# School of Law, Birkbeck, University of London

# Applying for ethical approval for research:

# Application form & guidance

**Requirement for ethical approval**

Ethical approval is required for any research undertaken by an undergraduate or postgraduate student or a member of staff in the School of Law which involves any of the following:

* Interaction with human participants, for purposes of collecting data
* Collection or review of individual or case-level administrative data, or archival material, not in the public domain
* Collection or review of sensitive data derived from social media platforms
* Risk to the safety or well-being of the researcher
* Potential impact on animals or the environment
* Risk of significant reputational damage to the School, College, discipline or academia more widely
* Requiring an individual to step outside accepted regulatory or legal norms
* Some forms of collaboration with international (academic or non-academic) bodies.

**Application process**

*Step one*

Please complete the form below (pages 5-15) and **submit it as a Word document** to the School of Law Ethics Committee.

Submit with your application all supporting materials, such as draft interview schedules, questionnaires, consent forms and information sheets. The application form covers risk assessment and data management; therefore most applications will not require a separate risk assessment form and data management plan. If you are a student, ensure that your supervisor has reviewed the application and completed the supervisor sign-off form. The completed sign-off form should also be submitted with the application.

(See the accompanying template consent form, template information sheet and supervisor sign-off form.)

*Step two*

If the application is assessed as **routine** by the School Research Ethics Officer, you will be informed that you should now upload the information to the [online ethics form](https://bbk.onlinesurveys.ac.uk/final-ethics-form-22-23-law). After submitting the online form, you should download the PDF and email it to the School of Law Ethics Committee. You will then be informed that the research can proceed.

If the application is **not routine**, it will be reviewed by the School Ethics Committee and (where applicable) the College Ethics Committee. Once any stipulated amendments have been made and the application is approved by the Committee(s), you will be informed that you should now upload the information to the [online ethics form](https://bbk.onlinesurveys.ac.uk/final-ethics-form-22-23-law). After submitting the online form, you should download the PDF and email it to the School of Law Ethics Committee. You will then be informed that the research can proceed.

**Please note that it is a strict requirement for ALL ethics applications to be submitted via the online system before the research commences. This is crucial for GDPR reporting, and applies across ALL Schools of the College.**

**Further information**

Some guidance on ethics applications for research involving human participants, and on distinguishing between routine and non-routine applications, is provided below.

When completing the application, please also refer to the additional information on ethical research provided by the [College](http://www.bbk.ac.uk/committees/research-integrity/). For further guidance on the ethical conduct of research, see the British Psychological Society’s [Code of Human Research Ethics](https://cms.bps.org.uk/sites/default/files/2022-06/BPS%20Code%20of%20Human%20Research%20Ethics%20%281%29.pdf) and the British Sociological Association’s [Guidelines on Ethical Research](https://www.britsoc.co.uk/ethics).

If you have any questions about your ethics application form or the application process, please contact Professor Jessica Jacobson, the School of Law Research Ethics Officer.

**Research involving human participants – some ethical considerations**

Most ethics applications from School of Law staff or students are for research involving human participants. Key ethical considerations in relation to research with human participants include the following:

*Informed consent*

As a researcher, you should ensure that all participants in your research understand:

* The purposes of the study
* Why they have been asked to take part in the research
* What data you are collecting, and how
* In what forms, how and for how long the data will be held, and whether it will be archived
* The voluntary nature of participation and how they can withdraw from the study
* Provisions for anonymity and confidentiality, as applicable.

In most cases, you should use a written consent form, along with an information sheet, in order to obtain informed consent. See the template information sheet and consent form that accompany this document.

