

UCL Research Ethics Committee

Guidelines on Completing the Application Form

The Application Process

The application form should be completed in plain English understandable to lay members and all abbreviations should be explained at the time of their first use. The completed form should contain sufficient information to enable a thorough ethical review to take place.

Please word process your form using a typeface such as Times New Roman or Arial with a font that is no smaller than 10 point. Also please expand the boxes on the form to accommodate your answers, but adhere to the maximum word limits where specified.

Please note that not all sections will be relevant to your study, but all fields should be completed. Simply mark irrelevant sections 'N/A'. Any appendices that are not relevant to the application should be removed.

If a project is deemed to be poorly planned, or may cause inconvenience to participants, or may put participants at risk, without any likelihood of producing worthwhile information or results, it will be rejected or referred back to the applicant for substantial amendment.

Section A: Application Details

A1: Project Information

Project Title: the project title should be provided exactly as it is registered on the UCL Ethics website.

Date of Submission: the date on which the form is submitted to the Administrator of the Research Ethics Committee should be entered here.

Proposed Start/End date: the study should not start until ethical approval has been given and this should be reflected in the preferred start date. The Committee does not take responsibility for any delay to the commencement of your research. However, under exceptional circumstances it may be possible for a project to be given urgent consideration (i.e. to meet the deadline for a funding body). If you wish to appeal for urgent review, please submit a covering note explaining why this is necessary.

Please provide the date when you plan to submit the finished project. It should be noted that ethical approval may only be given for one year. In such cases, an extension to approval then has to be sought (this does not necessitate the re-submission of a full application and can normally be done by Chair's action).

Project Identification (ID) Number: This is a unique identifier for each and every project you submit through the UCL Ethics Committee Website. If you do not have the relevant Project ID, or have forgotten it, go to <http://www.grad.ucl.ac.uk/ethics> If you have not yet registered your project, follow the instructions for doing so. If you have forgotten your Project ID, log on to your account and it will be listed in the 'To be Submitted' section.

A2: Principal Researcher

Please note that if the applicant is an undergraduate, taught graduate, or research graduate student, the Principal Researcher is the student's supervisor. For undergraduate independent studies projects, the Principal Researcher is normally the tutor for the independent studies course.

Declaration: The following are the responsibilities of the Principal Researcher:

- To ensure that each researcher/member of staff who will have access to children (i.e. anyone under 18 years of age) or vulnerable adults has undergone a satisfactory **criminal records check**.

For full details of UCL's policy on criminal record checks see:

http://www.ucl.ac.uk/hr/docs/criminal_record.php and for guidelines on working with children and vulnerable adults see: http://www.ucl.ac.uk/hr/docs/working_with_children.php

- To obtain approval from the UCL Data Protection Officer stating that the research is compliant with the Data Protection Act 1998. All applications for human participants research must be registered with the UCL Data Protection Officer. Please ensure that this has been done and that the **UCL Data Protection registration number** is entered in the space provided.

To register your project with the UCL Data Protection Officer you will need to visit the following web site: http://www.ucl.ac.uk/finance/legal_services/data_protection/index.php and download 'Form 2: Research Registration Form'. The form should be completed and emailed to: data-protection@ucl.ac.uk

- To ensure that the project complies with current professional, departmental and university guidelines, including UCL's **Risk Assessment** procedures and **insurance** arrangements.

