





Standard Operating Procedure: REDCap Service Agreement

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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
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1. PURPOSE

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

2. SCOPE



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

3. RESPONSIBILITIES

- 3.1. The FoM Research 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 or PA is also responsible for approving any additional services documented in the revised Service Agreement.
- 3.3. The FoM Research DM Team is responsible for sending the Service Agreement and for 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 Research REDCap.

4. RELATED SOPS/DOCUMENTS

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

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

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

6.1.2. The FoM Research 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 the PI or PA signs the service agreement which triggers an email to the FoM Research DM Team. The date the email was sent is documented as the date of approval for the Service Agreement. The DM Team creates the REDCap project and a copy of the Service Agreement is subsequently sent to the PI and the PA.

6.3. Negotiation

6.3.1. If the Service Agreement term 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 Research DM Team, PA and/or PI discuss new terms.

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



- 6.3.2.2. The FoM Research 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 records the rejection details in the Project Lifecycle Tool.
- 6.3.2.3. The FoM Research DM Team closes the project in the Project Lifecycle Tool. If the project ever resumes with FoM Research DM Team's involvement, a new process must be initiated.

7. REFERENCE(S)

N/A