Dublin City University
School of Computing
ETHICS COMMITTEE (SEC)

NOTIFICATION FORM FOR LOW-RISK PROJECTS AT UNDERGRADUATE OR TAUGHT MASTERS LEVELS

Please read the following information carefully before completing your application. Failure to adhere to these guidelines will make your submission ineligible for review.

1. **Download this form, complete the appropriate fields, attach additional pages (e.g. plain language statement) as appropriate and save as a PDF file**
2. **Completed applications must be uploaded to your School of Computing GitLab repo, and must be located in "`docs/ethics.pdf`".**
3. **Your SUPERVISOR will then be notified automatically and must approve your approach initially.**
4. **Your application should consist of one electronic file (PDF) only.** The completed application must include this form and also must incorporate all supplementary documentation, especially that being given to the proposed participants e.g consent forms, plain English language statement. It must be proofread and spell-checked before submission**.**
5. **All sections of the application form must be answered as instructed and within the word limits given.**
6. **Your ethics approval submission will be circulated to the School's Research Ethics Committee and you will be notified if/when it is approved**
7. **All projects must have either a derogation from an ethics approval requirement (as determined by your supervisor) OR must have an approved ethics submission (this form), before work with human subjects commences.**

Applications which do not adhere to these requirements will not be accepted for review and will require resubmission

Applications must be completed on this form; answers in the form of attachments will not be accepted, except where indicated. No hard copy applications will be accepted. **The project must not commence work with human subjects until written approval has been received from the School of Computing Ethics Committee (SEC).**

PROJECT TITLE	Mini Mental State Exam Application
PROJECT SUPERVISOR(S)	Prof. Gareth Jones

START AND END DATE	

Please ensure that <u>all</u> supplementary information is included in your application (in one electronic copy). If questionnaire or interview questions are submitted in draft form, please indicate this by putting (draft) after YES. A copy of the final documentation must be submitted for final approval when available.

	My application has been collated as one electronic file which includes the following documentation:	INCLUDED (mark as YES)	NOT APPLICABLE (mark as N/A)
	Bibliography		NA
	Recruitment advertisement (How are you getting volunteers?)		NA
	Plain language statement/Information statement	**YES**	
	Informed consent form	**YES**	
	Personal Data Security Schedule https://www.dcu.ie/sites/default/files/info/3._blank_data_security_schedule.xls		
	Evidence of external approvals related to the research		NA
	Questionnaire/Survey		**NA**
	Interview/Focus Group Questions		**NA**
	Debriefing material		**NA**
	Other (e.g. local government approval)		NA

Please note:

1. Any amendments to the original approved proposal must receive prior SCEC approval.
2. As a condition of approval investigators are required to document and report immediately to SCEC any adverse events, any issues which might negatively impact on the conduct of the research and/or any complaint from a participant relating to their participation in the study

1. ADMINISTRATIVE DETAILS

Project Type (select one):	
Undergraduate Project – Final Year	X
Undergraduate Project – non-final Year	
Taught Masters (Practicum)	

(projects at other levels, e.g. PhD or research Masters, should be approved by the University's REC if necessary)

1.1 INVESTIGATOR CONTACT DETAILS

SUPERVISOR(S): *Your supervisor and other academic staff who are assisting, it should be clear who is the person who is carrying out the research procedures.*

NAME	*SCHOOL/UNIT*	*EMAIL*

Prof. Gareth Jones	School of Computing	Gareth.jones@dcu.ie

STUDENT(S):

NAME	*SCHOOL/UNIT*	*EMAIL*
Matthew Nolan	School of Computing	Matthew.nolan45@mail.dcu.ie
Michael O'Hara	School of Computing	Michael.ohara29@mail.dcu.ie

DECLARATION BY SUPERVISOR(S)

The information contained herein is, to the best of my knowledge and belief, accurate. I have read the University's current research ethics guidelines, and accept responsibility for the conduct of the procedures set out in the attached application in accordance with the form guidelines, the SCEC guidelines (https://www.dcu.ie/researchsupport/researchethics.shtml), the University's policy on Conflict of Interest, Code of Good Research Practice and any other condition laid down by the Dublin City University Research Ethics Committee. I have attempted to identify all risks related to the research that may arise in conducting this research and acknowledge my obligations and the rights of the participants.

