## Ethical Review Procedures: Level 1

### Project Details & Self-assessment

This document is closely modelled on documents used in School of Philosophy, Psychology and Language Sciences provided by Ellen Bard and Cedric MacMartin.

This form is to be filled in and submitted at the same time as the project proposal or the funding application it applies to. The form should be submitted by the Principal Investigator, except in the following cases:

- Post-doctoral fellowships – the proposed postdoc mentor.
- UG, MSc, and PhD research projects – the supervisor.
- Visiting researcher – the staff hosting the visitor.

Please submit the completed form by email to: infkm+ethics@inf.ed.ac.uk

This address, with appropriate RT number once issued, should be used for all correspondence (including forms and attached documents). This is essential to ensure proper record keeping. No signature is required if the form is sent from a valid University email address.

### Project Details

1. **Type Of Project:**

   - [ ] Research grant proposal
   - [ ] UG final year project
   - [ ] MSc project
   - [ ] Post-doctoral fellowship
   - [ ] PhD project
   - [ ] Research performed by visiting researcher
   - [ ] Personal research
   - [ ] Other: ________________

2. **Is there a sponsor/ funding body?**

   - YES / NO

3. **Does the sponsor/funder require formal prior ethical review?**

   - YES / NO
   - If yes, by what date is a response required?

4. **Is any other institution and/or ethics committee involved?**

   - YES / NO
   - If YES, give details and indicate the status of the application at each other institution or ethics committee (i.e., submitted, approved, deferred, rejected):

5. **Title of Project**

6. **Researchers’ names, affiliations, emails**

   Include student/supervisor, post-doc/mentor, PI, or visitor/host.

7. **State which professional organisation guidelines you are using:**

   - [ ] School of Informatics research ethics code: http://www.inf.ed.ac.uk/research/ethics/
   - [ ] Other ethics code as required by funding body or professional organization:

   - Title: ________________________________
   - URL: ________________________________
Self-assessment

Refer to Level 2 form for details on any of the following points.

1. Protection of research participants’ confidentiality
   Are there any issues of CONFIDENTIALITY which are NOT ADEQUATELY HANDLED by normal tenets of academic confidentiality? YES / NO

   These include well-established sets of procedures that may be agreed more or less explicitly with collaborating individuals/organisations, for example, regarding:
   (a) Non-attribution of individual responses;
   (b) Individuals and organisations anonymised in publications and presentation;
   (c) Specific agreement with respondents regarding feedback to collaborators and publication.

2. Data protection and consent
   Are there any issues of DATA HANDLING AND CONSENT which are NOT ADEQUATELY DEALT WITH, and compliant with established procedures? YES / NO

   These include well-established sets of procedures, for example regarding:
   (a) Compliance with the University of Edinburgh’s Data Protection procedures (see http://www.recordsmanagement.ed.ac.uk);
   (b) Respondents giving consent regarding the collection of personal data (via consent form).

3. Significant potential for physical or psychological harm, discomfort or stress
   Are there any risks of:
   (a) psychological harm or stress for the participants? YES / NO
   (b) physical harm or discomfort for the participants? YES / NO
   (c) any kind to the researcher? YES / NO

4. Vulnerable participants
   Are any of the participants in the research vulnerable, e.g., children, patients, disabled participants? YES / NO

5. Moral issues and researcher/institutional conflicts of interest
   Are there any SPECIAL MORAL ISSUES/CONFLICTS OF INTEREST? These include:
   (a) Conflict of interest: potential benefit to the researcher, friends or family of a particular research outcome which might compromise the researcher’s objectivity or independence;
   (b) The need to keep the purposes of research concealed;
   (c) Use of participants who are unable to provide informed consent (e.g., children);
   (d) Situations where research findings would impinge negatively/differentially upon the interests of participants.

   YES / NO

6. Bringing the University into disrepute
   Is there any aspect of the proposed research which might bring the University into disrepute? For example, could any aspect of the research be considered controversial or prejudiced? YES / NO

7. Use of animals
   Does the research involve animals? YES / NO

8. Developing countries
   Does the research involve developing countries? YES / NO

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9. **Dual use**
   Is the research classified or does it have specific adversarial military applications?  YES / NO

10. **Terrorist or extremist groups**
   Does your research concern groups which may be construed as terrorist or extremist?  YES / NO

**Can you stop now?**

You may want to assure yourself that your ‘NO’ answers are correct by checking the detailed form in the next section.

If all the YES / NO answers are NO, the self assessment has been conducted and confirms the ABSENCE OF REASONABLY FORESEEABLE ETHICAL RISKS. This form should be signed by the researchers and submitted. The researchers may retain a copy for their own records.

If any answer is YES, please complete the relevant section in the Level 2 form below.
Ethical Review Procedures: Level 2

Detailed Assessment

This material should help you answer the questions in the self-assessment form. If any difficulties arise, you should fill in the relevant parts of this form in consultation with a near colleague who is not directly involved with the research. You can also seek advice from members of the School Ethics Panel, or from relevant Ethics Committees of other schools. You should file a new form if you receive advice on changes from the School or College Ethics Committees. For accountability, the School will view the most recent submission as accurate.

