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# RESEARCH ETHICS PROCEDURES

December 2016

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## RESEARCH ETHICS PROCEDURES

### Acknowledgments

The 2012 review of the Policy and Procedures for Research Ethics at the University drew heavily on a number of publicly available sources, with many contributions from these sources incorporated with aspects of the previous policy and procedures to produce the University's Research Ethics Policy and Procedures:

- King's College London, [www.kcl.ac.uk/innovation/research/support/ethics/about/index.aspx](http://www.kcl.ac.uk/innovation/research/support/ethics/about/index.aspx)
- Economic & Social Research Council Framework for Research Ethics, [www.esrc.ac.uk](http://www.esrc.ac.uk)
- National Children's Bureau (research section), [www.ncb.org.uk](http://www.ncb.org.uk)
- NHS Health Research Authority, [www.hra.nhs.uk/research-community/](http://www.hra.nhs.uk/research-community/)

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<i>Abbreviations used</i>	
DoS	Director of Studies
LREC	Local Research Ethics Co-ordinator
URESC	University Research Ethics Sub-committee

### *Research Supervisor and Director of Studies*

Where 'Research Supervisor' is used in this document, this would also refer to the 'Director of Studies' for research students.

### *December 2016 update*

This updated document reflects the changes from Faculty to School oversight in the research ethics processes in 2016-17, as Faculty Research Ethics Committees ceased to exist from 1 September 2016.

These Procedures describe the new process of review by a School level research ethics group, however, if your School does not have a such a group, please follow your individual School's guidance.

## RESEARCH ETHICS PROCEDURES CONTENTS

1.	WHICH RESEARCH PROJECTS NEED ETHICAL APPROVAL? .....	1
2.	RESEARCH ETHICS APPLICATION PROCESS.....	1
3.	OVERVIEW OF THE PROCESS AND DIFFERENT LEVELS OF ETHICAL APPROVAL .....	1
4.	WHAT DO I NEED TO DO AND WHAT ARE THE ROLES OF STUDENTS AND STAFF? .....	2
4.1	THE RESEARCHER.....	2
4.2	RESEARCH SUPERVISORS .....	2
4.3	RESEARCH MODULE LEADERS .....	2
4.4	LOCAL RESEARCH ETHICS CO-ORDINATORS.....	2
4.5	SCHOOL LEVEL GROUP .....	3
5.	WHAT HAPPENS IF DATA COLLECTION IS CARRIED OUT WITHOUT ETHICAL APPROVAL FOR THE PROJECT? .....	3
5.1	STUDENTS .....	3
5.2	STAFF .....	3
6.	HOW DO I APPLY FOR ETHICAL APPROVAL? .....	3
7.	OUTCOMES FROM COMPLETION OF THE RISK CHECKLIST .....	3
8.	WHAT HAPPENS AFTER SUBMITTING MY APPLICATION? .....	5
9.	MAKING CHANGES TO APPROVED STUDIES .....	6
10.	RESEARCH ETHICS PROTOCOLS.....	6
11.	LEARNED SOCIETIES.....	6
12.	INSURANCE AND INDEMNITY COVER .....	6
13.	RISK ASSESSMENTS .....	7
14.	SUMMARY OF THE ETHICAL APPROVAL PROCESS FOR STUDENTS AND STAFF APPLICATIONS.....	8
	<b>GUIDANCE APPENDICES.....</b>	<b>10</b>
A.	DATA SECURITY, RECORDS MANAGEMENT AND DATA RETENTION .....	11
B.	RESEARCH WITH CHILDREN AND YOUNG PEOPLE .....	13
C.	RESEARCH THAT MAY CAUSE PHYSICAL OR PSYCHOLOGICAL HARM OR NEGATIVE CONSEQUENCES.....	14
D.	RESEARCH THAT INVOLVES INTRUSIVE OR INVASIVE PROCEDURES .....	15
E.	LOCATION OF RESEARCH .....	16
F.	RESEARCH, AUDIT, SERVICE EVALUATIONS AND SECONDARY DATA ANALYSIS AND ETHICAL APPROVAL .....	17
G.	HEALTH RESEARCH AUTHORITY / NHS RESEARCH ETHICS COMMITTEES .....	18
H.	SECURITY-SENSITIVE RESEARCH .....	19
I.	GUIDANCE FOR COMPLETING YOUR APPLICATION .....	20
J.	SUPPORTING DOCUMENTATION GUIDANCE .....	33

## 1. Which research projects need ethical approval?

All *research projects*, including undergraduate major independent study projects at level 6, postgraduate projects, and staff projects, however straightforward, must be submitted for review and be approved prior to data collection.

All staff and students of the University who wish to undertake a research project involving human participants (i.e., research with or about people) must obtain ethical approval before commencing their research.

Studies involving further analysis of existing data may require ethical approval, depending on whether or not the nature of the data are sensitive or if individuals can be identified from the research. Please see the specific guidance appendix detailing when ethical approval is required for research studies involving further analysis of pre-existing data. Audits or service evaluations will normally require ethical approval. Please see the specific guidance appendix on such studies.

## 2. Research ethics application process

The online research ethics application system is available on these links.

Students: [www.leedsbeckett.ac.uk/studenthub/research-ethics.htm](http://www.leedsbeckett.ac.uk/studenthub/research-ethics.htm)

Staff: <https://www.leedsbeckett.ac.uk/staffsite/services/university-research-office/research-ethics/>

This Procedures document includes:

- An overview of the process of ethical submission, review and approval.
- The Risk Checklist and the ethical questions in the application process, together with guidance on completion of the questions.

## 3. Overview of the process and different levels of ethical approval

There are different levels of approval for staff and students whose research projects require ethics approval by the:

- Research Supervisor or Director of Studies ('Supervisor approval')
- Local Research Ethics Co-ordinator (LREC) ('Local level approval')
- School level approval
- University Research Ethics Sub-Committee (URESC) ('University level approval')

The level of approval required is dictated by the level of risk associated with the proposed research project. All staff and students undertaking research within or on behalf of the University are therefore required to complete the Risk Checklist to establish the risk level of the project. Once the level of risk is determined, researchers may also be required to provide more information – the online system will guide applicants through this process.

The Research Ethics Policy and relevant sections of the Research Ethics Procedures must be read before submission of an application and you will need to confirm you have done this and that you agree to adhere to the University's Research Ethics Policy and Procedures before the online system allows an application to be submitted.

In addition to ethical approval from the University, researchers may require other ethical approval depending on the type of project, e.g.:

- Researchers may be required to comply with ethical requirements from other bodies external to the University, such as the Health Research Authority and NHS Research Ethics Committees. See the guidance appendix on projects falling under the remit of these committees.

- If the research is being undertaken outside of the UK, approval from a committee within the host country may be required.
- For collaborative research, researchers should also check whether they need additional ethical approval such as approval from a collaborator's own university or organisation.

## 4. What do I need to do and what are the roles of students and staff?

### 4.1 The Researcher

The researcher (student or staff member) is responsible for the following:

*Prior to commencing the research project:*

- Ensuring they discuss the project with their Research Supervisor or Director of Studies if they are a student and with an LREC if they are staff, prior to seeking ethical approval;
- Completing the application for approval;
- Ensuring compliance with any other and/or additional requirements (such as those defined by the NHS, the law of the country within which the research is taking place, research collaborator(s) or any other relevant organisation or body);
- Obtaining ethical approval before any data collection commences for the project.

*Throughout the research/research project:*

- Operating in an ethical manner with due regard to the ethical considerations and challenges relevant to the research project;
- Operating within the provisions of the ethical approval granted;
- Ensuring that where the scope of the research project changes, that such changes are discussed with their Supervisor (for students) or LREC (for staff) to ensure the ethical approval they have been granted remains appropriate.

*Following completion of the research:*

- Ensuring data is stored securely and retained/destroyed in accordance with the Data Protection Act and the University's Records Retention Schedule;
- Ensuring dissemination of the findings is appropriate in terms of anonymity and confidentiality.

### 4.2 Research Supervisors

All student research projects should be discussed with the Research Supervisor or Director of Studies prior to submission for ethical approval. A formal application is then made to the Supervisor with the submission of the project's details for ethical approval. All Research Supervisors have the appropriate experience and expertise to effectively supervise students to successful completion according to the level of their programme of study or course and will be familiar with the policy and procedures for gaining ethical approval for projects.

### 4.3 Research module leaders

Research module leaders will advise students on the ethical approval processes and deadlines for obtaining approval, will monitor the ethical decisions made for a cohort, and will advise on the penalties for carrying out research without ethical approval in the research module handbooks.

### 4.4 Local Research Ethics Co-ordinators

LRECs are academic staff who have experience and expertise in reviewing submissions for ethical approval. They do this as representatives of the School level group, for research that is low risk in their specific area of expertise and they usually sit on their School level group to jointly consider higher risk, more complex submissions.

#### **4.5 School level Group**

Each School normally has a research ethics review group and a number of designated LRECs who are members of the group. The names of these groups vary across schools. Applications for ethical approval for higher risk, more complex research projects are considered by these groups. Applicants (and their Supervisors for student applicants) may be invited to meet the Group when the application is considered to discuss aspects of their submission to help the Group reach an appropriate decision in a timely fashion, and to assist applicants in their understanding of the Group's view of their submission. If a student and Supervisor are from different Schools then the procedures for the student's School should normally be followed.