If there exists any affiliation or financial interest for researcher(s) in this research or its outcomes or any other circumstances which might represent a perceived, potential or actual conflict of interest this should be declared in accordance with Dublin City University policy on Conflicts of Interest.

I and my co-investigators or supporting staff have the appropriate qualifications, experience and facilities to conduct the research set out in the attached application and to deal with any emergencies and contingencies related to the research that may arise.

Electronic Signature(s):

Supervisor(s): _____

*Print Name(s) here:*_____

Date: _____

2. PROJECT OUTLINE

2.1 SIMPLE DESCRIPTION *(Max. 300 words)*

Please outline, in terms that any non-expert would understand, what your research project is about, including what participants will be required to do. Please explain any technical terms or discipline-specific phrases.

Our project is based on the Mini Mental State Exam (MMSE). The MMSE is a 30-question exam to help diagnose and determine the level of severity of cognitive impairment. We aim to convert the exam to an application which can be used on a number of devices to improve the process of carrying out the exam. Converting the MMSE to an application will present the option for the patient to carry out the test without the aid of a nurse or doctor, depending on their range of motor functions. This will be determined by the administering medical professional.

2.2 AIMS OF AND JUSTIFICATION FOR THE RESEARCH *(Max. 400 words)*

State the aims and significance of the project. Where relevant, state the specific hypothesis to be tested. Please provide a brief description of background research, a justification as to why this research project should proceed in that context and an explanation of any expected benefits to the community. NB – all references cited should be listed in an attached bibliography.

We aim for our application to be used in medical practices to improve the current state of the MMSE. We want medical professionals to be able to embrace technology available to them. We believe that our application will make the process of conducting the exam to be much more efficient and less time consuming. The application will also be able to predict the level of cognitive impairment in the patients to help provide better treatment options for the patient.

2.3 DESCRIBE THE METHODOLOGY BEING USED TO ACHIEVE YOUR STATED AIMS

Provide an outline of the proposed method and state who is doing which task – include details of data collection techniques, the tasks participants will be asked to do, the estimated time commitment involved, and how data will be analysed. If the project includes any procedure which is beyond already established and accepted techniques please include a description of it. There should be enough detail provided to facilitate ethical review, but applicants are encouraged to keep it as succinct as possible.

We would have a questionnaire/feedback form for the medical professionals to fill in and give thoughts or criticisms on the application. We hope that from this feedback, we'd be able to pinpoint what aspects and features of our application we should focus on.

2.4 PARTICIPANT PROFILE

Provide the number, age range and source of participants. Please provide a justification of your proposed sample size. Please provide a justification for selecting a specific gender, age, or any other group if this is done in your project.

Our participant profile will include medical professionals that are willing to participate. Prior to this well user test the general functionality of our application with peers.

2.4(a) PARTICIPANT VULNERABILITY

Are some or all of participants vulnerable in any way? (e.g by virtue of the group they belong to, people who have undergone traumatic or adverse emotional events, people with diminished cognitive ability, power relations between researchers and participants etc.)? If they are, state what this vulnerability (or vulnerabilities) is and justify why this research is being done with such participants.

2.4(b) CHILD PARTICIPANTS (anyone under 18 years old)

*If your participants include children, you **must** confirm that you are in compliance with the research specific guidelines as detailed in "Keeping Children Safe - Policies and Procedures supporting Child Protection at DCU" - available at: **https://www4.dcu.ie/sites/default/files/policy/157%20-%20child_protection_handbook_rev1%282%29%281%29.pdf***

Please indicate your compliance with the following guidelines:	**Mark here**
We confirm that we have read and agree to act in accordance with the DCU Child Protection policy and procedures	
We confirm that we have put in place safeguards for the children participating in the research	
We confirm that we have supports in place for children who may disclose current or historical abuse (whether or not this is the focus of the research)	

2.5 EXPLAIN HOW PARTICIPANTS ARE TO BE RECRUITED

Please provide specific details as to how you will be recruiting participants. How will people be informed that you are doing this research? How will they be approached and asked if they are willing to participate? If you are mailing or phoning people, please explain how you have obtained their names and contact details. If a recruitment advertisement is to be used, please ensure you attach a copy to this application.

