

Standard Operating Procedure:  
REDCap e-Consent

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1	New document	December 1, 2021
2	Change of legal name and logo from BC AHSN to Health Research BC	March 18, 2022

<b>Approver Name</b>	<b>Approver Signature</b>	<b>Date</b>
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## 1. PURPOSE

- 1.1 To define the procedure to request and use REDCap to electronically consent subjects either on site or at home.

## 2. SCOPE

- 2.1 This procedure applies to all Health Research BC DM team members, designated Project Administrators (PA) and Principal Investigators (PI) involved in the set up and use of REDCap for e-consenting subjects.
- 2.2 Electronic Consent (e-consent) can be used in Health Research BC Research REDCap projects provided the Research Ethics Board (REB) has approved the use of e-consent for the project.

## 3. RESPONSIBILITIES

- 3.1 Health Research BC DM Coordinator is responsible for enabling the “Auto-Archiver + e-Consent Framework” function in the Survey Settings page within REDCap, upon request.
- 3.2 Qualified Investigator (QI) and/or Project Administrator (PA) is responsible for ensuring the REDCap project design and data collected is as approved by the REB.
- 3.3 QI and/or PA is responsible for managing user rights for authorized project team members.
- 3.4 Health Research BC DM Coordinator is responsible for providing any ongoing training and support.

## 4. RELATED SOPS/DOCUMENTS

- 4.1 SOP 100 – Health Research BC REDCap New Project Request
- 4.2 SOP 101 – Health Research BC REDCap Adding New Users
- 4.3 SOP 102 – Health Research BC REDCap User Training
- 4.4 SOP 103 – Health Research BC REDCap Service Agreement & Project Creation
- 4.5 SOP 111 – Health Research BC REDCap Project Lifecycle
- 4.6 How to Use the e-Consent Framework – Health Research BC REDCap

## 5. DEFINITIONS

- 5.1 **Principal Investigator (PI):** Primary individual in charge of and responsible for the proper conduct of a research project.
- 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 team:** Research assistants/nurses, data entry personnel and other personnel involved in the clinical research study and granted access to REDCap projects. The Research team members report to the PI but are generally supervised by the PA.
- 5.4 **Health Research BC Data Management (DM) team:** team that is responsible for managing projects in REDCap and assisting research teams in conducting research studies.
- 5.5 **REDCap Project:** A set of data entry forms, surveys, schedules and other data management tools pertaining to a specific study or research 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 e-Consent Project Request: Research project team requests a new REDCap project.
- *See SOP 100: Health Research BC REDCap New Project Request.*
- 6.2. REB-Approval for e-consenting, including all REDCap project design details must be obtained, or at least in the process of obtention, at the time of the request.
- 6.2.1 To easily identify e-Consent projects, the research team should include the word “e-Consent” in the project title.
- 6.3. Health Research BC REDCap DM team reviews the project and sends the research team a service agreement to acknowledge.
- *See SOP 103: Health Research BC REDCap Service Agreement & Project Creation.*
- 6.4. Once the agreement has been signed, Health Research BC DM team creates the e-Consent project.
- *See SOP 103: Health Research BC REDCap Service Agreement & Project Creation.*
- 6.5. Research project team creates an e-Consent instrument in the REDCap project
- *See How to Use the e-Consent Framework – Health Research BC REDCap*

- 6.5.1 Fields must include consent language, identifier fields, and either a yes/no field or a text box signature field.
- 6.6. Research project team requests e-consenting framework to be enabled by emailing [redcap@healthresearchbc.ca](mailto:redcap@healthresearchbc.ca) to enable the “Auto-Archiver + e-Consent Framework” function.
- 6.7. DM Team enables framework and notifies Research project team.
- 6.8. Research team navigates to the Survey Settings page of the e-Consent form and completes the e-Consent Framework options
  - *See How to Use the e-Consent Framework – Health Research BC REDCap*

## 7. REFERENCES

- Health Research BC REDCap Standard Operating Procedures and Documentation:  
<https://www.popdata.bc.ca/researchers/resources/REDCap>