Background Manual for using the Research Ethics Application Management System (REAMS)

BACKGROUND

(To read before making an application)

Trinity College Dublin

1. Preparation for ethics approval submission

NB. Does your research require ethics approval?

Not all research requires ethics approval only projects involving humans and/or their data and animals/living organisms. Even within this not all research requires ethics approval. Before you start consult this checklist of research projects not requiring ethics approval available here to verify if your research in fact requires ethics approval at all

Once you have verified that your research requires ethics approval then your preparation of an application for ethics approval should commence well in advance of the anticipated date of submission. This is necessary to ensure sufficient familiarity with ethics and data protection procedures, that all relevant and applicable training has been completed by members of the team, and that all documents required as part of the submission are available. Please leave adequate time for the completion of the form especially if you are a novice researcher and remember it may have to be approved by the PI and/or primary supervisor before submission is permitted. Think weeks rather than hours or days for the preparation process as a whole. As you complete the application, the characteristics of your project will determine the questions/sections that are appropriate to your project. You will only be presented with relevant questions/sections. It is good practice to complete a skeletal document first i.e., put in a few lines of summary, answer all closed (Yes / No etc. questions) so that all the sections and questions you will be asked will appear and you can work out where information fits best. Please note that the text boxes cannot include tables or diagrams. If these are necessary for large or complex applications, they can be inserted in an attachment under 'other documentation'. For applications on which a student is identified as the Principal Investigator, the nominated Supervisor will have access and editing rights for all elements of the application prior to the point of submission. It is recommended that students consult with their supervisor by email during preparation of an application - if and when feedback is required. Please note that the online application system does not support the inclusion of comments or so any edits pre submission must be agreed beforehand.

1.1 Education and course requirements for research ethics and data protection

1.1.1 Please consult the Policy on Good Research Practice for detailed discussion of good research practice and the role of research ethics and approval review.

1.1.2 All Trinity applicants, their supervisors (if the applicant is a student), and principal investigators (if applicable), in projects involving humans must complete and attach an up-to-date (annual update) Data Protection Training Module certification before submission will be permitted.

1.1.3 If a project is subject to the provisions of GDPR, all Trinity collaborators must complete and attach an up-to-date mandatory Data Protection Training Module certification, before submission will be permitted.

1.1.4 With the exception of PhD students who are Trinity members of staff, PhD students must complete and upload certification of completion of Research Integrity in the Open Scholarship Era Training before submission will be permitted.

1.1.5 Applicants will also find useful information about the classifications, storage and management of their research data at the following sites

- Policy on Good Research Practice
- Research data storage: https://www.tcd.ie/itservices/working-remotely/research-data/

1.2 Which ethics committee?

The school and departmental affiliation of the applicant or PI, and the characteristics of the project, will together determine the risk level and type of review that applies to each ethics application, and therefore the REC to which it will be routed for review (Section 4. Applicants should bear in mind that each REC is likely to have fixed dates of submission. These dates can usually be found on the REC local webpage. Note that, within the system, routing is automatic. It is governed by the characteristics of the project as cited above.

When your start a new application the risk for the project will be ranked as Risk 2 as a default and this will appear beside the project name on the top of each page. Once the project details page has been completed and saved, this will change to reflect the true risk of your project and therefore the level of ethics committee it will be routed to. Applicants should consult the relevant ethics committee local webpage to ascertain what specific deadline dates of submission. Further information concerning designated levels of risk is provided in Section 4 below. Do Note that risk level is provisional until submission.

1.3 What if you have or require ethics approval from another ethics committee?

All research undertaken by Trinity staff or students, which involves animals, humans, or human data (excluding archival data) requires some level of ethical review from Trinity, irrespective of whether the data are collected at a different institute/s, and regardless of whether ethics approval has been granted by another institution.

