National College of Ireland

Ethical Guidelines and Procedures for Research involving Human Participants

SEPTEMBER 2022

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). Sometimes, we collect data in order to evaluate a service or practice we are engaged in ("service evaluation"). The main difference between research and service evaluation is in the aim: research is trying to create new generalisable knowledge, and service evaluation is trying to evaluate whether a delivered service/practice is working well. One project may have both aims included in it. It can be confusing if a service or intervention is involved, whether or not research is being conducted. If new or competing interventions are being evaluated, then it is likely to be research, whereas if an existing service is being conducted anyway, with an evaluative component, then it is likely to be a service evaluation. Research requires consideration of the below guiding principles, whereas service evaluation does not require approval from an ethics committee.

2. 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.

2.1 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.

2.2 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.

2.3 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.

3. 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 both the School of Computing and the School of Business, including representatives from the Research Committee.

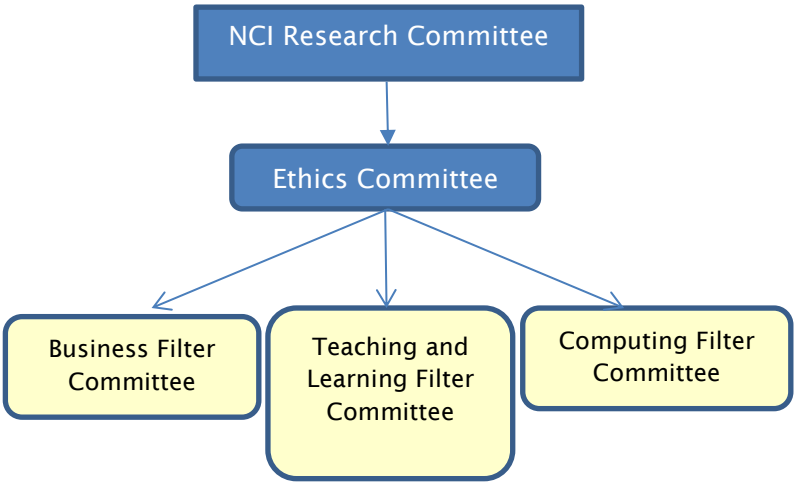


Figure 1: Committee Structures.

4. Review Process

Any staff or student of NCI wishing to conduct a study involving human participants should first submit the Ethical Review Application Form (included at the end of this document), to the relevant School Filter Committee at proposal stage. This initial review will result in a graded categorisation of ethical risk, as outlined below.

4.1 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).

4.2 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 older old (aged 85+)
- 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.

4.3 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

4.4 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.

