# Ethical Guidelines and Procedures for Research involving Human Participants

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## 1. Introduction

All research involving human participants that is conducted by students or staff at the National College of Ireland should be done so in an ethical manner. The college has therefore developed an Ethics Committee, which acts as a sub-committee of the Research Committee, to ensure that ethical principles pertaining to research involving human participants are upheld and adhered to. All researchers intending to use human participants as part of their projects are thus required to reflect upon any potential ethical issues and submit their research proposals for ethical review before commencing data collection.
This document gives an overview of the core ethical principles guiding research in NCI, while also documenting the procedures required for seeking ethical approval of research involving human participants.

### Am I conducting research?

Research is defined as "the attempt to derive generalisable new knowledge by addressing clearly-defined questions with systematic and rigorous methods" (NHS Health Research Authority). Research requires consideration of the below guiding principles

### Guiding Principles

In line with other research institutions, there are three core guiding principles governing the ethical conductance of research involving human participants at NCI. These principles stem from the Belmont Report (1979) published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. While it is recognised that these principles may be operationalised differently depending on the specific research discipline, it is recommended that these are consulted as a starting point for any research involving human participants.

### 1.1 Principle 1: Respect for Persons

This principle entails recognition that participants should be treated as autonomous individuals and hence should never be coerced or swayed into participating in a research project against their will. The participant's right to withdraw from a research study at any time should be respected, as well as their right to dignity and protection from harm.

Respect for individuals can often be implemented in practice via the process of informed consent, whereby potential participants are made fully aware of the requirements involved in participation. While it is recognised that in certain cases deception (i.e. the withholding of certain information from participants) may take place, this should only occur when it is robustly justified for the validity of the research. In cases where deception is justified, researchers should ensure that any potential risk resulting from this measure is minimised. Participants should also be fully debriefed on the nature of the research after it has taken place.

The principle of respect also requires researchers to protect individuals from vulnerable groups who may have diminished autonomy (see section 4.2 for more detail as to what constitutes vulnerable groups). Where full informed consent is not possible for such population groups, consent may instead be sought from their guardians. In all cases however clear assent, or willingness to participate, should be demonstrated from participants.

### 1.2 Principle 2: Beneficence and non-maleficence

This principle specifically focuses on the need to protect the well-being of participants. Any potential risk to participants should be minimised, whether that be risk of physical discomfort or of any psychological, emotional or social distress, while possible benefits should be maximised. Researchers adhering to this principle should thus ensure that any potential benefits derived from carrying out the study (e.g. in terms of knowledge gained) should outweigh potential risks. Even in cases where there is only a slight potential risk of harm, participants should be provided with appropriate support to alleviate this.

### 1.3 Principle 3: Justice

This principle emphasises the need to employ fairness in the distribution of benefits and risks to participants. The way in which participants are selected to take part in research should relate to the purpose of the study, as opposed to other factors such as availability or manipulability of participants. The exploitation of vulnerable populations should be avoided.

Where applicable, researchers are encouraged to consult guidelines stemming from their own professional bodies (e.g. The Psychological Society of Ireland) in addition to the general guiding principles above when planning their research. Researchers should also be sensitive to those issues which are specific to the population under investigation and the methodology that is employed in the project (e.g. qualitative methodologies involving the recording of data may raise issues relating to participants' right to anonymity, as well as the ethical management and use of data). Detailed consideration should be given to all these issues when planning research and when completing the Ethical Review Application form.

## 2. Ethics Committee

The NCI Ethics Committee was established by the Academic Council in 2012. Acting as a sub-committee to the Research Committee, its role is to oversee ethical issues arising from all research involving human participants that is conducted by students and staff of the college. The key purpose of this committee is to safeguard against any potential harm to participants, and to ensure that their rights are recognised in line with the guiding principles outlined above. The Ethics Committee reviews all research proposals posing ethical risk to the participants involved, however the decision as to whether projects pose ethical risk is firstly made via the appropriate Filter Committee which operates at School level (see organisational structure in Figure 1 below). The Filter Committees may review and approve research proposals which are of low ethical risk, while referring those of high ethical risk to be considered by the Ethics Committee (see categories of ethical risk in section 4.1).

While the Filter Committees are made up of staff members with subject-specific knowledge, membership of the Ethics Committee should comprise of no less than five representatives from the School of Computing and the School of Business & Humanities, and the Early learning Initiative (ELI) including representatives from the Research Committee.

