Title: Clinical Trial Sponsorship Review and Risk Assessment

SOP Reference: CTS-SOP002
Version and Date: v0.2 (23 August 2018)
Superseded SOP (version and date): N/A
Date Effective From: October 2018
Review Cycle: 2 Years
Date of Next Review: September 2020

Author: Christopher Beckwith, Clinical Research Support Officer

Signature: Date:

Approved by: Professor Vincent Reid, Deputy Chair

Signature: Date:

Document History

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1.0. BACKGROUND

1.1. All research falling under the remit of the Secretary of State for Health must have a formal sponsor. This includes all research in health and social care 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.

1.2. 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 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. For clinical trials which Lancaster University is to act as sponsor, a Clinical Trial Sponsorship Risk Assessment (Appendix I) must be completed by the Chief investigator and reviewed in collaboration by the Clinical Research Support Officer. This will allow for a comprehensive review of the clinical trial sponsorship application, identifying appropriate actions to mitigate any identified risk(s).

1.4. The Clinical Trial Sponsorship Risk Assessment will contribute to Lancaster University’s evaluation of the sponsorship request.

2.0. PURPOSE AND SCOPE

2.1. This Standard Operating Procedure (SOP) describes the process involved in the Clinical Trials Sponsorship Committee undertaking a clinical trial sponsorship review on the behalf of Lancaster University. It applies to requests for Lancaster University sponsorship of clinical trials, led by staff employed by Lancaster University; 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 clinical trial to be sponsored;
- 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.

3.0. CLINICAL TRIAL SPONSORSHIP REVIEW AND RISK ASSESSMENT

3.1. The Clinical Trials Sponsorship Committee will be responsible for assessing whether a clinical trial may be sponsored by Lancaster University.
3.2. A clinical trial sponsorship review and risk assessment is required for all clinical trials led by Lancaster University staff who hold a substantive employment contract with the institution.

3.3. In line with UK Policy Framework for Health and Social Care Research guidance, it is not expected that students will act as Chief Investigators for clinical trials. Exception is made for an experienced care practitioner or manager undertaking an educational qualification for continuing professional development or a doctoral-level study while employed by a health or social care provider or a university, or for a researcher undertaking a doctoral-level study in receipt of a fellowship.

3.4. The Clinical Trial Sponsorship Risk Assessment Form (CTS-FORM004) at Appendix I all relevant supporting documents must be submitted by the Chief Investigator as part of the clinical trial sponsorship request procedure outlined in Item 4.0 of CTS-SOP001 Clinical Trial Sponsorship. Support should be sought from the Clinical Research Support Officer should assistance be required while completing the risk assessment.

3.5. The Clinical Trial Sponsorship review and risk assessment will commence upon receipt of a valid application as defined in Item 4.3 of CTS-SOP001 Clinical Trial Sponsorship and may take up to 30 working days to complete.

3.6. The Clinical Trial Sponsorship Risk Assessment Form considers the following areas of risk for Lancaster University as a research sponsor:

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

Questions are arranged in sections and the answers will be subject to a likelihood score of Low, Medium and High. Mitigation strategies should be documented to address all concerns identified.

3.7. The completed Clinical Trial Sponsorship Risk Assessment Form and the Risk Analysis Matrix Tool (CTS-GD003) at Appendix II will be used to assess the potential risk(s) associated with a specific study in conjunction with all submitted trial documentation.

3.8. 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 should consider 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.
3.9. The Sponsor Review Checklist (CTS-FORM005) at Appendix III will be completed by the Clinical Research Support Officer on the behalf of the Clinical Trials Sponsorship Committee, documenting its feedback as appropriate. Feedback from the initial review and risk assessment will be provided to the Chief Investigator within 30 days.

3.10. The completed Sponsor Review Checklist will be sent to the Chief Investigator via email, detailing all comments, questions, points of clarification and changes required prior to confirmation of sponsorship.

3.11. The Clinical Trial Sponsorship Risk Assessment Form will be revisited during the life cycle of the study if any material changes are made to the study documentation, staffing or operational circumstances. The Risk Assessment Form (RAF) Completion, Review and Revision Record table should be completed. Superseded versions of the form should be retained as there may be multiple revisions to the form during the life cycle.