Swansea University

Research Governance Quality Policy

for Research Applications

Requiring NHS Ethical and/or HRA Approval

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**Abbreviations**

|  |  |
| --- | --- |
| CAPA | Corrective and Preventative Actions |
| GCP  | Good Clinical Practice |
| QA  | Quality Assurance |
| QC  | Quality Control |
| SMF | Study Master File |
| SOP | Standard Operating Procedure |
| SU | Swansea University |
| SUSOC | Swansea University Sponsorship Oversight Committee |

# PURPOSE AND SCOPE

The purpose of this document is to describe the quality management activities undertaken by Swansea University (SU) Research Governance in relation to SU sponsored studies, including personnel roles and responsibilities, training, quality assurance and audits, document management, record retention and reporting and corrective and preventative actions. This policy applies to all activities conducted by SU Research Governance on research applications requiring NHS ethical and/or HRA approval.

# RESPONSIBLE PERSONNEL

All SU Research Governance staff and SU Research staff should be familiar with this policy and conduct their working activities in accordance with it.

# POLICY

All SU sponsored studies (see Appendix 1) must adhere to this policy to ensure that they are conducted in accordance with the relevant regulations and requirements of Good Clinical Practice (GCP).

To meet regulatory expectations and ensure best practice, SU Research Governance must have quality systems with specific standards for each study process. The quality systems include:

* personnel roles and responsibilities,
* learning and development, policies and procedures,
* risk management,
* quality assurance and auditing,
* document management,
* record retention, and reporting,
* corrective and preventive actions,
* a procedure for investigating suspected fraud and misconduct.

## 3.1 Personnel Roles and Responsibilities

SU Research Governance are a qualified and responsible management team who provide governance of the whole study process. SU policies and Standard Operating Procedures (SOP) define procedures and responsibilities for all key research processes, from protocol development to preparation of the final study report and archiving of the study documentation.

All SU research staff should be familiar with this document and conduct their working activities in accordance with it. All SU research staff have the following responsibilities:

* Develop and maintain generic and study specific SOPs where appropriate, facilitating effective conduct.
* Undertake adequate training relative to individual work areas in order to prove that they are qualified by education, training and experience to perform their respective task in accordance with the conditions and principles of GCP.
* Maintain an up to date personal learning and development record, and address any training needs where required.
* Ensure correct use of the appropriate documentation (protocols, SOPs, guidance documents, template documents etc.) and actively update such documentation to reflect any change requirements.
* Effectively address issues relating to the use of incorrect versions of documents where necessary.
* Report to SU Research Governance instances where a study process or procedure has had a significant negative impact on the research participant or the scientific integrity of the trial, i.e. urgent safety measure or serious breach report.
* Assist during audits/inspections/investigations and act upon audit/inspection/investigation findings or recommendations in a timely manner and implement where appropriate.

## 3.2 Learning and Development

Swansea University is committed to staff education, learning and development. The aspiration is to help each other to be the best and to do our best, recognising the different needs and aspirations of every individual. In order to help and support staff to manage their own learning so that they maximise their potential, develop their skills, improve their performance and contribute to the knowledge and performance of their teams, SU staff development policy is available from Human Resources and on the staff website (<https://staff.swansea.ac.uk/human-resources/policies-and-procedures/staffdevelopment/>) and the process for managing and documenting learning and development can be accessed through the Development and Training Services team (<https://staff.swansea.ac.uk/dts/>)

## 3.3 Policies and Procedures

The SU Research Governance Quality Management system consists of the following documents:

* Policies
* SOPs
* Guidance documents
* Forms
* Templates

The process for preparation, review, approval and release of these documents is conducted by the SU Research Governance team and overseen by the SU Sponsorship Oversight Committee (SUSOC).

## 3.4 Risk Management

Quality Risk Management is an essential part of an effective quality system. Risk management is the systematic process of identifying, analysing and responding to risk. It involves maximising the probability and consequences of positive events and minimising the probability and consequences of negative events. Risk management principles are applied to effectively target resources to activities that present a greater risk to data integrity, participant safety and /or reputation. Controls are defined in procedures to prevent errors, identify potential problems, and intervene before the problems become serious.

There is a risk assessment form which must be completed for all SU sponsored studies during the application process, and this is available on the SU research governance website (<https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/>).

Studies are categorised into 3 risk areas – low, medium, high – with associated monitoring activities:

| **Risk level** | **Minimum additional requirements** |
| --- | --- |
| Low risk | Annual Progress Report  |
| Medium risk | Annual Progress Report One monitoring visit during the study recruitment period25% SDV |
| High risk | Annual Progress Report Annual monitoring visits during the study recruitment period 50% SDVSite Initiation Visit before recruitment can beginStudy Closedown Visit  |

## 3.5 Document Management

All process documents are reviewed annually and any updates are managed as stated in section 3.3 of this document.

## 3.6 Quality Assurance and Auditing

**Quality Assurance**

**Quality Control &**

**Monitoring**

**Audit**

**SOPs Validation**

**Training Templates**

**Quality Assurance:**

Quality assurance (QA) is the process of planned and systematic actions that are established to ensure that the study is performed and the data is generated, documented (recorded), and reported in compliance with GCP. Quality Assurance is the sum of all the activities that contribute to the quality of a study. It includes checks, quality control, monitoring and audit.

