Swansea University

Research Governance Sponsorship Policy

Guidance for Research Applications Requiring NHS Ethical and/or HRA Approval

Version tracker

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Appendix 2 Checklist

**Abbreviations**

|  |  |
| --- | --- |
| GCP  | Good Clinical Practice |
| HRA  | Health Research Authority |
| REC  |  |
| REIS  | Research, Engagement and Innovation Services |
| SOP | Standard Operating Procedure |
| SU | Swansea University |
| SUSOC | Swansea University Sponsorship Oversight Committee |

# INTRODUCTION

UK Policy Framework for Health and Social Care Research (2017) calls for an Organisational Sponsor in cases of Research in the NHS or Social Care.

# PURPOSE AND SCOPE

Swansea University (SU) will act as Sponsor in principle for research involving the NHS as defined in the UK Policy Framework for Health and Social Care Research (2017), where the Chief Investigator is either a substantive employee or the research is being carried out by a SU student with the 1st Supervisor as SU Staff member.

Swansea University Sponsorship Oversight Committee (SUSOC) and Research Governance department in Research, Engagement and Innovation Services (REIS) oversee the process, administration, and approvals.

The policy describes the REIS process for granting SU sponsorship.

The following processes take place, defined as stages 1 – 4:

* **Stage 1**: Obtain initial study information and determine pathway for appropriate regulatory framework and governance processes to be implemented.
* **Stage 2**: Conduct a full review of the study, including submission to the SUSOC, to ensure it meets appropriate standards, is scientifically sound and feasible in practice.
* **Stage 3**: Issue Sponsorship in Principle to allow further regulatory approvals to be gained.
* **Stage 4**: Issue full sponsorship upon all regulatory approvals and other required documentation being received

# 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.

The decision to grant SU sponsorship is based on a procedure involving the REIS Research Governance manager, members of the SUSOC and information provided by the study-specific Chief Investigator and members of the study team (including SU students).

Where SU is not the study sponsor, e.g. Ministry of Defence studies, the study will be subjected to the same rigorous review process as described in section 1.2 stages 1 – 3 inclusive.

* 1. **PROCEDURE**

Details of the entire sponsorship process, as well as other useful related resources, can be found on the: [Research Governance website](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/).

* + 1. **STAGE 1 Determine correct pathway**

**The first step** is to use the NHS research [Toolkit](https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.hra-decisiontools.org.uk%2Fresearch%2F&data=05%7C02%7Cresgov%40swansea.ac.uk%7C3c7ad3ec60f54f4ddfa608dc1bfaa7f3%7Cbbcab52e9fbe43d6a2f39f66c43df268%7C0%7C0%7C638416010574782147%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=gwWlr1HwWa6ZmsH7cJeXF6a1umSm0HJopRK9BOv%2B2rY%3D&reserved=0) to check eligibility.

The toolkit has been designed to pull together the resources required to understand what approvals may be needed to carry out a study. It contains links to existing Health Research Authority (HRA) decision tools as well as new ones developed especially for students. It provides access to five different decision tools designed to provide answers to the questions below:

• Is my study research?

• Is my research taking place in the NHS and does it need NHS Approval?

• Does my study need NHS REC review?

• What type of NHS REC review will I need?

• Can I carry out my research?

If the study is classed as research, the **Second Step** is to complete the following toolkit to determine if the study requires [NHS ethical review](https://www.hra-decisiontools.org.uk/ethics/).

For student research, please complete the [*planning and improving toolkit*](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/student-research-toolkit/)first.

If the study is eligible for sponsorship then an ethics application for sponsorship is submitted via the SU ['My Apps'](https://myapps.microsoft.com/) portal, using the Ethics app and ‘Healthcare Sponsorship’ form.

It is necessary to also complete the IRAS submission portal and it is recommended to become familiar with the IRAS portal.

**Note:** *When creating your Project within the Ethics app ensure you select “Healthcare Research Sponsorship” form.*

* + 1. **STAGE 2 SUSOC Review**

Sponsorship applications submitted through the Ethics app, will undergo a validation check upon receipt by the research governance team, and subsequent review by the SUSOC to ensure that the application is compliant with HRA standards, current legislation and SU policies and best practice.

All relevant study documents will need to be uploaded, as requested on the portal.

