

# Research and Knowledge Exchange Ethics and Integrity Policy

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## 1 Introduction

### 1.1 Purpose

Leeds Trinity University is committed to the highest standards in integrity and ethical conduct in research and knowledge exchange (RKE). This policy sets out the principles aimed at ensuring ethical research and knowledge exchange at the University and should be read in combination with other policies and processes, internal advice, guidance, and training for researchers and additional advice on ethical conduct in specific research and knowledge exchange practice which is produced on an ongoing basis by the University Research Ethics and Integrity Sub-Committee (REISC). Of particular note, this policy should be read in conjunction with other key policies and guidelines, including but not limited to:

Catholic Mission Strategy

[Research Data Management Policy](#)

[Data Protection Policy](#)

[Trusted Research Policy](#)

[Health and Safety Policy](#)

[Sustainability Policy](#)

[Curriculum for Social Justice](#)

[Student Academic Misconduct Policy](#)

[Research Misconduct Policy](#)

[Safeguarding Policy](#)

[Visiting Researcher Process](#)

[Conflict of Interest Code of Practice](#)

[Whistleblowing Policy](#)

[Research Involving Social Media: Ethics Considerations](#)

[Participant Reimbursement Guidelines](#)

[The use of group/block emails to recruit participants](#)

See the [Research and Knowledge Exchange Office intranet site](#) for a more comprehensive and up-to-date list.

The policy is reviewed annually by the University REISC and this is reported to the University Research and Knowledge Exchange Committee (RKEC).

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This document also provides an outline of responsibilities, ethical risk categorisation, and the principles of proportionate review, arrangements for ethical risk management, research ethics review for both staff and Post Graduate Researchers (PGRs) and students on taught programmes of study.

## 1.2 Definitions

**‘Research’** refers to the process of systemic investigation leading to new knowledge, insights or products, in line with key sector-wide definitions such as employed in the [UK Research Excellence Framework](#) and the [OECD Frascati manual](#). Research refers to all stages in the process including conceptualisation; design; ethics review and sponsor approval; data collection, management, and implementation; analysis; and publication, dissemination, and use.

Routine audit, testing, evaluation of University business, or day-to-day activity is excluded from this definition unless it is to be published and/or contributes to knowledge or external impact in ways that are beyond the day-to-day practice of teaching and learning.

**‘Knowledge Exchange’ (KE)** refers to a collaborative, creative endeavour that translates knowledge and research into impact in society and the economy. KE includes a set of activities, processes and skills that enable close collaboration between universities and partner organisations to deliver commercial, environmental, cultural, and place-based benefits, opportunities for students and increased prosperity. It is embedded through the [Knowledge Exchange Framework](#) and the [Knowledge Exchange Concordat](#).

**‘Research and Knowledge Exchange’ (RKE)** is an umbrella term that refers to everything covered by the above definitions of research and KE. This policy applies to both sets of activities and so RKE is used throughout to refer to both.

**‘Sponsor’** refers to the role the University plays in being responsible for RKE undertaken by its staff and students. The University is the ‘sponsor’ of the RKE activity. In practice these duties are discharged by the University REISC and Faculty Research Ethics and Integrity Committees (REIC). Sponsorship is a governance function and distinct from ethical review by peers, which is used to support researchers in designing ethical research and to help Committees reach decisions in discharging these responsibilities.

**‘Researchers’** refers to all Leeds Trinity University staff, approved visiting researchers, PGRs, supervisors of taught students or others acting on behalf of, or in collaboration with, Leeds Trinity researchers to undertake RKE activity as part of their (employment/student/partnership) relationship with Leeds Trinity University. This also includes research assistants, research associates, and similar roles employed to work in part, or in full, on a project involving Leeds Trinity University project leads or internal/external collaborators, whether they are employed by Leeds Trinity University or not.

**‘Project Lead’** (may also be referred to as ‘Principal Investigator’) refers to all Leeds Trinity University staff, approved visiting researchers, PGRs, supervisors of taught students or others acting on behalf of Leeds Trinity University to lead on RKE activity as part of their employment/student/partnership) relationship with Leeds Trinity University. Leading on such activity includes both leading a project team (e.g., as a principal investigator, project manager or student research supervisor) or being the sole

individual working on a project and entails being the individual ultimately responsible for an RKE project.

**‘Internal Collaborator’** refers to any Leeds Trinity University staff, approved visiting researchers, PGRs, students or others acting on behalf of Leeds Trinity University working with a project lead on a specific RKE project (may also be called a co-investigator or project team member) who will have access to some or all of any data collected in the course of the project and/or who will collaborate on the project in other ways (e.g., co-authoring outputs). This includes taught students (undergraduate and postgraduate), where the work is considered the sole effort of the student but the supervisor and/or module coordinator must be named as the project lead.

**‘External Collaborator’** refers to anyone working with a project lead on a specific RKE project as covered by the definition of internal collaborator above but who is not a member of Leeds Trinity University staff, approved visiting researcher, PGR, student or otherwise acting on behalf of Leeds Trinity University. This includes any project partners, whether individuals or organisations, who will play the role described above.

**‘Academic Freedom’** refers to the scope for researchers employed in Higher Education Institutions to ‘question and test received wisdom and to put forward new ideas and controversial or unpopular opinions without placing themselves in jeopardy of losing their jobs or the privileges they may have’ as set out in the [Education Reform Act \(1988\)](#) and enshrined in international declarations such as the [UNESCO Recommendation Concerning the status of higher education teaching personnel](#).

**‘Participants’** refers to all people or animals who might be involved in the research process in ways that assist with the provision of data or in the conceptualisation or analysis of data where they are not primarily directing the research or acting as project leads or collaborators in a formal sense (i.e., they are not engaging in the RKE under the terms of an employment or study contract with Leeds Trinity University or a partnership agreement with Leeds Trinity University).

**‘Stakeholders’** refers to all partners, collaborators, research users, or interested parties who may not be directly involved in the research or research process but who have an interest in the research.

**‘Integrity’** refers to the rigour underpinning RKE activity, the qualifications and capacity of researchers and others to undertake and supervise RKE activity, and accountability for the validity of findings. Integrity should be read as aligning to the [UK Concordat on Research Integrity](#). [Guild HE Research](#) is a signatory to this concordat and Leeds Trinity University is a member of Guild HE Research.

**‘Self-Assessment’** refers to the first stage of ethics and integrity review and approval that is mandatory for all RKE projects regardless of their purpose, nature, methods, outcomes, and/or outputs. The self-assessment stage will determine whether a full application and further review is required. For many projects, the self-assessment will indicate that no further action is required (e.g., very low risk desk research).

**‘Full Application’** refers to the application for ethics and integrity review and approval that some RKE projects will require, depending on the outcome of the self-assessment stage. Once a self-assessment

has been completed, the applicant will be informed whether they are required to complete a full application.

**‘Proportionate Ethical Review’** is the process of assessing the extent to which a Full Application meets the conditions and spirit of this policy, particularly in promoting a positive ethical contribution which is in line with the values of Leeds Trinity as an ethical research community and mitigates and minimises risks that arise in the process. Proportionate Ethical Review at Leeds Trinity is based on peer review and informs the governance and decision-making role of the University as sponsor of research.

**‘Local Ethics Coordinators’** – act as ethical reviewers making recommendations to the Faculty REICs and University REISC.

### 1.3 Scope

This policy applies to all research and knowledge exchange (hereafter ‘RKE’) activity conducted by, on behalf of, or in partnership with Leeds Trinity University (hereafter ‘Leeds Trinity’, ‘LTU’ and/or ‘the University’) or project leads or internal/external collaborators based at LTU.

## 2 Guiding Principles

RKE at Leeds Trinity should aim to make a positive social, intellectual, and ethical contribution to wider society in the UK and beyond, to our RKE community and to the participants and stakeholders in our RKE. Our RKE will promote and uphold the University's own values which are rooted in our Catholic Mission, those of the UK Concordat to Support Research Integrity (see Table 1) and embed the core principle of academic freedom. Researchers and reviewers should have constant reference to these values.

RKE at Leeds Trinity should also be conducted in compliance with legal requirements and key sector-wide benchmarks such as the [UKRIO Code of Practice for Research](#) and [Concordat to Support Research Integrity](#). At a disciplinary level, project leads and Faculty Research Ethics and Integrity Committees are also encouraged to have reference to subject and learned associations and any additional ethical guidance that they may produce. When working overseas, with external partners or on externally financed research projects there may be additional ethical codes and reference points.

Ethics and Integrity review and approval should not discourage controversial or high-risk RKE but ensure that risk is proportionate to the positive contribution and the pursuit of knowledge through academic freedom. Judgements about the balance between positive contributions and risk will be context and disciplinary specific and informed by peer review.

*Table 1: Values and principles in research integrity*

UK Concordat
<p><b>Honesty</b> in all aspects of research, including in the presentation of research goals, intentions and findings; in reporting on research methods and procedures; in gathering data; in using and acknowledging the work of other researchers; and in conveying valid interpretations and making justifiable claims based on research findings.</p> <p><b>Rigour</b>, in line with prevailing disciplinary norms and standards, and in performing research and using appropriate methods; in adhering to an agreed protocol where appropriate; in drawing interpretations and conclusions from the research; and in communicating the results.</p> <p><b>Transparency and open communication</b> in declaring potential competing interests; in the reporting of research data collection methods; in the analysis and interpretation of data; in making research findings widely available, which includes publishing or otherwise sharing negative or null results to recognise their value as part of the research process; and in presenting the work to other researchers and to the public.</p> <p><b>Care and respect</b> for all participants in research, and for the subjects, users and beneficiaries of research, including humans, animals, the environment and cultural objects. Those engaged with research must also show care and respect for the integrity of the research record.</p> <p><b>Accountability</b> of funders, employers and researchers to collectively create a research environment in which individuals and organisations are empowered and enabled to own the research process. Those engaged with research must also ensure that individuals and organisations are held to account when behaviour falls short of the standards set by this concordat.</p>
Leeds Trinity University Values
<p>Rooted in our Catholic Mission, our values Leeds Trinity is a diverse and inclusive community of people from all backgrounds and beliefs who share a common set of values:</p> <p><b>Dignity and Care:</b> We value the wellbeing, dignity, and contribution of each person by nurturing a community where students and staff can reach their full potential.</p> <p><b>Solidarity and Service:</b> We promote the Common Good by widening opportunity and participation, forming outward partnerships, and by making a positive contribution to society.</p>

**Honesty and integrity:** We uphold truth, honesty, and integrity, fostering personal and collective accountability by stewarding our resources well and cultivating an awareness of our responsibility for the environment and the communities around us.

