UNIVERSITY OF SUSSEX

Standard Operating Procedures for Sponsorship Approval

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SOP Reference:	**SOP/RGO/0**
Version Number:	**01**
Date:	**March 2022**
Effective Date:	**5 March 2022**
Review by:	**TBC (Two years from effective date)**
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Version	Effective Date	Reason for Change
01	5 March 2018	-
02	5 March 2022	Updated to reference PSRP

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Acknowledgement University Hospitals (Sussex)

[1] http://www.sussex.ac.uk/staff/research/governance

Contents

1.0 PURPOSE & SCOPE

1.1 The *UK Policy Framework for Health and Social Care Research* (2017) sets out the broad principles of good research governance in the research areas of health and social care. The Policy Framework applies to all research that relates to the responsibilities of the Secretary of State for Health. That is, research concerned with the protection and promotion of public health, research undertaken in or by the Department of Health, its non-Departmental Public Bodies and the NHS, and research undertaken by or within social care agencies. It includes clinical and non-clinical research; research undertaken by NHS or social care staff using the resources of health and social care organisations; and any research undertaken by industry, charities, research councils and universities within the health and social care systems that might have an impact on the quality of those services. Research which falls within the scope of this requires a research sponsor; the Sponsor is a company, institution or organisation which takes responsibility for the quality and governance of the project. More specifically:

1.2 The UK Policy Framework states that a Sponsor is 'The organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project.'[2]

1.3 The scope of the document is for all schools at the University of Sussex, all members of staff with substantive employment and students registered at the University (including Brighton and Sussex Medical School).

1.4 The University of Sussex, through its *Code of Practice for Research* is committed to promoting and upholding the highest quality academic, professional and ethical standards in all its activities and seeks to foster a culture of professional integrity. Failure to engage with and secure the required regulatory and procedural approvals will be considered a breach of the Code and may be investigated under the Procedure for the Investigation of Allegations of Misconduct in Research[3].

2.0 STANDARDS FOR RESEARCH

2.1 Good Clinical Practice (GCP)

2.1.1 **The University expects that *all clinical research involving human participants* is undertaken in line with the principles of GCP.**

2.1.2 **Good Clinical Practice** (GCP) is an international ethical and scientific quality standard for the design and conduct of clinical research involving humans. GCP is a set of core principles, which applies to all clinical investigations that could affect the safety and wellbeing of human participants. GCP is internationally recognised as best practice and compliance (including up to date training) and is a legal obligation in the UK/Europe for all trials of investigational medicinal products. GCP was developed by the regulatory authorities represented in the Tripartite International Conference on Harmonisation and provides international assurance that:

(i) Data and reported results of clinical investigations are credible and accurate, and; (ii) The rights, safety and confidentiality of participants in clinical research are respected and protected.

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[2] UK Policy Framework for Health and Social Care Research (2017) , p.31

[3] https://www.sussex.ac.uk/webteam/gateway/file.php?name=procedure-for-the-investigation-of-allegations-of-misconduct-in-research-june-2018.pdf&site=377

3.0 RESPONSIBILITIES

3.1 The *Chief Investigator* (CI) is responsible for making a request to the University of Sussex to act as Sponsor and fulfilling the terms of the 'Conditions of Sponsorship Agreement' issued when the study has been formally accepted for Sponsorship.

The *University Research Governance and Quality Assurance Committee (RGQAC) Sponsorship Sub-Committee* is responsible for reviewing and accepting Sponsorship on behalf of the University.

3.2 The *Sponsorship Sub-Committee* (SSC) is responsible for reviewing and giving approval to sponsorship requests from across the University based on recommendations from the Pre-Sponsorship Review Panel.

