

## **UCL RESEARCH ETHICS COMMITTEE**

### **GUIDELINES FOR COMPLETING THE ETHICS LOW RISK APPLICATION FORM**

These guidelines are for low risk application being submitted for Chair's Action review, as oppose to the full UCL Research Ethics Committee (UCL REC). If you are submitting to the full UCL REC you should refer to those guidelines and application form.

Read through these guidelines carefully before completing your application for ethical review.

#### **Why is ethical approval required?**

In order for research to result in benefit and minimise risk of harm, it must be conducted ethically. UCL's review processes are intended to ensure this whilst remaining sensitive to the needs of researchers.

The aim of ethical review is to protect participants. Participants have the right to know who has access to their data and what is being done with it. They are a valuable part of the research process and not merely a means of accessing data. However, ethical review also helps to protect the researcher. By obtaining ethical approval you are demonstrating that you have adhered to the accepted ethical standards of a genuine research study which could increase recruitment potential.

You will need to consider the following fundamental principles in relation to your research design and conduct:

- The collection of data and informed consent;
- The rights of participants to withdraw from the research without fear or penalty;
- Doing everything possible to ensure confidentiality and anonymity for participants and associated practices for the storage and access to data;
- Providing participants with adequate information concerning the research, its outcomes and how it will be used;
- The need to protect researchers from unintended constraints or pressure arising through misuse of research ethics provisions by powerful research subjects.

#### **Research without ethical approval**

It is generally accepted that funders, such as research councils will not provide financial support for research that does not have ethical approval. Many publications will now no longer accept for publication results of research that was not ethically approved. As such, researchers may need to present evidence of ethical approval in order to publish their results to the wider research community.

Researchers will not be covered by the College's insurance if ethical approval is not obtained prior to commencement. This means that should a participant make a claim regarding the research, then the staff or student would be personally liable.

Changes to modern society have seen an increase in litigation as a means of solving disputes. If ethical approval has not been obtained, the individual researcher bears personal responsibility for any claim.

You should note that if you undertake research without ethical approval, UCL takes no responsibility for the study (financial or otherwise). Undertaking research without ethical approval will be considered to be misconduct. You must ensure that you leave adequate time for review and any required revisions to the submitted proposal. If you are planning to conduct the research overseas you should note that ethical approval will be conditional on the securing of local ethical approval in the study country(ies).

#### **How do I know if my project is low risk?**

Chair's Action review is only for those projects deemed to be low risk (minimal risk). Projects deemed to be more than minimal risk, and therefore not classed as low risk include:

- Research involving vulnerable groups.

- 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.

## The Application Process

The completed form should contain sufficient information to enable a thorough ethical review to take place. If a project is deemed to be poorly planned, or may cause inconvenience to participants or put them at risk, without any likelihood of producing worthwhile information or results, it will be rejected or referred back to the applicant for substantial amendment.

Though not all sections will be relevant to your study, *all fields* should be completed; simply mark irrelevant sections ‘N/A’.

The boxes on the form can be expanded to accommodate your answers, but try to adhere to the maximum word limits where specified. Use a typeface that is easy to read, such as Times New Roman or Arial with a font that is no smaller than 10 point.

### **Using Plain English**

It is extremely important that your application is written in plain English and understandable to lay members; avoid jargon wherever possible and provide explanations for abbreviations or technical terminology.

## Section A: Application details

### **Title of Project**

The project title should be exactly as it was registered on the UCL Ethics website. If there is an additional shorter or lay person’s version, provide this also.

### **Proposed start date**

The study should not start until ethical approval has been given and this should be reflected in the preferred start date. Also, the start date given should not be the start of your research programme/course but rather the start date by which you propose to start data collection.

### **Proposed end date:**

Provide the date when you plan to submit the finished project/data collection. Approval will be granted for a specific length of time, but if the project is not completed by this point an extension to

approval must be sought. This does not necessitate the resubmission of a full application and can normally be done by Chair's action, unless there are substantial changes to the research design.

### **Project Ethics Identification Number**

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

### **Principal Investigator (PI)**

Enter the details of the person who is leading the project. A student or a staff member can be the named study PI.

### **Position held**

Is the PI a student (Undergraduate/Masters/PhD) or member of UCL staff (to include staff role)?

### **Faculty/Department**

State the PI's faculty or department.

### **Course Title**

If the PI is a student, state the title of the course the project relates to.

### **Contact Details**

These contact details will be used for all correspondence relating to this ethics application. You should use your UCL email.

### **Co-investigators/partners/collaborators**

List all other co-investigators/partners/collaborators who will work on the project to include external collaborators. This includes those with access to the data such as transcribers. It is accepted that some names, such as those of transcribers, may not yet be known. However, if names are not currently known, provide the roles and responsibilities of all other organisations and researchers are clearly set out.

### **Funded Projects**

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. Note, 'funding' includes non-monetary awards such as laboratory facilities.

### **Name of Sponsor**

For UCL ethical review, a 'sponsor' is the organisation taking overall responsibility for the research. This is not the same as a funder. For UCL staff and students the sponsor will normally be UCL. Research can have more than one sponsor and, in such cases, you must outline what responsibilities are being taken on by each sponsor.

If UCL is not the sponsor, you will need to explain why you are submitting the project for UCL ethical review and not to the sponsor.

### **Student Projects**

For student researchers, provide the name of your supervisor, his/her position within the faculty/department and his/her contact details.

## **Section B: Project details**

### **Brief background & aims of the project**

In this section you should provide a brief summary of your project in **lay terms** to include the intended aims and value of the project. 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.

### **Methodology and Methods:**

Outline what research methods you plan to use e.g. interviews, questionnaires, observation, focus groups etc. Tick all that apply. Some explanations for the categories have been given below.