**Respect and Inclusivity:** We demonstrate our inclusivity by promoting equality in the opportunities we offer, in the right of everyone to contribute and by cultivating a safe community rooted in a culture of mutual respect.

**Knowledge and Excellence:** We aspire to stimulate keen scholarship and the pursuit of academic excellence by providing the highest standards of teaching, learning and research and by continuously improving on our performance.

### 3 Responsibilities

The University bodies, committees, departments, and individuals included below are responsible for those aspects of the RKE ethics process as listed, plus any other responsibilities that emerge in applying this policy.

#### 3.1 University Executive

- Promoting the values of Leeds Trinity as an ethical RKE community; and
- receiving reports on ethics and integrity matters as required and provide operational oversight of the policy and conduct.

#### 3.2 Academic Board and Research and Knowledge Exchange Committee (RKEC)

- Promoting the values of Leeds Trinity as an ethical RKE community;
- considering approval of recommendations for changes to policies and procedures from the University REISC, via RKEC and to Academic Board, where necessary.
- receiving annual summary reports on Faculty and University REISC activity from the University REISC; and
- receiving recommendations for changes to policies and procedures from the University REISC.

#### 3.3 University Research Ethics and Integrity Sub-Committee (REISC)

- Promoting the values of Leeds Trinity as an ethical research community;
- developing, implementing, and disseminating policies, procedures, and guidelines;
- promoting a supportive University culture around ethical considerations;
- developing, providing, and monitoring provision of ethics training for staff and PGRs;
- making outcome decisions on full applications that exceed the remit (i.e. meet Category E criteria (see Section 5)) and/or expertise of Faculty REICs, including ensuring that the Health and Safety representative on the committee is involved in the decision making process related to any Category E risk assessments;
- considering second appeals against outcomes of full applications to Faculty REICs;
- considering first appeals against outcomes of full applications reviewed by University REISC;
- receiving regular reports, *via* meeting minutes and other reporting, and annual audits of review and approval activity by Faculty REICs;
- facilitating annual audits of approved applications by Faculty REICs;
- reporting regularly on the above and its own activity to RKEC;

- regularly reviewing and updating the Research and Knowledge Exchange Ethics and Integrity Policy and related procedures and guidance;
- making recommendations for changes to other policies, procedures, and guidance;
- ensuring consistency of practice across Faculty REICs;
- supporting (e.g., providing advice and contributing to the pool of panel members) and monitoring (progress and outcomes) research misconduct investigations and panels; and
- seeking, when necessary, legal and/or expert advice on research and knowledge exchange ethics-related matters.

### 3.4 Local RKE Ethics and Integrity Coordinators and Taught Programme RKE Module Leaders

- Promoting the values of Leeds Trinity as an ethical research community;
- ensuring that RKE complies with this policy and other University policies named in Section 1 above;
- liaising with Faculty REIC Chairs (or Deputies when required in absence of Chairs);
- reviewing full applications (initial and revised) and making recommendations to project leads and Faculty REICs;
- maintaining open, honest, and collegiate dialogue with project leads (excluding taught students), including, but not limited to, providing advice before submission and after review;
- completing mandatory ethics training;
- undertaking and regularly updating other training and development activities as required; and
- maintaining an up-to-date working knowledge of ethics-related matters in the disciplines in their area of responsibility.

### 3.5 Faculty Research Ethics and Integrity Committees (REICs)

- Promoting the values of Leeds Trinity as an ethical RKE community;
- ensuring that RKE complies with this policy and other University policies named in Section 1 above;
- monitoring completion of mandatory ethics training for staff and postgraduate researchers;
- making decisions on full applications taking into account ethical review;
- maintaining open, honest, and collegiate dialogue with project leads (excluding taught students), including, but not limited to, providing advice before submission and after review;
- completing mandatory ethics training;
- undertaking and regularly updating other training and development activities as required;
- maintaining an up-to-date working knowledge of ethics-related matters in the disciplines in their Faculty;
- cascading, when necessary, relevant knowledge and information down to staff, PGRs, and students in their Faculty;
- seeking, when necessary, advice from staff outside of the Faculty REIC;
- referring, when necessary, full applications that meet Category E criteria (i.e., high risk) or that otherwise exceed the Faculty REIC's remit and/or expertise to the University REISC;

- making recommendations for changes to policies, procedures, and guidelines;
- conducting an annual audit of approved applications and reporting results to the University REISC; and
- providing inductions for new members of the Faculty REIC and facilitating ongoing development opportunities for members.

### 3.6 Faculty REIC Chairs and Deputies

- Promoting the values of Leeds Trinity as an ethical RKE community;
- liaising regularly with Local RKE Ethics and Integrity Coordinators;
- chairing Faculty REIC meetings;
- making outcome decisions on full applications, in consultation with other Faculty REIC members on behalf of the University as sponsor of all research at Leeds Trinity University
- allocating reviewers for full applications and coordinating the process of ethical review;
- maintaining open, honest, and collegiate dialogue with project leads (excluding taught students), including, but not limited to, providing advice before submission and after review;
- completing mandatory ethics training;
- undertaking and regularly updating other training and development activities as required;
- maintaining an up-to-date working knowledge of ethics-related matters in the disciplines in their Faculty;
- disseminating and promoting policies, procedures, and guidelines; and
- providing regular summary reports on Faculty REIC activity and mandatory ethics training completion to Faculty Boards.

### 3.7 Faculty Deans and Heads of Schools (and Equivalents)

#### 3.7.1 Faculty Deans

- Promoting the values of Leeds Trinity as an ethical RKE community;
- disseminating and promoting policies, procedures, and guidelines;
- appointing Local RKE Ethics and Integrity Coordinators, Faculty REIC members, and Faculty REIC Chair and Deputy Chairs;
- promoting Faculty culture around ethical considerations; and
- promoting completion of mandatory ethics training for staff and postgraduate researchers.

#### 3.7.2 Heads of School

- Promoting the values of Leeds Trinity as an ethical RKE community;
- monitoring and ensuring completion of mandatory ethics training by staff, through Performing and Developing Reviews;
- maintaining an up-to-date working knowledge of ethics-related matters in the disciplines in their School; and
- disseminating and promoting policies, procedures, and guidelines.

### 3.8 Programme, Module Leaders and Supervisors of research and taught programme students

- Promoting the values of Leeds Trinity as an ethical RKE community;
- aiming at, where possible, embedding social solidarity and the common good (see Section 4.1) in all RKE;
- ensuring any RKE comply with this policy and other University policies named in Section 1 above; and
- specifically ensuring that students are adequately prepared to understand and comply with this policy in conducting RKE activity associated with their studies.

### 3.9 Staff, PGRs, and approved visiting researchers

- Promoting the values of Leeds Trinity as an ethical RKE community;
- aiming at, where possible, embedding social solidarity and the common good (see Section 4.1) in all RKE;
- ensuring any RKE comply with this policy and other University policies named in Section 1 above;
- applying for ethics review and approval for all RKE, completing at minimum the self-assessment and, if required, following any further steps as outlined in Section 5 below;
- completing mandatory ethics training;
- undertaking and regularly updating other training and development activities as required; and
- maintaining an up-to-date working knowledge of ethics-related matters in their discipline.

### 3.10 Postgraduate and Undergraduate Students

- Promoting the values of Leeds Trinity as an ethical RKE community;
- aiming at, where possible, embedding social solidarity and the common good (see Section 4.1) in all RKE;
- ensuring any RKE conducted for relevant module assessments, including but not limited to dissertations and any work involving collecting data from participants, complies with this policy and other University policies named in Section 1 above;
- applying for ethics review and approval for all relevant RKE activity, completing at minimum the self-assessment (or module-specific equivalent) and, if required, following any further steps as outlined in Section 6 below;
- completing any ethics training as required by their programme of study; and
- undertaking other training and development activities as required and as directed by supervisors.

### 3.11 Academic Partnerships Unit and Franchise Partners

#### 3.11.1 Academic Partnerships Unit

- Promoting the values of Leeds Trinity as an ethical RKE community;
- ensuring that franchise partners are aware of and have adequate procedures in place to comply with this policy and other University policies named in Section 1 above;

- reporting regularly on approvals and other ethics-related matters in franchise partners to the relevant Faculty REIC;
- ensuring that all audit requirements are met;
- ensuring that partners appoint Local RKE Ethics and Integrity Coordinators;
- overseeing the operation of self-assessment, approval and use of standard protocols at module level;
- acting as a point of liaison between Faculty REICs, University REISC and partners; and
- ensuring that student applications for review are progressed to Faculty REICs where necessary.

### 3.11.2 Franchise partners

- Promoting the values of Leeds Trinity as an ethical RKE community;
- ensuring that student RKE complies with this policy and other University policies named in Section 1 above;
- providing information, support, learning and guidance to students to ensure that they comply with this policy;
- enacting procedures for ethical review and approval as set out in this policy;
- ensuring that Local RKE Ethics and Integrity Coordinators are in place;
- ensuring that Local RKE Ethics and Integrity Coordinators play an active role in their relevant Faculty REICs;
- ensuring that module leaders provide ethical review in a timely way;
- ensuring that any standard protocols are used appropriately and that RKE approved under these remains within the terms of the standard protocol;
- conducting an annual audit of approved applications and reporting results to their Faculty REIC; and
- liaising with their Faculty REIC regarding the timing of meetings and student approvals.

## 4 Ethical and integrity considerations in research and approval

In making and reviewing applications *via* self-assessment or full application, researchers, project leads, internal/external collaborators, Local RKE Ethics Coordinators, and Faculty and University-level reviewers should have regard to the following considerations.

### 4.1 Social solidarity and the common good

Promoting social solidarity and the common good are central to LTU's mission as a higher education institution, through its commitment to social justice, enhancing opportunities, collaboration, and adding value to the lives of its students, staff, and the wider community of all who engage with it. This ethical vision is grounded in LTU's Catholic foundation and principles of inclusivity, care, and integrity, as well as the [University's signing of the United Nations Sustainable Development Goals \(SDG\) Accord](#)

It is the responsibility of LTU as an institution and researchers, project leads, and internal/external collaborators to live up to this [mission and core values](#) in any RKE they are involved in.