*Protection of participants’ health, safety and welfare*

Researchers are obliged to protect the physical, social and psychological wellbeing of their participants, to preserve their dignity and rights, and to safeguard their anonymity and confidentiality. Relevant considerations include:

* Vulnerability of participants (e.g. children, individuals with poor mental health, individuals with learning disabilities, individuals in any form of state detention) and implications for their capacity to provide informed consent
* Whether participation in the research (e.g. involving discussion of sensitive or painful topics or experiences) may cause distress, and methods of mitigating risks of distress, such as through careful framing of questions and the adoption of an empathetic & flexible approach
* Whether and how participants can be signposted to relevant support, before or after participation in the research
* Ensuring that no risks to physical safety arise through participation in the research
* Provision for reporting a participant’s disclosure of risk to themselves or others (arrangements for which should be reflected in the consent form).

*Anonymity and confidentiality*

Research participants must be assured that all information they give will be treated with the utmost confidentiality and that their anonymity will be respected at all times unless otherwise agreed or determined by law.

Where relevant, participants should be told about where information about them will be stored, who will have access to it, and what use will be made of it. Procedures for data storage must conform to the Data Protection Act.

Stated, explicit permission must be obtained for any non-confidential use of participant information. Express permission must also be obtained for access to specified information from confidential records such as medical notes or educational records. Where relevant, any limitations to confidentiality (e.g. obligations under law, or where there may be a threat to the participant or others) must be explained.

**Distinguishing between routine and non-routine research**

*Routine – i.e. research in line with normal disciplinary practice*

* research projects which so closely follow previous research already given ethical approval within the last 3-5 years (depending on disciplinary norms) that the ethical issues are identical and have already been considered (the clock does not restart each time an application is received; this timeline refers to the original application)
* projects that have less than minimal potential risk of harm to participants and others affected by the proposed research and this risk can be mitigated by following best practice already established within the discipline.

*Sensitive:*

* a research methodology which raises ethical questions but which has not been previously considered by the appropriate Ethics Committee
* a research methodology where participants are to be subjected to questions, or other procedures which carry a risk of being harmful to their physical or mental well being
* the research requires data from a set of participants who may not have the capacity to give informed consent, for example children and vulnerable populations
* the research involves groups where permission of a gatekeeper is normally required for initial access to members
* projects where there is a risk to the safety of the researcher in terms of their physical and mental wellbeing
* projects which involve international partners

*Extremely Sensitive:*

* the research involves (or might appear to involve) deception, or is conducted without participants’ full and informed consent at the time when the study is carried out
* the research involves access to personal information or confidential information on identifiable living individuals or the research combines existing datasets in a way where anonymised individuals might become identifiable
*note this point does not relate to all human participant research, just human participant research where there is a real risk that anonymity cannot be protected*
* all cases where the subjects of the research are members of the College (staff or students) or are closely related to members of the College
* all cases of predictable media interest or sensitivity
* all cases where there is a conflict of interest
* all cases where the veracity of source material cannot be readily checked (e.g. material from anonymous sources)
* all cases where there is a significant risk of reputational damage to the College (which includes a consideration of the source of funding for the research)
* all cases where the research team is undertaking security sensitive research. Security sensitive research includes research commissioned by the military or under an EU security call, research that requires the researchers to obtain security clearance or research into terrorist or extremist groups
* all cases where the research team need to access illegal materials
* all cases where the research team need to access extreme materials. In this case, extreme materials may refer to materials which are harrowing or distressing and/or to materials (such as extreme violence/pornography or materials which promote extreme political or religious views) which are not in themselves illegal but may be related to, or closely aligned to, illegal behaviours.

It should be noted that these are not exhaustive lists and all proposals should be considered from the perspective that they may be sensitive or extremely sensitive rather than from the presumption that the research is in line with normal disciplinary practice.

Guidance to complete the 22/23 ethics form

1. **Title of study.**

*Note: Please fill in the title of the project.*

Click or tap here to enter text.

1. **Person responsible for the study. If you are a student or research assistant/post doc, the person responsible for the study will be your supervisor. If you hold a personal fellowship you are responsible for the study.**

*Note: Question 2 and 3 are closely linked, question 2 asks who ultimately is responsible for ensuring that all data collection is undertaken correctly whereas question 3 asks who is actually collecting the data.*

Click or tap here to enter text.

