National College of Ireland

**Ethical Guidelines and Procedures for Research involving Human Participants**

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September 2022

**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**

Jean Redfearn

**Student Number (if applicable)**

18201997

**Email**

x18201997@student.ncirl.ie

**Status:**

Undergraduate □

Postgraduate √

Staff □

**Supervisor (if applicable)**

Himanshu Rathee

**Title of Research Project**

**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**

19/09/22 12 weeks

**The rationale for the project**

**Develop a web application**

**The research aims and objectives**

**The research design**

**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:**

1. **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.**

1. **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.

**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.**

**What inclusion or exclusion criteria will be used?**

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

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

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

**Can study participants withdraw at any time without penalty? 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?**

*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?**

**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 data (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 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.

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)?**

**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 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 \_\_\_\_\_\_\_\_\_\_\_**

**Signature of Supervisor (where appropriate):**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Any other information the committee should be aware of?**