Ethical consideration in RKE should go beyond the avoidance of unethical behaviour and include concern for how the activity and its outcomes can make a positive contribution and help further social solidarity and the common good. RKE should aim to do good, as well as ensuring that it does not do bad. Researchers, project leads, internal collaborators, Local RKE Ethics Coordinators, and Faculty and University-level reviewers are encouraged to address this in applications for ethical approval and their review.

#### 4.2 Research and Knowledge Exchange Activity using documentary sources

Full ethics and integrity review is generally not required for primary or secondary research which is principally based on reviewing or analysing literature, texts, documents, archival material, anonymous records, or datasets and where access to this material does not require direct contact with human participants. Ethics considerations around data derived from social media are covered in Section 4.3. In the case of such RKE, an initial self-assessment (see Section 6) is still mandatory to formally record the project and to receive confirmation that a full application is not required.

However, a full application may be necessary even in these cases, where the documents or data are particularly sensitive, include personal data, require enhanced security or data protection, or the topic of the research has additional risks. A comprehensive list of those cases that might require full review cannot be provided here but examples include where there are risks associated with public opinion or stakeholders and others with an interest in the research material/data. A full application may also be required if the RKE raises other ethical concerns or carries a certain amount of risk (see Section 4) for the project leads and internal/external collaborators involved or LTU as an institution.

Project leads are responsible for ensuring that the use of data/material complies with the restrictions set down by the provider of such materials as a condition of their use and should consider any ethical implications such restrictions entail.

#### 4.3 Research involving social media

Social media refers to the means of interactions among people in which they create, share, and/or exchange information and ideas in virtual communities and/or networks. Examples of social media platforms include Facebook, Twitter/X, blogging sites (e.g., Wordpress), video sites (e.g., YouTube), online messaging services, discussion forums, etc. Social media platforms hold vast quantities of naturally occurring data or can be used to access large groups of individuals to yield data, providing academics with an opportunity to gather data that would otherwise take time and considerable resource and effort to obtain. It is the responsibility of the project lead, internal/external collaborators, and supervisors and module coordinators to ensure that data is collected and analysed with due regard for ethics, integrity, quality, and respect for the appropriate legal, regulatory, and disciplinary principles, including those of the social media user themselves who may be the subject of such work.

Social media users are defined as human participants if they are observed or their data is used for RKE purposes. Furthermore, most social media data is defined as personally identifiable data under the General Data Protection Regulation. Simply removing the unique username of the author from the rest of the data may not be sufficient to guarantee anonymity if the content of the social media text

contains specific information (e.g., personal information about the author or another person). Likewise, it may also be possible to search for the content online and thus determine the identity of the author. Social media companies often process user's data and own it, undertaking their own research based on it. Therefore, in all cases where social media data is being used in RKE, ethical approval must be gained prior to collecting and analysing data.

See the Leeds Trinity University guidance on [Research Involving Social Media: Ethical Considerations](#) for more information.

## 4.4 Research involving human participants

### 4.4.1 Key principles

RKE involving human participants should recognise the following key principles:

- alignment with other Leeds Trinity University policies and practice (e.g. those set out in Section 1.1) and relevant legal requirements, for instance pertaining to Health and Safety, Data Protection and sector wide practice;
- ensure that the scale and depth of involvement of human participants is proportionate to the positive contribution, RKE requirements, and risks involved in the project;
- mitigate and, where appropriate, minimise the risks and potential risks to human participants and ensure that these are proportionate to the RKE requirements and positive contribution of the RKE;
- maximise the quality and impact of the RKE, including its positive contribution;
- ensure that human participants are involved as far as possible in decision making in the RKE and their involvement and other obligations arising from other policies and legal requirements are met as fully as possible;
- project leads and internal/external collaborators have a duty of care toward human participants, including their physical, mental, spiritual, and emotional wellbeing and to ensure their participation is a positive experience in the context of, and proportionate to, the RKE objectives and methods; and
- where possible, avoidance and/or minimisation of harm: project leads and internal/external collaborators must take all reasonable and possible steps to avoid and/or minimise harm.

Wherever project leads or internal/external collaborators suspect or consider that these principles cannot be met, are at risk, or where outcomes are deviating from the planned and reviewed expectation they must suspend the activity leading to these risks and seek advice from the project lead, Local RKE Ethics and Integrity Coordinator, or Faculty REIC Chair. The appropriate action may include resubmitting RKE plans for ethical review or withdrawing an ethics and integrity approval outcome.

### 4.4.2 Vulnerable adults, children, and safeguarding

Some human participants may be regarded as vulnerable. Vulnerability should be understood as context specific rather than a characteristic belonging to a particular person, though some stakeholders, human participants, project leads, or internal/external collaborators may routinely be regarded as *potentially* vulnerable for the purposes of protecting their interests. This is the case where

their characteristics have an impact on their capacity to participate, experience of participating, or capacity to give free, specific, explicit, and informed consent. Human participants with the following characteristics require additional consideration regarding their participation, safeguarding, and consent:

- children and young people under the age of 18;
- people with limiting health conditions or disabilities, where this is related to their capacity participate in the RKE, experience of participating in the RKE, or capacity to give informed and explicit consent;
- people in conditions in which their capacity to participate, experience of participating, or provision of informed and explicit consent may be influenced by others, such as some types of proxies or gatekeepers. This includes people in any form of custody or dependent power relation with others, including the state; and
- people who are in some form of relationship or power relation with project leads, internal/external collaborators, or other human participants, including students and staff of Leeds Trinity University.

Vulnerability should be judged in the context of the [University's Safeguarding Policy](#).

Where project leads or internal/external collaborators are working with vulnerable adults or children they may require additional legal checks (for instance a criminal records check from the Disclosure and Baring Service). In these cases, any approval may be conditional on the satisfactory completion of these checks being in place and the RKE should not take place until this is the case. On approval, Faculty or University REICs should contact the project lead and relevant internal/external collaborators, as well as Human Resources, to inform them that such additional steps are required. It is then the responsibility of the project lead and internal/external collaborators to inform the relevant REIC once these additional checks have been satisfactorily completed and that Human Resources have the relevant record, including dates, conditions, and any reference numbers. Where additional checks are required, the relevant RKE must not commence until satisfactory completion of these has been assured.

#### 4.4.3 Legal and other requirements and professional standards

There are a number of legal requirements that researchers should have regard to in undertaking RKE involving human participants. These include Data Protection legislation and the Mental Capacity Act (2005). All RKE should comply with the [University's Safeguarding Policy](#) which sets out how the University upholds legal requirements.

Project leads and internal/external collaborators who are members of a regulated profession must ensure that RKE involving human participants or personal data complies with any standards set by any external bodies regulating their profession. Such professional standards are additional to and not a replacement of the need for ethical review and University approval under the terms of this policy.

#### 4.4.4 Consent

Project leads and internal/external collaborators undertaking RKE involving human participants must satisfy themselves that participants are enabled by the provision of adequate information and

opportunities to engage in discussion about the research and to provide voluntary consent which is clear, specific, explicit, and informed.

This consent may be provided and recorded in different ways but should always be appropriate to the participant's needs, proportionate to the RKE, objectives, positive benefit, and risks involved in the RKE. The recording of consent should be balanced with other objectives and obligations such as principles of privacy by design as set out in the [General Data Protection Regulation and Data Protection Act](#).

Methods for securing clear, specific, explicit and informed consent should be set out in full applications for ethics review and University approval and changes to these methods would normally require further review. Key considerations in specifying these methods and for reviewing them include ensuring that participation is voluntary, that participants have sufficient information and context-specific capacity to provide consent, and that they are adequately informed about the RKE, their participation, and any risks and positive contributions involved. Consent must not be linked to the provision of any other service, benefit, or reward (the provision of proportional participant incentives to recognise time and other expenses are an exception to this; see the [University Participant Reimbursement Guidelines](#) for detail).

Consent may be obtained from vulnerable people or people who are potentially vulnerable and this may involve additional permission secured from proxies or gatekeepers. The arrangements for such consent should be clearly explained, reviewed, and proportionate to the RKE, objectives, positive benefit, and risks. Consent should normally be specific to all stages of the RKE process, including different forms of publication and dissemination.

Consent related to personal data must comply with the [University's Data Protection Policy](#) and the relevant legislation. There are a variety of legal bases for the use of personal information in research, including 'Public Task', 'Legitimate Interest' and 'Consent'. Consent will often be utilised where other legal bases are not relevant. Where consent is used as a legal basis it should be specific to the collection, storage, processing, and use of personal data. It may be necessary to distinguish between the ethical principle of seeking consent for involvement in research as a subject or participant and consent related to the legal requirements associated with processing of personal data, i.e. the legal basis for collecting personal data may be 'Public Task' while ethical principles may still suggest that consent should be sought. Any change to the RKE purpose, method, storage, processing, or dissemination after consent has been given will not normally be permitted and may require additional consent to be provided for these changes.

The right of participants to withdraw consent is an important principle and the procedure for withdrawal (and its limitations, including but not limited to the point after which they can no longer withdraw) should be clearly explained to participants. No service, benefit, or reward (including participant incentives) should be removed where a participant withdraws, except where this relates to future participation that will not happen as a result of withdrawal.

In some strictly limited cases, there may be scope for RKE where consent is not secured or where consent is on the basis of 'opt-out'. In these cases, the alternative legal basis for processing any

personal data should be clearly spelled out. This may be the case in some observational research or in cases where deception is a legitimate research method. In these cases, review, categorisation, and management processes should be clearly set out, fully justified, and proportionate to the RKE objectives, positive contribution, and risks. Arrangements for dealing with unintended participants or people who may participate indirectly should be set out and reviewed in the ethical review process.

There are a range of sources of guidance, good practice, and advice which may be considered in designing practices and processes for securing and recording consent. Some examples are set out in the Appendix.

#### 4.5 RKE involving human tissue

Research involving human tissue and materials will be strictly limited. The Human Tissue Act (2004) provides a framework for regulating the collection, storage, and use of human material and tissues and this must be adhered to at all times. Leeds Trinity University does not hold a license for the collection, storage and use of human tissue. However, there are some strictly limited exceptions that permit collection, storage and use of certain limited types of human tissue for research purposes using very specific and limited techniques. Collection, storage and use of these tissues and methods may be possible on a strictly controlled and limited basis on a case-by-case basis. Any work with human tissue should be the subject of a Full Application and detailed documentation and monitoring will be required in any cases that are approved, demonstrating why the RKE activity is permissible without an HTA license being in place.

