STANDARD OPERATING PROCEDURE (SOP)

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Reviewed and Approval

This reviewer agrees with the technical content of the document and that this document is approved for implementation at the Melbourne Children's.

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Document History

Revision	Modified by	Effective Date [DD/MMM/YYYY]	Description of Change
1.0	Laura Galletta	04/SEP/2026	New Issue

Contents

1. PURPOSE

To document procedures for managing changes and modifications to the configuration of a project and its data capture forms in OpenClinica (OC).

This version of the standard operating procedure (SOP) is intended for use in MCRI-Sponsored clinical trials that use OpenClinica and that are subject to the full rigors of compliance with Good Clinical Practice (GCP).

1.1. Quality Improvement

Managing modification to the configuration of a project has a direct impact on the quality of the data collected during a clinical trial. It is an important quality management activity in clinical research.

Documenting CRF changes ensures that modifications are systematically evaluated, approved, and traceable, thereby maintaining data integrity, facilitating continuous improvement of data collection processes. This reduces the risk of data errors and protects the validity of study results, thus supporting regulatory compliance and inspection readiness throughout the clinical trial lifecycle.

2. BACKGROUND

Case Report Form (CRF) modifications in clinical trials are systematic updates made to electronic or paper data collection instruments to align with changes in study protocols, regulatory requirements, or to resolve data entry issues. They are crucial for maintaining data integrity and ensuring that only relevant, accurate, and protocol-compliant data is collected.

Modifying CRFs in OC involves updating existing forms to change their layout, add or retire questions, or modify validation logic, all without losing historical data. The best practice is to create a new version of the CRF, rather than editing a version that has already been used for data entry. OC supports the creation of different versions of the same CRF, which can then be added to the Production (live) project once approved.

Changes to CRFs or other project configurations may adversely affect existing project data; therefore, all changes must be appropriately controlled. Proposed changes should be assessed to determine whether comprehensive testing, including User Acceptance Testing (UAT), is required before being implementation in the Production project.

3. SCOPE

This SOP applies to all clinical trials sponsored by the Murdoch Children's Research Institute (MCRI), that are using MCRI's OpenClinica (OC) instance.

This SOP is applicable to all MCRI researchers involved in clinical trials that are responsible for the design and maintenance of a clinical trial database, including Sponsor-Investigators, Principal Investigators (PIs), clinical trial managers, research coordinators, and database managers/data managers.

4. RESPONSIBILITY

Managing changes to projects in MCRI's OC instance is the responsibility of the research project team.

The following is the responsibility matrix for change management:

Role	Responsibility	Scope
Participating Trial Site Team | Site Data Manager | Data Entry Staff	• Identifies any issues with the CRF (i.e. bugs, feature enhancements). • Compiles a list of issues and reports to Sponsor.	Participating Trial Site Team
Data Management Team | Data Manager	• Receives requests for CRF modifications and/or identifies and/or solves issues. • Modifies CRFs as needed. • Advances/escalates issues to other team members, as required. • Documents and records modifications to CRFs in Trial Master File (TMF). • Updates participating site staff on status of issues. • Provides training to Participating Trial Site teams in relation to modified CRFs affecting data entry requirements.	Trial Coordinating Centre (Sponsor)
Statistician | Clinical Trial Manager	• Identifies and/or solves issues. • Reviews and completes user acceptance testing (UAT) of proposed modifications. • Provide subject matter expert advice and direction on change management.	Trial Coordinating Centre (Sponsor)
Sponsor-Investigator	• Identifies and/or solves issues. • Reviews, and where required, completes user acceptance testing (UAT) of proposed modifications. • Approves and signs-off on proposed modifications prior to release to production environment.	Trial Coordinating Centre (Sponsor)

5. PROCEDURE

5.1. Regulations and Standards

ICH E6(R3) Guideline for Good Clinical Practice states:

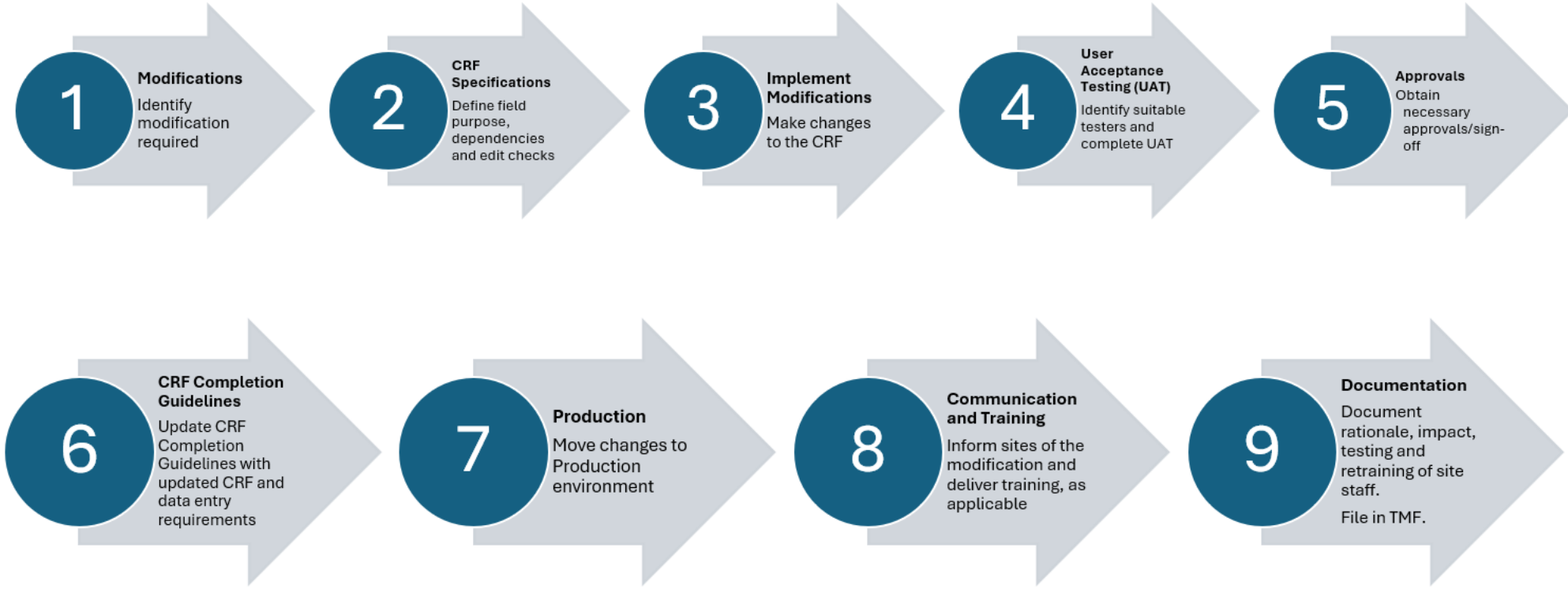
Section 4.3.4 (c):

"Systems should be appropriately validated prior to use. Subsequent changes to the system should be validated based on risk and should consider both previously collected and new data in line with change control procedures."

Section 4.3.4 (f):

"Where relevant, validation procedures (until decommissioning) should cover the following: system design, system requirement, functionality testing, configuration, release, setup, installation and change control."

5.2. Workflow


1
Modifications
Identify modification required
2
CRF Specifications
Define field purpose, dependencies and edit checks
3
Implement Modifications
Make changes to the CRF
4
User Acceptance Testing (UAT)
Identify suitable testers and complete UAT
5
Approvals
Obtain necessary approvals/sign-off
6
CRF Completion Guidelines
Update CRF Completion Guidelines with updated CRF and data entry requirements
7
Production
Move changes to Production environment
8
Communication and Training
Inform sites of the modification and deliver training, as applicable
9
Documentation
Document rationale, impact, testing and retraining of site staff.
File in TMF.

5.3. Types of Modifications

Some types of modifications to CRFs or other project configurations may have an adverse impact on existing project data, and therefore it is important that the modification process be controlled. Proposed changes should be reviewed initially to determine whether comprehensive testing is required before implementing the changes in the Production project, or if a risk-proportionate approach should be taken. Refer to Section 5.7 for further information on how to assess the risk of making changes to the database.

