# GUIDANCE ON COMPLETING THE ETHICS FORMS

10/29/2013

University Ethics Committee

Please use this guidance for all applications for ethics approval to the UEC and Departmental/School Ethics Committees

**General guidance**

The form should normally be used for applications to the University Ethics Committee (UEC), Departmental Ethics Committees (DECs) or School Ethics Committees (SECs). Departmental Ethics Committees (DECs) and School Ethics Committees (SECs) may add some supplementary questions if they choose to do so, and should provide additional guidance that is specific to the types of investigation typically taking place there. This might be in the form of additional text giving examples of aspects that typically arise in Departmental/School research, or of important but subtle points that might be missed by less experienced investigators.

Applicants must ensure that they have read the University's Code of Practice on Investigations involving Human Beings (www.strath.ac.uk/ethics/) before completing the form.

The form is used for all investigations involving human participants. Applications for ethical approval for investigations involving the National Health Service in any way must be made under the governance arrangements for National Health Service Research Ethics Committees and where ethical approval is required from the NHS using the form issued by IRAS. Generic framework applications should be submitted on the appropriate University generic framework application form.

The application will be judged entirely on the information provided in this form and any accompanying documentation - full grant proposals to funding bodies should not be attached. The application should, as much as possible, be written in plain English and should explain any abbreviations, acronyms etc used. The Code of Practice (www.strath.ac.uk/ethics/) contains guidance on information sheets and on consent forms. It is important to ensure that the different types of documentation you provide are consistent – for example that the procedure explained to participants is the same as that described on the form – as otherwise your application may be delayed.

Applications which are not signed and/or do not include the required additional forms (e.g. participant information sheet and consent form) will not be considered by the UEC and will be referred back to the Chief Investigator.

The form is designed for completion in Word, and should in any case be typed rather than handwritten. The text boxes on the form will expand to allow you to enter as much information as you require. Please do not delete any sections, even if they are not relevant. If you have difficulty filling out the form in Word, please contact the UEC Secretariat in Research & Knowledge Exchange Services on extension 3707 or email ethics@strath.ac.uk

**Purpose**

The form applies to all investigations (other than generic applications) on human subjects undertaken by staff or students of the University that fall within the scope of the University's Code of Practice on Investigations involving Human Beings. Such investigations may fall within the remit of the University Ethics Committee (see Code of Practice Section B1) or the Departmental Ethics Committees (see Code of Practice Section B2). However, this form should NOT be used for generic applications (there is a separate form for this) or any investigation involving clinical trials or the National Health Service (including staff, patients, facilities, data, tissue, blood or organ samples from the NHS). Applications for investigations involving the NHS must be made under the governance arrangements for National Health Service Research Ethics Committees (see Code of Practice Section B9) and where ethical approval is required from the NHS the form to be used is that issued by IRAS.

**Language**

The form should be completed in language that is understandable by a lay person. Please explain any abbreviations or acronyms used in the application. Guidance on completing this application form is attached in order to assist applicants and further information is available in the Code of Practice.

**Attachments**

Participant Information Sheets (PIS) for volunteers and Consent Forms to be used in the investigation must be submitted with the application form for consideration by the Committee. A template for the PIS and Consent Form can be found on the Ethics web page. Please refer to the guidance on page 6 of this document to help you complete the PIS and Consent Form.

**Specific guidance on each question**

**Question 1**
Ensure the title relates to the research that will be undertaken, not just the subject matter. The title should be the same as that detailed on Participant Information Sheets and Consent Forms. However, if the title of the investigation would potentially give rise to demand characteristics then an alternative title may be used in communication with participants provided any deception is fully explained in a debriefing session.

**Question 2**
The Chief Investigator is the (Grade 7 or equivalent) member of staff at Strathclyde with overall responsibility of the work being carried out at, or under the auspices of, the University of Strathclyde. In the case of student projects, the Chief Investigator should be the student's supervisor. In the case of projects with external collaborators, the lead Strathclyde investigator, who is a Grade 7 or above member of staff, should be the Chief Investigator.

**Question 3**
Details of all other investigators at Strathclyde should be added here, with the format repeated in the final text box as many times as necessary. Please note that all email addresses should be to a University or other secure site. Personal telephone numbers (as opposed to work numbers), other than mobile phone numbers, should not be given.

