Standard Operating Procedure	Lancaster University

Title: Health and Social Care Research Project Risk Assessment Procedure (non-CTIMP)

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Document History

Version	Date	Reasons for Change
1.0	**23 August 2018**	**Original**
2.0	**7th May 2025**	**Updated to reflect the new remit of the health and social care research sponsorship committee and new risk assessment procedure, including introducing a new criterion for requiring a risk assessment. New title to distinguish between the project risk assessment completion procedure and risk-based review route.**

1. 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 individual, organisation or partnership that takes responsibility for the initiation, management, and financing (or arranging the financing) of the study. The sponsor must also satisfy itself that the study meets the relevant standards and ensure that arrangements are put and kept in place for assessing and managing risk for their health and social care research portfolio.

1.3 The Health and Social Care Research Sponsorship Committee are responsible for ensuring that there are robust processes in place to ensure that anticipated risks of research sponsored by Lancaster University have been considered, that appropriate mitigations are in place, and that the remaining risks are accepted by the university ahead of authorising sponsorship of a research project.

2. PURPOSE AND SCOPE

2.1. This Standard Operating Procedure (SOP) describes the procedures approved by the Health and Social Care Sponsorship Committee for completing a sponsorship risk assessment and mitigation plan. It applies to all requests for Lancaster University sponsorship of health and social care research led by staff employed by Lancaster University (this includes research where Lancaster University post graduate researchers or MSc candidates will be conducting the research); where funding bodies require that a formal sponsor be identified as part of the application; and which fall under the UK Policy Framework for Health and Social Care Research.

2.2. The process will allow Lancaster University to:

- Identify and assess the risks associated with the health and social care research to be sponsored;
- conduct a proportionate sponsorship review;
- Implement appropriate risk mitigation plans as necessary; and
- Ensure that appropriate arrangements are in place for the effective management of the study at the host organisation and participating sites.

2.3. 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 this nature.

3. HEALTH AND SOCIAL CARE RESEARCH SPONSORSHIP RISK ASSESSMENT COMPLETION PROCEDURE

3.1. For health and social care research where Lancaster University is to act as sponsor, the chief investigator is responsible for ensuring that all potential risks have been considered and mitigated against where possible. A Sponsorship Project Risk Assessment Form **(HSCRS-FORM0005)** must be completed by the Chief investigator, in liaison with the Clinical Research Governance team. This will allow the Clinical Research Governance team to conduct a proportionate review of the application.

3.2. The Project Risk Assessment will contribute to the evaluation of the sponsorship request, identify any remaining risks, and determine Lancaster University's ability to act as sponsor.

3.3. The Sponsorship Project Risk Assessment Form **(HSCR-FORM005)** considers the following areas of risk for Lancaster University as a research sponsor:

- Study design;
- Participants' and researchers' rights and safety;
- Facilities, equipment, skills and resources; and
- Documentation, governance and compliance.

3.4. Questions are arranged in sections and the answers will be subject to a risk score and level of risk (Low, Medium, and High), as outlined in the Risk Scoring Matrix **(HSCR-GD005)**. Mitigation strategies should be documented to address all concerns identified. An overall risk score will then be calculated to assist in identifying where adjustments must be made to design to ensure research sponsored by Lancaster University carries as little risk as possible.

3.5. The risk assessment is dependent on an understanding of risks associated with the study and the knowledge, skills and expertise of the research team responsible for its delivery. For example, a high-risk study undertaken by an experienced research team may have its risks addressed through routine management processes whereas a low-risk study undertaken by an inexperienced research team may require additional management actions to mitigate risks. The risk assessment considers the predicted circumstances at the time the study is scheduled to be delivered. For example, availability of key resources or staff will impact the delivery of the study.

3.6. Once complete, the Project Risk Assessment Form (HSCR-FORM005) must be submitted by the Chief Investigator or delegated individual as outlined in the Health and Social Care Research Sponsorship Procedure SOP **(HSCR-SOP001)**. Support can be sought from the Clinical Research Governance team should assistance be required while completing the risk assessment.

4. PROCEDURE FOR ONGOING REVIEW OF RISK

4.1. The Project Risk Assessment Form (HSCR-FORM005) must be revisited during the life cycle of the study, by the chief investigator, in liaison with the clinical research governance team, if any material changes are made to the study documentation, staffing or operational circumstances.

4.2. The risk assessment must be revisited following serious adverse events that require urgent safety measures to be employed, or after recommendations from study oversight committees. The Sponsorship Project Risk Assessment Form (HSCR-FORM005), and the Review and Revision Record table must be updated in line with the re-assessment. Superseded versions of the form must be retained as there may be multiple revisions to the form during the life cycle.

4.3. The sponsor must be notified of any changes to the risk assessment and rating. The Health and Social Care research sponsorship committee reserves the right to refuse sponsorship for projects where the risk level falls outside of the university risk appetite, and the researcher is unable to carry out actions to reduce that risk. They also reserve the right to re-assess the offer of sponsorship, should any major changes take place during the study.

5. Associated Documents

5.1 HSCR-FORM005 Project Risk Assessment Form

5.2 HSCR-GD005 Project Risk Scoring Matrix