Human Subjects Exemption from Full Ethical Review Form Including Access to UCD Students & University-Wide Surveys

An Exemption from Full Ethical Review is not an exemption from ethical best practice and all researchers are obliged to ensure that their research is conducted according to HREC Guidelines. Depending on the nature of the study described below your study may require a preliminary review by the HREC Chairs and may be subject to further clarification.

Please do not alter the format of this form and submit it as a word document.

Section A: General Information

I apply for Exemption from Full Ethical Review of the research protocol summarised below, on the basis that *(select Yes or No)**:***	
a) All aspects of the protocol have received ethical approval from an approved body (e.g. Hospitals, hospices, prisons, health authorities)	**No**
b) The research protocol meets one or more of the criteria for exemption from review as detailed in Section 3 of *Further Exploration of the Process of Seeking Ethical Approval for Research (HREC Doc 7)*	**Yes**
I am also requesting permission to access UCD Students for one of the following *(select Yes or No)**:***	
c) I am accessing students from one school only and will seek permission from the Head of that school	**No**
d) I am seeking permission to access UCD Students from more than one school *(accessing students in more than one school will require HREC approval)*	**Yes**
e) I am seeking permission to conduct a university-wide survey of UCD students *(if the research is a campus-wide student survey[1] and involves students from two or more schools, then permission to schedule the survey will be sought from the University Student Survey Board (USSB) on your behalf after this form has been reviewed by a HREC Chair and/or HREC Committee).*	**No**
I have also read the following Guidelines *(select Yes or No)**:***	
(i) HREC Guidelines and Policies specifically Relating to Research Involving Human Subjects http://www.ucd.ie/researchethics/policies_guidelines/	**Yes**
(ii) The UCD Data Protection Policy http://www.ucd.ie/dataprotection/policy.htm	**Yes**
(iii) The Data Protection Guidelines on Research in the health sector, (if applicable) https://www.dataprotection.ie/documents/guidance/Health_research.pdf	**N/A**
For all the latest versions of the HREC Policies and Guidelines please see the research ethics website: http://www.ucd.ie/researchethics/policies_guidelines/	

1. ***PROJECT DETAILS***

[1] Where the target population comprises students drawn from two or more schools and the survey encompasses university-wide activities or services

[2] The **Clinical Indemnity Scheme** (CIS) is the main scheme under which the State Claims Agency (SCA) manages all clinical negligence claims taken against healthcare enterprises, hospitals and clinical, nursing and allied healthcare practitioners covered by the scheme. Under the CIS, the State assumes full responsibility for the indemnification and

a)	**Project Title:**	**Convolutional Neural Networks for iOS Gesture Recognition**		
b)	**Study Start Date:** (dd/mm/yy)	**18/10/16**	**Study Completion Date:** (dd/mm/yy)	**19/05/17**
c)	**Start Date of Data Collection:** (dd/mm/yy)	**21/11/16**	**Completion Date of Data Collection:** (dd/mm/yy)	**21/04/17**

NOTE: In no case will approval be given if recruitment and/or data collection has already begun

2. ***APPLICANT DETAILS***

a)	**Name of Applicant** *(please include title if applicable):*	**Philip Corr**		**UCD Student Number:** *(if applicable)* **12318581**
b)	**Applicant's position in UCD** *(please put 'yes' in relevant space):*	**Staff**	**Postgraduate**	**Undergraduate**
		No	**Yes**	**No**
c)	**Academic/Professional Qualifications**	**BScE**		
d)	**Applicant's UCD Contact Details**	**UCD Telephone** *(if applicable)*	**UCD Email** ***(bearing reference to applicant's name)***	
			philip.corr@ucdconnect.ie	
e)	**Applicant's UCD Address** *(UCD school address* ***NOT home address.****)*	**UCD School of Electrical and Electronic Engineering** **UCD Engineering and Materials Science Centre** **Belfield, Dublin 4, Ireland.**		
f)	**Name of Supervisor** *(please include title if applicable):*	**Dr. Guenole Silvestre**		
g)	**Supervisor's UCD Contact Details**	**UCD Telephone**	**UCD Email:**	
		+353 1 7162852	**guenole.silvestre@ucd.ie**	
h)	**UCD Investigator(s) and affiliations**	*(name all investigators & co-investigators on project)*		
i)	**Funding** *if applicable*	**Source**	**Amount**	
			€	