Risk assessment guidance and forms should be available from your department or refer to UCL Safety Services webpage: http://www.ucl.ac.uk/efd/safety_services/www/guidance/risk_assessment/index.htm

With the majority of research involving human participants there are elements of risk. It is therefore essential that such research has the required approvals and appropriate **insurance** arrangements in place before it commences. 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, primarily in areas of clinical research, the insurer requires prior notification of the project before cover can be provided. Staff or students undertaking the following types of studies will need to complete an insurance form when applying to the UCL Research Ethics Committee for ethical approval of their project:

- Clinical trials which use drugs or vaccines
- Trials of medical devices
- Studies which use radiation, surgery or anesthesia as the intervention
- Studies which will enrol over 5000 subjects

A cover note summarizing the terms and conditions of the UCL Insurance Policy is available from the Administrator of the UCL Research Ethics Committee (ethics@ucl.ac.uk)

For the UCL Research Insurance Registration Form go to:

<http://ethics.grad.ucl.ac.uk/uclinsurance.php>

- To protect the rights and welfare of human research participants and be knowledgeable about the requirements of UCL's policies and procedures for the protection of human participants.
- To ensure that each participant understands the nature of the research and his/her participation in it and takes whatever steps are necessary to gain that comprehension.
- To provide a copy of the approved **informed consent** (see C7 below) document to each participant at the time of consent, unless this requirement has been waived by the Ethics Committee.
- If required to report progress of approved research to the Ethics Committee on an annual basis through completion of the '**Continuing Review Approval Form**'.
- To report promptly any **proposed changes** in previously approved research to the Ethics Committee. The changes may not be initiated without prior review and approval, except where necessary to eliminate apparent immediate hazards to the participants.
- To report promptly to the Ethics Committee any **unanticipated problems or adverse events** involving risks to participants or others. Both non-serious adverse events and serious adverse events must be reported.

Reporting Non-Serious Adverse Events

The researcher should inform the Administrator of the Research Ethics Committee within ten days of an adverse incident occurring and provide a full written report that should include any amendments to the volunteer information sheet and study protocol. The Chair or Vice-Chair of the Ethics Committee will confirm that the incident is non-serious and report to the Committee at the next meeting. The final view of the Committee will be communicated to the researcher.

Reporting Serious Adverse Events

The Committee should be notified of all serious adverse events. The sponsor of the research project should be informed in accordance with the researcher's contractual obligations. The researcher should inform the Ethics Committee immediately the incident occurs. Where the adverse incident is unexpected and serious, the Chair or Vice-Chair will decide whether the study should be terminated pending the opinion of an independent expert. The adverse event will be considered at the next Committee meeting and a decision will be made on the need to change the information leaflet and/or study protocol.

A3: Applicant(s) Details

Space for two applicants (if different from the Principal Researcher) is provided. If there are more than two applicants please copy these boxes and provide information on all the applicants.

A4: Sponsor/Other Organisations involved & Funding

- a) Sponsor: Indicate the institution which takes overall responsibility for the project/on whose behalf the work will be done and provide contact details of any external institutions involved.
- b) Other organisations: You should also seek permission if you intend to conduct research in any organisation outside UCL and provide evidence of this permission e.g. a letter from an organisation allowing the researchers to interview their staff. In such cases you should submit copies of documentation you will be using/have used when approaching external organisation (e.g. approach letter or email).
- c) Funding: You should provide details of the funding you have received / will be receiving for this study. If the application is solely funded by UCL this should be stated.

Please ensure that the relative roles and responsibilities of UCL, other institutions, and UCL researchers are clearly outlined.

In the event that permission letters from sponsors and the other organisations involved are not available at the time of application, the Principal Researcher should confirm that these will be available should they be required for audit purposes.

A5: Chair's Action

The Head of Department or Chair of the Departmental Ethics/Research Committee can recommend Chair's action but only if the project meets the criteria of minimal risk as defined in the Terms of Reference of the UCL Ethics Committee as copied below:

A recommendation for Chairman's Action as outlined in the Terms of Reference will be deemed appropriate if the research involves minimum risk. For example research studies NOT involving:

- intrusive interventions [including MRI]
- sensitive topics
- deception
- vulnerable groups, for example, children and young people or other vulnerable groups such as those with a learning disability or individuals in a dependent or unequal relationship.

