Guidance for Filling in Ethics Forms

Overview
All research has the potential to be exploitative and damaging, even when intended to benefit the greater public good. Even research that does not appear to have implications for human participants may raise other ethical issues to do with intellectual property, sponsorship, roles in research, and so on. Every School has an Ethics Committee that oversees all ethical applications for that School and functions as a sub-committee to the University Teaching and Research Ethics Committee (UTREC). Generally ethical approval will be granted, on behalf of UTREC, by the School Ethics Committees (henceforth referred to as SECs); however, in some instances the School will pass applications to UTREC for approval.

For many experimental laboratory studies, these can seem rather minor (not having to answer all questions in case the participant finds them personal, making clear they can withdraw at any time). But do not regard this process as mundane or trivial:

Data collection can only begin once approval has been obtained.

Some research may pose extra risks to participants. The topics below, although not an exhaustive list, are examples of research that is likely to have significant ethical issues and may extend the time to gain ethical approval. For research with significant ethical issues please anticipate not less than 4 weeks from time of submission to collection of data.

Research raising significant ethical issues includes:

- Research involving deception
- Research involving vulnerable groups (such as children aged 16 and under; those lacking capacity; or individuals in a dependent or unequal relationship with anyone on the research team)
- Research involving sensitive topics (such as sexual behaviour; legal or political behaviour; their experience of violence)
- Research involving sensitive data (data, as defined by the data protection act, which is personal information about an identifiable individual. The presumption is that, because information about these matters could be used in a discriminatory way, and is likely to be of a private nature, it needs to be treated with greater care than other personal data. This includes asking information on political opinion, race or ethnic origin, religious beliefs, trade union membership, Physical or mental health status, sexual life, details of offending or court appearance.
- Research involving access to records of personal or confidential information (including genetic or other biological information);
- Research involving access to potentially sensitive data through third parties (such as employee data or information on relatives);
- Research that could induce psychological stress, anxiety or humiliation or cause more than minimal pain (e.g. repetitive or prolonged testing);
- Research involving invasive interventions that would not usually be encountered during everyday life (e.g. administration of drugs or other substances, vigorous physical exercise or techniques such as hypnotherapy);
- Research that may have an adverse impact on employment or social standing (e.g. discussion of an employer, discussion of commercially sensitive information);
- Research that involves the collection of human tissue, blood or other biological samples.

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• Research involving crimes or criminal behaviour.

General Guidance
This guidance does not substitute for familiarizing yourself with the issues surrounding research ethics provided by various sources. Please ensure you understand the ethical issues for your type of study.

• Declaration of Helsinki: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

Forms
The forms are updated regularly so please use the most current forms:
• UTREC form (available from: http://www.st-andrews.ac.uk/utrec/ethicalapplication/)
• Data Management Plan form (available from: http://www.st-andrews.ac.uk/psychology/ethics/)

Email Addresses
Undergraduate students should not put their email address on anything provided to participants (e.g. advertisement, information sheet, consent form).

Dates
There are dates in several places: front page, page 2 (Research Information), page 7 (Declaration). Please check the dates. Many submissions suggest the study is due to start (page 2) before the form has been submitted (front page) or the ethics committee will meet to discuss applications. An easy error to catch that wastes the committee’s time.

Anonymous/Coded/Attributable Data
A common misunderstanding in filling out these forms is the difference between anonymous and coded data. It is critical to understand the difference between these types of data. The committee often sees procedures that are unsuitable for the type of data being collected (e.g. saying data is anonymous but asking for email addresses along with the data). If you need to use coded data please include a justification in the ethical statement.

Attributable: The data being collected will be attributed to the participant in the research output.

Anonymous: No one (not even the person collecting data) can ever (even theoretically) connect an individual’s identity with the data they provide.

Anonymised: It is possible to connect the data to an individuals’ identity. However, the researcher has removed all potentially identifying information from the data.

Coded: Participants identity can be connected to their data. However, participants identifying information is kept separately from the collected data. Usually

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using a securely stored “key” that links the raw data to the participants’ identity.