- **Interviews** can take many forms, including:
  - *structured interviews*, which follow a set list of questions;
  - *semi-structured interviews*, which use an interview guide listing a set of issues to be explored;
  - *unstructured interviews*, which involve spontaneous generation of questions in the natural flow of interaction, and where the interview is driven by the interviewee rather than the interviewer.
- **Focus groups** involve a group of participants sitting together to discuss a set of research questions or topics. This may entail the researcher acting as a moderator for the discussion.
- **Questionnaires** including online surveys and can be qualitative or quantitative.
- **Action research** is often community- or organisation-based and is carried out in the field. This approach involves testing ideas in practice as a means of improving social, economic or environmental conditions and increasing knowledge. Action research proceeds in a spiral of steps consisting of planning, action, and evaluation. It provides a basis for further planning of critically informed action.
- **Observation** of participant/s in their own environment, or in the environment that is being studied. Data collection through observation can be structured or unstructured, with the observer as a collaborative participant (participant observation) or external to the environment.
- **Documentary analysis** involves the systematic analysis of written material, both printed versions and online material to illicit meaning/interpretation. This can include the use of personal records, meaning records which pertain to an individual, such as company employment records.
- **Controlled trial** - A type of trial in which observations made during the trial are compared to a standard, called the control. The control may be observations of a group of participants in the same trial or observations from outside the trial (for example, from an earlier trial, which is called a historical control)
- **Intervention** - A process or action that is the focus of a study. Interventions include non-invasive approaches, such as surveys, education, and interviews as well as invasive – approaches such as drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available. Interventions
- **Systematic review** is research where published research is the research data that is to be analysed. You can read more on this on the EPPI Centre website:  
<http://eppi.ioe.ac.uk/cms/Default.aspx?tabid=67>
- **Secondary data analysis** involves analysing data that has already been collected by someone else, which includes data that was previously collected for research purpose. You can read papers on secondary data analysis on the UK Data Services website:  
<https://www.ukdataservice.ac.uk/use-data/secondary-analysis/reusing-qualitative-data/reuse-articles>.

### **Overview of project (lay language)**

In this section, describe and justify your project's overall design, include details of samples/measurements to be taken and the method of data collection you have chosen together with a thorough description of the topics/questions to be asked.

### **Attachments**

If available, provide copies of your chosen methods and state whether they are in draft or the final version. For example, topic guides for semi-structured interviews, surveys, aptitude/personality tests, non-standardised questionnaires.

For standardised questionnaire just provide the name and details of the questionnaire together with a published reference to its prior usage.

### **Code of Ethics**

UCL staff and students engaged in research should work with reference to a nationally recognised professional code of conduct suitable for their research specialism. The following link provides examples of relevant codes of conduct [http://ethics.grad.ucl.ac.uk/codes\\_of\\_conduct.php](http://ethics.grad.ucl.ac.uk/codes_of_conduct.php).

### **Location of Research**

#### **Indicate where the research will take place**

Indicate whether the study will take place solely in the UK, solely overseas (to include the rest of Europe), or within the UK and overseas.

#### **Research occurring outside the UK – Local Ethical Approval**

For research taking place overseas, clarify whether local research or ethical approval/permissions is required in the study country/ies. If local approval is not required or possible, provide an explanation as to why.

If local approval is required, clarify whether this has already been obtained (if so attach evidence) or been applied for. Evidence of local approval (if required) will need to be provided before ethical approval will be granted.

To assist you with checking which local ethics committee you may need to apply to, *The International Compilation of Human Research Standards* listing provides details of Research Ethics Committees in over 100 countries, including key organisations such as local ethics committees. The listing was compiled by the Office for Human Research Protections, US Department of Health and Human Services and can be viewed here:

<http://www.hhs.gov/ohrp/sites/default/files/internationalcomp2016%20.pdf>.

Further information on overseas research can be accessed on the Research Integrity website (<https://www.ucl.ac.uk/research/integrity/research-ethics/outside-the-uk>)

### **Travel Safety & Insurance**

#### *Travel Safety*

You should check the travel advice on the Foreign and Commonwealth website and state whether the advice raises concerns for the location/region where the research will take place. This applies to staff/students who are from or live in that country/region.

(<https://www.gov.uk/government/organisations/foreign-commonwealth-office>).

If you or members of your research team are travelling overseas we advise that you regularly check the FCO guidance for any changes to the travel advice.

#### *Insurance*

UCL holds Public Liability Insurance which would cover a student's research, on the basis that the researcher/UCL were found to be legally liable. For the majority of studies the cover is automatic. However, for a minority of clinical research studies the insurer requires prior notification of the project before cover can be provided: <http://ethics.grad.ucl.ac.uk/procedures.php>

For **research conducted overseas**, a *travel insurance form* will need to be submitted to UCL Finance so that an insurance cover note can be issued. For further information and guidance visit: <http://www.ucl.ac.uk/finance/insurance> (you will need your UCL login details).

#### **Location(s) data collection will take place**

Describe the location(s) where the research will be conducted; this could include using online methods, postal mail or telephone communications. The research should be carried out in suitable surroundings with due observance of established safety practices.

### **Local approvals required**

If you need to seek permission to conduct research in any organisation outside UCL, you need to 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).

If approval has not yet been obtained, you should clarify in the application form whether approval has yet to be sought, or if you are waiting to hear back from the relevant organisation.

## **Section C: Details of Participants**

### **Does the project involve the recruitment of participants?**

In this form 'participants' means human participants **and** their data (including sensor/location data, observational notes/images, tissue and blood samples, as well as DNA).

### **Participant Details**

State the maximum number of participants required for the research, along with the upper and low age limits including a justification for the age ranges.