If your school does not have a School level group, please follow your School's guidance.

### **5. What happens if data collection is carried out without ethical approval for the project?**

#### **5.1 Students**

Any attempt to gain an unfair advantage, whether intentional or unintentional, is a matter of academic judgement and may be considered to be unfair practice. Examples of unfair practice include, but are not limited to, non-compliance with the University's Research Ethics Policy and Procedures, failure to gain ethical approval for relevant submitted work, cheating, plagiarism, self-plagiarism, collusion, ghostwriting and falsification of data. Definitions of these offences and the serious consequences of unfair practice can be found in our Academic Principles and Regulations, **Academic Integrity section:** <https://www.leedsbeckett.ac.uk/public-information/academic-regulations/>

#### **5.2 Staff**

Staff who do not obtain appropriate ethical approval for their research may not be allowed to publish their research and may be subject to the University's staff disciplinary processes: see [Policy & Procedures for Investigating Allegations of Misconduct in Research](#).

### **6. How do I apply for ethical approval?**

The researcher (student or staff member) who is conducting the project must apply online. All applications from students and staff begin with completion of the Risk Checklist and the resulting questions. The online system guides applicants through the process.

This Procedures document includes an overview of the process of ethical submission, review and approval. The Guidance section on the Risk Checklist, together with the Research Ethics Policy and Procedures, must be read before completion of the Checklist and submission for ethical approval and you will be required to tick a box in the application to confirm you have done this and that you agree to abide by the University's Research Ethics Policy and Procedures.

### **7. Outcomes from completion of the Risk Checklist**

The first part of the application process is completion of the Risk Checklist. Depending on the answers, the project will be provisionally classified as Risk Category 1, 2 or 3. The online system will guide you through the process and the appropriate section to complete.

Category	Student applicants	Staff applicants
<b>Risk Category 1</b>	If your study has been provisionally classified as Risk Category 1, your Research Supervisor (or Director of Studies) can normally give approval for the project.	If your study has been classified as Risk Category 1, you do not need ethical approval for the project.
<b>Risk Category 2</b>	<p>If your study has been provisionally classified as Risk Category 2, your Supervisor (or Director of Studies) can recommend approval for your study by the LREC.</p> <p>Your Supervisor may disagree with your assessment and ask you to make revisions or reject your application. When the Research Supervisor is happy to recommend the application for approval, they will send the forms to the LREC.</p> <p>The LREC will review your project and then decide to approve it, ask for revisions, reject it or pass it on for review by the School level group.</p>	<p>If your study has been provisionally classified as Risk Category 2, your project will be considered for ethical approval by the LREC.</p> <p>The LREC will review your project and then decide to approve it, ask for revisions or pass it on for review by the School level group.</p>
<b>Risk Category 3</b>	<p><b>Postgraduate Research Students</b></p> <p>If your study has been provisionally classified as Risk Category 3, your Supervisor or Director of Studies can recommend approval for your study by the LREC.</p> <p>If your Director of Studies recommends approval of your project they will refer it to the LREC who will review your project and decide whether to grant ethical approval, request revisions, reject the application or refer it to the School level group for review.</p> <p><b>Undergraduate and Taught Postgraduate Students</b></p> <p>If your study has been provisionally classified as Risk Category 3, you should consult with your Research Supervisor immediately as it is unlikely you will be able to proceed and you should negotiate a project that is of lower risk. However, if you have already discussed the project with your Supervisor and they have agreed that a case for approval is warranted, proceed in line with the details above for Research Students.</p>	<p>If your study has been provisionally classified as Risk Category 3, your project will be considered for ethical approval by an appropriate LREC.</p> <p>The LREC will review your project and then decide to approve it, ask for revisions or pass it on for review by the School level group.</p>
<b>Q23</b>	If question 23 has been answered 'yes', your application will be reviewed by the Chair of the University Research Ethics Sub-committee. The answer does not affect the Risk Category.	



## 8. What happens after submitting my application?

For all applications submitted to LRECs or the School level group, if adequate information has been submitted the application will be reviewed and you will be notified with a decision as soon as possible. The decisions are categorised as follows:

Decision	Details
<b>Approved</b>	<p>The application is satisfactory and needs no amendment. The researcher can commence data collection.</p> <p>The LREC, the School level group or the University Research Ethics Sub-committee may give recommendations or comments for consideration by the applicant.</p>
<b>Revisions required</b>	<p>‘Revisions required’: these could include, e.g.,</p> <ul style="list-style-type: none"> <li>• Providing more information.</li> <li>• Submitting further supporting documentation.</li> <li>• Revising responses to the questions in order to answer any queries of the reviewer/s.</li> <li>• Clarifying processes not clear to the reviewer/s.</li> <li>• Where details of primary/major aspects of the study to be reviewed have not been submitted or are present in supporting documentation but not mentioned in the application, or these is a substantial amount of information missing.</li> <li>• Where there are no or insufficient details regarding recruitment.</li> <li>• Where the aims/purpose of the study and the methodology/data analysis are not fully understandable.</li> <li>• Where there is no Participant Information Sheet and/or consent form; where the Information Sheet or consent form is not understandable to its target participants; or the Information Sheet and/or consent form do not contain key information for the participants.</li> <li>• When a project should have been submitted to an NHS or other external Research Ethics Committee first for approval.</li> </ul> <p>For projects considered by School level group, applicants will normally have the opportunity of one further submission only.</p> <p>Once the revisions have been submitted, the project can be approved (with or without recommendations/comments) or may be rejected if the revisions are not satisfactory, and the project remains ethically unsound.</p>
<b>Rejected</b>	<p>The study is deemed unethical and a resubmission is not allowed (this may be after an application has been submitted twice).</p>

## 9. Making changes to approved studies

Further approval may be required if you wish to make significant changes to an approved study, and you must consult with your Research Supervisor (for student applicants) or LREC (for staff applicants), in case a revised application should be submitted.

## 10. Research ethics protocols

Following the introduction of the University Research Ethics Policy and Research Ethics Procedures, schools have been asked to develop (short) ethical guidance which is specific to their areas of teaching and expertise. It is hoped that this will form a reference point for staff when advising students on their research projects. Protocols can also be produced for:

- Areas or topics which regularly raise queries in the School which are not addressed specifically in the Research Ethics Policy or the Research Ethics Procedures.
- Commonly occurring situations, such as research with children or young people in some subject areas, or research involving a physical intervention, so the applicant can confirm that there is an approved protocol that appropriately covers the ethical issues raised by their research, so allowing for local rather than school level approval.

Protocols should result in approval processes that are robust and research which adheres to the University Research Ethics Policy. If a protocol has been used for a research project, reference must be made to this in the application.

## 11. Learned Societies

The Research Ethics Policy (A2.4.3) states that researchers must ensure their proposed research projects follow the ethical guidelines of an appropriate learned society recognised by their School. Schools are responsible for identifying appropriate learned societies with ethical guidelines. During the application process you will be asked to name the appropriate learned society for the project. Your Supervisor (for student applicants) or LREC (for staff applicants) will be able to advise you on your School list.

## 12. Insurance and indemnity cover

While insurance and indemnity cover is in place for University student and staff research projects based in the UK that receive ethical approval, some projects will require individual confirmation of cover from the University's Insurance & Risk Officer before data collection commences. These projects would include **clinical trials, projects involving an invasive procedures and certain projects undertaken outside of the UK (see Guidance Appendix E for more details of these projects)**. These should be discussed with the Insurance & Risk Officer prior to submission of the research ethics application and confirmation of cover should be included in the supporting documentation.

Please note:

- A project is required to have the appropriate level ethical approval confirmation before any data collection commences in order to have insurance and indemnity cover (retrospective approval is not allowed).
- It is not ethical to carry out research without insurance and indemnity cover.

### 13. Risk assessments

Some types of research projects may require a risk assessment to consider health and safety issues (the risk assessment should not be confused with the Risk Checklist for research ethics). Risk assessment is the responsibility of your subject area and you need to be aware of what your subject area's requirements are.

