Standard Operating Procedure

5.5.1 Electronic Data Handling

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<td>Author/s</td>
<td>C Strauss</td>
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<td>D Currow</td>
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Introduction/Background
The correct management of research data and files is crucial to the integrity of the final results. Correct management enables researchers to accurately substantiate publication results, and also meet reporting and auditing requirements.

Objective
This SOP describes the procedure for electronic data management, data entry and error resolution. A comprehensive manual for electronic Case Report Form (eCRF) completion and data entry will be available for each site to refer to for specific routine site data management.

Scope
This SOP applies to all sites involved in clinical studies conducted by the IMPACCT Trials Coordination Centre (ITCC). It also applies to all staff involved in clinical studies conducted by the ITCC irrespective of individual organisational employment, role or position.

Ownership and Responsibility
Responsibility of the Principal Investigator
It is the responsibility of the Principal Investigator to ensure that all data and files are accurately managed. The task may be delegated to another suitably trained individual as documented on the Staff Signature and Delegation Log (refer SOP 4.2.4 Delegation of Duties) but the responsibility remains with the Principal Investigator.

Responsibility of the ITCC
- To develop the paper data collection worksheets and eCRFs in the web-based Research Management System for each study
- To monitor and maintain the accessibility, security and functionality of the Research Management System
- To monitor data quality and accuracy by performing systematic data verification
- To coordinate data archiving and retention
Procedure

1. Source documents

Source documents include original documents, data and records (hospital records, clinical file charts, laboratory notes, diaries, checklists, dispensing records, etc.). These documents allow for reconstruction and evaluation of the study. Data held within source documents are the first record of clinical observations. Examples include (but are not limited to):

- original signed consent form;
- pathology reports to confirm blood results used as eligibility screening;
- clinical records charting patient clinical assessment, used to monitor patient eligibility or progress;
- Dangerous Drug Accountability signature sheets to show correct checking and dispensing procedures;
- Data collection worksheets where patient information, (such as, vital signs, patient responses to specific questions, assessments made while with the patient, among others), are recorded during a patient visit (especially if this forms the only record of the information and is not a transcription recorded elsewhere);
- quality of life or other participant completed questionnaires and forms completed as part of the study measures, and where this recording is the original or only recording of the scores and responses at that time.

Source data may also include the data recorded within case report forms (CRFs) or contained on audiotapes if these data forms clinical data from which analysis is conducted and not contained within other source documents. For example, if clinical observations, survey responses or patient reported outcomes are recorded directly within the CRF and used as study data, this is then source data (refer SOP 4.9.2 Source Data and Documentation).

2. Research data management system (RDMS)

The ITCC uses REDCap as the primary research data management system for all studies. This web-based system was developed to support research work by providing access to tools that:

- enable the online design of electronic Case Report Forms (eCRFs) and questionnaires
- allow for web-based and email-based form completion
- enable data entry from multiple sites with a single coordinating site
- provide for basic reporting of results with features such as percentages, graphs, and tables
- allow export of data to other programs such as Excel, Access or SPSS.
The REDCap consortium has a standing committee that oversees review of the REDCap software platform as to its ability to be utilised in a validated environment for a study. The committee performs rigorous validation tests on each LTS version. LTS is a dedicated version of REDCap released at 6-month intervals. Interim updates contain only bug/security updates (no new features). These REDCap test scripts are all documented on the REDCap Community collaboration/messaging platform and available to all REDCap partner institutions.

REDCap is a password-protected system used by the ITCC for entry of all participant data collected during the course of each study procedure.

REDCap captures the data through a range of eCRFs specific for each study. Access to the web-based system is granted by the ITCC National Project Officer. There are several levels of user access to REDCap:

- **Administrator access** – a very limited number of people have password access to enable website design and maintenance.
- **Manager access** – users can check and query data entered by others, with access to the forms provided by the administrators. This level of access enables data correction and query generation, reporting and download functions.
- **Project officer access** – users can access a restricted number of forms (allocated by the manager) and are able to view the eCRFs for printing and direct data entry only. Access can be restricted to specific people for specific eCRFs, such as pharmacists to access the randomisation eCRFs.

Nominated and delegated study staff will be granted access to enter data only. This will require each user to access REDCap through their unique username and password. **This access must not be given to anyone else through the sharing of username and passwords.**

System training and instructions are provided during site initiation for each study. There are also additional training modules available in REDCap. All users must complete training before being granted access to the REDCap for each study. This training ensures that all users are up to date with the use of REDCap and the restrictions and capabilities. Training completion must be documented on the REDCap Training Record (Template 41) and submitted to the Data Management team with all access requests.

REDCap keeps a record of the access details provided to all levels of users.

3. **Data collection**

The points at which specific data are collected are specified within the study protocols (e.g. the table of study measures). All investigations, forms, questionnaires and all other data are to be included.

