SOP 30 – REDCap Project Archiving

1.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to outline the process for archiving REDCap projects that have completed data collection, analysis and reporting activities. This SOP describes the requirements for restricting access to completed REDCap projects while ensuring study data remain securely retained and available for future inspection, audit or regulatory requirements. It also describes the process for restoring access to an archived REDCap project when additional review, corrections or analysis are required.

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 that REDCap projects are archived in accordance with this procedure once project activities have been completed.

The Principal Investigator or delegated study personnel are responsible for:

- Ensuring data collection, data cleaning and analysis activities have been completed prior to archiving.
- Confirming that all required study data, codebooks, data dictionaries and supporting records have been downloaded and retained in accordance with institutional and regulatory requirements.
- Reviewing and updating project user access prior to project archiving.
- Initiating project archival and requesting project restoration when required.

1.3 Procedure

a) Preparation for Archiving

Prior to archiving, the Principal Investigator or delegated study personnel should confirm that all project activities have been completed and that the REDCap project is no longer required for routine operational use. The project should have completed data collection, data review, analysis and reporting activities before progressing to archival.

b) Transition to Analysis and Review Status

- Refer to SOP-29 REDCap Data Clean Up and Analysis Process.

c) Data Retention and Export

Prior to archiving, the study team should ensure that required project outputs have been retained in accordance with applicable regulations, sponsor requirements and institutional policies. This may include:

- Final study datasets.

- Data dictionaries.
- Codebooks.
- Statistical outputs and reports.
- Other project-specific records required for long-term retention.

d) User Access

Ensure that Principal Investigator/ Project Owner has the correct rights in case the project needs to be restored in the future by a member of the REDCap admininistration team.

e) Project archiving

Once all project activities have been completed, the Principal Investigator or delegated study personnel should move the REDCap project to a completed status. This is done by selecting “Mark project as Completed” in the project setup and then other functionality section. Archived projects will no longer be available for routine data entry or project activities but will remain securely retained within the REDCap environment. Note that once a project has been moved to a completed status, users will no longer be able to open the project. They will be required to request a member of the REDCap administration team to restore the project to regain access.

f) Unarchiving a Project

In exceptional circumstances, an archived project may require restoration to permit additional review, correction of identified errors, audit activities or other approved project requirements. The Principal Investigator or delegated study personnel should submit a request for project restoration outlining the reason access is required.

g) Restoration of Access

Following approval of the request, the archived project may be restored to the appropriate project phase. Access permissions may be reinstated for authorised personnel to perform the approved activities. All activities performed following restoration should comply with applicable study procedures and requirements.

h) Re-Archiving

Once the required activities have been completed, the project should again undergo the archiving process. User access should be reviewed, permissions restricted as appropriate, and the project returned to completed status. Documentation relating to the restoration and re-archiving process should be maintained as part of the study records.

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
- MCCT SOP 15 - Document Management and Version Control
- MCCT SOP 29 - REDCap Data Clean Up and Analysis Process

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.
Participant	A participant is a person that is the subject of the research.
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