**Question 4**
The same information as under (3) is given for non-Strathclyde investigators.

**Question 5**
If the investigation is taking place overseas, then the Researcher needs to provide the name of a local supervisor and confirm that the supervisor has received a copy of the University's Code of Practice (www.strath.ac.uk/ethics/). Please refer to section B11 of the Code of Practice.

**Question 6**
The location, or locations, of the investigation should be given. These should be places suitable for the type of investigation to be undertaken and where both participants and investigators are safely able to carry out the work. If this is not apparent then there should be some mention of this under the section on Potential risks or hazards. You must ensure that adequate Health & Safety arrangements are in place to prevent injury and harm to participants and investigators. Note that the Committee reserves the right to visit testing sites and facilities.

**Question 7**
Investigations should not begin until ethical approval is confirmed. The start date should be after the date of the Committee meeting.

**Question 8**
The sponsor will normally be the University of Strathclyde, the NHS, or an external body with management responsibility. If the investigation is within the remit of the DEC/SEC, has no external funding and has no NHS involvement, then the Head of Department can decide whether the University can sponsor the study and can sign the form at the relevant section. If the investigation comes within the remit of the UEC, has external funding or is an application to the NHS, then sponsorship must be decided through the Research & Knowledge Exchange Services (RKES) procedure. Further information can be obtained from the UEC Secretariat in RKES at ethics@strath.ac.uk

**Question 9**
If a body outside the University of Strathclyde is to fund the investigation, it should be stated here. In such instances the project will need to go through the RKES Risk Management and Sponsorship approval procedure – as mentioned at 8 above.

**Question 10**
You should describe what you consider to be the main ethical issues which may arise during the investigation, and how you propose to address them. If you answered 'yes' in Questions 13 or 16 then you should particularly address the issues mentioned there.

**Question 11**
Give a brief outline of the background, purpose and the possible benefits of the investigation. This should include a statement on the academic rationale and justification for conducting the investigation. Please use plain English and explain any acronyms or specialist terms used.

**Question 12**
In this section, you should indicate what kinds of participants you will include. Please summarise the number and age range for each group of participants involved in the investigation. Also, provide information on the inclusion/exclusion criteria, that is, the grounds on which you will select participants from volunteers. This could include gender, special skills, attributes, medical conditions etc.

You should detail any screening procedure, that is, the procedure by which the inclusion/exclusion criteria are applied, and in addition the way(s) in which certain participants are selected for a second or later stage of an investigation (for example where a questionnaire to a wide group is followed up by interviews to a small group).

**Question 13**
If any of the categories mentioned in the Code of Practice (www.strath.ac.uk/ethics) Section B1 are applicable to your investigation then you should answer 'yes' here. The application will then be considered by the UEC rather than the DEC/SEC. For all categories mentioned in the Code of Practice (www.strath.ac.uk/ethics) Section B1(b) (participant considerations), please provide details here.

**Question 14**
Describe your recruitment method(s), e.g. by letter, email, advertisement, and detail your process from initial invitation to the point of consent – see Section B4 of the Code of Practice for further information. You should report reimbursements for time or expenses incurred, plus any additional fee/incentive for participation.

**Question 15**
In this part of the form you should confirm how consent is to be obtained, and whether there are any special problems in obtaining informed consent. The section of the Code of Practice (www.strath.ac.uk/ethics/) on Consent (Section B4) discusses how to deal with special cases such as children and those with legal guardians. If consent is obtained on the basis of limited information on the purpose and methodology of the study, then the research involves an element of deception. Full informed consent should then be obtained at a subsequent point in time (usually directly after the study in a debrief session) and the participants should have the opportunity to remove their data from the study on receiving full information. If participants have already signed a consent form, another signature is not usually required after full information is given.

**Question 16**
Give a brief outline of the overall design/methodology being employed, for example interview, experimental, observation, randomised control trial, etc. This should broadly indicate why the methodology is appropriate to the research objectives, including a justification of the chosen sample size. In the question on techniques you should give a more detailed description of the precise techniques involved and of the ways in which the participants are involved. If you indicated that one or more of the categories mentioned in the Code of Practice Section B1 is applicable to your investigation then you must explain the ways in which they arise in the study. Where an invasive procedure is involved, the application should state who will be performing the procedure; if that person is medically qualified, this fact should also be stated. The duration of the study for participants and frequency of testing (if repeat testing is necessary) should be described.

**Question 17**
Include as much information as possible on the relevant experience of the investigator for this investigation.

