



Procedure	Research Ethics Procedures
Organisation	Leeds Beckett University
Author(s)	Charlotte Pettitt (Research Ethics and Integrity Manager) Stuart Morris (Research Excellence Manager)
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Links to other internal policies / procedures	<ul style="list-style-type: none"> • LBU Research Ethics Policy • LBU Code of Good Practice for Research • Academic Regulations - Section 10: Academic Honesty • Policy & Procedures for Investigating Allegations of Misconduct in Research • Fitness to Practise Policy • Staff disciplinary procedures • Student Code of Conduct • University Open Research Policy. • University Data Protection Policy, • Risk Assessment Procedure • LBU Safety, Health and Wellbeing Policy • ‘Approach to the Prevent Duty’ • University’s Code of Practice on Freedom of Speech and Expression • University’s Travel guidance and procedures • LBU’s Statement on Responsible Research • Due Diligence Policy • LBU Invasive Procedures Guidance • University Records Retention Schedule
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1. Introduction

Purpose

- 1.1 The purpose of this document is to set out the procedures to be followed for the submission and review of ethics applications, clearly setting out the roles and responsibilities and the process involved.
- 1.2 These procedures should be read in conjunction with the [University Research Ethics Policy](#), which sets out the general principles that underpin the University's approach to research ethics, and alongside the [University Code of Good Practice for Research](#) which sets out the standards of good research practice to be understood and followed by all University staff and students.

Scope

- 1.3 These procedures are provided for all staff and students at the University who are carrying out a research project, and staff involved in assessing applications for ethics review.
- 1.4 They apply to all research conducted at, or under the auspices of Leeds Beckett University and include:
 - All employees engaged in research.
 - All students at the university.
 - Other individuals who are undertaking research using University premises or facilities and/or in the name of the University.
- 1.5 All research requires either favourable opinion from an ethics review or an assessment to be undertaken to confirm that an ethics review is not required.
- 1.6 Any research project, as defined in the [University Research Ethics Policy](#), undertaken by those included in the scope of these procedures must receive favourable opinion from an ethics review before the research project commences. This may be given at supervisor, local, school or University level, depending on the nature of the research proposal. Further details concerning the different levels of review are provided in Section 4 of this document.
- 1.7 Retrospective review is not permissible in any circumstance and ethics review must always be sought prior to any form of data collection being carried out.

Importance of ethical review

- 1.8 Review of an ethics application ensures that research is conducted responsibly, protects participants, and maintains the integrity of the research process. It safeguards participants' rights, safety, and well-being whilst also protecting researchers and the institution from potential harm.

1.9 The principles of ethical research, which are fully set out in the [University Research Ethics Policy](#), ensure that researchers:

- Carefully consider the ethical implications at every stage of their project.
- Prevent future issues by addressing potential ethical concerns before starting the research.
- Safeguard the rights, dignity, safety, and wellbeing of participants, whilst reducing the chance of physical or psychological harm from research activities.
- Protect their rights as researchers to pursue legitimate investigations.
- Uphold the University's reputation in relation to research undertaken by its staff and students.
- Are properly insured to conduct their studies.
- Reduce the likelihood of negligence claims against themselves, the University, or any collaborators.
- Can provide evidence of a favourable opinion from an ethics review.

1.10 Review of an ethics application is vital for ensuring that research is conducted responsibly, ethically, and with the best interests of participants, researchers, and society in mind.

1.11 Ethical considerations should be addressed at the very earliest stages of research planning. Inclusion of ethical principles from the outset will almost certainly influence key aspects of research design. The University will expect researcher to provide evidence that they have carefully considered all potential ethical risks and challenges before proceeding.

2. [Roles and Responsibilities](#)

Researcher

2.1 Prior to research commencing the researcher is responsible for:

- Discussing the project with their research supervisor (or Director of study), if a student. Staff may discuss with their Local Research Ethics Coordinator (LREC) if felt necessary.
- Applying for and obtaining a favourable opinion from an ethics review.

2.2 Throughout the research project the researcher is responsible for:

- Operating in an ethical manner with due regard to the ethical considerations and challenges relevant to the research project.
- Operating within the parameters of the favourable opinion from the ethics review.

- Ensuring that if the scope of the research project changes, these changes are discussed with their supervisor (for students) or LREC (for staff) and to ensure that the ethics review remains appropriate. Where necessary an amendment to the initial application may be made.

2.3 Following completion of the research, the researcher is responsible for:

- Ensuring research data is stored securely and retained/destroyed in accordance with the [Data Protection Act](#), and the [University Records Retention Schedule](#).
- Ensuring that confidentiality and anonymity are appropriately considered in the dissemination of the findings.

2.4 Throughout all stages of the research project, the researcher is responsible for ensuring compliance with the [University Research Ethics Policy](#), the [University Code of Good Research Practice](#), and any other relevant University guidelines, procedures or position papers.

2.5 Furthermore, researchers must ensure they are compliant with any relevant external requirements or laws, such as those defined by the NHS, the law of the country within which the research is taking place, requirements from funders and collaborators, or any other involved organisation or body.

2.6 Researchers are encouraged to undergo periodic training and development in research ethics as appropriate to their discipline at to undertake any mandatory training provided by the University.

Undergraduate (UG) and Postgraduate Taught (PGT) students

2.7 UG and PGT students must submit an ethics application for any research being carried out. Students cannot commence their research until a favourable opinion from an ethics review has been granted.

2.8 Students must consult their research supervisors (or their Director of study/module lead if more appropriate) regarding their ethics applications as they are responsible for supporting the students' applications.

2.9 It is the responsibility of the student to submit the ethics application in a timely and correct manner using the Worktribe Ethics System

Postgraduate Research (PGR) students

2.10 Ethics applications must be submitted by PGR students for all research being carried out. Students cannot commence their research until a favourable opinion from an ethics review has been granted.