In respect of research projects for which there is existing ethics approval/ animal licence from an appropriate external body or a Recognised Research Ethics Committee, ethical approval must also be obtained from Trinity. Usually, it is required that the external documentation is complete and has

been approved or has been “approved in principle” (the only pending item being the provision of approval by Trinity)

1.3.1 It is essential to prepare the Trinity ethics application form in conjunction with the external form/s to ensure that all information required by Trinity is included on the external ethics application and that the level of detail provided across both (all) applications is compatible. This will help prevent extensive revisions being required by the different approving parties.

1.3.2 With the exception of projects involving animals, it is recommended that ethical approval is obtained first from the relevant external Recognised Research Ethics Committees.

1.3.3 The research ethics application forms used by external ethics committees are generally similar to those used by Trinity. There may however be important differences that reflect the distinct character of other institutions.

1.3.4 Some external ethics committees will first require approval in principle from Trinity before they process their local ethics application. This is not possible within REAMs.

1.3.5 It is expected that an applicant should make every effort to have all external ethics approval in place when submitting. If that is not possible, applicants may apply for approval in respect of the sites for which there is completed documentation and subsequently seek to obtain approval for additional sites through the amendment process. Applicants are cautioned that amendments that deviate from minor changes may be require a full application.

1.3.6 Health Sciences: Projects that have ethics approval from the Joint Research Ethics Committee (JREC) (St James’s and Tallaght University hospitals) – by virtue of their Trinity affiliation, do not require additional ethical approval from Trinity. If, however, any such projects require a hospital Data Protection Impact Assessment (DPIA), this must be submitted to the Trinity Data Protection Officer (DPO) for review. If the project includes other sites (in addition to those covered by the Joint Research Ethics Committee (JREC) (St James’s and Tallaght University hospitals) ethical approval by a Trinity REC is then required.

1.3.7 In the cases in which ethical approval has been granted by an external ethics committee, site, the submission to Trinity research ethics committee must include: the previously approved ethics application form including all supplementary appendices, attachments, and (as applicable) any agreed data protection documentation (DPRA / DPIA), together with the letter of approval.

Please consult the relevant Trinity REC during early planning/ before submission if the application materials are in a language other than English.

1.4 Which approvals are required before submission is possible?

In the case of all student applications, primary supervisors must approve the application before it can be submitted. It is critical therefore that sufficient time is allocated for the primary supervisor to review the application, and for any recommended revisions to be implemented (i.e., in advance of a REC submission deadline).

If the applicant is not the PI, the project PI must approve the application to make possible its submission.

As outlined in 1.3, if ethics approval / licence (including animal studies licence) is required for another site/ institution, this approval/documentation and (if applicable) any related data protection documentation (i.e., DPRA, DPIA), must be completed, approved and uploaded prior to submission.

1.5 Which attachments are required before submission is possible?

As the form is being completed, a list of required attachments will be generated. For a submission to be made, all required attachments must first be completed and uploaded. Starting an application early will allow identification, development, and completion of all relevant documents. The necessary steps could include, for example, obtaining permission to access a site or database, completing the Garda vetting application, completing GDPR training. See below for a list of potential attachments.

If a Participant Information Leaflet is required, three templates are available depending on the data processing involved in the research: PIL for research where Personal Data will not be processed; PIL for research where Personal (Health) Data will be processed; PIL for research where Personal (non-Health) Data will be processed.

NB. Data Protection Review

The REAMS application contains certain questions that trigger the need for a review by the data protection office. Applicants are advised to check these prior to starting their application in REAMs as it could result in an extended application process. Information is available here

Should a review be required the DPO will oversee this and provide a 'letter of completion' for the applicant to upload in REAMs before submission is possible.