1. **Name and role of person collecting data. if you are a student or RA/post doc please say name, UG/Masters/PhD student or RA/post doc.**

Click or tap here to enter text.

1. **Names of any co- applicants (Staff, PhD, Masters): Co-applicants (Staff, PhD, Masters) and their specific role (e.g. Staff, Masters, PhD, PI/CoI on grant etc). For team projects this may include undergraduate co-applicants. For grant funded research this may involve collaborators at other institutions.**

*Note: This question simply wants to know who else is working on the project.*

Click or tap here to enter text.

1. **Date of application.**

Click or tap here to enter text.

* 1. **When is data collection due to start?**

Click or tap here to enter text.

1. **Please list the email addresses of all applicants.**

Click or tap here to enter text.

1. **School.**

Click or tap here to enter text.

1. **Department.**

Click or tap here to enter text.

1. **If you are a student what is your programme of study?**

*Note: PhD students, post docs and academic staff do not need to complete this question.*

Click or tap here to enter text.

1. **Is your application routine or non routine?**

*Note: The College has three levels of classification for ethics – routine (which presents minimal risk of harm to participants or is analogous in terms of risks and methods to a project which has received ethics approvals in the last 3-5 years), Sensitive (which poses a greater risk of harm so requires scrutiny from the School Committee) and extremely sensitive (which requires scrutiny by the College Ethics Committee). If you are not sure which category applies, your supervisor and/or DREO can advise.*

Click or tap here to enter text.

1. **Is your research externally funded?**

Click or tap here to enter text.

* 1. **If yes, is the funder ESRC?**

*Note: ESRC define what they consider to be an appropriate level of ethics committee and only the College Ethics Committee meets these requirements. We therefore need to know that all ESRC-sponsored research has had the appropriate level of scrutiny.*

Click or tap here to enter text.

1. **Where will the data collection take place?**

*Note: Please select as many of the options given here as relevant: in a lab, on campus, in a participants home in the UK, in a public place in the UK, virtually within the UK, in a participants home outside the UK, in a public place outside the UK, virtually outside the UK.*

Click or tap here to enter text.

1. **Briefly (approx. 200 words) describe the purpose and rationale of the research, make the objectives of the study clear.**

*Note: The answer to this section should be written with a consideration of the ethical issues posed by the research objects and is therefore should be written specifically for this application.*

Click or tap here to enter text.

1. **Describe the methods and procedures of the data collection, please provide FULL information: Do not merely list the names of measures and/or their acronyms; summarize them briefly (e.g. Buss- Durkee Hostility Inventory: a standardized self-report measure of trait aggression). Include any information about any interventions, interview schedules, duration, order and frequency of assessments and so on. It should be clear exactly what would happen to participants.**

Click or tap here to enter text.

1. **Please list all instruments, materials and techniques described above and confirm they are attached (e.g. questionnaires, specific information about particular techniques such as EEG). These are in addition to the general information sheet about the study, the consent form, the protocol and any further necessary information such as a Data Management Plan.**

Click or tap here to enter text.

1. **Who will the participants be? Describe (a) the groups of participants that will be recruited; (b) the main inclusion and exclusion criteria; (c) make clear how many participants you plan to recruit into the study in total and (d) the expected age range of your participants.**

Click or tap here to enter text.

* 1. **Are there any potential conflicts of interest with your participants? A conflict of interest is a situation where personal or professional factors could affect - or could be reasonably assumed by an external party to have affected - your judgement in your research. In some situations a conflict of interest is unavoidable.**

*It is a part of undertaking your research ethically that potential conflicts of interest are declared.*

Click or tap here to enter text.

* 1. **Do you anticipate that you will recruit Birkbeck staff and/or students (or people closely related to Birkbeck staff and students) in your data collection?**

*Note: It is a part of undertaking your research ethically that potential conflicts of interest are declared.*

Click or tap here to enter text.

