

Guidelines For The Preparation Of A Submission To The University's Ethics Committee For Approval Of Study

General Instructions

1. All investigators should read the *University of Surrey Ethical Guidelines for Teaching and Research* before submitting a proposal to the Committee, and where appropriate, refer to the *Policy and Guidance Notes on the Donation and Use of Human Specimens in Teaching and Research in the University of Surrey* for all trials involving blood or other human specimens. Researchers undertaking clinical trials should also refer to the *EU Directive on Good Clinical Practice in the Conduct of Clinical Trials* and ensure that their protocol complies with *The Medicines for Human Use (Clinical Trials) Regulations* which were implemented on 01 May 2004.
2. The **Protocol Cover Sheet** should be completed and returned with your detailed protocol, and all other relevant documents, to the Secretary of the Ethics Committee. No action in respect of facilities and dates should be taken until Committee approval has been obtained.
3. The letter of approval relates to your specified research protocol; the Committee should be notified of any changes to the proposal, any adverse reactions, or if the study is to be repeated using a different group of research participants. The Committee should also be advised when your research project has been completed.

The Protocol Cover Sheet

1. **All** sections should be completed; sections not appropriate to your submission should be identified by 'N/A'.
2. Section 2 should contain the names of all those directly concerned with the study. All those named **must** sign the final section of the form. **N.B.** Submissions from researchers who are registered as students of the University **must** include their supervisor as a Principal Investigator.
3. Section 3 **must** contain the signature of the supervisor, where appropriate, to indicate that (s)he has read and approved the protocol submission.
4. Section 4 should contain the names of those who make other contributions to the study, e.g. statisticians, analysts, phlebotomists. Where collaborators have direct contact with the volunteer subjects, such as the phlebotomist, the agreement of the collaborator to perform the task must be provided in writing.
5. In sections 5, 6 and 9, the answer 'N/A' is not acceptable, but 'none' could be. The answers to these questions may have important ethical implications and therefore they should be answered fully. Proposers should note that all information submitted to the Committee is treated as confidential.

6. Section 10 should contain information relating to applications to/approval from NHS Research Ethics Committees in cases where the research meets the specified criteria.
7. Section 11 should provide details of any risk assessments that have been carried out in relation to the research project, either for potential participants or the researchers themselves. A risk assessment is simply an examination and written statement of the potential hazards (anything that can cause harm) and risks (chance, high or low that someone will be harmed by the hazard) associated with the research, their significance and the measures which have been put in place to minimise or control them.
8. Sections 12 and 13 should provide information relating to the potential risks and benefits for those participating in this research.
9. Section 14 should provide information relating to the arrangements for collection, retention, use and disposal of research data, including measures to ensure the confidentiality of personal data.

Accompanying Documents

All submissions should include the following documents:

- A summary of the project, (approx. 500 words), including its principal aims and objectives**
- A detailed protocol for the project**
- An Information Sheet for participants**
- A copy of the Consent Form for participants**
- A completed Protocol Submission Pro-Forma: Insurance**

In instances where a proposal has received the prior approval of another Research Ethics Committee, the University Committee will accept the submission in the form of a completed Protocol Cover Sheet, together with the documentation submitted to the REC, and written confirmation of their approval.

The following points are intended as a guide to the type of information required in the Accompanying Documents.

A detailed protocol for the project should include:

- a brief background to the study;
- the objectives of the study; the hypothesis to be tested;
- criteria for the selection of participants - inclusion and exclusion criteria;
- the number of participants to be recruited;
- experimental design and the methods to be used; a summary table is very helpful where participants are to undergo a variety of treatments or tests over a period of time;
- study evaluation and statistical analysis;

Information Sheet for participants should include:

- a brief description of the project, in a form that can be understood by participants;
- the use or potential benefits of the study;
- whether the GPs of the participants will be contacted to confirm their suitability for the study, (a copy of the proposed **letter to the GP** should be included in the submission). **N.B.** It has been agreed with the University's insurers that the subject's GP will be contacted regarding their suitability for inclusion in a drug trial where there is no sponsoring pharmaceutical company, and for any other clinical trials where the subject's health and medical record is relevant.
- the obligations and commitments of the participant during the study;
- the rights of the participant - the right to withdraw from the study without having to give a reason and confidentiality of all identifiable information and data;
- any expenses or payments to be made and any conditions attached to these;
- a short statement providing information on who participants can contact if they have a complaint or concerns about the study. Suggested wording: "Any complaint or concerns about any aspects of the way you have been dealt with during the course of the study will be addressed; please contact [insert name of Principal Investigator], Principal Investigator on [insert contact number]."

Consent Form for participants should include:

- acknowledgement that:
 - a full explanation of the project has been received;
 - all questions have been answered;
 - all advice, information and instructions have been understood;
- agreement to:
 - take part in the study voluntarily;
 - comply with the instructions and co-operate fully;
 - contact being made with the participant's GP;
- a record of:
 - the rights of the participant;
 - the agreement concerning any payments or expenses;

The Consent Form should carry the names of the investigator, the participant and, in the case of research involving vulnerable groups, a witness, all of whom should sign and date the form; a copy should be given to the participant. If appropriate, the witness should be an independent person who can certify that the consent was taken in ethically sound circumstances e.g. that no undue influence etc. was used which might vitiate the consent. It is suggested that this form should be the only document to contain the name of the participant. In all subsequent records, data and documents, the participant should be identified only by a code number to provide confidentiality. The Consent Form and code should be held in a secure place.

Protocol Submission Pro-Forma: Insurance

Please refer to **Insurance Guidelines** before completing this form. All sections should be completed; sections not appropriate to your submission should be identified by 'N/A'.

Questionnaires and Interviews

The complete questionnaire must be submitted to the Committee. Where information is to be obtained by interview, details of the line of questioning should be provided. Researchers are asked to note that a separate consent form is not required for questionnaire-only research, where consent is implicit in

completion and return of the questionnaire. However, the questionnaire should include a section which advises potential participants that there is no obligation for them to complete it, and that non-completion will be without prejudice.

In appropriate cases, researchers should also recognise and advise potential participants if there is a risk that their anonymity may be compromised by the disclosure of certain demographic information, such as rank and gender within an organisation, and options should be provided for participants to omit sections of the questionnaire, or to provide partial responses to certain questions in order to avoid this.

Correspondence related to the approved project

If the project includes distribution of a survey or questionnaire to members of the University community, researchers are asked to include a statement advising that the project has been reviewed by the University's Ethics Committee.

All correspondence should be on University stationery, and should clearly state the title of the project and the name of the participating University School/Department. Replies should be directed to an address within the University. Exceptionally, where a project is being conducted at another institution, e.g. as part of a PhD collaborative programme, the stationery of an external institution is acceptable. In either case, requests for replies to be sent to private addresses are not advised.

Examples of such correspondence are:

- requests for collaboration with professional bodies or individuals
- requests for assistance in locating suitable participants
- requests for assistance in the completion of questionnaires
- letters to participants' GPs
- general correspondence with participants

Proposers are advised to submit specimen letters to the Committee.

If applicants require further information or advice, they should contact the Secretary to the Ethics Committee, Mrs Catherine Ashbee, Tel: (01483) (68)9041, Email: C.Ashbee@surrey.ac.uk.