- 2.11 Students must consult their research supervisor (or supervisory team if more appropriate) regarding their ethics application as they are responsible for supporting the students' application.
- 2.12 It is the responsibility of the student to submit their ethics application in a timely and correct manner using the Worktribe Ethics System.

Franchise Students

- 2.13 Franchise students are subject to the same ethical requirements through the [University Research Ethics Policy](#) and Procedures.
- 2.14 Franchise students must apply for ethics review through paper-based forms as detailed in points 3.61-3.63. Guidance on ethics review for franchise student should be sought from the local School Research Ethics Coordinator (SREC).

Staff

- 2.15 Ethics applications must be submitted by staff for all research being carried out. Staff cannot commence their research until a favourable opinion from an ethics review has been granted.
- 2.16 In line with the [ESRC ethical framework](#), a single review process should be followed for collaborative research with the Lead Investigator being responsible for submitting an ethics application. For interdisciplinary research across different schools within the University, the single ethics application should be submitted to the Lead Investigators school. If required, the reviewer can refer to another reviewer in the collaborative school for further review.

Research Supervisor

- 2.17 All student research projects must be discussed with their research supervisor (or director of studies if more appropriate) prior to submission of an ethics application.
- 2.18 Supervisors overseeing the research projects of students have a responsibility to consider whether their student's research needs an ethics review or if their student's research will involve matters excluded from the review process.
- 2.19 Supervisors are the first point of review for student applications, therefore all research supervisors should have the appropriate experience and expertise to effectively support students to successful completion according to the level of their programme or course of study. Supervisors are expected to be familiar with the [University Ethics Research Policy](#) and Procedures.

Research Module Leaders

- 2.20 The context of a research module may vary across subject areas, for example it may be a final year project, Research Methods module or Dissertation module. The Research module leader refers to the leader for taught modules containing research elements for which students need an ethics review.
- 2.21 Research module leaders must advise their students on the ethics review processes, deadlines for obtaining a favourable opinion from an ethics review and advise on the penalties for carrying out research without such as per the [University Academic Regulations - Section 10: Academic Honesty](#)

Local Research Ethics Coordinators (LREC)

- 2.22 Local Research Ethics Coordinators (LRECs) are academic staff who have experience and expertise to review ethics applications. They do this as representatives of the school and the subject area. They will review research allocated to them depending on the local school-based process.
- 2.23 LRECs usually sit on their School-level Ethics Committee/forum to jointly review more complex applications and consider ethical issues within their area.
- 2.24 LRECs also have responsibility for cascading ethics information to their subject areas where required.

School Research Ethics Coordinator (SREC)

- 2.25 School Research Ethics Coordinators (SRECs) are dedicated academic staff who have relevant experience and expertise to have oversight of research ethics for the whole school.
- 2.26 The SREC is usually responsible for leading the School-level Ethics Committee/forum which is described in section 4. They also represent their school on the University Research Ethics Sub-Committee.
- 2.27 The role of SREC may consist of coordinating local school-level ethics training, monitoring the decisions of ethics applications within their school, carrying out school wide ethics audits, and acting as a point of escalation for complex applications within the school.

3. [Applying for an Ethics Review](#)

Worktribe Ethics System

- 3.1 All ethics applications should be made via the Worktribe Ethics system. This can be accessed via the following link: <https://leedsbeckett.worktribe.com>

- 3.2 Guidance on how to use the system is available via the [Research Systems webpages](#) and the Research Ethics communities on [MyBeckett](#).

When to apply

- 3.3 Researchers should apply for an ethics review when submitting a research proposal. Prompt completion and submission of an ethics application must be carried out to prevent any delays.
- 3.4 It is essential for researchers to consider the timelines not only for ethics review but also for any potential amendments or additional permissions required. The review process may involve back-and-forth communication with the reviewer, so early submission is advised to facilitate a smoother progression for research projects. Researchers should keep in mind that certain types of studies, such as those involving vulnerable populations or sensitive topics, may require further scrutiny and input from specialised panels or committees, which can extend the review period (e.g. Disclosure and Barring Service Check). Proactive planning and transparent communication with relevant stakeholders will help ensure all ethical requirements are fulfilled without unnecessary delay to research.
- 3.5 Grant conditions frequently require that a favourable opinion from an ethics review be obtained before submission of a grant application. This is especially true for European funding, where contract negotiation does not occur prior to adequate ethics review being completed.
- 3.6 If the research project changes it may be necessary to amend the ethics application (see points 3.45 – 3.49).

What to include in an application

- 3.7 The [Applicant Training Guidance](#) for an ethics application using the Worktribe system provides some useful direction on the information needed in an ethics application. In addition to this researchers should also refer to the [University Research Ethics Policy](#), which sets out the general principles that underpin the University's approach to research ethics, and the [University Code of Good Practice for Research](#) which sets out the standards of good research practice.
- 3.8 Further external guidance and links concerning good practice in research and ethical guidelines can be found on the University's [Research Ethics web pages](#).
- 3.9 For further help in understanding the ethical issues in research, students should seek the advice of their project supervisor, and staff should contact their LREC or SREC.

Student Applications

- 3.10 Students should utilise the [Applicant Training Guidance](#) when submitting an ethics application on the Worktribe system and should seek support from their module/course staff for assistance with completing the application.
- 3.11 All student applications must be approved by their supervisor before they can proceed in the process. See point 3.57 for a workflow of the review process.
- 3.12 For student applications categorised as low risk, the supervisor is the sole reviewer and should give a final response on the application. For student applications categorised as medium or high risk, an LREC will be assigned to review after the supervisor has approved the application.

External Approval

- 3.13 For student applications, only PGR students can submit evidence of external ethics review (where their research has received a favourable ethics review elsewhere), and in this case, their application would be categorised as low risk.
- 3.14 Please see points 3.21-3.28 for more information on external approvals.

