Ethical Approval for Research – Issues and Procedures

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Faculty of Science and Technology Research Ethics Committee

Research Ethics Approval

- For the purposes of Research Ethics:
  - Research means all research that involves human participants as subjects undertaken as a part of formal University activity.
  - The phrase 'human participants' refers to persons used in all types of research.
    - Additional safeguards are needed if children are used as participants.
- Qualitative based research projects may include:
  - Personal interviews
  - Questionnaires
  - Interviews
  - Focus groups,
  - Observation of groups *etc*.
- Quantitative and experimental research may include:
  - Questionnaires,
  - Surveys,
  - Trials *etc*

The Faculty Research Ethics Committee (FREC)

- Made up of eight members, one from each school in the Faculty, plus one external and one lay member
  - Each faculty has its own Research and Ethics Committee

- Science and Technology FREC members:
  - Prof Chris Harris (Chair) – School of Psychology
  - Prof Judy Edworthy - School of Psychology
  - Dr David J. Price - School of Biomedical & Biological Sciences
  - Dr Matthew Barlow – School of Marine Science & Engineering
  - Martin Beck - School of Computing & Mathematics
  - TBA - School of Geography, Earth and Environmental Sciences
  - Dr Jane Grose - External Representative
  - Rev. David Evans - Lay Member
  - Paula Simson - Committee Secretary

Applying for Ethical Approval

- You will need to complete a Science and technology application form
  - The application is an electronic one to be found at https://exchange.plymouth.ac.uk/intranet/research/Public/apply/ethics.htm
  - There is also an Ethical Approval Guidelines document to help you with the form
- When returning the form you will also need to include:
  - **Participant Information sheet (aka Briefing Document)**
  - **Consent form**
  - There are templates / models to help you with this
- Email all documentation to the Committee Secretary (Paula Simpson), who forwards it to the FREC
- FREC will respond back with approval or comments
  - If there are comments, you will need to re-submit revised documentation
- The FREC will respond fairly quickly to applications
- How long an application takes for approval depends on how quickly you are able to address the comments (if any) made
- This whole process is quite painless!

Ethical Protocol:

- Informed Consent
  - All participants in your study must be provided with sufficient information so they are able to give an informed consent to take part in your study
- Risk and Harm
  - Any risk or harm needs to be assessed.
  - It goes without saying any risk or harm should be minimised
- Confidentiality and Anonymity
  - Avoid the collection of 'personally identifiable information'
  - Names are not recorded with raw data.
  - Use an ID number and mapping document to link names with ID
- The Data Protection Act
  - All data collected must comply with the Data protection act
- Experimental Design & appropriate methods
  - Poor experimental design=time wasted for participants, researcher, sponsor + no useful outcomes

Completing the Ethics Application (1)

- The information required is under the following headings –

- 2. Application
  - This section requires general information about the project

- 3. Procedure
  - describe the procedure in straightforward language and in sufficient detail so that a lay person can understand what participants are expected to do and what might happen to them
  - State how long it will take

- 3.4 Deception
  - Deception of participants is possible
  - Need to justify
  - Must also include debriefing document

Completing the Ethics Application (2)

4. Breakdown of Participants

- Be very clear about who your participants are
- Participants should not be coerced onto a research project!
  - This section requires general information about the project

5. Non-Vulnerable Adults (those 18 or over)

6. Minors < 16 years

- Informed consent both from participant and parent (or legal guardian)
- Opt-in vs opt-out
- Need to include consent forms and information sheets with form

6. Minors 16-18 years old

- Desirable to obtain informed consent from the parent/legal guardian, although it is recognised that young people aged between 16 and 18 are generally competent to give independent consent.

Completing the Ethics Application (3)

8. Vulnerable Groups
   - Only for participants of ANY age who are vulnerable by virtue of a medical or psychological condition

9. External Clearance
   - For <18 CRB check

10. Physical Risk Assessment
   - Include things like:
     - Use of electrodes
     - Physically stressed (e.g. exercise)

11. Psychological Risk Assessment
   - Risk of psychological harm is more difficult to identify than physical risk.
   - Nevertheless it is the researcher's responsibility to assess psychological risk to participants.
   - Viewing explicit/sensitive material, emotional stress, recounting traumatic events

Completing the Ethics Application (4)

12. Research over the internet

- Research over the internet is an evolving paradigm, and the committee do not wish to be proscriptive. The main problems that **must** be addressed are

1) how do you ensure participants informed consent and the right to withdraw?
2) how will you maintain confidentiality and data protection ?
3) how will you prevent fraudulent use either by outsiders or by participants?

13. Conflicts of Interest and Third Party Interests

- Third party interest refers to any other individual, group, or institution who have a stake in the outcome of the research result

Informed Consent

- Key concept underlying ethics, two parts:

1. Participant Information sheet
2. Consent form

Participant Information Sheet:

- Participant Information Sheet:
  - Informs participants about the study
  - What is expected of them
  - What their rights are
  - What information is collect
  - And how it is collected

- Include:
  - Aim of research
  - Description of procedure
    - In lay terms
    - Approx procedure time
    - Any video or audio recordings

  - Benefits of proposed research
  - Right to withdraw
  - Right of reply

- The FREC provides a template to help you with this

- The Participant Information Sheet MUST be phrased in lay-terms, easy to understand
  - Get someone else to proof read before submitting!

The Consent form

- The Consent form

- If your study only requires participants to complete and return a questionnaire, then no consent form is needed:
  - Consent is implied by returning the questionnaire.
  - But you must include the participant information sheet with the questionnaire.

- For all other studies then a consent form must be signed by each participant.
  - The Ethics Committee provides a model consent form, which will normally suffice for this purpose

Further Information:

- UOP Documents
  - Research Policies & Procedures:
    - https://exchange.plymouth.ac.uk/intranet/research/Public/papers/1.%20Research%20Policies%20&%20Procedures/01%20Research%20ethics%20policy.doc
  - Ethical Approval forms
    - https://exchange.plymouth.ac.uk/intranet/research/Public/apply/ethics.htm

- Vinson, N.G. & Singer, J.A. (2008). A Practical Guide to Ethical Research Involving Humans. In Shull, F., Singer, J., Sjøberg , D. (Eds) *Guide to Advanced Empirical Software Engineering*. pp. 229-256, Springer.
  - http://cogprints.org/6740/

Codes of Practice

- British Education Research Association (BERA)
  - http://www.bera.ac.uk/publications/
- British Psychological Society (BPS) Ethical Principles for Conducting Research with Human Participants
  - http://www.bps.org.uk/the-society/code-of-conduct/support-for-researchers_home.cfm
- British Sociological Association
  - http://www.britsoc.co.uk/equality
- Economic and Social Research Council (ESRC) Research Framework
  - http://www.esrc.ac.uk/ESRCInfoCentre/opportunities/research%5Fethics%5Fframework
- Barnardo's Statement on Ethical Research Practice
  - http://www.bris.ac.uk/education/research/centres/creole/resources/ethics/barnados.pdf