#### 4.6 Research involving animals

Research involving animals will not be undertaken at LTU. Specifically, no research will be undertaken by LTU staff, approved visiting researchers, PGRs, students or others acting on behalf of the University on LTU premises that requires licensed approval under the Animals in Scientific Procedures Act (1986) and the Amendment Regulations (2012).

In limited cases RKE involving animals may be undertaken in instances where animals are incidental participants in research, where there is no risk of harm to the animal from the RKE, and where the RKE data is collected from human participants interacting with animals (e.g., RKE with police dog handlers or horse-riding communities). In these instances, the RKE should be reviewed in the normal way and all ethical considerations in this document will apply.

Even in these circumstances, research involving animals should consider the following (3Rs):

- Replacement - use of animal cells or if possible non-animal alternatives.
- Reduction - using fewer animals.
- Refinement - minimise pain and enhance welfare throughout an animal's life.

For the avoidance of doubt, all LTU staff, approved visiting researchers, PGRs, students or others acting on behalf of the University must be able to opt-out of research involving animals.

#### 4.7 RKE, the environment, and cultural heritage

Project leads and internal/external collaborators should ensure that their RKE and RKE conduct has due regard to any harm or risk of harm to the environment, including other living creatures, plant and

microbial life, habitats, or environmental resources (e.g., air, soil, water). The principles and requirements of the [Nagoya Protocol](#) should be considered in the design and conduct of RKE and ethical review. RKE conduct should manage and minimise these risks and any risk should be proportionate to positive benefit, RKE, and RKE objectives. Project leads and internal/external collaborators should also ensure that RKE and RKE conduct does not cause unnecessary or harmful loss or damage to artefacts or information related to the understanding of cultural heritage. Activities that directly or indirectly promote or condone such harmful loss or damage should not be undertaken unless ethics and integrity approval has been granted on the grounds that such activity is justified to enhance cultural heritage and/or the understanding of it.

Harms and risks should be identified in RKE plans and considered in ethical review. Where necessary further environmental risk assessments may be required (see Section 4.12). All RKE should comply with University policies on Health and Safety and use of controlled substances (see Section 4.12).

#### 4.8 RKE overseas

RKE outside of the UK may involve additional risks or legal and ethical considerations. Project leads and internal/external collaborators should ensure that they have fully considered these risks, obligations, and considerations and they should be reflected in the design and conduct of RKE and ethical review. Project leads and internal/external collaborators should have due regard to and respect for local legal requirements, social and cultural norms, and expected standards. For example, in some countries local RKE permits are required where data collection will take place. All RKE overseas should comply with other policies including the [Research Data Management Policy](#), the [Data Protection Policy](#), [Overseas Travel Guidance](#), and the [Trusted Research and External Collaborations Policy](#).

Any additional risks associated with overseas RKE should be balanced against RKE, RKE objectives, and positive contributions in a proportionate way. Risks should be minimised and managed wherever possible. Considerations of risk should extend beyond project leads and internal/external collaborators and include participants (direct and indirect), the use of research assistants (who should be considered as researchers even where not employed by LTU), and stakeholders.

Wherever researchers, project leads, or internal/external collaborators suspect or consider that these principles cannot be met, are at risk, or that outcomes are deviating from the planned and reviewed expectation, they must suspend the activity leading to these risks and seek advice from the project lead, Local RKE Ethics and Integrity Coordinator, or Faculty REIC Chair. The appropriate action may include resubmitting RKE plans for ethical review.

#### 4.9 RKE partners and external collaborations

Some partners and external collaborations will involve additional risks or considerations and obligations. Partners and external collaborators and their role in RKE should be clearly set out in the design and conduct of RKE and considered in ethical review.

All RKE with partners and external collaborators should be logged and risk assessed in the [Trusted Research and External Collaborations Risk Register](#).

#### 4.9.1 Working with UK and EU Higher Education Institutions

Working with other UK or EU HEIs as partners or external collaborators will not usually be regarded as an additional risk. This should be logged and risk assessed using the [Trusted Research and External Partnerships](#) process.

#### 4.9.2 Working with the NHS, Social Care, Police and Prison Service

RKE with specific types of external partner may require alternative ethical approval from an external Research Ethics Committee, with such RKE classed as Category D (see Section 4.2). The [UK Policy Framework for Health and Social Care Research](#) offers further guidance. Researchers, project leads, Local RKE Ethics and Integrity Coordinators, and Faculty REICs should consult the [Integrated Research Application System](#) website for further information. The self-assessment process will indicate where external review and approval is necessary, from one of the following bodies:

- Administration of Radioactive Substances Advisory Committee (ARSAC);
- Confidentiality Advisory Group (CAG);
- Gene Therapy Advisory Committee (GTAC);
- Health Research Authority (HRA) for projects seeking HRA Approval;
- Medicines and Healthcare products Regulatory Agency (MHRA);
- NHS / HSC R&D offices;
- NHS / HSC Research Ethics Committees;
- National Offender Management Service (NOMS);
- Social Care Research Ethics Committee.

Where this is the case, applications should be made through [the IRAS system](#). Researchers and project leads with approval for a specific project from an external authority accessed by IRAS should log this approval with their Faculty REIC, ensuring that a record is kept of all study and approval documents and IRAS ID number.

#### 4.9.3 Working with other partners

Many other partners may require additional permissions or ethical approval. Each RKE project will have its own specificities. It is the responsibility of project leads and internal/external collaborators to take all reasonable steps to ensure that any external permissions and approval requirements are documented in their RKE plans and considered as part of the ethical review process. Where ethical review is undertaken externally and approval given by an external project sponsor, LTU researchers will need to complete self-assessment indicating this is the case and then forward the appropriate documentation (application and approval) to the Local RKE Ethics and Integrity Coordinator for record keeping.

#### 4.10 RKE approved by another Higher Education Institution in the UK or European Union

Many RKE projects that have already been approved by another Higher Education Institution (HEI) in the UK or EU, where one or more LTU researcher is an external collaborator and not the project lead, will not normally require separate LTU ethical approval. This is the case where the external HEI is the project sponsor. An initial self-assessment is still mandatory, but rather than submitting a full

application, a copy of the outcome notification indicating approval and the application form that has been approved should be submitted to the Local RKE Ethics and Integrity Coordinator and held as a record of approval. Faculty REICs or University REISC may deem (including after review by a Local RKE Ethics and Integrity Coordinator) that a full application, covering LTU involvement, is required. Where work across a project is interdisciplinary, separate ethical approval for each part may be required, including as part of funder requirements.

#### 4.11 RKE approved by another Higher Education Institution outside the UK/EU

In the case of projects that have already received approval from an HEI or other recognised approving body outside the UK, separate LTU ethical approval is required. This is due to different ethical approval processes and standards being applied in different countries and the requirement that all LTU researchers comply with UK standards and practices for RKE ethics and integrity.

#### 4.12 Health and Safety Considerations and Risk Assessments

RKE conduct should ensure that there is a risk assessment in place to consider foreseeable risks associated with RKE activities, including the nature of the activity, the participants (where applicable) and location. The risk assessment should include project leads, researchers, internal/external collaborators, participants, and anyone else involved in the RKE indirectly.

For RKE that meets Category A criteria (i.e., very low risk) and where a full application is not required, the self-assessment will constitute a valid risk assessment. All full applications for ethics and integrity approval must include the completion of health and safety risk assessment, available from the [Health and Safety Intranet page](#) (supervisors, module coordinators, and project leads must ensure relevant templates and guidance are provided to students and others without Intranet access). Completed risk assessments must be reviewed and approved (by way of signature) by the line manager, supervisor, or module coordinator of the project lead or taught student prior to submission of the full application.

Where the RKE meets Category E criteria (i.e., high risk), where the RKE is planned to take place in a location that the Foreign and Commonwealth Office advises against for all or all but essential travel, and/or where the line manager, supervisor, or module coordinator feels unable to approve the risk assessment, the full application with the included risk assessment will be referred to the University REISC for review. In these cases, the Health and Safety representative on the University REISC will be responsible for reviewing and approving the risk assessment.

Local RKE Ethics Coordinators and Faculty REICs should not be involved in reviewing or approving risk assessments. Unless superseded by guidance from Health and Safety, the Research and Knowledge Exchange Office will be responsible for holding records of all approved risk assessments for RKE.

#### 4.13 Conflicts of Interest

Conflicts of interest (such as personal or organisational considerations including, but not limited to, competition, familial relationship with participant(s), rivalry, and financial matters) must be identified, declared, and addressed to minimise the risk of poor practice. Failure to do so could constitute misconduct. One of the aims of ethical review is to assess potential conflicts of interest, determine whether RKE activity should go ahead, or provide conditions that must be met to adequately address

the conflict of interest were the activity to go ahead (through, for example, declarations, safeguards, and the conduct and reporting of activity).

Researchers, project leads, and internal/external collaborators are responsible for complying with LTU's [Conflict of Interest Code of Practice](#) and any other University policies and procedures pertaining to conflict of interest. Members of Faculty REICs and the University REISC and anyone asked to contribute to ethical review must recuse themselves when there are potential conflicts of interest or they lack impartiality related to a review or decision on ethical approval.

#### 4.14 Trusted Research and National Security

The University [Trusted Research Policy](#) and process responds to government policy and the National Security Act. It sets out processes for understanding and assessing potential additional risks that should be incorporated in ethical approval in addition to the normal ethical and integrity considerations. These risks stem in the main from the potential of hostile state, terrorist, and criminal actors using RKE data and findings in ways they were not intended and the potential for harm to the University from data loss and misuse. Wherever RKE has the potential misuse by these actors or where there are certain types of partnership, the Trusted Research Policy and risk assessment should be followed. External partnerships should be logged in the external partnerships register.

#### 4.15 Data management

Effective management of data (covering the generation, collection, use, storage, and security of data, especially personal data) is vital to ethical RKE activity. LTU as an institution and its members of staff, PGRs, and students are responsible for complying with LTU's [Research Data Management Policy and Data Protection Policy](#). Explicit confirmation that these and any other relevant policies and/or procedures will be adhered to is a condition of University approval for RKE activity.