The following research would normally be considered as involving MORE than minimal risk:

- Research involving vulnerable groups as defined in C3.
- Research involving sensitive topics – for example participants’ sexual behaviour, their illegal or political behaviour, their experience of violence, their abuse or exploitation, their mental health, or their gender or ethnic status.
- Research involving groups where permission of a “gatekeeper” is normally required for initial access to members – for example, ethnic or cultural groups, native peoples or indigenous communities.
- Research involving deception or which is conducted without participants’ full and informed consent at the time the study is carried out.
- Research involving access to records of personal or confidential information, including genetic or other biological information, concerning identifiable individuals.
- Research which could induce psychological stress, anxiety or humiliation or cause more than minimal pain.
- Research involving intrusive interventions – for example, the administration of drugs or other substances, vigorous physical exercise, or techniques such as hypnotherapy. Participants should not encounter such interventions, which may cause them to reveal information which causes concern, in the course of their everyday lives.

Section B: Details of the Project

Details of the project should be provided in non-technical English, so that all members of the Ethics Committee can readily understand them.

B1: Brief Summary and Intended Value of the Project

Please provide a brief summary of your project in lay terms. If the project is a Class Research Project please include aims and objectives of the course. In terms of the intended value of the project, it is important to justify why the research needs to be carried out. This is particularly important if similar research has been carried out in the past or if the same study population has been used before. The Committee will scrutinise the validity of the project and principal research questions and will refer it back to the researchers if it feels that the justification for engaging in the project is unclear (max 500 words).

B2: Research Protocol

In a maximum of 500 words, characterise your research protocol, type of procedure and/or research methodology. It is important that you provide sufficient detail for the Committee to appreciate precisely what you intend to do and how you intend to achieve your research aims and objectives. Any non-standard questionnaires, psychological tests etc. should be attached; for standardised questionnaires, it is necessary only to provide the name and details, together with a published reference to its prior usage.

B3: Location of the Study

If the study is to be carried out overseas it is important to state clearly and precisely what steps have been taken to secure research AND ethics permission in your study country. It is assumed that local research and ethics approval will be obtained and evidence of this should be attached.

Data Protection Issues

If the study is to be undertaken in a country or countries within the European Economic Area then registration for Data Protection should be made within that country and confirmation provided to the UCL Data Protection Officer (see contact details at A2).

If the study is to be undertaken in a country or countries outside the European Economic Area then it is important to state clearly and precisely what steps have been taken to secure registration for Data Protection within that country. You must also inform the UCL Data Protection Officer.

If the country in which the study is to be undertaken does not have Data Protection legislation then you will be expected to act in accordance with the UK Data Protection Act 1998, and inform the UCL Data Protection Officer.

If the data is to be collected overseas but the research is to be undertaken in the UK you must register your project with the UCL Data Protection Officer.

If the research is to be undertaken in conjunction with researchers in a country or countries outside the European Economic Area you must consult the UCL Data Protection Officer. (Transfer of personal data outside the E.E.A. is prohibited by the UK Data Protection Act 1998).

B6: Ethical Considerations

Please outline any ethical issues that might arise from the proposed study and how they are to be addressed. You might want to refer to issues such as informed consent, the degree of confidentiality and anonymity that can be assured, anonymisation procedures, protection from harm, right to withdraw, the storage of sensitive data etc. Please note that all research projects have some ethical considerations. Do not leave this section blank.

Section C: Details of Participants

C1: Participants to be Studied

Researchers must be able to demonstrate that they can justify the numbers of participants they plan to recruit; the age range and gender mix. In particular, if an upper age limit is specified justification should be given.

C2: Databases and/or Storage of Data

The Principle Researcher is responsible for the secure storage of data, either in paper files or electronic database. In accordance with the UCL Information Security Policy, Databases should be registered with the departments Computing Representative for liaison with Information Services. All filing systems and databases containing personal data should also be registered with the department's Data Protection Co-ordinator. Any enquiries regarding the secure storage of data should be made to the UCL Data Protection Officer, who is also the UCL Records Manager.

