UNIVERSITY OF LINCOLN

CLINICAL GOVERNANCE - STANDARD OPERATING PROCEDURE

ETHICS APPLICATIONS

CG-QMS SOP CG05

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Version History	**Reason for change**

NOTE: All SOPs are subject to regular review.

Please ensure that the version of this SOP is the most up-to-date.

OUT OF DATE DOCUMENTS MUST NOT BE USED AND HARD COPIES SHOULD BE DESTROYED

1. PURPOSE

To outline the process for developing a clinical trial or clinical study ethics application.

2. SCOPE

This SOP applies to all UoL sponsored clinical research or where LinCTU (Lincoln Clinical Trials Unit) are providing support in obtaining necessary ethical / regulatory permissions.

3. BACKGROUND

3.1 The Chief Investigator (CI) has overall responsibility for the submission of the Health Research Authority (HRA) / ethics application. However, preparation may be delegated to a person with the relevant knowledge, skills and experience.

3.2 When applying for a favourable ethics opinion from a recognised National Health Service Research Ethics Committee an application must be submitted via the Integrated Research Application System (IRAS).

3.3 All applications are made using the Integrated Research Application System (IRAS) portal which can be accessed at https://www.myresearchproject.org.uk.

3.4 When applying for a favourable ethical opinion from a University of Lincoln Research Ethics Committee an application must be submitted via the Lincoln Ethics Application System (LEAS) https://lncn.ac/leas.

3.5 An HRA application (via IRAS) and NHS ethics application (via IRAS) is required where:

- NHS patients / service users are recruited as participants (except where noted below)

3.6 A HRA application (via IRAS) and UoL ethics application is required where:

The study involves NHS staff, premises or facilities (no involvement of patients/service users as participants)

Or where the study involves NHS patients/service users and is one of the following:

- Projects limited to the use of samples/data samples provided by a Research Tissue Bank (RTB) with generic ethical approval from a REC, in accordance with the conditions of approval.
- Projects limited to the use of data provided by a Research Database with generic ethical approval from a REC, in accordance with the conditions of approval.
- Research involving previously collected, non-identifiable information
- Research involving previously collected, non-identifiable tissue samples
- Research involving acellular material
- Research involving the premises or facilities of care organisations

3.7 A HRA application is not required where:

The study is a single centre student project in the NHS (undertaken at United Lincolnshire Hospitals NHS Trust (ULHT), Lincolnshire Partnership Foundation Trust (LPFT), Lincoln Community Health Services (LCHS) or the East Midlands Ambulance Service (EMAS)), that:

- is undertaken primarily for the purpose of obtaining an educational qualification.
- does not require NHS REC review.
- is limited to one NHS organisation in England (single site).
- is not applying for support from the NIHR Clinical Research Network (CRN).

In these instances, a UoL ethics application via LEAS should be submitted. Sponsorship will be confirmed as part of the ethics review process (in accordance with SOP CG02 Sponsorship and SOP E-R01 Ethical Review).

3.8 A regulatory application is required where:

A clinical trial falls within the scope of the EU Clinical Trials Directive and the Medicines for Human Use (Clinical Trials) Regulations 2004 or the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) and should be submitted in accordance with CG06 Regulatory Application.

Note: The University of Lincoln will not take on sponsorship where an external member of staff or organisation(s) is/are the lead. Under these circumstances it may be more appropriate for the lead organisation to act as sponsor.

3.9 Lincoln Clinical Trials Unit (LinCTU)

Lincoln Clinical Trials Unit (LinCTU) may support the Chief Investigator in applying for HRA / ethics approval in accordance with the agreed terms and conditions of a signed service level agreement (SLA).

4. CROSS REFERENCES

4.1 CG-QMS SOP CG02 Sponsorship

4.2 CG-QMS SOP CG04 Protocol Development

4.3 CG-QMS SOP CG06 Regulatory Application

4.4 CG-QMS SOP CG07 Trial Master/Site File(s)

4.5 CG-QMS SOP CG10 Adverse Events

4.6 CG-QMS SOP CG14 Trial Closure

5. PROCEDURE

Where the Chief Investigator is employed by the University of Lincoln

The Chief Investigator or delegated nominee shall:

5.1 Prepare the Study/Trial protocol and supporting documents (including Local Document Pack) in accordance with SOP CG04 Protocol Development

5.2 Complete an ethics application in accordance with section 3 above (either IRAS or LEAS) found at:

https://www.myresearchproject.org.uk

or

https://lncn.ac/leas

5.3 Prior to requesting electronic authorisations for the application, the CI (or their delegated nominee who is completing the ethics application on their behalf) should confirm sponsorship in accordance with SOP CG02 Sponsorship.