All modifications will require a level of UAT. A risk proportionate approach should be taken when considering what modifications should undergo full UAT. Examples of modifications that MAY be deemed not to require explicit UAT prior to release are:

- Minor, simple alterations or corrections to the text of alerts etc.
- Minor, simple alterations or corrections to the configuration of a small number of data variables/data collection fields
- Archiving of a case report form
- Addition of existing forms to events
- Removal of forms from events

It should be noted that even minor modifications should be reviewed by another member of the research team prior to implementing any changes.

5.4. Change Management – Participating Trial Sites

- Participating Trial Site staff identify the need for a modification or update with part of a system/software (e.g. bugs, feature enhancements)
- Participating Trial Site staff collates list of issues and informs Central Trial Coordinating Team
- Where applicable, participating trial site staff undertake UAT, confirming modifications are working as expected.
- Participating Trial Site staff receive updates (on completion of modifications and implementation to the production environment) from Central Trial Coordinating Team and communicates these to all relevant site staff.
- Site Data Manager and/or Site Study Coordinator coordinate any training required to effectively implement the change.

5.5. Change Management - Central Trial Coordinating Centre

- Data Management Team identifies issues internally or receives requests for CRF modifications from Participating Trial Sites.
- Issues are recorded on the MCTC234 Template | CRF Change Control Log.
- Proposed modifications are discussed by the Central Trial Coordinating Team/Data Management Team and an evaluation made as to whether or not these modifications:
    a) Are deemed required
    b) Affect all participating trial sites, or only a subset
    c) Timeframe for implementing the modifications

- If a modification is deemed required, the Data Management Team makes the required changes/modifications to a defined CRF. Refer to the following OpenClinica Guidance: Create and Modify Case Report Forms (CRFs)
- Once modifications are complete, the Data Management Team facilitate UAT. Refer to MCTC235 SOP | User Acceptance Testing.
- Once UAT is complete, deemed successful, and modifications are deemed production ready with the relevant approvals obtained (e.g., Sponsor-Investigator), the modifications can be moved to the production environment.
- The Data Management Team makes the required changes in the production environment by uploading the new version of the CRF. This can be completed via either of the following mechanisms:
    a) Replace the existing version; (or
    b) Add the modified CRF as a new version.

Refer to Section 5.4.10.1 "Replace a Defined CRF" in the following OpenClinica Guidance: Create and Modify Case Report Forms (CRFs) for step-by-step instructions.

Refer to Section 5.4.10.2 "Add a New Version of a Defined CRF" in the following OpenClinica Guidance: Create and Modify Case Report Forms (CRFs) for step-by-step instructions.

- The CRF version number and date of release to production environment must be documented on the MCTC234 Template | CRF Change Control Log.
- Where required, CRF Completion Guidelines must be updated with any new modifications and communicated to Participating Trial Site teams.
- Training sessions should be held for major CRF changes which have implications for data entry requirements. These training sessions should occur prior to modifications being moved to the production project.
- The process repeats for each subsequent set of changes made.

5.6. Emergency Modifications to CRFs

Where an urgent change is required to address a critical issue, participant safety concern, data integrity issue or system failure, the change may be implemented using the applicable emergency modification process.

Emergency modifications must be documented, appropriately authorised and retrospectively reviewed and tested as soon as practicable.

5.7. Impact and Risk Assessment

Each modification must be assessed to determine its potential impact on study data, participant safety, study conduct and system functionality. The assessment should consider whether the change:

- affects existing data
- changes the meaning or interpretation of previously collected data
- affects calculations, validation or branching logic

- affects data exports or downstream systems
- requires changes to study documentation
- affects participants already enrolled; or
- requires regulatory or ethics approval.

The level of testing and approval required must be proportionate to the assessed risk.

5.8. Form Versioning

All changes to an approved CRF, form configuration and/or visibility settings must have a unique version identifier. A new version must be created when a change could affect:

- the data collected or its interpretation
- field labels, response options or units
- data types or validation rules
- calculated fields
- branching or conditional display logic
- required/optional fields
- automated alerts or notifications; or
- the structure or configuration of the form.

The version number and effective date must be recorded in the study's CRF/form documentation.