We would attempt to make contact with medical professionals that work with the MMSE and would be willing to test our application. We would also use peers to test the application in order to give us an outside opinion.

2.6 PLEASE EXPLAIN WHEN, HOW, WHERE, AND TO WHOM RESULTS WILL BE DISSEMINATED, INCLUDING WHETHER PARTICIPANTS WILL BE PROVIDED WITH ANY INFORMATION AS TO THE FINDINGS OR OUTCOMES OF THE PROJECT?

The results will be anonymized before publishing and they will be available to the grading team of the project and upon request of the participants, the results will be provided to the mediacl

2.7 ARE OTHER APPROVALS REQUIRED TO GAIN ACCESS TO ANOTHER LOCATION, ORGANISATION ETC.? (e.g. a School or company)

YES or NO
No

(If YES, please specify from whom and attach a copy of the approval documentation. If this is not yet available, please explain when this will be obtained.)

3. RISK AND RISK MANAGEMENT

3.1 JUSTIFICATION OF STATED LEVEL OF RISK TO RESEARCH PARTICIPANTS

You must provide a justification for the stated level of risk, as indicated on the cover page of your application. Note that the level of risk may be influenced by the vulnerability of the research group, the methods employed and the nature of the research itself. For further information on risk levels, please refer to the Levels of Review information on the website: https://www.dcu.ie/researchsupport/researchethics.shtml

3.2 DOES THE RESEARCH INVOLVE:

	YES or NO
• use of a questionnaire? (attach copy)?	YES
• interviews (attach interview questions)?	NO
• observation of participants without their knowledge?	NO
• participant observation (provide details in section 2)?	NO
• audio- or video-taping interviewees or events?	NO
• access to personal and/or confidential data (including student, patient or client data) without the participant's specific consent?	NO
• administration of any stimuli, tasks, investigations or procedures which may be experienced by participants as physically or mentally painful, stressful or unpleasant during or after the research process?	NO
• performance of any acts which might diminish the self-esteem of participants or cause them to experience embarrassment, regret or depression?	NO
• investigation of participants involved in illegal activities?	NO
• procedures that involve deception of participants?	NO
• administration of any substance or agent?	NO
• use of non-treatment of placebo control conditions?	NO
• collection of body tissues or fluid samples?	NO
• collection and/or testing of DNA samples?	NO
• participation in a clinical trial?	NO
• administration of ionising radiation to participants?	NO

3.3 POTENTIAL RISKS TO PARTICIPANTS AND RISK MANAGEMENT PROCEDURES

Identify, as far as possible, all potential risks to participants (physical, psychological, social, legal, economic, etc.), associated with the proposed research. Please explain what risk management procedures will be put in place to minimise these risks.

There are no risks to the participant

3.4 ARE THERE LIKELY TO BE ANY BENEFITS (DIRECT OR INDIRECT) TO PARTICIPANTS FROM THIS RESEARCH?

YES or NO
… YES

(If YES, provide details.)

If the application is successful it may be able to provide faster and more accurate diagnosis and treatment

3.5 ARE THERE ANY SPECIFIC RISKS TO RESEARCHERS?

Examples include use of dangerous materials, asking certain types of questions, research being undertaken in certain locations, researchers working alone in isolated areas, etc.

YES or NO
… NO

(If YES, please describe and explain what risk management procedures will be put in place to minimise these risks.)

3.6 DEALING WITH ADVERSE/UNEXPECTED OUTCOMES

Please describe what measures/protocols you have put in place in the event that there are any unexpected outcomes or adverse effects to participants arising from involvement in the project.

If an adverse outcome occurs, one of the team members will be able to troubleshoot and solve any error that may occur.