5.4 Once sponsorship is confirmed the IRAS form, LEAS form (where relevant) and supporting documents shall be finalised and authorisations requested.

Note: Any changes made to the IRAS form after electronic signatures have been assigned shall invalidate all signatures on the form. If changes must be made, they shall be notified and approved by Sponsor prior to implementation; the form must be re-signed by all parties prior to submission.

5.5 Once electronic authorisations are received, the IRAS application should be submitted following the instructions in the eSubmission tab in IRAS.

5.6 The LEAS application should be submitted in in accordance with SOP A-01 Ethical application.

NHS Ethical Approval Process

5.7 Research projects which raise no material ethical issues may apply for NHS REC approval using the Proportionate Review Service (PRS).

5.8 The NHS REC must notify its decision within 60 days of receiving the valid application submitted for full REC review, and within 21 days for applications submitted using the PRS.

5.9 An NHS REC can reach the following decisions:

- Final decision – which could be favourable (with conditions) or unfavourable.
- Provisional decision with a request for further written information.
- No opinion

5.10 Once NHS REC approval has been granted, the research must not start at a site until all other relevant approvals have been granted (including any regulatory approval) and any NHS R&D has given local R&D Management Permission, or Continued Capacity and Capability in England and Wales, for that site.

5.11 A copy of the NHS REC favourable opinion letter must be filed in the Trial Master File (TMF) in accordance with SOP CG07 Trial Master/Site File(s). Copy to any relevant participating sites/organisations.

5.12 Once all required approvals have been obtained, the final approved versions of the study documents shall be sent to Sponsor (sponsor@lincoln.ac.uk) for the Sponsor's electronic file.

5.13 After approval, the HRA must be informed, and an application submitted for approval of any amendments to the protocol; this includes any changes to the end date specified in the application. All amendments must be approved by Sponsor in the first instance and should be processed in accordance with SOP CG12 Amendments.

5.14 The CI also has the following responsibilities:

- Provision of Annual Progress Reports (APRs) and Development Safety Update Report (DSUR) in accordance with SOP CG10 Adverse events.
- Notification of Suspected Unexpected Serious Adverse Reactions (SUSARs), Adverse Events (in CTIMPs), and relevant Serious Adverse Events (SAEs) for non-CTIMP studies in accordance with SOP CG10 Adverse Events.
- Inform the ethics committee, Sponsor, Regulatory Authority (where required), NHS R&D Department when the project finishes, or terminates early, using the end of study declaration. In accordance with SOP CG14 Trial Closure

UoL Ethical Approval Process

5.15 The UoL ethics review process will be processed in accordance with SOP E-R01 Ethical Review.

5.16 Copies of any ethics correspondence should be retained in accordance with SOP CG07 Trial Master File.

Regulatory Approvals

5.17 If MHRA Regulatory Authority approval is required (CTIMPs and Medical Device Clinical Investigations only), this must be submitted in accordance with SOP CG06 Regulatory Applications.

NHS R&D Permission (Confirmation of Capacity and Capability)

5.18 The Chief Investigator shall:

5.19 Seek local NHS R&D Management Permission/Confirmation of Capacity and Capability where the recruiting site is involving:

- NHS Staff
- NHS Patients
- Tissues
- Organs
- Data
- NHS Facilities
- NHS Equipment

5.20 The process for obtaining R&D Permission is also completed using IRAS. Detailed guidance and instructions on completing and submitting R&D application forms can be found on the IRAS website.

5.21 Once the application is complete it will be automatically and electronically submitted through the IRAS system, as per the instructions on the E-Submission tab. The documents will then be sent electronically through IRAS to the relevant R&D office(s) for review.

5.22 If the project includes sites in England, Wales or Northern Ireland, the NRSPCC team will liaise with the coordinating centres for each nation and share relevant documents to facilitate study setup.

Registration of clinical trials

5.23 Registration of clinical trials is a formal condition of a NHS Research Ethics Committee (REC) favourable opinion. Registration should occur before the first participant is recruited and no later than six weeks after recruitment of the first participant.

'Clinical trials' are defined as:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an Investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

5.24 The Chief Investigator shall:

- Register the study on ClinicalTrials.gov.
- Add the ClinicalTrials.gov reference to the protocol
- Maintain the ClinicalTrials.gov entry throughout the life of the study.

  Note: Where the CI does not have a clinicaltrials.gov account they should contact the University's PRS administrator samlewis@lincoln.ac.uk or where the University is not the sponsor the PRS administrator of the sponsoring organisation.

6. FLOW CHART

None required.