#### 4.16 Dissemination and Open Access

Project leads and internal/external collaborators have an ethical duty to disseminate the outputs of RKE in a manner that provides a complete and accurate report of all findings, free from selection that could be misleading. Plans for responsible dissemination of outputs, where relevant, should be included in applications for ethical approval. Applicants may consider guidelines such as those produced by the [Committee on Publication Ethics](#). Consideration should be given to open access to data and outputs and guidance, such as the [Budapest Open Access Initiative \(BOAI\)](#) and the [Concordat on Open Research Data](#), should be adhered to, in line with LTU's data management policies.

Stated authorship of outputs should include all those who have made a significant intellectual or practical contribution to the work (see the [Contributor Roles Taxonomy \(CRediT\)](#) guidelines). No one who meets these criteria should be excluded from authorship. Anyone listed as an author of an output should be prepared to take public responsibility for it and be able to identify their contribution.

#### 4.17 Copyright and Intellectual Property

Applications for ethical approval should try to anticipate the implications the proposed RKE activity may have in relation to copyright, intellectual property, and related matters such as forming companies. Guidance from relevant Financial Procedures (e.g., on [Intellectual Property Rights](#) and [Companies and Joint Ventures](#)) and other University sources (e.g., on [Copyright](#)) should be consulted

to ensure that such matters are handled in accordance with legal requirements and ethical good practice. The Head of Business Development might also be consulted for further support.

Copyright and intellectual property concerns should be considered alongside ethical duties around dissemination and open access. Alternatives to copyright such as [Creative Commons](#) may be considered. Applicants may consider guidelines such as those produced by the [Committee on Publication Ethics](#).

#### 4.18 Artificial Intelligence in RKE

Various forms of Artificial Intelligence (AI) have an increasing role in society and in RKE activity. Project leads, internal/external collaborators and ethics and integrity reviewers should have due regard to ensuring that the use of AI in RKE activity should not compromise other aspects of this policy and other relevant policies, including RKE integrity and the use of data. Any automated processing of participant data should be in line with the LTU [Research Data Management Policy and Data Protection Policy](#) and comply with the relevant legal obligations (e.g. under the Data Protection Act (2018)). Specifically, researchers should be aware of AI tools that store and publish research data, particularly personal data and therefore that use of AI may lead to publication of this data. Any use of AI should be clearly and comprehensively acknowledged and described in self-assessment and full application as well as outputs from the RKE activity.

#### 4.19 Finance, Purchasing and Insurance

Project leads are responsible for the financial management of RKE projects and should ensure that all financial activity is carried out in accordance with relevant LTU policies and procedures (available on the [Finance intranet site](#)).

Consideration should be given in applications for ethical approval to purchasing and the selection of suppliers and goods provided, considering the environmental sustainability of the purchasing of goods and services for RKE projects as well as LTU's mission to promote social solidarity and the common good (see Section 4.1). Choice of suppliers should be based on the environmental, social, cultural, and economic impact of the suppliers as well as value for money. Similar consideration should be given to the impact of different forms of travel for RKE activity.

#### 4.20 Academic freedom and reputational damage

LTU recognises and endorses that academic freedom and freedom of speech and expression within the law has fundamental importance for RKE activity, in line with the [Code of Practice on Freedom of Speech and Expression](#) and any other relevant University policies and UK Government legislation. Academic freedom includes, but is not limited to, the rights to carry out RKE without commercial or political interference, disseminate and publish RKE findings, and express one's opinion publicly without institutional censorship.

Project leads and internal/external collaborators should conduct themselves in accordance with the institutional and individual duties inherent in academic freedom, as set out in Sections 22 and 34 of [UNESCO's Recommendation concerning the Status of Higher-Education Teaching Personnel](#). Academic freedom entails the responsibility to respect the democratic rights and freedoms of others and to refrain from all forms of harassment, prejudice, and unfair discrimination.

Consideration must be given in applications for approval and in review of applications to potential conflicts between academic freedom and reputational damage (to LTU and/or to the individuals or other organisations involved in the RKE activities in question).

#### 4.21 Disciplinary norms

It is recognised that RKE takes place within different disciplinary contexts, involving different disciplinary norms. These disciplinary norms are often codified in guidance and information produced by disciplinary subject organisations and learned societies. Project leads, internal/external collaborators, and reviewers are encouraged to consider and recognise disciplinary norms in interpreting the ethical considerations relevant to a particular RKE project.

#### 4.22 Integrity and appropriate rigour in RKE conduct

Ethics and integrity processes are not intended to judge the quality of RKE activity. However, reviews should ensure that RKE activity is undertaken with honesty, openness, and in line with the [UK Concordat on Research Integrity](#).

[Project leads and internal/external collaborators should consult the UKRIO Code of Practice for Research and the associated checklist.](#)

#### 4.23 Other Considerations

Ethics and integrity review is a complex process and no policy can set out all considerations that might be relevant. As such, project leads, internal/external collaborators, and reviewers may need to take into account a wide range of other considerations that may impact on the positive contribution and risks associated with any particular RKE project.

## 5 Categorising risk, proportionate review, and approval

### 5.1 Ethical Review and Approval

Ethical approval is awarded by the Faculty REICs operating on behalf of the University REISC which discharges the University responsibility as sponsor of research at Leeds Trinity. In some circumstances the Chair or Deputy Chair (acting on behalf of the Committee) may take Chair's Action to approve full applications between meetings of the Committee. This is usually where the RKE is regarded as low risk after mitigations (Category B below).

Ethical review is provided by applicants, Local RKE Ethics and Integrity Coordinators, and any member of the Faculty REIC. Ethical review operates on the basis of peer review and includes a recommendation to the Committee about whether the proposed RKE proposal should be approved, revised, or escalated for further review and consideration.

### 5.2 Principles for risk categorisation and proportionate review

RKE at Leeds Trinity University should pursue a positive contribution to society, researchers and others involved in RKE (including Leeds Trinity University as an institution), participants, and other stakeholders, especially as it aligns with our Catholic mission and values. It is expected that this positive contribution should outweigh risks and harm. All risks (of any type including but not limited to physical, mental, emotional, relational, spiritual, reputational, and financial) should be managed

and minimised as much as possible. As such, a consideration of ethics and integrity is expected to inform a RKE project from its inception.

Ethical review and risk management procedures in RKE conduct should be proportionate to a reasonable assessment of the RKE, RKE objectives, potential positive contribution, and risks. For this reason, five distinct categories of risk are outlined with criteria for assessing which category and ethical review process is relevant to any particular RKE project. Self-assessment is used as the beginning of the process of ethical review, which may also include the submission of a full application for consideration and ethical review by Local RKE Ethics and Integrity Coordinators or external review by a competent authority. Reviews of full applications by Local RKE Ethics and Integrity Coordinators will include a recommendation to the Faculty REISC or University REISC. Faculty REICs and the University REISC then act as the approver of the application, acting on behalf of the University as sponsor of the RKE.

### 5.3 Review Stages, Review categories and Risk Approval criteria

Following ethical review RKE ethics and integrity submissions will be categorised as follows:

Category	Typical characteristics	Criteria for Approval	Typical Example*	Review and approval mechanism
Category A: Low risk without Human Participants/Sensitive subjects	Desk based RKE focussed on non-sensitive subjects without human participants.	Very Low Risk	<ul style="list-style-type: none"> <li>- Literature review</li> <li>- Systematic review on a non-sensitive topic.</li> <li>- Archival RKE where data is not sensitive or personal.</li> <li>- Lab based study where there are no additional H&amp;S or ethical considerations.</li> <li>- Use of published quantitative data or data from a repository, archive or website which does not include personal data.</li> <li>- Social Media RKE where there are no sensitive aspects and no personal data.</li> </ul>	Stage 1: Self-Assessment only

<p>Category B: Low-Risk involving human participants or sensitive subjects.</p>	<p>Desk based study involving some sensitive subject or human participants but local coordinator review suggests this is low risk.</p>	<p>Low risk with effective mitigations</p>	<ul style="list-style-type: none"> <li>- Study involving professionals as participants, interviewed in a public building on a topic that is low risk.</li> <li>- Study involving no human participants but with some sensitive subjects but there are no other risk factors, beyond standard risk mitigation.</li> <li>- Social media RKE including data gathered from the public domain where personal data is involved but where risk is low.</li> </ul>	<p>Stage 2: Full Application submitted for Local RKE Ethics Coordinator review</p>
<p>Category C: Moderate risk on a sensitive topic and/or involving human participants</p>	<p>RKE involving human participants where additional (to Cat2) risk mitigation is needed. Desk RKE on a sensitive subjects where additional risk mitigation is needed.</p>	<p>Moderate risk with effective mitigations</p>	<ul style="list-style-type: none"> <li>- A study with human participants where this requires risk mitigations.</li> <li>- A Systematic Review on a sensitive subject.</li> <li>- Social media RKE where there is personal data or moderate risk.</li> <li>- Secondary analysis of data containing personal information.</li> </ul>	<p>Stage 3: Full Application referred by Local Coordinator for Faculty RKE Ethics and Integrity Committee review</p>
<p>Category D: RKE requiring external review</p>	<p>RKE involving human participants in, or taking place in, a health, social care, prison, police or other externally</p>	<p>Requires External Review</p>	<ul style="list-style-type: none"> <li>- A study involving NHS patients.</li> <li>- A study in a secure setting or involving offenders.</li> <li>- A study in a social care setting.</li> <li>- A study involving medical equipment,</li> </ul>	<p>Stage 3: External Review – <a href="#">Integrated Research Application System</a>.</p>

	regulated context.		devices, or investigational products, or human tissue from NHS patients.	
Category E: RKE with high risk prior to mitigations	-RKE submission rejected by a Faculty Research Ethics and Integrity Committee on appeal. - RKE which is deemed high risk by the Faculty Research Ethics and Integrity Committee	High risk with effective mitigations	- RKE involving human participants where there is risk of harm but where the mitigations in place offset this and where the beneficial contribution outweighs the risk.	Stage 4: Full Application referred by Faculty REIC for University Research Ethics and Integrity Sub-Committee review
Category F: RKE considered too high risk – ethical approval rejected		Moderate-High risk with insufficient mitigations		

\* these examples are not comprehensive.