If you are not obtaining your data from individuals but from a third party you must obtain a statement from the third party that the data has been collected in accordance with the Data Protection Act 1998. This statement must be included in your application for Data Protection registration.

C3: Vulnerable Research Participants

If your research involves participants in these categories, please provide the necessary information and justification as appropriate.

Children: Children should only be involved in research where it is absolutely essential and the information cannot be gained by using an adult participant. When a choice of age groups is possible,

older children should be involved in preference to younger ones, although some research questions are specific to younger children and babies.

Other vulnerable groups: Research on a participant with a learning disability or cognitive impairment or individuals in a dependent or unequal relationship.

Please note that all research involving those who lack capacity or who during the research project come to lack capacity or who during the course of the research project come to lack capacity, must be approved by an appropriate body (in most cases this is the NRES) operating under the Mental Capacity Act 2005.

C5: Recruitment

How will potential participants in this study be (i) identified, (ii) approached and (iii) recruited? If you will be advertising, a copy of the advert/poster/recruitment email should be included. Recruitment literature (i.e. recruitment letter or webpages) should also be submitted. A web based recruitment drive will require a Data Protection disclaimer on the web page. An advertisement for participants for the project will also require a Data Protection disclaimer within the text. The recruitment process will involve the need for a criminal record check if any researcher/member of staff will have access to children or vulnerable adults. Please include the wording for this with your application for Data Protection registration.

C7: Consent

An investigator must not involve a human being as a participant in research without giving due regard to obtaining informed consent of the participant or the participant's legally authorised representative.

The Committee may waive the requirement of the investigator to obtain a signed consent form for some or all participants if it finds and documents that:

- The research could not be practicably carried out without the waiver or alteration.
- The waiver or alteration will not adversely affect the rights of the participants.
- The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality and/or
- The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context.

In cases in which the documentation is waived, the Committee may require the investigator to provide participants with a written statement regarding the research. If you wish the Committee to waive the requirement of informed consent, please explain fully in the context of your proposed project, why you believe that informed consent should be waived.

The following should be taken into consideration in relation to informed consent:

1. Providing Vital Information to Participants

It is important to inform the participants, prior to participation, about what they will be required to do during the research project. This allows the participants to give informed consent about their understanding of the nature of the task and the purpose of the project. Participants should be assured that their data will be treated confidentially and anonymously. However, they also need to be informed that their data may be used for the purpose of publication, if there is such an intention.

The aim is to provide an overview of the research project as honestly and as sensitively as possible while the emphasis is on the procedure. Participants should be made to feel that they can trust the researcher with their well-being before, during and after their participation. Receiving written informed consent provides protection not just for the participant but also for the individual researcher and their institution.

2. Consent and Children

Young people aged 16-18 with sufficient understanding are able to give their full consent to participate in research independently of their parents and guardians. Children under 16 **may be** able to give their full consent providing they have been counselled and do not wish to involve their parents and they have sufficient maturity to understand the nature, purpose and likely outcome of the proposed research. The ethics committee always gives particular consideration on this issue.

In addition, participation in the research must always be in the child's best interests. However, the Ethics Committee would regard it as unwise for an investigator to allow the participation of a child in a project where parental consent was not forthcoming or a competent child was not in agreement.

Important special considerations relate to research projects involving children: please refer to the guidance for researchers produced by the **National Children's Bureau**, which can be found in the 'research' section of the NCB website: www.ncb.org.uk and the **MRC Ethics Guide: Medical Research Involving Children 2004** website:

<http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002430>

3. Parental Consent

Parental consent is required where it is viewed that a child is incapable of understanding the implications of taking part in a study or where the child is regarded as incompetent to consent. Although the child's assent is advisable, the power to consent, in law, is that of his/her parents or legal guardian. Those acting for a child are only acting legally if participation in the project is of benefit to the child. If it is not, the parent or guardian could be said to be acting illegally. One parent can give consent but it is preferable to have both. Where there is parental disagreement as to whether an 'incompetent' child should be volunteered for research, it is possible that one parent could apply to court to block the child's participation. The Ethics Committee may in such circumstances advise that where there is disagreement, the child should not be included in the research.

