Standard Operating Procedure	Lancaster University

Title: Health and Social Care Research Sponsorship Procedure A (Post-award)

SOP Reference: HSCR-SOP001A	**Date Effective From:** 6th May 2025
Version and Date: v2.0 (06th May 2025)	**Review Cycle:** 2 Years
Superseded SOP (version and date): CTS-SOP001 v1.2 (11th July 2018)	**Date of Next Review:** 6th May 2027

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Date: 6th May 2025

Document History

Version	Date	Reasons for Change
1.0	**05 September 2017**	**Original document**
1.1	**01 May 2018**	**Change of title, reformatted and included details on the pre-award and post-award processes**
1.2	**11 July 2018**	**Included new details of the ethics system, REAMS**
2.0	**06th May 2025**	**Complete review, updated to cover all Health and Social study sponsorship and new application procedure**

1.0. BACKGROUND

1.1. As mandated in the UK Policy Framework for Health and Social Research all research falling under the remit of the Health Research Authority and Devolved Administrations must have a formal sponsor. This includes all health and social care research that involves NHS patients, their tissue or information, staff, equipment or other resources of the NHS. There are similar requirements for research involving social care practitioners, clients, and resources, where this falls under the Secretary of State for Health's remit [1].

1.2. The 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]. The sponsor must satisfy itself that the study meets the relevant standards and ensure that arrangements are put and kept in place for management, monitoring and reporting**.**

1.3. The sponsor is ordinarily expected to be the employer of the Chief Investigator (CI) in the case of non-commercial research or, in the case of commercial research, the funder.

1.4. Universities and colleges are usually the preferred sponsor for educational research conducted by their own students, unless the student is employed by a health or social care provider that prefers to take on this role.

1.5. The responsibilities of the sponsor include:

- identifying and addressing poorly designed or planned research and poor-quality research proposals, protocols or applications.
- satisfying itself that the investigators, research team and research sites are suitably trained, experienced and qualified to undertake their delegated duties.
- 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.
- ensure appropriate arrangements are made to make 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.
- ensuring arrangements for information about the findings of the research to be 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.
- putting and keeping in place arrangements for adequate finance and management of the research project, including its competent risk management and data management; and

- 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.

1.6. Sponsors can formally delegate one or more of the elements of sponsorship, for example, to the CI, clinical trial unit or another third party, but the sponsor remains accountable for all aspects of sponsorship whether delegated or not. The sponsor must implement procedures to ensure appropriate oversight of all delegated functions.

1.7. If no one is willing to take on the role of sponsor, the study may not proceed.

2.0. PURPOSE AND SCOPE

2.1. This Standard Operating Procedure (SOP) describes the processes involved in obtaining sponsorship of a health and social care research study from Lancaster University, for research that is led by a Lancaster University staff member or student; where funding bodies require that sponsor be identified as part of the application, or which fall under the UK Policy Framework for Health and Social Care Research [1].

2.2. Health and social care research that has a statutory requirement to obtain a sponsor is defined as research that is designed to derive generalisable/or transferable new knowledge that is 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; or research undertaken within adult social care agencies. It includes clinical and non-clinical research undertaken within the health and social care systems that might have an impact on the quality of those services [1].

2.3. Research led by Lancaster University researchers taking place within a UK care home and/or hospice settings must also obtain Lancaster University sponsorship, and ethical favourable opinion from a National Research Ethics Service Ethics committee, regardless of the services management or funding arrangements or the outcome of the 'Do I need NHS REC Review' decision tool provided by the Health Research Authority (HRA).

2.4. The process will allow Lancaster University to:

- Identify and assess the risks associated with the study to be sponsored;
- implement appropriate risk mitigation plans as necessary;
- ensure that relevant regulatory approvals are in place prior to the initiation of the study;
- ensure that appropriate insurance and indemnity arrangements are in place to cover the liability of the investigator and sponsor which may arise in relation to the study;
- provide oversight of any delegated functions; and
- oversee the management and conduct of the study at the host organisation and participating sites.

2.5. Lancaster University has a sole signatory who may authorise sponsorship of any health and social care research project. This individual is the Head of Research Quality and Policy; the responsibility may be delegated to a member of Research and Enterprise Services who has an equal or higher level of authority should the signatory be unavailable.

2.6. Lancaster University does not sponsor research studies classified as a Clinical Trial of an Investigational Medicinal Product (CTIMP) as defined by the Medicines for Human Use (Clinical Trials) Regulations 2004; therefore, this procedure does not apply to studies of that nature. Studies falling under the remit of the Medical Devices Regulations (2002) may be sponsored on an ad hoc basis but must be discussed with the Clinical Research Governance team well in advance of any grant application to ensure this is feasible.

3.0 POST-AWARD PROCEDURE: HEALTH AND SOCIAL CARE RESEARCH SPONSORSHIP REQUEST

3.1. The Post-award Sponsorship Application Procedure Flowchart (HSCR-FLOW002) provides an overview of the sponsorship request process that is to be applied at the post-award stage.

3.2. The CI must declare that the study is a health and social care research project and submit a formal sponsorship request to the clinical research governance team, who will work alongside the Health and Social Care Research Sponsorship Committee to review any application, ensure suitability for sponsorship, and readiness for submission to the regulator.

3.3. Requests should be submitted as early as possible, with a recommended minimum of 35 working days prior to planned submission for regulatory approvals to allow sufficient time for review. If the project requires both Faculty Ethical approval and sponsorship, we recommend you apply at least 35 working days before you intend to submit for Faculty Ethical approval.