**Question 18**
You should say how data are handled, specifying whether it will be fully anonymised, pseudo-anonymised, or just confidential, and whether it will be securely destroyed after use. You should also state how and where it will be stored, who has access to it, and how long it will be stored. It is a normal expectation that data will be stored securely on University premises.

For further guidance, see section D1(b) and Annex 9 of the Code of Practice (www.strath.ac.uk/ethics). University guidelines on the Data Protection Act can be found at www.strath.ac.uk/dataprotection. The University's policy on encryption should be followed at http://www.strath.ac.uk/it/security/encryption.

**Question 19**
Full details should be given of any potential risks or discomfort for participants, any burdens imposed and any preparatory requirements (e.g. special diet, exercise), as well as any steps/procedures taken to minimize these risks and/or discomforts. Details should also be given of any potential risks to investigators (e.g. location of interview). You should follow the University's Risk Management Framework to evaluate risk (see http://www.strath.ac.uk/safetyservices/aboutus/riskmanagement/).

**Question 20**
A debriefing of participants may be appropriate in some investigations, for example to enable participants to express how they felt during an investigation, to offer counseling, to communicate views on the whole process that they were not able to do previously, or possibly to explain a study which involved deception.

**Question 21**
Detail all anticipated presentations, reports, articles and papers.

**Question 22**
The Chief Investigator and Head of Department must sign this part of the form. In signing off the application Head of Departments/Heads of School are indicating that they are happy that the study is consistent with departmental strategy, that the staff and students who will be carrying out the study have the appropriate expertise to undertake the study, that the study makes appropriate use of available resources and facilities within the relevant department and that there are no other departmental-specific issues relating to the study of which the Head of Department is aware. Heads of Departments are not being asked to sign the application form to indicate that they are happy to approve the ethics of a study.

**Question 23**
If the investigation is within the remit of the DEC/SEC, has no external funding and has no NHS involvement, then the Head of Department can decide whether the University can sponsor the study and can sign the form accordingly. If the investigation comes within the remit of the UEC or has external funding or has NHS involvement then sponsorship must be decided through the Research & Knowledge Exchange Services procedure. The application should be referred by the DEC/SEC to the UEC Secretariat in RKES at ethics@strath.ac.uk.

**Question 24**
All research involving human participants must have insurance cover. The answers you give in this section help the Ethics Committee to consult the University's insurers if required. Please answer all questions to ensure that the appropriate insurance cover is in place for your study.

**Guidance on the Participant Information Sheet and Consent Form**

A template for the Participant Information Sheet (PIS) and Consent Form can be found online at www.strath.ac.uk/ethics.

**Information for participants**
The guiding principle is that all participants should be told as much as they might reasonably be expected to know in terms they will understand, about the purpose and procedures involved in the investigation, in order to be able to make an informed choice about whether or not they wish to participate. Please list items which should be addressed on the PIS for participants:

- Background and purpose of the investigation with possible benefits.
- Investigator(s)' name, affiliation and contact details.
- Status/role of investigator(s) (e.g. staff, undergraduate/postgraduate student).
- Funding body for the investigation (if applicable).
- Nature of the participants sample: any screening procedures necessary; any inclusion/exclusion criteria; any special skills/attributes involved.
- Confidentiality and anonymity of participant details. While confidentiality and anonymity must be guaranteed by the researchers, there are certain circumstances where information provided by the participant may have to be disclosed to others e.g. where someone is at risk of harm or has been harmed. This will be discussed with the participant at the time so that they are aware of this and can be involved (or not) in how best to pass this information on. The participant's identity and any personal identifier information should not be disclosed.
- The nature of the investigation and what is involved for participants.
- Duration and location of the investigation and participant timetable.
- Any potential risks or discomfort for participants, any burdens imposed, any specific preparatory requirements (e.g. special diet, exercise). If there are no risks then you do not have to have a section which tells the participants that there are no risks unless the description of the study might give rise to such a belief.
- Any payment/reimbursement to be made.
- Person to whom questions/concerns should be directed before, during or after the investigation. Plus the name of an independent person to whom any questions may be directed or further information may be sought from – this is normally the secretary to the Ethics Committee.
- Adequate debriefing/feedback after participation.
- Where participants are minors or otherwise unable to give their full consent, a named individual responsible for their care will be asked to provide consent on their behalf.
- Ethical approval has been obtained/is being sought.
- Refusal to participate or withdrawal from an investigation should not affect any other aspects of the way a person is treated (e.g. best medical care).
- Participants' right to withdraw data (except in anonymous questionnaires, where this is generally not possible).
- How the data from the investigation will be stored, how long it will be retained and, where appropriate, if it will be used in any other future investigation.