4. Participants' Right to Withdraw from the Study

It is important to bear in mind that participants have the right to decline to take part in the study. This should be stated clearly on the information sheet and consent form and participants' attention should be drawn to the fact that they have the right to withdraw from the study without any penalty at any stage. Moreover, participants need to be assured that they will be given an opportunity to discuss the purpose and/or the procedure with the researcher at the beginning and end of their involvement.

5. Benefits

Any benefits that participants may reasonably expect should be described. Investigators should be frank about benefits and not overestimate or magnify the possibility of benefit to the participant. Payment to participants should not be listed or described in the benefits section.

6. Deception

Although researchers often state the nature of participation in detail, they may have to mislead the participants regarding the true purpose of the study, that is they provide a cover story. This is often dictated by the research question but it is nevertheless a form of deception – usually introduced to control participant bias. For example, if a researcher is interested in examining the assertiveness in males and females under two conditions, namely, same gender and mixed-gender groups, the participants are told that they will be working on problem solving that requires team work. The concern here is that knowing the true purpose of the study could influence participants' behaviour in the group. It needs to be stressed here that inclusion of a cover story needs to be assessed by an expert in the research field and by the departmental ethics committee very carefully in deciding whether the benefits of the procedure outweigh any risks to the participants. Under such circumstances full debriefing must be provided.

7. Confidentiality Protections

The regulations require that participants be told the extent to which their personally identifiable, private information will be held in confidence. For example, sponsors, funding agencies, IRB may review research records. Some studies may need sophisticated encryption techniques to prevent confidentiality breaches or to protect the investigator from involuntary release of participants' names etc. Advice for maintaining confidentiality of databases must be sought from the department's computing representative and Information Services. Advice for maintaining confidentiality of paper files must be sought from the UCL Data Protection Officer, who is also the UCL Records Manager.

8. Contact Persons

The identification of contact persons to answer participants' questions about the research and the rights of the participant should be provided. These areas must be explicitly stated and addressed in the consent process and documentation. A single contact person is not likely to be appropriate to answer questions in all areas. Questions about the rights of research participants may best be referred to persons not on the research team. Each consent document can be expected to have at least two names with local telephone numbers. **Information Sheet and Consent Form**

The information sheet is vital and must be completed carefully following the guidelines given below and using the pro forma Information Sheet included in the application form as a guide. You must provide separate Information Sheets where the differences between participants or different sections of the research require it (e.g. an Information Sheet for a child and a separate one for his/her parents, or an Information Sheet for those filling in a questionnaire and a different one for participants being interviewed).

Participant Information Sheet

Participant Information Sheets must be designed to assist participants to make informed choices. Potential recruits must be given sufficient information to allow them to decide whether or not they want to take part.

Researchers must take the steps necessary to ensure that all participants in the research understand the process in which they are to be engaged, including why their participation is necessary, how it will be used and how and to whom it will be reported so that the prospective participant can make an informed decision about whether (s)he really does want to take part.

It is highly recommended that the information provided is presented on headed paper and is accurate, clear and simple. The information should be specific to the proposed research and appropriate for the social and cultural context in which it is being given. The writer should use:

- simple words, sentences and paragraphs
- requests rather than commands
- the active voice (e.g. we will book) rather than the passive voice (e.g. appointments will be booked)
- a personal approach (e.g. we, you, your baby) rather than the impersonal (e.g. student, subject, they, those, he or she)

Jargon and acronyms should be avoided or accompanied by a clear explanation in everyday language. The whole information sheet should be understandable to a lay person.