NB. Trial of Medicinal Product or Medical Device

Where a research project involves such an intervention, REAMs requires the attachment of a letter of compliance from the Head of Clinical Sponsorship Oversight. More information is available here

A further list of attachments that may be required depending on the project's characteristics

A. Animal participant projects

(i) Animal Licence

- External animal licence for project

(ii) If your application is a first submission to AREC

- Short AREC application form
- HPRA project application form
- HPRA NTPS template (excel document)
- Project protocol (AREC)
- Score sheets (AREC)

(iii) If your AREC project is an amendment to an approved application, please append

- Cover letter (AREC)
- Final approved version of the AREC form
- HPRA project amendment application form
- Final approved version of project protocol
- Final approved version of the score sheets
- Final approved version of the original HPRA application
- Any additional documentation pertaining to the current amendment

B. Human participant projects

- Approval from another REC (finalised approved application form, approval letter etc)
- Documentation indicating permission/authority to access site or data source
- Consent form
- Explicit consent form or informed consent form
- Data collection instruments (all)
- Data extraction list
- Interview schedule / observation schedule/ other
- Questionnaire/s
- Participant information leaflet
- Participant assent form
- Permission to access site
- Processor agreement
- Recruitment documentation
- Research integrity module certification
- Research Consent declaration
- Trinity staff access permissions
- Trinity access permissions

C. Other

- Data protection Training certificate (applicant, primary supervisors, PI in all instances and all other Trinity members if the project involves the processing of personal data)
- Data Protection Impact Assessment (DPIA) (Final) from external site/s including all amendments
- Declaration and guidelines for interviewing or testing with adults or children (School of Psychology only)
- External ethics approved application form
- Garda Vetting Clearance
- Joint data controller agreement
- Letter of agreement / permission to access from institutions/organisations agreeing to host the research project, assist with participant recruitment, access to data etc.
- Letter of agreement / permission to access staff or students of Trinity (e.g., school, Faculty Dean, Director of Research, Director of UG or PG programmes) agreeing to host the project, assist with participant recruitment etc. addressed
- Licence to access source
- Methods, measurement used
- Non-disclosure agreements or other such agreements for third parties such as companies involved in doing transcriptions

1.6 Other general information

It is recognised that recruitment from the general population may unwittingly include some participants that are at risk of vulnerability. While this may be acceptable in many cases (except if the participants are children), for all project types, the appropriate safeguards must be in place.

There are specific protocols to be observed by Trinity staff and student researchers who are seeking to recruit staff and students of Trinity as participants

There are additional access and ethics processes that must be followed if the researcher is external to Trinity (Policy on Access to Trinity College Staff and Students for Research Purposes by External Organisations).

2. Characteristics that define the assessed risk of projects and the resultant routing pathways

It is important to understand this section, as the system will automatically route the application to the appropriate REC prior to submission, and each REC may have specific submission deadlines.

2.1 Overview of assessed risk of project

Within the REAMS system, the routing of human research projects to a specific REC is automatic. Routing is based on three main elements

Whether the project involves animal or human research: In the project details section, it will be determined whether the project includes animal or human participants. This will dictate not only the tabs sections that will then have to be completed by the applicant, but also the routing of the application.

School and Faculty of the applicant: Depending on the assessed risk of the project (see 2.3 below) projects will be routed to the relevant local Level 2 or 3 committee. In addition, some centres have their own REC and members of these centres should use these centres as their affiliation address if they wish to be routed to these committees.

Assessed risk level of application.

NB. REC Override Committee

Where an applicant or a REC believes that another REC would be better to review an application, there is an 'Override Committee' facility in REAMs to accommodate this. Clicking this enables the application to be redirected to another REC of choice. This other REC should be consulted in advance.

2.2 Risk level of application.

2.2.1 Projects involving Humans or their data

From an ethics perspective, the assessed risk is determined by certain characteristics of the project. Based on this determination, each project will be classified as either very low-risk, low-risk, or moderate to high-risk. This classification in turn dictates the review level (1, 2 or 3) that is appropriate for the application. and for projects involving human participants or data in Table 1b. They may be summarised as follows:

A. Level 1 (Human):

- Very low-risk research has no apparent risk to the participant
- Projects must have all the following characteristics:
    - conducted in non-vulnerable participants (never children)
    - explores non-intrusive topics
    - conducted using low-risk methods
    - the participants cannot be identified either directly or indirectly in either the research data or other study administration data i.e., contact details.