External supervisors

- 3.15 If a student has an external supervisor, they should list their internal Leeds Beckett University supervisor on their application on Worktribe where possible.
- 3.16 However, if a student only has an external supervisor, they should still complete their application through the Worktribe system. When asked to select their supervisor, they should enter the name of their SREC. As courtesy, students should email their SREC to advise them this application is coming and to explain the circumstances.
- 3.17 Once the application is submitted, the applicant can download a copy of the application. (Steps for this can be found in the [Applicant Training Guidance](#).) They should share this with their external supervisor and get formal approval. This formal approval should then be shared with the SREC and added to the application on Worktribe as a record.
- 3.18 The SREC should only approve only once formal approval from the external supervisor has been received. The SREC does not need to review the application but should act as the proxy for the external supervisor. The application can then continue as per the usual arrangements.

Staff Applications

- 3.19 Staff should utilise the [Applicant Training Guidance](#) in order to use the Worktribe system.
- 3.20 All staff applications must be submitted to an LREC for review.

External Review

- 3.21 Researchers must register their research when they are acting under the auspices of the University, including when the research has received a favourable ethics review elsewhere. Copies of the review from the external ethics committee must be logged on Worktribe.
- 3.22 This can be done for staff and PGR's through the first question on the 'scope' tab which asks about external review. This will result in their application being categorised as low risk.

IRAS applications

- 3.23 If a researcher is applying for an ethics review from the Health Research Authority, NHS Research Ethics Committee, Social Care Research Ethics Committee, Ministry of Defence Research Ethics Committee or His Majesty's Prison and Probation Service Research Ethics Committee, applications must be made through the [Integrated Research Applications System \(IRAS\)](#). All research submitted through IRAS requires an institutional sponsor, who will take overall responsibility for the quality and governance of the research project, including its management and monitoring. For any research undertaken by staff and students working under the auspices of the institution, the University will usually act as sponsor. Formal confirmation from the Sponsor must be obtained prior to an application through IRAS. Please speak to one of the IRAS sponsors for further guidance on this and see the IRAS guidance on the [Research Ethics Webpages](#).
- 3.24 Once a favourable ethics review opinion has been gained through IRAS, the researcher must submit evidence of this review through Worktribe as per any other external approval.

Light Touch Ethics Approval

- 3.25 The principle of a 'light touch ethics approval' is desirable when a robust external research ethics review process has taken place. The University holds a list of external institutions / committees that have been judged to be sufficiently robust. The University Research Ethics Sub – Committee (URESC) maintains oversight of this list and details of institutions / committees on the list can be found on the [Research Ethics Webpages](#).
- 3.26 Where an ethics review has been received from an institution / committee that is included on the 'light touch' list, then the application would be categorised as low risk. The application must still be reviewed by the appropriate SREC to confirm they are happy to support the external review.
- 3.27 If the committee's procedures are not deemed sufficiently robust, then the researcher must seek full research ethics review as set out above (and it may also be necessary to seek an ethics review via the other committee).

3.28 Where an ethics review has been received from an institution / committee that is not included on the 'light touch ethical approval list' then the researcher is able to request review of the committee from URESC. Full details on how to make this request are set out in the 'light touch ethical approval' protocol which can be found on the [Research Ethics Webpages](#).

Block Approval

3.29 Due to the high volume of taught students submitting ethical applications, a member of staff can submit a 'block' approval ethics application on behalf of the research of a group of taught students (UG/PGT). Further guidance on this can be found in the 'Block Approval Guidance' on the [Research Ethics Webpages](#).

3.30 A supervisor can apply for block approval for a small group of students, or a module leader can apply on behalf of a whole module of students. In both instances the course director will need to provide a statement of support to be attached to the application.

3.31 Block approval is only applicable for taught students (undergraduate and post-graduate taught) and where the project fits into specific criteria as set out in the Guidance.

3.32 Staff members must have in place mechanisms to ensure the research taking place under the approval adheres to the scope of the approval and to the [University Research Ethics Policy](#).

Supporting Documentation

3.33 It may be necessary for supporting documentation to be submitted alongside an ethics application. This could be a variety of documentation types, but most common are consent forms, participant information sheets, advertisements, data management plans, permissions, or health & safety risk assessments.

3.34 All supporting documentation used for a research project must be submitted and approved as part of the ethics application. This can be done via the Documents tab on Worktribe. Applicants should use the function to categorise the documents within an application to make it easier for the reviewer to navigate.

Ethical Risk Categorisation

3.35 The ethical risk categorisation within the Worktribe Ethics system is assigned by the University based upon allocation rules.

3.36 Ethics applications default to be categorised as medium risk unless they fit into the categories for either low risk or high risk.

Low risk

3.37 An ethics application can be categorised as low risk if it meets all the following criteria:

- **The research project uses only secondary data.**
(Secondary data is information that already exists. It will have been collected by others for a different purpose and is usually readily available, although special permission may sometimes be needed. Secondary data may include data curated for public access and display, data from other research projects with the correct permissions to be reused in research, or material held in archives or private collections.)
- **The data is publicly available.**
(Publicly available means data that is freely available in the public domain, including, but not limited to, already published literature, information in the media, or on the internet.)
- **The data does not include any identifiable data.**
(The data cannot lead to the identification of anyone, including any personal data protected under GDPR and protected characteristics under the [Equality Act 2010](#), or through piecing information together or via usernames/screennames.)

3.38 An ethics application can also be categorised as low risk if it has already been approved elsewhere by an organisation on the LBU Light Touch Ethical Approvals list.

High Risk

3.39 An ethics application is categorised as high risk if it meets any of the following criteria:

- **The research falls under the Prevent Duty.**
(This is research commissioned by the military, research commissioned under an EU security call, research involving the acquisition of security clearances, or research concerning terrorist or extremist groups. This does not include historical studies of terrorism (e.g. history of the IRA), mainstream media analysis of reporting of terrorism (newspaper archives) or public perception of terrorism (interviews or surveys).)
- **The research project involves security sensitive information.**
(This includes accessing, storing or transmitting materials. These materials may relate to: illegal or extremist activity (e.g. organised crime, drug-taking, human-trafficking, cyber-crime, terrorism, or political-extremism), or of a confidential nature relating to the military, police or security services (e.g. material covered by the Official Secrets Act, relating to IT encryption, requiring security clearance, or has been commissioned by the military under a security call).)
- **There is potential to cause physical harm or psychological distress to the researcher beyond every day lived experience.**
- **Participants of the research project will be unable to give informed consent.**
(This may be due to the nature of the research or as a result of the participant lacking capacity to provide informed consent.)