Please note that the Committee will only accept information sheets that include the following:

Title of the Study (this should be in lay language)

- You should begin by making it clear that this is a study in which the volunteer is being requested to participate and that such participation is voluntary. This paragraph has been inserted into the pro forma information sheet for your convenience, but may be amended where necessary.
- Aims of the research and possible benefits.
- Who you are recruiting (who should, and who should not, take part)
- What will happen if the participant agrees to take part (when, where and how long etc.)
- Any risks or inconveniences
- Possible benefits (it is good practice to offer participants a copy of the final report)
- Arrangements for ensuring anonymity and confidentiality and how far these can be realistically guaranteed (if there are possible limits to this). 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).
- Explain that the participant can withdraw at any time and any limitations on ability to withdraw their data (e.g. after anonymisation).
- Name of the researcher and contact details participants should use to indicate if they would like to take part or if they have any questions/concerns.

Informed Consent Form

Although you are asked to retain the substance of the paragraphs in the consent form provided you are free to modify the language if it is inappropriate for the intended participants. Please also see the optional clauses, which you could integrate into the form.

C8: Deception

For guidance on projects involving deception, see Guidance Note C7 above.

C9: Debriefing

You should consider the following when you debrief your participants.

A full debriefing should provide the participants with any necessary information to complete their understanding of the nature of the research. As a researcher you are obliged to discuss with the participants their experience of the research in order to monitor any unforeseen negative effects or misconceptions. Debriefing does not involve telling the participant about the research, or handing them a sheet of paper with a description of the research on it. This is provision of information rather than debriefing, and although providing the participant with information is an important part of the research process, it should not be confused with debriefing.

Although debriefing is important and in many cases essential, it is not always possible. For instance, many forms of observational research do not allow the researcher to debrief his/her participants and debriefing would not therefore form part of the research process. Also, not all participants wish to be debriefed. Many people are quite happy to assist you in your research, but have perfectly good reasons for not being interested in its purpose. You are obliged to respect the rights of any participant who, on completion of the research, wishes to leave without discussion (in exactly the same way that you are obliged to respect the rights of any participant who wishes to withdraw from the research at any stage). Although as a researcher you are generally obliged to offer a full debriefing, your participants are not obliged to accept it.

However, whenever the possibility of any form of adverse reaction exists, you need to consider how your debriefing will monitor for this. Adopt a 'worse case scenario' approach, and plan for how you will deal with it. Although it is highly unlikely that such a situation will develop, we must be prepared

beforehand in case it does. Ask yourself how you can make the participant feel good about the research, how you can reassure them you are not stupid, or deficient in any way. Satisfy yourself that you prepared to debrief your participant in such a way that, no matter what the nature of the research or the experiences involved, they will leave the research situation feeling as good, or better than they did when they entered. It is this concern for the individual participant which lies at the heart of effective debriefing, and you are ethically bound to adhere to this principle.

Debriefing, then, focuses on the rights and well-being of the participant. Its aim is to ensure the participant leaves the research in as positive a frame of mind as they had on entering. It is a dialogue rather than a lecture, and is about the participant's response to the research rather than the research itself. Effective debriefing concludes the act of participation and provides closure for the participant. A properly debriefed participant leaves the research situation feeling they have made a valued contribution – bear this in mind.

Section D: Details of Risks and Benefits to the Researcher and the Researched

D1: Risk Assessment

See A2 above on Risk Assessment procedures.

D2: Insurance

See A2 above on insurance for UCL studies. If necessary, please attach a copy of your UCL insurance registration form and other related correspondence to your ethics application.

D3 / D4: Potentially Harmful Activities

All reasonably foreseeable risks, discomforts, inconvenience and harms that are associated with the research activity, should be described. Investigators should be forthcoming about risks and not underestimate or gloss over reasonably foreseeable risks. If additional risks are identified during the course of the research, the consent process and documentation will require revisions to inform participants as they are re-contacted or newly contacted.