B. Level 2 (Human):

- Low-risk research carries no greater risks or discomfort to the participant than usually encountered during normal daily life.
- Projects must have all the following characteristics: conducted in non-vulnerable participants (never children), explores a non-intrusive topic and does not employ any of the methods or project types listed under Level 3 (see Table 1a).

C. Level 3 (Human):

- Moderate to high-risk research, is research where the risk or discomfort is greater than that usually encountered during normal daily life.
- Projects that are: conducted in vulnerable participants (including children), explore intrusive topics, employ any moderate to high-risk methods or project types (see Table 1a).

Table 1a: Summary characteristics that determine the risk levels of projects with human data or participants

REC Level 1: **Very low risk**	No identifiable data Non-intrusive topics

	Low risk of vulnerability None of level 3 criteria **Low risk methods (if results to be published)** • Quality assurance studies • Anonymous Surveys • Unrecorded and anonymous observation of individuals in public areas • Audits of standard practices or tests • Data from a secondary source: -Publicly available information - Non-publicly available data source with permission
REC Level 2: **Low risk**	Identifiable and non- identifiable data Non-intrusive topics Low risk of vulnerability None of level 3 criteria **Most methods except those cited as specifically Level 3** Non-invasive biological samples
REC Level 3: **Moderate & high risk**	Identifiable and non-identifiable data Intrusive topics Moderate or high risk of vulnerability, particularly where participants recruited are: • Children (under 18) • Prisoners • Asylum Seekers • Participants who require support to give consent Participants with a dependant relationship with the researcher **All methods, but specifically:** • Projects involving a degree of deception • Research involving collection of non-invasive biological samples or tissues hair, nails, saliva, semen, urine, buccal epithelial cells in **patient** populations

	• Research involving invasive procedures of any kind or the collection of **invasive** biological samples or tissues or blood samples (except pin prick) from human (healthy or patient) volunteers. • Research involving the collection of biological samples by any method or of any size yielding information including genetic analysis that could impact upon treatment (e.g., Human DNA sequencing). • Research involving interventions that are not usual practice that could have an impact on participants i.e., testing a new teaching methodology, a new psychological or care intervention. • Research that intends to identify illegal activity. **All projects that have a high risk, specifically** • Research where information obtained may have legal, economic or social consequences for research. participants or their establishments. • Health Research Projects that require consent declaration form as defined by the Health Research Regulations 2018, & amendment 2021. • Projects where each participant is paid (over and above token gestures and expenses) (See Gift Voucher Policy. • Research that has a military role • Research that may have a dual purpose that could be misdirected to do harm.

2.2.2 Projects involving Animals

From an ethics perspective, the assessed risk is determined by certain characteristics of the project. On the basis of this determination, each project will be classified as either very low-risk, low-risk, or moderate to high-risk. The characteristics that determine the assessed risk for animal studies are detailed below in Table 1b.

Table 1b: Summary characteristics and project routing for animal research

AREC Research in the laboratory setting that involves vertebrate animals (including foetal forms of mammals beyond two thirds of their development in utero) and cephalopods. Projects that fall under this category will be routed to the animal research ethics committee (AREC) (committee review).

1. **<u>Very low risk</u> wildlife and ecology projects**: these projects will be routed to Level 1 and if student projects will be reviewed by the supervisor
    - Sampling sustainable numbers from populations of invertebrate subjects (other than cephalopods), irrespective of subsequent processes.
    - Observations of vertebrate subjects left undisturbed in their natural environment,
    - Non-destructive measurement or observation of wild / managed environments
    - Translocations of small numbers (compared to local population sizes) of individuals of a native species between sites all within the local area

2. **Category 1: <u>Low risk</u> wildlife and ecology projects.** These projects will be routed to the School of Natural Sciences REC as they are low risk (Level 2), they will take the expedited review route.
    - Translocations of large numbers of individuals of a native species or from further than they can travel naturally, or of non-native species.
    - Capture and removal of wild vertebrates, under licence from the relevant specialist body, or those deemed vermin.
    - Brief (less than a 2 hours) capture of small numbers (as a proportion of the local population) of wild vertebrates and return to their original site of capture.