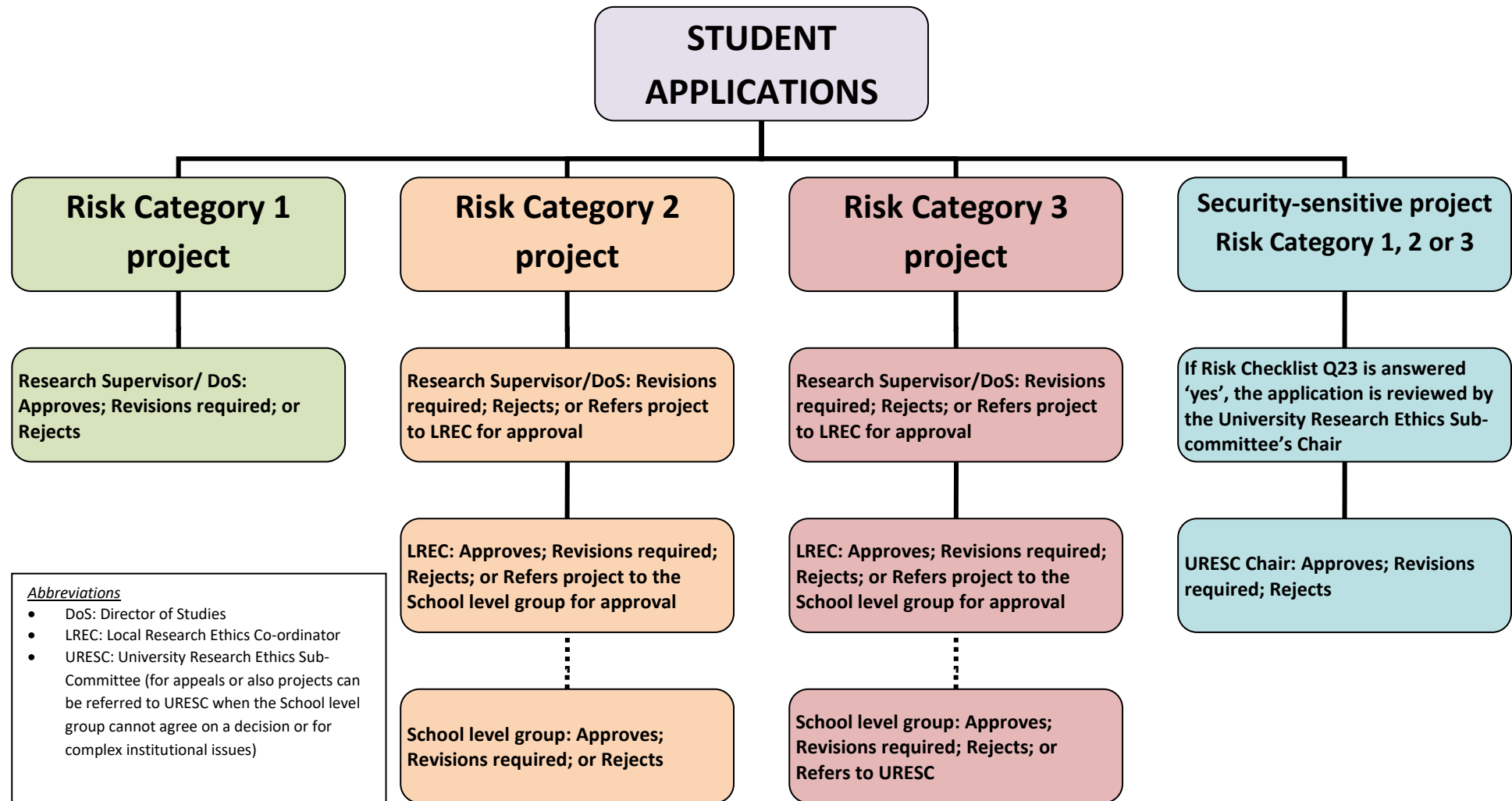
If the conduct of research puts participants and/or the researcher at risk then an appropriate risk assessment must be undertaken before data collection commences and this must show that risks are being managed effectively. If your project involves any of the following, you would normally need to undertake a risk assessment before commencing data collection (these are examples and not a definitive list):

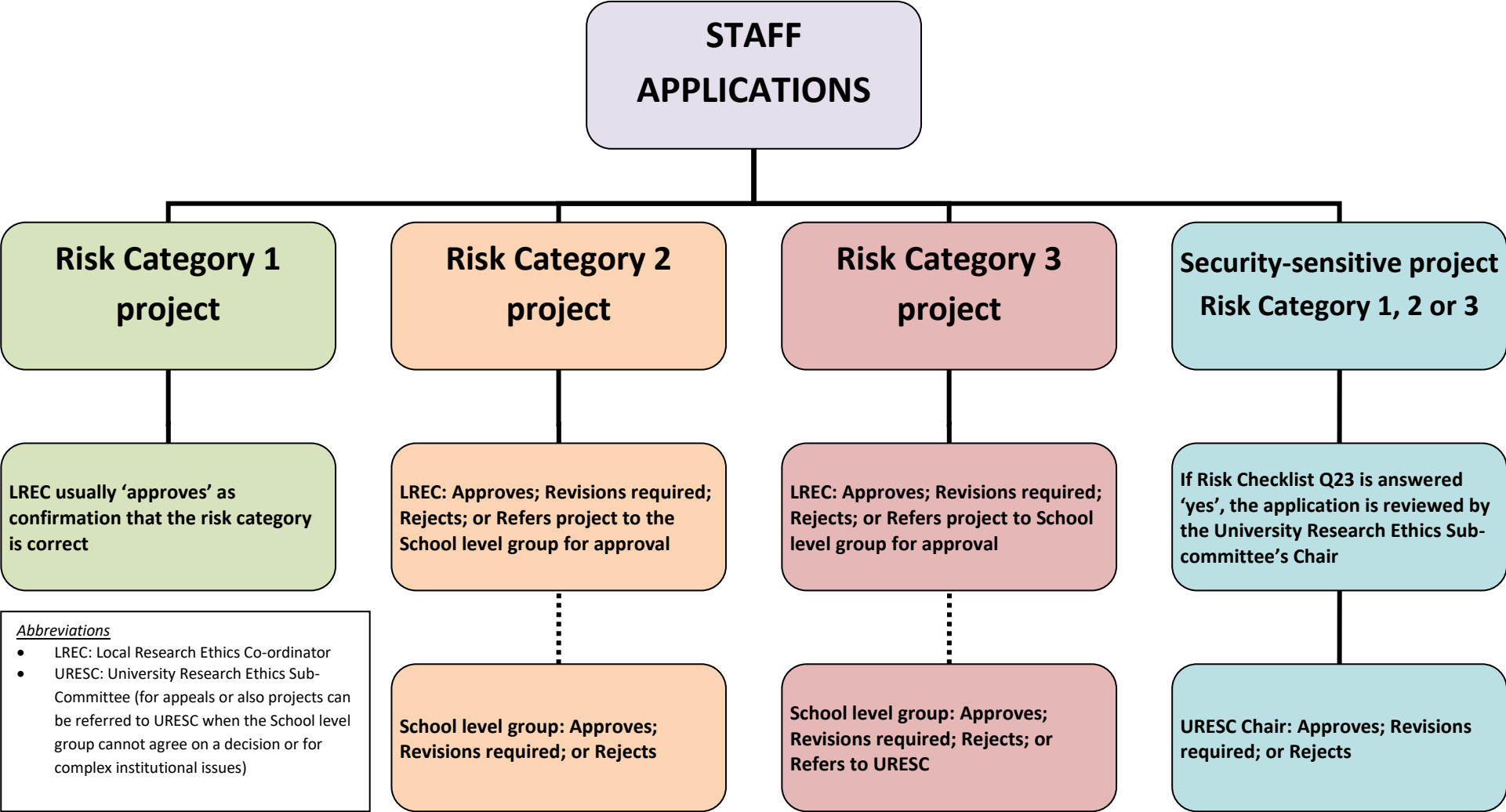
- If the study places the participants or researcher at any risk greater than that encountered in their daily life (e.g., research work undertaken alone or off campus);
- Data collection outside of the country where the student is enrolled;
- The administration of food substances;
- Invasive procedures, or physical or psychological interventions.

When you do submit a risk assessment form with your research ethics application, this should have been reviewed and approved by your Research Supervisor or Director of Studies.

Please note that although you may produce a risk assessment in support of your application for research ethics, the granting of ethical approval does not constitute confirmation that you are fully compliant with the requirements of Health and Safety Legislation. You should make further checks with those who are 'competent' to make such judgements to ensure that this is the case. If you have any queries about this, please contact your School Safety Health and Wellbeing Co-ordinator.

14. Summary of the ethical approval process for students and staff applications





## **GUIDANCE APPENDICES**

## A. Data security, records management and data retention

For all projects, see the Research Ethics Policy section A3.3 regarding data storage and retention. The following points should be considered in research ethics applications.

### Data security and records management

- The researcher needs to make reference to their duties under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018. Has the processing of the data been considered and has the issue of the sensitivity of the data been considered in relation both to data protection and general lawfulness?
- What steps will be taken to ensure the confidentiality and/or anonymity of personal information? Give details of anonymisation procedures and of physical and technical security measures. Any identifying data need to be removed in addition to names. Personal data held on mobile devices must be encrypted.
- Who will have access to personal information relating to the study? Confirm that any necessary wider disclosures of personal information (e.g., to the Research Supervisor, translators, transcribers, etc) have been properly explained to participants.
- The student or staff researcher (and for student projects, the Research Supervisor) must take responsibility for ensuring appropriate storage and security for project information including research data, consent forms and administrative records and, where appropriate, confirm the necessary arrangements will be made in order to process copyright material lawfully.
- Provide a specific location at which research data will be stored during the project.