If I am a student (undergraduate or graduate) at NCI, a Filter Committee will first review your proposal. Filter Committees sit within each school, and are made up of staff members with subject- specific knowledge. Filter Committees should comprise of at least three members.

Any staff or student of NCI wishing to conduct a study involving human participants should submit the Ethical Review Application Form. The review will result in a graded categorisation of ethical risk, as outlined here.

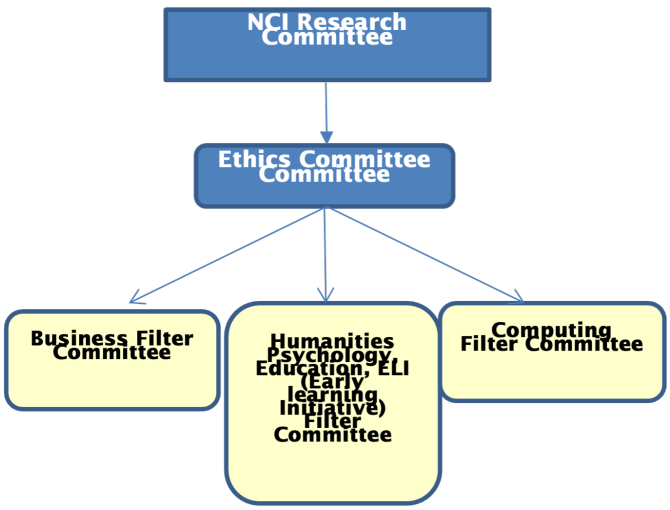


Figure 1: Committee Structures.

## 3.1 Categorisation of Ethical Risk

### Research category A

Research in this category poses little ethical risk to the participants involved. Specifically, it refers to research involving human volunteers, but excluding studies involving:

- therapeutic interventions
- new research methodologies
- vulnerable populations (see section 4.2)
- deception of the participants
- any other significant physical, social or psychological risk to participants

### Research category B

Research in this category involves human volunteers including studies involving:

- therapeutic interventions
- new research methodologies
- vulnerable populations (see section 4.2)
- deception of the participants
- any potentially significant risk to participants

### Research Category C

This specifically refers to research involving human volunteers who are service users, patients, staff, records, etc., within the sphere of the HSE or similar setting (but not including clinical trials of investigative medicinal products).

## 3.2 Vulnerable groups

There are a number of participant populations that may fall under the heading of 'vulnerable groups'. These groups require consideration of unique ethical challenges regardless of the nature of the project. Research involving such populations should therefore always be reviewed by the Ethics Committee.

Groups that may be classed as vulnerable include, but are not limited to:

- Children (under 18 years of age)
- The very elderly
- People with an intellectual or learning disability
- Individuals or groups receiving help through the voluntary sector
- Those in a subordinate position to the researcher (e.g. employees)
- Any other groups who might not understand the research and consent process

Note: in addition to the Ethical Review process, any researchers intending to work directly with children will be required to undergo Garda Vetting in advance of the proposed research.

## 3.3 Exemption from Full Ethical Review

In certain limited cases, researchers can apply for an exemption from full ethical review. In such cases, the Ethical Review Exemption form should be completed, explicitly detailing why the exemption is sought.

In completing this form, researchers must declare that the research does not involve any of the following:

- Vulnerable groups
- Sensitive topics
- Risk of psychological or mental distress
- Risk of physical stress or discomfort
- Any other risk to participants
- Use of drugs or invasive procedures (e.g. blood sampling)
- Deception or withholding of information from participants
- Conflict of interest issues
- Access to data by individuals or organisations other than the researchers
- Any other ethical dilemmas

### 3.4 Outcomes of Review Process

Following consideration of research projects submitted for Ethical Review, each Filter Committee will submit a report to the Ethics Committee summarising the applications considered and the decisions made.

For research that is deemed to fall under Research Category A (low ethical risk), a favourable outcome at the relevant Filter Committee will be sufficient to secure ethical approval. Research falling under the other two categories must however be considered by the Ethics Committee before approval may be granted.

