DM 103 REDCap Service Agreement
- 4.3. FoM Research DM 104 REDCap Project Creation and Initiation
- 4.4. FoM Research DM REDCap User Rights Guidelines
- 4.5. FoM REDCap How to Use the e-Consent Framework

### 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 Research 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 a computer-based consent form rather than traditional paper documentation. Consent forms can be administered through a REDCap survey via computer, mobile phone or tablet.
- 5.7. **Auto-Archiver + e-Consent Framework:** Survey settings option that 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 responses is saved as a PDF in the File Repository.

## 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 the requesting the use of REDCap e-consenting.

If the e-Consent project is a separate project from the research project:

- 6.2. e-Consent Project Request:
- 6.3. Research project Team requests a new REDCap project (see FoM Research DM 102 REDCap Project Request).
  - 6.3.1.1. The Research Team should include the word “e-Consent” in the project title.
  - 6.3.2. FoM Research DM Team reviews the project and sends the Research Team a Service Agreement to acknowledge receipt of the new project request. (see FoM Research DM 103 REDCap Service Agreement).
  - 6.3.3. FoM Research DM Team creates the e-Consent project (see FoM Research DM 104 REDCap Project Creation and Initiation).
- 6.4. E-Consenting Framework



- 6.4.1. Research Team creates an e-Consent instrument in the REDCap project (*See How to Use the e-Consent Framework*).
  - 6.4.1.1. Fields must include consent language, identifier fields, and either a yes/no field or a text box signature field.
- 6.5. Research Team emails the FoM Research DM Team to request activation of the “Auto-Archiver + e-Consent Framework” function, which enables the e-consenting framework.
- 6.6. FoM Research DM Team enables e-consenting framework and notifies Research Team.
- 6.7. Research Team navigates to the Survey Settings page of the e-Consent form and completes the e-Consent Framework options (*See FoM REDCap How to Use the e-Consent Framework*).

## 7. REFERENCE(S)

- 7.1. C&W REB Guidance for Electronic Informed Consent

<https://ethics.research.ubc.ca/sites/ore.ubc.ca/files/documents/E%20consent%20final%20April%2029%20with%20links.pdf>

<http://www.phsa.ca/researcher/Documents/CW%20Econsent%20Guidance%20May1-2020.doc>

[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)