### Data retention

- What provisions have been considered for the secure retention of sensitive or personal data? State how long study information including research data, consent forms and administrative records will be retained, what format the information will be kept in and where the data will be stored.
- Any personally identifiable data that is held on any mobile device should be encrypted. This includes data stored on USB memory sticks, laptop/netbooks, pcs, smart phones, servers and emails.
- Where results are collected individually, but the outcomes are anonymised, what data protection procedures are in place to ensure the protection of personal details and at what point and how will these be destroyed?
- A web link will be provided here to the University's [Records Retention Schedule](#) when this is finalised.

### The General Data Protection Regulation (GDPR) and the Data Protection Act 2018 and sensitive personal data

To ensure compliance participants must be informed about what information will be held about them and who will have access to personal, identifiable information. For sensitive personal data, participants must provide consent with the following statement on the consent form:

*'I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be treated in accordance with the terms of the General Data Protection Regulation (GDPR) and the Data Protection Act 2018.'*

The Act classifies sensitive personal data as consisting of information to the following:

- data relating to a person's racial or ethnic origin;
- political opinions;
- physical or mental health condition;
- sexual life;
- religious beliefs or other beliefs of a similar nature;
- membership of a trade union;
- any proceeding for any offence committed or alleged to have been committed by the participant.

General Data Protection Regulation: <https://www.gov.uk/government/publications/guide-to-the-general-data-protection-regulation>

Data Protection Act 2018: <http://www.legislation.gov.uk/ukpga/2018/12/contents/enacted>

University Data Protection Policy: <https://www.leedsbeckett.ac.uk/public-information/student-regulations/>



## **B. Research with children and young people**

**ALL research with young people below the age of 16 years must be discussed with your Research Supervisor or Director of Studies in the first instance (who will then discuss this with a Local Research Ethics Co-ordinator) (student applicants), or the LREC (staff applicants), prior to completion of the Risk Checklist.**

For research involving child participants the researcher must always ensure that the best interests of the person is the primary concern. Researchers must consider the following issues: children have the right to be properly informed and where possible, their fully informed consent must be obtained and checked as appropriate throughout the research study. It is recognised that whether a child under the age of 16 is considered as 'vulnerable' depends on several factors such as the child's circumstances, their susceptibility to coercion or feelings of obligation, the type of research being undertaken and how the research is being undertaken. Researchers must therefore take all of these factors into consideration when assessing whether child participants under the age of 16 should be deemed as 'vulnerable' and thus whether they need to tick 'yes' or 'no' on the Risk Checklist.

In situations where a child is too immature or vulnerable to give such consent or where any other circumstances may limit the extent to which this can be obtained from him or her, the researcher must seek the support and approval of those who are caring for the child (assent should be obtained from younger children as appropriate). Any legal requirements in relation to those responsible for the child must be adhered to. Also steps must be taken to put such individuals or organisations at their ease. If any distress occurs, the research process must immediately be halted.

It is therefore recognised that some research studies with young people will require consideration at school level and others may not. Careful consideration of projects involving young people remains a key requirement of the ethics procedures and LRECs have the discretion to make decisions on what level of approval is required on a project by project basis.

Schools are empowered to produce school-specific protocols for research involving children and young people, which take into account different local factors, such as students on courses providing a professional qualification related to under 16 year olds.

For all projects involving children and young people, researchers are recommended to refer to the guidance for researchers produced by the National Children's Bureau.

## **C. Research that may cause physical or psychological harm or negative consequences**

Any study that may cause harm to the participants or researchers because they are conducting the research study must be carefully considered in the first instance by an appropriate Local Research Ethics Co-ordinator. LRECs will take into account the context in which the research is being out, for example, the specific nature of the study, who the participants are and the experience and expertise of the research team. Physical harm and psychological harm might be related to procedures such as:

### **MRI scans or ultrasound**

If your study involves medical imaging techniques such as MRI scans or ultrasound, then you should consider the additional ethical implications of such procedures. This includes the safety implications of your chosen scanning technique and the potential for distress due to the scanning procedure itself.

### **Use of ionising radiation**

Research projects involving ionising radiation exposure to participants must be conducted in accordance with the Standard Operating Procedures under Ionising Radiation (Medical Exposure) Regulations 2000 IR(ME)R. All research studies conducted in the UK that involve exposure to ionising radiation (e.g., diagnostic X-rays, CT scans, DXA scans, Radiotherapy and Radionuclide imaging) or the administration of radioactive substances must be ethically reviewed by an NHS Research Ethics Committee (see the Guidance appendix on the National Research Ethics Service and NHS Research Ethics Committees).

If participants will be exposed to ionising radiation, separate approval documentation must be submitted with the application. This can be downloaded from the Research Ethics web page.

### **Psychological stress, humiliation or negative consequences**

Examples of procedures that might fall into this category include: discussing past traumatic events with a participant that could potentially induce 'flashbacks' or deterioration in mental health; interventions designed to alter or investigate self-harming behaviours or negative self-image; the potential for disclosures being made to friends/family of the participants.

### **Research in sensitive areas**

Examples of sensitive areas might include: studies which investigate children's understanding or experiences of sexual activity; research into criminal or illicit activity, e.g. drug use or sex working. *Note that there are separate procedures for research in security-sensitive areas.*

### **Insurance and indemnity cover for projects that may cause harm**

Projects that may cause harm or negative consequences may require individual insurance and indemnity cover confirmation – check if in doubt with the Insurance & Risk Officer.

## D. Research that involves intrusive or invasive procedures

**Use intrusive or invasive procedures:** Any study that involves intrusive or invasive procedures must be carefully considered in the first instance by an appropriate Local Research Ethics Co-ordinator. They will decide if the application needs to be considered at school level.

Giving food or food based products or legal substances in recommended doses are not considered as an intrusive or invasive procedure and are normally Category 2 risk.

### **Physically invasive procedures**

If your study involves the use of human tissue, please seek guidance and check whether your study requires approval from an NHS Research Ethics Committee.

**Note: The University does not currently have a licence for storage of human tissue, so it is crucial that guidance is obtained prior to applying for ethical approval for any study that involves the collection, storage and analysis of any form of human tissue.**

Moderately invasive procedures include the following routine procedures for trained researchers working under appropriate conditions: taking less than 40ml blood, collecting bodily waste, and taking cheek swabs.

It is expected that simple measures will be taken to manage the sorts of risks presented by these types of procedures which are likely to be standard processes routinely used in specific parts of the University. The researcher will be expected to detail measures taken within the application for ethical approval and the participant information sheet. It is expected that safety (including exclusion criteria), storage, potential for pain, discomfort or embarrassment, and procedures for dealing with adverse effects will be covered.

More invasive, intrusive or potentially harmful procedures which are not routinely undertaken must be identified for all such complex projects. Example procedures include muscle biopsies, taking more than 40ml of blood during the course of the study and electrical stimulation. Some techniques may be covered by normal risk management procedures within faculties, while others may require special management procedures to be agreed within the School (in which case these should be detailed within the application).

### **Insurance and indemnity cover for projects involving invasive procedures**

Projects involving invasive procedures may require individual insurance and indemnity cover confirmation – check with the Insurance & Risk Officer.

## E. Location of research

Where the researcher is based at the University but conducting research outside of the UK, or in the case of collaborative research with international institutions, the researcher should, where possible, refer to international guidelines for the country where the research is being carried out in addition to applying for approval within the University. In cases where ethical or legal permissions are required from local organisations or gatekeepers, it is the researcher's responsibility to ensure that these have been obtained prior to commencing the study.

For the research ethics application, the following information must be included:

- Is the proposal in accordance with the laws of the country/countries in which it is proposed that the investigation will take place?
- Does this include compliance with local laws on Data Protection and Intellectual Property?

Specific details will be required to assure the reviewer/s that this has been done with due diligence.

### **The International Compilation of Human Subject Research Protections**

<http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html>

The International Compilation of Human Research Standards was compiled by the Office Human Research Protections, United States Department of Health and Human Services and gives listings for Research Ethics Committees in over 100 countries.

### **Insurance and Indemnity Cover and research outside of the UK**

Research conducted outside of the UK that has received research ethical approval in the University, is covered by the University's worldwide Public Liability policy.

However, certain invasive research such as healthcare or therapy may need to be agreed by the University's Insurance and Risk Officer to ensure no further endorsement to the policy is required, especially in North America, or that Professional Indemnity is not required.

Further, should the Foreign and Commonwealth Office (FCO) advise only essential or against all travel to a specific destination, our Travel and Injury policy may not cover you and your project and you should discuss with the Insurance and Risk Officer, Martin Watson, [m.watson@leedsbeckett.ac.uk](mailto:m.watson@leedsbeckett.ac.uk), ext 23454.

## **F. Research, audit, service evaluations and secondary data analysis and ethical approval**

### **When is ethical approval required?**

The University requires all research projects undertaken by staff or students to undergo ethical review.

Sometimes an external funder, participating organisation or other body involved in the study may require evidence of ethical approval as a condition of their collaboration (even when the study is not deemed to be research). When this is the case you should contact your LREC so they can advise on requirements.

### **What is the definition of 'research'?**

While there is no universally agreed definition of 'research' we have chosen to use the following definition:

*Research is a form of disciplined enquiry which aims to contribute to a body of knowledge or theory.*

This does not normally extend to general coursework assignments, but does apply to final year undergraduate dissertations or projects.

