IMPORTANT: ALL FIELDS MUST BE COMPLETED. THE FORM SHOULD BE COMPLETED IN PLAIN ENGLISH UNDERSTANDABLE TO LAY COMMITTEE MEMBERS.

SEE NOTES IN STATUS BAR FOR ADVICE ON COMPLETING EACH FIELD. YOU SHOULD READ THE ETHICS APPLICATION GUIDELINES AND HAVE THEM AVAILABLE AS YOU COMPLETE THIS FORM.

APPLICATION FORM

SECTION A APPLICATION DETAILS

A1

Project Title: Braille E-reader

Date of Submission:	Proposed Start Date: as soon as approved
UCL Ethics Project ID Number:	Proposed End Date:

If this is an application for classroom research as distinct from independent study courses, please provide the following additional details:

Course Title: N/A Course Number: N/A

A2

Principal Researcher

Please note that a student – undergraduate, postgraduate or research postgraduate cannot be the Principal Researcher for Ethics purposes.

Full Name: Dr Maurice Paul David Burke	Position Held: Lecturer
Address: Department of Medical Physics & Biomedical Engineering University College London Malet Place Engineering Building London WC1E 6BT, UK	Email: maurice.burke@ucl.ac.uk Telephone: Fax:

Declaration To be Signed by the Principal Researcher

- I have met with and advised the student on the ethical aspects of this project design *(applicable only if the Principal Researcher is not also the Applicant).*
- I understand that it is a UCL requirement for both students & staff researchers to undergo Disclosure and Barring Service (DBS) Checks when working in controlled or regulated activity with children, young people or vulnerable adults. The required DBS Check Disclosure Number(s) is: N/A
- I have obtained approval from the UCL Data Protection Officer stating that the research project is compliant with the Data Protection Act 1998. My Data Protection Registration Number is:
- I am satisfied that the research complies with current professional, departmental and university guidelines including UCL's Risk Assessment Procedures and insurance arrangements.
- I undertake to complete and submit the 'Continuing Review Approval Form' on an annual basis to the UCL Research Ethics Committee.
- I will ensure that changes in approved research protocols are reported promptly and are not initiated without approval by the UCL Research Ethics Committee, except when necessary to eliminate apparent immediate hazards to the participant.
- I will ensure that all adverse or unforeseen problems arising from the research project are reported in a timely fashion to the UCL Research Ethics Committee.
- I will undertake to provide notification when the study is complete and if it fails to start or is abandoned.

SIGNATURE: **DATE:**

A3 **Applicant(s) Details** *(if Applicant is not the Principal Researcher e.g. student details):*

Full Name: Kezia Sinclair-Horne	
Position Held: Undergraduate Student	
Address:	Email: kezia.sinclair-horne.19@ucl.ac.uk Telephone: +447557954788 Fax:
Full Name: Nikos Zavaropoulos	
Position Held: Undergraduate Student	
Address:	Email: nikos.zavaropoulos.19@ucl.ac.uk Telephone: +44 7842 035555 Fax:
Full Name: David Huang	
Position Held: Undergraduate Student	
Address:	Email: david.huang.19@ucl.ac.uk Telephone: +44 7586 073793 Fax:
Full Name: Jonathan De Souza Holt Position Held: Undergraduate Student Address:	Email: jonathan.holt.19@ucl.ac.uk Telephone: +44 7470920076 Fax:

A4 **Sponsor/ Other Organisations Involved and Funding**

α) **Sponsor:** ☒ **UCL** ☐ **Other institution**
If your project is sponsored by an institution other than UCL please provide details:

β) **Other Organisations**: If your study involves another organisation, please provide details. *Evidence that the relevant authority has given permission should be attached or confirmation provided that this will be available upon request.*

χ) **Funding:** What are the sources of funding for this study and will the study result in financial payment or payment in kind to the department or College? *If study is funded solely by UCL this should be stated, the section should not be left blank.*

No funding or financial arrangements will be made.

A 5 **Signature of Head of Department or Chair of the Departmental Ethics Committee**
(This must not be the same signature as the Principal Researcher)

I have discussed this project with the principal researcher who is suitably qualified to carry out this research and I approve it. The project is registered with the UCL Data Protection Officer, a formal signed risk assessment form has been completed, and appropriate insurance arrangements are in place. *Links to details of UCL's policies on data protection, risk assessment, and insurance arrangements can be found at: http://ethics.grad.ucl.ac.uk/procedures.php*

UCL is required by law to ensure that researchers undergo a Disclosure and Barring Service (DBS) Check if their research project puts them in a position of trust with children under 18 or vulnerable adults.