3. **Category 2: <u>Low risk</u> wildlife and ecology projects.** These projects will be routed to the School of Natural Sciences REC (Level 2) as they are slightly higher risk than Category 1 they will take the committee review route.
    - Capture and removal of wild vertebrates without licence from the relevant specialist body
    - Translocations of large numbers of individuals of a native species or from further than they can travel naturally, or of non-native species

4. **<u>Moderate risk</u> wildlife and ecology projects.** Because of the higher risk of these projects, they will be routed to the Level 3 committee
    - Studies involving vertebrate wildlife, suffering pain, suffering or lasting harm beyond that inflicted by a trained vet giving an injection
    - Permanent damage to wild populations or environments
    - Additions of alien or invasive species

2.3 Personal Data (Human studies)

If your project involves the processing of Personal Data you will be routed to Level 2 or 3.

Only very low risk research projects that use irrevocably anonymised data and administration data that has no personal data can be routed to Level 1.

For the purposes of this section Personal Data means information about a particular living individual, which can directly or indirectly identify them. Personal data includes information which has been pseudonymised i.e. (identifying characteristics replaced with a pseudonym or a value which does not allow the individual to be directly identified, and a key to link the two is kept separately to the source data).

2.4 Risk of vulnerability in humans

Participants who are at risk of vulnerability are not always vulnerable; their vulnerability may change with the situation and environment; their vulnerability may change over time. For example, the nature/ topic of the research itself may influence whether a project with participants at risk of vulnerability would be routed to a Level 3 REC. Trinity research policy gives special consideration to protecting the wellbeing of individuals at risk of vulnerability. Therefore, projects from the following groups are always routed to Level 3.

For the purposes of this Section, vulnerable means but is not limited to any participants from the following groups:

- Children: For the purposes of research children are anyone under the age of 18. All projects involving child participants, or their data, are routed to Level 3 REC.
- Prisoners.
- Asylum seekers: these are migrants that are driven from their home.
- Persons who require support to give consent:
    - these may include adults with mental health illnesses, one or more learning disabilities, literacy difficulties, cognitive impairments or communication disabilities. Not all the people in these groups will require support to provide consent and where this is the case, depending on the other characteristics of the project, these projects could be routed to Level 2 (Low risk) (see below).
- Participants who have an unequal power relationship with the researcher e.g., student/ lecturer, employee/ manager, carer clinician / person they care for that cannot be mitigated for.
- Participants who have just been diagnosed with a life-limiting/threatening condition/dies or who are terminally ill.

As cited above, if the participants could be considered vulnerable but have capacity to provide informed consent without support, these projects could be routed to Level 2 (Lower risk), if the other characteristics are appropriate. Participants who may be at risk of vulnerability can be supported indirectly by ensuring that the Participant Information Leaflet is accessible and suitable for their capabilities, that they have capacity sufficient to understand the information being provided and can volunteer independently to be part of the project. If participants who at risk of vulnerability require further support to partake in the project, then the project is deemed to be of a higher risk and will be routed to Level 3.

2.5 Intrusive topics (Human studies)

While all research involving human participants is intrusive to some degree, intrusive topics are those likely to cause risk or discomfort greater than that usually encountered during daily life. It is considered that these put the participant at higher risk. Projects that collect data concerning intrusive topics will be routed to a Level 3 REC.

For the purpose of this section, intrusive topics include, but are not limited to, any of the following topics: abortion, abuse, bankruptcy, bullying, child abuse, gun control, self-harm, trauma or whistleblowing.

