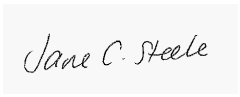
UNIVERSITY OF SUSSEX

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Applying for Sponsorship by the University of Sussex

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1. Purpose and scope

All research falling under the UK Policy Framework for Health and Social Care Research requires a sponsor. The University of Sussex will consider taking on sponsorship according to certain Criteria of Sponsorship.

This standard operating procedure (SOP) describes the process for applying for University of Sussex sponsorship and gaining sponsor approval. It applies to all University staff, Postgraduate Researchers (PGR) and, where applicable, Master's students[1] (including Brighton and Sussex Medical School) who are seeking University sponsorship for research studies conducted under the UK Policy Framework for Health and Social Care Research.

This SOP is expected to be used in conjunction with the relevant University of Sussex policies and the Code of Practice for Research.

2. Abbreviations

CTIMPs	Clinical Trials of Investigational Medicinal Products
HSC SCC	University of Sussex Health and Social Care Sponsorship Sub-Committee
PGR	Postgraduate Researcher
PSRP	Pre-Sponsorship Review Panel
REIG	Research Ethics, Integrity & Governance
SREIO	Senior Research Ethics & Integrity Officer responsible for sponsorship
SOP	Standard Operating Procedure

3. Background

The UK Policy Framework for Health and Social Care Research covers research involving patients, health care professionals, service users, or their relatives or carers. This includes research involving them indirectly, for example, using information that the health or social care services have collected about them. Research sites may be situated within the NHS (e.g., hospitals, health centres, GP surgeries) and/or sites in non-NHS settings (e.g., care homes, local authorities, charities, hospices, schools, prisons, and the independent sector).

All research falling under the UK Policy Framework for Health and Social Care Research requires a sponsor. The sponsor is a company, institution or organisation that takes overall responsibility for effective arrangements being in place to set up, run and report a research study. Appendix A indicates the types of study that require sponsorship, and Appendix B describes sponsor responsibilities in more detail.

Applying for University sponsorship is a two-stage process. Studies are reviewed initially by the Pre-Sponsorship Review Panel (PSRP). The PSRP is a cross-organisational committee that is owned, invested and managed by the four collaborating partners; University of Sussex, University of Brighton, Sussex Partnership NHS Foundation Trust and University Hospitals Sussex NHS Foundation Trust. It is co-ordinated by the Sussex Health and Care Research Partnership. The PSRP provides feedback and advice to investigators, to ensure that research studies can meet the quality and

[1] Student research - Health Research Authority

standards expected by the sponsor in relation to safety, design and conduct. The PSRP review will reach one of three (3) outcomes:

- ☐ Application supported (with or without minor amendments)
- ☐ Application supported with modifications recommended
- ☐ Application unsupported

Following recommendation by the PSRP, sponsorship applications are considered by the University of Sussex Health and Social Care Sponsorship Sub-Committee (HSC SCC) . The HSC SSC will ensure the research is in line with the UK Policy Framework for Health and Social Care Research and that the University's Criteria of Sponsorship are met.

4. Responsibilities

- ☐ Chief Investigators are responsible for:
    - Ensuring that the University of Sussex Criteria of Sponsorship can be met before submitting an application for sponsorship.
    - Accepting, and adhering to, the 'Conditions of Sponsorship'.
- ☐ The PSRP are responsible for initial review of applications for sponsorship by the University of Sussex, and providing expert feedback and advice to the applicant.
- ☐ Members of the HSC SCC are responsible for the review and approval of applications for sponsorship by the University of Sussex.
- ☐ The SREIO is responsible for screening the application for common errors and co-ordinating the review and approval process using the Infonetica Ethics RM system.
- ☐ Anyone applying for University sponsorship must follow this SOP.

5. Procedure

5.1. Prior to making an application for sponsorship

5.1.1. Chief Investigators should ensure that the University of Sussex Criteria of Sponsorship are met.

5.2. Review by the PSRP

5.2.1. The Chief Investigator (or delegate) (the "applicant") will submit the application documents required by the PSRP to psrp@sussex.ac.uk (see Pre-Sponsorship Review Panel).

5.2.2. The PSRP will inform the sponsorship team (researchsponsorship@sussex.ac.uk) of a new application and share the application documents.

5.2.3. The SREIO will:

- ☐ Check the application documents for common mistakes and omissions.
- ☐ Complete the Initial Sponsor Review Report and return it to the PSRP (psrp@sussex.ac.uk).

5.2.4. The PSRP will:

- ☐ Review the application documents.

- ☐ Provide brief verbal feedback to the applicant following the review meeting.
- ☐ Provide written feedback to the applicant (PSRP Review Report).

5.2.5. For applications that are **supported (with or without minor amendments)**, the PSRP will send the PSRP Review Report to the sponsorship team (researchsponsorship@sussex.ac.uk) and recommend that the application progresses to sponsor review.

5.2.6. For applications that are **supported with modifications recommended**:

- ☐ The applicant will make the recommended modifications and return the revised application documents to the PSRP (psrp@sussex.ac.uk).
- ☐ The PSRP will review the revised documents and may return to the applicant for further modifications.

5.2.7. When the PSRP are satisfied with the quality of the application, they will recommend the application for sponsorship.

5.2.8. For applications that are **unsupported**, the applicant must re-submit the application to a future meeting of the PSRP.