### **Audit**

Audit is defined as assessing the level of service being provided against a set of predetermined standards. This generally involves analysing existing data with results usually being used/distributed locally in order to effect change to improve/change the level of service currently being provided. Such audits do not generally require ethical approval, but if you are not sure seek guidance from a Local Research Ethics Co-ordinator.

### **Service evaluation**

Service evaluation is undertaken to benefit those who use a particular service and is designed and conducted solely to define or judge current service. Participants will normally be those who use the service or deliver it. It involves an intervention where there is no change to the standard service being delivered (e.g., no randomization of service users into different groups). These may not require ethical approval.

### **Secondary analysis of service evaluations data**

It is possible to use data collected from participants during a service evaluation that did not receive ethical approval or a completed research study that did receive appropriate ethical approval for later research in the form of secondary analysis as long as:

- The data is completely anonymous when provided to the researcher
- It is not possible to identify participants from any resulting report
- Use of the data will not cause damage and distress

Secondary analysis of existing data sets is therefore a possibility for undergraduate student major independent studies. However, if you are unsure whether you may require ethical approval because of the nature of the data please check with your Supervisor if you are a student, or an LREC, if you are a member of staff.

### **Summary**

Ideally all projects should be logged on the online application system – audits and service evaluations may fall into Risk Category 1 depending on your answers to the checklist questions.

## **G. Health Research Authority / NHS Research Ethics Committees**

Some projects may be required to comply with ethical requirements from an NHS Research Ethics Committee and/or require NHS R&D permissions. If researchers are uncertain, or need guidance on how to do this, they are advised to check the specific guidance on the above links, or consult an appropriate LREC with the relevant experience in their School.

### **Approval within the University**

Once ethical approval has been received, the project will require ethical approval in the University. Compliance with the requirements of the NHS Research Ethics Committee, with submission of the associated application documentation to that Committee and letter of approval, together with a covering letter outlining compliance with associated issues within the University (e.g., governance, consents and permissions, data storage, liability and insurance, risk assessment, etc.) may be sufficient in seeking approval within the University, but seek guidance on this for your particular project. Depending on the risks involved, the project may be approved by the LREC or require school level approval.

## H. Security-sensitive research

The research ethics process has been expanded to include a declaration of research in security-sensitive areas, including terrorism. The general ethical justification for doing this is straightforward: unauthorised acquisition and use of security-sensitive information can carry risks to the public, and even legitimate researchers can be suspected of obtaining it and using it in ways that can be harmful, with costs to those researchers. Oversight helps to prevent both kinds of harm.

To declare as a student or member of academic staff that one is using security-sensitive information is in keeping with openness in research, and helps to reduce misidentifications of information-gathering as suspect or criminal.

If question 23 on the Risk Checklist has been answered 'yes', the researcher must complete and submit with the online ethics application a supplementary document, the *Security-sensitive research form*, available on the Research Ethics web page.

These projects will be reviewed by the Chair of the University Research Ethics Subcommittee.

This process is based on the guidance provided by Universities UK in *Oversight of security-sensitive research material in UK Universities guidance* (2012).

<http://www.universitiesuk.ac.uk/highereducation/Pages/OversightOfSecuritySensitiveResearchMaterial.aspx#.VtbJTk3cuUk>

## I. Guidance for completing your application

Please read through these guidelines carefully before completing your application. Failure to complete the relevant sections of the application adequately will delay your project.

The Risk Checklist is the first stage in gaining ethical approval for your research study. It will assist you and those reviewing your study in identifying the level of risk and the associated ethical issues presented by your project.

If you answer **NO** to all the risk questions, your study is considered to be low risk with no major ethical issues to address and will be classed as Risk Category 1.

When you tick **YES** to any item in the Risk Checklist that you will then need to complete the resulting questions (the online system will guide you through the process) and explain how you intend to manage the risks involved in the study.

### RISK CHECKLIST

WILL YOUR RESEARCH STUDY.....?		Help
1	Involve direct and/or indirect contact with human participants?	This includes where you talk to people, interview them, take measurements from them, have them complete questionnaires, access information about them, etc.
2	Involve analysis of pre-existing data which contains personal or sensitive information not in the public domain?	Pre-existing data sources include interview transcripts, questionnaires, census data, etc. If these are not freely available in the public domain AND if they contain personal information (eg, names, locations, etc.) or sensitive data (eg, health conditions, religious beliefs, etc.) then studies including this information will be categorised as Risk Category 2 or 3. Please note there is minimal risk involved (Risk Category 1) when using data from secondary sources, eg, books, journal articles, etc., which are already in the public domain.
3	Require permission or consent to conduct?	If research involves primary data collection with human participants then their permission or consent must normally be obtained prior to them taking part in the study. Informed consent means that research participants must be made fully aware of the purpose, methods and intended possible uses of the research, what their participation in the research entails and what risks, if any, are involved. To do this you will usually be expected to produce a Participant Information Sheet plus a consent form for them to agree to participate in the research. If your study only uses data sources which are already in the public domain you will not need to ask anyone for permission to access the data sets or records of information.



4	Require permission or consent to publish?	If you intend to publish the findings from your study (eg, in a research report or journal article) you may require permission or informed consent to do so. For example, if your research has been commissioned by an external body, they may want prior approval before publication. Also, if the research involves human participants, they may wish to approve the content prior to publication. However, there are no constraints on you in terms of publishing your research if the information you have evaluated is publicly available to everyone for free.
5	Have a risk of compromising confidentiality?	Confidentiality is concerned with who has the right of access to the data provided by participants. All research studies should ensure the confidentiality of information supplied by research subjects. If your research study is likely to contain confidential information which is NOT already in the public domain, then there is a risk associated with this. Also, consider if there are limits to confidentiality and if you are required to disclose (unsought) information given to you by a participant during the research process for professional body or legal reasons.
6	Have a risk of compromising anonymity?	Anonymity refers to concealing the identities of participants in outputs from the research. All research studies should ensure the anonymity of respondents is respected (unless it specifically states that the research will not be anonymous and the research participant agrees to this). Therefore, if your study includes contact with named participants there could be a risk to anonymity.
7	Collect / contain sensitive personal data?	The presumption is that, because information about these matters could be used in a discriminatory way, and is likely to be of a private nature, it needs to be treated with greater care than other personal data. In general, sensitive personal data usually refers to any information that, if disclosed, could cause upset either to individuals, groups or organisations. The Data Protection Act 1988 includes the following categories of information that could be deemed as 'sensitive': data relating to a person's racial or ethnic origin, political opinions, physical or mental health condition, sexual life, religious beliefs or other beliefs of a similar nature, or membership of a trade union. Other types of sensitive data could include information related to criminal activity or law breaking, eg, drug use, etc.

8	Contain elements which you OR your Supervisor are NOT trained to conduct?	It is unethical to conduct badly designed or poorly analysed research projects so you should have the expertise to carry out your research study, or undertake the training necessary prior to starting, or work under the supervision of someone who has the expertise required for the study. If you or your Supervisor are NOT trained to carry out all of the elements of your research study then training will be required prior to data collection.
9	Use any information OTHER than that which is freely available in the public domain?	Information which is freely available in the public domain includes that already published in research literature, the media or on the internet, etc.
10	Involve respondents to the internet or other visual/vocal methods where participants may be identified?	This would include internet research where visual images are used, and where sensitive issues are discussed and also research involving visual / vocal methods where participants or other individuals may be identifiable in the visual images used or generated.
11	Include a financial incentive to participate in the research?	Consideration must be given when financial incentives, beyond payment of out of pocket expenses, are included in a research study and Local Research Ethics Co-ordinators will decide on the level of approval required.
12	Involve your own students, colleagues or employees?	Due to concerns over coercion or feelings of obligation, projects involving staff conducting research with their own students or a researcher wishing to include their colleagues or employees, will need careful consideration.
13	Take place outside of the country where you are enrolled as a student, or for staff, outside of the UK?	Consideration will be needed on in-country ethical approval, risks for projects taking place off-campus, and possibly insurance and indemnity cover.
14	Involve participants who are particularly vulnerable or at risk?	<p>If any of the participants need special consideration regarding issues of informed consent and/or there is potential for perceived pressure to participate, the research study may be classified as Risk Category 3. If you consider that any of the participants could be particularly vulnerable or at risk, have a dependent relationship with members of the research team or the research organisation/s, or have particular difficulties with providing fully informed consent, the study will have a higher risk.</p> <p>For projects with participants under the age of 16, see the Guidance appendix for when these participants would be considered 'vulnerable'.</p>