Minor administrative or configuration changes that do not affect the data collected or its interpretation may be either documented as revisions without creating a new form version (where permitted by the study's change-control requirements) or recorded through minor version numbers such as v1 to v1.1 as opposed to v1 to v2

5.9. Testing Prior to Release to Production Environment

Thoroughly testing modifications to a CRF involves more than just creating a record and having a quick look that everything is working well. Each modification should be tested and/or reviewed by all relevant stakeholders to ensure that it is working as expected.

Testing must verify that:

- the revised form operates as intended
- existing functionality remains unaffected
- calculations and validation rules operate correctly
- branching and conditional logic function correctly
- required fields behave as intended
- alerts and automated processes operate correctly; and
- existing data remain accessible and interpretable.

The testing performed and outcomes must be documented. Refer to MCTC235 SOP | User Acceptance Testing, for further information on completing and documenting UAT activities.

5.10. Logging of Modifications

Modifications made to CRFs should be logged and include documentation of the following:

- Rationale/reason for the change
- Name of who requested the modification
- Description of the modification
- Outcome of UAT
- Approval for the modification
- Release date of the modification, and
- Any other relevant information.

The records must provide sufficient evidence to reconstruct the history of changes made to the form throughout the study.

Annotations to this effect can be made in OC itself; however, they are more readily reviewable if summarised in a Change Control Log. Refer to MCTC234 Template | CRF Change Control Log Template.

5.11. Publish History

In OpenClinica, the "Publish History" function provides a record of the different versions of a study design that have been published to the Test or Production environment. It provides a historical view of what the study configuration looked like at each publication point. Publish History shows a viewable snapshot of each revision (in Test or Production) that is created. In OpenClinica, form versions cannot be overwritten; therefore, each modified CRF has to be published as a new version number. The version of the form which is visible at sites can also be individually adjusted.

Refer to the following OpenClinica Guidance: https://docs.openclinica.com/oc4/launching-and-managing-studies/useraccesssharing/#content-17549, for further information on Publish History.

6. COLLABORATORS

Name / Role	Department / Group	Affiliation
Luke Stevens	*Clinical Epidemiology & Biostatistics Unit (CEBU)*	*MCRI*
Sri Joshi	*Clinical Epidemiology & Biostatistics Unit (CEBU)*	*MCRI*
Richard Hall	*Melbourne Children's Trial Centre (MCTC)*	*MCRI*
Billy McMahon	*Cancer Therapies*	*MCRI*

7. REFERENCES AND RELATED DOCUMENTS

- MCTC234 Template | CRF Change Control Log
- OpenClinica Guidance: Create and Modify Case Report Forms (CRFs); https://docs.openclinica.com/3-1/study-setup/study-setup-build-study-create-case-report-forms-crfs/
- OpenClinica Guidance: Using OpenClinica as a Data Manager; https://docs.openclinica.com/oc4/using-openclinica-as-a-data-manager/
- OpenClinica Guidance: Using OpenClinica as an Administrator; https://docs.openclinica.com/3-1/brief-overview/
- MCTC231 SOP | CRF Design and Development
- MCTC232 Guidance | CRF Design and Development
- MCTC235 SOP | User Acceptance Testing (UAT)
- MCTC236 Template | UAT Testing Log Template
- MCRI Data Governance Framework
- MCRI Data Management Policy

8. GLOSSARY

Case Report Form (CRF)

A form that collects and contains Study Event information for a Study Participant.
A Case Report Form (CRF) is a crucial paper or electronic document used in clinical research to systematically record all protocol-required information for each participant in a study. CRFs serve as the primary data collection tool, ensuring consistent, accurate, and complete data for analysis, which helps evaluate the efficacy and safety of medical interventions and answer specific research questions. They are vital for regulatory compliance and the overall success of a clinical trial, capturing details such as demographics, vital signs, and treatment outcomes for each individual participant.

Central Trial Coordinating Team

A group of MCRI researchers (at the Sponsor-level) organised to coordinate the planning, development, operations and conduct of an MCRI-sponsored, Investigator-Initiated, clinical trial.

Clinical Trial

The World Health Organization (WHO) definition for a clinical trial is: 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'.