There should also be a justification for the sample size, such as a power calculation. Determining the optimal sample size for a study assures an adequate power to detect statistical significance. Hence, it is a critical step in the design of a planned research proposal. Using too many participants in a study is expensive and exposes a higher number of subjects to the procedure. Similarly, if a study is underpowered, it will be statistically inconclusive and may render the whole research a failure.

Not all research will use a power calculation, and so you should provide an explanation/justification for the sample size as relevant to your research.

### **Recruitment/Sampling**

How will potential participants in this study be (i) identified (or will participants self-identify themselves by responding to an advert for the study), (ii) approached (by email or in person) and (iii) recruited (consent process)?

What are the inclusion/exclusion criteria and are these appropriate?

In terms of recruitment, there should be no evidence of bias or coercion to take part in the study. This can occur, for example, when there is a power relationship/imbalance between the recruiter and recruited; e.g. students might feel pressurised to take part in the research if they are directly approached by someone in a position of authority, such as their tutor.

### **Informed Consent**

The principle of 'Informed Consent' is absolutely central to best practice in research ethics. This means that you have provided participants with all the necessary information for them to be able to make an informed decision about whether or not to take part. This includes information about the study (why its being done, the benefits, the risks, the potential outcome), what is expected of them (time required, risks/benefits, what they will be asked to do), what happens afterwards (for the study, to their data, the results of the research), and who to contact should they have any concerns.

All participants need to be given adequate information about the study so that they can make an informed decision about whether to participate. If participants are not fully informed then any consent given will only be partial consent, which is insufficient for most research. Partial consent is generally only accepted when an element of deception is necessary (i.e. when full knowledge would affect the results of a test/questionnaire). However, participants must still be given full information about the study as far as is possible without affecting the results. Any deception must be justified in the ethics application and an explanation provided for how you will debrief participants after and how you will manage participants responses to the deception.

Consent must also be freely given with no coercion or pressure to participate. This may also include any perceived pressure to participate, whereby the researcher may be in a position of power/authority over the participant. An explanation of how this will be managed should be provided.

### How do I inform participants; what format should I choose?

Many researchers choose to use an information sheet; is a written document which sets out all the required information. The advantage of a written information sheet is that you and your participants have a record of all the relevant information about the study. In most cases this is supplementary to, rather than replacing, a discussion between the researcher and the potential participant.

When writing an information sheet, or any other recruitment documentation, you should consider the participants you are looking to recruit; their age and education, and any disabilities, such as blindness, so that you can create an information sheet that is accessible and appropriate to that participant. You may need to have several versions; one for each group of participant, especially for child participants. Guidance on how to write recruitment documents such as information sheets can be found here: <https://ethics.grad.ucl.ac.uk/advice.php>.

Information sheets are not always used, with some providing the information verbally. The important thing is that participants have adequate information about why, how, when, with who, and where the study is taking place in order to enable them to give their 'fully' informed consent to take part in the research. However you choose to do this should be clearly set out and if an information sheet is not to be used, you should provide an explanation for why and how you will ensure participants are fully informed.

### Time frame

Adequate time should be given in order to allow the participant to absorb the information at his or her own rate. If this is not possible you will need to give a justification for this.

### Recording Consent - Consent Forms

Participant's consent and what they consented to needs to be recorded and this is usually done by using a written consent form, which participants sign and return to the researchers. For instance, research involving interventions, tests, assessments, interviews, focus groups, some observational studies, etc. normally use a consent form.

Consent forms should contain what it is that you want participants to consent to, which could be set out in a list of bullet points, and participants should have the option of consenting to or not consenting to each bullet point. Under the General Data Protection Regulation (GDPR) which will replace the current Data Protection Act 1998 in May 2018, consent must be unambiguous and obtained for each purpose (processing activity). This means that consent will not be valid for data protection purposes if several purposes have been unnecessarily bundled together so that an individual has to accept all of them or none of them.

For example, retention of contact details to invite participants to take part in future research is a distinct processing activity to the initial research and therefore separate consent must be obtained if you wish to rely on consent for the processing of personal data, and it may be that for some activities associated with your research that require personal data consent is the only legal basis available. Likewise use of the images of participants collected as part of a research study at a conference is also a separate processing activity and individuals should not generally have to consent to this just to take part in the research study. Though the GDPR comes into effect in 2018, research due to continue past this date should be compliant with the GDPR before this date.

If you are not intending to seek opt-in consent from participants, you must justify this in section 27c and state clearly **what legal basis** you will be using to process the data, which is required under UK data protection laws.

### *Legal basis*

The processing of personal data (collecting, storing, using) requires, what is often referred to as, a *legal basis* or a *condition for processing*. Opt-in consent is one such condition and will likely be the condition used for most research using personal data. If you are using sensitive personal data, then this would be 'explicit consent', which must be expressed in a clear statement of consent, and be done so in words, not actions. If you are going to rely on opt-in consent as the legal basis to process personal data it is important that you first consider how you would manage a situation where a

participant wished to withdraw this as such a request from a participant is likely to require you to delete the personal data you have collected about them.

There are other conditions listed in schedule 2 of the Data Protection Act 1998 and at Article 6 of the GDPR. However, if you are not intending to seek participant consent via an opt-in or some other form of an unambiguous action, then you need to use a condition other than consent. In these circumstances, you are strongly advised to contact the Data Protection team to ensure that the condition you choose is appropriate and that you are aware of the legal implications and participants rights for that condition.

#### Recording Consent - without consent forms

If it is not appropriate for consent to be recorded in a written format, then you will need to explain on the application form why this is the case and how you will obtain and record the informed consent. Under the GDPR consent cannot be inferred from silence or inactivity; it needs a clear affirmative action. Therefore you will need to detail how this will occur if you are not using a consent form and you wish to rely on consent for the processing of personal data.