1. **Describe any potential risks to or adverse effects on the researcher who is collecting the data resulting from conducting the research and what measures have been taken to address them? Describe any discomfort or inconvenience that researchers may experience including distress resulting from the subject matter.**

**Include information about location of the study and when the study is taking place if this introduces possible safety risks to the researcher. Please ensure that your methods have a valid safety and risk assessment.**

Click or tap here to enter text.

1. **Describe any potential risks to or adverse effects on the participants resulting from participation and what measures have been taken to address them? Describe any discomfort or inconvenience that participants may experience. Include information about procedures that for some people could be physically stressful or might impinge on the safety of participants, e.g. noise levels, visual stimuli, equipment; or that for some people could be psychologically stressful or distressing, e.g. mood induction procedure, questions about sensitive or painful personal experiences.**

Click or tap here to enter text.

1. **Is there a possibility of a participant disclosing (or the researcher identifying) any issues of concern (e.g. legal, emotional, psychological health)? If yes please describe.**

Click or tap here to enter text.

1. **Describe the recruitment procedures for the study. Give details of how potential participants will be identified and/or recruited. Include all advertising materials (posters, emails, letters etc.) as appendices and refer to them as appropriate. Describe any screening and selection procedures (e.g. collecting SES information) and explain why they are necessary.**

Click or tap here to enter text.

1. **Describe the procedures to obtain informed consent. Describe when and how consent will be obtained. Give details of who will take consent and how it will be done. If you plan to seek informed consent from vulnerable groups (e.g. people with mental or physical health problems or learning difficulties, victims of crime, individuals in any form of custody or detention, those aged under 18), say how you will ensure that consent is voluntary and fully informed. Please note that taught students are not allowed to carry out research with vulnerable groups and/or on sensitive topics such as discrimination, bullying and harassment, whistleblowing.**

Click or tap here to enter text.

1. **Will consent be written?**

Click or tap here to enter text.

* 1. **If yes, will this be based on your school’s template consent form? (you will be required to provide a copy of the form)**

Click or tap here to enter text.

1. **What will participants be told about the study? Will any information on procedures or the purpose of the study withheld? If any information is to be withheld, justify this decision.**

Click or tap here to enter text.

1. **Will you provide a written information sheet? If yes, you will need to provide a copy.**

Click or tap here to enter text.

1. **Describe the procedures in place for making sure that participant personal information and data collected will be treated with confidentiality and their anonymity respected. Please list all people who will have access to the data. This description should include how you will protect your participants identity as you collect the data, as you analyse the data, and in anything you produce from the data such as a thesis, paper or other report for a third party. It should also consider how, and up to what stage, a participant may withdraw their data from the analysis. Please note, sharing raw data (i.e. data which has not been effectively anonymised) with an external organisation is not permitted unless a suitable data sharing agreement is in place and the necessary consents have been obtained from participants.**

Click or tap here to enter text.

1. **Will participants receive payments, expenses or other benefits and inducements?**

*Note: For many studies this question will not be relevant.*

Click or tap here to enter text.

1. **At the end of the study, what will participants be told about the investigation? Give details of debriefings, ways of alleviating distress that might be caused by the study etc.**

Click or tap here to enter text.

1. **Has the person carrying out the study had previous experience of all of the procedures to be used in the study? If not, who will supervise and/or train that person?**

Click or tap here to enter text.

1. **Describe what you have done to ascertain that you are not collecting more personal data than you need or data which is not pertinent to your research questions.**

*Note: Ethical research is rigorous and well though through. You understand why you are asking the specific questions to participants and how these questions will help to answer your research questions whether this is a single study or part of a longitudinal data set. You have thought through how to minimize the personal data you collect – for example you may not need an individual to give their name at the start of an interview for the data from that interview to still be relevant and you do not impose on your participants by asking them questions which are unlikely to be used in your final analysis.*

Click or tap here to enter text.

