UTS IMPACCT Trials Coordination Centre

Standard Operating Procedure

5.5.3 Electronic Data Capture (EDC) System Access

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Author/s	J Hao, M Sidhu
Approved	M Agar
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Introduction / Background

The access rights of the personnel assigned to the study project should be identified before starting the data collection phase. The IMPACCT Trials Coordination Centre (ITCC) needs to ensure that Electronic Data Capture (EDC) system access rights are granted to trained personnel only in a timely manner.

Objective

This SOP describes the procedure for EDC access within the ITCC including the Palliative Care Clinical Studies Collaborative (PaCCSC) and Cancer Symptom Trials (CST). In most cases, EDC access request occurs after the site personnel complete EDC system training during site initiation. Subject to approval by the PaCCSC/CST National Manager, others may request access to the EDC at various times throughout the study.

Scope

This SOP applies to all sites involved in clinical studies conducted by ITCC/PaCCSC/CST. It also applies to all staff involved in clinical studies conducted by ITCC/PaCCSC/CST irrespective of individual organisational employment, role or position.

Ownership and Responsibility

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 Principal Investigator and/or delegate

- To document completed EDC system training on the REDCap Training Record (Template 41) and submit to the ITCC team with all EDC access requests.
- To archive the EDC system login details of study personnel sent via email from the ITCC.

Responsibilities of the ITCC National Project Officer (or delegate)

- To set up the roles and responsibilities of personnel within per REDCap project

Responsibilities of the PaCCSC/CST National Manager

- To grant the EDC access rights to trained personnel in a timely manner when requested by the ITCC

Responsibility of the IMPACCT Trials Coordination Centre

- To draft an EDC system training schedule containing a list of attendees and a potential timeline to each study site
- To provide EDC system training and instructions during site initiation for each study site
- To identify a list of trained personnel as REDCap users for each study site

- To raise EDC access request tickets to the PaCCSC/CST National Manager when requested by the Principal Investigator
- To send EDC system login details via email to the requested REDCap user with the principal investigator in copy for information and archiving.
- To maintain, manage and troubleshoot all EDC access issues.

Procedure

1. EDC system safety and access rights

- 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 (Long Term Support) 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 users can use AAF (Australian Access Federation) to login.
    - Researchers at the University of Technology Sydney (UTS) can log in using their university staff credentials.
    - External users from non-AAF institutions (e.g., data collectors in hospitals and allied health facilities, health departments and LHDs, etc) need an AAF Virtual Home account to get access.
    - The data manager from UTS-ITCC needs to submit a ticket to request access for external users. The decision to approve or deny access to this database is recorded and communicated via email in REDCap to the applicant.
    - If the access is approved, the data manager will apply via UTS Service Connect online to the UTS eResearch Team to organise access to REDCap for the applicant. The applicant receives notification to activate their account via email. Upon account activation, the data manager provides access to the relevant project as per the details on the approved Access Request Form.
    - Access for third parties is valid for up to a maximum of one year.
    - The data manager maintains a list of all users who have access to the database.
    - External researchers are required to store data on firewall protected file shares with access restricted to relevant project personnel only. This evidence is asked as part of the application for access process.
- Each user is identified by a personal, anonymous pseudonym (user code) which is

supplemented by an individual password. After five unsuccessful attempts, the account will be automatically locked by the system for 15 mins.

- Every 3 months the operator is required to change their password; user-chosen passwords cannot include previously used passwords. A system time out will automatically disconnect the user after 30 min of inactivity (this time is calculated by two separate send/receive data from/to the REDCap EDC system) with the scope to limit unauthorised access from a computer left unattended while accessing the REDCap EDC system. Moreover, specific profiles are drawn to users, resulting in different rights (access blocked, consultation only, reading-writing) on each of the server's functions.
- 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 <u>must not</u> 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.

2. Data entry access rights

- The access rights of the personnel assigned to the study project should be identified before starting the data collection phase.
- A training schedule is drafted containing a list of attendees and a potential timeline.
- The REDCap User Access Dashboard is a reporting tool designed to assist administrators in the management of users that have been granted access to the REDCap project.

- The User Access List can be filtered by project status and project purpose. The administrator is responsible for reviewing the User Access List regularly to ensure that each person listed still requires access to each project.
- The REDCap user rights can be broken down to the tasks involved in each different role within the project (role assignment). The study owner will assign/re-assign individuals to six different types of Data Access Groups (Project Manager, Central Monitor, Principal Investigator, Site, Pharmacist, Invoice). Data Access Groups provide the ability to place barriers between the sites' data. (*refer* SOP 5.5.1 Electronic Data Handling)

Role	Access rights
Project Manager	Allows read-only access to all the eCRF forms and to the data management and extraction tools. Allows the opening of queries in each editable field of the eCRF forms.
Central Monitor	Allows the opening of queries in each editable field of the eCRF forms.
Principal Investigator	Allows the user to enter data and validate. Typically, it represents the account for Principal Investigators and close deputies. The user is allowed access to forms only concerning its site.
Site	Allows the data entry without the possibility to validate the data entered. The user is allowed the access only the forms concerning its site of belonging.
Pharmacist	Allows the read-only access to the Pharmacovigilance section.
Invoice	Allows read-only access to Invoicing section.