3.7 HOW WILL THE CONDUCT OF THE PROJECT BE MONITORED?

Please explain how the supervisor will monitor the conduct of the project (especially where several people are involved in recruiting or interviewing, administering procedures, etc.) to ensure that it conforms with the procedures set out in this application

The supervisors of our projects will be updated on the progress and recruitment of the testers through meetings and emails.

3.8 SUPPORT FOR PARTICIPANTS

Depending on risks to participants you may need to consider having additional support for participants during/after the study. Consider whether your project would require additional support, e.g., external counselling available to participants. Please advise what support will be available.

We can support for our application.

3.9 DO YOU PROPOSE TO OFFER PAYMENTS OR INCENTIVES TO PARTICIPANTS?

YES or NO
… NO

(If YES, please provide further details.)

3.10 DO ANY OF THE RESEARCHERS ON THIS PROJECT HAVE A PERSONAL, PHILOSOPHICAL, FINANCIAL OR COMMERCIAL INTEREST IN ITS OUTCOME THAT MIGHT INFLUENCE THE INTEGRITY OF THE RESEARCH, OR BIAS THE CONDUCT OR REPORTING OF THE RESEARCH, OR UNDULY DELAY OR OTHERWISE AFFECT THEIR PUBLICATION?

YES or NO
… NO

(If YES, please specify how this conflict of interest will be addressed.)

4. CONFIDENTIALITY/ANONYMITY

4.1 WILL THE IDENTITY OF THE PARTICIPANTS BE PROTECTED?

YES or NO
… YES

(If NO, please explain why.)

IF YOU ANSWERED YES TO 4.1, PLEASE ANSWER THE FOLLOWING QUESTIONS:

4.2 HOW WILL THE ANONYMITY OF THE PARTICIPANTS BE RESPECTED?

Please bear in mind that where the sample size is very small, it may be impossible to guarantee anonymity/confidentiality of participant identity. Participants involved in such projects need to be advised of this limitation in the Plain Language Statement/Information Sheet. If you intend to fully anonymize the data, please provide details

Names will be withheld and anonymized when publishing any findings

4.3 LEGAL LIMITATIONS TO DATA CONFIDENTIALITY

Participants need to be made aware that confidentiality of information provided cannot always be guaranteed by researchers and can only be protected within the limitations of the law - i.e., it is possible for data to be subject to subpoena, freedom of information claim or mandated reporting by some professions. This information should be included in your Plain Language Statement and Informed Consent Form. Depending on the research proposal and academic discipline, you may need to state additional specific limitations.

State how and where participants will be informed of these limitations

This will be stated in the Plain Language Statement and Informed consent form.

5. PERSONAL DATA - COMPLIANCE WITH THE GENERAL DATA PROTECTION REGULATION

Personal data is data relating to a living individual (i.e. the 'Data Subject') who is, or can be, identified either from the data itself or from the data in conjunction with other information that is in, or is likely to come into, the possession of the 'Data Controller' (i.e. DCU and its constituent units e.g. research teams etc.). ***Further information on personal data is available from the DCU Data Protection Unit at https://www.dcu.ie/ocoo/dp/guides.shtml***

5.1 IS PERSONAL DATA BEING PROCESSED AS PART OF THIS PROJECT?

YES or NO
… **YES**

If YES, Please indicate your compliance with the following guidelines:	**Mark here**
We confirm that we have read and agree to act in accordance with DCU Data Protection Unit guidance and procedures regarding personal data	**X**
We confirm that we have put in place a Personal Data Security Schedule (PDSS) for the project and have attached it to this application	**X**

Please see the GDPR and the Research Ethics Process section of the SCEC main webpage for guidance

IF YOU ANSWERED YES TO 5.1, PLEASE ANSWER THE FOLLOWING QUESTIONS:

5.2 WHAT KIND OF PERSONAL DATA IS BEING PROCESSED?

Note special categories of personal data include health data, genetic data and/or data relating to ethnicity/race of participants, their sex lives and/or sexual orientation

Minimal Patient information, such as name and age. Results of MMSE for patients.

5.3 WILL ANONYMISATION/PSEUDONYMISATION OF THE PERSONAL DATA BE UNDERTAKEN?

YES or NO
… YES

(If NO, please explain why.)