2.6 Low risk methods (Human studies)

The methods used in different projects vary significantly and consequentially they differ in their risk. Very low risk research may not be subject to ethics approval-consult the checklist here unless it is to be published. If outputs are to be published then to be classified as very low risk research and routed to a Level 1 pathway, a **project must use only methods** from the following list

- Anonymous data collection e.g., surveys
- Audits of standard practices or tests (see *Search: Audits of standard practice and /or quality assurance/ quality improvement studies)*
- Data extraction from publicly or non- publicly available (with permission) data (see *Search: Publicly available data)*
- Quality assurance studies (see *Search: Audits of standard practice and /or quality assurance/ quality improvement studies)*
- Unrecorded (no audio, visual or electronic recordings etc) and anonymous observation of individuals in public areas
- Data from a secondary source (see *Search: Secondary Analysis*)

- Publicly available information
- Non-publicly available data source accessed with permission

Search: Audits of standard practice/ quality assurance/ quality improvement

The terms audit (including clinical audit) and quality improvement and quality assurance although different are often used interchangeably from an ethics point of view, as the principles that apply to them are the same.

NB. If outputs are published low risk methods may need ethics approval

Audits, quality improvements, or assurance projects of themselves are not research. If, however, the outputs are published either in a thesis or in another form, then they are considered as research, i.e., from an ethical perspective. As the data are being used for a purpose different from that for which they were originally collected, there may be further ethical and legal considerations.

Search: Publicly Available Data

More than ever within a digital and Open Research Environment (Data sharing Policy for Good Research Practice), researchers can access data collected by others. Overtly public data can be obtained directly, without permission or licence. Such data may include information concerning public figures, derived from blogs or other digital sources. As such data will usually have been collected for a different purpose, their use may constitute secondary analysis. Researchers should not assume that they can or should undertake analysis of such data, as they are not the owner of the data and may not have permission for the data to be used in research. While the risk associated with this type of research is likely to be low, it must nonetheless be assessed, and ethical approval may be required. Relevant considerations are the category of researcher (student or staff) and the level of risk. For example, the research may relate to an intrusive topic or concern vulnerable persons (see Secondary analysis).

Search: Secondary analysis

Can be defined as the re-analysis of data that were collected by another person for a separate or different purpose, perhaps when addressing a distinct research question. The secondary use of data is similar to secondary analysis. It is characterised by the re-analysis of data that have already been collected by the investigator, for a purpose separate or distinct from that which was originally define, including the intent to address a different research question.

The secondary use and secondary analysis of data can give rise to ethical issues relating to informed consent. Specifically, the secondary use or analysis of data may extend beyond the originally specified purpose of the research/ data collection – to which participants gave consent. The consent given by participants must explicitly allow for secondary use and/or secondary analysis. There may also be data protection implications arising from secondary use and/or secondary analysis, that were not anticipated at the time the participants gave consent.
The reuse of data has many advantages, and many research funders now commonly require data to be archived and made publicly accessible. To be suitable, and subsequently made available for

secondary analysis therefore, data need to be collected, stored, and accessed in a manner that is ethically and lawfully appropriate.

The ethical risk associated with the secondary use and/or analysis of data ranges from low risk in projects which use anonymous, and/or quantitative data that concerns non-intrusive topics, to high-risk projects such as qualitative studies on intrusive topics or projects which use personal or sensitive data. Depending on the nature of the original ethical approval, and the consent given by the (human) participants, projects that will use data for a purpose other than originally specified, may require subsequent ethical approval. Consult your supervisor and/ or local research ethics committee to discuss any such considerations before making an application.

2.7 Projects and methods that are automatically High risk

(routed to Level 3 (Human studies))

As indicated in Table 1a, projects are always routed to Level 3 if they explore intrusive topics or recruit participants that have a particular risk of vulnerability. In addition, methods or projects that are considered to be moderate or high risk are also routed to Level 3 ethics committees. The relevant characteristics are listed in Table 1a above.

3. The review process and outcomes

3.1 The objective of reviewing

Researchers are entitled to an ethical review system in which decisions flow from clear policies, are applied evenly, are discipline appropriate, and are without bias or prejudice. It is reasonable to expect that reviews will be comprehensive, fair and carried out in a timely manner by competent, knowledgeable, appropriate diligent reviewers.