j. EXTERNAL APPLICANTS ONLY *(if study is not associated with any UCD staff member or school)*			
a) External Investigator(s) *if applicable*	**No**	**If YES, please provide name(s)**	
b) Name of Organization			**Relationship with External Organization**
c) Address of Organization			
d) External Investigator(s) *if applicable*			
e) Project Title:			
f) Start Date of Data Collection:	(dd/mm/yy)	**Completion Date of Data Collection:**	(dd/mm/yy)

k. INSURANCE *Please note that UCD's existing insurance policy providing cover in relation to research work and placements, being undertaken by UCD staff and students, is currently limited to* ***Public Liability*** *only. Provisions of other types of insurance cover, as listed in the table below, are the sole responsibility of the researcher.* *Please select* ***Yes*** *or* ***No*** *and provide details, where required. Please do not assume that you do not require insurance.* *NOTE:* ***This section is mandatory*** *– your application will not be processed unless this section is completed.*	
i. **Does this study require medical malpractice or clinical indemnity insurance?**	**No**

Is relevant insurance cover already in place? (Yes/No) Insurance Holder's Name:	
ii. **Is this study covered by Clinical Indemnity Scheme (CIS)[2]?**	**No**
Healthcare Provider's Name:	
iii. **Is there any blood sampling involved in this study?**	**No**
Who will be taking samples? Insurance details:	
iv. **Are there other medical procedures involved in this study?**	**No**
Details of Procedures:	
v. **Does this study involve travelling outside of Ireland?** *If **Yes**, please name the country/countries where the researcher will travel in the field below*	**No**
Name country/countries outside of Ireland:	
The Office of Research Ethics will liaise with the Insurers and will advise you of any specific requirements, if necessary.	

Section B: Research Design & Methodology

3. ***RESEARCH PROPOSAL***

a) Methods of data collection		*(please select the appropriate box and provide brief details)*
i	standard educational practices **No**	

[2] The **Clinical Indemnity Scheme** (CIS) is the main scheme under which the State Claims Agency (SCA) manages all clinical negligence claims taken against healthcare enterprises, hospitals and clinical, nursing and allied healthcare practitioners covered by the scheme. Under the CIS, the State assumes full responsibility for the indemnification and management of all clinical negligence claims.

ii	standard educational tests **No**	
iii	standard personality tests **No**	
iv	standard psychological tests **No**	
v	interviews or focus groups **No**	
vi	public observations **No**	
vii	persons in public office **No**	
viii	using existing data only **No**	
ix	surveys/questionnaires **No**	
x	audio/video recordings **No**	
xi	Other*(please specify)* **Yes**	**I will be recording gestures entered into an iPhone by a user tracing the numbers 0 to 9 on the screen. The participants will be anonymous and will give their consent before participating in the research.**
b) Who are the participants or informants? *(including size and composition)*		**My research is open to the general public and I will record data from a maximum of 500 people.**
c) Where are you recruiting the participants from?		**Given that the only equipment needed is an iPhone, I will not be fixed to a time or place for recruiting. I will be recruiting friends and family and I will be asking them to help me in recruiting further participants.**

i	**Are participants external to UCD?**	**Yes**
ii	**Do you have permission to access these participants?** *(provide details of organization/group and attached a copy of the permission if applicable)*	**N/A**

*If you are recruiting UCD students please ensure that you complete **Section E** below.*

d) Aims and Objectives of the study *(in brief lay language – no more than 300 words)*