3. Pre-requisites for data entry

- Each user must be trained on the REDCap EDC system prior to being granted permission to work in the production mode of the eCRF under ‘Forms and Documents’ REDCap project.
- A training record will be created and maintained.
- Training records will be stored in the Trial Master File.
- Training materials (i.e., slides) can be accessed from the ‘Forms and Documents’ REDCap project (*refer* 8.0 Essential Documents). This project is to be used for storing and retrieving files and documents used for the study. The UTS-ITCC team upload files to ‘Forms and Documents’ REDCap project for retrieval, so that the site staff can download documents in the file list.

Instrument	Definition	Access
Study protocol	All versions of protocol, protocol amendments, and product information	Project Manager, Central Monitor, Principal investigator, Site

PICFs	All versions of Participant/Caregiver Information Sheet and Participant/Caregiver Consent Form (e.g. Master, Withdrawal, Sub-study)	Project Manager, Central Monitor, Principal investigator, Site
Worksheets	Also called Case Report Forms (CRFs), including concurrent medication log, AE log, SAE template. It's recommended to be maintained in a folder for each participant.	Project Manager, Central Monitor, Principal investigator, Site
Ethics and regulatory	ANZCTR Trial registration, CTN listing, Insurance, HREC approval	Project Manager, Central Monitor, Principal investigator, Site
Advertising and marketing	All versions of advertising and marketing materials (e.g. staff poster, public poster, clinic card, referral form)	Project Manager, Central Monitor, Principal investigator, Site
Guides and instructions	All types of guides and instructions related to the study (e.g. Instrument scoring manual, COVID script, face to face interaction record (COVID), sub-study procedure manual, email template)	Project Manager, Central Monitor, Principal investigator, Site
Assessment tools – (participants/caregiver)	Individual booklets and/or forms of assessments and questionnaires.	Project Manager, Central Monitor, Principal investigator, Site
Other patient facing documents	All types of patient-facing documents (e.g. Emergency Card, Patient ID card, participant study summary, Safety Poster, drug dosing instructions, Patient Diary instruction, Patient Pack instructions and coversheets)	Project Manager, Central Monitor, Principal investigator, Site
Site initiation training slides	The training sessions cover Pharmacy, Regulations, Monitoring and Management, Protocol and Implementation, and Data Management.	Project Manager, Central Monitor, Principal investigator, Site, Pharmacist

- Access to the eCRF is not granted until the identified users have completed the training on the eCRF. Such training will be arranged through online site-training workshops, review of the study specific slides, and general REDCap self-directed training slides.
- REDCap EDC System training and instructions are provided during site initiation for each study. There are also additional training modules available in REDCap. This training

ensures that all users are up to date with the use of REDCap and the restrictions and capabilities of the system.

- Training completion must be documented on the REDCap Training Compliance Form and submitted to the data management team.
- Access to the development eCRF is allowed to all investigators as they may be requested to include and randomise at least a test patient by the site initiation, under the supervision of UTS-ITCC, if needed.
- 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 Coordinating Principal Investigator. If the REDCap EDC system is modified in any way, training should be considered depending on the complexity of the modification. This will be a simple user guide or may require more detailed training.
- Once the training is completed, login details are sent via email to the user with the Principal Investigator in copy for information and archiving (*refer* SOP 8.4.1 Archiving). In order to avoid account scam, at the first access, every user is asked to change the system generated password received.
- If access to the REDCap EDC system must be closed or revoked due to one reason or another, the ITCC team member responsible for the management of the specific EDC system will revoke access to the site and/or/or individual(s). This is rare and, in most instances, access will be inherently restricted when the study closes and further data entry is not possible. When the study is closed, the data closure checklist should be completed (Template 50). Anyone accessing the project will be unable to enter further data and will have to contact the ITCC team member responsible for managing the REDCap entry of that study if there is a subsequent need to enter further data (Template 49).

Related SOPs

4.2.4 Delegation of Duties

5.5.1 Electronic Data Handling

8.0 Essential Documents

8.4.1 Archiving

Related documents

Template 41: REDCap Training Record

Template 50: ITCC Data Closure Checklist

Template 49: ITCC Database Unlock Form

References

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Annotated with TGA comments 2000 (accessed 07/02/2020)

https://www.tga.gov.au/sites/default/files/ich13595an.pdf

History			
Version	Date	Author	Reason
1.0	03/12/2021	J Hao	New procedure
1.1	25/03/2022	M Sidhu	Addition about closing access to sites

Approval		
Version	Approval Name	Approval Signature
1.1	M Agar