4. **Electronic recording**

Study data will be recorded in several files for both the administration of the study and collection of subject data.
At each site, a Patient Master Index (Template 12) will contain the confidential subject contact information and will be the only link between individual subjects and the ID number. Each site will generate a site-specific Patient Master Index (PMI) for subjects recruited at that site. For those sites who have a local licence to REDCap, an electronic PMI has been developed by ITCC for import into local systems and is available on request.

The ITCC will maintain a register of data entry and checking, the date of return to the study site for correction, the date of return or correction, and the date of resolution. This log will enable paper or electronic data to be tracked for query resolution, completeness, and invoice generation. Within REDCap, this record is automatically generated.

The data files will be held and administered in the ITCC and will contain the subject data as downloaded from the Electronic Data Capture System (REDCap). These data will then be transferred to the data set for analysis on request and on completion of study enrolment.

5. Data entry

- Data from each site will be entered into eCRFs contained within the web-based interface (REDCap) specifically developed for each study. REDCap is password protected to reduce the risk of unauthorised access.
- Each user is then granted access to specific studies/projects within REDCap.
- The REDCap eCRFs for each study are developed and tested for functionality prior to site initiation.
- Subsequent changes and updates to the REDCap eCRFs and database are implemented in response to an identified issue, to correct an error or discrepancy, following a protocol amendment or upon request from the lead Investigator. These processes are detailed in the internal ITCC Electronic Case Report Form Work Instructions.
- No personally identifying information will be entered into REDCap at any time. Specific care is to be taken when recording clinical information such as notes within Serious Adverse Events.
- The ITCC will download and store the REDCap study data (eCRFs) on a regular basis as an excel file saved on a local UTS network drive. Access to the network drive is only granted to internal ITCC staff and must be approved by the PaCCSC/CST National Manager or ITCC National Project Officer. The data can then be transferred to the study statistician using SOP 5.5.2 Data Transfer for conversion into other file types for analysis.

5.1 eCRF data entry

- The data collection worksheets will be designed to capture the required data and to enable smooth data entry in the eCRFs through similar question and response structures to minimise data entry errors.
Data recorded on the worksheets will be transferred to the REDCap eCRFs.

On completion of data entry for each form, the study site will 'submit' the data and will be required to change the data 'status' from Incomplete to Unverified.

Any further changes to the data will initiate a log of changes in the form of an audit trail.

A copy of the original data collection worksheet will be forwarded to the ITCC to enable verification of data entry and for filing.

6. **Data verification**

   The ITCC will systematically conduct a manual check of the data recorded on the data collection worksheets against the eCRF data recorded in the Electronic Data Capture System (REDCap) to verify completeness and accuracy of data entry.

   The extent of the data checking will be decided by the study investigator group and in accordance with the study Monitoring Plan (Template 35) and Data Management Plan (Template 10).

7. **Data safety**

   The REDCap system is held within an off-site server. This server has specific back-up and safety in accordance with the practice of the system.

8. **Data archiving**

   Electronic archiving (refer SOP 8.4.1 Archiving) can take place once:

   - Study recruitment is complete;
   - All data have been entered;
   - All data have been checked and errors resolved;
   - The database has been locked to any further changes;
   - The eCRF data have been downloaded as the final data set and sent to the study statistician;
   - The main results publication has been accepted for publication in a peer reviewed journal; or
   - The decision has otherwise been made by the Lead Investigator to archive the data.

   At this point the REDCap database administrator is informed of data closure using the form of notification in accordance with the requirement of the RDMS (Template 13).

   The database owner will confirm destruction to the REDCap Administrator to enable removal of the study data from the online research data management platform. The data will then be permanently deleted from the research data management system in accordance with their Standard Operating Procedures.

8.1 **Data retention**

   The retention of closed or locked data will be in accordance with the study protocol, ethics approval, and the NHMRC [Australian Code for the Responsible Conduct of Research](https://www.nhmrc.gov.au/guidelines-and-research/european-code-of-conduct).
The database will be electronically archived or deleted, after the study team confirms that data can be deleted, and a secure archive back-up has been generated (refer SOP 8.4.2 Record Destruction). The process will be minuted for auditing purposes.
Related SOPs
4.9.2 Source Data and Documentation
5.23.1 Data Collection Worksheet Completion
5.5.2 Electronic Data Transfer
5.18 Monitoring
8.0 Essential Documents
8.4.1 Archiving
8.4.2 Record Destruction

Related documents
Template 10: Data Management Plan
Template 12: Patient Master Index
Template 13: Data Closure Form
Template 35: Study Monitoring Plan
Template 41: RedCAP Training Record

References
Australian Code for the Responsible Conduct of Research 2018 (accessed 07/02/2020)


National Statement on Ethical Conduct in Human Research (2007)- Updated 2018- (accessed 07/02/2020)

PaCCSC Work Instructions
PaCCSC Electronic Case Report Form Work Instructions
Praxis Australia
## History

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