



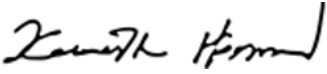

Standard Operating Procedure: REDCap Project Request

SOP Number:	102
Version Number:	2.0
Approved Date:	May 21, 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"> • Branding • General updates to wording 	May 21, 2024

APPROVALS

Approver Name	Approver Signature	Date
Kenny Hammond Manager, Research Data Services UBC Faculty of Medicine		May 21, 2024
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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 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 DM Team is responsible for reviewing project requests and quotes.
- 3.2. The PI or PA is responsible for initially contacting the FOM DM Team and submitting the REDCap Project Request Form.
- 3.3. The FoM Team is responsible for the creation of requested project(s) and for providing four (4) hours of in-kind training support to the Research Team.

4. RELATED SOPS/DOCUMENTS

- 4.1. FoM DM SOP 101 REDCap Project Lifecycle
- 4.2. FoM DM SOP 103 REDCap Service Agreement
- 4.3. 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 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 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 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 REDCap Project Request 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 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 Team will discuss the project request with the Manager, Research Data Services or their delegate.
- 6.4. Once service terms are approved by the PI or PA, the FoM DM 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 DM SOP 103 REDCap Service Agreement). Approval of the Service Agreement is required to create the project.
- 6.5. FoM DM Team communicates with the Research Team to provide consultation and training options upon request. For projects that have been identified to require additional services, meeting(s) will be set-up to discuss details, determine the services required and to provide a general quote if necessary.

7. REFERENCE(S)

- 7.1. Health Canada Food and Drug Regulations Amendment 1024:
<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices/regulations/amending-food-drug-regulations-1024-clinical-trials.html>