- **The research will involve actively deceiving participants.**
(Examples of deception include a project which may involve covert observation in a physical or online environment, participants taking part in a project without their knowledge, deliberately falsely informing participants, withholding information from participants or misleading participants in such a way that they are likely to object or show unease when debriefed about the study. This does not apply when blinding participants to different treatment/trials providing they have been appropriately informed.)
- **There is potential to cause physical harm or psychological distress beyond everyday lived experiences to participants of the research.**
- **The research involves a high-risk invasive procedure as per the [LBU Invasive Procedure Guidance](#).**
(These are classified as: muscle biopsy, rectal thermometer monitoring, invasive imaging requiring sedation, intravenous injections.)

3.40 Applications categorised as high risk follow the standard review process in the same way applications categorised as medium risk would.

Allocation of Reviewers

- 3.41 The allocation of reviewers varies across the different schools depending on the requirements of the relevant school.
- 3.42 The allocation of reviewers within the system is done by the Ethics Administrator who is a member of the school Professional Services team, usually within their Research Support staff or Academic Support team.
- 3.43 The Ethics Administrator will have an 'allocation sheet' which specifies which LREC should be allocated which type of reviews. This is managed locally within the school and may differ between staff and students.

Review Outcomes

- 3.44 There are three possible outcomes from an ethics review.
1. The application is returned to the applicant for **revisions** as requested by the reviewer. The application can go between reviewer and applicant multiple times for revision if the reviewer requests.
 2. The application has been approved by the reviewer so is given a response of **Favourable Opinion**. At this point, the research is permitted to commence.
 3. The application has been rejected by the reviewer so is given a response of **Unfavourable Opinion**. After receiving an unfavourable opinion, the applicant must create a new application if they wish to re-submit. The reviewer must provide a reason for why the application has received an unfavourable opinion.

Changes to Previously Reviewed Research Projects

- 3.45 Following initial review, researchers are expected to remain alert to any emerging ethical considerations throughout the duration of their project. It may be necessary to extend or amend the ethics application if the original review has expired or if changes to the research introduce new ethical implications. A favourable opinion from an ethics review must be obtained before any changes are implemented and before research continues.
- 3.46 To apply for an amendment, researchers must use the 'amend' option within Worktribe on their initial application record.
- 3.47 Once submitted this will then follow the standard route of review (see point 3.57 and 3.58 for workflow diagrams).
- 3.48 Guidance on submitting an amendment to a research project via Worktribe can be found in the [Applicant Training Guidance](#).
- 3.49 If an application needs the project end date extending, then a full amendment is not required, as it is possible to simply extend the date through Worktribe. Guidance can be found within the [Applicant Training Guidance](#).

Appeals

- 3.50 If at any stage the application for ethics review is likely to be rejected, this will normally be referred to the applicant with the deficiencies of the application identified, giving the applicant the opportunity of a further submission.
- 3.51 Where an application, following further submission for ethics review, is not approved at supervisor or local level, the researcher can request that their application is reviewed by the relevant School Research Ethics Co-ordinator, who can request advice from the relevant School Research Ethics Forum / Committee if required.
- 3.52 If the application, following review by the School Research Ethics Co-ordinator, is not approved, a formal appeal is permitted, on one of two grounds:
- That there were procedural irregularities within the review process that could have influenced the outcome of the application; or
 - That there is evidence of inadequate review, prejudice, bias or adverse review of methodology beyond that which relates to ethics within the review process which demonstrably influenced the decision.
- 3.53 The following process should be followed for a formal appeal:
- The matter should be raised formally with the University Research Ethics Sub-Committee.

- All appeals must provide the name of the applicant on the original ethics application, the Supervisor's name where the original ethics review application was made by a student, the relevant grounds and any supporting information.
- Appeals must be made within 10 working days of the applicant being notified of the final ethics review decision at School-level or otherwise becoming aware of the alleged procedural irregularity.
- The University Research Ethics Sub-Committee will review the appeal.
- The applicant and a representative of the school, have the right to attend the meeting and speak to the issue.