The aim of this study is to train a neural network to recognize a user from the way they trace a number on an iPhone screen. In order to achieve this I will record participants entering the numbers 0 to 9 on an iPhone. I will also be recording the participants age to the nearest year, their sex, their native language and whether they are right or left handed. These details are required to ensure that my data set is not biased towards a subsection of the population. The participants will not be identifiable through the recorded data and hence, the participants will be anonymous. I will use this data set to train a neural network. This neural network will learn how the general population enters numbers into an iPhone through this training. From this, the neural network will be able to identify which number a user enters into an iPhone even though the way the user enters the number will be slightly different every time. An example of where these algorithms have application is in mobile phone security. It is essentially impossible to copy the way a user traces a number on their screen as there are tiny subconscious details that change every time. The algorithms can recognize these details and identify that it is indeed the owner of the phone, but a person trying to illegally gain access to a phone can not recognize these details, and hence, they can't copy them.

e) Research Design *(in brief lay language – no more than 300 words)*

I will need a minimum of 10,000 data samples using the index finger and 10,000 using the thumb in order to train the neural network successfully. These 20,000 samples will be comprised of 1,000 samples of each of the

numbers 0 to 9 for both the index finger and thumb. I will get each participant to enter the number 0 to 9 eight times. This means I will have 80 gestures per person. This will allow me to reach 20,000 samples with 250 participants. This is however a minimum and ideally I would get more than 20,000 samples. I will set a maximum number of participants at 500 people and if I manage to get this many participants I will then have 40,000 samples comprised of 2,000 samples of each of the numbers 0 to 9. This is the maximum amount of data that I will collect.

I will split the data into a training set and a test set. The training set will be used to train the neural network and 70% of the data will be allocated to this set. The remaining 30% will be allocated to the test set and this will be used to test the neural network after it is trained.

Section C: Basis for Exemption

4. ***RESEARCH PARTICIPANTS: RISK, HARM, SELECTION AND CONSENT***

a)	**Is this research likely to involve any foreseeable risk to participants, above the level experienced in everyday life?** *(select Yes or No)*	**No**
Does this research involve the following: *you are advised to read the HREC Guidelines documents – see HREC Policies & Guidelines (select Yes or No): http://www.ucd.ie/researchethics/information_for_researchers/policies_guidelines/]*		
i	Any vulnerable groups? *(this includes UCD Students)*	**No**
ii	Sensitive topics that may take participants feel uncomfortable? *(i.e. sexual behavior, illegal activities, racial biases, etc.,)*	**No**
iii	Use of drugs?	**No**
iv	Invasive procedures? *(e.g. blood sampling)*	**No**
v	Physical stress/distress, discomfort?	**No**
vi	Psychological/mental stress/distress?	**No**
vii	Deception of/or withholding information from subjects?	**No**
viii	Access to data by individuals or organizations other than the investigators?	**No**
ix	Conflict of interest issues?	**No**
x	Any other ethical dilemma? *(if the answer is **YES** please provide details below)*	**No**

5. ***ETHICAL APPROVAL FROM ANOTHER BODY***

a) Has this study received Ethical Approval elsewhere? *(e.g. hospital REC or other external body or for data collected by another organization for a specific purpose – select Yes or No)*		**No**
*If your answer is **No** please proceed to Section 6*		
b) Ethical Approval from body other than UCD for this study or parts of this *study (select Yes or No)*		**Yes / No**
i	Name of Organization that has approved the study?	
ii	Approval Number/Ref	
iii	Approval Date	
Please provide a copy of the approval with this form as a supporting document		
c) Provide a brief account of aspects of the study not covered by external approval		
d) Can you confirm that you will seek full ethical approval from UCD HREC for all non-approved aspects of the study? *(select Yes or No)*		**Yes / No**
Please note that a grant of exemption from full ethical review will only be granted by UCD HREC for those aspects of the study that have been approved and are under the jurisdiction of the approving body		
Approval from an approved body *(select Yes or No)*		
i	Have <u>all</u> aspects of the study received ethical approval from an approved body?	**Yes / No**
ii	Does the approving body have jurisdiction over aspects of the study?	**Yes / No**

<u>6. USE OF EXISTING DATA</u>

a) **If you are using existing data, please explain why this study is exempt from a full ethical review?** *(e.g. data collected by another organization for a specific purpose)*

I will also be using the MNIST dataset. It is a modified version of the NIST character dataset. The NIST, National Institute of Standards and Technology, dataset consists of hand-written characters written by american high school students and Census Bureau employees. The only modifications made in converting from the NIST dataset to the MNIST dataset are modifications that make the hand-written digits more convienient for machine learning. E.g. the data set is normalised to be 28 x 28 pixels in size.

