Staffordshire University
Application for Ethical Approval of Research Project (Long Form)
Faculty of Business & Law

This form must be completed by the researcher, and submitted (in the case of undergraduate –and graduate projects) to the designated supervisor, who should consider it and if approved, then forward it to the Faculty Ethics Panel . The latter should keep it on file as an agreed record of the research being undertaken. Proposals for staff research projects that require ethical approval should also be considered by this Committee.

1. RESEARCHER

Name:

Faculty:

Supervisor/ Head of Field:

Academic status of applicant:

Commencement and expected duration of project:

2. RESEARCH PROJECT

Title:

Please offer a brief paragraph indicating answers to the following questions where relevant:

- Where the research is to be carried out;
- Whether adequate facilities are in place enabling the project to be properly carried out;
- Whether procedures are in place given the occurrence of any adverse event;
- Names of other individuals or organisations involved in the project;
- Whether other approvals have been gained or are to be sought.

3. PURPOSE OF RESEARCH PROJECT

Please offer a brief paragraph indicating:

1. The aims and objectives of the project;
2. Its rationale;
3. The research question or specific hypotheses to be tested;
4. The background to the project.

NB. It is not the job of the Faculty Research Ethics Committee to consider the methodology of the research project. However this Committee does need assurance that the appropriate methodology has been properly considered before it can consider whether the project is ethically justifiable.

4. BRIEF OUTLINE OF PROJECT

Please offer a summary of the procedures it is proposed to follow in carrying out the project. Such descriptions might vary according to the nature of the project and the academic area involved, but they should normally include at least the following:

1. The design of the project (including, where appropriate, issues of statistical power);
2. The procedures to be followed;
3. The participation of subjects in the project;
4. How the design of the project and the procedures followed are likely to assess the research question or test the hypothesis in question or establish some significant result.

5. RECRUITMENT OF SUBJECTS

This section should contain clear information indicating the basis on which the proposed participating subjects are appropriate to the project. Normally researchers should adequately answer the following questions:

1. The number of subjects involved in the study (including the adequacy of the sample size) and how it is proposed to recruit them;
2. Whether there are any inclusion or exclusion criteria, together with their justification;
3. The age range of subjects; the gender balance of subjects; and the state of health of subjects;
4. Whether there is any inducement to participate in the study;
5. Whether the project involves any special groups requiring some additional justification or permission (e.g. whether subjects are especially vulnerable, i.e. children, students, the elderly, those with learning difficulties or mental health problems, those with some disadvantage or dependency, those in hospital or those in prison).

NB Researchers must also ascertain from their Supervisor whether or not they need to obtain Criminal Records Bureau clearance to enable this project to proceed. If this is the case the application must make clear whether or not it has been obtained. Any data collection or other activities requiring this clearance must not begin until it has been obtained

6. PARTICIPATION OF SUBJECTS

Please provide two documents. These are an Information Sheet and a Consent Form, and each should be attached to your application. The first must ensure that the subject has a proper understanding of their participation in the project, and the second that they have given informed and voluntary consent to their involvement in it. Some notes for guidance follow.

INFORMATION SHEET

This will be provided to the subject prior to taking consent, and must explain the broad purpose of the project, the basis on which the subject has been chosen, what is required of the subject in the project, whether there are any possible disadvantages or risks in taking part, the benefits gained by taking part (either to the subject, the researcher or the scientific community), what will happen if something goes wrong, what happens to any information obtained about the subject, the expected results of the study, who is responsible for it, and a contact name. The Information Sheet must be written in a clear, informative, and intelligible way.

The Information Sheet must include a description of how subjects are involved in each stage of the study. This should relate back to §4 above. Their participation will vary according to the nature of the project, but will explain what is required of each subject (i.e. what kinds of measurements or observations will be undertaken, and by what means) and especially those that involve some risk or discomfort or which have other ethical implications (i.e. administration of substances, sampling of bodily fluids or tissue, or placebo or control groups, or genetic information).

CONSENT FORM

A properly designed Consent Form must also be attached to this application. It should include [a] the title of the research project as in Section 2 above, [b] opportunity for confirmation by the subject that they have read and understood the Information Sheet (see above) and have been able to ask questions, [c] that their involvement is voluntary and that they have the right to withdraw at any time without providing reasons and without their rights being affected, and [d] that they understand that personal information about them may be looked at by researchers or other responsible individuals.

The Consent Form should indicate how individual informed and voluntary consent will be obtained. Sometimes (as in the case of Question 5 in §5 above) it will be necessary to indicate how parental or guardian agreement will be obtained.

The Consent Form must include space for properly dated signatures of the subject that they agree to participate in the project, together with the names of the person taking consent and/or the researcher.

7. INFORMATION AND DATA

The application must contain a clear statement of what information will be collected about each subject, the data obtained as part of the procedures described in §4, how it is proposed the data will be stored, how the data contributes to the project, together with a statement of how long it will be stored and how eventually discarded.

Please offer answers to the following questions:

1. What information about the subject do you wish her or him to disclose to you in order for the project to commence?
2. What data will be gained about the subject in the various stages of the project?
3. What form does this data take (measurements, observations, audio/video tape recording)?
4. How will this data be stored (manually or electronically)?
5. How is protection given to the subject (e.g. by being made anonymous through coding and with a subject identifier code being kept separately and securely)?
6. What assurance will be given to the subject about the confidentiality of this data and the security of its storage?
7. Is assurance given to the subject that they cannot be identified from any publication or dissemination of the results of the project?
8. Who will have access to this data, and for what purposes?
9. How is the data relevant to the project and the determination of its results?
10. How will the data be stored, for how long, and how will it be discarded?

8. RISK, HARM AND OTHER ETHICAL CONSIDERATIONS

This final section invites an estimate by the researcher of the perceived benefits or outcomes of the project weighed against the possible harms caused to the participating subject. Please submit two brief paragraphs. The first should identify both [a] any potential risks or hazards that might be caused to subjects or the researcher, in addition to any discomfort, distress or inconvenience to them, together with any ethical problems or considerations that the researcher considers to be important or difficult in the proposed project; and [b] offer an explanation of how it is proposed to deal with them, along with any justificatory statements.

The second paragraph provides an opportunity for the researcher to highlight any remaining ethical considerations and to respond to them in a way which may assist the Research Ethics Committee in arriving at some judgement upon the proposal. This second paragraph is not an invitation to take on the work of the Committee, but rather emphasises the expectation that both researcher and Committee share the responsibility for assuring that the proposed research will be carried out ethically and with full regard to ethical principles.

9. SIGNATURES OF RELEVANT PERSONS

I undertake to carry out the project described above in accordance with ethical principles. I have completed the application in good faith. I accept that providing false information constitutes scientific fraud and will be subject to appropriate disciplinary procedures.

Signature of Researcher Date

I have examined this proposal, confirm that the rationale and methodology is appropriate and that it can proceed to the stage of ethical consideration.

Signature of Supervisor or relevant Head of Unit Date

This research proposal has received ethical approval either by a supervisor on behalf of the Committee or has been considered by the Committee and received ethical approval.

Signature of Chair of Faculty Ethics Panel Date