3.2.1 Decisions and the responsibility for Sponsorship rest entirely with the SSC.

3.2.2 The SSC is responsible for:

- reviewing and recommending University policy on all areas of research sponsorship under the terms of the HRA's UK Policy Framework and successors to the framework
- understanding and monitoring high risk research that falls outside of the remit of the UK Policy Framework, making recommendations to the Research Governance and Quality Assurance Committee
- undertaking and providing management oversight of the necessary high-level auditing of any Clinical Trials on behalf of the sponsor as required by the Medicines & Healthcare products Regulatory Agency (MHRA)
- providing oversight of proportionate monitoring of all sponsored non-CTIMP projects as expected by the Health Research Authority (HRA)

3.3 The UK Policy Framework for Health and Social Care Research (2017) stipulates that 'The *Sponsor* has overall responsibility for the research, including:

a. identifying and addressing poorly designed or planned research and poor quality research proposals, protocols or applications and ensuring 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 and
   - are scientifically sound (e.g. through independent expert review), safe, ethical, legal and feasible and remain so for the duration of the research, taking account of developments while the research is ongoing;

b. satisfying itself that the investigators, research team and research sites are suitable;

c. 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;

d. 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; and

e. ensuring appropriate arrangements are made for making information about the research publicly available before it starts (unless a deferral is agreed by or on behalf of the research ethics committee); agreeing appropriate arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after it has finished; and ensuring arrangements for information about the findings of the research to be made available, including, where appropriate, to participants;

f. ensuring that, where expected or required, the research has approval from a research ethics committee and any other relevant approval bodies before it begins;

g. verifying that regulatory and practical arrangements are in place, before permitting the research to begin in a safe and timely manner;

h. putting and keeping in place arrangements for adequate finance and management of the research project, including its competent risk management and data management;

i. 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, including its conduct and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments.'[4]

Formal confirmation from the designated Sponsor via the Sponsor's Representative must be obtained prior to an application for Host Organisation or NHS Research Ethics Committee (REC) approval.

3.4 ***The Pre-Sponsorship Review Panel***

3.4.1 The scope of the Panel covers research that:

- Is intended for sponsorship by one the Joint Clinical Research Office's (JCRO) Partners (which are the University of Sussex, University of Brighton, University Hospitals Sussex NHS Foundation Trust (UHSx) and Sussex Partnership Foundation Trust (SPFT))
- Has NHS Trust, Social Care involvement with a requirement to seek Health Research Authority (HRA) approval, via the Integrated Research Application System (IRAS).

3.4.2 On behalf of the Sponsoring' Partner the Panel will be responsible for ensuring that all research that requires the Partner to act as a sponsor has had appropriate expert input into the design, conduct and management.

