THE UNIVERSITY OF BRITISH COLUMBIA
Digital Solutions
Faculty of Medicine

Standard Operating Procedure:
REDCap Project Creation and Initiation

SOP Number:	104
Version Number:	1.0
Approved Date:	December 14, 2020
Department/System:	Digital Solutions– Data Management /REDCap

DOCUMENT HISTORY

Version Number:	Summary of Changes Made:	Effective Date
1	New Document	December 16, 2020

APPROVALS

Approver Name	Approver Signature	Date
Gurm Dhugga Associate Director, Research & Digital Technologies UBC Faculty of Medicine		December 16, 2020
Ashley McKerrow Team Lead, Data Management UBC Faculty of Medicine		December 16, 2020

1. PURPOSE

1.1.   To define the procedure used for project requirements gathering, creation, and initiation processes for the UBC Faculty of Medicine (FoM) Research Data Management (DM) Team and the Research/Project Team.

2. SCOPE

2.1. This procedure applies to all FoM Research DM Team members, Principal Investigators (PI) and Project Administrators (PA) involved in project creation and initiation.

3. RESPONSIBILITIES

3.1. The Principal Investigator (PI) and/or Project Administrator (PA) is responsible for requesting the project using FoM REDCap Project Request Form.

3.2. The FoM DM Research Team is responsible for the authorization of project creation.

3.3. FoM Research DM Team is responsible for the creation and set up of the project in REDCap, enable and provide project access for the PA user account and REDCap training and consultation for the PA.

3.4. If additional support is requested for project development:

3.4.1. The PI and/or PA is responsible for providing project specific information and documentation for the project requirements.

3.4.2. The FoM DM Research Team is responsible for documentation of project requirements with an estimated timeline and for obtaining required approvals, when necessary.

4. RELATED SOPS/DOCUMENTS

4.1. FoM REDCap Project Request Form

4.2. FoM REDCap User Right Guidelines

4.3. FoM Research DM SOP 101 REDCap Project Lifecycle

4.4. FoM Research DM SOP 102 REDCap Project Request

4.5. FoM Research DM SOP 103 REDCap Service Agreement

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. **Digital Solutions (DS) Systems Team:** Team responsible for the configuration, operation and maintenance of the FoM servers and underlying platforms.

5.6. **REDCap Project:** A set of data entry forms, surveys, schedules and other data management tools pertaining to a specific research study or project.

5.7. **Service Agreement**: The joint contract agreed to by both the FoM Research DM Team and the PI or PA for commencement of work and services related to REDCap project data management as outlined. For clinical trials sponsors this document constitutes transfer of responsibility of duties for services under section 5.2 of ICH E6 GCP as adopted by Health Canada under the Food and Drug Regulations Amendment 1024.

5.8. **Project Lifecycle Tool**: An active, internal project used by the FoM Research DM Team to track the lifecycle of projects and to assist in REDCap data management.

5.9. **Project Requirements**: The documents used by FoM Research DM Team and research Team which details all or part of the project. This may include but is not limited to: the protocol, Case Report Form (CFR) designs, hardware/software requirements, study configuration, study event definitions, Data Management Plan, statistical analysis plan, randomization model, training requirements, support requirements, internal testing plan, and any ongoing developments within the project.

5.9.1. It is noted that some projects may require no additional services from the FoM Research DM Team. It's the research Team's responsibility to document the details of the study.

6. PROCEDURE

6.1. Project Creation

6.2. *This applies to projects with a Service Agreement that has been approved and signed by the PI and/or PA (see* FoM Research DM SOP 103 REDCap Service Agreement*)*

6.3. The FoM Research DM Team creates the project in the database according to the data entered by the PI or PA on the FoM REDCap Project Request Form (*see* FoM Research DM SOP 102 REDCap Project Request)

1.1.1. The DM Team creates the project with predefined user roles and adds their user account to the Research DM Team role.

1.2. Project Initiation

1.2.1. The DM Team adds the PA and/or PI user account to the new project and assigns the user account(s) to the appropriate role(s). (*See FoM REDCap User Rights Guidelines*).

1.2.2. The PA and/or PI is notified by email, that the requested project has been created. Instructions on how to set a REDCap project and links to training material are provided.

1.3. Project Requirements Gathering for Additional Project Development Support

1.3.1. If additional services are requested, the DM Team sets up meetings with the PI and/or PA to further define the project requirements as necessary. Specialized Digital Solutions Systems Team members can be brought in to assist with the definitions and scope of configuration as needed.

1.3.2. The PI and/or PA provides the DM Team with the information required to define the project requirements.

1.3.3. The PI and/or PA and necessary FoM Research DM Team members complete the project requirements to detail requested services. These details are also included in the Final Service Agreement. If the initial agreement has been approved and additional service are requested following approval, an amendment to the original Service Agreement will be created.

1.4. Approval

1.4.1. The PI is fully responsible to review and approve the project requirements before any design work can be initiated by the FoM Research DM Team.

1.4.2. The DM Team is notified of the project requirements and must approve of the requests before the designs are implemented.

2. REFERENCE(S)

2.1. Network of Networks (N2) resources - Network of Networks (N2) Standard Operating Procedures, Version 8. Effective May 2019.