

UNIVERSITY OF WOLVERHAMPTON INSTITUTIONAL SPONSORSHIP POLICY - HEALTH AND SOCIAL CARE RESEARCH

1. BACKGROUND

The Health Research Authority's (HRA) [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.

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. 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'.

Formal confirmation from the Sponsor must be obtained prior to an application for the permissions and approvals for health and social care / community care research in the UK using the Integrated Research Application System (IRAS).

2. SCOPE

This policy applies to all University of Wolverhampton staff and students who are required to apply for institutional sponsorship for research which is:

- Concerned with the protection and promotion of public health
- Undertaken in the Department of Health and/or with a non-departmental public body
- Undertaken within the NHS
- Undertaken by or within social care agencies.

3. SPONSORSHIP RESPONSIBILITIES

The University of Wolverhampton ("the University") acts as the designated sponsor and discharges the responsibilities of sponsorship through the Sponsorship Sub-Committee (SSC).

The University operates a model of sole and co-sponsorship, with the final decision as to the preferred sponsorship model being subject to the review and approval of the SSC. Where co-sponsorship is agreed, a co-sponsorship contract will be drafted and agreed. This contract will define the responsibilities of the relevant Principal Investigator (PI), NHS Trust/s, and University/ies.

The Sponsor has overall responsibility for the research, including:

- a) Identifying poorly designed or planned research and poor quality research proposals, protocols or applications and ensuring that research proposals and protocols are appropriate, accurate and high quality:
 - 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 to conduct the proposed research;
- 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 data and tissue accessible before the research starts (unless a deferral is agreed by or on behalf of the research ethics committee):
 - i. adhering to agreed arrangements, with adequate consent and privacy safeguards, in a timely manner after it has finished;
 - ii. 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, changes in legislation or other developments.'

4. APPLYING FOR UNIVERSITY SPONSORSHIP

The Principal Investigator (PI) is responsible for:

- a) making an application to the SSC to request that the University of Wolverhampton act as Sponsor.
- b) fulfilling the terms of the 'Conditions of Sponsorship Agreement' issued when the study has been formally accepted for Sponsorship (see section 7 below).

The PI must be a substantive member of University staff. Holders of honorary contracts will not be eligible to apply for University sponsorship without a University PI.

In the case of a study which is being undertaken by a student as part or in fulfilment of an academic qualification, the application for sponsorship should normally be made in the name of the student's University-employed supervisor. The supervisor will therefore normally take responsibility as named PI. The SSC will expect that, as part of the arrangements for the study, the Supervisor takes responsibility for ensuring that the student undertakes research activities that are appropriate to their abilities and experience. The student shall receive appropriate training and have sufficient supervision arrangements in place before the research commences.

The following documents should be enclosed, numbered and sent to researchsponsorship@wlv.ac.uk

- 1) Covering letter to Chair of the Sponsorship Sub-Committee (Name, address) (max 1 side of A4).
- 2) Evidence of ethical approval from the relevant Faculty Ethics Committee
- 3) Completed draft IRAS Form (www.myresearchproject.org.uk).
- 4) Detailed research protocol using a recognised template (e.g. <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/>)
- 5) Supporting documentation:
 - a) Participant Information Sheet for each group of participants involved in the study with new version number and date in footer of the document (age appropriate/ lay user accessible)
 - b) Consent/assent form for each group of participants involved in the study with a new version number and date in the footer of the document
 - c) recruitment materials: emails / posters / letter of approach to for e.g. GPs; gatekeepers; interview schedules and topic guides
 - d) all validated questionnaires to be used
 - e) researcher designed questionnaires to be used
 - f) Evidence of financial support (funding letters etc.) and evidence of management authorisation of the project
 - g) If the study is in Primary Care, please state whether the CRN has been engaged in relation to providing support

The Committee cannot review and decide on applications that are missing required minimum documentation.

5. SPONSORSHIP APPROVAL

The Sponsorship Sub-Committee is responsible for reviewing, accepting and monitoring sponsorship on behalf of the University.

The SSC will review sponsorship requests for research projects where:

- The substantive employer of the PI is the University
- The NHS partner will not act as Sponsor;
- The third party partner will not act as Sponsor;
- The research project does not have a NHS or third party partner
- The project is related to an academic qualification and the University is likely to be able to provide sponsorship on the basis of being able to provide acceptable oversight and the management of appropriate levels of risk given the institution's status as an educational establishment

Each sponsorship application will be assessed on its merits, and a sponsorship decision made based on a detailed understanding of the precise nature of the study.

Following consideration of an application, the Sub-Committee will make one of the following decisions:

- a) Full approval of the application as submitted. A letter will be issued confirming the University's Sponsorship.
- b) Provisional approval pending the addressing of minor issues identified
- c) Rejected with comments. Where major revisions are necessary, requiring re-application.

Further information and/or documentation may be requested of the PI as necessary. The PI may need to be available in person to answer any additional questions raised by the Sub-Committee.

The Sub-Committee reserves the right to seek specialist advice which may include, but is not limited to, subject experts, Legal, Insurance and Health & Safety.

The Sub-Committee, upon decision of the Chair, may delegate the checking of issues identified to the Committee Officer, a selection of members or request that the application be reconsidered by the whole Sub-Committee.

Wherever possible, the Sub-Committee will allow the resubmission of amended applications in response to review between meetings to avoid delays to the commencement of research.

In exceptional circumstances the Chair may request that a resubmission be only considered at a further meeting of the Sub-Committee.