15	Involve any participants who are unable to give informed consent?	Any such projects must be given special consideration and will normally be considered at school level. Note observation studies of people in public places do not qualify for special consideration here. Seek further guidance regarding participants over the age of 16 who lack the capacity to give informed consent and the Mental Capacity Act 2005, as the School level group or URESC cannot give ethical approval for such projects.
16	Involve data collection taking place BEFORE informed consent is given?	It is sometimes not possible to get informed consent prior to data collection as this would prejudice the outcome of the research project. Such research projects would normally be classified as Risk Category 3.
17	Involve any deliberate deception or covert data collection?	For projects where full information to the participant would invalidate the research or would be meaningless, or psychological experiments where prior disclosure would invalidate the responses and so contradict the purpose of the project, the following principles should be adopted: Withholding of information from participants should only occur when the researcher is clear that the aims and objectives of the research cannot be achieved, and the welfare of the participants assured, by any other means; debriefing should normally follow participation; and where deception has been substantial, the participant should be offered the option of withholding the data in accordance with the principle of participation by informed consent.
18	Involve a risk to the researcher or participants beyond that experienced in everyday life?	Where the risk to the participants and researchers is beyond what they would normally experience in their everyday life special consideration must be given to such risks and Local Research Ethics Co-ordinators will decide on the level of approval required. This may also include research in sensitive areas.
19	Cause (or could cause) physical or psychological harm or negative consequences?	Any study that may cause harm to the participants or researchers because they are conducting the research study must be carefully considered in the first instance by an appropriate Local Research Ethics Co-ordinator. Physical harm and psychological harm might be related to procedures such as: MRI scans or ultrasound, use of ionising radiation, psychological stress, humiliation or other negative consequences. This may also include research in sensitive areas. See the Guidance appendix for more details.
20	Use intrusive or invasive procedures?	Any study that involves intrusive or invasive procedures must be carefully considered. Giving food or food based products or legal substances in recommended doses are not considered as an intrusive or invasive procedure . See the Guidance appendix for more details.

21	Involve a clinical trial?	Any clinical trial needs to be carefully designed and should be discussed with an appropriate Local Research Ethics Co-ordinator in the first instance and the University Insurance & Risk Officer.
22	Involve the possibility of incidental findings related to health status?	Where research involves measurement or procedures that may reveal underlying health conditions these must be dealt with appropriately. You must clearly indicate, both in the application and on the Participant Information Sheet, how you will deal with any such incidental findings. Where any issue arises, the participant must be fully informed by the researchers about this and be advised to raise the issue with their medical physician or GP. When a participant is informed of incidental findings, you must ensure that appropriate referral or counselling services are available.
23	Fit into any of the following security-sensitive categories: concerns terrorist or extreme groups; commissioned by the military; commissioned under an EU security call; involve the acquisition of security clearances? If yes, see Help for guidance.	<p>If answered 'yes', you must complete and submit with your online ethics application a supplementary document, the Security-sensitive research form, available via these links: <a href="#">Student</a> or <a href="#">Staff</a>.</p> <p>These projects will be reviewed by the Chair of the University Research Ethics Sub-committee.</p>

## **CLASSIFICATION**

<b>The following guidance will help classify the risk level of your study:</b>	
<b>Risk Category 1</b>	If you answered <b>NO</b> to all the above questions, your study is classified as Risk Category 1 (literature reviews will be Risk Category 1).
<b>Risk Category 2</b>	If you answered <b>YES</b> to any question from 1-13 and <b>NO</b> to all questions 14-22, your study is provisionally classified as Risk Category 2.
<b>Risk Category 3</b>	If you answered <b>YES</b> to any question from 14-22, your study is provisionally classified as Risk Category 3.

## RESEARCH ETHICS APPROVAL

PROJECT DETAILS	Help
<b>Project title</b>	<p>Ensure the project title reflects the research project and the stated aims.</p> <p>For projects with human participants, you may wish to provide a simpler title on the Participant Information Sheet and Consent Form from your project title which is understandable to the intended participants; if you do provide a simpler title, the meaning must be the same as the project title, i.e. you must not mislead participants.</p>
<b>Details of the project</b>	Give an overview of your project. For literature reviews, give an outline of sources to be used (up to 100 words).

CONFIRMATION STATEMENTS	Help
<p><b>The results of research should benefit society directly or by generally improving knowledge and understanding.</b></p> <p><i>If you cannot identify a benefit you must discuss your project with your Research Supervisor to help identify one or adapt your proposal so the study will have an identifiable benefit.</i></p>	<p><b>Potential Benefit:</b> Ethics Committees consider the balance of potential benefit against potential harm. Your research should have some potential benefit, from undergraduate students who are learning how to conduct appropriate research studies through to experienced researchers who are making an original contribution to knowledge and understanding in their specialist area. If you cannot easily identify a potential benefit, discuss this with your Research Supervisor or amend your research study to include one.</p>
<p><b>Confirm you have read the Research Ethics Policy and the Research Ethics Procedures and will adhere to these in the conduct of this project.</b></p>	<p>You are also required to indicate that you have read the University's Research Ethics Policy and Procedures, including these guidelines, and will abide by these when conducting your research.</p>

## **RESEARCH ETHICS APPROVAL – Risk Category 2 and 3**

For projects in Risk Category 2 and 3, some of the following issues may be relevant for inclusion in the research ethics application. The list is not exhaustive and submissions should include coverage of all aspects which impact on ethical approval. In particular, ensure that you have addressed the points in the Risk Checklist which have been answered ‘yes’.

Remember that the reviewers will be considering the following questions when reviewing your application in order to be able to give ethical approval:

- Is it ethical to conduct the research project?
- Is the proposed method of investigation appropriate, thorough and ethical?
- Does the research project meet the requirements of the relevant Research Ethics Principles (Research Ethics Policy A2.4)?
- For projects being considered by the School level group, remember that these groups have members from different areas and lay members - make sure your application is comprehensible to all.
- If a question does not apply to your project, you can put ‘Not applicable’ or ‘N/A’.

<b>1</b>	<b>Project Overview</b>
<b>Please give a brief overview of your study, including a summary of your aims and objectives.</b> <u>Help:</u> Describe the purpose of the research and what question(s) the project should answer.	
<u>Further Help:</u> Provide the academic/scientific justification and background of the study. Make reference to the literature in the area of the research.	
<b>2</b>	<b>Methodology</b>
<b>Please give a description of your methodology, including any data collection and analysis methods.</b>  <u>Help:</u> Give an outline of your study here. If the project is complex, you can also submit your research proposal/protocol if this would help the reviewer’s understanding of the project. Include details of your (or your Research Supervisor’s) appropriate skills and qualifications to carry out this research.	
<u>Further Help:</u> <ul style="list-style-type: none"><li>• Does selection and formulation of the research questions, and the design of the research project ensure that the outcomes are not pre-determined?</li><li>• Describe the methods to be used in the analysis of the results and if advice has been sought on these and from whom.</li><li>• For studies conducted on the internet with a website set up for the study, include the web address.</li><li>• For questionnaires or tests that need permission from the authors to use, advise how admission will be sought (if permission has already been received, include this as a supporting document).</li><li>• Flowcharts are often very useful in explaining the research process and the different stages, step by step, with a timeline – this could be included as a supporting document.</li></ul>	

<b>3</b>	<b>Main Ethical Considerations</b>
<p><b>Please give a description of the main ethical considerations involved in the study.</b></p> <p><u>Help:</u>  All research projects will have ethical issues, and you will be asked later in the process on recruitment, voluntary participation and the right to withdraw, but highlight here the main ethical considerations for your study (which may concern, e.g., the type of participants, the sensitive nature of the study, the data collection process, a lone researcher carrying out research off-campus, security-sensitive research) and advise how you will address the main issues. If the project is funded, give details here, and whether there are any potential conflicts of interest involved in the study.</p>	
<p><u>Further Help:</u></p> <ul style="list-style-type: none"> <li>• <i>Children and Vulnerable Adults:</i> If the study involves people in these groups what specific provisions will be put in place, and how will informed consent be obtained and from whom?</li> <li>• <i>Protection from harm:</i> depending on the project, consider potential adverse effects, risks or hazards; think about the potential for pain, discomfort, emotional and mental distress, damage to financial or social standing, inconvenience or changes to lifestyle for participants.</li> <li>• <i>Independence:</i> give details of the origin of any external funding; Identify any areas of possible conflict of interest; and whether any restrictions have been placed on the research by the funding body or any gatekeeper/third party.</li> </ul>	
<b>4</b>	<b>Human Participants</b>
<p><b>If your study includes Human Participants (or their data), please give a description of who will be included.</b></p> <p><u>Help:</u></p> <ul style="list-style-type: none"> <li>• Please note this should include sample size/number of participants, whether the project will focus on any particular groups/individuals, if it will include any at risk or vulnerable participants, participants aged 16 years or under, etc. Please also specify your rationale for including / excluding groups of participants.</li> <li>• If the research involves secondary data not in the public domain, give details in this section.</li> </ul>	
<p><u>Further Help:</u>  Justify the number of participants to be recruited, the age range and gender mix, where appropriate.</p> <p>For secondary data analysis:</p> <ul style="list-style-type: none"> <li>• Give the name of the dataset/s and the owner</li> <li>• If the data is not in the public domain, do you have the owner's permission/licence to use the data?</li> <li>• If the data is not anonymised, give details on how you will anonymise it</li> <li>• Are you conducting analysis within the remit it was originally collected for?</li> <li>• Was consent gained from the original participants for subsequent analysis?</li> </ul>	