[4] UK Policy Framework, pp. 23-24

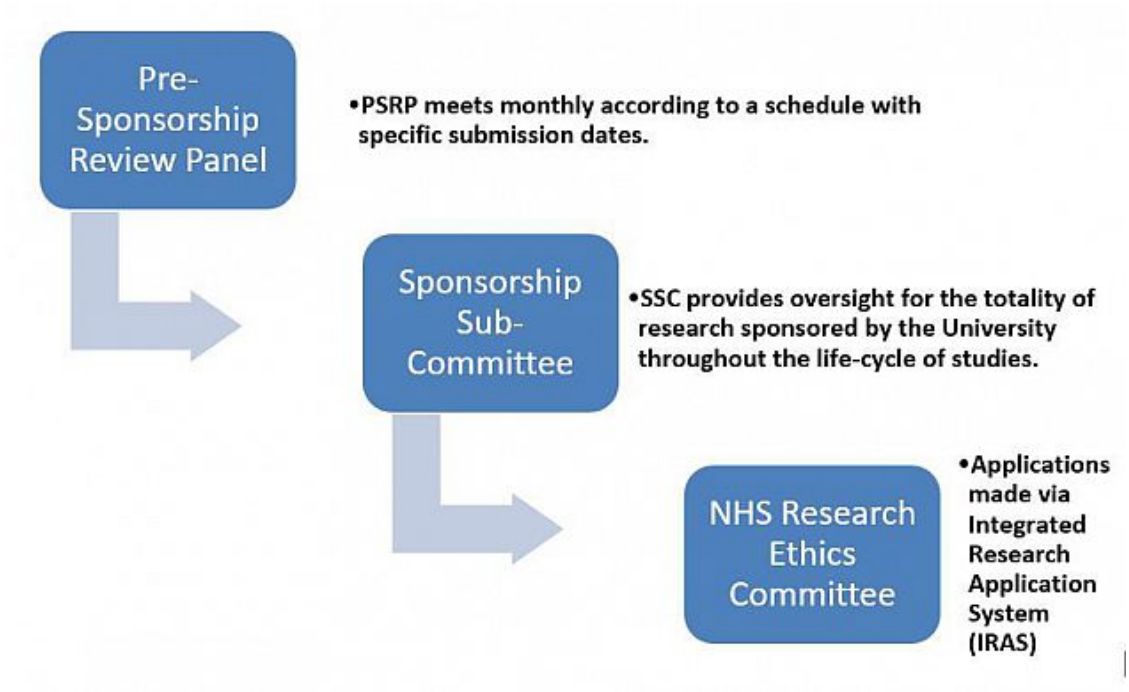
3.4.3 Through the provision of expert review of the study proposal, the Panel will provide feedback and advice to researchers to meet the quality and safety criteria expected by sponsoring organisations. The Panel will then make recommendations of each application for sponsorship to the sponsoring organisation.

3.4.4 The aim of the Panel is to improve the quality of sponsorship applications whilst avoiding delays due to revisions and resubmissions to Sponsorship Committees, the HRA and Ethics Committees.

3.5 ***The Research Ethics, Integrity and Governance Team in Research and Enterprise***

3.5.1 The Research Ethics, Integrity and Governance Team provides administrative oversight and leadership of sponsorship processes, servicing the Sponsorship Sub-Committee and representing the university on the Pre-Sponsorship Review Panel.

4.0 PROCEDURE



Sponsorship application process

4.0.1 The Chief Investigator (CI) is required to submit a formal application for Sponsorship.

4.0.2 Applying for sponsorship occurs in a two-stage process:

Application to the Pre-Sponsorship Review Panel (PSRP) – section 4.3 below

Application to the Sponsorship Sub-Committee (SSC) – section 4.4 below

4.0.3 The University of Sussex will review Sponsorship requests for research projects where:

- The substantive employer of the CI is the University of Sussex
- The NHS partner will not act as Sponsor;
- The third-party partner will not act as Sponsor;
- The research project does not have an NHS or third-party partner
- The project is related to an academic qualification and the status and level of the student is compatible with HRA eligibility criteria for them to act as the Chief Investigator under the responsibility of a suitable academic supervisor[5]

4.1 *Who* should request Sponsorship

4.1.1 It is usually the responsibility of the CI on a project to request Sponsorship. However, it is recognised that this responsibility may be delegated to another member of the research team with sufficient knowledge of the research activity.

4.1.2 If research is being conducted as part of an academic qualification below doctoral level the responsible Supervisor should request sponsorship on behalf of the individual undertaking the qualification. The Sub-Committee will expect that, as part of the arrangements for the study, the Supervisor takes ***demonstrable responsibility*** for ensuring that the student undertakes research activities that are appropriate to their abilities and experience. The student shall receive appropriate training (such as GCP) and have sufficient supervision arrangements in place before the research commences.

4.2 *When* to request Sponsorship

4.2.1 The CI should liaise with University Research Governance Officer as early as possible to discuss Sponsor responsibilities. The CI is expected to request Sponsorship once funding for a research project has been confirmed, or in the case of student research projects when the Academic Supervisor has approved the study.

4.2.2 In circumstances where the funding body requires confirmation of Sponsorship prior to submission of the funding application, the CI should contact the Research Governance Officer in Research and Enterprise Services (researchsponsorship@sussex.ac.uk).

