Swansea University Sponsorship and Oversight Committee (SUSOC)

Terms of Reference (ToR)

The remit of the SU Sponsorship and Oversight Committee (SUSOC) is to ensure that SU staff and student studies sponsored by the SU comply with the requirements of the UK Policy Framework for Health and Social Care Research (2017) and/or the Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments, and to standards of Good Clinical Practice (GCP).

The Committee will review all SU staff and student applications for University sponsorship or co-sponsorship for studies that require sponsorship under the UK Policy Framework for Health and Social Care Research (2017).

The Committee will also review applications for clinical trials carried out and provide appropriate sponsor oversight of sponsored studies on behalf of the University, ensuring compliance with sponsor responsibilities and other applicable legislative requirements.

Specifically, the Committee will:

1. Receive and review sponsorship applications from University staff and students, and approve, conditionally approve, or reject applications.
2. Receive and review sponsorship applications for clinical trials carried out in the UK.
3. Ensure that studies sponsored or co-sponsored by the University can be undertaken within the requirements of the UK Policy Framework for Health and Social Care Research (2017), the Medicines for Human Use (Clinical Trials) Regulations 2004, to include areas around Human Tissue Act (HTA) , Mental Capacity Act (MCA), Ionising Radiation (IRMER) , GDPR, Medical Devices, Prison Research regulations and subsequent amendments, and to standards of Good Clinical Practice;
4. Ensure that the projected financial plans for studies provide the necessary and adequate funding with which to deliver the study and are in line with the current costing attribution of the Department of Health.
5. Ensure that studies have the necessary insurance cover from the outset.
6. Ensure the study have received appropriate peer review of the scientific design and quality of the study.
7. Ensure that a robust risk-assessment is carried out in order to inform the Committees decision on whether to issue Sponsorship approval. The risk assessment any subsequent agreed actions for monitoring, managing or mitigating risk.

Reports

- Quality Assurance Audit and Monitoring reports completed since the last meeting
- Annual and End of Study REC reports submitted since the last meeting
- Development Safety Update Report (DSUR) reports submitted since the last meeting
- Protocol and/or GCP violations/serious breaches, with any Medicines and Healthcare products Regulatory Agency (MHRA) reported serious breaches also being referred immediately to the Chair of the Committee.
- Suspected Unexpected Serious Adverse Reaction (SUSAR) line reporting, with immediate referral to the Chair of the Committee.

Membership	The committee will comprise of 5 members 1. Chair 2. Research Governance Manager 3. Research Quality Assurance Officer 4. Human Tissue Act Officer 5. Rep from FMLS And consultees from the SU (as and when) on specific areas covering Clinical Trials, Sport Science, Data, Radiation, Medical Devices and Social Care.
Quorate for meetings	At least 4 will need to be present to constitute a quorate for decisions to be made. Decisions shall be taken by a majority vote of a meeting of the committee. Each member of the committee will use their best endeavours to reach a consensus on decisions, acting reasonably and co-operatively in order to reach agreement.
Frequency of Meetings	The committee will meet digitally every month.
Agenda SU Sponsorship Research Projects	Project documents will be distributed at least five (5) days prior to the date of the proposed meeting.

The Committee reports to the University Research Integrity: Ethics & Governance committee.