The main purpose of ethical review is the protection of the animal and human participants. The principles applied in respect of human research are based on the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. These principles include respect for persons and their autonomy, beneficence, non-maleficence and justice (achieving a favourable risk benefit ratio) across all aspects of a research project. It is recognised that the conduct of research can also present risks for researchers. The protection of researchers and research sites are further purposes of ethical review. These should also be given specific consideration when preparing an application. A broadly similar set of principles are applied in animal research (Policy on Good Research Practice).

Main areas of ethical review

- That the benefits of the project are likely to outweigh the risks to the participants.
- Participants and their data are protected while permitting human participant autonomy.
- Potential ethical issues, including risk to researchers, are identified and brought to the attention of researcher, with a view to ensuring that the research is ethically sound.
- Consideration is given to the suitability of the proposed research methodology, in so much as this bears upon the ethical integrity of the project.
- Ensuring that research conducted under the auspices of Trinity complies with Trinity standards, regulations, and legal requirements and obligations.
- In human studies this applies particularly in relation to privacy legislation. With respect to applications that do not also require a DPO review, it is expected that a Trinity REC review will ensure compliance with all relevant data protection requirements and regulations.
- Reviewers will expect that ethics applications are written with sufficient clarity, and that the project is described in a level of detail sufficient to ascertain if it is ethically sound.

NB. It is not the purpose of the ethical review to:

- Serve in lieu of supervision
- Assist in the development of a project
- Correct minor matters of methodology or design
- Proof-read the documentation and correct errors in spelling, grammar and syntax
- Correct or make editorial changes to already validated data collection instruments

This noted, major inadequacies in any of these areas may result in a decision that the application is rejected, or that revisions are required. In some cases, particularly where revisions are extensive and rejects, specific feedback will not be provided. If, for example, the revisions are too extensive or have too many implications for other sections in the application or the methodological rigour of the proposed project is so poor that it is not likely to succeed in achieving the objectives of the study, or if it may increase the risk of harm to participants, the reviewers will not necessarily indicate the means by which such deficiencies should be addressed.

3.2 The Review Process

As described in Section 2 the parameters of Animal or Human research, School / centre of the applicant and assessed risk will dictate the appropriate REC for review of the application. The present section provides further detail concerning the review pathway.

NB. All self (in the case of staff) or supervisor (in the case of student) declares are NOT permitted. Expedite Reviews are also no longer badged within REAMs. All ethics applications will now be coordinated by the REC and they will decide how to treat them eg proportionate/ chair review or full committee review.

3.2.1 Pre-appprovals

Regardless of risk level, before an application lands with the REC for review they may have to undergo a pre-approval stage where a supervisor and/or PI must read the application and ensure it is ready to proceed to the REC for review.

(i) <u>Student-led Projects</u>

With normal supervisory support, the student will complete the application, develop and upload the relevant attachments. Then the supervisor must complete the associated declaration in REAMS for the submission to proceed. If the student is working on a project that has another person as PI (i.e.,

not the student), the PI must complete the associated declaration on the ethics application before it can be submitted.

Once the application is submitted, it will be routed to the supervisor (status: with primary supervisor), who has two options:

- send back to the applicant to make revisions
- send on to the REC for ethical review

NB. the supervisor must declare that they have read the application and approve it can be passed onto the REC for ethical review

(ii) Staff-led Projects

Academic staff who plan to conduct research that meets the criteria for Level 1 review, will complete the application, and upload the relevant attachments. If the staff member is working on a project that has a that has another person as PI, the PI must complete the associated declaration before it can be submitted.

Once the application is submitted, it will be routed to the PI (status: with principal), who has two options:

- send back to the applicant to make revisions
- send on to the REC for ethical review

NB. the PI must declare that they have read the application and approve it can be passed onto the REC for ethical review

3.2.2 REC Committee review Level 1, 2&3

Regardless of risk level, projects will be processed in accordance with the relevant REC schedules and procedures. These can be found on the local REC websites.

The REC will decide how to review the project according to level of risk. eg proportionate/ chair review or full committee review.