CRF Modifications

CRF (Case Report Form) modifications in OpenClinica refer to the process of updating, editing, or versioning the electronic forms used to collect study data. Because study protocols often change, OpenClinica allows for the modification of CRFs while maintaining the integrity of data already collected.

Dataset

A collection of data and metadata from records such as CRFs, Study Events, etc. that matches a dataset definition and is exported to a file whose format can be selected for use in other applications.

Defined CRF

An Excel spreadsheet composed of Sections, Item Groups, and Items that you create for use in OpenClinica. A defined CRF can have multiple versions. You assign it to one or more Study Events in one or more Studies

Delete

A delete action  completely removes the information from the OpenClinica system. Deleted information cannot be restored, although the audit log tracks the deletion action. Nearly all information in OpenClinica is removed rather than deleted because removed information can be restored.

Good Clinical Practice (GCP)
A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, 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 participants are protected.

Item
Also known as a data Item. A single question in a CRF. Items have metadata attached to them. Each Item has an OID attached to it. Items can have multiple Edit Checks attached to them through either metadata or Rules.

Item Group
A grouping of Items in a CRF. Item Groups can be repeating (for example, recording multiple Adverse Events on one form) or non-repeating.

OID (Object Identifier)
System-generated unique identifiers that OpenClinica uses to directly reference key entities in a Study. OIDs are essential for importing data, creating Rules, and using data exported from OpenClinica to certain formats.

OpenClinica
OpenClinica is a cloud-hosted, open-source software platform used for electronic data capture (EDC) and clinical data management (CDM) in clinical trials. It helps researchers design and manage clinical studies, capture patient and operational data electronically via eCRFs, and ensure regulatory compliance through features like audit trails and edit checks. OpenClinica supports various aspects of a trial, including patient-reported outcomes (ePRO), randomization, supply chain management, and reporting, with solutions designed to be flexible and user-friendly.
See https://www.openclinica.com/ for more information.

Production Environment
A production environment in OpenClinica is the live, validated, and secure setting where real, patient-facing clinical trial data is collected, managed, and stored. It is the final, official repository used for regulatory compliance and study analysis, as opposed to a test or development environment.

Study
A study within OpenClinica is a discrete database, including all the metadata and data for it. The data contained within an OpenClinica (OC) study is completely siloed and separate from data stored within other OC projects.

Remove
A remove action  makes the information unavailable in the OpenClinica system. You can restore information that has been removed to make it available again. Most information in OpenClinica is removed so that it can be restored, although in some cases, information can

be deleted. See also the glossary description for Delete.

Roles
Categories for users in OpenClinica that determine the tasks available to them in the application.

Rules
Customized methods used to trigger actions on records such as the automatic generation of a Discrepancy Note, email, etc. Rules are stored in XML files. They can be built directly in an XML file and uploaded to OpenClinica or built in OpenClinica using the Rule Designer feature.

Sites
Locations where the Study is taking place, although they do not have to be physical locations. You can work with OpenClinica at the Site level, which limits the view of the Study to a specified Site.

Study
In OpenClinica, a clinical trial or clinical research project, including all the metadata and data for it.
A study within OC is a discrete database. The data contained within an OC Study is completely separated from data stored within other OC studies.

Study Event
A visit or encounter in the Study where data is captured or created. A Study Event packages one or more case report forms (CRFs). Also referred to as an Event.

Trial Master File (TMF)
Filing repository controlled by the Sponsor/Sponsor-Investigator. It is the collection of essential documents that allows the Sponsor responsibilities for the conduct of the clinical trial, the integrity of the trial data and the compliance of the trial with Good Clinical Practice (GCP) to be evaluated.

User
A person using the OpenClinica software. A user can have one or more Roles in one or more Studies or Sites. For some automated processes, the user can be an automated system.

Internal users with MCRI network accounts may utilise this to log into OC provided an OC Administrator has added their MCRI username to OC's "allow list". Non-MCRI personnel require an internal OC user account in order to log in. The password for these users is managed within OC.

User Acceptance Testing
User Acceptance Testing (UAT) is the final phase of software testing, performed by real users

or clients to validate that a system works as intended in real-world scenarios before going live. It confirms the software meets business requirements and is ready for production, acting as the last check before deployment.

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