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:

Date of Submission:	Proposed Start Date:
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:	Course Number:

A2 Principal Researcher

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

Full Name:	Position Held:
Address:	Email:
	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:
- 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:	
	Position Held:	
	Address:	Email:
		Telephone:
		Fax:
	Full Name:	
	Position Held:	
	Address:	Email:
		Telephone:
		Fax:

A4

Sponsor/ Other Organisations Involved and Funding

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

b) 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.*

c) 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.*

A5

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 <u>simple prose</u> outlining the intended value of the project, giving necessary scientific background** *(max 500 words)*.

B2 **Briefly characterise in <u>simple prose</u> 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).*

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?

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?**

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.*

SECTION C DETAILS OF PARTICIPANTS

C1

Participants to be studied

C1a. Number of volunteers:	
Upper age limit:	
Lower age limit:	

C1b. Please justify the age range and sample size:

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.

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**

How will you ensure that participants in these groups are competent to give consent to take part in this study? *If you have relevant correspondence, please attach it.*

C4

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

☐ **Yes** ☐ **No**

If yes, please specify the level of payment to be made and/or the source of the funds/gift/free service to be used.

Please justify the payment/other incentive you intend to offer.

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.

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?

C7

CONSENT

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

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.

C8

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

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

A poorly written Information Sheet(s) and Consent Form(s) that lack clarity and simplicity frequently delay ethics approval of research projects. The wording and content of the Information Sheet and Consent Form must be appropriate to the age and educational level of the research participants and clearly state in simple non-technical language what the participant is agreeing to. Use the active voice e.g. "we will book" rather than "bookings will be made". Refer to participants as "you" and yourself as "I" or "we". An appropriate translation of the Forms should be provided where the first language of the participants is not English. If you have different participant groups you should provide Information Sheets and Consent Forms as appropriate (e.g. one for children and one for parents/guardians) using the templates below. Where children are of a reading age, a written Information Sheet should be provided. When participants cannot read or the use of forms would be inappropriate, a description of the verbal information to be provided should be given. Please ensure that you trial the forms on an age-appropriate person before you submit your application.

Information Sheet for in Research Studies

You will be given a copy of this information sheet.

Title of Project:

This study has been approved by the UCL Research Ethics Committee (Project ID Number):

Name

Work Address

Contact Details

We would like to invite to participate in this research project.

Details of Study:

Please discuss the information above with others if you wish or ask us if there is anything that is not clear or if you would like more information.

It is up to you to decide whether to take part or not; choosing not to take part will not disadvantage you in any way. If you do decide to take part you are still free to withdraw at any time and without giving a reason.

All data will be collected and stored in accordance with the Data Protection Act 1998.

When you have completed your Information Sheet, please DELETE the advice section below from your application form before submitting it to the Committee.

Details of Study MUST include the following:

- Aims of the research and possible benefits.
- Who you are recruiting
- What will happen if the participant agrees to take part (when, where, how long etc)
- Any risks (e.g. need for disclosure of information to a third party, possibility for distress)
- Possible benefits (it is good practice to offer participants a copy of the final report)
- Arrangements for ensuring anonymity and confidentiality (see optional statements below for examples). To ensure compliance with the Data Protection Act participants must be informed of what information will be held about them and who will have access to it (this relates to information that is identifiable or could potentially be linked back to an individual.)

Statements which researchers MIGHT also include as appropriate:

- A decision to withdraw at any time, or decision not to take part, will not affect the standard of care/education you receive.
- If you agree to take part you will be asked whether you are happy to be contacted about participation in future studies. Your participation in this study will not be affected should you choose not be re-contacted.
- You may withdraw your data from the project at any time up until it is transcribed for use in the final report (*insert date).*
- Recorded interviews will be transcribed (written up) and the tape will then be wiped clear.
- If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form.
- Submission of a completed questionnaire implies consent to participate.
- As participation is anonymous it will not be possible for us to withdraw your data once you have returned your questionnaire.

Informed Consent Form for in Research Studies

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Project:

This study has been approved by the UCL Research Ethics Committee (Project ID Number):

Thank you for your interest in taking part in this research. Before you agree to take part, the person organising the research must explain the project to you.

If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you to decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

Participant's Statement

I

- have read the notes written above and the Information Sheet, and understand what the study involves.
- understand that if I decide at any time that I no longer wish to take part in this project, I can notify the researchers involved and withdraw immediately.
- consent to the processing of my personal information for the purposes of this research study.
- understand that such information will be treated as strictly confidential and handled in accordance with the provisions of the Data Protection Act 1998.
- agree that the research project named above has been explained to me to my satisfaction and I agree to take part in this study.

Signed: Date:

When you have completed your Informed Consent Form, please DELETE the advice section below from your application form before submitting it to the Committee.

Statements which researchers MIGHT include as appropriate:

- I understand that my participation will be taped/video recorded and I consent to use of this material as part of the project.
- I understand that I must not take part if
- I agree to be contacted in the future by UCL researchers who would like to invite me to participate in follow-up studies.
- I understand that the information I have submitted will be published as a report and I will be sent a copy. Confidentiality and anonymity will be maintained and it will not be possible to identify me from any publications.
- I understand that I am being paid for my assistance in this research and that some of my personal details will be passed to UCL Finance for administration purposes.
- I agree that my non-personal research data may be used by others for future research. I am assured that the confidentiality of my personal data will be upheld through the removal of identifiers.

This is not an exhaustive list and you should consider whether you need to amend any of these statements or design different ones that are more applicable to your research.

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).**

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.

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

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.

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		

Please note that correspondence regarding the application will normally be sent to the Principal Researcher and copied to other named individuals.