5	Recruitment, Voluntary Participation, Consent and Right to Withdraw
<p><b>If your study includes Human Participants, please give a brief description of the recruitment process, how you will ensure voluntary participation, if (and how) informed consent will be obtained prior to participants taking part in the study, and the right of withdrawal from the research process.</b></p> <p><u>Help:</u></p> <ul style="list-style-type: none"> <li>• This should include clear information on how participants will be identified, approached and recruited; whether the study will include any covert research or deliberate deception; whether help is required from a third party/ gatekeeper to access participants; what information you will give participants, etc.</li> <li>• If expenses or any incentives are to be offered to participants, give full details.</li> <li>• If your research involves students, colleagues and/or other employees then you must specify the rationale for this and how you will address issues of coercion or feelings of obligation.</li> <li>• Regarding withdrawal from the study, discuss the different stages/dates a participant could withdraw or withdraw their data, and how they could do this.</li> </ul>	
<p><u>Further Help:</u></p> <p><i>Selection and recruitment of participants</i></p> <ul style="list-style-type: none"> <li>• Ensure you have clearly described how: <ul style="list-style-type: none"> <li>▪ Potential participants will be identified.</li> <li>▪ Potential participants will be approached.</li> <li>▪ Participants will be recruited and selected.</li> </ul> </li> <li>• How will you assure the reviewer that participation is voluntary? Include in the submission any posters, emails and communications to potential participants.</li> </ul> <p><i>Information to participants</i></p> <ul style="list-style-type: none"> <li>• How will the participant be given full information on the aims, methods, any source of funding of the project, and proposed use of the study?</li> <li>• Are the anticipated benefits and potential risks of the study, and any discomfort it may entail included?</li> <li>• Is the right to withdraw from the project fully set out?</li> <li>• A Participant Information Sheet should be included in the application.</li> </ul> <p><i>Consent</i></p> <ul style="list-style-type: none"> <li>• How will informed consent be obtained?</li> <li>• If consent will not be in written form, the justification for this should be included, and full details of how consent will be provided.</li> <li>• A consent form or a child's assent form should be included in the application where appropriate.</li> </ul> <p><i>Covert research and research involving any deliberate deception</i></p> <p>For projects where full information to the participant would invalidate the research or would be meaningless, or psychological experiments where prior disclosure would invalidate the responses and so contradict the purpose of the project, the following principles should be adopted:</p> <ul style="list-style-type: none"> <li>• Withholding of information from participants should only occur when the researcher is clear that the aims and objectives of the research cannot be achieved, and the welfare of the participants assured, by any other means.</li> </ul>	



- Debriefing should follow participation as a matter of course and the debriefing document should be including in the supporting documentation.
- Where deception has been substantial, the participant should be offered the option of withholding the data in accordance with the principle of participation by informed consent.

<b>6</b>	<b>Risks and Benefits</b>
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**Please give a brief description of how, when and where the research will take place and whether there are any risks and/or benefits involved.**

Help:

- This should include information on what participants will be required to do, the rationale for this and the level of risk involved.
- When considering risks, please refer to risks to the participants (e.g., for research in sensitive areas), the researcher, any other parties to the research; and also any health and safety issues for anyone involved (e.g., for lone researchers carrying out fieldwork)
- If participants will be exposed to ionising radiation, separate approval documentation must be submitted with this application.

Further Help:

*Risks to participants*

- Assessment, if relevant, of health-related issues like physical or psychological harm, and include details of any discomfort or stress.
- Consideration should also be given to societal factors, e.g., risks to a person's social standing, privacy, personal values and beliefs, relations with family and friends and community, and work-related effects.
- Sensitive areas of research might include studies which investigate children's understanding or experiences of sexual activity; research into criminal or illicit activity, e.g. drug use or sex working.
- Any disclosures relating to illegality, e.g., drug-use, sexuality and sexual practices, or deviant/criminal behaviour should have a very careful consideration of risk to the participant; and the nature of the final research report should also address issues of confidentiality and anonymity.
- For research involving a physical intervention, it may be a requirement that the Research Supervisor or staff member who is appropriately qualified, is present and observing during the data collection.

*Risks to researchers*

- Assessment of any specific health and safety provisions which would be required, relating both to physical and mental health.
- Assessment of whether the researchers have the appropriate experience, including training in questioning and reporting on sensitive issues, to undertake the project.
- If the researcher is a lone-researcher, what protocols are planned to ensure safety?

*Health and Safety*

- Are there any health and safety issues either for participants and the researcher?
- Has advice been taken on how these might be addressed, and from whom?

*Benefits*

- Give details of possible benefits. Be realistic about any benefits to the participants. If there are no benefits to participants, this can be stated.

<b>7</b>	<b>Personal Data, Anonymity and Confidentiality</b>
<p><b>Please specify what type of information/data will be collected/analysed and the source(s). In addition, specify if and how you will ensure the anonymity of participants and keep information confidential.</b></p> <p><u>Help:</u> This should include information on whether you are collecting new information/data or using that that is already in the public domain; whether the data you are using includes personal details; how the data will be processed and stored; who will have access to it; how and when it will be destroyed; the Data Protection requirements for any sensitive personal data, etc. In addition, include whether there may be any requirements for disclosure of information to other parties due to professional practice or legal reasons. If there are limits to confidentiality, explain clearly how the participants would be advised about these limits and possible outcomes.</p>	
<p><u>Further Help:</u> <i>Confidentiality and anonymity</i></p> <ul style="list-style-type: none"> <li>• How will confidentiality and anonymity of participants be secured?</li> <li>• Are there any issues relating to information provided by public bodies, corporations, contractors etc?</li> <li>• If the identity of a person, company, etc, is likely to be disclosed or inferred or discoverable, how will this be discussed with the potential participant, and what impact might the outcomes of this have on the proposed project?</li> <li>• If you are using quotations (with the participant’s consent), you may need to paraphrase any verbatim quotes to ensure anonymity.</li> <li>• Are there circumstances in which the requirements of professional practice might impact on confidentiality and anonymity provisions?</li> <li>• How will any participants be clearly informed about any limits to confidentiality, their rationale and possible outcomes?</li> </ul> <p><i>Sensitive Personal Data</i></p> <ul style="list-style-type: none"> <li>• To ensure compliance with the Data Protection Act 2018 participants must be informed about what information will be held about them and who will have access to personal, identifiable information. For sensitive personal data, participants must provide consent with the following statement on the consent form: ‘<i>I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be treated in accordance with the terms of the Data Protection Act 2018.</i>’</li> </ul>	
<b>8</b>	<b>Reporting and Dissemination</b>
<p><b>Please give details of the planned dissemination and specify if the findings from the research will be published and whether any permission is required for this.</b></p> <p><u>Help:</u> This should include information on the methods of dissemination (e.g., dissertation/thesis) and/or what will be published and where. Specify if any permission is needed (e.g., from participants, clients, gatekeepers, etc.) prior to publication, and whether there are any potential issues relating to Intellectual Property Rights when creating or using materials.</p>	
<p><u>Further Help:</u> <i>Dissemination</i></p> <ul style="list-style-type: none"> <li>• What are the planned methods of dissemination (e.g., undergraduate or postgraduate dissertation, doctoral thesis, research report, intended publication in journal or book, conference presentation)?</li> </ul>	

<ul style="list-style-type: none"> <li>If you are not offering a summary of the results of the study to the participants, explain why.</li> </ul> <p><i>Intellectual Property</i></p> <ul style="list-style-type: none"> <li>Is the researcher aware of the wide variety of reproduction methods which are restricted in respect of protected data; and the possible implications of any copyright infringements?</li> <li>Have any relevant permissions in respect of this been obtained (e.g., the use of previously unpublished material)? Permissions should be included in the supporting documentation.</li> <li>If online material is being used, do any international laws impact on this?</li> <li>Is there knowledge of how to use licences and assignment of rights when creating or using material protected as intellectual property?</li> </ul>	
<b>9</b>	<b>Location of research</b>
<p>Will the research take place outside of the country where you are enrolled as a student, or for staff, outside of the UK?</p> <p><b>YES</b>   <input type="checkbox"/>   <b>NO</b>   <input type="checkbox"/>   <b>If yes, give details below.</b></p> <p><u>Help:</u> If yes, please specify where the research will take place and what will be involved. Research must comply with the laws of the country where it is taking place and also comply with local Data Protection and Intellectual Property legislation: you must confirm that your research is compliant with local requirements and how you have ascertained this. Advise if the project requires ethical approval in-country and how this has been ascertained. If approval is required, a copy of this should be included in the application or details of the process of how it will be obtained. Please make reference to insurance and indemnity cover for the project where relevant.</p>	
<p><u>Further Help:</u></p> <ul style="list-style-type: none"> <li>For student projects, explain how the researcher will be supervised (e.g., an in-country Supervisor employed by the University).</li> <li>See the Research Ethics Procedures Handbook for guidance when the project needs to be referred to the Insurance &amp; Risk Officer for confirmation of insurance and indemnity cover.</li> </ul>	
<b>10</b>	<b>Collaborative Projects</b>
<p><b>Is the research is a collaborative project (i.e., it involves more than one institution)?</b></p> <p><b>YES</b>   <input type="checkbox"/>   <b>NO</b>   <input type="checkbox"/>   <b>If yes, give details below.</b></p> <p><u>Help:</u> If yes, please specify the other institutions involved and if ethical approval needs to be / has been given by them. Please also specify what procedures have been put in place to ensure ethical compliance from all partners.</p>	
<p><u>Further Help:</u> Be clear who is providing insurance and indemnity cover for the project (e.g., if there are student or staff participants from different universities).</p>	
<b>11</b>	<b>Any other permission or external ethical approval required to undertake the project</b>
<p><b>Please specify if the project requires any other ethical approval or permissions not mentioned previously in this application and how and when these will be obtained.</b></p> <p><u>Help:</u></p> <ul style="list-style-type: none"> <li>Other permissions: ethical approval does not give the right of access to the University's students, staff or the use of University premises to carry out research, and you may need to</li> </ul>	

contact an appropriate University gatekeeper for agreement to approach potential participants, to advertise for participants, or for the use of premises, so please give details.

