SOP 29 – REDCap Data Clean Up & Analysis

1.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to outline the process for transitioning a REDCap project from active data collection to the data clean up and analysis phase. This procedure describes the activities required to ensure data integrity, restrict unauthorised changes to study data and prepare datasets for analysis.

1.2 Scope & Responsibilities

This SOP may be applied to all University of Melbourne sponsored REDCap projects, including clinical trials, observational studies, registries and other research projects that utilise REDCap for data capture and management. Sponsor-Investigators/Coordinating Principal Investigators (CPIs), Principal Investigators (PIs), Trial Coordinators, Data Managers, Research Coordinators and other authorised study personnel are responsible for ensuring the procedures described in this SOP are followed prior to commencing data analysis.

Note that for operational projects needing to use the data clean up/ analysis phase is unlikely.

1.3 Procedure

- Transition to Data Clean Up & Analysis

  Once data collection activities have concluded, or an interim analysis is required, the PI or delegated study personnel should initiate the transition of the REDCap project to the data clean up and analysis phase. This process is intended to minimise the risk of unintended data modification and support the integrity of study outcomes.

a) Project Preparation

Prior to analysis, the project team should undertake the following activities:

- Move the REDCap project to the appropriate analysis/ clean up phase. This will automatically disable any survey/ automated survey invitations (ASIs)/alerts. This will mean that participants will no longer be able to complete any surveys.
  - Verify that all planned data collection activities have been completed.
  - Review outstanding queries, missing data and data discrepancies.
  - Ensure the project documentation is complete and up to date.

b) Data Quality Review

The study team should perform a comprehensive review of project data using available REDCap data validation and quality management tools. Any identified issues should be investigated and resolved prior to dataset extraction. The review may include:

- Missing data assessments.
- Validation rule checks.
- Identification of out-of-range or inconsistent values.

- Resolution of data queries and discrepancies.
- Verification of critical study endpoints and key variables.

c) Record Locking and User Access

Following completion of data verification activities, records should be locked and, where applicable, electronically signed to prevent additional changes. User rights should be reviewed and updated to ensure access permissions align with activities required during the analysis phase. For large datasets, rather than locking individual records, updating the relevant user rights will provide the required level of security and be less time consuming.

d) Data Export and Analysis

Authorised study personnel, including the Principal Investigator, delegated study staff or biostatistician, may export data from REDCap for analysis. Data exports should be performed using approved project procedures and only by personnel with the appropriate level of access.

e) Data Security and Storage

All exported datasets must be stored, transferred and accessed in accordance with applicable institutional, sponsor, ethics, privacy and regulatory requirements. Appropriate safeguards must be maintained to ensure confidentiality, integrity and security of study data throughout the analysis and reporting process. REDCap has a send-it function which allows for research data to be sent to external collaborators directly. Sending information over email is not acceptable.

1.4 References & Useful Links

- ICH Guideline for Good Clinical Practice *https://www.tga.gov.au/resources/publication/corporate-reports/ich-guideline-good-clinical-practice*
- NHMRC: National Statement on Ethical Conduct in Human Research (2007) - Updated 2018 *https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018*
- Australian Clinical Trial Handbook – Guidance on conducting clinical trials in Australia using 'unapproved' therapeutic goods *https://www.tga.gov.au/resources/guidance/australian-clinical-trial-handbook*

1.5 Supporting Templates and Work Instructions

- MCCT SOP 13 - Site Close-Out and Archiving
- MCCT SOP 14 - Data Sharing and Access Procedure for the Release of Data for IITs

- SOP 30 – REDCap Project Archiving

1.6 Glossary

Clinical Trial	Clinical trials can involve investigating new or existing medicines, medical devices and other medical or non-medical interventions. For example, a clinical trial could involve new drugs, medical devices, biologicals, vaccines, surgical and other medical treatments and procedures. Psycho-therapeutic and behavioural therapies help service changes, preventative care strategies and educational interventions are also examples of clinical trials. Researchers might also conduct clinical trials to evaluate diagnostic or screening tests and new ways to detect and treat disease.
Good Clinical Practice (GCP)	A standard for the design, conduct, performance, monitoring, auditing, recording, analyse, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.
Investigator	A person responsible for the conduct of the clinical trial at a trial site. There are four types of Investigator roles used to describe Investigators with different levels of responsibility for the conduct of clinical trials. These are described below. • Sub-Investigator Any individual member of the clinical trial team designated and supervised by the Principal Investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). May also be referred to as Associate Investigator. • Coordinating Principal Investigator (CPI) If a study is conducted at more than one study site, the Principal Investigator taking the additional responsibility for coordination of the study across all sites in a region is known as the Coordinating Principal Investigator (CPI). This role applies to externally sponsored studies where the Sponsor may be a collaborative research group, commercial Sponsor or an institution. The Principal Investigator at each site will retain responsibility for the conduct of the study at their site. • Principal Investigator The PI is the person responsible, individually or as a leader of the clinical trial team at a site, for the conduct of a clinical trial at that site. As such, the PI supports a culture of responsible clinical trial conduct in their health service organisation in their field of practice and, is responsible for adequately supervising his or her clinical trial team. The PI must conduct the clinical trial in accordance with the approved clinical trial protocol and ensure adequate clinical cover is provided for the trial and ensure compliance with the trial protocol. • Sponsor-Investigator An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a participant. The term does not include any person other than an individual (eg, it does not include a corporation or an agency). The obligations of a sponsor investigator include both those of a sponsor and those of an investigator.

Investigator-Initiated Trials (IITs)	A clinical trial which is initiated and organised by an Investigator i.e. an individual rather than a collaborative group, company, or organisation. In these cases, the Investigator will take on the role of the trial sponsor and will then be responsible for the extensive GCP and regulatory requirements associated with both the management and conduct of the trial.
Research	"Includes at least investigation undertaken to gain knowledge and understanding or to train researchers" (National Statement on Ethical Conduct in Human Research 2007 [Updated 2018]). For the purpose of this guidance, research includes any research that requires submission to and approval from an HREC and/or research governance office. This may include (but is not limited to) observational research, clinical trials, quality assurance projects and laboratory research.
Sponsor	An individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study.
Study Team	Refers to the extended group of people involved in a research study. This includes the investigator team and any additional members of staff who are involved in the set-up or conduct of the study e.g. research nurse, research assistants.
Trial Coordinator	A Trial Coordinator has a significant role in the management of the clinical trial at the Sponsor level and provides leadership in clinical trial activities to ensure that the trial is completed within budget, on time and of the highest quality. A Trial Coordinator is responsible for managing the planning, implementation, and tracking of the clinical monitoring process, administration, and start-up of the clinical trial at the participating site and maintaining an overview of the conduct of the trial at sites. Some common roles and responsibilities performed by the Trial Coordinator include: • Participate in protocol development, CRF design and clinical study report writing • Guide in the creation and development of important study documents and manuals • Conduct feasibility assessments • Develop study budgets • Oversee participant recruitment • Oversee overall trial conduct • Ensure compliance of site-staff with the trials Standard Operating Procedures • Ensures compliance to all regulatory requirements both at a local and international level • Ensures compliance to all data protection requirements both at a local and international level • Ensures compliance to all safety reporting requirements both at a local and international level • Conduct team meetings and site-staff training programs • Overall responsibility of the trial • Supervise in-house clinical trial staff

1.7 Revision Chronology

Document History			
Version	**Effective Date**	**Summary of Changes**	**Author**
1.0	02 September 2026	Initial Version	Renata Phyland