3.54 The possible outcomes of an appeal are:

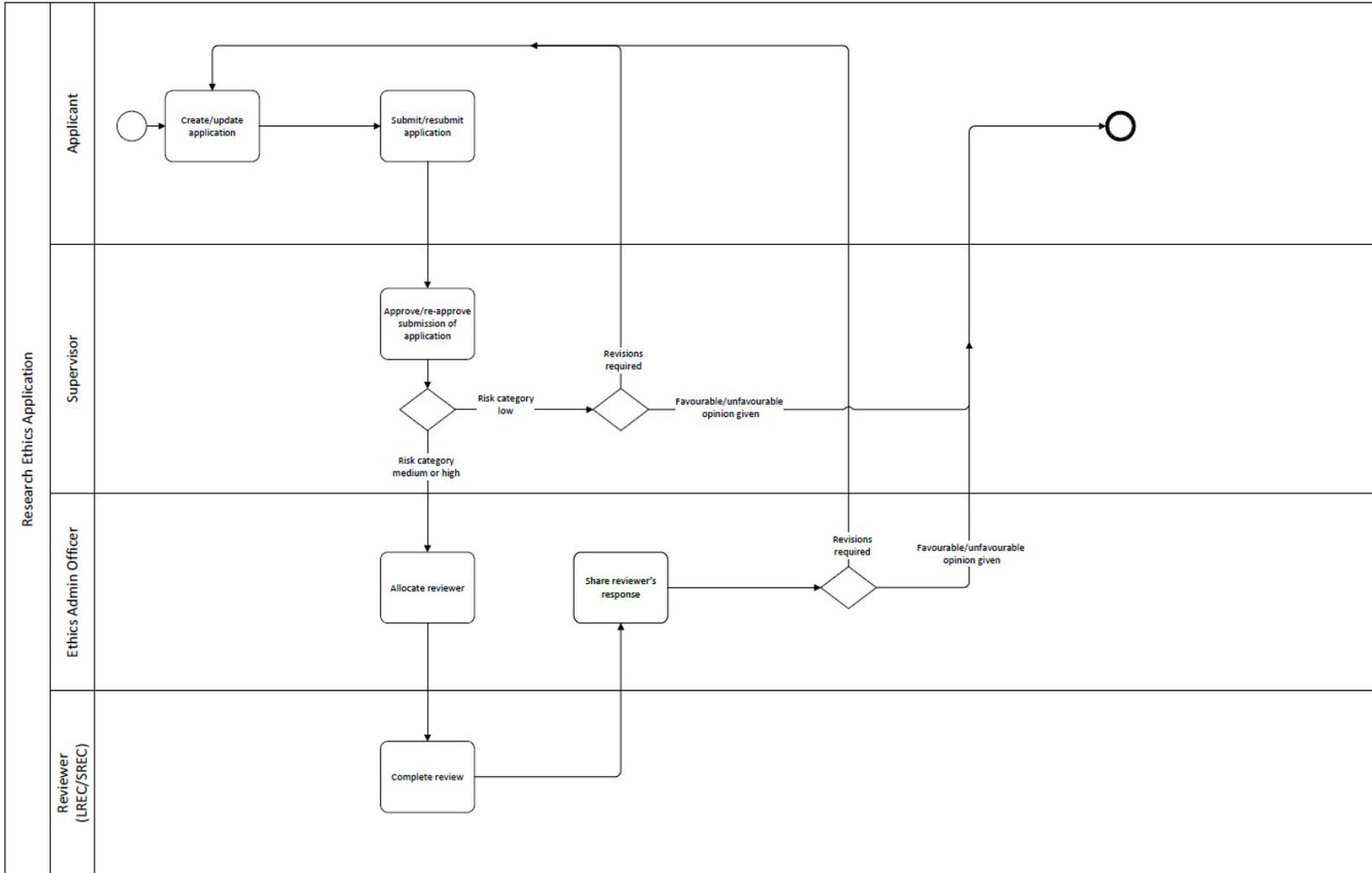
- Uphold the original decision.
- Uphold the claim for and appeal and instruct an independent reviewer to re-assess the original application.

3.55 The outcome of the appeal will be communicated in writing, usually within 20 working days of receipt of the appeal.

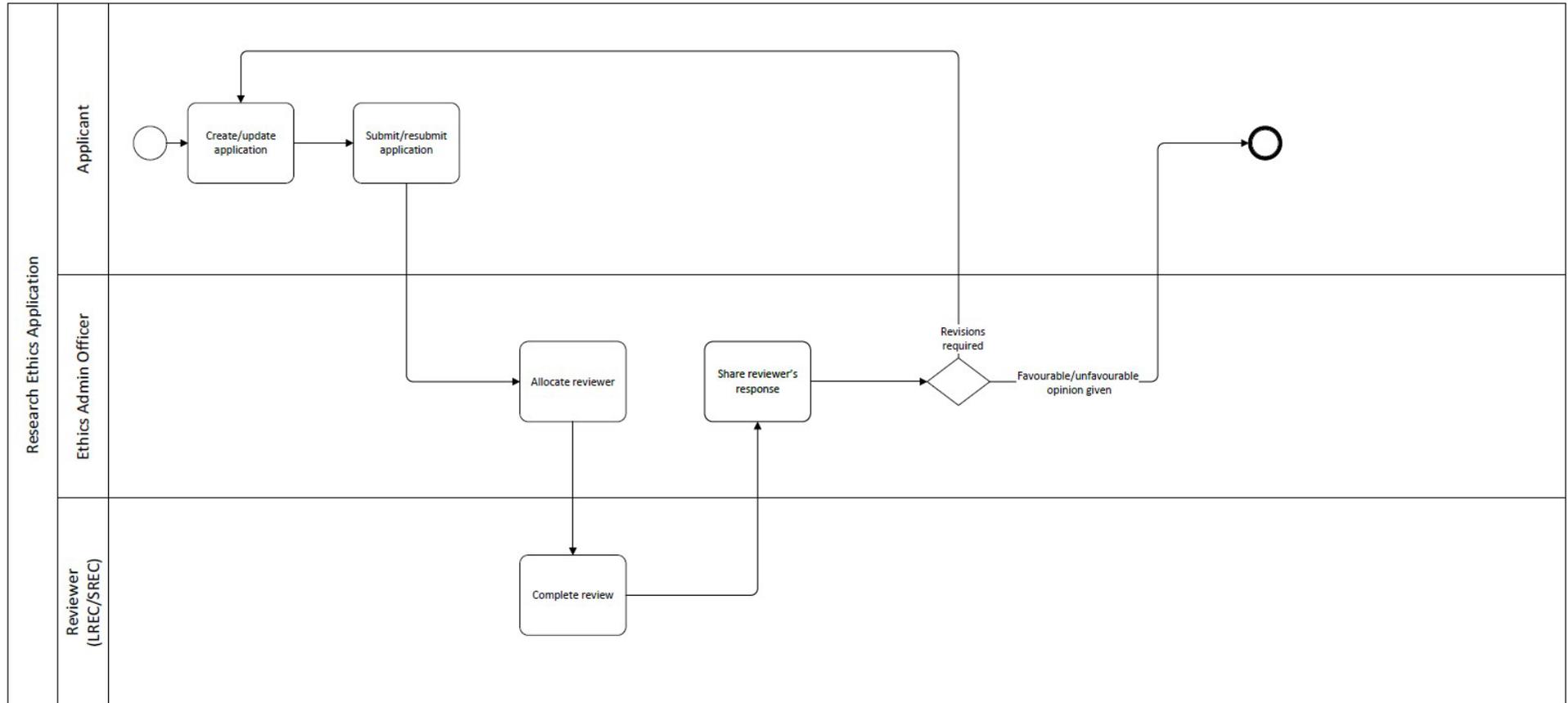
3.56 The decisions regarding matters referred to the University Research Ethics Sub-Committee are final and there is no further appeal mechanism.