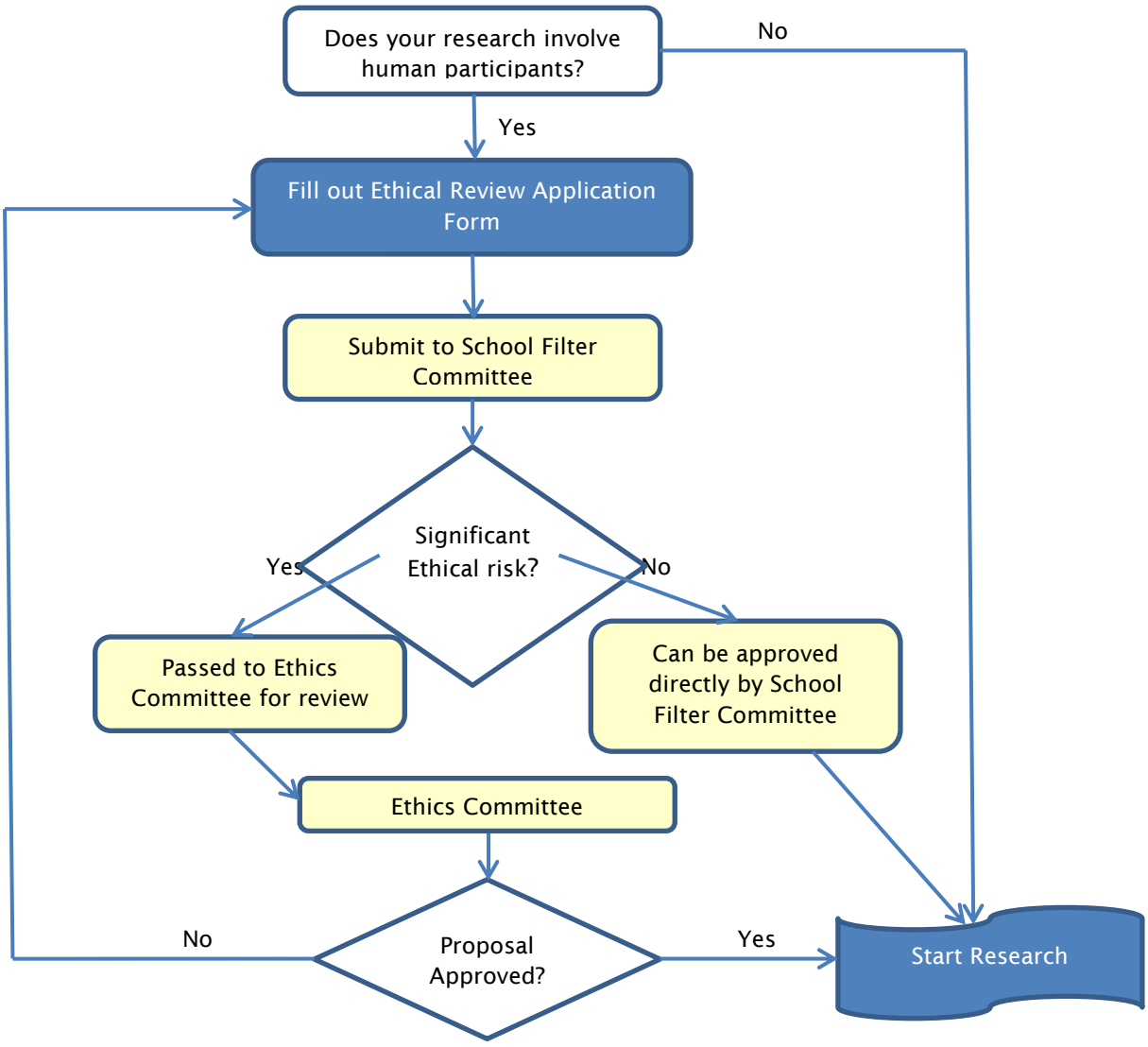


Figure 2: Process chart for seeking Ethical Approval

Ethics Application Checklist

To be submitted alongside 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 include 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.	□
	□

National College of Ireland

Human Participants Ethical Review Application Form

All parts of the below form must be completed. However in certain cases where sections are not relevant to the proposed study, clearly mark NA in the box provided.

Part A: Title of Project and Contact Information

Name

Marta Pacheco Merino

Student Number (if applicable)

21179999

Email

x21179999@student.ncirl.ie

Status:

Undergraduate ☒
Postgraduate □
Staff □

Supervisor (if applicable)

Title of Research Project

Matchmaking

Category into which the proposed research falls (see guidelines)

Research Category A ☒
Research Category B □
Research Category C □

Have you read the NCI Ethical Guidelines for Research with Human Participants?

Yes ☒
No □

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

Has this research 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 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 Proposal

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

Proposed starting date and duration of project

Starting on 10th of October

The rationale for the project

Finishing Higher Diploma in Science in Computing

The research aims and objectives

I'm developing an application based in the topic of gaming, that will retrieve information from the user an connect it to a database of videogames, in order to match the user with the best options based on their answers. It's just made with entertaining purposes and data will be stored safely.

The research design

The steps to follow will involve finding information about videogames databases and similar applications, connecting my base app to the chosen database, building a series of questions that will be asked to the user and what information from the answers will get retrieved, and design a system to match the answers of the user with the information of the external database. Then, I will put everything together in a eye-catching front-end and test it, first myself in a technical way, and then with some relatives/friends to see if the application is accurate enough.

