THE UNIVERSITY OF BRITISH COLUMBIA
Digital Solutions
Faculty of Medicine

Standard Operating Procedure:
REDCap Instrument Design and Development

SOP Number:	107
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 in the design, development and quality assurance of Instruments for REDCap projects supported by UBC Faculty of Medicine's (FoM) Research Data Management (DM) Team. The INSTRUMENT Design Team consists of whoever is in charge of designing the forms for the REDCap project.

2. SCOPE

2.1. This procedure applies to all FoM DM Team members, Principal Investigators (PI), Project Administrators (PA) and additional identified Research/Project Team members using FoM REDCap.

3. RESPONSIBITILES

3.1. Research/Project Team is responsible for Instrument preparation, design, development, testing, and revisions.

3.2. Research/Project Team is responsible for the content contribution and review of the Instruments.

3.3. PI and/or PA is responsible for providing the details and requirements of the Instruments and project design to assist with the development and design.

3.4. PI and/or PA is responsible for reviewing and performing quality control procedure on Instruments.

4. RELATED SOPS/DOCUMENTS

4.1. FoM Research DM SOP 101 REDCap Project Lifecycle

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. **Instrument/Case Report Form (CRF):** A print, optical, or electronic document designed to record 'protocol-required information' to be reported to the sponsor on each subject.

5.7. **Clinical Data Acquisition Standards Harmonization (CDASH):** In 2008 the Clinical Data Interchange Standards Consortium (CDISC) released CDASH. CDASH are standardized data collection fields used on Instruments. The CDASH standard provides a set of data collection fields that are divided into sixteen domains, and was designed to be applicable to clinical studies regardless of therapeutic area or phase of development.

5.8. **Common Data Elements (CDEs):** CDEs are standard data collection fields that enable rapid and standardized implementation of data collection across clinical studies. CDEs have been developed by several organizations such as the National Institute of Neurological Disorders and Stroke (NINDS): https://commondataelements.ninds.nih.gov.

5.9. **Data Quality Monitoring:** A set of rules intended to ensure data integrity and improve data quality by bringing attention to data that are out of the expected range, inconsistent, illogical or discrepant. When data meet the predefined criteria of a rule, a flag or warning notifies the PI and/or PA that the data point should be carefully examined to ensure the accuracy of the data point.

5.10. **Data Quality Rules:** rules that can be run on project data to check for discrepancies in a project's data. REDCap includes a set of pre-defined rules and project rules can also be created.

5.11. **Referential Question:** A question where the answer (or lack of an answer) to one or more questions is contingent upon the answer to another question.

6. PROCEDURE

6.1. Instrument Preparation

6.1.1. Research/Project Team meets with the PI and/or PA to discuss Instrument requirements and content. This meeting should take place before the study protocol has been approved, if possible. Clinical Data Management, statistical, clinical, safety, quality, and regulatory personnel will help to ensure that the data collected with Instruments meet the needs of the study from all pertinent perspectives.

6.1.2. Research/Project Team considers the following elements in the content of the Instruments:

- If the project is using any standard questionnaires, use pre-existing Instruments from the REDCap Shared Library whenever possible.

- Standards – Wherever possible, existing standards should be used (e.g. CDASH, or other relevant Common Data Elements)
- Layout – Data fields should be arranged in a clear and easy-to-follow manner. Data that are logically related should be grouped together. Multiple choice answers are preferred to open text fields. Any open text fields must have enough space for the information to be recorded. There should be logical flow to match the way data would be found in source.
- Wording – all questions and prompts should be concise and specific. Leading questions should not be used and questions should be phrased in the positive to avoid potential confusion negatively phrased questions can cause.
- Coding – Data should be collected in coded format whenever possible. Formats include: multiple-choice, yes and no, check boxes and selections lists. This minimizes errors and reduces data processing time.
- Minimal use of referential questions – To minimize potential confusion referential questions should be used after careful consideration. Instructions should note where to skip to and not what to skip.
- Minimized redundancies – Data based on the same measurement should not be collected more than once or in more than one place. Collection of raw data is typically preferable to collecting calculated values. Raw data are also easier to verify from source documents.

6.1.3. PI and/or PA is responsible to check that all necessary licenses and agreements are up to date for any forms to be used and specific copyright requirements are met (examples: forms created by an independent source with prescribed format based on rating Instruments).

6.1.4. Research/Project Team prepares and assigns the annotations and coding, if applicable, for each data element with statistical personnel.