We recommend you use the SU document templates provided within the Ethics app. The documents have been designed to ensure compliance with relevant standards and legislation.

You will be informed by the portal when the Sponsor review has taken place (within 10 working days). If amendments to your application are required, you will be informed as soon as possible and a further 5 working days after submission of the amended application should be allowed for re-review by the Sponsor.

* + 1. **STAGE 3 Sponsorship in Principle**

This is awarded to a study once it has gone through stages 1 and 2, and been deemed of an appropriate standard. It is awarded via the SUSOC to ensure SU oversight and insurance considerations.

This is the first step before any NHS Research Ethics Committee (REC)/HRA approval booking may occur. Sponsorship in principle will be issued together with a copy of the University Indemnity certificate, which you will need to include with your submission to the IRAS portal together with the SUSOC approved documents for IRAS submission.

When approval in principle is given it is on the understanding that the applicant must meet all sponsor requirements for the application and during the delivery of the study. This includes the submission of reports and sponsorship support visits /audits.

**3.1.4 STAGE 4 Full sponsorship**

To obtain full sponsorship, a study must then obtain external regulatory approvals from the organisations listed below. All approvals will be provided via the IRAS portal.

* **NHS Ethics**

This is an Independent REC opinion provided through the UK Health Departments’ Research Ethics Service. It protects the rights, safety, dignity, and wellbeing of research participants. This is booked via the NHS IRAS portal.

* **HRA Approval**

It is the approval process required for research to commence in the NHS. It brings together an assessment of governance and legal compliance undertaken by dedicated HRA staff.

* **Capacity and Capability in the NHS**

The local feasibility procedure undertaken by an NHS Organisation to assess and confirm whether the organisation has the resources, policies and service

users required to successfully deliver the research study to time as well as meet regulatory requirements for its conduct.

**Note**: The 'Capacity and Capability in the NHS’ will be likely require direct correspondence between the study CI/Research Team/Sponsor and the Health Board’s ‘Research & Development’ department, to confirm the above mentioned study arrangements.

**4. REVIEW and APPROVAL**

The review process will be carried out annually. This policy will be reviewed and approved by the SUSOC.

**5. REPORTING REQUIRMENTS**

The SUSOC meets every 2 months and a report will be provided to the committee ahead of each meeting, for study oversight purposes. The report will provide metrics related to studies awarded SU sponsorship, serious breaches of GCP/Protocol, submission of amendments to studies. The meeting also allows discussion of issues affecting research governance such as SUSOC membership, Infonetica portal issues and future development, staff training and any other business as arises.

**6. RELATED POLICIES AND PROCEDURES**

## 6.1 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

## 6.2 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



**Appendix 2 Checklist for documents need for sponsorship**

|  |  |  |
| --- | --- | --- |
| **Mandatory documents** | **Submitted?**  | **Comment** |
|  | **Yes** | **No** | **N/A** |  |
| IRAS |  |  |  |  |
| Protocol |  |  |  |  |
| PIS |  |  |  |  |
| Consent |  |  |  |  |
| CV |  |  |  |  |
| GCP training certificate |  |  |  |  |
| SU Research Integrity training evidence |  |  |  |  |
| IRMER certificate  |  |  |  |  |
| HTA certificate |  |  |  |  |
| Safeguarding certificate |  |  |  |  |
| MCA certificate |  |  |  |  |
| Medical Device HRA certificate |  |  |  |  |
| OID |  |  |  |  |
| PIC |  |  |  |  |
| Schedule of Events or SoECAT |  |  |  |  |
| Peer review evidence |  |  |  |  |
| Risk assessment  |  |  |  |  |

|  |  |  |
| --- | --- | --- |
| **Study specific documents** | **Submitted?** | **Comment** |
|  | **Yes** | **No** | **N/A** |  |
| Declaration form for consultees |  |  |  |  |
| GP letter |  |  |  |  |
| Questionnaires |  |  |  |  |
| Web-based tools |  |  |  |  |
| Research Passport |  |  |  |  |
| Advertisement material: |  |  |  |  |
| * Posters
 |  |  |  |  |
| * Text of emails
 |  |  |  |  |
| * Radio adverts wording
 |  |  |  |  |
| * Reminder texts/emails
 |  |  |  |  |
| MTA |  |  |  |  |
| Manufacturers Instruction Manual |  |  |  |  |