D8: Research involving use of drugs or genetically modified materials

If your research involves the use of drugs you will need to complete Appendix 1.

Participant information sheets for studies generating data for drug licensing purposes must follow the format of the pro forma participant information sheet contained in section C of the application form. Individuals involved in blind randomised studies have a right to know which treatment they were given after the trial has been completed, or if a trial is stopped for any reason.

The arrangements for informing participants must be clearly stated and explained in the information sheet. See: http://www.ucl.ac.uk/efd/safety_services_www/guidance/gm/index.htm for Genetic Modification Safety Committee guidance and forms.

D9: Use of radiation

If your study involves the use of **non-ionising radiation** (this does NOT include the use of MRI scanners) you will need to complete Appendix II. It is highly recommended that the proposed research is discussed with the Departmental Non-Ionising Radiation Protection Supervisor (DNIRPS) for your department effecting the exposure at an early stage, in order to provide accurate information on the risks of exposure in the participant information sheet and consent form. Special attention must be paid to pregnant/potentially pregnant women, those who are breast feeding, or other groups who may be at special risk.

For information: Research projects involving ionising radiation exposure to participants must be conducted in accordance with the Standard Operating Procedures under Ionising Radiation (Medical Exposure) Regulations 2000 IR(ME)R. All research studies conducted in the UK that

involve exposure to ionising radiation (e.g. diagnostic x-rays, CT scans, DXA scans, radiotherapy and Radionuclide imaging) or the administration of radioactive substances must be ethically reviewed by a REC under the UK Health Departments' Governance Arrangements for RECs. This does not include University RECs such as the UCL Research Ethics Committee. As such, if the research study does involve ionising radiation, an application has to be made using the NRES/IRAS system. It is also strongly recommended that you contact the R&D office of the relevant NHS Trust for further advice on other permissions/approvals that may be required as part of your project. Further details can be found on the NRES website.

D10: Research Involving Medical Devices

If your study involves the use of a medical device in the UK that is CE-marked and is being used within its product indication you will need to complete Appendix III.

For guidance please refer to:

MHRA's guidance on the registration of medical devices:

<http://www.mhra.gov.uk/Howweregulate/Devices/Registrationofmedicaldevices/index.htm#3>

and

the European Commission's guidance document 'Definitions of medical devices, accessory and manufacturer' (MEDDEV 2.1/1):

http://ec.europa.eu/health/medical-devices/files/meddev/2_1-1_04-1994_en.pdf

Or if you are still uncertain whether your product would be classified as a medical device please send an enquiry via email to: mb-md-a-era@mhra.gsi.gov.uk

Submission of Application Form and Supporting Documentation

The Principal Researcher should sign the application and submit it for approval to the Head of Department who should then also sign it. In instances where the Principal Researcher is the Head of Department, another appropriate individual should give approval.

When the application is complete, please submit a signed electronic copy of your application to ethics@ucl.ac.uk Physical paper copies will not be required.

It is important that your application is submitted as a single pdf document and includes any supporting documentation, all in one file.

What happens next?

Your application will be sent to the committee members who will review your application and present their comments at the meeting. The Principal Researcher will then be sent notification by letter (copied to the applicant) of the committee's decision within 1 week of the meeting. The committee may make one of the following decisions:

- **Approved:** The application is satisfactory and needs no amendment or correction.
- **Approval in Principle:** The application is essentially ethically sound, however the researcher needs to make some minor amendments before it can be approved (normally by Chair's action).
- **Deferred:** The Committee could not reach a decision and needs to seek further advice.
- **Not Approved:** The application is seriously flawed and requires major revision before it can be reconsidered.

- **Rejected:** The study is deemed unethical.

Please note that ethical approval is usually given for the full duration of the project. Should you wish to make an amendment to an approved study, you will need to submit this as an 'amendment request'. Applications can only be amended after ethical approval has been granted.