For example, in the case of an audio-recorded interview, you may begin the interview by asking the participant to confirm that they give their consent to take part in the research. For self-completion questionnaires submission of the completed questionnaire implies consent to participate (you should make this clear in your Information Sheet).

Observation studies where you are observing an area (such as how a space is used), where you do not intend to single out any individual, and where it would not be possible to identify individuals from your report, may not require individual consent. If you are going into buildings or organisations, information about the study should still be provided to participants and permission from host organisations/ gatekeepers (e.g. the school and class room teacher) will still be needed. If you are observing individuals within non-public buildings, such as how they use a space, or time spent in a space, you should consider whether you need to gain their individual consent for this and state this in the application form along with an explanation if you are not intending to gain their consent.

In some cases written consent is impractical or inappropriate (for example if the research participant could not read or write). Research ethics committees will consider such cases on their individual merits and you will need to explain clearly how informed consent will be sought and recorded.

Whichever option you choose, there must be a record of the following;

- Who consented
- When they consented
- What they were told at the time (information provided for informed consent)
- How they consented
- Whether they withdrew their consent and when

#### General Data Protection Regulation (GDPR)

The GDPR comes into force on May 2018 and will replace the Data Protection Act 1998. The GDPR places more responsibility on being open and transparent on how an individual's personal data is to be held, used, stored and shared.

From this date participants must be provided with a **privacy notice**; a statement, or document that discloses the ways in which an organisation will obtain, record, hold, alter, retrieve, destroy or disclose, personal information. The privacy notice should be given to participants *before* they consent to participate.

Though the GDPR does not come into effect until 2018, if your study is to continue past this date you should ensure your research complies with the GDPR now.

Further guidance on privacy notices can be found on the Legal Services webpage for GDPR guidance: [http://www.ucl.ac.uk/legal-services/guidance/dp\\_GDPR](http://www.ucl.ac.uk/legal-services/guidance/dp_GDPR)



The Information Commissioner's Office also provides additional advice: <https://ico.org.uk/for-organisations/guide-to-data-protection/privacy-notice-transparency-and-control/>

### Withdrawing Consent

Participants should have the right to change their minds about participating and to withdraw from the study without any repercussions. You should inform participants about their right to withdraw before they consent. In addition, to withdrawing from the research, participants should be given the opportunity to withdraw their own data from the project up until the point when it is no longer practical to do so. For example, if the study involves anonymous questionnaires that are not collecting identifiable data, then this would be at the point at which the questionnaire is submitted.

Participant should be advised of this before they consent as well as be provided with contact details to use to make the request. A record should be kept of a request for withdrawing data, when it was made, by whom and what data was withdrawn.

### *Withdrawing consent and data protection*

It is important that you also consider what the **legal basis** is under data protection law for collecting/using the personal data necessary for your research, because if the legal basis is the consent participants provide, then as well as the right to withdraw that consent and stop future processing of their personal data, they also have the right to have their personal data withdrawn **at any stage**. This is the right to erasure, also known as the *right to be forgotten*. Should a participant ask you to withdraw their data from the project you should destroy identifiable data relating to that individual, and keep a record of this. If you receive a request before the final report has been published then you should remove any identifiable data from the final report and destroy identical data stored.

If the data has been completely anonymised and it is not possible to identify an individual's data then this will not be possible. However, participants must have been informed that this would happen before they consented to participate.

If you receive a request *after* the final report has been published you may not need to remove the data from the published report if there is no personal data in the report. You would however need to destroy identifiable data you are still storing.

If you are not relying on opt-in consent as the legal basis for the processing of personal data under data protection law, then the right to erasure of personal data may in certain circumstances be limited. This will apply if the processing is necessary for the performance of a task carried out for reasons of public interest which is likely to be the other main legal basis available to researchers. Here you should consider the participant's right to have their data erased against the impact this would have upon the research – meaning would it undermine the research. Remember that if you chose not to erase the data on this basis you are overriding the participant's right to be forgotten and so this must be considered very carefully and not chosen simply due to the time required to withdraw the data. **You should seek advice** from the Data Protection & FOI team in these circumstances: <http://www.ucl.ac.uk/legal-services/contacts/dp-foi>

Regardless of the legal basis for collecting and using personal data you should always think carefully beforehand what personal data you will collect and at what point (if at all) it would not be possible to identify an individual participant's data (not possible to withdraw).

### **Attachments**

You should submit copies of all recruitment documents even if in draft form, if they are available. For instance:

- Copies of any adverts/posters/recruitment emails or webpages you intend to use.
- Information sheets and consent forms.
- Approach letters to gatekeepers seeking permission to do research on their premises/in their company, etc.

### **Dissemination of results**

One benefit to participating in a research study is that participants can be informed of the results of the research, which may be in via a copy of the final report. Many studies also offer to inform

participants about how they did on a particular aspect of the study, such as their balance, etc. However, it is not always possible to know at the outset what information and findings the study could generate. [Attachment: \*Refer to guidance note: Feeding Back Results and Reporting Disclosures.]

## Section D: Accessing/Using Pre-collected Data

### **Access to data**

If you are obtaining data from a third party, you will need to explain how you will obtain the data. You must obtain a statement from the third party that the data has been collected in accordance with the Data Protection Act 1998 (GDPR from May 2018). This statement must be included in your application for Data Protection registration.

### **Accessing pre-collected data**

In this section you will need to confirm whether your study involves the use of previously collected data. (\*Refer to Secondary Data Analysis guidance note – see ethics website.) If ‘no’, move to Section E of the application form. If ‘yes’, you will need to provide the name and owner (if applicable) of the dataset(s).

### **Are the data in the public domain?**

Material that any member of the public is (legitimately) free to access and use, without having to obtain permission from anyone else, would be considered as being in the public domain. For example, news reports, openly available research data, published Government reports, publically accessible webpages, etc.