1. Protection of research participants’ confidentiality

Refer to the University Data Protection Policy to ensure that the relevant conditions relating to the processing of personal data under Schedule 2 and Schedule 3 are satisfied. Details are available at: http://www.recordsmanagement.ed.ac.uk.

1. If the research requires the collection of personal information from e.g., universities, schools, employers, or other agencies about individuals without their direct consent, what information will be sought and why will written consent for access to this information not be obtained from the participants themselves?

2. If any part of the research involving participants will be recorded using any electronic medium, what medium is to be used and how will the recordings be used?

3. Who will have access to the raw data?

4. If participants will be identified in your records, how will their consent to quotations/identifications be sought?

5. If they will not be identifiable, how will anonymity be preserved?

6. Will the datafiles/audio/video tapes, etc. be disposed of after the study?

7. If not, how long they will be retained and how will they eventually be disposed of?

8. How do you intend the results of the research to be used?

9. If feedback of findings will be given to participants, how and when will this feedback be provided?

2. Data protection and consent

Participants have the following rights over observations and records of their own behaviour:

- If they are engaging in any activity outside their normal daily routine (for example answering a questionnaire, listening for a particular syllable), they must be given some account of what they will be asked to do before they start, and must formally consent to participation;
• In any event, if they will be observed or recorded, they must be informed of and consent to the kinds of record taken;
• They must be assured of anonymity in any publication or dissemination;
• They must consent to how the data will be used;
• They must be free to withdraw from participation at any time.

1. Explain how and when written consent will be obtained from participants or from those responsible for participants unable to consent meaningfully on their own behalf. (If further discussion of this form is needed, please attach a copy of any information sheets and consent forms.)

2. If participants cannot meaningfully provide formal consent in this way, normally someone who is legally able to act on their behalf, for example a parent or legal guardian, must do so. If any of the following cases apply, explain how you will obtain the necessary consent and if you will not, how you can proceed ethically without doing so.

• administrative consent in lieu of participants’ consent
  (Administrative consent may be deemed sufficient:
   i. where the data collection involves aggregated statistical information and where the collection of data presents no invasion of privacy and no potential social or emotional risks:
   ii. where studies focus on the development and evaluation of curriculum materials, resources, guidelines, test items, or programme evaluations rather than the study, observation, and evaluation of individuals.)

• the consent of parents on behalf of minors,
• the consent or assent (at least verbal) of minors,
• the consent of participants who do not share a language with the researcher,
• the consent of participants with special educational needs.

3. Significant potential for physical or psychological harm, discomfort or stress
If the research could induce any psychological stress or discomfort, state the nature of the risk and what measures will be taken to deal with such problems.

If the research requires any physically invasive or potentially physically harmful procedures, give details and outline procedures to be put in place to deal with potential problems.

If the research involves the investigation of any illegal behaviour, give details.

If there is a real risk of disclosure of activities which should be reported to the authorities, a warning to this effect must be included in the Informed Consent documents. Please provide the wording of this
warning.

If there is any purpose to which the research findings could be put that could adversely affect participants, describe the potential risk for participants of this use of the data. Outline any steps that will be taken to protect participants.

If the research could adversely affect participants in any other way, give details and outline procedures to be put in place to deal with such problems.

If the research could adversely affect particular groups of people, describe these possible adverse effects and the protection to be put in place against them.

If the research is expected to benefit the participants, directly or indirectly, give details.

If the true purpose of the research will be concealed from the participants, explain what information will be concealed and why.

If participants will NOT be debriefed at the conclusion of the study, explain why not.

4. Vulnerable participants
What criteria will be used in deciding on the inclusion and exclusion of participants in the study?

If any of the participants are likely to be in any of the following vulnerable categories, indicate the category and describe the measures that will be used to recruit, protect and/or inform participants:

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Protection/Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>under 16 years of age</td>
<td>in the care of a Local Authority</td>
</tr>
<tr>
<td>known to have special educational needs</td>
<td>physically or mentally ill</td>
</tr>
<tr>
<td>vulnerable in other ways</td>
<td>members of a vulnerable or stigmatized minority</td>
</tr>
<tr>
<td>unlikely to share a language with the researcher</td>
<td>in a student-teacher relationship with the researchers</td>
</tr>
<tr>
<td>in any other dependent relationship with the researchers</td>
<td>likely to have difficulty in reading and/or comprehending any printed material distributed as part of the study</td>
</tr>
</tbody>
</table>

If participants will receive any financial or other material benefits because of participation, what benefits will be offered to participants and why?

5. Moral issues and researcher/institutional conflicts of interest
The University has a draft ‘Policy on the Conflict of Interest’. Regarding research the draft states that a conflict of interest would arise in cases where an employee of the University might be

“...compromising research objectivity or independence in return for financial or non-financial benefit for him/herself or for a relative or friend...”