Gender/Sex
Almost every study utilizing human participants collects data on their biological sex and/or gender identity. This question is not nearly as straightforward as most people assume and must be handled with care and sensitivity. You should make the wording of your question clear about what you are asking the participant to report. The question must have response options that are inclusive of all identities. The example below covers this in the most basic way – researchers wishing to find out more about gender-inclusive survey design may wish to consult this 2014 publication from the UCLA Law School or the Human Rights Campaign website.

Example:
Sex assigned at birth: Male  Female  Neither  Prefer Not to Say

Example:
Gender Identity:  Male  Female  Neither  Prefer Not to Say

Specific Guidance to Complete the Forms
Project Description
This is a key piece of information, hence on the front page. Describe the general theme of the research, not the specifics. The description should be put in plain language. Instead of: “This study is being conducted to investigate which cue is dominant when interpreting a projectile’s vector” try “This study investigates how people catch a ball”. Please keep technical jargon – pretty much any ‘theory’ or ‘process’ – to an absolute minimum. Remember that what is written here will be reviewed by UTREC and may be published publicly.

IMPORTANT: In the project description you must also include what you are proposing to do, who the participants are, where the experiment will take place and how you are doing it (eg survey, interview).

Example:
What: Studies of how the brain processes visual information.
Who: Adult volunteers capable of attending appointments in St Andrews.
Where: School of Psychology & Neuroscience, St Andrews, UK.
How: Electroencephalography (i.e. brainwaves) and behavioural measurements elicited in response to visual stimuli.

Ethical considerations
We understand that 90 words is not nearly enough to address all the issues raised by this question. Use this to highlight the important ethical considerations. It is critical that you address how data will be stored. Remember that what is written here will be reviewed by UTREC and may be published publicly. This example below was from a simple in-lab perception study:

Example:
The research will be collecting anonymous data from human participants. Participants will be provided with enough information to make an informed decision regarding participation and will be free to withdraw from the experiment at any time.

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without having to provide a reason. Informed consent will be documented using a signed consent form. Data will be stored indefinitely on password-protected computers and data may be shared through open-access websites. Further details are provided in response to Q28.

1 Estimated Start Date:
Please ensure this is no less than 4 weeks from the application review date. Dates that are only a few days after the committee meeting (or which occur in the past) are unrealistic.

2 Estimated Duration of Project
This should cover the expected time to collect and analyse the data. It is sufficient if this is a rough estimate because ethics approval is in any case given for 5 years.

9.a Participants
In general, give approximate details of age range. Don’t limit yourself artificially: “Undergraduate and postgraduate students” is preferable to “Adults aged 18-22” because the former allows you to test a 23-year-old PhD student while the latter does not. Don’t forget to specify the recruitment method (e.g. voluntary sample via word of mouth).

9.b Estimated Duration
Give a sensible duration for an individual participant. Give a realistic estimate including the time it takes to read instructions and consent material and answer participants’ questions prior to beginning of data collection. This should be consistent with what is told to the participants during recruitment and on the information sheet. Suggested language given to the participant is to say “The experiment will take about x minutes.” Using language with an upper limit “no more than 1 hour” is not recommended as it unnecessarily limits the experimenter.

11 Inducement
An inducement is anything you give to participants to induce them to participate in an experiment. These can range from things with nominal value (e.g. stickers) to cash payments. It is important to ensure that any inducement is not “coercive”. When conducting research using participants from outwith the U.K. you should explain how you have determined that the inducement values are appropriate. Participants direct costs incurred as a consequence of participating in the study (e.g. bus fare, parking) are not inducements and reimbursable without justification.

A wide variety of inducements are used, but the most common ones used are cash and prize draw entries.

Cash:
The standard cash inducement approved is £5 for an experiment lasting 1 hour. It is simplest to use a fixed inducement amount than to calculate a per-hour inducement total. For example if you anticipate your experiment lasting 1-hour use a fixed inducement of £5. Inducements are not a salary or wage and do not have to be calculated based on actual minutes each individual participant participated.

Prize Draws:
Prize draws are also allowed. If using a prize draw you need to detail how this draw will occur fairly, how you will maintain participant confidentiality, and, if using anonymous data, how you will ensure that it is not possible to associate email addresses with collected data.

