DOCUMENTATION AND TRAINING FOR CLINICAL RESEARCH COMPUTER SYSTEMS

SOP Number: BTC-SOP-IT-008

SOP Version: 2.0

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	NAME	TITLE
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Release Date:	05/03/2024	**Implementation Date:**	05/04/2024

Review Due:	05/04/2026

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 Please note that versions may be superseded before their planned review date.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

Contents

1. PURPOSE

This document forms part of the overall set of IT SOPs for the BTC which aim to cover Good Clinical Practice (GCP) requirements.

The purpose of this SOP is to describe standard procedures for producing documentation and training for systems developed in accordance with the BTC-SOP-IT-001, Software Development for Clinical Research Computer Systems.

This SOP describes the processes required to ensure competent and consistent use of software systems within the BTC and specified sites. It outlines the process of creating system documentation and user guides, as well as organising user training.

2. SCOPE

This SOP defines the process for developing documentation and training users on systems developed by the BTC Systems Team.

This SOP does not apply to any documentation and training for software outside of this remit.

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 respond to requests for supporting information or supplementary resources required for the production of user documentation.

4.2 Trial Manager/Co-ordinator or delegate

It is the responsibility of the trial manager/co-ordinator or delegate to produce and maintain user documentation and provide training to users of the system.

4.3 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.

4.4 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 Creating User Documentation

The Research Systems Technical Developer develops the database according to the process defined in BTC-SOP-IT-001 Software Development for Clinical Research Computer Systems. Due to their involvement in the development process the Trial Manager/Co-ordinator should already be familiar with the functionality of the database, however, additional training can be provided by the IT team if required.

Once the system has been tested, the Trial Manager/Co-ordinator writes the user documentation. This can be part of the general trial documentation sent to sites or a standalone document.

5.2 User training

When the database is first released, the Trial Manager/Co-ordinator will identify to what extent there is a need for training, who the suitable trainers could be and what format it should take. All users on the delegation log who might need to access the database should be trained. The Trial Manager/Co-ordinator may however decide that sending the user documentation in advance will be sufficient.

When a system changes through controlled releases (see BTC-SOP-IT-004, Configuration Management), the Trial Manager/Co-ordinator needs to update the documentation and, if appropriate, train users on the new features.

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-IT-001	Software Development for Clinical Research Computer Systems SOP
BTC-SOP-IT-004	Configuration Management 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	Updates to role and team names due to restructure.