Title: Clinical Trial Sponsorship

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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. The sponsor is ordinarily expected to be the employer of the chief investigator in the case of non-commercial research or, in the case of commercial research, the funder.

1.4. Universities and colleges should accept the role of sponsor for all 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;
- 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;
- 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 chief investigator, 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 sponsor role, 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 clinical trial with Lancaster University for research that is led by staff employed by Lancaster University; where funding bodies require that 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;
- Ensure that relevant regulatory approvals are in place prior to the initiation of the clinical trial;
- 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.

2.3. At the pre-award stage, research defined as a clinical trial by the Lancaster University Clinical Trials Policy for which Lancaster University will be the likely sponsor, the Chief Investigator will be required to register their proposed clinical trial with the Clinical Research Support Team at least 30 working days prior to the bid submission deadline.

2.4. At the post-award stage, the Chief Investigator must submit a formal request for sponsorship of a clinical trial to the Lancaster University Clinical Trials Sponsorship Committee. The sponsorship request must be made a minimum of 30 working days prior to planned submission for regulatory approvals to allow the Committee to assess the risks associated with the initiation and delivery of the study on the behalf of the sponsor, Lancaster University.

2.5. Lancaster University has a sole signatory who may authorise sponsorship of any health and social care research project that falls under the UK Policy Framework for Health and Social Care Research. This individual is the Head of Research Quality & Policy. The responsibility of the sponsor signatory may be delegated to a member of Research and Enterprise Services who has an equal or higher level of authority.
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.

3.0. PRE-AWARD PROCEDURE: CLINICAL TRIAL SPONSORSHIP REGISTRATION

3.1. The Clinical Trials Sponsorship Pre-Award Process Flowchart (CTS-FLOW001) at Appendix I provides an overview of the clinical trial sponsorship registration process that is to be applied at the pre-award stage.

3.2. The Chief Investigator must indicate in the costing pro forma whether their research will be categorised as a clinical trial.

3.2. It is a mandatory requirement that a Clinical Trial Registration Form (CTS-FORM001) at Appendix II is submitted to the Clinical Trials Support Team at clinical.research@lancaster.ac.uk to a research bid submission. It is the Chief Investigator’s responsibility to complete and submit the registration form along with a draft version of the application at least 30 working days prior to the bid submission.

3.3. Sponsorship of a clinical trial must be considered early in the study’s development and engagement of the Chief Investigator with the Clinical Trials Support Team is strongly encouraged to access guidance and support where required.

3.4. Upon receipt of the Clinical Trial Registration Form, a Lancaster University Clinical Trial Registration Number (LU-CTRN) will be issued and the Clinical Research Support Officer will review the registration form and draft version of the application, providing feedback and guidance where necessary.

3.5. Should expert advice be required to support the bid development, the Clinical Research Support Officer will approach the appropriate member(s) of the Clinical Trials Sponsorship Committee to seek additional guidance. This guidance will be relayed to the Chief Investigator by the Clinical Research Support Officer on the Committee’s behalf.

3.6. Where applicable, the Chief Investigator will liaise directly with appropriate member(s) of the Clinical Trials Sponsorship Committee to discuss their draft application and to receive guidance and support during bid development.

3.7. Where research funding is awarded for the delivery of the clinical trial, the Chief Investigator must inform the Clinical Trials Support Team of the successful bid outcome as soon as possible by emailing clinical.research@lancaster.ac.uk

4.0 POST-AWARD PROCEDURE: CLINICAL TRIAL SPONSORSHIP REQUEST

4.1. The Clinical Trials Sponsorship Post-Award Process Flowchart (CTS-FLOW002) at Appendix III provides an overview of the clinical trial sponsorship request process that is to be applied at the post-award stage.
4.2. The Chief Investigator must declare that the study is a clinical trial and submit a formal clinical trial sponsorship request to the Clinical Trials Sponsorship Committee a minimum of 35 working days prior to planned submission for regulatory approvals.

4.3. The clinical trial sponsorship request should be made by one of the following methods:

- Submitting the Clinical Trials Sponsorship Request Form (CTS-FORM002) at Appendix IV and relevant supporting documents as listed in the Clinical Trial Sponsorship Document Checklist (CTS-GD001) at Appendix V to clinical.research@lancaster.ac.uk; or
- Submitting a request via the Lancaster University Research Ethics Application Management System (REAMS) when the system is live, including all relevant supporting documents as described during completion of the online application.

Submission of all necessary documentation as outlined above will be deemed to be a valid application and an email confirming whether the application is valid will be sent within 30 working days of submission. An incomplete application will delay the start of the sponsorship review.

4.4. Upon receipt of a valid application, the Clinical Trials Sponsorship Committee will undertake a sponsorship review and risk assessment in relation to the initiation and delivery of the clinical trial. The sponsorship review and risk assessment may take up to 30 working days.

4.5. The sponsor should be aware of the potential foreseeable risks and hazards associated with the research study and the harm that would result should it occur prior to agreeing to act as sponsor and will consider:

- Risks to the participant;
- Risks to the researcher; and
- Risks to the institution.

4.6. The Clinical Trials Sponsorship Committee will review the application and evaluate the suitability for sponsorship, ensuring that effective management arrangements are developed to mitigate the risks associated with the study should they arise. The Clinical Trials Sponsorship Committee will undertake the initial review within 30 working days. The Chief Investigator may be approached by the Committee throughout this period and asked to provide supplemental information to support the completion of the risk assessment.

4.7. Upon completion of the initial risk assessment, the Clinical Trials Sponsorship Committee may provide recommendations, requesting amendments or additions to the application. If recommendations are made by the Committee, the Chief Investigator will make the necessary changes to the application within 30 working days.

4.8. The Clinical Trials Sponsorship Committee will review the revised application within 30 working days to ensure that the requested changes have been applied.

4.9. If further revisions are required, the Chief Investigator will be allocated 30 working days to make the additional changes. If revisions need to be requested by the Clinical Trials
Sponsorship Committee beyond a second occasion, the Chief Investigator will be asked start the sponsorship request process again and resubmit the application in its entirety.

4.10. If the original application requires no amendments or when the requested revisions have been satisfactorily completed, the Committee will issue a letter confirming sponsorship of the clinical trial within 30 working days.

4.11. Although the Clinical Trials Sponsorship Committee will endeavour to review and confirm sponsorship for the research study within the aforementioned timelines, during times of high demand this may not be possible. In this instance, the Committee will clearly communicate any delays to Chief Investigator from the outset and throughout the sponsorship application process.

4.12. If Lancaster University is unable to sponsor the research study or sponsorship has been requested from another organisation, it is the responsibility of the Lancaster University Chief Investigator or lead investigator (if Lancaster University is not the lead research institution) to complete and submit the Clinical Trial Collaboration form (CTS-FORM003) at Appendix VI to clinical.research@lancaster.ac.uk. The University will maintain a register of the institution’s involvement in clinical trials for monitoring purposes.