Judgements of risk would usually take the following forms:

- **Category A: Very Low risk** – the RKE has very low or no risks. Positive contribution outweighs the risks, usually assessed by self-assessment.
- **Category B: Low risk with effective mitigations** – there are some low-level risks associated with the RKE but the mitigations applied in the planned RKE conduct (including after recommended revisions) are judged to be effective in reducing these to an acceptable level. Positive contribution outweighs risks after mitigations, usually assessed via a full application, review and recommendation from the Local RKE Ethics and Integrity Coordinator and approved by a Faculty REIC acting on behalf of the University as sponsor of the research.
- **Category C: Moderate risk with effective mitigations** – there are some moderate risks associated with the RKE but the mitigations in the planned RKE conduct (including after recommended revisions) are judged to be effective in reducing these to an acceptable level. Positive contribution outweighs risks after mitigations, usually assessed via a full application and review by the Local RKE Ethics and Integrity Coordinator and one other member of the committee who both make recommendations to the Committee as a whole.
- **Category E: High risk with effective mitigations** – the RKE is of a high-risk nature and requires substantial mitigations. The mitigations applied in the planned RKE conduct (including after recommended revisions) are such that positive contribution outweighs risks after mitigations,

usually assessed via full application, review and recommendations as at Category C and consideration for approval by the University RESIC.

- **Category F: Moderate to High risk with ineffective or insufficient mitigations** - there are moderate or high risks associated with the planned RKE and the mitigations are insufficient to reduce risks to a level where the positive contribution outweighs the risks. This may include cases where the risks are moderate but the positive contribution is of insufficient merit to warrant the risks after mitigations. Category F is usually assessed by review, recommendation, revisions, and escalation to the University RESIC.

#### 5.4 Monitoring and Reporting

Faculty REICs and the University REISC will monitor ethical review at all levels for which they are responsible. This role means that approval decisions may be revisited where there is evidence that criteria for approval have been judged incorrectly or there is evidence of RKE conduct which deviates from the approved submission.

At each scheduled meeting, Faculty REICs should monitor self-assessment and any Chairs' actions between meetings and request further review where deemed necessary, including by requesting a full application in the case of self-assessment-only approval. Faculty REICs are also required to produce an annual report for the University REISC and these should include data on the volume of applications by stage of review and risk judgement.

The University REISC will monitor the work of Faculty REICs on an ongoing basis and this will include reviewing annual reports and use of these to produce an annual Leeds Trinity University Ethics and Integrity Statement.

#### 5.5 Pre-Approved Standard Protocols

##### 5.5.1 Standard Protocols in staff and PGR RKE

In some circumstances, where a standard RKE approach with substantively similar data collection and analysis techniques and in similar contexts with standard tools and processes and similar levels of positive contribution and risk, there is scope for approval of a Standard Protocol. In these cases, project leads would not need to re-apply regularly for ethical review. Instead, they can apply to have a Standard Protocol approved, with review and approval operating under the same ethics and integrity framework as full applications. Subsequent self-assessment review would select this Standard Protocol. It is the responsibility of project leads and internal/external collaborators to ensure that RKE conduct is within the terms of the Standard Protocol. Faculty REICs should monitor self-assessments and the use of Standard Protocols. The use of Standard Protocols should be included in the annual review from Faculty REICs and University REISC. An approved Standard Protocol should be re-reviewed regularly (every three years as a minimum).

##### 5.5.2 Standard Protocols in taught programme RKE

Standard Protocols may also be adopted at module level for taught student RKE projects (see Section 5.5). These Standard Protocols would be required to set out a series of pre-agreed RKE topics, processes, and practices (including standard consent and information tools) normally associated with Level 6 or 7 dissertation/research project modules, but should apply wherever student-led RKE activity

takes place. Module Leaders and/or project supervisors are responsible for applying for approval for Standard Protocols which should be used where they anticipate that students will undertake RKE which is likely to be categorised at Category B or higher and usually where similar RKE will be undertaken by multiple students or repeatedly by single students.

Module Leaders and/or supervisors can apply for approval of Standard Protocols at module level on any taught postgraduate or undergraduate module that meets both of the following conditions:

1. the Standard Protocols will mean that students undertake activity that would typically be classed as Category B or C (i.e., low or medium risk); and
2. all student RKE will follow a process within the terms of the Standard Protocol (an approach with substantively similar data collection and analysis techniques and in similar contexts with standard tools and processes for ensuring consent and therefore similar levels of ethical risk).

Module Leaders are required to notify the Faculty REIC of any changes to the module that may mean that the approved Standard Protocol no longer applies (e.g., if the nature of the assessment changes from that included in the Standard Protocol application). Standard Protocols should have an approval duration set out in the initial application and any renewal applications, normally being not more than three years.

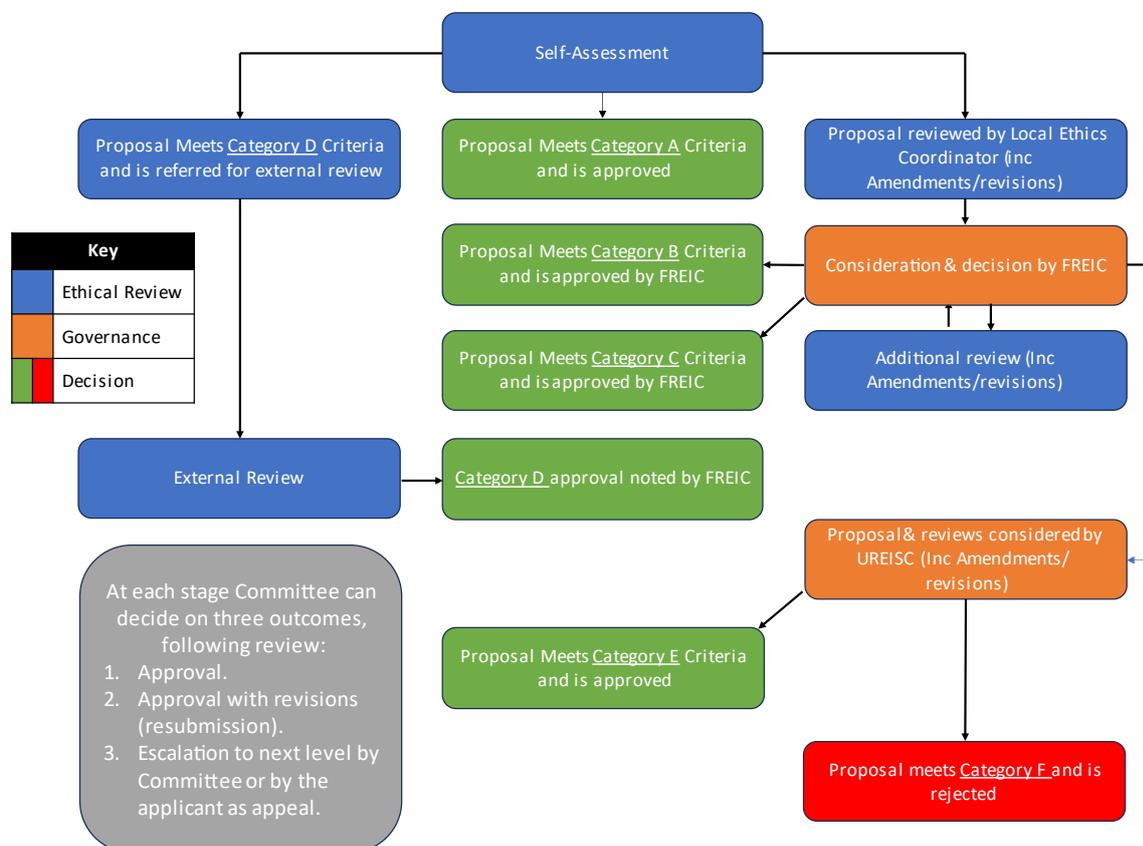
Module Leaders are responsible for contributing to the annual audit of ethics and integrity approvals by reporting on student projects and so must maintain sufficient records to enable this. In the event that a student project deviates from the approved Standard Protocols, the module coordinator should ensure that the student follows the general procedure for taught programme student RKE projects (see Section 6.2).

Where supervisors apply for the approval of a Standard Protocol, Module Leaders may provide ethical review and a recommendation to the FREIC. Where Module Leaders apply for the approval of a Standard Protocol, the application will be reviewed by a Local RKE Ethics and Integrity Coordinator.

Where pre-approved Standard Protocols are to be used, students will be able to select these Standard Protocols at self-assessment stage. It is the primary responsibility of students to ensure that their RKE adheres to these Standard Protocols. Assessment practices must ensure that this is the case and that any changes to Standard Protocols and associated tools are subject to further review as in the process set out in Section 6.3.8.

## 6 Process for Ethics and Integrity Review, Approval, and Management

Figure 1: Outline Process for Ethical Review



### 6.1 Ethical Review and Approval

There is a distinction between ethical review and approval. Ethical review is undertaken by peer reviewers who make recommendations to project leads and researchers on ways that positive contribution and risks may be managed and balanced and to Faculty REICs and University REISC on whether a proposal meets the terms of this policy. Ethical Approval is provided by Faculty REICs or University REISC on behalf of the University as the sponsor of the RKE. In making approval decisions these committees should have due regard to the ethical review provided by peer reviewers. Local RKE Ethics and Integrity Coordinators can provide ethical reviews and/or be a member of a Faculty REIC. They may therefore combine both roles, but should normally only adopt one in relation to each application for approval.

## 6.2 Staff and Post Graduate Researchers

### 6.2.1 Approval by the Faculty REIC

The Faculty REIC may approve RKE ethics applications on behalf of the University REIC, which is responsible for discharging the University's role as sponsor of research at LTU. Faculty REICs will normally approve RKE applications after ethical review, with a recommendation made to the Faculty REIC as the outcome of that review.

Where an RKE application is self-assessed as Category A it will usually receive an automatic approval and the RKE may commence, pending confirmation from the Faculty REIC. The Faculty REIC will have oversight of these self-assessments and automatic approvals and may confirm or revisit these decisions where necessary, though the latter action should be in limited and exceptional circumstances. Where consideration reveals that multiple self-assessment-based approvals are subject to question, Faculty REICs should recommend that the University REISC revise the self-assessment process.