6.1.5. Research/Project Team retains versions and files all preparatory documentation in the appropriate study specific folder.

6.2. Design

6.2.1. Research/Project Team retains a final approved version of all Instruments and files them in the study specific folder.

6.2.2. Research/Project Team identifies and uploads any standard forms from a bank or library of standard forms.

6.2.3. Research/Project Team makes any modifications or drafts of unique forms considering layout, wording, coding, minimal use of referential questions, redundancies in the design of the Instruments and makes recommendations to the Design Team accordingly.

6.2.4. Research/Project Team assigns variable names to each question in the content with meaningful and consistent names, keeping them as short as possible and produces a list of variables. These rules should help interpretation when extracting collected data and conducting any statistical analysis.

6.2.5. Research/Project Team sorts the list of variables into data structures conducive to statistical analysis and logistical flow of the data. This will avoid the need for mapping or conversion at a later time.

6.3. Data Quality Monitoring

6.3.1. PI and/or PA will identify study variables that require particular Data Quality Monitoring.

6.3.2. Research/Project Team will develop Data Quality Rules in REDCap Data Quality Module.

6.3.3. Testers, which may consist of PI and/or PA, and INSTRUMENT design Team will regularly run the Rules listed in the REDCap Data Quality Module and verify all flagged variables and edit data as necessary. All data changes are tracked within the REDCap tracking system.

6.4. Instrument Completion Guidelines

6.4.1. If needed, Research/Project Team writes project-specific Data Entry Instructions, including instructions for completion of Instruments and acceptable methods of correcting or changing the data.

6.4.2. PI and/or PA document training of all personnel with access to the REDCap project.

6.5. Change Control and Versioning

6.5.1. Research/Project Team reviews any requests for Instrument changes with the appropriate members, which usually includes PI and/or PA, statistician, clinical, regulatory personnel.

6.5.2. Research/Project Team implements any approved changes in REDCap in ‘Draft Mode’ following applicable steps in section 6.2.

6.5.3. Research/Project Team reviews the changes with PI and/or PA and, upon approval, pushes the changes to production. REDCap automatically logs the changes in the Project Revision History.

6.5.4. Research/Project Team documents all changes. Each revision must contain a clearly identified version number. A document history note must be created with notation of the changes made, reasons for change. There must also be note made regarding communication to sites if Instruments are changed during the time that a study is active.

7. REFERENCES

7.1. Califf RM, Karnash SL, Woodlief LH. *Developing systems for cost effective auditing of clinical trials*. Controlled Clinical Trials.1997;18:651–660.

7.2. Calvert WS, Ma MJ. *Concepts and Case studies in Data Management*. Cary, NC: SAS Institute Inc; 1996.

7.3. CDISC CDASH Core and Domain Teams. *Clinical Data Acquisition Standards Harmonization (CDASH)*. Austin, TX. Clinical Data Interchange Standards Consortium; 2008. Available at https://www.cdisc.org/standards/foundational/cdash/cdash-model-v1-0

. Accessed March 14, 2012.

7.4. Grinnon ST, Miller K, Marler JR, Lu Y, Stout A, Odenkirchen J, Kunitz S. *National Institute of Neurological Disorders and Stroke Common Data Element Project - approach and methods*. Clin Trials. 2012 Jun;9(3):322–329. PMID: 22371630.

7.5. Stone K. *NINDS common data element project: A long-awaited breakthrough in streamlining trials*. Ann Neurol., 2010 Jul; 68(1): A11–A13. PubMed PMID: 20583225.

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

7.7. International Conference on Harmonisation. *Harmonized Tripartite Guideline for Good Clinical Practice*. 2nd ed. London: Brookwood Medical Publications; 1996.

7.8. Pharmaceutical Inspection Co-Operation Scheme (PIC/S) Annex 11 *Computerized Systems v2011* (guidance document adopted by Health Canada 2007.)

7.9. Proschka S. *Practical Guide to Clinical Data Management*, Second Edition. Boca Raton, FL: CRC Press; 2007.

7.10. Code of Federal Regulations, Title 21, Part 11, *Electronic Records; Electronic Signatures*. Washington, DC: US Government Printing Office; 1997.

7.11. Spilker B. *Guide to Clinical Trials and Developing Protocols*. New York, NY: Raven Press; 1984.

7.12. US Food and Drug Administration. *Guidance for Industry: Computerized Systems Used in Clinical Trials*. Washington, DC: US Department of Health and Human Services; 2007.