The MNIST dataset is an open source data set which is intended for use with Neural Network research. I will use it as a bench mark for my own data set. In order to verify my dataset's accuracy I will convert the greyscale images that the MNIST dataset is comprised of, to iOS gestures. The iOS gestures are simply a collection of x, y co-ordinates and so, the data represented by the MNIST dataset will not be changed. Therefore, there is no need for a full ethical review as I will only be using this dataset as it is intended to be used.

More information on the dataset can be found at:

http://yann.lecun.com/exdb/mnist/

Section D: Confidentiality and Data Protection

7. DATA COLLECTION DETAILS

a)	**What arrangements are in place to ensure that the identity of each participant remains confidential?**		
I will not be recording names of participants and there is no audio or visual aspect to my research. I will be recording the participants age to the nearest year, their sex, their native language and whether they are right or left handed. This is not enough information to identify the participants and so, there is no way of personally identifying the participants from the data I record.			
b)	**Please indicate the form in which the data will be collected** (*select Yes or No and provide short details, if applicable)* *For explanation of the terms below please refer to* ***Personal Data Definitions & Examples*** *short guide*		
i	Anonymous	**Yes**	**The participant will not be identifiable from the data I record.**
ii	De-identified (or anonymised)	**No**	
iii	Identifiable	**No**	
iv	Potentially identifiable	**No**	
c)	**Indicate the form in which the data will be stored and/or accessed** (*select Yes or No and provide short details, if applicable)*		
i	Anonymous	**Yes**	**The data will be stored in a database and will be open source so that it can facilitate further research in the future. This does not change the fact that the participants will be anonymous.**
ii	de-identified (or anonymised)	**No**	
iii	Identifiable	**No**	

iv	Potentially identifiable **No**	
d)	**Describe the measures that will be taken to protect the confidentiality of the data to be collected**	
i	Who will have control of the data generated by the research?	**Philip Corr, Guenole Silvestre**
ii	Where will the data will be stored/ or archived, does this comply with the HREC guidelines?	**The data will be stored in an Sqlite database.**
iii	In what format will the data be stored?	**The format will be sqlite. This is a database format whereby the data is stored in tables. A row in the table will correspond to a number entered by the user.**
iv	For how long will the data be stored?	**The data will be stored indefinitely.**
e)	**Responsibility for data collected in the study** *(select Yes or No)*	
i	Will the data generated by the research be destroyed?	**No**
ii	Will the data be destroyed at or before the end of the study?	**No**
iii	Who will be responsible for destroying the data at the end of the period indicated in 7 d) iv?	
iv	Will the data be archived?	**Yes**
v	Will the archived data be intended for personal use only?	**No**
vi	Will the archived data be made available to other researchers?	**Yes**
If yes, please provide details of where the archive will be held and what restrictions for use will be put in place		**The archive will be publicly available online.**
vii	Who will be responsible of the archive and future use of data? *(please provide a name)*	**Philip Corr and Guenole Silvestre**
viii	Do you intend publishing all or part of your data?	**Yes**
If yes, *please note that some journal editors require assurances (in addition to ethical approval) that data were collected ethically and that all consents, assents and other permissions were granted prior to the start of data collection.*		

If this study does not involve UCD students or university-wide surveys please proceed to Section F

Section E: Access to UCD Students

Where researchers are hoping to access UCD students in more than one school, Part 1 must be completed. If your research is a university-wide student survey, Parts 1 and 2 must be completed. For information on the process of securing access please see the policy document: *Research Access to UCD Students: A policy for UCD Staff/Students and external organizations.*

Part 1: Request for Permission to Access Students

1.	**Accessing Students?**	**Yes**
a)	**Are you accessing students from more than one school?**	**Yes**
b)	**Do you wish to conduct a university-wide student survey?**	**No**
If your answer to 1(b) is yes, please also complete Part 2 below.		