The draft policy also states that the responsibility for avoiding a conflict of interest, in the first instance, lies with the individual, but that potential conflicts of interest should always be disclosed, normally to
the line manager or Head of Department. Failure to disclose a conflict of interest or to cease involvement until the conflict has been resolved may result in disciplinary action and in serious cases could result in dismissal.

If your research involves a conflict of interest or any situation which could be construed as a conflict of interest, please give details.

6. **Bringing the University into disrepute**

If on the level 1 form you have answered that some aspect of the proposed research “might bring the University into disrepute”, please elaborate alongside how this might arise, and what steps will be taken by the researcher to mitigate and manage this, to minimise adverse consequences to the University.

7. **Use of animals [based on EU FP7 guidelines]**

If the proposed research will use animals, please provide the following information:

1. Describe how you have applied the 3Rs: Reduction, Replacement, Refinement.
2. Describe and justify:
   - species and numbers of animals used;
   - humane end points and pain and suffering;
3. Describe how you have explored alternatives to using animals.
4. Answer the following questions:
   - Are those animals transgenic small laboratory animals?
   - Are those animals transgenic farm animals?
   - Are those animals cloning farm animals?
   - Are those animals non-human primates?

8. **Developing countries [based on EU FP7 guidelines]**

Questions to consider include:

1. Does the research project provide benefit to the local community (in terms of access to healthcare, education, allocation of property rights, capacity to assess and use modern technologies while respecting the population’s own choices and needs, etc.)?
2. Does the research project use local resources (genetic resources, animals, and plants)?

**How to deal with research involving developing countries**

The categories of issues requiring special attention include:

- A disproportionately heavy burden of diseases (particularly infectious diseases); the breadth and depth of poverty; and high levels of illiteracy
- Wide disparities in health systems and in access to health care; and imbalance between the often-ample resources available for research and the meagre resources available for even basic health care
- Inadequate scientific and ethics infrastructures for the required reviewing process
- The extent of disempowerment of the poor in their personal and communal lives
- Knowledge of the ways in which people of other cultures traditionally view themselves as individuals embedded in communities with respect to the changing boundaries between perceptions of the self that differ from the classical western notion
- The need to understand what it means to be ill in contexts very different from those known to researchers and what can be expected from those one consults for help under those
9. Dual use [based on EU FP7 guidelines]

1) What is considered as potential dual use
Generally speaking, dual use is a term often used in politics and diplomacy to refer to technology which can be used for both peaceful aims and adversarial military aims. Ethical issues of dual use might arise in cases where:

- (d) Classified information, materials or techniques are used in research;
- (e) Dangerous or restricted materials e.g. explosives are used in research;
- (f) The specific results of the research could present a danger to participants, or to society as a whole, if they were improperly disseminated.

2) How to deal with potential dual use
Regarding implications for the use of and misuse of the research and products, the following measures and strategies can be applied:

- (c) The researcher should show awareness of potential risks to participants and society as a whole from inappropriate dissemination of their results;
- (d) Appropriate measures to deal with dangerous or restricted materials should be detailed, where applicable;
- (e) An appropriate strategy to deal with issues of informed consent and risk management for participants and for society where classified information, materials or techniques are concerned should be demonstrated;
- (f) An advisory board should be included in the project, which should identify risks to participants from particular research activities and devise a strategy for minimising and dealing with these risks;
- (g) The dissemination and communication strategy of the study results to a wider audience should be controlled by the advisory board, which should report to the relevant funding body on a regular basis.

EU FP7 ethical guidelines can be found at http://cordis.europa.eu/fp7/ethics_en.html.

10. Terrorist or extremist groups

If your research concerns groups which may be construed as terrorist or extremist, please fill in the following form and submit it with your ethics form.

Prevent Duty supplementary form
The Terrorism Act (2006) outlaws the dissemination of records, statements and other documents that can be interpreted as promoting or endorsing terrorist acts.

1. Does your research involve the storage on a computer of any such records, statements or other documents? Yes / No
2. Might your research involve the electronic transmission (eg as an email attachment) of such records or statements? Yes / No
3. If you answered ‘Yes’ to questions 1 or 2, you are advised to store the relevant records or statements electronically on a secure university file store. The same applies to paper documents with the same sort of content. These should be scanned and uploaded. Access to this file store will be protected by a password unique to you and your School Research Ethics Officer. Please indicate below that you agree to store all documents relevant to questions 1 and 2 on that file store: Yes
3a. Please indicate below that you agree not to transmit electronically to any third party documents

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in the document store: Yes

4. Will your research involve visits to websites that might be associated with extreme, or terrorist, organisations? Yes / No

5. If you answer ‘Yes’ to question 4, you are advised that such sites may be subject to surveillance by the police. Accessing those sites from university IP addresses might lead to police enquiries. Please acknowledge that you understand this risk by putting an ‘X’ in the ‘Yes’ box. Yes

6. By submitting to the ethics process, you accept that your School Research Ethics Officer and the convenor of the University’s Compliance Group will have access to a list of titles of documents (but not the contents of documents) in your document store. Please acknowledge that you accept this by putting an ‘X’ in the ‘Yes’ box. Yes

Countersigned by supervisor/manager

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