HEAD OF DEPARTMENT TO DELETE BELOW AS APPLICABLE

I am satisfied that checks: **(1) have been satisfactorily completed**
(2) have been initiated
(3) are not required

If checks are **not** required please clarify why below.

Chair's Action Recommended: ☐ **Yes** ☐ **No**

A recommendation for Chair's action can be based only on the criteria of minimal risk as defined in the Terms of Reference of the UCL Research Ethics Committee.

PRINT NAME:

SIGNATURE: **DATE:**

SECTION B DETAILS OF THE PROJECT

B1 **Please provide a brief summary of the project in simple prose outlining the intended value of the project, giving necessary scientific background** *(max 500 words)*.

Scientific Background

There are 2 million people living in the United Kingdom with some form of vision loss, including 400,000 individuals with deafblindness. Many blind people use braille, a tactile coded language system, to read signs, books, letters and much more. Braille can be taught to individuals with sight loss at any age and this system does not rely on one's ability to hear. Current methods for blind people to 'read' documents include text-to-speech which relies on hearing, industrial printers, and other unaffordable methods. Our project aims to create an easy-to-use device, suitable for all ages and something that is affordable, which is where a lot of current available solutions fall short.

Project Summary

This project aims to prove the concept of a refreshable, affordable braille e-reader using magnetic actuation to displace pins that display a character. We also aim for the device to have a built-in camera that can scan text and digitise it to then be displayed on the device. An initial prototype will be given to visually impaired survey participants to gain feedback on its efficacy and usability.

Intended Value

We aim to give blind users the ability to read documents, books and any text on a device that is affordable and can give them daily independence. There are a few similar devices available on the market, but they are very expensive and therefore not affordable by the mass market. We want to assess the users' experiences quantifying usability beyond the error rate or other technical challenges. We want to know if the device is easy to use, responds fast enough to the user's needs and if it solves a real problem they have.

B2 **Briefly characterise in simple prose the research protocol, type of procedure and/or research methodology (e.g. observational, survey research, experimental). Give details of any samples or measurements to be taken** *(max 500 words).*

Research Protocol

We will recruit 1-5 braille using people, aged 18+, to use our prototype and give feedback on the device. They will sign a consent form to allow us to use their data and results. They will be informed that there is no financial reward for participating. We will send an email around UCL to ask for volunteers. They must be fluent in braille and can be from any background/gender/etc. We will send participants an information sheet and consent form before the trial. Participants can withdraw from trial at any time.

At the trial, the participant will be reminded of the terms and conditions and will be fully briefed on what is expected of them during the trial. This will be given to them in printed braille and for those with hearing abilities they will also be spoken to verbally. Any questions the participant has will be answered by a member of the research team.

Quantitative and qualitative data will both be collected from the participant by them completing the survey. All participant personal data will be anonymised, and their individual answers will help guide further development of the device

Research Methodology

Participants will use the braille e-reader prototype and asked a series of questions. All participants will be asked the same questions so that the data can be collated and compared. The questions asked are included in the questionnaire below. The e-reader prototype will display a series of letters in braille and the user will read them. The questions will assess the effectiveness of the advice, and make sure that the different pins can be distinguished between.

Attach any questionnaires, psychological tests, etc. (a standardised questionnaire does not need to be attached, but please provide the name and details of the questionnaire together with a published reference to its prior usage).

B3 **Where will the study take place (please provide name of institution/department)?**
If the study is to be carried out overseas, what steps have been taken to secure research and ethical permission in the study country?
Is the research compliant with Data Protection legislation in the country concerned or is it compliant with the UK Data Protection Act 1998?

UCL Medical Physics and Biomedical Engineering Department

B4 **Have collaborating departments whose resources will be needed been informed and agreed to participate?**
Attach any relevant correspondence.

B5 **How will the results be disseminated, including communication of results with research participants?**

We aim to publish the results in our research paper and the participant can receive a copy if they choose so on their consent form.

B6 **Please outline any ethical issues that might arise from the proposed study and how they are be addressed.** *Please note that all research projects have some ethical considerations so do not leave this section blank.*

All personal data will be anonymised and stored confidentially so there is no risk that the participant can be identified from any of the research content in the research paper. All data will be handled in accordance with the 2018 data protection act.

The consent forms are the only documents which will hold the participant's name; any other documents will use an anonymised number to ensure that the personal data cannot be associated with the volunteers.

SECTION C DETAILS OF PARTICIPANTS

C1 **Participants to be studied**

C1a. Number of volunteers:	1-5
Upper age limit:	No limit
Lower age limit:	18

C1b. Please justify the age range and sample size:

Participants must be able to make informed consent so they must be over the age of 18. People can become partially sighted or blind at any age so there is no upper limit. We have selected a small sample size as this is an initial study that is solely for the purpose of gaining feedback. Participants must not have a pacemaker or other medical device that is affected by magnets.

