Guidelines for the preparation of a submission for ethical approval (University Ethics Committee and NHS Research Ethics Committees)

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 **Ethics Application Form (EAF)** should be completed, dated, signed and returned with your detailed protocol, and all other relevant documents, to the Research Integrity and Governance Office, ethics@surrey.ac.uk
   No action with respect to subject recruitment and enrolment should be taken until the Committee has confirmed a favourable ethical opinion.
3. The letter confirming favourable ethical opinion relates to your specified research protocol; the Committee should be notified of any changes to the protocol, any adverse reactions, or if the study is to be repeated using a different group of research participants. A further submission to the UEC will be required in the event that the study is not completed within five years. The Committee should also be advised when your research project has been completed.

How to complete the Ethics Application Form

1. **ALL** sections should be completed; any sections not appropriate to your submission should be identified by 'n/a'.
2. Section C should have the relevant boxes ticked and the documents should be submitted in the **correct order**.
   NB. Please submit documentation as one PDF file with the documents in the order they appear on the EAF. If you are unable to merge the documents; submit them with a filename that reflects the contents, including a number corresponding to where there are listed on the EAF, e.g. 1. Protocol, 2. Participant Information Sheet, etc. Please do not submit zip files.
3. Section D should contain the names of all those directly concerned with the study. All those named **must** sign the relevant section of the form.

NB. Where signatures are not present we will return the form to the researcher, as such, not including signatures can significantly delay the review process.

Accompanying Documents

Submissions should include the following documents:

Ethics Application Form

A detailed protocol of the project

Participant Information Sheet/s

Consent Form/s

Risk Assessment

Examples of recruitment advertisements (including emails and posters, if applicable)

Interview questions (if applicable)

A completed Insurance Pro-forma

Please ensure that your documentation includes the following:

Version control: version x, dd/mm/yy (i.e. your first submission is likely to be version 1, if any changes are subsequently made it would then need to be updated to version 2, and so on). The date should be the date that you are changing the version number.

Page numbers: This is particularly important for the Protocol, and for longer Participant Information Sheets.

Where a study is using an online questionnaire; researchers should submit their Participant Information Sheet, Consent Form, and questionnaire as they would appear to participants. The existing templates would need to be tailored accordingly.

In instances where a proposal has received the prior agreement of another Research Ethics Committee (i.e. an NHS committee) an EAF would not need to be completed, written confirmation of the REC's favourable ethical opinion would need to be sent, together with all documentation listed on the letter (in the order listed on the letter), to rigo@surrey.ac.uk. Please see the Sponsorship section on page 6 of this document.

Documents on the checklist

The following points are intended as a guide to the type of information required in the Accompanying Documents specified in the checklist on the EAF. Not all of the points are applicable to all research; researchers are expected to tailor the advice accordingly.

A detailed protocol for the project should include:

- version number and date (e.g. version x, dd/mm/yy);
- 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; recruitment methods; method for taking informed consent;
- experimental design and the methods to be used (NB: a summary table is very helpful where participants are to undergo a variety of treatments or tests over a period of time);
- information on the collection, retention, use and disposal of research data and the measures in place to ensure the confidentiality of personal data;
- ethical issues;
- consideration for implications of working with other institutions, e.g. data protection, etc;
- consideration for working overseas, e.g. Travel guidance;
- study evaluation and statistical analysis.

Participant Information Sheet should include:

- University of Surrey logo, and the logo of any collaborators;
- version number and date (e.g. version x, dd/mm/yy);
- the title of the study, and the participant type/group if applicable;
- an introduction of yourself (name, qualification that the study is being undertaken for) and the purpose of the information sheet;
- a brief description of the project, in a form that can be understood by participants;
- an explanation as to why they have been invited to take part;
  - *certain age group, gender, patient group, have a particular trait, have been referred, expressed interest*;
- information on what will happen if they choose to withdraw;
  - *legal rights, employment, student status, standard care not affected;*
  - *collected data/samples destroyed, collected data/samples kept (it may be possible to withdraw participation at any point, but realistically data could only normally be withdrawn up until analysis)*;
- the obligations and commitments of the participant during the study. You must make clear:
  - *What participants will have to do and how long it will take;*
  - *If screening is involved: pathway of inclusion / exclusion;*
  - *The types of information you will be collecting; whether this will be personal data (are they or can they be identified, think about combinations of information that renders data identifiable) or anonymous/anonymised data;*
  - *What else you will be accessing/collecting: samples/tissue, medical notes, test results, assessments;*
  - *Whether you are taking audio/video recordings or photographs and whether it is possible to opt out of this;*
  - *Researchers should include any expenses or payments to be made and any conditions attached to these, it is the norm that travel expenses are reimbursed. Keep in mind that compensations are made for time and inconvenience (not for risk) at comparable rates to the minimum wage (to avoid coercion) and that participants should be aware these count as income and might affect their benefits*;

- information on what will happen to any data/samples provided, differentiate between anonymous data and personal data *(those that render someone identifiable, such as name, contact details, audio/video recordings, photographs, rare conditions, small groups);*
  - *Research data are stored for **at least** 10 years following their last access and project data (related to the administration of the project, e.g. your consent form) for at least 6 years in line with the University of Surrey policies (Data may be disposed of earlier than after 10 years provided that all data that is needed to reach the conclusion is accessible e.g. questionnaire answers entered electronically, interviews transcribed), change this accordingly if longer storage is required by your funder;*
  - *Explain what will happen to data and samples, whether they will be used in future research and whether and how (ethical) approval and consent will be sought;*
  - *Add who will have access to them and if any will be monitored by / transferred to a third party;*
  - *information on how data will be stored, for how long, and where (e.g. securely stored for the required retention period);*
- the possible disadvantages or risks of taking part;
  - *the researcher should consider all physical and emotional risks to participants;*
- the possible benefits of the study;
  - *There may not be any direct benefits to the participants, but researchers might wish to state that participation may contribute to a further understanding of the subject field;*
- what happens when the research study stops;
  - *option for receiving a summary of the results (if applicable);*
  - *potential for the results to be published;*
  - *results to be presented at a conference, written up to contribute towards a qualification;*
- a short statement providing information on who participants can contact if they have a complaint, or any 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 researcher], Principal Investigator on [insert contact number].* You should also include contact details for a supervisor, if applicable, along with someone independent to the research team, e.g. Head of School.

NB: Please supply University contact details only. Any materials that will be given to potential research participants (such as recruitment letters and information sheets) should not include home addresses, personal email addresses or mobile phone numbers. An exception can be made to the use of mobile numbers only when you have bought a sim card or mobile phone that will be used exclusively for research purposes and will be destroyed when data generation is complete. If you intend to do this, please make this clear in your application.

- if it is possible that a participant might share information with you suggesting that they, or someone else, may be at risk of significant harm you should add: *However, in certain exceptional circumstances where you or others may be at significant risk of harm the researcher may need to report this to an appropriate authority. This would usually be discussed with you first.*

Examples of those exceptional circumstances when confidential information may have to be disclosed are:

- *The researcher believes you are at serious risk of harm, either from yourself or others*
- *The researcher suspects a child might be at risk of harm*
- *You pose a serious risk of harm to, or threaten or abuse others*
- *As a statutory requirement e.g. reporting certain infectious diseases*
- *Under a court order requiring us to divulge information*
- *We are passed information relating to an act of terrorism*

- *a statement confirming that 'This study has been reviewed and received a favourable ethical opinion from the University of Surrey Ethics Committee'.*

A template can be found here.