The word legitimately is included in brackets because for Higher Education purposes, as opposed to journalistic purposes, the material has to be legitimately available before it can be regarded as being in the public domain.

### **Are data available online, such as through chat rooms, blogs, forums and social media considered to be in the public domain?**

If you need to go through a process in order to ‘join’ a website in order to access the data (e.g. by registering, being invited to join) then the site is not in the public domain and concerns for anonymity, confidentiality, data protection and privacy will apply. In the case of such website (1) ethics approval is required; (b) the permission of the website controller/moderator to carry out the research should be obtained and (c) the informed consent should be obtained from the users of the website in order to be able to use data that they have created (e.g. conversations). It is also good practice to ask prospective human participants if they would prefer to be referred to by their internet name or by their real name.

If on the other hand you can simply access the data without going through a process in order to join the website, then the data should be considered as being in the public domain. Accordingly, consent and ethical approval is not required. However, there are grey areas and so it is worth obtaining ethics approval if in doubt. Refer to the British Psychological Society’s Code on Internet-mediated Research: <http://www.bps.org.uk/system/files/Public%20files/inf206-guidelines-for-internet-mediated-research.pdf>.

### **Are the data anonymized?**

You will need to outline whether the data is anonymous and if not whether you plan to anonymise it or whether you plan to use individual level data and link data to individuals.

Data is only truly anonymised if it is impossible to identify subjects from that information and, if relevant, any other information that UCL holds. For example, if you have a list of research subjects and anonymise it by giving each one a number, but keep a list of the numbers with the names of the subjects, the information has not been anonymised. In this case, it is personal data, and the project must be registered with the UCL Data Protection Officer.

Here are a few resources to help you anonymise your data:

- The UK Data Service has published clear guidance to anonymise quantitative and qualitative data. <https://www.ukdataservice.ac.uk/manage-data/legal-ethical/anonymisation>
- The Information Commissioner's Office has produced a useful code of practice. <https://ico.org.uk/media/1061/anonymisation-code.pdf>

### Are the data sensitive?

The Data Protection Act 1998 (<http://www.legislation.gov.uk/ukpga/1998/29/section/2>) states that "sensitive personal data" means personal data consisting of information as to:

- a) the racial or ethnic origin of the data subject,
- b) their political opinions,
- c) their religious beliefs or other beliefs of a similar nature,
- d) whether they are a member of a trade union (within the meaning of the Trade Union and Labour Relations (Consolidation) Act 1992),
- e) their physical or mental health or condition,
- f) their sexual life,
- g) the commission or alleged commission by them of any offence, or
- h) any proceedings for any offence committed or alleged to have been committed by them, the disposal of such proceedings or the sentence of any court in such proceedings.

**In addition, under GDPR biometric or genetic data that is being processed with the intention of identifying a living person has been added to the list.**

More detailed guidance can be found on the Information commissioner's website <https://ico.org.uk/for-organisations/guide-to-data-protection/key-definitions/> and includes a guidance entitled 'Determining what is personal data' <https://ico.org.uk/media/for-organisations/documents/1554/determining-what-is-personal-data.pdf>.

### Analysis and consent:

State whether analysis of the data you will be conducting is within the remit it was originally collected for and if not, whether explicit consent gained from participants for subsequent/future analysis of their data.

**Note: If you ticked any of the boxes in this section marked with an asterisk (\*), ensure that you give further details in Section E: Ethical Issues.**

## Section E: Ethical Issues

### Ethical issues:

All research raises ethical issues, and these should be highlighted and addressed in this section. **Do not leave this section blank.** You should address the ethical issues your research raises and how you will manage these issue, including mitigate any risks.

Examples of ethical issues include, but are not limited to:

#### Power relations

Where the relationship between you and the potential participant might be influential i.e. if prospective participants are your colleagues or students, this must be acknowledged. You should also provide an explanation of how you will deal with predictable problems resulting from the prior relationship (i.e. how will you counteract a perceived pressure to participate on the part of the volunteer).

## Conflicts of Interest

If there are conflicts of interest you should indicate how these will be managed or mitigated.

## Action Research/Research in your own Workplace

You must evaluate the extent to which your own role impinges on the research process. It is recognised that students often have dual roles and may be studying and carrying out research whilst continuing an additional professional role. If this is relevant to your research, you may find it useful to read a King's College London guidance paper: Research in the Workplace:

<http://www.kcl.ac.uk/innovation/research/support/ethics/training/workplace.aspx>. This guide includes some of the common conflicts which arise from this type of research and how to address these in a research ethics application.

## Consent, deception and covert methods

The research involves an element of deception or covert methods (observation or other data collection methods), whereby fully informed consent is not obtained, partial consent is sought or participants are included without their knowledge.

*NB: This does not include observation of individuals in public spaces.*

In general, covert research is discouraged, although it is recognised that covert designs are necessary in exceptional cases. One example might be an observational study in a public setting (and this could include online environments, such as internet chatrooms), where it would not be feasible to reveal the nature of your research to everyone in the setting. Another example might be a study involving deception of participants, where you don't reveal the true purpose of the study (or reveal it only after the study is completed).

In considering whether covert methods are justifiable, it's useful to look at the ESRC guidance in the [Framework for Research Ethics](#) (2015, p31) which states: '*Covert research may be undertaken when it may provide unique forms of evidence that are crucial to the research objectives and methodology or where overt observation might alter the phenomenon being studied. The broad principle should be that covert research should not be undertaken lightly or routinely. It is only justified if important issues are being addressed and if matters of social significance which cannot be uncovered in other ways are likely to be discovered.*'

Is the deception relatively mild? For example, people whose movements are charted throughout the day would be told of the potential inconvenience of having an observer following them around. It may be decided to reserve information about how the results are to be used (e.g. comparing the time younger and older people spend on a mobile phone) until the observations are concluded, but this withholding does not vary greatly from the consent to have their behaviour observed.