6. DATA/SAMPLE STORAGE, SECURITY AND DISPOSAL

For the purpose of this section, "Data" includes that in a raw or processed state (e.g. interview audiotape, transcript or analysis). "Samples" include body fluids or tissue samples.

6.1 HOW AND WHERE WILL THE DATA/SAMPLES BE STORED?

Note that the SCEC recommends that all data be stored on campus – please justify any off-site storage.

Any physical documents will be stored on campus and any electronic files will be stored on an external drive also stored on campus

6.2 WHO WILL HAVE ACCESS TO DATA/SAMPLES?

If people other than the main researchers have access, please name who they are and explain for what purpose.

Our project supervisor, project team members

6.3 HOW LONG IS THE DATA TO BE HELD/RETAINED FOR?

*Note that with very few exceptions **personal data** may not be retained indefinitely. It is up to the unit or research team to establish an upper retention limit for each category of personal data under its control.*

Until the duration of the project has elapsed

6.4 IF DATA/SAMPLES ARE TO BE DISPOSED OF, PLEASE EXPLAIN HOW, WHEN AND BY WHOM THIS WILL BE DONE?

*Note that simply deleting files is not sufficiently secure. The additional steps to be taken to maintain data security should be given. **Personal data** must be disposed of in a safe and secure manner at the end of its retention period. If the data is stored in a: a) paper based format then shredding or disposal via a secure bin is recommended; or b) if it is stored in an electronic based format then deletion of the record or full anonymization of the data is recommended.If data/samples are NOT being disposed of, please justify this decision.*

Any physical documents containing info will be shredded. Any electronic files will be deleted and purged from the systems.

8. PLAIN LANGUAGE STATEMENT *(Attach to this document. Approx. 400 words)*

A Plain Language Statement (PLS) should be used in all cases. This is written information in plain language that you will be providing to participants, outlining the nature of their involvement in the project and inviting their participation. The PLS should specifically describe what will be expected of participants, the risks and inconveniences for them, and other information relevant to their involvement. Please note that the language used must reflect the participant age group and corresponding comprehension level – if your participants have different comprehension levels (e.g. both adults and children) then separate forms should be prepared for each group. The PLS can be embedded in an email to which an online survey is attached, or handed/sent to individuals

in advance of their consent being sought. See link to sample templates on the website: ***https://www.dcu.ie/researchsupport/ethicsapproval.shtml***

PLEASE CONFIRM WHETHER THE FOLLOWING ISSUES HAVE BEEN ADDRESSED IN YOUR PLAIN LANGUAGE STATEMENT/ INFORMATION SHEET FOR PARTICIPANTS:

	YES or NO
Introductory Statement (Supervisor and student names, school, title of the research)	**Y**
What is this research about?	**Y**
Why is this research being conducted?	**Y**
What will happen if the person decides to participate in the research study?	**Y**
How will their privacy be protected?	**Y**
How will the data be used and subsequently disposed of?	**Y**
What are the legal limitations to data confidentiality?	**Y**
What are the benefits of taking part in the research study (if any)?	**Y**
What are the risks of taking part in the research study?	**N**
Confirmation that participants can change their mind at any stage and withdraw from the study	**Y**
How will participants find out what happens with the project?	**Y**
Contact details for further information (including SCEC contact details)	**Y**
Details relating to GDPR Compliance if Personal Data is being sought	**Y**

If any of these issues are marked NO, please justify their exclusion:

There is no risk to the participants in the study.

8. INFORMED CONSENT FORM *(Attach to this document. Approx. 300 words)*

In most cases where interviews or focus groups are taking place, an Informed Consent Form is required. This is an important document requiring participants to indicate their consent to participate in the study, and give their signature. If your participants are minors (under 18), it is best practice to provide them with an assent form, while their parents/guardians will be given the Informed Consent Form. In cases where an anonymous questionnaire is being used, it is enough to include a tick box in the questionnaire (underneath the information section for participant), where participants can indicate their consent.
See link to sample templates on the website: ***https://www.dcu.ie/researchsupport/ethicsapproval.shtml***

NB – IF AN INFORMED CONSENT FORM IS NOT BEING USED, THE REASON FOR THIS MUST BE JUSTIFIED HERE.