Consent Form for participants should include:

- University of Surrey logo, and the logo of any collaborators;
- version number and date (e.g. version x, dd/mm/yy)
- the title of the study, and the participant type/group if applicable
- acknowledgement that:
  - *a full explanation of the project has been received (including the relevant version number and date for the current participant information sheet);*
  - *all questions have been answered;*
  - *all advice, information and instructions have been understood;*
  - *the procedure for the option to withdraw has been adequately explained, including information on what will happen to data;*
  - *anything else that the research team are planning to do with the data that the participants should be aware of has been stated;*
- agreement to:
  - *take part in the study voluntarily;*
  - *comply with the instructions and co-operate fully;*
  - *contact being made with the participant's GP*;*
  - *data being handled in accordance with the Data Protection Act (or however the researcher intends to use it – this should be stated clearly);*
  - *audio and/or video recording;*
  - *receiving summary of results (if applicable);*
  - *data sharing with third parties for monitoring or collaboration (if applicable);*

The Consent Form should carry the names of the investigator, the participant and a witness (where appropriate), all of whom should sign and date the form; a copy should be given to the participant. 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. The forms should normally be on University headed paper.
A template can be found here.

* When contacting GPs (for any reason) a copy of the participant's Consent Form must be included in the documentation, along with a letter to the GP.

Risk Assessment

A risk assessment **must** be included with your application; if you feel this is not relevant to your research you **must** provide a written statement to explain this. The 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. You should include both hazards to participants and researchers, you may use existing risk assessments in your department/Faculty. Guidance and templates can be found via the Health & Safety website.

Protocol Submission Pro-Forma: Insurance

Please refer to the **Insurance Proforma Guidance** 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.
Any advertisements or questionnaires themselves should contain a line stating ***'This study has been reviewed and received a favourable ethical opinion from the University of Surrey Ethics Committee'.***
Advertisements should also clearly state an end date for recruitment.
NB. Please note that recruitment posters being used on the University of Surrey campus should **only** be put up on dedicated poster boards. Where applicable, please ensure you obtain permission from the appropriate authority.

Sponsorship

If your research will require a review by an NHS Research Ethics Committee, and you will be requesting sponsorship from the University of Surrey via the Integrated Research Application System (IRAS), the process is as follows:

1) Send your draft IRAS form, along with ALL supporting documentation to rigo@surrey.ac.uk. **NB: To create a PDF of your draft form you will need to select the 'Print' button on the navigation bar.**
2) The Research Integrity and Governance Office (RIGO) will review the documentation, offering feedback on the content of the IRAS form and ensuring the University's research governance is being followed.
3) RIGO will contact you to provide you with any comments, or to advise that the application is ready for submission.

   NB: Please do not submit your application for signature without correspondence with RIGO first.
4) Once you have the go-ahead from RIGO you can request the relevant signatures, via the 'Authorisations' tab. If you are a student you will need to request your supervisor's signature first, once this has been obtained you can then request the signature from the sponsor.
5) You will receive confirmation via IRAS once the form has been authorised.

There are two questions in the IRAS form that will require the sponsor's details to be listed, A4 and A64-1; for which you will need to enter the following:

Status: *Academic*
Dr Sophie Wehrens
Research and Enterprise Support
University of Surrey
Guildford
GU2 7XH
T: 01483 683490
F: 01483 683791
sophie.wehrens@surrey.ac.uk

If you are unsure of which approvals you require please refer to the HRA website http://www.hra.nhs.uk/research-community/before-you-apply/determine-which-review-body-approvals-are-required/ , or contact the RIGO to discuss.

After receiving your FEO from REC…

If the University of Surrey is sponsoring the study

1. Email your REC FEO letter, and all supporting documentation listed on the REC letter, to rigo@surrey.ac.uk;
2. Once this is received the RIGO will issue acknowledgement of the REC decision, and the study can then begin.

If the University of Surrey is NOT sponsoring the study

1. Email your REC form, all supporting documentation, and FEO letter to rigo@surrey.ac.uk;
2. The RIGO will review the submission and issue acknowledgement of the REC decision, the study can then begin.

Contacts

If applicants require further information or advice about making a submission to the UEC, they should contact:

ethics@surrey.ac.uk