

Standard Operating Procedure

Title: SUBMISSION TO RESEARCH ETHICS COMMITTEE		
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1. BACKGROUND

Ethical approval of research is one the main principles of the Declaration of Helsinki, ICH Good Clinical Practice and the Research Governance Framework:

“The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the Investigator and the Sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.” (Declaration of Helsinki, Edinburgh 2000)

“A trial should be conducted in compliance with the protocol that has received prior institutional review board / independent ethics committee approval / favourable opinion.” (ICH GCP 2.6)

“The Department of Health requires that all research....is reviewed independently to ensure it meets ethical standards.” (Department of Health Research Governance Framework, 2001)

The primary responsibility of the Research Ethics Committee is to safeguard the rights, safety and well being of research subjects. Examination and consideration of the following points achieves this:

- The suitability of the protocol including the objectives of the study, the potential for reaching sound conclusions with the smallest possible exposure of subjects, and assessment of the possible risks and inconveniences together with possible benefits to the patient and others.
- The literature available on the drug, device, process or other phenomenon under study.

- The suitability of the patient information and consent forms and procedure and the means of recruitment.

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- The suitability of the investigator for the proposed study. This includes their qualifications, experience, supporting staff, and available facilities.
- The provision for compensation and/or treatment in the case of injury or death of a subject if attributable to a clinical trial, and any insurance or indemnity to cover the liability of the investigator and sponsor.
- The amount and method of payment, if any, made to subjects

2. PURPOSE

To describe the duties of Investigators making submissions to a Research Ethics Committee. Research Ethics Committee may be a local (LREC) or multi centre committee (MREC). Applications to an MREC must be made through the Central Allocation System, although Investigators may request review by a REC of their choice, or may choose from a list offered by the CAS Office. There are specified REC for trials with Medical Devices; **any** study with a Medical Device must be reviewed by one of these RECs.

3. OTHER RELATED PROCEDURES

SOP 002: Definition of Responsibilities
 SOP 006: Study Files and Filing
 SOP 007: Informed Consent
 SOP 010: Adverse Event and Serious Adverse Event reporting
 SOP 011: Review of Protocol Amendments

4. WHEN

Written approval from the appropriate Research Ethics Committee **must** be received before recruitment strategies (e.g. advertisements) are commenced, or the first patient is approached regarding the study. **No** pre-trial 'work up' (eg scans or blood tests) may be undertaken without the subject's informed consent; this *cannot* be sought in advance of a favourable opinion from a REC.

If a substantial amendment to the protocol is necessary, written approval from the Research Ethics Committee for such amendment must be received before any change to the protocol is implemented. The only exception to this is if it is necessary to implement a change in order to eliminate an immediate hazard to the study participants.

During the study, correspondence with the appropriate Research Ethics Committee should be maintained as described below. The Committee must be informed of the completion of the study.

5. WHO

It is the responsibility of the Investigator to obtain approval for the study from the appropriate Research Ethics Committee. The investigator must sign the appropriate

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Research Ethics Committee application form. For multi centre studies, the Chief Investigator is responsible for obtaining Main REC approval and the Principal Investigator at each study site must obtain approval from the Local Ethics Committee (“SSI” or site-specific approval) for that site.

6. HOW

For the current national guidelines and procedures for obtaining Research Ethics Committee approval, please see the website of the National Research Ethics Service (NRES): www.nres.org.uk.

Details of the Local Research Ethics Committee (LREC) including contact details and addresses can be obtained from the Trust Research & Development Manager and/or the R&D Administrator.

6.1. Before Study start

- If a multi-centre study has already obtained appropriate REC approval then the submission will be to the LREC for their information and “SSI” approval of locality issues.
- The study protocol, Investigator Brochure (for drug or device trials), approval from the Regulatory Authority (where applicable), questionnaires and diaries that may be used for data collection, must be submitted to the appropriate Research Ethics Committee.
- The Patient Information Sheet and Informed Consent Form must be submitted on headed paper.
- The curriculum vitae of all investigators and co-investigators involved in the study should be submitted to the Research Ethics Committee.
- The submission package should also include a covering letter detailing all documents submitted, including version number, date and number of copies.
- The Principal Investigator must respond immediately if the Research Ethics Committee makes any recommendations for improvement to the study or conditions before approval is given. Wherever possible, the Chief Investigator (and co-investigators) should attend the meeting of the Ethics Committee.

The correspondence from the Research Ethics Committee should contain the following information:

- The clearly stated opinion of the Committee.

- The protocol title and identifying reference.

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- The documents reviewed (including version numbers and dates).
- A statement that the Committee operates in accordance with ICH GCP.
- Any advice relating to the conduct of the study
- A list of the members reviewing the study.

6.2. During the Study

- If there are any protocol amendments, serious adverse events or unexpected adverse events that are likely to affect the safety of the subjects or the conduct of the study, the appropriate Research Ethics Committee must be informed.
- The Chief Investigator **must** submit an annual progress report to the Research Ethics Committee that gave the favourable opinion for the study.

6.3. End of Study

The Chief Investigator **must** inform the appropriate Research Ethics Committee that the study has ended and provide a written report of the study outcomes.

All documentation and correspondence relating to the Research Ethics Committee must be filed in the Trial Master File (Study File) and, in the case of multi-centre studies, copies sent to the Sponsor or co-ordinating centre.