Workflows

3.57 Student applications



3.58 Staff applications



Status of Ethics Applications

3.59 The status of all ethics applications can be found on the application record within the Worktribe system. The status will change as the application process proceeds. There are several different statuses which may show, as explained below:

In progress	An application has been created.
Submission	The application has been submitted for review.
Review	The application has been allocated to a reviewer and is awaiting review.
Revision	The application has been sent back to the applicant for revisions.
Revision Submission	The applicant has resubmitted the application back for review following revisions.
Response	The reviewer has made a final decision on the application and is with the ethics officer to be processed.
Favourable Opinion	The reviewer has approved this application and research can commence.
Unfavourable Opinion	The reviewer has rejected this application.
Withdrawn	The application has been withdrawn.
Amendment	An applicant has selected to amend a previously approved ethics application
Amendment Submission	The amendment has been submitted for review.
Amendment Review	The amendment has been allocated to a reviewer and is awaiting review.
Amendment Revision	The amendment has been sent back to the applicant for revisions.
Amendment Revision Submission	The applicant has resubmitted the amendment for review following revisions.
Amendment Response	The reviewer has made a final decision on the amendment.

User roles within the system

3.60 Worktribe has different user roles which can be assigned to users to give access to different aspects of the system. Users may be allocated more than one role. Allocation of these roles is done by those with system admin permissions for Worktribe.

Admin	High level administration use (at institutional level).
Ethics Admin	Administration of ethics applications (usually at a school level).
Ethics Create	Ability to create an ethics application. All users have this by default.
Ethics Reporting	Access to in-systems ethics reporting menu. (Usually allocated to the Admins, SRECs, Directors of Research & Knowledge Exchange and Deans for each school.)

Alternative Ethics Review Route

- 3.61 In circumstances which prevent the submission of ethics applications through the Worktribe Ethics system, applicants may instead use paper-based forms.
- 3.62 The Chair of URESC will review any proposed paper-based forms to ensure they comprehensively address all required ethical considerations and standards and adhere to the [University Research Ethics Policy](#).
- 3.63 Comprehensive records must be kept of any paper-based ethics applications to support accountability, institutional oversight, and the required auditing, such as the annual audit report. These must be available to be submitted to URESC if required.

4. Governance

School Research Ethics Committee / Forum

- 4.1 Each school must have a Research Ethics Committee/forum to carry out the operationalisation of the [University Research Ethics Policy](#) and Procedures at school level. This committee/forum is overseen by the School Research & Knowledge Exchange Sub-Committee as per their Terms of Reference. The operationalisation of the [University Research Ethics Policy](#) is driven by the requirements of the school.
- 4.2 The school Research Ethics Committee/forum is usually led by the SREC and will usually be open to all LREC's across the school.

University Research Ethics Sub-Committee

- 4.3 The University Research Ethics Sub-Committee (URESC) is responsible for overseeing the development and implementation of the Research Ethics Policy and Procedures. URESC is a sub-committee of the [Research and Enterprise Committee](#) and must report to them every cycle.

- 4.4 URESA provides advice to the [Research and Enterprise Committee](#) on the development of institutional policies and guidelines relating to ethical issues in research. URESA monitors all ethics applications and activities and ensures that the institution is compliant with all external requirements and standards.

Management of Research Protocols & Guidance

- 4.5 Research Ethics-related protocols & guidance may be produced for areas or topics which regularly creates queries/issues and are not addressed within the Ethics Policy or Procedures, or for commonly occurring situations such as research involving substances or invasive procedures.
- 4.6 Research Protocols & Guidance should result in 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 should be made to this in the ethics application.
- 4.7 Research Protocols & Guidance are required to be reviewed biennially to ensure they remains in line with sector practice and both internal and external guidance and requirements. Each document must display the author, the review date and version history to allow for review. The Research Ethics and Integrity Manager will monitor all Research Protocols & Guidance to ensure they remains up to date.
- 4.8 Research Protocols & Guidance should be approved by the Research Ethics Committee at either school or University level, depending on if it is relevant at only school or institution wide.
- 4.9 Research Protocols & Guidance should be stored on the [University Research Ethics webpages](#) along with the Ethics Policy and Procedures. This is managed by the Research Services Team.

5. Monitoring and Reporting

Monitoring and Auditing

- 5.1 Ongoing monitoring can be done through Worktribe by those who are assigned to the Ethics Reporting user group (see point 3.60).
- 5.2 Ongoing monitoring at school level is the responsibility of the SREC and should be carried out in the way they see most appropriate. They may also carry out spot check audits through the Worktribe system to ensure that research is compliant within their school.
- 5.3 Institution wide monitoring will be carried out by the Research Integrity and Ethics Manager, who may share their findings with other senior members of the Research and Enterprise Team where appropriate. Spot check audits may be carried out throughout the

Worktribe system to ensure that ethics applications remain compliant with the [University Research Ethics Policy](#) and Research Ethics Procedures.

Annual Audits

- 5.4 Each year, every school must submit an Annual Research Ethics Audit Report to URESC to reflect on the previous years' ethics applications and to ensure compliance with the [University Research Ethics Policy](#). A template is provided by URESC to each school to ensure continuity.
- 5.5 The data can be taken from the Annual Audit Report within Worktribe through the Reporting page. This is set up and managed by the Research Integrity & Ethics Manager. This report is accessible within Worktribe to those with the Ethics Reporting User Group (see point 3.60).