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Example text for ethical statement Q28:
Participants will be offered the option to submit their email address into a prize draw to win one of five Amazon vouchers worth £50. The data will maintain anonymity and participants email addresses will remain confidential by having participants report their email address on the participant consent form. To assure fair and random selection of voucher winners, the free draw will be carried out by the school’s specially assigned employee Jackie MacPherson. After completion of the study, Ms. MacPherson will be provided with a list of e-mails addresses of those who took part in the study and the five winners will be generated at random from this list.

16 Consent
“Will you obtain written consent” is an unclear question. The interpretation we are taking is that it refers to a physically signed piece of paper. This does not apply to many studies. If you are not obtaining consent through this means simply say “no” to this question and describe your consent procedure in the response to question 28.

Example text for Q28:
Q16: As this study is taking place online it is not practical to obtain signed consent from participants. Therefore we will be providing participants with a check box to use to indicate a participant’s explicit consent to take part in the study. At the conclusion of the questionnaire we will again ask if they consent to their data being included in the study. Any participant who does not reach the end of the questionnaire will be considered to have rescinded consent and their data will be destroyed.

28 Ethical statement
This statement should describe the proposed research in enough detail that the reader understands what you are going to do. If necessary, refer to appendices that contain further specific information about the experiment. Inserted here is a check for reading these instructions. Please demonstrate you’ve read these instructions by changing the colour of the first word of your ethical statement to green. The ethical statement should demonstrate that you have an understanding of research ethics and that your study will be conducted ethically. The following is not sufficient for an ethical statement:

There are no serious ethical concerns in this study.

Instead, your statement should demonstrate that you understand the ethical issues that arise in experimentation and that you have designed the study to respect these issues. If there are no serious concerns you should state why. For most experiments at a minimum you should address the following questions:

1) What are the benefits from the study?
2) What is the experimental protocol?
3) How will participants be selected and recruited?
4) How will you obtain informed consent?
5) What is your assessment of the risks from conducting the study?

Ethics Form Questions 13-21:
There are several questions on the ethics form that ask for an explanation in the ethical statement, for example, if you have answered NO to any of the questions 13–21. If this is the case, please clearly label the question your explanation is addressing in the ethical statement.

**Ethical Statement Example (feel free to use as a template):**

**Benefits**

The proposed experiment will investigate how motion information is integrating across space and time. It will use a variety of stimuli (described in methods below) to uncover the processes used in integrating information to detect motion. This experiment will help further the understanding of how the brain processes moving objects. Motion processing has been implicated in a wide range of neuropsychiatric disorders (e.g. schizophrenia) and a more complete understanding of how the normative brain processes work may help us understand these disease states.

**Experimental Protocol**

The methods of this experiment are very similar to one previously approved by the committee (PSXXXXX). Active participation in the study involves one (1) data collection session that lasts approximately one hour. At the beginning of the visit, approximately 10 minutes will be spent on consent and screening, with the remainder on data collection. All volunteers will have their vision tested by means of an eye chart, and will be asked to complete a questionnaire containing basic demographic information (questionnaire attached in appendix A). Participants will be allowed to continue with the study if and only if the consent and screening stages are completed successfully. If participants are either screened out of the study or decline to consent they will still receive an inducement equivalent to a full session (£5).

Participants will view a number of white dots on a black background. Some proportion of the dots will move in a specific direction while the remainder will move in random directions. The participant’s task will be to determine which direction the dots are moving. Participants will indicate their responses by pressing buttons on a keyboard or gamepad. We will vary multiple aspects of the stimulus: stimulus duration, speed, visibility, number of moving dots, total number of dots, size of dots, and distance between dots. Not all participants will see all combinations. Following completion of the data collection session participants will be thanked for their participation and given the written debrief statement and be given an opportunity to ask any questions they have about the experiment.

**Selection and Recruitment of Participants**

Participants will be aged 16 and up and recruited from the staff and student population of the University of St Andrews. Participants will be recruited through a written ad posted at various places around the University of St Andrews and the school SONA system (example advertisements are attached).