Some projects may require that certain factors are unknown to participants prior to them taking part, or it may be the case that participants are intentionally misled to some degree about the true nature of the study.

As a general rule, serious deception should be avoided whenever possible since it jeopardizes the integrity of informed consent by:

- giving false information about the investigators or the research purpose; or
- omitting information about the real purpose of the research.

For research involving deception:

- (1) the use of deception must be justified in the protocol to show that the research cannot be performed in the absence of deception and the benefits of the research will sufficiently outweigh any risks that deception may create;
- (2) research participants cannot be deceived about significant aspects of the research that would affect their willingness to participate or that would cause them physical or emotional harm; and
- (3) deception must be explained to participants (debriefed) as early as feasible. A debriefing script must be included in the protocol and should include a detailed description of the ways in which

deception was used and why; when and by whom the debriefing will be administered should also be included; and

(4) true “informed consent” cannot be given if the true nature of the research is deceptively presented and you may wish to add a sentence in the consent form giving the participant the option to withdraw his/her data (particularly if it is of a sensitive nature) after (s)he has learnt the true nature of the research.

*“Research designs often require that the full intent of the study not be explained prior to participation. Although we have described the general nature of the tasks that you will be asked to perform, the full intent of the study will not be explained to you until after the completion of the study [at which point you may withdraw your data from the study]”*

### **Risks & Benefits**

As part of the review the potential risks should be balanced against the potential benefits; both should be stated clearly on the information sheet.

#### **Are there potential benefits to participants**

You should set out clearly whether there are any benefits to participating in the study. Note that not all projects will benefit the participants directly, but might serve the public good.

#### **Do you intend to offer Incentives/compensation:**

If you intend to make payments to participants you need to specify the amount to be paid and/or service to be offered as well as provide a justification for this. Payment should not over-ride the principles of freely given and fully informed consent. Participants should know – before they start the research – that they can refuse to answer questions or withdraw from the study at any time without losing their payment.

The use of payment as an ‘incentive’ to participation is controversial. Incentive payments can be seen as coercive – or as exerting undue influence on potential participants’ decisions about whether to take part in research. A particular concern is that participants from financially disadvantaged groups may be more vulnerable to this kind of coercion – because they need the money, and so their consent is not truly ‘freely given’ if payment is involved.

Nonetheless, one argument made in favour of payment to participants is that it reduces non-response bias, and thus increases the sample quality. Precisely *because* payment encourages responding, it can help researchers to achieve a sample that is more representative of the population being studied than could otherwise be achieved.

If payments are used *because* they are an inducement to participate then you can’t avoid the ethics considerations outlined above. The question you have to consider is whether it represents an *undue* inducement to participate; meaning that it leads participants to agree to participate when they may not have without payment.

As a rough guide, you could look at the time and effort required for participants against the incentive/compensation you wish to offer. Levels of incentives should be reflective of the burden of participation (time and effort required of participants for the study). For example, a £20 voucher for every participant who completes a short survey would generally be considered undue inducement, whereas 100 participants being out into a draw to win a £20 voucher would likely be considered much more proportional to the burden of participation; depending on what the burden of participation is.

Ask yourself the following questions:

- Could it distort the participant's judgement of the risks and benefits of participation?
- Could it interfere with their freely given and fully informed consent? How will you ensure it does not?

Because of these ethics questions, the UCL REC will scrutinise carefully any plans to pay research participants. So, if you propose to make any kind of payment to participants in your research, you need to think carefully about *why* it is necessary, and *how* it is done. We suggest the following useful guidance:

- develop guidelines for when and how payment is made;

- ensure you have a clear and explicit justification for paying participants that you can give to the ethics committee;
- ensure that participants who choose to withdraw from the research will still receive payment;
- consider carefully any cases where there is concern that people are consenting because of payment and not because they wish to take part; and
- develop a general policy on describing payments in the consent process.

### **Is there any risk of harm for participants?**

What is the potential for harm to participants? Nearly all projects involving participants have the potential to cause pain, discomfort, stress (physical and/or psychological) however minor they might be. Projects should recognise this potential and explain what the risks are and how they will be minimised/addressed/managed.

You must ensure that those taking part in research will not be caused distress. They must be protected from physical and mental harm. This means you must not embarrass, frighten, offend or harm participants. Normally, the risk of harm must be no greater than in ordinary life, i.e. participants should not be exposed to risks greater than or additional to those encountered in their normal lifestyles. The researcher must also ensure that if vulnerable groups are to be used, they must receive special care. For example, if studying children, make sure their participation is brief as they get tired easily and have a limited attention span. Researchers are not always accurately able to predict the risks of taking part in a study and in some cases a therapeutic debriefing may be necessary if participants have become disturbed during the research.

You should consider if there are ways to minimise the risks, and take steps to do so. You should also ensure that participants are fully informed of any risks before they consent to participate.

### **Is there any risk of harm to you as a researcher?**

What about the risks to yourself as the researcher? This includes, but is not limited to, lone working in potentially unsafe environments. Examples include overseas research where the FCO has advised against all travel, lone working at night in non-public places, or going into participant homes alone, especially where there are other risk elements to consider (for example, the study may be looking at domestic abuse).

Researcher's safety is an important ethical consideration, for everyone involved in a study:

- If you are undertaking research for your PhD, or at an early stage in your career, you may be working in relative isolation and that can open you up to greater research risks than if you are working in a team.
- If you are working on someone else's study, you – and they – need to think about whether the research could pose any risks to you or other members of your team.
- If you are an experienced researcher or research supervisor, the same considerations apply, but you may also be managing these issues for other, less experienced, colleagues.

