



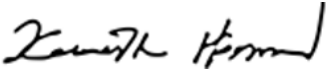

Standard Operating Procedure: REDCap Service Agreement

SOP Number:	103
Version Number:	2.0
Approved Date:	May 20, 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 • Minor changes to wording 	May 20, 2024

APPROVALS

Approver Name	Approver Signature	Date
Kenny Hammond Manager, Research Data Services UBC Faculty of Medicine		May 20, 2024
Anastasia Dropol Team Lead, Data Management UBC Faculty of Medicine		May 20, 2024

1. PURPOSE

- 1.1. To define the procedures for the creation, distribution and approval of a Service Agreement between UBC Faculty of Medicine (FoM) Data Management (DM) Team and a Research/Project Team.



2. SCOPE

- 2.1. This SOP applies to all FoM DM Team members, Principal Investigators (PI) and Project Administrators (PA) involved in the Service Agreement for REDCap support.

3. RESPONSIBILITIES

- 3.1. The FoM DM Team is responsible for supervising REDCap project requests, the Service Agreement process and has the final approval for Service Agreements with additional requests, including agreed upon exceptions.
- 3.2. The Principal Investigator (PI) or Project Administrator (PA) is responsible for reviewing and approving the Service Agreement. “If additional services are requested, the PI is also responsible for signing off on additional work directly with the FoM DM Team.”
- 3.3. The FoM DM Team is responsible for sending the Service Agreement, managing the progress of the Service Agreement review and documenting the outcomes.
- 3.4. The DM Team may consult with REB and/or Privacy for guidance on any project submitted to FOM REDCap.

4. RELATED SOPS/DOCUMENTS

- 4.1. FoM REDCap Project Request Form
- 4.2. FoM REDCap Service Agreement
- 4.3. FoM DM SOP 101 REDCap Project Lifecycle
- 4.4. FoM DM SOP 102 REDCap Project Request

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. Service Agreement Preparation

6.1.1. The FoM DM Team reviews the completed FoM REDCap Project Request Form (see FoM DM SOP 102 REDCap Project Request) to prepare a Service Agreement which:

- Details the agreed upon terms of service between the FoM DM Team and the Research/Project Team
- Outlines responsibilities and scope

6.1.2. The FoM DM Team emails the Service Agreement to the project requestor for acknowledgment and signature via the Project Lifecycle Tool.

6.2. Approval of Service Agreement

6.2.1. The PI, or PA on behalf of the PI, approves the Service Agreement via electronic approval. Once the terms are agreed to, the PI or PA signs the service agreement which triggers an email to the FoM DM Team. The date the email was sent is documented as the date of approval for the Service Agreement. The DM Team creates the requested REDCap project and a copy of the signed Service Agreement is subsequently sent to the PI and the PA.

6.3. Negotiation

6.3.1. If the Service Agreement terms are not accepted, the PI notifies the DM Team that they would like to negotiate the terms of the agreement.

6.3.2. The FoM DM Team, PA and/or PI discuss new terms.

6.3.2.1. If new terms are agreed upon by all, the DM Team will revise the Service Agreement for the project.



- 6.3.2.2. The FoM DM Team may opt not to accept the changes to the Service Agreement. In this case the DM Team notifies the PI by email, copying the PA, and records the rejection details in the Project Lifecycle Tool.
- 6.3.2.3. The FoM DM Team closes the project in the Project Lifecycle Tool. If the project ever resumes with FoM DM Team's involvement, a new process must be initiated.

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>