Where an RKE application is reviewed by a Local RKE Ethics and Integrity Coordinator with a recommendation that the proposal warrants a Category B approval, the Faculty REIC Chair or Deputy may normally provide a routine Chair's Action approval between meetings. In these cases, the RKE may proceed pending confirmation by the Faculty REIC.

Where an RKE application is reviewed by a Local RKE Ethics and Integrity Coordinator with a recommendation that the proposal warrants a Category C approval or higher, it should normally receive an additional review and be considered by the Faculty REIC in full.

Where a Faculty REIC decides that an RKE application is likely to involve greater than moderate risk (i.e., potentially Category E) or involves tensions or contradictions between our values, they may escalate an application to the University REISC.

Where a Faculty REIC decides that an application requires revisions they may offer approval subject to those revisions or require further review subsequent to revisions. Project Leads should make all efforts to respond positively to these requested revisions.

Where a project lead disagrees with recommended revisions, they may request that the application is escalated for consideration by the full Faculty REIC or University REISC.

### 6.2.2 'Fast-track' review and Chair's Action

As an exception to the standard process, some full applications may require 'Fast Track' review where a strong justification is in place. This is the case where the full application is being considered for Category C approval but there are good reasons why this must be completed prior to the next meeting of the Faculty REIC. Applicants will have the option of requesting fast-track review when submitting their application. It is the Chair/Deputy of the Faculty REIC who will decide whether the fast-track request is accepted. Fast-track applications should be reviewed in the same way as other applications but Chairs/Deputies of Faculty REICs may take Chair's Action, organise a decision of the Committee between meetings, or organise an extraordinary meeting of the Committee.

### 6.2.3 Self-Assessment

Project leads should ensure that the self-assessment process is completed for all RKE projects before they begin, leaving enough time for submitting a Full Application and for review and possible resubmission prior to the intended project start date. The self-assessment process will enable project leads to give an overview of their RKE activity and identify where a further, more detailed, submission for ethics and integrity approval is necessary. The criteria for judging whether self-assessment is sufficient or whether a further full application is required include whether the RKE activity:

- involves the collection and/or storage of primary data (including but not limited to personal data that could be used to identify individuals) or tissue and bodily fluids defined as relevant material under the Human Tissue Act 2004 from or about human participants;
- exposes (or may expose) individuals involved in any part of the activity to physical, psychological, or other harm;
- involves data collected in a setting or from participants that requires external ethical review;
- presents (or may present) risk to the environment and/or society;
- presents (or may present) risk to the reputation of the University, its staff, its students, or others operating on behalf of it (e.g., substantial adverse media attention, negative impact on core business, loss of external trust); and/or
- raises any other ethical issues not covered above.

### 6.2.4 Full Application

The full application will involve a detailed outline of the conduct of the proposed research, covering all aspects of the Ethics and Integrity considerations set out in Section 4. The format of the proforma for this full application will be reviewed regularly by the University REISC and may be updated or amended as required.

### 6.2.5 Review by a Local RKE Ethics and Integrity Coordinator

Local RKE Ethics and Integrity Coordinators (hereafter 'Local Coordinators') will be based in each academic school. All schools will require at least one Local Coordinator who is also a member of the Faculty REIC, though there may be cases where schools share coordinators or appoint more than one coordinator, based on the workload in that School. Where a Local Coordinator is the project lead or another named member of the project team, review will be undertaken by a different Local Coordinator.

Ethics and integrity review by Local Coordinators will assess whether full applications can be recommended for Category B approval or receive further review. Local Coordinators may make the following recommendations to the Faculty REIC:

1. Approve at Category B (including any conditions such as DBS checks being satisfactorily completed).
2. Approval subject to satisfactory revisions (resubmission).
3. Escalation for additional review and Category C approval (including with revisions).

### 6.2.6 Review by a second reviewer

Where Full Applications are escalated to the Faculty REIC they should be considered by two reviewers which may include the Local Coordinator. The exception to this is where there is a potential conflict of interest such as when the Local Coordinator is involved in the project as a researcher, project lead, internal collaborator, supervisor, or module coordinator.

Reviewers may make the following recommendations to the Faculty REIC:

1. Approve the Full Application as Category B, C, or (following external review) Category D, (including any conditions such as DBS checks being satisfactorily completed).
2. Approval subject to satisfactory revisions (resubmission).
3. Escalation to the University REISC.

### 6.2.7 Review by the University Research Ethics and Integrity Committee

The University REISC discharges the responsibility of the University as sponsor of research at Leeds Trinity. University REISC should normally provide an overview and confirmation of Faculty REIC decisions. Where the University REISC does not confirm a Category B-D approval it can ask that the research project be suspended and/or for further revisions to the full application. However, this will be in exceptional circumstances and only used where there are reasons for concern about a Faculty REIC decision.

In some circumstances, the University REISC may be required to provide a review of a Full Application. This is the case where a decision has been escalated to the University REISC for Category E approval or *via* appeal (see Section 6.2.8). Where the University REISC provides ethics and integrity review it should involve consideration or prior reviews and recommendations and any comments from the Faculty REIC. The University REISC may require further ethical review from one or more competent authorities within or external to its membership. In these circumstances the University REISC can make the following decisions:

1. Approval at Category A-E (including any conditions such as DBS checks being satisfactorily completed).
2. Approval with revisions (resubmission).
3. Rejection as Category F.

Approval by the University REISC means that the RKE can proceed, subject to any conditions being met.

### 6.2.8 Appeals and decisions by the University Research Ethics and Integrity Committee

Where a Local Coordinator or Faculty REIC recommend revisions and resubmission, project leads should make efforts to comply with this recommendation and revise the Full Application in good faith. However, where a project lead considers that the substance of the suggested revisions or a category F decision is not in line with this policy, they may appeal that decision. The process is as follows:

- (a) Informal dialogue with the Local Research Ethics and Integrity Coordinator or Faculty REIC. Coordinators, committee members and project leads should endeavour to reach a collegiate outcome which is in line with this policy and those others referenced in it.

- (b) Where informal dialogue does not reach a resolution a project lead can choose to escalate the appeal to the next level (i.e. appeal of a Local Ethics and Integrity Coordinator decision should go to the Faculty REIC and appeal of a Faculty Committee decision should go to the University REISC).
- (c) The University REISC decision is final.

#### 6.2.9 Amendments to approved RKE activity

Changes to the RKE protocol or activity on a project which has previously received ethical approval under Category A-E may require further review, where these changes are related to the ethical and integrity considerations (or others) set out in Section 4. Further review may also be required where the project lead, internal/external collaborators, participants, or others consider that the mitigations outlined in the self-assessment and/or full application are not in practice sufficient to reduce risks to acceptable levels. It is the responsibility of project leads and all internal/external collaborators engaged in RKE to inform the relevant Faculty REIC where this is the case. Further review to consider amendments may start either at self-assessment and/or full application, depending on the initial category of approval, and will be treated in the same way as a new application, except that it is desirable for project leads and researchers to demonstrate where amendments are suggested to ensure that further review is effective and timely.

Local Coordinators (and additional reviewers where necessary) will conduct an initial review of the amendment request form and reach the following recommendation to the Faculty REIC:

1. Approve the amendment as Category B, C, or (following external review) Category D, (including any conditions such as DBS checks being satisfactorily completed).
2. Approval subject to satisfactory revisions (resubmission clarifying how concerns raised will be addressed, typically via a revised full application and a separate document outlining responses to the concerns raised).
3. Escalation to the University REISC.

Chair's Action decisions on amendments are subject to the same approval conditions as outlined in Section 6.2.1 and 6.2.2. In the event that a Chair's Action decision rejects the amendments, and the Faculty REIC endorses this judgement, a new self-assessment and/or full application will be required.

### 6.3 Taught Programme Student RKE Projects

For undergraduate modules where an individual RKE project forms the main assessment (e.g., dissertation or final project modules), supervisors are normally the project lead. Module leaders will normally act as the Local Coordinator for the purpose of ethical review. The module leader will make recommendations to the Faculty REIC about approval.

Supervisors may also submit Standard Protocols for pre-approval where they wish for students to be able to undertake research which required approval beyond Category A. Again, Module leaders will undertake review and make recommendations to the Faculty REIC for approval. Module leaders may also submit Standard Protocols for approval but these will then be reviewed by other Local Coordinators and members of the Faculty REIC.

Module leaders, with supervisors, are responsible for ensuring that students follow the ethics and integrity approval procedure and that suitable education and training is provided to allow students to do this, acting as researchers on RKE activity undertaken on behalf of the supervisor as Project Lead.

Self-assessment, and potentially full application, should be incorporated within module practice. Failure to apply for and receive ethical approval for these assessments should trigger consideration under the [Student Academic Misconduct Policy](#). Approval is necessary prior to any RKE activity commencing.

#### 6.3.1 Student responsibilities

Students are responsible for submitting their own self-assessment and full application where necessary. Failure to submit for ethical review should be considered as potential misconduct under the [Student Academic Misconduct Policy](#). It is the responsibility of each student to ensure that they only commence any RKE activity where an appropriate approval is in place.

#### 6.3.2 Module Leader and supervisor roles and responsibilities

Supervisors are in the role of project lead for taught programme student research. Module Leaders are responsible for ensuring all students on their module receive appropriate information, education, and training about the need for ethics and integrity review and the process. Module leader and/or supervisors should provide collective and individual guidance, as appropriate, to students to support them in completing the self-assessment and full application.

The process for taught programme students is substantively the same as that set out in Figure 1, though Module Leaders may provide ethical review in place of Local Coordinators, with the same recommendations following review being available as for staff RKE.

The exception to Module Leaders acting as Local Coordinators is where they are themselves the applicant requesting approval of one or more Standard Protocols (see Section 5.5.2). In those cases, an appropriate Local Coordinator would normally provide initial ethical review.

#### 6.3.3 Faculty REIC Role

The Faculty REIC will not normally review individual ethics applications to be undertaken via taught programme student applications and will only do so in the event that RKE by taught programme students falls outside of Category A or pre-approved Standard Protocols. In these cases, it will be the supervisor that takes responsibility for ethics application as a Project Lead with the student working under their direction as a researcher or internal collaborator and the application will be considered in the same way as a staff application.

Faculty REICs should audit approvals as a result of self-assessment and the operation of Standard Protocols.