- Gatekeepers: permission of a gatekeeper may be required for initial access to participants or to carry out data collection on their premises.
- If your project requires approval from an external ethics committee, this should normally be obtained prior to submitting this application.
- If a Disclosure and Barring Service check is required due to the specific participant group, give details.
- Regarding insurance and indemnity cover, some projects will require individual confirmation of cover. See the Research Ethics Procedures document for more details.

**Further Help:**  
 Other external ethical approvals required normally before receiving ethical approval within the University would include, for example, research coming under the remit of NHS Research Ethics Committees, the Ministry of Defence, the National Offender Management Service (prisons and probation), or the Social Care Research Ethics Committee.

<b>Name of the Learned Society</b>
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**Help:**  
 Give the name of the appropriate learned society whose code of ethical practice has been followed for the project.

**Further Help:**  
 The Research Ethics Policy (A2.4.3) states that researchers must ensure their proposed research project follows the ethical guidelines of an appropriate learned society recognised by their School. Schools are responsible for identifying appropriate learned societies with ethical guidelines for different areas/types of research projects. Seek guidance from your Research Supervisor, research module leader or LREC if you are not sure of your appropriate learned society.

## J. Supporting documentation guidance

### What to submit with the application

*Key points to remember:*

- PARTICIPANT INFORMATION SHEET AND CONSENT FORM: You must submit the Participant Information Sheet/s and consent form/s (where appropriate) with the application.
- You must also submit EVERY COMMUNICATION a participant will see or receive. Failure to do so will cause delays to the application.

### Examples of what could be submitted with the application, depending on the research project

- Participant Information Sheet/s
- Consent Form/s
- Assent Form (usually for children participants)
- Recruitment documents (eg, posters, flyers, email invitations, advertisements)
- Measures to be used (eg, questionnaires, surveys, interview schedules, psychological tests)
- Letters/communications to and from gatekeepers/third parties
- Evidence of any other approvals or permissions (eg, NHS research ethics approval)
- Research proposal/protocol (no more than 2-3 A4 pages): *It is not a requirement that this is included, however, if this would help with the understanding of a complex project, please include*
- Risk assessment form: *It can be helpful to include a risk assessment form for certain projects, such as those involving a physical intervention; where data collection is taking place off-campus; or where there are risks to participants or the researcher beyond what is experienced in everyday life*
- For projects involving ionising radiation, specific approval documentation is required
- For projects involving security-sensitive research, the Security-sensitive research form is required
- Confirmation of insurance cover (required for certain projects – check if in doubt)
- Other documents specific to your project

### General guidance for supporting documentation

There are no set templates for documents at a University level, however this does not preclude subject areas or faculties providing templates to students. **The documents should be designed or revised specifically for the target participants and the project**, taking into account:

- Use of language which is accessible to the participants
- The presentation should be appropriate to the participants (e.g., font size, use of graphics)

## ***Participant Information Sheet***

Below are examples that could be included on a sheet, depending on the type of project. It should be stated from the start who is doing the research and for what purpose so be clear as to who you are and why you are doing this research. Early on the sheet (title/first paragraph), identify the research as a Leeds Beckett University, School (name) (undergraduate/ postgraduate/ research student) project.

- Project title (this must be understandable to a potential participant)
- Your name and your Supervisor's name
- Locate yourself: state the type/level of project and your institution/course (e.g., final year undergraduate project at Leeds Beckett University, School and name your course)
- Participation is voluntary
- Participation inclusion/exclusion criteria are stated
- Description of the purpose of the study (that can be understood by a potential participant)
- Description of what is involved (that can be understood by a potential participant), including the method of data collection and the type of data that will be collected
- The participant does not have to respond to a question/task if they do not wish to
- The approximate time involved in participating
- Details of any benefits in taking part. There may be no direct benefit to the participant and this can be stated
- Details of any risks or disadvantages in taking part
- Sources of advice or on-going support
- The information from this study will be used to \_\_\_ (e.g., produce your undergraduate dissertation). The people who are likely to read the final report in an official capacity are \_\_\_ (e.g., your Supervisor and other examiners)
- A statement that participants will not be identifiable in any way and an explanation of how this will be achieved (e.g., by using participant numbers or changing names and other identifying information)
- The interview will be audio-taped
- The audio-recording will be destroyed following transcription and anonymised quotations might be included in the final report
- Participation will be confidential and details of any limits to confidentiality
- For focus groups, there may be ground rules regarding confidentiality
- The data will be stored securely and the people who will have access to the raw data will be \_\_\_ (e.g., you and your Supervisor)
- The participant can stop the study at any time during the data collection. The participant can ask for part or all of his/her data to be destroyed. The participant can do this without penalty and without providing a reason. The participant can withdraw their data by \_\_\_ (e.g., email you quoting their participant number, which can be found at the top of this Information Sheet) and this must be done by \_\_\_ (date)
- Contact details for you (your university email address), your Supervisor (their university email address and direct dial telephone number) and an independent contact (name, university email address and direct dial telephone number)
- The project has received ethical approval from the Local Research Ethics Co-ordinator/School (name) level group, in line with the University's Research Ethics Policy

### *Points to consider*

- ✓ Is it a friendly invitation to participate? Ensure all printed information being sent outside the University is legible, understandable to the participant, and is free from typographical and grammatical errors. Do you need to consider translating parts into languages other than English? The use of graphics can give the sheet a professional look and make the sheet easier to read and understand. Remember, if a person does not understand the information they are being given about a research study, then they cannot give informed consent to take part.
  - ✓ Is it clear who is doing the research and for what purpose? It should be clear who you are and why you are doing this research.
  - ✓ Use of data: Will you communicate the outcome with participants? If not, explain why.
  - ✓ Researcher's contact details: Do not include your home address/home telephone number/ personal email – you can use your University address, your student email and your mobile telephone number. Keep yourself safe.
  - ✓ Research Supervisor's contact details: Make it easy to make contact - include their telephone number and email details. (For students on professional courses, you should normally include your Supervisor's professional qualifications after their name.)
  - ✓ Independent contact: This should be someone not involved in the project in case of concerns or complaints not satisfactorily resolved by the researcher and their Supervisor.
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### **Consent form**

Below are points that could be included on a consent form, depending on the type of project:

- Project title
- Your name and your Supervisor's name
- Identify the University and your course

### *Statements with yes/no boxes for the participants to answer*

- I confirm that I have read and understood the Participant Information Sheet for the above study and understand what is expected of me.
- I understand that my participation is completely voluntary.
- I understand that I am free to stop the study at any time during the data collection and I am free to withdraw my data from the study until \_\_\_\_ (date or stage of project).
- I give my consent to be audio-taped during the interview.
- I agree to the use of direct quotations providing that any quotations are anonymised by use of a false name (if applicable).
- I confirm that I have been given the opportunity to ask questions regarding the study, and if asked, my questions were answered to my full satisfaction.

- Information relevant to the Data Protection Act.
- Space for the participant's name, signature and date
- Space for the researcher's name, signature and date

Points to consider

- ✓ Include tick boxes or yes/no boxes for each statement, in case a participant does not agree with all the statements.
  - ✓ For research involving younger children where you want them to sign to agree to the study, include an assent (not consent) form appropriate to the age group.
- 

***Poster/advertisement/invitation to participate in a project***

Below are points that could be included on a poster/invitation, depending on the type of project:

- Project title or topic
- Your name and contact details (i.e. University email address) and Supervisor's name
- State who you are (e.g., undergraduate student at Leeds Beckett University on which course)
- Details of who you are recruiting (e.g., female students who are 18 – 25 years old) and any exclusion criteria (e.g., 'Please do not take part if you are allergic to caffeine')
- What participation will involve (e.g., 'Completing a questionnaire on...') and where it will take place
- The approximate time involved in participating
- Recruitment end date (i.e., when you will no longer be recruiting participants)
- If using a gatekeeper to recruit participants, give their details
- That the project has received ethical approval from the Local Research Ethics Co-ordinator OR School (name) level group in accordance with the Research Ethics Policy of the University

Points to consider

- ✓ Check if you need permission to display your poster.
  - ✓ Remember to remove the poster when recruitment ends.
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