You should also consider the following more general considerations:

#### Physical safety

If you are doing fieldwork, always make sure someone knows where you are, and the timescale for your visits. If you are working in a team, it can be useful to make sure that each member has the telephone numbers of the others and for them to have their phone with them at all times. For highly risky research – e.g. in high crime areas, involving evening fieldwork, visiting participants' homes – make sure that someone knows where you are and that you have arrangements to contact someone to let them know you have finished and are on the way home or back to the office.

#### Emotional safety

Are there systems in place to deal with issues that arise, such as disclosures and debriefing if collecting sensitive data? Is there someone you can call to talk to if you've done an upsetting interview, without breaching confidentiality? Research reports often present objective 'findings', but sometimes research can be upsetting for the researchers as well as the respondents.]

Is there a procedure in place which outlines the potential risks that you might face and how these will be addressed/minimised/managed?

The Social Research Association also provides a useful overview, highlighting five key dimensions of potential risk to researchers:

- risk of physical threat or abuse;
- risk of psychological trauma, as a result of actual or threatened violence or the nature of what is disclosed during the interaction;
- risk of being in a compromising situation, in which there might be accusations of improper behaviour;
- increased exposure to risks of everyday life and social interaction, such as road accidents and infectious illness; and
- risk of causing psychological or physical harm to others.

If the research places you as the researcher at any risk greater than what you would encounter in your daily life (e.g. interviewing alone or in dangerous circumstances) then you will need to complete a project risk assessment form.

If you need to complete a risk assessment form guidance and forms should be available from your department, or you can refer to the UCL Safety Services Webpages:

- [https://www.ucl.ac.uk/estates/safetynet/guidance/risk\\_assessment/index.htm](https://www.ucl.ac.uk/estates/safetynet/guidance/risk_assessment/index.htm)
- Lone Working: [http://www.ucl.ac.uk/estates/safetynet/guidance/lone\\_working/index.htm](http://www.ucl.ac.uk/estates/safetynet/guidance/lone_working/index.htm)

## Section G: Data Storage & Security

### **Will the research involve the collection and/or use of personal data?**

If your research involves the collection and or use of personal data as defined in the application form you will need to register your project with the UCL Data Protection team through the Legal Services Department before the data is collected and you will need to quote your data protection registration number on the application form.

### **The Data Protection Act 1998**

The DPA applies to personal data which is defined as data which relates to a living individual who can be identified either

- a) from that data, or
- b) from that data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual.

More detailed guidance can be found on the Information Commissioner's website <https://ico.org.uk/for-organisations/guide-to-data-protection/key-definitions/> and includes a guidance entitled 'Determining what is personal data' <https://ico.org.uk/media/for-organisations/documents/1554/determining-what-is-personal-data.pdf>.

The Act does not apply to information about deceased people, but you may still owe a duty of confidentiality after death.

In May 2018 the **General Data Protection Regulation (GDPR)**, which will replace the Data Protection Act 1998, will **expand** the definition of 'personal data' to mean *any information* relating to an identified or identifiable natural person ('data subject'); one who can be identified, directly or indirectly, in particular by reference to an identifier such as:

- a name;
- an identification number;
- location data;
- an online identifier;
- or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

### **Is the research collecting or using sensitive personal data & culturally sensitive data?**

You will need to outline whether your research involves ‘sensitive’ personal data as defined by the UK Data Protection Act 1998 (*special category data under the GDPR*) or data that might be considered sensitive in some countries, cultures or contexts.

If ‘yes’, you will need to outline whether **explicit consent** will be sought for its use and what **data management measures** are in place to adequately manage and protect the data e.g. encryption.

The following links provide guidance on managing data.

- UCL Data Safe Haven: <http://www.ucl.ac.uk/isd/itforslms/services/handling-sens-data/tech-soln>
- Research Data Management: [http://www.ucl.ac.uk/library/research-support/research-data/best-practices/guides/sensitive\\_information](http://www.ucl.ac.uk/library/research-support/research-data/best-practices/guides/sensitive_information)
- The Digital Curation Centre: <http://www.dcc.ac.uk/digital-curation/what-digital-curation>

“Sensitive personal data” means personal data consisting of information as to:

- a) the racial or ethnic origin of the data subject,
- b) their political opinions,
- c) their religious beliefs or other beliefs of a similar nature,
- d) whether they are a member of a trade union (within the meaning of the Trade Union and Labour Relations (Consolidation) Act 1992),
- e) their physical or mental health or condition,
- f) their sexual life,
- g) the commission or alleged commission by them of any offence, or
- h) any proceedings for any offence committed or alleged to have been committed by them, the disposal of such proceedings or the sentence of any court in such proceedings.

**In addition, under GDPR biometric or genetic data that is being processed with the intention of identifying a living person has been added to the list.**

### **Data Protection Registration Number**

If your research involves the collection and or use of personal data as defined in the application form you will need to register your project with the UCL Data Protection team through the Legal Services Department before the data is collected and you will need to quote your data protection registration number on the application form.

If you do not have a registration number, you will need to clarify why on the application form.

### **During the project**

#### **Type of data, data storage and access.**

##### Type of data



You should provide an outline of the type of data that will be generated from the project, such as completed questionnaires, audio recordings of interviews, transcripts of interviews, photographs, field notes, etc. and be clear as to whether the data will be identifiable, anonymised, or pseudo-anonymised.

### Storage of data

State where and in what format all data will be stored during the study, which includes the write up and dissemination period.

There must be appropriate levels of security in place for the personal data being processed, both from within, and outside of the university. For example, it is not advisable to carry research data on USB sticks as these can easily be lost as well as the data accessed by others if found. Equally, research data which is held in paper format should be stored in lockable filing cabinets, or a locked room. Personal or confidential data should not be left accessible on desks. If you are not planning on storing data within UCL (services or premises) you should think about who may have access to the data where it is stored.

