UNIVERSITY OF LINCOLN

CLINICAL GOVERNANCE - STANDARD OPERATING PROCEDURE

RECRUITMENT AND CONSENT

CG-QMS SOP CG09

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Approved by: Signature:	UREC See original

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OUT OF DATE DOCUMENTS MUST NOT BE USED AND HARD COPIES SHOULD BE DESTROYED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 the recruitment and consent of participants for clinical research sponsored by the University of Lincoln (UoL) or supported by the Lincoln Clinical Trials Unit (LinCTU).

2. SCOPE

This SOP applies to all UoL sponsored clinical research or where LinCTU are providing support in Trial Management.

3. BACKGROUND

3.1 The Chief Investigator (CI) has overall responsibility for maintaining recruitment records in accordance with the Protocol. However, day-to-day management may be delegated to a person with the relevant knowledge, skills and experience as recorded on RF CG08-RF01 Study Delegation Log.

3.2 The local Principal Investigator (PI) for a multi-site trial has overall responsibility maintaining recruitment records in accordance with the Protocol at their local site. However, day-to-day management may be delegated to a person with the relevant knowledge, skills and experience and experience as recorded on RF CG08-RF01 Study Delegation Log.

3.3 The term “Participant” refers to an individual who consents to take part in a clinical study.

3.4 The exact procedure for participant recruitment should be detailed in the individual study protocol. The study Protocol should state clearly the consent process, the planned number of participants and the time period to achieve this.

3.5 All relevant staff working on studies must be completely familiar with the recruitment and consent procedure.

3.6 The delegation of obtaining Informed Consent to an appropriate and suitably qualified member of the research team is the responsibility of the CI/PI; what is considered appropriate should be considered on a study basis, taking account of circumstances, the NHS Partner Organisation's local general consent Policy and in accordance with Good Clinical Practice and the Declaration of Helsinki 96.

3.7 ICH-GCP described informed consent as

A process by which a participant voluntarily confirms his or her [sic. their] willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant’s decision to participate. Informed consent is documented by means of a written signed and dated informed consent form.

3.8 The Clinical Trial Regulations define informed consent as:

"A person gives informed consent to take part in a clinical trial only if his [sic. their] decision:

a) is given freely after that person is informed of the nature, significance, implications and risks of the trial;

and

b) either:

i. is evidenced in writing, dated signed, or otherwise marked, by that person so as to indicate his [sic. their] consent, or

ii. if the person is unable to signor to mark a document so as to indicate his [sic. their] consent, is given orally in the presence of at least one witness and recorded in writing."

3.9 The same definition also applies to the giving of informed consent by a person with parental responsibility or a legal representative, on behalf of the trial participant.

3.10 Assent to enter a trial may be given by a legal representative of the potential participant in accordance with Statutory Instruments 2004, 1031 and 2006, 2984 and their amendments and/or in accordance with the Mental Capacity Act, 2005.

3.11 Where the clinical trial is sponsored by the University of Lincoln electronic consent (eConsent) may be obtained in accordance with Guidance: Seeking consent by electronic methods (eConsent) https://lncn.ac/econsent.

3.12 CTIMP STUDIES: Participant recruitment and consent may only commence once all permissions are in place and the Sponsor had sent the Green Light email – see SOP CG08 Trial Initiation.

4. CROSS REFERENCES

4.1 ICH GCP

4.2 Clinical Trial Regulations - SI 2004/1031 The Medicines for Human Use (Clinical Trials) Regulations 2004 and any subsequent amendments

4.3 Guidance: Seeking consent by electronic methods (eConsent) https://lncn.ac/econsent

4.4 Trial Protocol, Information sheets and Consent Forms

4.5 CG09-RF01 Screening and Enrolment Log

4.6 CG-QMS SOP CG08 Trial Initiation

5. PROCEDURE

5.1 Any potential participant should be recorded on CG09-RF01 Screening and Enrolment Log

5.2 The CI / PI or designated nominee should discuss the trial and any trial related activity with the potential participant and obtain consent in accordance with the trial protocol.

5.3 Once enrolled onto the trial each participant should be allocated a unique study number in accordance with the protocol. The allocated study number should be entered onto the CG09-RF01 Screening and Enrolment Log

Note: Under no circumstances should duplication of study numbers occur.

5.4 At each site entries on the Screening and Enrolment Log must be in chronological order, but the allocated study number does not need to be consecutive.

5.5 The CI shall keep a master list of all trial participants. This may be generated from the Trial database or as a master Screening and Enrolment Log

5.6 A copy of the completed Screening and Enrolment Log should be retained in the appropriate TMF / ISF.

6. FLOW CHART

Not required.