STU-SOP-DMS-007 – Standard Operating Procedure on Case Report Form Development

1. Purpose and Definitions

This Standard Operating Procedure (SOP) describes the procedure of developing, managing and amending paper Case Report Forms (CRF) which align to the ethically approved protocol for a research project.

2. Background

Project CRFs will be developed to capture data required by the research protocol which has received required ethical and regulatory approvals. Subsequent amendments to CRFs will follow a standardised procedure to ensure that data collection is accurate and consistent across all participants.

Clinical Trials of Investigational Medicinal Products (CTIMPs) must also adhere to the Medicines for Human Use (Clinical Trials) regulations which includes the principles of Good Clinical Practice (GCP).

3. Roles and Responsibilities

The **Sponsor** is responsible for overseeing the CRF design process adheres to GCP. It is usual for CRF design to be delegated to the Chief Investigator

The **Chief Investigator** (CI) collaborating with the research team is responsible for assuring the design of CRFs complies with GCP and the approved protocol. The CI is responsible for CRF approval.

The **Trial Manager** (TM) is responsible for coordinating the design and implementation of the project CRF. This includes ensuring site staff have access to current CRFs and training in their completion for the research project.

The **Data Manager** (DM) with the research team is responsible for ensuring that the CRFs are designed, finalised and approved prior to the database build. In some instances, this be in conjunction with database build. The DM may have a role in training in the completion of the project CRFs.

The **Trial Statistician** (TS) is responsible for advising on CRF design to ensure that all data required for project analysis are captured.

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

Research data shall be collected using CRFs, designed to collect accurate and complete data aligned to the approved research project protocol**.**

CRF development will usually start in parallel with protocol development.

When designing CRFs it is advisable to follow the principles outlined in the CRF Design Guidelines document (STU-AD-GDN-007) and to consult the EQUATOR Network website.

Templates of commonly used CRFs in the STU CRF Library (STU-AD-TMP-023) should be adapted as required.

4.1 General Principles

- CRFs must be available prior to the initiation of the research project and any site is open for recruitment.
- CRFs shall not be accepted as source documents without prior consultation and approval by the sponsor or delegate.
- Any changes required to the CRF must be discussed with the research project team before they are implemented.
- CRFs (and amendments) should be documented on a CRF Approval Form (STU-AD-FRM-017).
- CRFs must be version controlled and dated whether available as electronic, paper or both
- The CRF Completion template (STU-AD-TMP-024) should be adapted as required to ensure that clear, standardised instructions are given to all participating sites.
- The data management plan (STU-AD-TMP-025) and the CRF completion guidelines (STU-AD-TMP-024) must be reviewed following every amendment and, updated where necessary.
- Completed and approved CRFs are used to create a specification and database development (STU-SOP-DMS-009).
- If problems arise with CRF completion:
    - New guidelines or training should be given to all those completing the CRF to ensure that requirements are clear
    - Any problems and corrective actions should be recorded within the Quality Management System (QMS) and filed within the Trial Master File (TMF).

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

- UK Medical Devices Regulations 2002 - http://www.legislation.gov.uk/uksi/2002/618/made
- EQUATOR Network (http://www.equator-network.org/

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-GDN-007	CRF Design Guidelines	Q-Pulse
STU-AD-FRM-017	CRF Approval Form	Q-Pulse
STU-AD-TMP-023	CRF Library	Q-Pulse
STU-AD-TMP-024	CRF Completion Guidelines	Q-Pulse
STU-AD-TMP-025	Data Management Plan	Q-Pulse

7. Abbreviations

List of Abbreviations	
CI	Chief Investigator
CRF	Case Report Form
CTIMP	Clinical Trial of an Investigational Medicinal Product
DM	Data Manager
GCP	Good Clinical Practice
QMS	Quality Management System
STU	Swansea Trials Unit
TM	Trial Manager/Trial Co-ordinator/Project Manager
TMF	Trial Master File
TS	Trial Statistician

8. Appendices

Appendix 1: Document History

Version No:	3	**Effective Date:**	20-Jun-2024
Description of changes:	Update to procedure		

Appendix 2: CRF Development Flowchart