The level of security, will be largely dependent on the type of data being processed. Personal data which is to be held electronically, should have appropriate measures in place to minimise any risk, and to prevent unauthorised access, accidental loss, or destruction e.g. encryption.

To increase the security of data processing, it is advisable to anonymise/pseudonymise data to as great an extent as possible. Further information on this is available on the Data Protection & FOI webpages as well as the Research Data Management pages, including their best practices guidance.

- <http://www.ucl.ac.uk/finance/legal/dp-research>
- <http://www.ucl.ac.uk/library/research-support/research-data/best-practices>

### Who has access to the data

State who will have access to the data during the study, this includes the research team, supervisors, transcribers, etc.

If you are transferring personal data to a third party for the provision of a service you will need to ensure that a data processing agreement appropriate is in place which stipulates exactly what they can do with the personal data.

If you are considering using a cloud provider or an outsourced service such as transcription you should ensure that you are aware of the circumstances and location in which the provider will process the information it receives. Meaning where they are based, how the data will be sent to them and what they will do with that data. For example, a transcriber may want the audio files sent to them via UCL Drop Box, they will transcribe the files on their computer and return the transcriptions to the researcher via the UCL Drop Box, and then deleted the files from their computer.

Some providers often have servers where data is stored, and backed up within a number of different countries. This is important as data sent via the cloud provider will go through the service and so travel through the country that server is based in. This could involve therefore a transfer of personal data to a country **outside the European Economic Area** such as the United States, if so there are additional things to consider.

For instance, although you and the participant are based in the UK, the servers for the website you are using for the online survey may be based in the United States, and so when the participant submits their response, the data is first transferred to the US before than being transferred to the UK (see below for more guidance).

In addition, you should also check their terms and conditions as some websites state that they will make use of the data submitted via their website, or also have ownership of that data and be able to use it for the purposes. It is very important therefore that you check where online servers are based and what claims they make over data being sent via their servers.

Further guidance on cloud computing and data transfers can be found here:

<http://www.ucl.ac.uk/legal-services/guidance/dp-cloud-computing>

### **Will data be processed or sent outside of the European Economic Area?**

You should provide details of where the locations of the research is being conducted, including information about the circumstances in which the research may be transferred to other countries; including servers based in other countries (see above). If the personal data is to be transferred outside the European Economic Area (EEA) and the receiving country is not subject to an *adequacy* decision from the European Commission (EC), then additional measures set out in the DPA (and the GDPR) will need to be in place in order to make the transfer legal. The consent of the participants to such a transfer would be one such measure.

For international research collaborations that involve the transfer of personal data, the data may not therefore be transferred to countries outside the EEA unless that country has been deemed to have adequate data protection regulations by the EC, unless the explicit consent of the data subject has been obtained, or there is an appropriate EC approved contract with the recipient of the data, specifying appropriate data protection requirements that must be upheld. Thus, researchers must be exceptionally careful when contemplating the transfer of research data containing personal data overseas. In most cases, the safest option will be to anonymise the data prior to transfer, if this is not viable ensuring that data subjects give explicit consent for the overseas transfer during data collection may be the most suitable way forward.

Further information on the transfer of personal data overseas is available at: <http://www.ucl.ac.uk/legal-services/guidance/dp-data-transfer>

## **After the Project**

### **Storage, retention and destruction of data**

Similar to the previous questions, you will also need to state what data will be kept *after* the project, where it will be stored, how it will be kept secure and who will have access to it.

You should consider carefully how long you need to retain the data you collect and if this can be securely destroyed or deleted when the study is complete you should include reference to this. If personal data is to be retained at the end of the study you should indicate how long and provide details as where and how it will be retained and kept secure.

Advice on storing and presenting data can be found on the Research Data Management webpages: <http://www.ucl.ac.uk/library/research-support/research-data/best-practices/guides/storing>

### **Will data be archived for use by other researchers?**

If you intend to make the personal data available to other researchers/organisations you should ensure that you seek consent for this from participants at the outset. You will need to be as clear as possible on what data will be made available, where, to whom, and what for what purposes. The type of research the data may be used for may well not be known at this stage, but participants need to be aware that the data could be used for a wide-range of research. You should also be clear on whether any data will not be made available or if there will be restrictions or limitation to access.

Further guidance can be found at <http://www.ucl.ac.uk/library/research-support/research-data/best-practices/guides/sharing>.

The UK Data Archive have very useful guidance for researchers on managing data and archiving data for future use: <https://www.ukdataservice.ac.uk/>

**If your research is funded**, the funder may have a requirement that research data is archived to allow for future use, such as the ESRC. Therefore, it is important that you know what the funder's requirements are regarding research data, and ensure that this is built into your research data management plan and consent process.

## **UCL Records Office**

When all essential paper documents are ready to archive, contact the UCL Records Office by email at [records.office@ucl.ac.uk](mailto:records.office@ucl.ac.uk) to arrange ongoing secure storage of your research records unless you have made specific alternative arrangements with your department, or funder.

All records should be retained or disposed of according to UCL retention schedules and appraisal guidelines established by the Records Management Programme. For information on the UCL Records Management Service, visit <http://www.ucl.ac.uk/library/about/records-office/transfer-records>

## **Section H: Declaration**

When you have completed your application form you should read it through to check that the information is complete and that you have uploaded the relevant supporting documentation (e.g. recruitment advert, non-standardised questionnaires, interview topic guide or interview schedule, participant information sheet and consent form).

The final section is the applicant declaration which asks you to confirm that the information that you have provided is accurate to the best of your knowledge and belief.

If you are a student researcher, you will need to discuss your application form with your supervisor and then your supervisor will need to countersign your declaration to confirm that (s)he has discussed with you the ethical issues of your research and supports your application.