[5] https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/

4.2.3 The University's Sponsorship Sub-Committee has oversight of all new sponsorship approvals and business related to the maintenance of sponsorship through the study's life-cycle.

4.3 Applying for University Sponsorship – the Pre-Sponsorship Review Panel (PSRP)

4.3.1 The Pre-Sponsorship Review Panel (PSRP) is a joint venture by the University of Sussex, University of Brighton, University Hospitals (Sussex) NHS Trust (UH(s)) and Sussex Partnership NHS Foundation Trust (SPFT).

4.3.2 The PSRP is made up of academics, clinical researchers, quantitative and qualitative researchers, research governance representatives, disease area and specialist experts, research nurses, patient and public involvement members, statisticians and trial and data managers. The panel includes representatives of the Sussex Research Ethics, Integrity and Governance Team to represent the Sponsor and ensure that governance implications are considered at an early review stage.

4.3.3 The Panel uses its wide expertise to review studies and make sponsorship recommendations to each of its four partners. *Only the sponsor can make formal decisions relating to acceptance of studies for university sponsorship.*

4.3.4 A study that meets required standards will be **recommended** to the Sponsorship Sub-Committee.

4.3.5 Applicants should consult the PSRP Document Submission Form[6] before starting their application to ensure the appropriate documentation is submitted for PSRP review.

4.3.6 The PSRP meets monthly. Applicants should check https://www.bsms.ac.uk/research/support-and-governance/pre-sponsorship-review-panel.aspx to ensure awareness of submission deadlines.

[6] https://www.bsms.ac.uk/research/support-and-governance/pre-sponsorship-review-panel.aspx

4.4 Applying for University Sponsorship – the Sponsorship Sub-Committee

4.4.1 Upon recommendation by the PSRP, applicants should submit all documents that have been reviewed and signed-off by the PSRP and a covering letter to researchsponsorship@sussex.ac.uk setting out how each point raised by the Panel has been addressed.

4.4.2 Precise submission requirements will be set out on :

http://www.sussex.ac.uk/staff/research/governance/sponsorship/ssc

4.4.3 ***To reduce delays to the commencement of research, the majority of studies that are reviewed by the PSRP will be accepted for Sponsorship by the SSC (after receiving recommendation from the Panel)** by Chair's Action *between* **SSC meetings.*** *Exceptions* **to this are:**