**Options for the Participant Information Sheet**

- Offer to send information about the results of the investigation to participants (if requested).
- Researcher(s) will monitor well-being of participants at all times.
- Arrangements for responding to adverse outcomes in the event of personal injury/damages.

**Informed consent**

Check list for points that should be mentioned on all consent forms, which participants need to sign.

1. Their participation is voluntary.
2. Their signature on the consent form indicates:
   (a) that they are aware of what their participation involves, and of any potential risks;
   (b) that all their questions concerning the investigation have been satisfactorily answered.
3. They can terminate their participation at any time without giving a reason and without any of their rights being affected (this is particularly important for students who might be concerned that it could be counted towards their success in their course).
4. They can also ask to have their data withdrawn from the investigation.
5. They are under no obligation to respond to all aspects of the investigation: for example, they can refrain from answering any survey question(s) about which they feel uncomfortable.
6. They understand that all information they give will be treated with the utmost confidentiality and their anonymity will be respected at all times.
7. Where relevant, they give their consent to the investigators to access specified records, e.g. medical notes.
8. Where relevant, they give permission for the investigator to maintain records of the investigation should a follow-up to the investigation be conducted in the future, or a further investigation be undertaken.
9. For investigations where it has been decided that 'no fault compensation' cover will be provided the following wording should be included in the consent form - 'In agreeing to participate in this investigation you should be aware that you may be entitled to compensation for accidental bodily injury, including death or disease, arising out of the investigation without the need to prove fault. However, such compensation is subject to acceptance of the Conditions of Compensation, a copy of which is available on request.'
10. Where human biological samples are taken (e.g. blood samples or biopsy samples) then the following statement should be included in the consent form – 'All human biological samples will be the property of the University of Strathclyde'.
    Where it is proposed to carry out DNA analysis of material in any samples then the following statement should be included in the consent form – 'I consent to DNA in the samples being analysed'.
11. Where participants are audio or video recorded, specific consent for this must be given. If recording is optional then a 'yes/no' at the end of the statement can be used. If recording is integral to the study such that the person cannot participate without being recorded then the statement should simply be that the participant consents to the recording.

**Important notes on your application**

- If the investigation is within the remit of the UEC and there is any variation to any aspect of the investigation (location, investigators, methodology, risks, etc.) then the secretariat to the Ethics Committee should be notified in writing immediately (ethics@strath.ac.uk) and the Ethics Committee (or Convener of the Ethics Committee acting on behalf of the UEC) given time to consider these. Research & Knowledge Exchange Services should also be notified in this instance as any sponsorship decision may be affected. There are implications to insurance cover of carrying out work which has not been ethically approved.
- Should anything occur during the project which may prompt ethical questions for any similar projects the Chief Investigator should notify the Ethics Committee.
- Insurance, sponsorship and other approval requirements from appropriate external bodies must also be in place before the project can commence.
- These guidance notes are designed to give general advice on completing an ethics application. However, there may be specific studies in which the normal guidance given here would be inappropriate and the UEC will consider alternative protocols if fully justified or give advice on possible alternative procedures.

**Submitting your application**

For applications to the University Ethics Committee, the completed form should be sent (with electronic signature) to ethics@strath.ac.uk in the first instance. Before submitting your application, please check your documentation specifications:

- Has a separate consent form and a participant information sheet been developed and attached for each group of participants?
- Are the consent forms and information sheets easily understood by all potential participants?
- Does the consent form seek consent for each relevant procedure?
- Does the consent form make clear that participants are free to withdraw at any time without giving reason and (if appropriate) without affecting their situation (e.g. school, work, care, treatment, etc.)?
- Does the information sheet contain contact details of the investigators?
- Will participants have adequate time to consider their involvement prior to giving informed consent and is this reflected in the application?
- Do the consent forms, participant information sheets, advertisements and correspondence carry the appropriate University logo?
- Are questionnaires pitched at the appropriate level for participants?
- Please number the documents in their file name to reflect the order you would like them presented to the Committee members in the meeting's agenda papers.