

DATABASE LOCK

SOP Number: BTC-SOP-IT-007

SOP Version: 2.0

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Implementation plan

This Standard Operating Procedure (SOP) should be implemented within two weeks from Release Date for studies that are being setup.

For ongoing studies applicable sections of this SOP should be implemented as far as possible immediately after the implementation date, unless impractical for the circumstances e.g. too close to the end of study.

If unsure, the BTC Director and/or Quality Assurance Manager should advise.

Note to User:

It is your responsibility to ensure that you are using the latest approved version of this SOP. Please note that versions may be superseded before their initial review date.

THIS IS AN UNCONTROLLED VERSION WHEN PRINTED.

If you are reading this document in printed form, please check that the version number and date match the most recent SOP's details. Current versions of all Bristol Trials Centre (BTC) SOPs and accompanying documents are available on the BTC Teams QA channel.

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1. INTRODUCTION AND PURPOSE

Database locking is required to prevent changes to data after the data entry is complete, and the data are clean and ready for analysis.

The purpose of this SOP is to describe the standard procedures for locking and unlocking a study database.

2. SCOPE

This SOP applies to data collected for research studies undertaken within the BTC where data is stored electronically in a computer system and source data is either collected from a set of source documents and transcribed for storage in the system, or directly entered by an appropriately authorised user into the system. The processes covered in this SOP are:

- Locking database
- Unlocking database

The Chief Investigator (CI) must be made aware of this SOP and as a minimum, be signposted to the SOP by BTC.

NB: Throughout this document the terms 'research', 'trial', and 'study' will be used interchangeably to denote those projects which fall under the remit of the UK Policy Framework for Health and Social Care Research 2017.

3. DEFINITIONS

For definitions, acronyms and abbreviations relevant to IT please refer to the BTC-RES-IT-001 Definitions and Acronyms (IT) available on the BTC Teams QA channel.

For all other definitions, acronyms and common abbreviations relevant to research projects and general management of research refer to the BTC-RES-TM-001 Definitions and Acronyms, also available on the BTC Teams QA channel.

4. RESPONSIBILITIES

Any delegation of responsibilities should be formally agreed by all parties and clearly documented.

4.1 Research Systems Technical Developer or delegate

It is the responsibility of the Research Systems Technical Developer (or delegate) to ensure that the computer system and its associated data is safely and securely locked or unlocked as requested.

4.2 Trial Manager/Co-ordinator or delegate

It is the responsibility of the Trial Manager/Co-ordinator or delegate to notify the Research Systems Technical Developer when the requirement to lock or unlock a clinical trial database is met.

4.3 Study Statistician

It is the responsibility of the Study Statistician to review the dataset prior to locking.

4.4 SOP Author(s) or delegate

It is the responsibility of the SOP author(s) (or an appropriately qualified/trained delegate) to:

- Generate, finalise, and revise the SOP in accordance with the BTC-SOP-QM-001 Development and Management of SOPs.
- Ensure that the SOP remains fit for purpose.
- Provide relevant training and education materials to ensure that staff are aware of their responsibilities in relation to SOP content and management.

4.5 SOP user

It is the responsibility of the SOP user to:

- Ensure compliance with this document.
- Review procedures during use of the SOP and inform the QA manager of any changes required using the Change Request mechanism on the BTC Teams QA channel.
- Undertake training on all aspects of this SOP and record training on the BTC Teams QA channel.

5. SPECIFIC PROCEDURES

5.1 Database Lock

The Trial Manager/Co-ordinator will add a new task/ticket on the BTC ticketing system system notifying the Research Systems Technical Developer that a clinical trial database needs to be locked.

The process for locking the database will depend upon the underlying system. For example, it may be managed by putting up a holding page for the web application and updating application user access or making case report forms (CRFs) read-only within the application. The method used must prevent the relevant data being changed and be fully documented within the ticket or by adding references to system documentation.

5.2 Unlocking a database

The Trial Manager/Co-ordinator will add a new task/ticket on the BTC ticketing system system to notify the Research Systems Technical Developer that a clinical trial database needs to be unlocked. The process for unlocking the database will depend upon the locking mechanism used. This will be detailed in the original database lock ticket and the database change log.

Any changes made to unlock the database should be documented in the ticket requesting the database is to be unlocked.

6. SUPPORTING DOCUMENTS TO BE USED

Number	Title
BTC-RES-IT-001	Definitions and Acronyms (IT)
BTC-RES-IT-002	Website References – IT SOPs
BTC-RES-TM-001	Definitions, acronyms and abbreviations relevant to research projects and management of research
BTC-SOP-QM-001	Development and Management of SOPs

7. CHANGE HISTORY

Previous version and date	New version and date	Summary of review
NIL		New document
V1, 28 Jul 2021	No change	SOP was reviewed and required no change; review date was amended but the SOP version number and date were not changed
V1, 28 Jul 2021	V2, 5 March 2024	Job titles amended match BTC restructuring. Removed reference to different locking types as not required (5.1). Added requirement for change log in 5.2.