5.3. Review by the HSC SCC

5.3.1. Following recommendation for sponsorship by the PSRP, the SREIO will instruct the applicant to complete the sponsorship application form on the Infonetica Ethics RM system. Applicants are advised to check the HSC SSC submission and meeting dates.

5.3.2. After completing the sponsor application form, and ensuring that all accompanying documents have been uploaded, the applicant will submit the application.

5.3.3. Upon receipt, the SREIO will screen the sponsorship application form and accompanying documents for completeness. If issues are found, then the SREIO will add comments to the form on Infonetica Ethics RM and send a 'Change Request' to the applicant. The applicant will address the comments and re-submit the application.

5.3.4. Following successful screening, the Head of REIG, REIG Senior Manager, or Director of Research and Innovation Services will complete the Sponsor Risk Assessment.

5.3.5. The SREIO will share the application with all members of the HSC SCC.

5.3.6. Members of the HSC SCC will:

- ☐ Review the sponsorship application and accompanying documents.
- ☐ Add their comments to the application form on Infonetica Ethics RM.
- ☐ Discuss the application at the next meeting of the Committee.

5.3.7. Following the meeting, the SREIO will:

- ☐ Add any additional points raised at the meeting as comments onto the Infonetica Ethics RM system.
- ☐ Send a 'Change Request' to the applicant.

5.3.8. The applicant will address the comments and re-submit the revised application.

5.3.9. HSC SSC will determine whether the revised application requires further review by the full committee or proportionate review by the Chair and Deputy Chair of the HSC SCC,

together with either the Head of REIG or REIG Senior Manager. Additional specialist reviewers may also be asked to review the revisions and may provide further comments. Where further changes are required and added to the application, the SREIO will send a further 'Change Request' to the applicant.

5.3.10. Once all issues and comments have been addressed satisfactorily by the applicant, the Chair of the HSC SSC and the sponsor will issue approval, and the SREIO will send the Sponsor Approval Letter.

6. Related documents

Criteria of Sponsorship

Initial Sponsor Review Report

PSRP Review Report

Sponsor Risk Assessment

Conditions of Sponsorship

Infonetica Ethics RM User Guides

7. References

University of Sussex Research Ethics Policy

Code of Practice for Research

UK Policy Framework for Health and Social Care Research

Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

8. Appendices

APPENDIX A. Types of study that require sponsorship

APPENDIX B. Sponsor responsibilities

VERSION HISTORY

Version number	Effective date	Reason for update
1.0	12-Oct-2026	Original version

APPENDIX A. Types of study that require sponsorship

- ☐ Studies involving NHS patients, their identifiable data, or their tissue.
- ☐ Studies involving adults (over 16 years old) lacking the capacity to consent for themselves.
- ☐ Studies involving NHS staff or NHS facilities/premises.
- ☐ A Clinical Trial of an Investigational Medicinal Product.
- ☐ A Clinical Investigation or other study of a Medical Device that is non-CE marked, or is CE marked and is being used outside of its current intended purpose or has been modified.
- ☐ A Phase 1 Clinical Trial of an Investigational Medicinal Product using healthy volunteers and taking place outside of the NHS.
- ☐ Social Care research that is:
    - Funded by the Department of Health and Social Care (England).
    - Involves people lacking capacity (in England and Wales).
    - Involves integrated health and social care services.
    - Involves intergenerational social care research where both adults and children, or families, are research participants.
- ☐ Staff and/or offenders in prison establishments or the probation service.
- ☐ Research undertaken, funded or sponsored by the Ministry of Defence.

Further information is available at University of Sussex Research Sponsorship.

APPENDIX B. Sponsor responsibilities

The sponsor has overall responsibility for the research, including:

- ☐ Identifying and addressing poorly designed research and ensure that research proposals and protocols:
    - Take into account systematic reviews of relevant existing research evidence and other relevant research in progress.
    - Make appropriate use of patient, service user and public involvement.
    - Are scientifically sound, safe, ethical, legal and feasible, and remain so for the duration of the research.
- ☐ Satisfying itself that the investigators, research team and research sites are suitable.
- ☐ Ensuring that roles and responsibilities of the parties involved in the research and any delegation by the sponsor of its tasks are agreed and documented.
- ☐ Ensuring adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project.
- ☐ Ensuring appropriate arrangements are made for:
    - Making information about the research publicly available before a study starts.
    - Agreeing appropriate arrangements for making data and tissue accessible in a timely manner after a study has finished (with adequate consent and privacy safeguards).
    - Ensuring arrangements for information about the findings of the research are made available, including, where appropriate, to participants.
- ☐ Ensuring that, where expected or required, the research has approval from a Research Ethics Committee and any other relevant approval bodies before it begins.
- ☐ Verifying that regulatory and practical arrangements are in place, before permitting the research to begin in a safe and timely manner.
- ☐ Ensuring arrangements are in place for adequate finance and management of the research project, including its competent risk management and data management.
- ☐ Ensuring that effective procedures and arrangements are kept in place and adhered to for reporting (e.g. progress reports, safety reports) and for monitoring the research.
- ☐ Sponsors of CTIMPs have particular legal obligations:
    - Ensuring that the study complies with the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 and Good Clinical Practice.
    - Ensuring that adequate insurance or indemnity is in place to cover the potential liability of the sponsor.