There is a hierarchy of quality assessment:

1. Self-check
2. Formal documented Quality Control (QC)
3. Independent audit

**QA Activities conducted by the QA Officer:**

* Review of all study documents during study set up
* Review of protocol, GCP non-compliance and serious breach reports, including follow up to ensure actions completed
* Conduct on-site support visits using a risk-based approach
* Review of study amendment applications and associated documentation
* Assist with study closure notifications and submission of final reports to regulators
* Review of annual progress reports
* Review of safety reports

**Self-Check and Quality Control**

Quality Control (QC) is an activity that involves the review of factors in a process as the process is occurring. This may be a self-check of one’s own work or it may be performed by a member of staff who is familiar with the procedures but has not personally undertaken the work. All QC checks should be documented and the documented evidence of QC should be retained. QC checks are applied to critical stages of data collection and handling to ensure that data is reliable and has been processed correctly. QC checks will be performed according to the risk level of a study with risk levels as stated in section 3.4 of this document.

Monitoring is a QC activity which involves a system of ongoing checks to oversee the progress of a study and ensure that it is conducted, recorded and reported in accordance with the protocol, SOPs, GCP and the applicable regulatory requirements.

**Independent Audit**

The SU Research Governance team has responsibility for assessing risk at a regulatory compliance level but is not responsible for assessing all risks (e.g. financial, commercial, intellectual property) across every process. This responsibility falls under the remit of SU central governance and is outside the scope of this document.

**Quality Management Issues**

The SUSOC meets every 2 months to discuss quality assurance issues across SU sponsored studies. The terms of reference for the SUSOC are located on the SU Research Governance website (<https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/susoc/>)

## 3.7 Data Recording and Correction

The principles of GCP require staff to fully document study activity. In practice, this includes ensuring a full audit trail of key discussions through documented notes and actions from meetings. The format of these notes can vary depending on the type of meeting, for example it is acceptable to document notes and actions via e-mail for a team meeting, but for a more formal meeting, for example a Study Management Group Meeting or Independent Monitoring Committee meeting there is the expectation that formal minutes and actions are taken.

Any corrections should be made in line with GCP i.e. one line through the incorrect text which is initialled and dated.

## 3.8 Record Retention and Reporting

Both hard and digital copy study resource is in the form of central documentation (Study Master File (SMF), or portions thereof) and participant-specific records. Effective management of ongoing studies requires access to all of these resources. Hard copy study files are retained overnight in locked cabinets within the study team office(s). Offices should be locked and accessible to authorised staff only. Digital study records should be kept on a SU server according to the SU Research Integrity Policy framework. Please refer to the SU Staff Intranet for further guidance on records management, and security of data. Appropriate access arrangements should be in place ahead of any monitoring visit by the Sponsor, e.g. Honorary Research Contract, study databases, access to NHS-based computers.

Data in multi-centre studies are often stored in study-specific databases. During the process of developing electronic data capture tools, the sponsor will consider the digital preservation of any electronic essential documentation and ensure that the electronic records will remain accessible throughout the retention period.

The regulations require all essential documents in the SMF to be retained for audit and inspection by the sponsor and the regulatory authorities once the study has been completed. Archiving an SMF also enables a study to demonstrate compliance to standards of GCP and to safeguard against claims of misconduct.

The required retention period should be defined on a study by study basis. The retention period should be specified in the study protocol and relevant study agreements, and compliant with current legislation. The process for archiving is set out in the SU Research Integrity Policy framework (<https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-integrity/>).

## 3.9 Corrective and Preventive Actions (CAPA)

Incidences of protocol and/or GCP non-compliance are not uncommon. The majority of these instances are technical deviations, which do not result in harm to the study participants or significantly affect the scientific value of the reported results of the study. These cases should be documented and appropriate corrective and preventive actions taken. The procedure for the capture, documentation and escalation of protocol or GCP non-compliances is documented in STU-SOP-TM-011 Identifying and Assessing Deviations, Breaches and Urgent Safety Measures (<https://swanseatrialsunit.org/governance>)

Prospective or planned deviations from the protocol (for example, from the subject eligibility criteria) are classed as protocol waivers and are permitted on a case-by-case basis by the study Chief Investigator.

3.10 Fraud and Research Misconduct

Whilst the majority of people involved in research are dedicated and diligent, there have been a small number of high profile examples where misconduct has occurred. These can have a major impact on the research study and University and we need to ensure suspicions are dealt with fairly, effectively and in a timely manner. Information on the procedures for dealing with suspected incidences of fraud or research misconduct can be found on the SU Research Integrity web pages: (<https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-misconduct/>)

# REFERENCES

## Referenced SOPs and Policies

- SU Sponsorship Policy

- SU Research Integrity Policy framework P1415-956

- SU Policy on Research Misconduct P1920-793

-SU Staff Development Policy P1718-241

## Referenced Forms and Templates

- STU-SOP-TM-011 Identifying and Assessing Deviations, Breaches and Urgent Safety Measures (<https://swanseatrialsunit.org/governance>)

## Other References

-UK Policy Framework for Health & Social Care Research

-UK Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004 No. 1031) as amended

-Health Research Authority (<https://www.hra.nhs.uk/>)

-Principles of Good Clinical Practice (as outlined in Directive 2005/28/EC)

-Data Protection Act (2018)

-Human Tissue Authority (<https://www.hta.gov.uk/>)

-Human Tissue Act 2004

-Medical Research Council e-learning (<https://bygsystems.net/mrcrsc-lms/>)

-UK Research Integrity Office (<https://ukrio.org/>)

Appendix 1 - Swansea University Sponsorship Flowchart