C2 **If you are using data or information held by a third party, please explain how you will obtain this. You should confirm that the information has been obtained in accordance with the UK Data Protection Act 1998.**

N/A

C3 **Will the research include children or vulnerable adults such as individuals with a learning disability or cognitive impairment or individuals in a dependent or unequal relationship?** ☐ **Yes** ☒ **No**

C4 **Will payment or any other incentive, such as gift service or free services, be made to any research participant?**

☐ **Yes** ☒ **No**

C5 **Recruitment**

(i) Describe how potential participants will be identified:

(ii) Describe how potential participants will be approached:

(iii) Describe how participants will be recruited:

Attach recruitment emails/adverts/webpages. A data protection disclaimer should be included in the text of such literature.

The individuals recruited will need to be able to read braille; these can be seeing people, blind individuals or partially sighted people, all who have learnt to read braille. We will ask people we know and send an email asking for participants around our department at UCL (department of medical physics and biomedical engineering).

C6 **Will the participants participate on a fully voluntary basis?** ☒ **Yes** ☐ **No**

Will UCL students be involved as participants in the research project? ☒ **Yes** ☐ **No**

If yes, care must be taken to ensure that they are recruited in such a way that they do not feel any obligation to a teacher or member of staff to participate.

Please state how you will bring to the attention of the participants their right to withdraw from the study without penalty?

The right to withdraw is clearly stated in the Information Sheet and Informed Consent Form which will be sent in advance when we respond to them via email. We will also inform them orally and/or in braille at the beginning of the trial.

C7 **CONSENT**

Please describe the process you will use when seeking and obtaining consent.

We will seek informed consent before participants are allowed to take part in the trial. We will provide the Information Sheet and Informed Consent Form in advance via email so they can read it and decide whether they want to participate. At the trial they will be given a oral briefing or a briefing in braille and we will ask them to sign the form. They will be given copies of the information and consent sheets in braille and any questions they have will be answered by a member of the research team. We will remind them that they are able to withdraw from the trial at any time without reason. Their forms will be kept securely and held in accordance with the Data Protection Act 1998 whereby they are treated as confidential documents.

A copy of the participant information sheet and consent form must be attached to this application. For your convenience proformas are provided in C10 below. These should be filled in and modified as necessary.

In cases where it is not proposed to obtain the participants informed consent, please explain why below.

N/A

C8 **Will any form of deception be used that raises ethical issues? If so, please explain.**

No

C9 **Will you provide a full debriefing at the end of the data collection phase?** ☒ **Yes** ☐ **No**

If 'No', please explain why below.

C10 **Information Sheets And Consent Forms**

VirtualEyes Participant Information Sheet

You will be trialling a new braille device that can refresh and display different characters. During the trial, several characters will be displayed, and you will be asked to identify the character and state which pins are up or down. After the trial you will be asked a series of feedback questions. The feedback can be given verbally or written down depending on your wishes/needs.

We will protect any personal data in accordance with the data protection act of 2018.

Participant Informed Consent

I _____

- Have read the participant information sheet and understand what the study involves
- Understand that I can withdraw from the trial at any time
- Consent to the use of my personal information for this research
- Understand that my data will be stored in accordance to the data protection act of 2018

Signed:

Date:

Optional:

I would like to be sent a copy of the findings of this trial to my email:
_____

VirtualEyes Participant Questionnaire

Section 1 - To be completed by member of VirtualEyes

Display character then answer following questions:
Can the participant state which character is being displayed correctly?
Can they say which pins (1-6) are up and which are down correctly?

Character	Character correct? (Y/N)	Pins correct? (Y/N)
1		
2		
3		
4		
5		

Section 2 - To be completed by participant (verbal answers accepted if needed)

Usefulness
On scale from 1 (least useful) to 10 (very useful) please assess using the statements below how useful you found the VirtualEyes product

Statement	Score (1-10)
It is useful	
It gives me more independence	
It meets my needs	
It saves me time	
It helps me be more productive	

Ease of use
On scale from 1 (difficult) to 10 (very easy) please assess using the statements below how easy you found the VirtualEyes product to use

Statement	Score (1-10)
It is simple to use	
It is user friendly	
I could use it without instructions	
I didn't notice any inconsistencies	
I can use it successfully	

Ease of Learning
On scale from 1 (difficult) to 10 (very easy) please assess using the statements below how easy it was to learn to use the VirtualEyes product

Statement	Score (1-10)
I learned how to use the product quickly	
I can remember how to use it	
I could teach someone else how to use it	

Satisfaction
On scale from 1 (unsatisfied) to 10 (very satisfied) please assess using the statements below how satisfied you are with the VirtualEyes product

Statement	Score (1-10)
I am satisfied with the product	
I would recommend it to a friend/ fellow braille user	
It works exactly how I'd want it to	
I feel I need it	
It is fun to use	

Section 3: To be completed by participant (verbal answers accepted if needed)

General Feedback:

Please leave any other comments you may have about our product and if you have any suggested improvements, please tell us.