6. Breaches in ethical conduct

Research Misconduct

- 6.1 The [University Research Ethics Policy](#) sets out the Universities expectations that all research carried out in its name should comply with the requirements and expectations of the Research Ethics Policy and the Research Ethics Procedures.
- 6.2 Staff who do not obtain appropriate ethics review for their research may be in breach of the Research Ethics Policy and Procedures. Therefore they may be subject to the [University Disciplinary Procedures](#) or investigated for research misconduct as per the [University Policy for Investigating Allegations of Misconduct in Research](#).
- 6.3 In the interests of openness, good practice and the reputation of the University, members of staff, and students of the University, and members of the public, are entitled to raise concerns about the ethical practices in research, and particularly in relation to compliance with the [University Research Ethics Policy](#).
- 6.4 Where the circumstances invoke related policies of the University these may also be applied. This may include the following University regulations, policies, and procedures:
 - [Fitness to Practise Policy](#)
 - [Staff Disciplinary Procedures](#)

Academic Honesty

- 6.5 For students, any attempt to gain an unfair advantage in a research project, whether intentional or unintentional, is a matter of academic judgement. This may be considered to be unfair practice as it may be a breach of the [University Research Ethics Policy](#) and Procedures. Definitions of these offences and the serious consequences of unfair

practice can be found in the [University Academic Regulations Section 10 - Academic Honesty](#).

- 6.6 Academic honesty is a fundamental principle within the University and is strongly linked to good academic practice. The University has processes to investigate alleged breaches of academic honesty by students and where a breach is admitted or found, appropriate penalties are applied.
- 6.7 The University seeks to educate its students about academic honesty prior to assessment to both reduce breaches of academic honesty and to highlight the severity with which certain offences will be dealt. Students who may have fallen short of good academic practice will be investigated and learning opportunities will be provided to enable students to avoid further breaches of the regulations. Academic judgement regarding the nature and severity of the case will be applied prior to investigation of a suspected breach of academic honesty.
- 6.8 For further information on academic honesty please see the [University Academic Regulations Section 10 – Academic Honesty](#).

7. Other procedural issues relating to ethics review

Data Management

- 7.1 Research Data is information which has been created, collected, or recorded to evidence research findings. Whilst usually digital, it can also be non-digital for example artwork, biological material, or laboratory notebooks. Research Data Management refers to the organisation, storage, and preservation of research data throughout the lifecycle of a project.
- 7.2 As per the [University Research Ethics Policy](#), all staff and post graduate taught researchers must take full responsibility for ensuring appropriate storage and security for all study information including research data and consent forms. All staff researchers and PGR students must incorporate a Data Management Plan into their ethics applications (guidance can be sought from the [Library Research Services Team](#)).
- 7.3 In the case of taught students, research supervisors are responsible for appropriate storage and security of all study information. Taught students must consult their research supervisor about the appropriate data management measures to be taken and complete the data management questions within their ethics application.
- 7.4 More information can be sought on [Research Data](#) from the Research Services Team within the library, and within the [University Open Research Policy](#).

Data Protection

- 7.5 Researchers must ensure that all processing of personal data for research purposes is in accordance with the UK Law (see the [UK General Data Protection Regulation](#) (GDPR) and the [Data Protection Act 2018](#) in particular) and in accordance with the [University Data Protection Policy](#).
- 7.6 For more information and clarity around data protection, students should contact their research supervisors, and staff may contact the Information Governance Team.
- 7.7 Further information on what constitutes personal data can be found on the [Information Commissions Office website](#).

Data Protection Principles

- 7.8 Researchers must ensure that the processing of personal data complies with the following principles of the Data Protection Act 2018.
- **Lawfulness, fairness and transparency**
Researchers must identify an appropriate lawful basis for processing personal data. Please refer to the [University's Data Protection Policy](#) (section 12) to ascertain the appropriate lawful basis for processing the personal data. Where the legal basis relied on is consent from the data subjects, researchers must be able to demonstrate that explicit consent was received and data subjects were provided with all information about the processing, including their right to withdraw. Researchers must demonstrate the provisions in place to satisfy, where possible, the data subjects rights
 - **Purpose limitation**
Personal data obtained for the research must only be processed for a specified and lawful purpose and shall not be processed in any manner incompatible with that purpose.
 - **Data minimisation**
Researchers must only collect and process personal data that is minimum, necessary and proportionate to fulfil the lawful purpose. Researchers must not collect excessive personal data that is not compatible with those purposes.
 - **Accuracy**
Researchers must keep the personal data accurate and up to date.
 - **Storage limitation**
Researchers must have appropriate provisions and retention in place to ensure that personal data is not kept for longer than is necessary for that purpose as per the [University Records Retention Schedule](#).
 - **Integrity and confidentiality**
Personal data must be kept safe from unauthorised access, accidental loss or destruction. Researchers must have appropriate technical and organisational

measures in place to protect the personal data they are processing for their research.

- 7.9 All personal data must be processed in accordance with the data subject's rights and researchers must be able to demonstrate the relevant provisions in place to fulfil these rights. For further details about the rights of individuals under the Data Protection legislation, please refer to the [University's Data Protection policy](#) (section 8).

Data Protection Impact Assessment (DPIA)

- 7.10 A DPIA may be required for staff research when personal data is being processed for the research e.g. involving research participants. A DPIA is designed to ensure processing of personal data is in compliance with the Data Protection legislation and assesses the risks to the rights and freedoms of the individuals resulting from the processing of personal data.
- 7.11 Please refer to the University's brief guidance on [Data Protection and Research Guidance](#) and the [DPIA Guidance](#). Staff should contact the Information Governance team to complete the DPIA.