On the basis of this review, four key outcomes may arise:

1. Research proposal approved (no recommendations)
2. Research proposal approved pending minor revisions (to be accepted by the Chair and Research Supervisor)
3. Research proposal approved pending major revisions (to be resubmitted and approved by the Ethics Committee)
4. Research proposal rejected (resubmission necessary)

A summary of the processes involved in applying for ethical approval can be seen in Figure 2.

### Appeals

Appeals against the Committee's decision may be made within ten working days. In this case, at least three members of the Ethics Committee, none of whom will have reviewed the initial application, may review this along with any additional information submitted by the applicant.

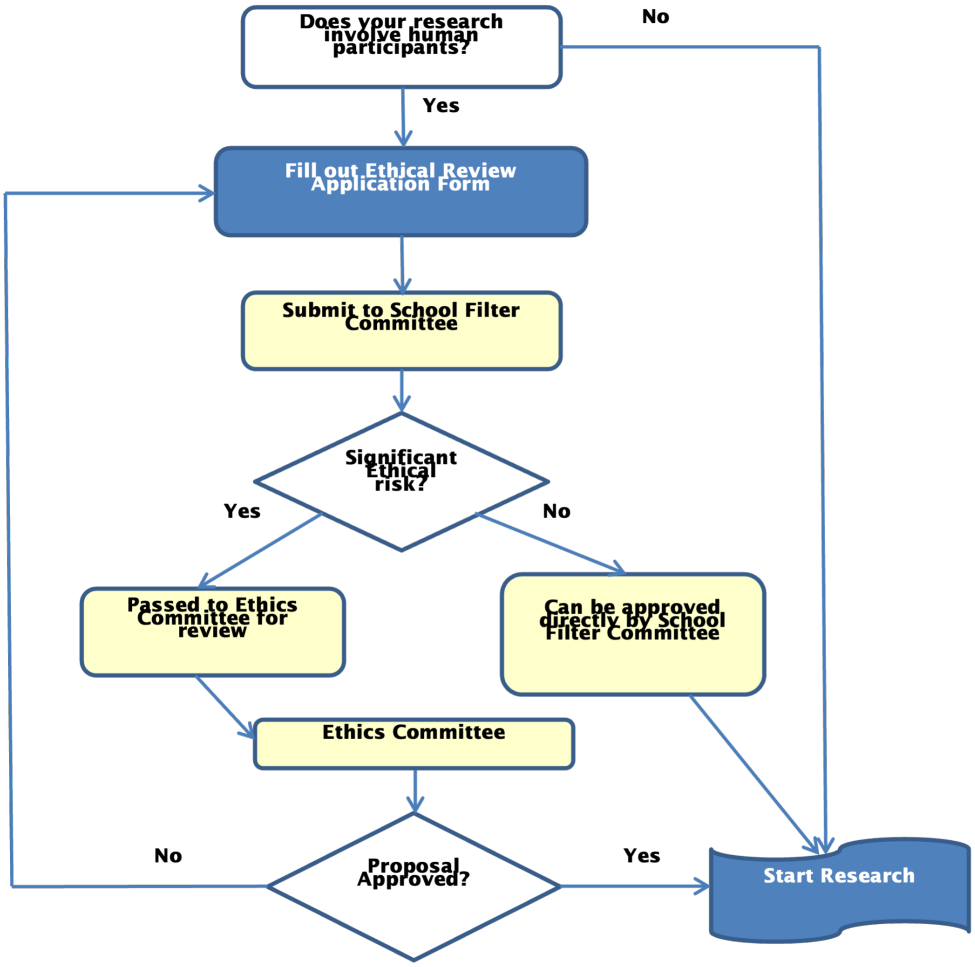


Figure 2: Process chart for seeking Ethical Approval

**Ethics Application Checklist**
To be submitted alongside three printed and signed copies of the ethics application.

Please complete the below checklist, ticking each item to confirm that it has been addressed.

