THE UNIVERSITY OF BRITISH COLUMBIA
Digital Solutions
Faculty of Medicine

Standard Operating Procedure:
REDCap Project Request

SOP Number:	102
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 procedures to request a new REDCap project hosted in the UBC Faculty of Medicine (FoM) REDCap.

2. SCOPE

2.1.   This SOP applies to all FoM Research Data Management (DM) Team members involved in project management and Principal Investigators (PI) and designated Project Administrators (PA) involved in the initial request for a new project and support services.

3. RESPONSIBILITIES

3.1.   The FoM Research DM Team is responsible for reviewing project requests and quotes.

3.2.   The PI or PA is responsible for initially contacting the FOM DM Research Team and submitting the REDCap Project Request Form.

3.3.   The FoM DM Research Team is responsible for the creation of requested projects and for providing ongoing training and support to the Research Team.

4. RELATED SOPS/DOCUMENTS

4.1.   FoM Research DM REDCap Project Request Form

4.2.   FoM Research DM SOP 101 REDCap Project Lifecycle

4.3.   FoM Research DM SOP 103 REDCap Service Agreement

4.4.   FoM REDCap Project Request Form

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.   **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.

5.7. **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.

6. PROCEDURE

6.1. PI or PA completes and submits the FoM REDCap Project Request Form. A separate Form is required for each new project, even if there are multiple or copied projects from the same PI or Research Team. The information provided in this form provides basic project information and outlines service resource requirements.

6.2. FoM DM Research Team completes a preliminary review of the request to determine project eligibility based on PI/Project Lead's UBC FoM Faculty membership and project purpose.

6.3. If the project request needs further review, the FoM DM Research Team will discuss the project request with the Associate Director, Research & Digital Technologies.

6.4. Once service terms are approved by the PI or PA, the FoM DM Research Team emails the Service Agreement, through the Project Lifecycle Tool, to the project requestor. Additional copies of the Service Agreement are sent to the PI and PA (*see* FoM Research DM SOP 103 REDCap Service Agreement). Approval of the Service Agreement is required to create the project.

6.5. FoM DM Research Team communicates with the Research Team to provide consultation and training options. For any projects that have been identified to require additional services, meetings will be set-up to discuss details. The meeting is held to determine the services required and provide a general quote if necessary.

7. REFERENCE(S)

N/A