The research sample and sample size
Please indicate the sample size and your justification of this sample size. Describe the age range of participants, and whether they belong to medical groups (those currently receiving medical treatment, those not in remission from previous medical treatment, those recruited because of a previous medical condition, healthy controls recruited for a medical study) or clinical groups (those undergoing non-medical treatment such as counselling, psychoanalysis, in treatment centres, rehabilitation centres, or similar, or those with a DSM disorder diagnosis).

If the study involves a MEDICAL or CLINICAL group, the following details are required:

a) **Do you have approval from a hospital/medical/specialist ethics committee? If YES, please append the letter of approval. Also required is a letter from a clinically responsible authority at the host institution, supporting the study, detailing the support mechanisms in place for individuals who may become**

distressed as a result of participating in the study, and the potential risk to participants.
If NO, please detail why this approval cannot or has not been saught.

b) Does the study impact on participant's medical condition, wellbeing, or health?
If YES, please append a letter of approval from a specialist ethics committee.
If NO, please give a detailed explanation about why you do not expect there to be an impact on medical condition, wellbeing, or health.

The nature of any proposed pilot study. Pilot studies are usually required if a) a new intervention is being used, b) a new questionnaire, scale or item is being used, or c) established interventions or questionnaires, scales or items are being used on a new population. If no such study is planned, explain why it is not necessary.

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

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

Part C: Ethical Risk

Please identify any ethical issues or risks of harm or distress which may arise during the proposed research, and how you will address this risk. Here you need to consider the potential for physical risk, social risk (i.e. loss of social status, privacy, or reputation), outside of that expected in everyday life, and whether the participant is likely to feel distress as a result of taking part in the study. Debriefing sheets must be included in the appendix if required. These should detail the participant's right to withdraw from the study, the statutory limits upon confidentiality, and the obligations of the researcher in relation to Freedom of Information legislation. Debriefing sheets should also include details of helplines and avenues for receiving support in the event that participants become distressed as a result of their involvement in this study.

As the information provided is not going to be sensitive, I don't see risks in this matter.

Do the participants belong to any of the following vulnerable groups?
(Please tick all those involved).

- ☒ Children;
- ☐ The older old (85+)
- ☒ People with an intellectual or learning disability
- ☒ Individuals or groups receiving help through the voluntary sector
- ☐ Those in a subordinate position to the researchers such as employees
- ☐ Other groups who might not understand the research and consent process
- ☐ Other vulnerable groups

How will the research participants in this study 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.

The research participants will be people from my closest circles and, if needed, taken from voluntary Internet testers (Reddit/Twitter)

What inclusion or exclusion criteria will be used?

No exclusion will be made, everyone who might play a videogame ever in their lives will be welcome to join the research.

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

Text through Interenet.

Does the study involve deception or the withholding of information? If so, provide justification for this decision.

No.

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

I will retrieve all the user answers in a protected document. No legal documents will be signed, as it's trivial and never personal info.

Can study participants withdraw at any time without penalty? If so, how will this be communicated to participants?

Yes, they can. They will be informed at the beginning of the procedure.

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

Everything will be explained as many times as needed, and just go ahead once everything is understood and consented.

Please include copies of any information letters, debriefing sheets, and consent forms with the application.

Part D: Confidentiality and Data Protection

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

□ Identified ☒ Potentially Identifiable □ **De-Identified**

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

The information will be stored safely/encrypted.

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.

No illegal behaviours info will be colected.

Please indicate any recording devices being used to collect data (e.g. audio/video).

Nothing.

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?

Just myself (Marta Pacheco Merino)

Is there a possibility that the data 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 data will be stored for secondary analytic purposes.

No extra purposes for the data.

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 (e.g. submission for examination, reporting, publications, presentations)?

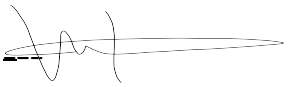
All users will have access to the final application.

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.

Nothing will be exposed.

Part E: Signed Declaration

I confirm that I have read the NCI Ethical Guidelines for Research with Human Participants, 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 09/10/2022

Signature of Supervisor (where appropriate):

Date _____

Any other information the committee should be aware of?
