DECOMMISSIONING APPLICATIONS AND ARCHIVING DATA

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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 set up.

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 Please note that versions may be superseded before their initial review date.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.

Contents

1. INTRODUCTION AND PURPOSE

Clinical Trials Regulations require that all clinical trial data shall be recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification. The confidentiality of records that could identify subjects shall be protected, respecting the privacy and confidentiality rules in accordance with the requirements of the Data Protection Act 2018 and the Common Law Duty of Confidentiality.

The purpose of this SOP is to describe the standard procedures for archiving and decommissioning Clinical Research Computer Systems by the BTC.

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:

- Archiving data
- Decommissioning systems

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 Database Manager 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 archived or decommissioned, as appropriate.

4.2 Trial Manager/Co-ordinator or delegate

It is the responsibility of the Trial Manager/Co-ordinator or delegate to:

- Notify the Database Manager when the requirement to archive a system is met
- Ensure adequate measures are in place to archive non-system data, such as paper documents and electronic files stored outside of the study computer system (e.g. a screening log stored as an Excel file etc.) as outlined in the BTC-SOP-TM-003 Study Closedown SOP.

4.3 Study Statistician

It is the responsibility of the Study Statistician to:

- Undertake the final analysis of the study data prior to archiving
- Ensure that all statistical documentation (paper and electronic) is archived as outlined in the BTC-SOP-ST-001 Statistics SOP.

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 General Considerations

On completion of a study a final dataset must be securely retained for the agreed period of time in a ‘locked’ format so that data cannot be further altered or deleted.

A copy of this dataset can be requested by those authorised to view the data.

Archiving would normally occur following the natural completion of a study, after the analysis and publishing phase. However, in certain circumstances, archiving may take place prematurely, for instance, if recruitment is low and it is decided the study should be closed early.

If a study is abandoned prior to commencement (i.e. once all relevant approvals are in place, all documentation has been finalised, and all participating sites have the information they need, but before any patient recruitment and subsequent data collection), the computer system or parts thereof will be decommissioned rather than archived.

5.2 Archiving

The Trial Manager/Co-ordinator will add a new task/ticket on the BTC ticketing system or equivalent system notifying the Database Manager that a study has completed, and that the data is due for archiving.

The actual archive process will differ depending on the underlying system used to develop the database and software specific work instructions should be followed. Regardless of the software used, the following procedures must be followed:

a) Access to the system will be restricted to prevent data changes post archiving.

b) A copy of data files used for statistical analysis will be stored in a secure location. Only authorised members of the database management team will have access to the files.

c) The database system will be archived so that it can be reinstated if necessary.

   i. For bespoke developed systems, the final production version of source code will be stored in the source control system and should not be updatable. The underlying database installation file (e.g. SQL Server) should be archived so that it can be reinstated. This can be a copy of the database or the database definition scripts including definitions for reports and any other resources required to recreate the system.

   ii. For off the shelf systems, the metadata used to define the project/database should be archived. The metadata must be sufficient to reinstate the project if required and will differ depending on the system used. For example, for REDCap the data dictionary (metadata and code book) and the REDCap project XML file will be stored in the archive location.

d) Archived data will be retained in line with the study protocol, the length of time will depend on the type of data being held.

e) Any project specific scheduled jobs or automated tasks, such as data exports or notifications, will be disabled.

The location of the archives, any instructions to reinstate the database and the expiry date will be documented.

Once complete, the BTC service desk task/ticket will be closed and the Trial Manager/Co-ordinator will be informed that the study system has been archived.

5.3 Decommissioning

The Trial Manager/Co-ordinator will add a new task/ticket on the BTC ticketing system or equivalent system notifying the Research Systems Technical Developer that a study has been discontinued and that the study system can be decommissioned.

The actual archiving process will differ depending on the underlying system used to develop the database and software specific work instructions should be followed. Regardless of the software the following procedures must be followed:

a) Access to the system will be restricted to prevent data changes post archiving.

b) The database system may be archived as it may aid future database development. There is no time limit for keeping the archived system.

   i. For bespoke developed systems, the final production version of source code will be stored in the source control system and should not be updatable. The underlying database installation file (e.g. SQL Server should be archived so that it can be reinstated. This can be a copy of the database or the database definition scripts including definitions for reports and any other resources required to recreate the system.

   ii. For off the shelf systems, the metadata used to define the project /database should be archived.

c) Any project specific scheduled jobs, integration processes or automated tasks, such as data exports or notifications, will be disabled.

d) Any related working or temporary data, such as temporary tables or data sources for mailmerge, will be deleted.

If appropriate the location of the archives, any instructions to reinstate the database and the expiry date will be documented in the ticketing system.

Once complete, the BTC ticketing system task/ticket will be closed and the Trial Manager/Co-ordinator will then be informed that the study system has been decommissioned.

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
BTC-SOP-TM-003	Study Closedown SOP

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, 05 Mar 2024	Updated role names due to BTC restructure. Added requirement to save system installation file during archiving process in 5.2.