

SYSTEM BACKUP AND RESTORATION FOR CLINICAL RESEARCH COMPUTER SYSTEMS

SOP Number: BTC-SOP-IT-003

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 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 you are using the latest approved version of this SOP. Please note that versions may be superseded before their planned review date.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

As outlined in the International Conference on Harmonisation (ICH) E6 Good Clinical Practice (GCP), a system should “Maintain adequate backup of the data.” GCP regulates specific requirements for computerized systems, specifically:

“5.5.3 when using electronic trial data handling and/or remote electronic trial data systems:

- Ensure and document that the electronic data processing system(s) conforms to the sponsor’s established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e. validation).
- Maintain SOPs for using these systems.
- Ensure that the systems are designed to permit data changes in such a way that the data changes are documented, and that there is no deletion of entered data (i.e. maintain an audit trail, data trail, edit trail).
- Maintain a security system that prevents unauthorised access to the data.
- Maintain a list of the individuals who are authorised to make data changes.
- Maintain adequate backup of the data.
- Safeguard the blinding, if any (e.g. maintain the blinding during data entry and processing).”

The purpose of this SOP is to describe the standard procedures undertaken for ensuring suitable backup and recovery measures are in place for all software and hardware systems which fall under the direct responsibility of the BTC.

This SOP describes the processes and steps required to ensure that systems deployed within the BTC are reliably backed up, to a secure location where applicable, and in an appropriate format which allows system restoration to a required point in time. This will ensure that in the event of system failure, either because of software or hardware faults, selected systems can be restored to a functional state within a reasonable time frame.

2. SCOPE

This SOP defines the backup and recovery procedures for software deployed and hardware maintained within the BTC, this includes but is not limited to: clinical study data; documents and files relating to study management; database and application services used in support of study data collection and management.

This SOP is not expected to apply to any software or hardware systems outside the remit of the BTC, for instance, software deployed, or servers maintained by the University of Bristol or University of Bristol or University Hospitals Bristol and Weston NHS Foundation Trust (UHBW).

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

It is the responsibility of the Research Systems Technical Developer to implement a suitable backup and recovery process for each relevant BTC system, including adequate documentation describing those backup and recovery routines.

4.2 University of Bristol

It is the responsibility of the University of Bristol for backing up systems falling under its remit as per the Universities backup policies.

4.3 University Hospitals Bristol and Weston NHS Foundation Trust

It is the responsibility of the UHBW for backing up systems falling under its remit as per the Trust backup policies.

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 log 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 Backing up data stored within a clinical study system

- a) Data will be routinely backed up at a minimum once per 24 hour cycle, customarily out of normal operating hours, and stored in a secure location separate from the system on which the data resides.
- b) For data stored within a database system, such as SQL/MySQL Server, full database backups will be taken in accordance with point 5.1.a. Subject to operational requirements and database capability additional database backups, e.g. transactional log, may be taken at routine intervals between full backups. These additional backups will be used to facilitate system restoration to within a narrower time frame, for instance, to recover data to within one particular hour of a selected day, rather than recovering to the night before.
- c) For data stored outside of a database system, such as data stored in a file system, backups will be taken in accordance with point 5.1.a. File structure(s) must be preserved where applicable, either by direct copy from a file location or archival within a cabinet file, such as a compressed zip file.

5.2 Backing up documents and files supporting clinical study systems

- a) Documents and files used in support of study data collection and study management will be stored in specified file shares and backed up in accordance with point 5.2.b.
- b) Specific file shares configured on either University or UHBW Trust servers are backed up in accordance with University or UHBW Trust policies, as applicable. These file shares may contain study data and/or supporting files as a result of points 5.1.a, 5.1.c and 5.2.a.

5.3 Backing up application source files

- a) Application source files for clinical study systems must be stored and maintained in a source control system. This source control system will be backed up and stored in a secure location separate from the server on which the system resides.

5.4 Backing up servers

- a) Backups of servers hosted by the University are routinely performed in accordance with University policies.
- b) Backups of servers hosted by the UHBW Trust on the Health and Social Care Network (HSCN) are routinely performed in accordance with Trust policies.

5.5 General backup information

- a) Backup procedures for individual systems, file locations and schedules will be defined in working instructions (WI) for each specified system.
- b) The result of backup routines must be logged in an appropriate place on the relevant server and, where applicable, backup routines will be configured to notify the BTC Systems Team in the event of a backup failure, preferably via email.
- c) Backup routines maintained within the BTC will have a cyclic retention policy of no less than 7 days. For backups maintained by the University of Bristol or the UHBW Trust the retention policy will be determined by their respective guidelines.

5.6 Restoring a system to a useable state

- a) In the event that a system which falls within the remit of the University of Bristol or UHBW Trust needs to be restored from a backup, a call will be logged with their respective Helpdesk and/or Network teams, who will provide an estimated timescale for the restoration.
- b) In the event that a system maintained within the BTC needs to be restored from a backup, that system will be restored as required from a suitable available backup.
- c) In the event that a system needs to be restored all affected users will be informed as appropriate.

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, 05 Mar 2024	Job titles amended due to BTC restructuring. Minor changes to grammar used.