1. I agree to obtain informed written consent from all human participants aged over 18 who are involved in this research (or if circulating digitally, I will ensure that informed consent is completed, and will have the participants indicate their informed consent by continuing with their study engagement). ☐
2. I agree to obtain informed written consent from the parents of anyone aged under 18 in this research (or from the schools if appropriate), and informed written assent from those under 18 in this research. ☐
3. I append a letter of agreement from a clinically responsible individual agreeing to (where appropriate) help me recruit/provide clinical support in the event that participants become distressed/host the study data collection. ☐
4. I append a letter of agreement from an external institution or organisation agreeing to host the study. ☐
5. I agree to comply with NCI's Data Retention Policy. ☐
6. I have appended a) information sheet, b) consent form/assent form, c) debriefing sheet. ☐
7. I have provided details of how non-anonymised data will be stored, in a safe and encrypted manner. ☐
8. I have included my contact details and those of my supervisor (where appropriate). I have only included my NCI email address and not included any personal contact information. ☐
9. I have given sufficient details on the proposed study design, methodology, and data collection procedures, to allow a full ethical review, and I understand that my failure to give sufficient detail may result in a resubmission being required. ☐
10. I understand that if I make changes to my study following ethical approval, it is my responsibility to seek an ethics amendment if the change merits ethical consideration. ☐

# Educational Research/Study Ethical Review Application Form

All parts of the below form must be completed.

## Part A: Title of Research/Study Project and Contact Information

Name:

Student Number (if applicable)

Email

Status:

Undergraduate

Postgraduate

Staff

Supervisor (if applicable)

Title of Research/study Project

Have you read the NCI Educational Research Ethical Guidelines for Research?

Yes No

Please indicate any other ethical guidelines or codes of conduct you have consulted

Has this research proposal been submitted to any other research ethics committee?

Yes No

If yes please provide details, and the outcomes of this process, if applicable:

Is this research proposal supported by any form of research funding?

Yes No

If yes, please provide details, and indicate whether any restrictions exist on the freedom of the researcher to publish the results:

## Part B: Research/Study Proposal

Briefly outline the following information (not more than 200 words in any section).

Proposed starting date and duration of research/study project

The rationale for the project

The research/study aims and objectives

The research/study design

The methods of analysis. Give details here of the analytic process (e.g. thematic analysis planned if qualitative, statistical procedures planned if quantitative. It is not sufficient to name the software to be used).

**Research Study/project Procedure**

Please give as detailed an account as possible of a participant's likely experience in engaging with the project, from the point of first learning about the study, to study completion. State how long project participation is likely to take what is involved. Please attach all questionnaires, interview schedules, scales, surveys, and demographic questions, etc. in the Appendix.

## Part C: Project Benefits

Please provide some details with regards to research/study/project benefits based on the 8 guiding principles (on page 2)

How will the participants be selected, approached and recruited? From where will participants be recruited? If recruiting via an institution or organisation other than NCI please attach a letter of agreement from the host institution agreeing to host the study and circulate recruitment advertisements/email etc.

What inclusion or exclusion criteria will be used?

How will participants be informed of the nature of the study and participation?

What procedures will be used to document the research/study participants' consent to participate?

Can research/study participants withdraw at any time? If so, how will this be communicated to participants?

If vulnerable groups are participating, what special arrangements will be made to deal with issues of informed consent/assent?

## Part D: Confidentiality and Information/Data Protection

Please indicate the form in which the Information/Data will be collected.

Identified Potentially Identifiable De-IdentifiedC

What arrangements are in place to ensure that the identity of participants is protected?

Will any information about illegal behaviours be collected as part of the research process? If so, detail your consideration of how this information will be treated.

Please indicate any recording devices being used to collect information/data and how it will be used (e.g. audio/video).

Please describe the procedures for securing specific permission for the use of these recording devices in advance.

Please indicate the form in which the data will be stored.

Identified Potentially Identifiable De-Identified

Who will have responsibility for the data generated by the research?

Is there a possibility that the information will be archived for secondary data analysis? If so, has this been included in the informed consent process? Also, include information on how and where the information will be stored for secondary analytic purposes. (Please note: read the NCI Research Data retention Policy)

If not to be stored for secondary data analysis, will the data be stored for 5 years and then destroyed, in accordance with NCI policy?

Yes No

**Dissemination and Reporting**

Please describe how the participants will be informed of dissemination and reporting of research/ study findings (e.g. submission for examination, reporting, publications, presentations)?

If any dissemination entails the use of audio, video and/or photographic records (including direct quotes), please describe how participants will be informed of this in advance.

## Part E: Signed Declaration

I confirm that I have read the NCI Educational Research Ethical Guidelines, and agree to abide by them in conducting this research. I also confirm that the information provided on this form is correct (Electronic signature is acceptable).

Signature of Applicant

Date

Signature of Supervisor (where appropriate):

Date

Any other information the committee should be aware of?