**Informed Consent**

Participants will be provided an information sheet detailing all relevant information (attached). The researcher will give this form in person to the participants and will ensure that each participant fully understands what participation in the experiment entails. After receiving the participant information, participants will be given a consent form (attached) that asks for the participants express consent to take part in the study and to have their data used and stored indefinitely.

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Risks
Risk of Harm from Experimental Apparatus: This study will have participants interact with a computer in a manner that is consistent with how participants use computers in their day-to-day lives, as such it is not anticipated that there will be any increased risk of harm do to participation.

Risk of Loss of Confidentiality of Participant Information: Data collected from participants will be anonymous; it will not be possible to connect the identity of a participant to their data. Therefore there is no danger of inadvertent disclosure of potentially harmful information.

Risk of Incidental Findings: Because we are performing a vision-screening test there is a possibility that participants may be concerned about their eyesight. If the participant raises such a concern the researcher will remind the participant that they are not clinicians and cannot make any clinical interpretation of the test. The researcher will provide a written statement the participant can bring to an optician for appropriate advice (e.g. participant was tested wearing spectacles standing 20 ft. from an eye chart and was unable to discern 20/40 letters).

[Detail any other risks you have considered and how it will be addressed (e.g. distress, incidental findings, infection, discovery of illegal activity).]

q21: We will not let participants omit answers to some of the questions because doing so would preclude the ability to use the rest of the collected data to address the research question. However, the questions (attached in appendix B) are not asking for sensitive personal information and should not cause undue stress for the participants. The participant will be informed they are free to withdraw and still receive the promised inducement should they not wish to answer the questions. Therefore, there is minimal potential for harm.

Document checklist
The documentation checklist is intended to help you remember important documents that are needed for submission. All documents submitted should be the versions you intend to use. **Important: The checklist does not include boxes for all documents required by the School of Psychology & Neuroscience.** Common things forgotten by applicants include:

- Research Data Management Plan
- Copies of all advertisements for all platforms you want to use (e.g. SONA and notice board), these ads may differ in length and/or format
- Copies of all questionnaires given to participants.

All documents included in the application should be listed on the Application Cover Sheet. **Please note that incomplete applications will be returned without review!**

Ethical amendments
If during the course of the research project it becomes necessary to change any aspect of the protocol (i.e. changing how you recruit participants) you **must** submit an ethical amendment form. This is a simple form, and can, in most cases, be reviewed quickly. Please clearly explain what is being changed and why. To facilitate rapid review it is important to

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clearly explain the changes in way that can be reviewed without having to find the original application. If no new ethical issues are created by these changes please state: “No new ethical considerations are created by the proposed changes”. If new ethical considerations are created by the proposed amendment include a complete explanation of how these new ethical issues will be addressed.

**Application quality**

Please remember, your ethical form is not an internal document that only the ethics committee has access to. **It will be stored in the long-term and is available to external parties, including freedom of information requests by the public or media.** Each individual form must be a complete assessment that stands on its own, irrespective of previous approvals, and that you would be happy showing as an example of your work to journalists, grant committees, etc.
Please note as this is very important

Email contact with research participants who are promised anonymity and/or confidentiality

If you have stated in your ethical application and consent form that participants’ personal data is anonymous and/or confidential you could be in breach of ethics and breaking Data Protection laws if you send a mass mail to all participants that reveals the email addresses of other participants.

Things to consider

1. Send individual emails if this is practical
2. Write an email in draft form and only add the names once you are happy with the content
3. If you need to contact large groups use mail merge. (CAPOD provide training in the setup and use of mail merges)
4. It is advisable that you do not use “bcc” as a means of contacting multiple participants. It is very easy to mistakenly use “cc” or even the “to” fields.

It is important that you adhere to data protection legislation. Any complaint made to the University by a participant about a data breach must be formally investigated. This includes the possibility of a report being sent to the Information Commissioner who has powers to impose fines on the University.

If you are aware of a complaint of this nature please do not respond to it yourself. Bring it immediately to the attention of the Convenor of the Ethics Committee or the Head of School.