Plain Language Statement:

Introduction to the research:

The project that we are doing relates to the Mini Mental State Exam and the diagnosis/treatment of cognitive impairment. As it stands right now the test is done via pen and paper and we aim to update this to be done on an electronic device such as an iPad. We aim to create an application that will allow the medical profession or the patient (depending on severity of cognitive impairment) will be able to carry out the exam. Once the exam is carried out the medical professional can have the results processed by the application. This would make diagnosis and the treatment easier and faster allowing medical professionals to treat more patients effectively in less time.

Details of Involvement:

We want you to be among a small group of testers to help us refine our application. We want you to use our application to answer the questions on the Mini Mental State Exam and provide feedback. We may ask you to do the quiz a few times in order to build a profile for our prediction algorithm also and try to fine tune the algorithm to be as accurate as possible. We want you to find errors or point out areas which you feel could be improved upon. The way you provide this feedback will be a questionnaire which will contain questions about key areas then also have a section for you to write a short paragraph with any other feelings which you feel were not addressed by the questionnaire.

Personal Data – GDPR Compliance:

Any and all information provided by you or calculated by the application will be protected in accordance with GDPR and will be anonymized and destroyed after the duration of the project has elapsed. Any findings published from this will also be anonymized and aggregated and no personal info will be shared.

Advice as to arrangements to be made to protect confidentiality of data, including that confidentiality of information provided is subject to legal limitations:

We will take every precaution to ensure the data provided and feedback will remain confidential but if subject subpoena, freedom of information claim or mandated reporting by some professions we cannot guarantee confidentiality

Statement that involvement is voluntary:

Participants may withdraw from the program at any point and upon doing so their data will be removed from the application and no longer used in testing.

Any other relevant information:

Participants are asked to try to remain objective and free from bias when giving feedback if they have any previous relationship with the testers in order to gather accurate feedback.

If participants have concerns about this study and wish to contact an independent person, please contact:

The Secretary, Dublin City University Research Ethics Committee, c/o Research and Innovation Support, Dublin City University, Dublin 9. Tel 01-7008000, e-mail rec@dcu.ie

Informed Consent Form:

Research Study Title

The project that we are doing relates to the Mini Mental State Exam and the diagnosis/treatment of cognitive impairment. This will be done by converting the MMSE into an application to be used on an electronic device such as an iPad. All members are involved with School of Computing with the principle investigator being Prof. Gareth Jones (gareth.jones@dcu.ie)

Clarification of the purpose of the research:

The data needed will be the patients answers to the MMSE and their feedback on the application itself.

Confirmation of particular requirements as highlighted in the Plain Language Statement

Requirements include the completion of a feedback questionnaire in order to gauge the effectiveness and usefulness of the application and the info provided by it in relation to the level of cognitive impairment.

Participant – please complete the following (Circle Yes or No for each question)

I have read the Plain Language Statement (or had it read to me)	Yes/No
I understand the information provided	Yes/No
I have had an opportunity to ask questions and discuss this study	Yes/No
I have received satisfactory answers to all my questions	Yes/No
I am aware that my interview will be audiotaped	Yes/No

Confirmation that involvement in the Research Study is voluntary:

Participants may withdraw from the study at any point and not need to fill in any more feedback forms and any feedback given can be discounted from findings upon request.

Confirmation of arrangements to be made to protect confidentiality of data, including that confidentiality of information provided is subject to legal limitations:

The data provided to the research team will be protected to the best ability of the members of the team but the participant must be aware that the data provided is subject to legal limitations such as being subpoenaed by a court of law.

Confirmation of arrangements regarding retention/disposal of data:

I consent to my data then being deleted upon the completion of the duration of the research and grading progress.

Confirmations relating to any other relevant information as indicated in the PLS:

The data provided will not be used in further studies.

Signature:

I have read and understood the information in this form. My questions and concerns have been answered by the researchers, and I have a copy of this consent form. Therefore, I consent to take part in this research project

Participants Signature:_____

Name in Block Capitals:_____

Witness:_____

Date:_____