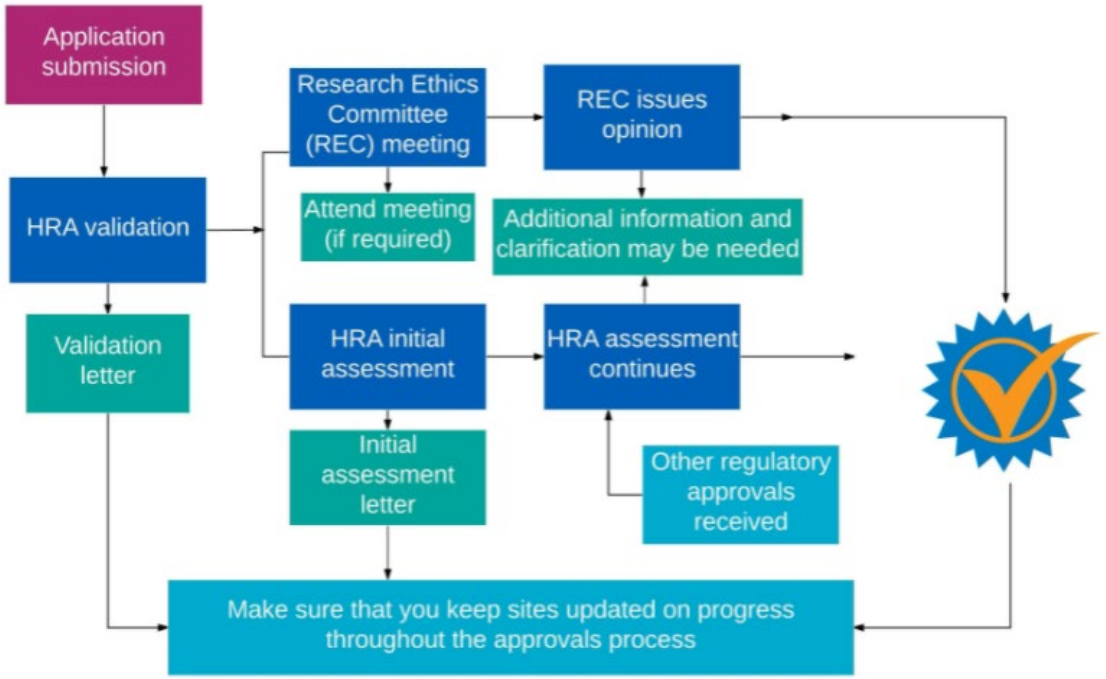
- **Applications for clinical trials of investigational or medicinal products (CTIMPs)**
- **Applications for research tissue banks (RTBs)**
- **Basic science studies (or similar) requiring specific medical supervision and oversight requiring the University's Clinical Trials insurance extension**
- **Any other studies identified as leading to non-standard risks or additional liabilities to the Sponsor (typically invoking additional insurance or specific risk mitigation measures)**

4.4.4 All researchers who have been granted University Sponsorship are required to agree to follow the University's ***Conditions of Sponsorship Agreement*** [7].

4.4.5 On receipt of the letter from the Sponsor's Representative indicating formal Sponsorship Approval and the Conditions of Sponsorship Agreement, the applicant may then commence Health Research Authority processes for the subsequent stages to allow the commencement of research:

https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/

[7] http://www.sussex.ac.uk/staff/research/governance/sponsorship/rgsops



Source: https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/

4.5 Right to withdrawal of Sponsorship

4.5.1 In line with its responsibilities as a recognised Sponsor of research, the University may withdraw Sponsorship that it has granted if there has been a breach of the 'Conditions of Sponsorship Agreement' or if matters come to light through the study that have significant legal, regulatory, financial or reputational consequences to the University.

5.0 SPONSORSHIP OF CLINICAL TRIALS OF INVESTIGATIONAL OR MEDICINAL PRODUCTS (CTIMPS)

5.1 To find out if the study is a CTIMP applicants should use the MHRA's algorithm ***Is it a clinical trial of a medicinal product?***

5.2 In cases where the University is asked to assume full and sole responsibility for a CTIMP the University will usually expect the CTIMP to operate within a Clinical Trials Unit (CTU).

5.3 In all cases, of a proposed sponsored CTIMP or a medical device or product the CI must ensure that the required MHRA approval is received**.**

5.4 Full procedures relating to sponsorship approval of CTIMPs can be found in **SOP/RG01, Standard Operating Procedures for Sponsorship Approval of CTIMPs** that is available from http://www.sussex.ac.uk/staff/research/governance/sponsorship/rgsops

6.0 REFERENCES

6.1 *UK Policy Framework for Health and Social Care Research*

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

6.2 *Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments* http://www.legislation.gov.uk/uksi/2004/1031/contents/made

6.3 *Is my study research?,* Medical Research Council – http://www.hra-decisiontools.org.uk/research/

6.4 *Is it a Clinical Trial of a Medicinal Product?*, Medicines and Healthcare Regulatory Agency (MHRA)

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949145/Algorithm_Clean__1_.pdf

6.5 *Code of Practice for Research*, University of Sussex https://www.sussex.ac.uk/webteam/gateway/file.php?name=code-of-practice-for-research-june-2018.pdf&site=377

6.5 *Good Clinical Practice*, International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use:

http://ichgcp.net/