1. **Please briefly describe the nature of the personal data you will be collecting. Personal data is data which can make an individual identifiable or which when used in combination with other data can make an individual identifiable.**

*Note: GDPR defines personal data as any information relating to an identifiable person who can be identified, directly or indirectly, by reference to (for example) 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”.*

*Personal data can thus include someone’s name, their email address, their IP address, their name on their social media accounts etc. In addition, if different identifiers are put together to make someone identifiable when each identifier on its own protects their identity this also constitutes personal data.*

Click or tap here to enter text.

1. **How many participants will you be collecting personal data from?**

*Note: You should always look to minimize the amount of personal data you need to collect, whilst being mindful that your research needs to retain its rigour.*

Click or tap here to enter text.

1. **Are you recording personal identifying information other than on the consent form (such as recording an individual’s name at the start of an interview recording)?**

Click or tap here to enter text.

1. **Will you be using any software (e.g. Qualtrics, Nvivo) in processing your data? If so, please name the software.**

Click or tap here to enter text.

1. **Will any third parties (e.g. a trascription service, an external collaborator) be involved in processing the data prior to anonymisation? If yes, please say who the third party is and what data processing they will be doing.**

Click or tap here to enter text.

1. **Why do you need to record personal identifying information?**

Click or tap here to enter text.

1. **How long will personal identifying information be kept and why has this time period been selected? (until the end of the study or (for students) assessment, for a defined period, in perpetuity etc.)**

Click or tap here to enter text.

1. **How are you ensuring that personal identifying information will be kept separate from research data? (for example, hard copy consent forms only held in a locked filing cabinet with research data on a password protected hard drive).**

Click or tap here to enter text.

1. **Will you be uploading your anonymised data to an online repository?**

Click or tap here to enter text.

1. **If you are collecting any special category data then further legal considerations apply. Is any of the data you are collecting considered to be special category data? Specify all that apply.**

*Note: Special Category data is personal data which has some additional protections under GDPR law so we need to ask you some questions specifically about this data if you plan to collect it to make sure we are enabling you to undertake your research within the law. Special Category Data is:*

* *Personal data revealing racial or ethnic origin*
* *Personal data revealing political opinions*
* *Personal data revealing religious or philosophical beliefs*
* *Personal data revealing trade union membership*
* *Genetic data*
* *Biometric data for identification purposes*
* *Data concerning health*
* *Data concerning a person’s sex life*
* *Data concerning a persons sexual orientation*
* *Criminal offence data*

Click or tap here to enter text.

* 1. **Is the lawful basis for processing this special category data public task or legitimate interest? (public task relates to research undertaken as part of day-to-day activities for the college, legitimate interest applies when the research is sponsored by an external body)**

*Note: Under GDPR legislation, personal data can only be collected if there is a legitimate reason to collect it, and additional restrictions apply to special category data. This is called the lawful basis for processing the data.*

*Collecting personal data and/or special category data for research purposes is considered to have a lawful basis which applies to university research.*

*As a university, we undertake research as part of our charitable mission as a public body. As such the lawful basis for collecting and processing personal data or special category data is normally public task.*

*However, in some instances an external funder has sponsored research which is undertaken by members of the College. In these cases, the lawful basis is no longer public task. Instead it is legitimate interest (i.e. we would be in breech f a contract with the funder if we did not collect and process this data as described in the application).*

Click or tap here to enter text.

* 1. **I confirm that the appropriate Article 9 condition for processing the special category data applies. This data processing is in the public interest for scientific or historical research purposes or statistical purposes, and shall be subject to appropriate safeguards, in accordance with data protection regulations, for the rights and freedoms of the data subject. Those safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation.**

**Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner.**

*Note: This question is phrased in a legal-ese way but we are simply asking you to confirm that:*

*1) you are collecting this data for research purposes – this is “the appropriate Article 9 condition for processing special category data”*

*2) You have considered the number of people you need to collect special category data from and have sought to minimize this as much a is practical for the research you are doing*

*3) You will hold the data securely and take reasonable steps to ensure the security of the data following standard approaches used by the College – for example that the identity of your participants and the data that they have provided to you will be separated and held in different secure locations so that in the event one list is discovered it is not possible to determine what data was provided by whom – and you have considered if/when the link between the participants and the dataset can be broken to render the dataset fully anonymous.*

*And*

*4) You understand that once the dataset is fully anonymized it ceases to be considered as special category data.*

Click or tap here to enter text.