Personal data sharing with third parties

- 7.12 Where personal data is shared with third parties e.g. funders or research partners, researchers must ensure there is appropriate documentation in place to ensure that the personal data has equivalent levels of protection. This could be a Data Sharing Agreement when sharing data with a country within the European Economic Area, or an International Data Transfer Agreement or Addendum to Standard Contractual Clauses.
- 7.13 Personal data must not be shared without appropriate level of scrutiny and documentation in place.
- 7.14 More detailed information and guidance on sharing personal data can be found on the [University Information Governance webpages](#) and the [ICO website](#). For additional guidance or support, staff should contact the Information Governance Team, and/or the Legal Team (where legal documentation with third parties will be required, for example, research agreements and data sharing agreements) at the earliest opportunity.

Insurance

- 7.15 Insurance and indemnity cover is in place for University student and staff research projects based in the UK that receive a favourable opinion from an ethics review. However, some projects will require individual confirmation of cover from the [University's Insurance & Risk Team](#) before data collection commences. These projects would include clinical trials, projects involving invasive procedures and certain projects undertaken outside of the UK. These should be discussed with the Insurance & Risk Team prior to submission of the research ethics application and confirmation of cover should be included in the supporting documentation of the application.

- 7.16 Please note that the University's insurance and indemnity cover will only cover a research project if the appropriate level of ethics review has been given before any data collection commences (retrospective review is not allowed).
- 7.17 It is not ethical to carry out research without insurance and indemnity cover. If you are unsure whether the standard university insurance and indemnity cover is sufficient for your research project, please discuss with the University's Insurance & Risk Team.

Health & Safety Risk Assessment

- 7.18 Some types of research projects may require a health and safety risk assessment completed as per the [University Safety, Health and Wellbeing Policy](#), and should be carried out in line with the [Risk Assessment Procedure](#). These are the responsibility of the subject area and are managed at school level; it is the researcher's responsibility to be aware of the necessary requirements around risk assessments.
- 7.19 If the conduct of a research project poses a threat to the health & safety of participants and/or researchers, it will be necessary for a health and safety risk assessment to be undertaken before data collection is started. A university health and safety risk assessment template can be downloaded from the [Health and Safety Service webpages](#).
- 7.20 When a health and safety risk assessment has been carried out, it should be submitted along with the ethics application as an additional document. Supervisors must review this prior to submission.
- 7.21 Please note that receipt of a favourable opinion for an ethics application which contains a health and safety risk assessment does not constitute confirmation of compliance with the requirements of the [UK Health and Safety Executive Legislation](#).
- 7.22 Further guidance can be sought from local school's [Safety, Health and Wellbeing co-ordinator](#), or the [University Health and Safety Service](#).

Prevent Duty

- 7.23 The University must adhere to the [Counter Terrorism and Security Act](#) which came into force in September 2015, placing a legal obligation on the University to have due regard 'to the need to prevent people from becoming terrorists or supporting terrorism'. This is known as the Prevent Duty. [University 'Approach to the Prevent Duty'](#) provides further details about governance of the Prevent Duty, awareness and training, organising and managing external speakers and events (see part B of the [University's Code of Practice on Freedom of Speech and Expression](#)).
- 7.24 All ethics applications contain a question around the Prevent Duty on the scoping tab. If an applicant answers yes to the question, the application is immediately categorised as high risk and the application will need to be reviewed by the chair of URESC.

Research outside of the UK

- 7.25 The University recognises the value and importance of international collaborations. Policies and regulations around international research and collaborations are in place to ensure compliance with laws and legislations and to mitigate any financial, reputational or research integrity disputes.
- 7.26 The [‘Trusted Research’](#) agenda encompasses a cross-sectoral agenda to protect UK research and innovation from security-related risks. Researchers should consider the Trusted Research agenda along with the following specific research security schemes below when carrying out international research or collaboration:
- Foreign Influence Registration Scheme (FIRS)
 - Official Secrets Act
 - Academic Technology Approval Scheme (ATAS)
 - Export Control Orders
 - National Security and Investment Act (NSI)
 - Higher Education Freedom of Speech Act
 - National Security Act
- 7.27 More details on how to comply with these schemes can be found in the [University Code of Good Research Practice](#). Researchers must refer to the [University’s Travel Guidance and Procedures](#) prior to commencing any research overseas. Researchers should consult the [Foreign and Commonwealth Office](#) for updates and advice on the destinations of their research.

Due Diligence

- 7.28 It is a mandated requirement for all research organisations receiving research funding to undertake Due Diligence checks on overseas third parties to comply with funding terms and conditions. It is also necessary in order to adhere to the [University Statement on Responsible Research](#).
- 7.29 Due diligence checks provide a way to mitigate any potential security issues associated with overseas research and provide assurance to LBU that international partners have the capacity and expertise to carry out the research project. For further guidance please refer to the [University Due Diligence Policy](#)

8. Definitions

Franchise Student	Franchise students are those enrolled at LBU but receive their teaching from a different institution (the franchise partner). LBU is the awarding institution, but the teaching and learning is provided by a partner institution, which is most usually outside of the UK. (see points 2.13-2.14)
IRAS	Integrated Research Application System (see points 3.23-3.24) used for ethics applications to the NHS and other bodies.
LREC	Local Research Ethics Coordinator (see points 2.22-2.24)
Prevent Duty	The Prevent Duty is a legal obligation placed on the university through the Counter Terrorism and Security Act (2015) to have due regard to prevent people from supporting terrorism or becoming terrorists. (see points 7.23-7.24)
PGT	Post-graduate Taught Student (see points 2.7-2.9)
PGR	Post-graduate Research Student (see points 2.10-2.12)
Secondary Data	Secondary data usually refers to data collected by someone else other than the researcher. It includes data curated for public access and display, data from other research projects with the correct permissions to be reused in research or material held in archives or private collections.
SREC	School Research Ethics Coordinator (see points 2.25-2.27)
UG	Undergraduate Student (see points 2.7-2.9)
URESC	University Research Ethics Sub Committee (see points 4.3-4.4)
Worktribe	Worktribe is the online software that the university uses to manage research including research ethics applications (see point 3.1)