3.4. In order to submit a formal request, the CI must submit a Post-award Sponsorship Request Form (HSCRS-FORM002) and all relevant supporting documents as outlined in the request form, to sponsorship@lancaster.ac.uk. This includes a Project Risk Assessment (HSCR-FORM005), which must be completed for all projects.

Submission of all necessary documentation as outlined on the form will be deemed to be a valid application and an email confirming validity will be sent within 4 working days of submission. An incomplete application will delay the start of the sponsorship review.

3.5. Upon receipt of a valid application, the CRGO will allocate each application to the appropriate review route (see approval route decision matrix HSCR-GD004). Where the CRGO or a Health and Social Care Research Sponsorship Committee delegate feel that additional review is required, they will move to the next level of review.

3.6. Studies that require full committee review (HSCR-GD004) will be reviewed at the next available committee meeting, cut-off dates for which are available on the sponsorship webpages.

3.7. For all applications, the CRGO will undertake an initial review, including an assessment of the project risks outlined as part of the Project Risk Assessment Form (HSCR-FORM005) in relation to the initiation and delivery of the research project. For all projects a CRGO sponsorship review checklist (HSCRS-FORM008) will be completed, and any feedback will be documented on the application and/or the checklist.

Where the project does not require a Faculty Research Ethics Committee (FREC) review, points 3.8-3.9 do not apply and instead move to point 3.10.

3.8. Should the project require Faculty Research Ethics Committee (FREC) review, as well as sponsorship, the CRGO will confirm that they are satisfied with the application so far by signing the review checklist and returning it to the CI; the CI can then proceed to submitting a REAMs application appending the checklist to the REAMs application where prompted. The FREC will then undertake their review procedure.

3.9. Once the application has been approved by the FREC, applicants must email the clinical research governance team to notify them. Here, the CRGOs will proceed with completing the sponsorship process outlined in item 3.10 onwards, to confirm full sponsorship.

3.10. Following review from the CRGO (and FREC review were applicable), projects requiring a level 2 review (HSCR-GD004) will undergo a review from a delegate from the committee. Projects requiring a level 3 review (HSCR-GD004) will be reviewed by a Health and Social Care Research Sponsorship Committee delegate, before being heard at the next committee meeting. At each stage the committee and its delegates' role will be to evaluate the suitability of the project and ensure that effective arrangements are in place to mitigate any risks associated with the study should they arise.

3.11. During the process, the CI may be approached and asked to provide supplementary information to support the decision-making process or the committee or its delegates may request amendments and/or additions to the application. If requests of this nature are made, the CI must make the necessary changes. Researchers should be aware that where these revisions are made or where applications do not follow the guidance on the Health and Social Care Research Governance webpages, delays to the 35 day time frame should be expected.

3.12. The Health and Social Care Research Sponsorship Committee or its delegate will review any revised applications to ensure that the requested changes have been applied.

3.13. If the original application requires no amendments, or when the requested revisions have been completed, the application will be authorised by a delegated member of the Health and Social Care Research Sponsorship Committee and the researcher will receive a letter on behalf of the committee confirming sponsorship, along with a copy of the university's insurance certificates.

3.14. Alongside the documents outlined in 3.13, CI's will be issued with a Chief Investigator delegation of duties declaration (HSCR-FORM004), outlining the conditions of sponsorship and their management responsibilities during the lifecycle of the project. This must be signed and returned to the clinical research governance team for the offer of sponsorship to be valid.

3.15. Although the Clinical Research Governance team will endeavour to review and confirm sponsorship for the research study within the timelines mentioned, should the application require amendments or adjustments, or during times of high demand, this may not be possible. In this instance, the Committee will clearly communicate any delays to CI from the outset and throughout the sponsorship application process.

3.16. If sponsorship has been requested from another organisation, the CI must ensure that projects are still registered with the Clinical Research Governance Team, and where required Faculty REC approval should be requested. The University will maintain a register of the institution's involvement in health and social care studies for audit and monitoring purposes.

3.17. The universities preference is for sole sponsorship by one legal entity. However, in exceptional circumstances they may consider requests for co-sponsorship on a case-by-case basis. The Chief Investigator must provide details of the request to the clinical research governance team for review well in advance of requiring a full sponsorship assessment.

3.18. Although Lancaster University will endeavor to support most research applications, there are some cases where they may be unable to act as sponsors. These include but are not limited to:

- Appropriate licenses not being available;
- where there are concerns over CI or PI suitability (training, conduct and patient safety concerns);
- research where the documentation provided by the CI is to not sufficient to allow adequate review of the project and its risks;
- lack of funding for proposed activities is in place;
- poor protocol quality, where the CI has not actioned the committees' comments or where the committee feels the updates are not of sufficient quality;
- where a study is deemed to be high risk and mitigating factors do not reduce that risk to low or moderate;
- where the committee feels for any reason another institution would be able to better manage the study;
- an amendment to the study design being proposed that cannot be supported, withdrawal of funding or a change in CI; or
- research where the CI has previously been found to be in breach of compliance with the RD&I approval process or Trust policies and SOPs.

4. Referenced Documents

5.1 HSCR-FLOW002 Sponsorship Application Procedure Flow Charts (post-award)

5.2 HSCR-FORM002 Post-award Sponsorship Request Form

5.3 HSCR-GD004 Review Route Guide

5.4 HSCR-FORM005 Project Risk assessment Form

5.5 HSCR-GD005 Risk Scoring Matrix

5.6 HSCR-FORM008 Sponsor Review Checklist

5.7 HSCR-FORM004 CI Responsibilities Declaration

5.8 HSCRS-FORM003 External Sponsor Collaboration form

References:

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

2. https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/#sponsor