* 1. **The processing of special category data must not: cause substantial damage or distress to individuals; or support measures or decisions with respect to a particular individual, unless the purposes for which the processing is necessary include the purposes of ‘approved medical research’. The term ‘approved medical research’ has a specific definition in the DPA 2018 which includes medical research carried out by a person who has approval to carry out that research from— a research ethics committee recognised or established by the Health Research Authority; a relevant NHS body e.g. an NHS trust or NHS foundation trust; or United Kingdom Research and Innovation or a body that is a Research Council for the purposes of the Science and Technology Act 1965. Please describe any relevant safeguards you have in place about to ensure you adhere to these restrictions where they apply to your research.**

*Note: This question makes explicit that when collecting special category data the onus is on the researcher to ensure that the research does not cause substantive damage or distress to the participant that the data is being collected from.*

*It also makes explicit that where the research could lead a participant to make decisions about accessing (or not) medical interventions of any kind HRA ethics approval is required.*

*If you are collecting special category data and either of these two situations apply, or could potentially apply, you must describe the safeguards you have put in place to protect the participants.*

Click or tap here to enter text.

* 1. **If you are processing data of this type you must complete and supply a data management plan and this must be reviewed by our Research Data Support Manager. Have you done this?**

*Note: Because there are additional legal restrictions around special category data we require that and research where special category data is being collected has a complete Data Management Plan and that this is approved by the Research Data Support Manager before ethics approval can be granted. You should include a copy of the Data Management Plan and a copy of correspondence confirming that the Research Data Support Manager has approved the plan as part of your submission for ethics approval.*

Click or tap here to enter text.

* 1. **Have you included specific information about the processing of special category data in the information sheet for individuals involved in this project.**

*Note: It is a legal requirement that we inform any participants who will be providing special category data with detailed information about how we will use their data.This information will be informed by your Data Management Plan and should be included with your ethics approval paperwork.*

Click or tap here to enter text.

1. **A Data Protection Impact Assessment (DPIA) is a process to help you identify and minimise the data protection risks of a project. You must do a DPIA for processing that is likely to result in a high risk to individuals or for any other major project which requires the processing of personal data.**

**To assess the level of risk, you must consider both the likelihood and the severity of any impact on individuals. High risk could result from either a high probability of some harm, or a lower possibility of serious harm.**

**For projects where the risk is lower, a data management plan should be sufficient.**

**For projects which have a low or very low risk of severe impact on individuals the information provided in the ethics application should be sufficient.**

**Which level of data management do you think is appropriate for this project?**

**Why?**

*Note: A Data Protection Impact Assessment (DPIA) is a requirement when there is a high risk of significant harm from the data processing being undertaken for research.*

*It is a significant undertaking to complete a DPIA, often taking several months, and these are more normally required for large complex projects or specific areas which house multiple projects (for example the baby and toddler labs).*

*A Data Management Plan is a document which sets out in detail how the collection, storing and processing of research data will be undertaken and is sufficient for projects with a lower risk of harm but where the risk is still substantive.*

*For projects where the risk of harm to participants is low the information about data management in the ethics application should be sufficient.*

*In this question we are asking you to confirm which level of data approval you think you need and why so we can ensure you are complying with your duties under data protection law.*

Click or tap here to enter text.

1. **Are any risk assessments required for this research?**

*Note: Similarly to the Data Protection case, you have some duties under Health and Safety law in terms of assessing risk. The form sets out when a risk assessment may be required, and we are simply asking you to confirm whether or not a risk assessment is required based on your reading if that information.*

Click or tap here to enter text.