SECTION D DETAILS OF RISKS AND BENEFITS TO THE RESEARCHER AND THE RESEARCHED

D1 **Have UCL's Risk Assessment Procedures been followed?** ☒ **Yes** ☐ **No**

If **No**, please explain.

D2 **Does UCL's insurer need to be notified about your project before insurance cover can be provided?** ☐ **Yes** ☒ **No**

The insurance for all UCL studies is provided by a commercial insurer. For the majority of studies the cover is automatic. However, for a minority of studies, in certain categories, the insurer requires prior notification of the project before cover can be provided.

If **Yes**, please provide confirmation that the appropriate insurance cover has been agreed. *Please attach your UCL insurance registration form and any related correspondence.*

D3 **Please state briefly any precautions being taken to protect the health and safety of researchers and others associated with the project (as distinct from the research participants).**

Room is tidy to prevent tripping. Participants will be guided over to the device. No liquids will be allowed near device to prevent electrical faults. We will ensure the participant does not have a pacemaker or another device affected by magnets. Participants are given a fire briefing before trial starts.

D4 **Will these participants participate in any activities that may be potentially stressful or harmful in connection with this research?** ☐ **Yes** ☒ **No**

If **Yes**, please describe the nature of the risk or stress and how you will minimise and monitor it.

D5 **Will group or individual interviews/questionnaires raise any topics or issues that might be sensitive, embarrassing or upsetting for participants?**

If **Yes,** please explain how you will deal with this.

No

D6 **Please describe any expected benefits to the participant.**

Learning about and contributing towards scientific research that will aid others. Participants can receive a free copy of research paper if they wish.

D7

Specify whether the following procedures are involved:

Any invasive procedure(s) ☐ **Yes** ☒ **No**

Physical contact ☒ **Yes** ☐ **No**

Any procedure(s) that may cause mental distress ☐ **Yes** ☒ **No**

Please state briefly any precautions being taken to protect the health and safety of the research participants.

Room is tidy to prevent tripping. Participants will be guided over to the device. No liquids will be allowed near device to prevent electrical faults. We will ensure the participant does not have a pacemaker or another device affected by magnets. Participants are given a fire briefing before trial starts.

D8

Does the research involve the use of drugs? ☐ **Yes** ☒ **No**

If **Yes**, please name the drug/product and its intended use in the research and then complete Appendix I

Does the project involve the use of genetically modified materials? ☐ **Yes** ☒ **No**

If **Yes**, has approval from the Genetic Modification Safety Committee been obtained for work? ☐ Yes ☐ No

If **Yes**, please quote the Genetic Modification Reference Number:

D9

Will any non-ionising radiation be used on the research participant(s)? ☐ **Yes** ☒ **No**

If **Yes**, please complete Appendix II.

D10

Are you using a medical device in the UK that is CE-marked and is being used within its product indication? ☐ **Yes** ☒ **No**

If **Yes**, please complete Appendix III.

CHECKLIST

Please submit ether 12 copies (1 original + 11 double sided photocopies) of your completed application form for full committee review or 3 copies (1 original + 2 double sided copies) for chair's action, together with the appropriate supporting documentation from the list below to the UCL Research Ethics Committee Administrator. You should also submit your application form electronically to the Administrator at: ethics@ucl.ac.uk

Documents to be Attached to Application Form (if applicable)	Ticked if attached	Tick if not relevant
Section B: Details of the Project		
• Questionnaire(s) / Psychological Tests	☒	☐
• Relevant correspondence relating to involvement of collaborating department/s and agreed participation in the research.	☐	☒
Section C: Details of Participants		
• Parental/guardian consent form for research involving participants under 18	☐	☒
• Participant/s information sheet	☒	☐
• Participant/s consent form/s	☒	☐
• Advertisement	☒	☐
Section D: Details of Risks and Benefits to the Researcher and the Researched		
• Insurance registration form and related correspondence	☐	☒
Appendix I: Research Involving the Use of Drugs		
• Relevant correspondence relating to agreed arrangements for dispensing with the pharmacy	☐	☒
• Written confirmation from the manufacturer that the drug/substance has has been manufactured to GMP	☐	☒
• Proposed volunteer contract	☐	☒
• Full declaration of financial or direct interest	☐	☒
• Copies of certificates: CTA etc…	☐	☒
Appendix II: Use of Non-Ionising Radiation		
Appendix III: Use Medical Devices		