The University reserves the right to refuse sponsorship if the research study cannot be adequately supported, does not meet relevant regulatory requirements, or when it believes the proposed project constitutes a risk to the organisation on safety, financial or legal grounds.

6. SPONSORSHIP MONITORING AND OVERSIGHT

Once the Sponsorship Sub-Committee has agreed that an application is suitable (and written confirmation has been issued), applicants can proceed with gaining HRA and NHS Research Ethics Committee approval. Applicants are strongly advised to read carefully the [HRA applicant guidance](#) to understand the subsequent processes to be followed and the documents needed to support an application.

All researchers who have been granted University Sponsorship are required to agree to follow the University's Conditions of Sponsorship.

The Sub-Committee will receive and monitor at each of its meetings a register of University sponsor-approved studies.

Sub-Committee approval will be required before a PI submits annual progress reports and end of study reports to the HRA/ REC.

7. CONDITIONS OF SPONSORSHIP

PIs of University sponsored studies will agree to be responsible for confirming that:

- a) They have undertaken the relevant qualifications/ training to undertake the study and are otherwise up to date in any required continuing professional development activities.
- b) There are adequate resources in place for the running of the study, in terms of funds, staff, facilities, and infrastructure.
- c) The care of trial subjects and/or study participants is assured during their participation in the study.
- d) Staff involved in the study have the appropriate training to deliver their delegated elements of the study.
- e) Regular and timely communication will be maintained throughout the study with the sponsor, and the NHS Research Ethics Committee.
- f) There will be full compliance with the study protocol and that any deviations and/or violations are documented and amendments submitted to the appropriate Research Ethics Committee.
- g) Where applicable to interventional studies, unblinding and randomisation procedures are followed at all times.
- h) That guidelines on informed consent are followed at all times.
- i) That records and reports are appropriately created, managed, stored, and archived.
- j) That all records and reports are readily available for internal or external audits.
- k) That all Serious Adverse Events are included in the annual reporting to the sponsor.
- l) That study participants are promptly informed in the eventuality that the study ends prematurely or is suspended.
- m) That the final report is provided to the NHS Research Ethics Committee, sponsor, and regulatory authorities, as appropriate.

8. WITHDRAWAL OF SPONSORSHIP

The University has the discretion to withdraw its sponsorship of a study where information on the original application changes without prior approval, including but not limited to changes to:

- The Principal Investigator
- Funding
- Co-sponsor status
- Randomisation strategy

In line with its responsibilities as a sponsor of research, the University may withdraw Sponsorship that it has granted if the PI or any member of the study team breaches the Conditions of Sponsorship, fails to comply with the University's Regulations and Policies, or if matters come to light through the study that have significant legal, regulatory, financial or reputational consequences to the University.

9. AMENDMENTS TO STUDIES APPROVED FOR SPONSORSHIP

Amendments to University Sponsored projects must be submitted for Sub-Committee review and approval in order for sponsorship to remain valid.

VERSION:	1	AUTHOR/ OWNER:	Jill Morgan/Research Policy Unit
Approved Date:	January 2020	Approved By:	Academic Board
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Appendix A:

UNIVERSITY ETHICS SUB-COMMITTEE SPONSORSHIP SUB-COMMITTEE

Purpose

The Sponsorship Sub-Committee is responsible for reviewing, approving and monitoring sponsorship of Health and Social Care Research on behalf of the University.

Terms of Reference 2019/20

The Sub-Committee has overall responsibility for sponsored research as stipulated in the UK Policy Framework for Health and Social Care Research (2017), which includes:

- a) identifying poorly designed or planned research and poor quality research proposals, protocols or applications and ensuring that research proposals and protocols are appropriate, accurate and high quality;
- b) satisfying itself that the investigators, research team and research sites are suitable to conduct the proposed research;
- 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;
- e) ensuring appropriate arrangements are made for making data and tissue accessible before the research starts (unless a deferral is agreed by or on behalf of the research ethics committee):
 - i. adhering to agreed arrangements, with adequate consent and privacy safeguards, in a timely manner after it has finished;
 - ii. 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, changes in legislation or other developments.'

The Committee will do this by:

- 1) Reviewing and approving applications for University Sponsorship of Health and Social Care Research projects
- 2) Maintaining and monitoring a register of University sponsor approved studies.
- 3) Approving annual progress reports and end of study reports before submissions to the HRA/ REC.
- 4) Acting as the point of contact for external bodies and adapting University procedures in the light of external requirements and changes.
- 5) Seeking specialist advice from research subject experts and Professional Services, i.e. Legal, Finance/Insurance and Health & Safety, when required
- 6) Advising the Ethics Sub-committee on related policies and procedures and revising this when appropriate.

- 7) Issuing guidance and advice on staff development needs and through the dissemination of good practice.

Frequency of Meetings: At least twice a year (additional committees convened as required)

Reporting Structure

- The Sponsorship Sub-Committee reports to the Ethics Sub-Committee.
- The Sponsorship Sub-Committee receives progress reports from Faculty Ethics Committees.

Quorum: 50%

Membership

- Dean of Research (Chair)
- A representative from the relevant Research Institute/ centres:
 - Research Institute in Healthcare Science
 - Institute for Community Research and Development
 - Caring for Lifelong Health Research Centre
 - The Centre for Psychological Research
 - The Sport and Physical Activity Research Centre
- Head of Doctoral Studies (FEHW)
- Research Policy Development Officer (Officer)
- Co-opted member(s) as deemed appropriate.