2. **Type of Study** *(interviews, focus groups, electronic or paper based questionnaires, etc)*			
Electronically recording participants entering the numbers 0 to 9 on an iPhone.			
Proposed Start Date:	**21/11/16**	**Proposed End Date:**	**21/04/17**
If the study will be repeated, please indicate the frequency: *(annual, twice-yearly, etc):*	**N/A**	**Target students** (which schools/colleges)	**University wide**
Any other Comments:			

Part 2: University-Wide Student Surveys ONLY

Please note that if you are seeking permission to conduct a university-wide survey you will need to complete this section. The Office of Research Ethics will process this permission on your behalf after your form has been reviewed and access to UCD students has been granted.

1. Title of Proposed Student Survey
2. **Survey Sponsor / Applicant** *(please include title if applicable):*

3. **Details of the Proposed Survey**	
Has this survey been conducted in UCD before?	**Yes / No**
If yes, why is an additional survey required?	

Section F: Signed Declaration

8. SIGNATURES ARE REQUIRED ONLY POST-REVIEW AND FOLLOWING SATISFACTORY RESPONSES TO ANY CLARIFICATIONS. Exemption Forms should be signed by the applicant and supervisor/head of school and the signed forms should be retained by the school.

I, the undersigned researcher, have read the *UCD Guidelines and Policy for Ethical Approval of Research Involving Human Subjects* and *Further Exploration of the Process of Seeking Ethical Approval for Research* and agree to abide by them in conducting this research. I confirm that, based on my understanding of these guidelines and policy documents, I consider that this research protocol meets the requirements for exemption from a full ethical review. I confirm that the information provided on this form is correct and accurate.

We the undersigned researchers acknowledge or agree with the University:

(a) It is our sole responsibility and obligation to comply with all domestic Irish and European legislation and to obtain such statutory consents as may be necessary;
(b) Not to commence any research until any such consents have been obtained;
(c) To furnish to the proper officer of UCD a true copy of any consent obtained;
(d) That neither the University, the Committee, nor individual members of the Committee accept any legal obligation (to us or to any third party) in relation to the processing of this application or to any advice offered in respect of it nor for the subsequent supervision of the research;
(e) That the research will be conducted in accordance with any approval for an exemption from full review granted by the Committee and in conformity with the documentation submitted with this application and with licence granted under any legislation;
(f) That the undersigned researcher(s) have read the most recent UCD Research Ethics Committee Guidelines and Policy for Ethical Approval of Research involving Humans – which are available on the UCD website (www.ucd.ie/researchethics) and agree to abide by them in conducting this research;
(g) Confirm that the information provided on this form is correct and accurate;
(h) In conducting research a researcher has both ethical duties and legal obligations. Compliance with one set of responsibilities does not guarantee compliance with the other - what is legally permissible may not be ethical and vice versa. It is for the researcher to inform himself and herself as to what ethical duties and legal obligations apply to his or her research and to comply with these duties and obligations;
(i) It is not acceptable for an applicant to treat the grant of ethical approval as absolving them from the responsibility of informing themselves of their legal responsibilities in relation to data protection and of complying with these;
(j) It must be understood that any ethical approval granted is premised on the assumption that the research will be carried out within the limits of the law;
(k) Ethical approval does not constitute any sort of advice or representation to the applicant that compliance with the requirements, as laid down by the UCD Human Research Ethics Committee, will be sufficient to comply with the applicable law in the area.

Signature of Applicant:	
Date:	

Endorsement of Supervisor *(if applicable***:** students who are being supervised are required to have their supervisor's knowledge and endorsement of the study. Supervisors confirm that they have read the above application, and are satisfied that the study appears to meet all requirements for a grant of ethical approval with Exemption from full review from UCD HREC.

Signature of Supervisor*(or designate):* **Date:**	

Approval of Head of School: Acknowledging exemption for this study and, if applicable, permission if the research concerns students from **one** UCD School or Unit, permission can be given by the relevant Head of School/Unit.

Signature of Head of School or Organization *(or designate):* **Date:**	