Faculty REIC meetings and offline review and decision making should be organised to align with taught programme requirements and assessments on taught programmes requiring ethical review. Approval should be timed to take account of Faculty REIC deadlines.

Faculty REICs should have due consideration to ensuring student progress and that review and approval timelines are structured so that students make progress in line with module requirements. This may necessitate that the timing of meetings is adapted to taught programme requirements at key times of the year.

#### 6.3.4 Use of standard protocols

Students may be undertaking research on a module where a Standard Protocol has been reviewed and approved. Where their proposed research is wholly in line with the approved standard protocol students will need to complete self-assessment indicating the Standard Protocol relevant to their research. Students, supervisors, and module leaders will need to ensure that the research is carried out in a way that is consistent with the approved standard protocol. Any departure from the Standard Protocol may require further review and approval.

#### 6.3.5 Self-Assessment

Each student should undertake a self-assessment and guidance and prior learning in relation to this should be included in modules containing assessments related to the self-assessment. Module Leaders are responsible for ensuring that all students are informed of the requirement for self-assessment and ensuring that this is considered as part of the module assessment process. Students undertaking RKE projects where a full application is likely to be necessary should ensure that self-assessment is submitted with sufficient time to enable a full application to be considered and approved prior to commencing with the research.

The self-assessment process will enable students to give an overview of their RKE activity and identify where a full application is necessary. It will also allow students to select standard protocols attached to their module. The criteria for judging whether self-assessment is sufficient or whether a further full application is required include:

- involves the collection and/or storage of primary data (including but not limited to personal data that could be used to identify individuals) or tissue and bodily fluids defined as relevant material under the Human Tissue Act 2004 from or about human participants;
- exposes (or may expose) individuals involved in any part of the activity to physical, psychological, or other harm;
- involves data collected in a setting or from participants that requires external ethical review;
- presents (or may present) risk to the environment and/or society;
- presents (or may present) risk to the reputation of the University, its staff, its students, or others operating on behalf of it (e.g., substantial adverse media attention, negative impact on core business, loss of external trust); and/or
- raises any other ethical issues not covered above.

#### 6.3.6 Full Application

In exceptional circumstances taught programme students may require a full application.

Students requiring a full application following self-assessment should submit this to the module leader. The full application will involve a detailed outline of the conduct of the proposed RKE project, covering all aspects of the ethics and integrity considerations set out in Section 4. The format of the

proforma for this full application will be reviewed regularly by the University REISC and may be updated or amended as required.

#### 6.3.7 Appeals

Students may appeal outcome decisions. First appeals will be considered by the module leader. If this does not resolve the matter, second appeals may be submitted to the Faculty REIC.

#### 6.3.8 Amendments to approved research

Changes to the nature of research conduct on a research project which has previously received ethical approval under Category A-E may require further review, where these changes are related to the ethical and integrity considerations (or others) set out in Section 4. Students are primarily responsible for ensuring that any departure from approved processes results in further review. Module leaders and supervisors (acting on their behalf) should guide students where this is the case. Where changes are outside of the initial approval a new self-assessment should be submitted and, where necessary, a full application. The full application should revise the previous application making clear where changes have been made. Further review of full applications will be undertaken by the module leader as per the process at Section 6.3.6.

### 6.4 Guarding Against Conscious and Unconscious Bias in Reviews

Members of the University REISC and Faculty REICs should guard against all forms of bias, including unconscious or implicit bias. Applications should be reviewed on an equal and independent basis without reference to the status, reputation or experience of the project lead and others involved in the research, except where this is related to the ethical considerations set out in the policy. Committee Chairs should encourage members to reflect on their positionality and possible bias in relation to confirmation, conformity, affinity, gender, race, age, and other forms of bias. The University REISC may need to regularly encourage training and development sessions to familiarise members with the risk of bias and methods of avoiding it.

## 7 Research Ethics and Integrity Committees

### 7.1 Terms of Reference

The Terms of Reference for these Committees should be consistent with the responsibilities set out in Section 3. The University REISC will be responsible for establishing and reviewing Terms of Reference for the University REISC and the Faculty REICs on an annual basis which will be reviewed and confirmed by RKEC.

### 7.2 The University REISC

It is the responsibility of RKEC/and Faculty leadership to ensure that Committees are adequately staffed and act in accordance with the provisions of this policy.

The University REISC should have the following members, as a minimum:

- A Chair and Deputy. The Chair should not normally be a member of a Faculty REIC.
- All Chairs of the Faculty REICs. Who may act as Deputy Chairs.
- A Representative of Academic Partnership Unit.

- A representative of the University Health and Safety Manager.
- A representative of the CELT.
- Director of Post-Graduate Research (Ex-Officio).
- Information Governance and Data Protection Officer.
- At least one independent (of the University) member.
- Additional members as required to fulfil its Terms of Reference, which might include PGR or Early Career Researchers to aid in the embedding of the policy and development of these researchers.

The University REISC should regularly review its membership and Terms of Reference to ensure that they are consistent with this policy and those mentioned in it. Members are expected to attend Committee meetings and provide a full contribution to the work of the Committee to meet the responsibilities set out in this policy. Failure to attend or contribute may result in removal from the committee. Such decisions are the responsibility of the Chair and should be reported to RKEC for approval.

Committee meetings will be quorate when the number of members present is equal to or greater than 50% of the full Committee plus 1 (e.g., if there are 10 members of the Committee, meetings will be quorate when 6 are present).

### 7.3 Faculty REICs

The Faculty REICs provide an important responsibility for each Faculty. It is the responsibility of the management team of each Faculty to ensure that Committees are adequately staffed and act in accordance with the provisions of this policy.

The membership of Faculty REICs should include, as a minimum:

- A Chair and Deputy.
- Each of the Local RKE Ethics and Integrity Coordinators.
- A member representing one of the other Faculty Committees.
- Additional members as required to fulfil the provisions in this policy.
- Where there are taught programmes delivered by partners there will be at least one representative of the Academic Partnership Unit.

Faculty REICs should regularly review their membership and report changes to their membership to the University REISC.

The Committee will be quorate when the number of members present is equal to or greater than 50% of the full Committee plus 1 (e.g., if there are 10 members of the Committee, meetings will be quorate when 6 are present).

At set points in the year, Faculty REICs may wish to invite Module Coordinators relevant to taught programmes to attend the Committee.

#### 7.4 Timing and conduct of meetings

Committee meetings should be timed and conducted to expedite the business of the committees. Due regard should be given to the needs of project leads and RKE activity, including where RKE is supported by funding (internal and external) and the needs of RKE funders and users. They should also be timed and conducted to ensure the progress of PGRs and taught programme students.

Committee considerations and decisions may be taken in full synchronous meetings or *via* asynchronous communication, noting also that Chair's Actions are possible between meetings, especially in response to ethical reviews indicating low risk (e.g. Category B status). Other than in the case of Chair's Action decisions, asynchronous decisions are subject to the same quoracy rules as Committee meetings. Committee Secretaries should keep a record of such decisions and that they have met quoracy requirements. Decisions taken between full meetings should be noted and recorded at the next full meeting.

#### 7.5 Audit and Reporting

Each year the Faculty REICs will report to the University REISC in relation to the following:

- The number of staff and PGR applications, decisions, and approvals by category and any commentary on the quality or volume of applications received.
- The number of taught programme student applications, decisions, and approvals in relation to the number of students being assessed on specified RKE modules, by programme.
- The operation and use of Standard Protocols.
- Reflections on the policy and process.

University REISC will collate and respond to these reports and produce an annual report for RKEC and an annual Research Ethics Statement for open publication.

## 8 Misconduct, compliance and complaints

Complaints from RKE participants should be dealt with through the [Student Academic Misconduct Policy or the Research Misconduct Policy](#), depending on whether the RKE is part of a taught programme or not, respectively. The procedure and process for making a complaint should be stated in the information given to RKE participants before seeking their consent.

Failure to secure appropriate ethical approval for RKE is considered misconduct for staff, PGRs, and taught programme students.

Where conditions are associated with approvals, such as seeking DBS clearance for working with vulnerable adults and children, the project lead and internal/external collaborators should inform the approving authority (e.g. Local Coordinator, Faculty RIEC or University REISC) that these have been satisfied prior to commencing with the RKE. The Human Resources service should maintain a record of all DBS clearances, the relevant dates, and any associated reference numbers.

## 9 Training, guidance, dissemination and review

The University REISC should produce and regularly review training and dissemination materials associated with this policy and relevant additional procedures, processes and protocols. The Committee should ensure that these are up to date and support researchers to use this policy and associated processes, procedures, and protocols to promote a positive ethical contribution and compliance with the policy.

In particular, the Committee should ensure that effective and proportionate minimum compliance training is in place and that all project leads and internal/external collaborators undertaking RKE at, for, or on behalf of Leeds Trinity University have completed this training prior to undertaking RKE that falls under this policy. The Committee should monitor completion of this training and report on this as part of its annual reporting process, including in the Annual Research Ethics and Integrity Statement.

## 10 Key Contacts

### 10.1 Local coordinators

#### 10.1.1 Faculty of Business, Computing and Digital Industries

**School of Business:**

TBC

**School of Computer Science:**

TBC

**School of Digital and Screen Media:**

TBC

#### 10.1.2 Faculty of Health, Wellness and Life Sciences

**School of Children, Young People and Families:**

TBC

**School of Health and Life Sciences:**

TBC

**School of Sport and Wellbeing:**

TBC

#### 10.1.3 Faculty of Social Sciences and Education

**School of Criminology, Investigation and Policing:**

TBC

**School of Law:**

TBC

**School of Psychology:**

TBC

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**School of Teacher Education:**

TBC

10.1.4 Other departments

TBC

10.2 Faculty Research Ethics Committee Chairs and members

10.2.1 Faculty of Business, Computing and Digital Industries

**Chair:**

Prof Steve Johnson

10.2.2 Faculty of Health, Wellness and Life Sciences

**Chair:**

Prof Carmen Clayton

10.2.3 Faculty of Social Sciences and Education

**Chair:**

Prof Lisa Webster

10.3 University Research Ethics and Integrity Sub-Committee Chair and Members

**Chair:**

TBC

10.4 Whistleblowing contact

Craig Williams

Whistleblowing Officer, Clerk to the Board of Governors and Company Secretary

[C.Williams@leedstrinity.ac.uk](mailto:C.Williams@leedstrinity.ac.uk)