STU-SOP-DMS-009 – Standard Operating Procedure on Database Development and Maintenance

1. Purpose and Definitions

This Standard Operating Procedure (SOP) describes the procedure of specification, design/development and validation of a research project database in the set-up and maintenance phase.

This SOP can also be used as a guide for non-research databases to produce validated data when required.

Definitions	
Database	A structured set of data collected and managed for a research project in a way that allows transparency of data entry, security and an audit of changes. Aims to provide confidence that project results achieved are dependable.

2. Background

Research data should be collected, recorded and managed in accordance with applicable regulations, the principles of Good Clinical Practice (GCP), the General Data Protection Regulation (GDPR), the current Data Protection Act, and the appropriate Swansea Trials Unit (STU) and Swansea University (SU) policies.

GCP states that all clinical research project information will be recorded, handled and stored in a way that allows accurate reporting, interpretation and verification.

All Data Management Systems (DMS) holding research project databases will be internally validated (detailed in STU-SOP-IT-001) and automatically capture an audit trail of user activity.

3. Roles and Responsibilities

Sponsor – responsible for ensuring that the database build and required maintenance is in accordance with the appropriate regulations and the approved protocol.

Chief Investigator (CI) – responsible for ensuring that the database specification remains aligned to the approved protocol.

Trial Management Group (TMG) – responsible for overseeing the suitability of data items and ranges collected, as required by the research project protocol.

Data Manager (DM) – Responsible for leading and coordinating database development including generating the Database Specification, building the database, drafting the testing documents and signing off the database for use once all testing is complete.

Database Tester (DT) – responsible for reviewing the requirements and expected behaviour of the database in alignment to the test specification. Testers will usually be STU staff or research team members with experience of the database structure, protocol and who understand the database specification.

Trial Manager (TM) – responsible for maintaining oversight of database delivery as per the project timelines, reviewing and approving the database development documentation and ensuring that operational aspects are covered within the database design.

Trial Statistician (TS) – responsible for ensuring the database specification is aligned to the approved protocol.

IT Officer (ITO) – responsible for the administration of the DMS. This role may be delegated.

External use of SOP: this SOP and Associated Documents (AD) may be used for research projects not adopted by STU where Swansea University (SU) staff and associated NHS organisations require guidance. In such instances, oversight responsibility for any associated tasks will not be the responsibility of STU.

4. Procedure

4.1 Research project database design

The Database Specification Document (STU-AD-TMP-026) detailing the data items required is usually drafted as per the approved research project protocol. A system-specific data dictionary template to list the data items should be used where available.

The Database Specification Document can include:

- visit schedule for the database
- number of repeats for a given visit, form or question
- any dynamic settings
- list of univariate and multivariate checks to be programmed into the database
- derivations
- list of visits/forms/questions requiring authorisation
- list of visits/forms/questions requiring role specific access

The database specification document must be agreed and approved by the Statistician, CI and Trial Manager prior to move to production.

4.2 Database development

A request for set-up of a research project database must be made to the ITO or delegate. Project database names must be suffixed with ‘Test’ or ‘Development’ to distinguish between databases. The research project database should be built using recognised naming conventions where possible.

4.3 Database testing

All research project databases must undergo a testing process prior to use in alignment with the Database Specification Document. Multiple DTs may be involved in testing.

4.3.1 Electronic Case Report Form (eCRF) screen testing

To verify that the database build is correct, complete and aligned to the CRF and the Database Specification Document, testing should ideally be performed by different people to those who designed and set up the database using screen testing template (STU-AD-TMP-029).

4.3.2 Validation, derivation and custom function testing

To ensure that the research project database is performing as expected, all custom functions, validations, derivations and notifications must be tested and documented using STU-AD-TMP-028.

The outcomes of the testing must be reviewed and any decisions documented on the test script. The Database Specification Document will be updated as required.

The DM must complete the Testing checklist (STU-AD-FRM-030) to ensure all aspects of the research project database have been tested.

4.4 Move to production

Following successful testing, the DM will prepare to move the database to production within the DMS by requesting approval from the ITO via the Move To Production Approval Form (STU-AD-FRM-019).

The ITO should complete the approval form and authorise the move to production within the DMS to make the database available for project use. The DM should be notified of approval via returned return of completed MTP Approval from the ITO.

When creating project databases the naming convention must clearly distinguish between development, testing or production project databases.

All project database development documentation must be filed in the Trial Master File.

4.5 Changes to a live database

Database changes may be required due to protocol changes or error(s) identified after the database has moved to production. If changes are required, the database specification documents will be updated as indicated in section 4.1.

A database change request form (STU-AD-FRM-020) must be completed listing all required changes and sent to the TS and TM. The changes will be reviewed and assessed for any potential impact to the existing study data. Resulting changes in data processes should be discussed with the study team and the TMG as necessary.

If a live database update is required, the ITO or delegate must notify users in advance where possible of the expected duration of downtime.

All changes should be made and checked (following section 4.3) in a test environment before updating the live database (following section 4.4). The level of testing required will be decided based upon the changes requested.

5. References

- Health Research Authority website (HRA) - http://www.hra.nhs.uk/
- Medicine and Healthcare products Regulatory Agency website (MHRA) - https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information
- UK policy framework for health and social care research (2017) - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- UK Medicine for Human Use (Clinical Trials) Regulations 2004 - http://www.legislation.gov.uk/uksi/2004/1031/contents/made

It is assumed that by referencing the principal regulations that all subsequent amendments are included in this citation.

6. Associated Documents

Number	Title	Location
STU-AD-TMP-028	Database Test Plan Template	STU Q-Pulse
STU-AD-FRM-019	MTP Approval	STU Q-Pulse
STU-AD-TMP-029	eCRF Screen Testing Template	STU Q-Pulse
STU-AD-FRM-020	Database Change Request Form	STU Q-Pulse
STU-AD-TMP-030	Testing Checklist Template	STU Q-Pulse

7. Abbreviations

List of Abbreviations	
CRF	Case Report Form
CI	Chief Investigator
DM	Data Manager
DMS	Data Management System
DT	Data Tester
eCRF	Electronic Case Report Form
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
ITO	Information Technology Officer
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
SU	Swansea University
TDG	Trial Development Group
TM	Trial Manager
TMG	Trial Management Group
TS	Trial Statistician

8. Appendices

Appendix 1: Document History

Version No:	3	**Effective Date:**	26-Mar-2024
Description of changes:	Clarification of terminology and procedure Addition of definitions Update to SOP template v5		