3.3 Review outcomes

Once an application has been reviewed, the applicant will receive notification of the outcome, and the outcome will be visible to them, their primary supervisor (if applicable), and the project PI (if applicable) within the system. If revisions are required, feedback will be given and the status of the application will be reset to draft once again permit editing by the applicant.

There are three potential review outcomes of ethical review: approval, make revisions or reject. The outcome that an ethical application receives will dictate when revisions can be submitted and therefore the potential length of time before approval is finally achieved.

3.3.1 Approval

After review by a supervisor, an 'Approved' outcome indicates that all ethical considerations have been addressed and appropriate data protection requirements are deemed to be in place. Only once approval has been granted, can data collection commence (in accordance with the dates indicated in the application).

3.3.2 Make Revisions

These can be minor or major in nature and the REC will decide and feedback to the applicant.

(i) Minor revisions reflect that the application provides adequate detail, accuracy, and consistency across sections, and that the supporting documentation is largely appropriate and complete. For minor revisions, the subsequent resubmission of an amended/corrected application may be dealt with in a shorter time frame that that required to assess the initial application. The following are typical of applications deemed to require minor revision.

- A requirement for minor changes to one section of the application that do not result in changes to other parts of the documents, appendices or attachments.
- Minor omissions of important information.
- Content errors which are few in number.

(ii) Major Revision may be required if an application is insufficiently detailed, contains inaccuracies or inconsistencies across multiple sections and/or documents. With respect to major revisions, the subsequent review of a revised application may not occur prior to the next submission date for the applicable REC. In many such cases, the degree of required revisions will include major redrafting, that may extend to several sections of the application and/or documentation. The following are typical of applications deemed to require major revisions:

- Several ethical issues were identified.
- The revisions will involve multiple changes or the provision of new information in the application or supporting documents.
- Inconsistencies detected across the application and the supporting documentation.

3.3.3 Reject

This is expected to be a rare outcome. It would reflect a project so poorly developed, and with ethical and/or data protection issues so substantial that an entire reconstruction of the project and application will be required. The following are typical of applications that may receive a reject outcome. As noted, the feedback provided concerning such applications is likely to be minimal and in such situations a new application will have to be submitted.

- Research that is ethically unsound and is unlikely to receive ethics approval even following major revisions. This may include research deemed to have a poor risk/ benefit ratio.
- Poorly written applications, that lack sufficient detail, and include substantive errors, or omissions.
- Research that has already commenced.
- Retrospective research. This may include for example, instances in which an innovation has been introduced and evaluated, and the researcher now wishes to apply for ethical approval so that they can publish the results. Depending on the aim of the project/analysis some retrospective database analysis may be undertaken without further ethical approval (see *Search secondary analysis*)

3.4 Amendments

Amendments is the term used when an applicant requests a change to their application after approval is granted. Amendments do not include subsequent rounds of data collection or another phase of a study using a different methodology. For these, a new ethics application is required. After approval has been granted by a Research Ethics Committee, an applicant may need to seek approval for changes which are necessary to maintain or enhance the integrity of the research project. Amendments are minor changes such as the inclusion of an additional member of the research team, the addition of a new data collection site, limited changes to the protocol that will not have a major impact on the content of the participant information leaflet, DPIA etc. Minor changes to the wording of an interview schedule, for example, do not require that an amendment be submitted, unless the content explored is substantially different. Student applicants are advised to discuss and consult with their supervisors when changes of any kind are being contemplated in order to ascertain if they are likely to meet the criteria for an amendment. More details on how to submit an amendment are included in the specific 'Making an Application' manual.

3.5 Appeals

In the unlikely event that the applicant disputes the basis of a major revision or reject decision, there is an appeal pathway. The appeal committee for Level 1 appeal is the Level 2 REC within the same Faculty with expertise most relevant to the content of the application. Likewise, the appeal committee for Level 2 appeals is the Level 3 REC within the same Faculty with expertise most relevant to the content of the application. The Research Policy Ethics Committee (REPC) acts as the appeal committee for Level 3 RECs and animal application appeals (Policy on Good Research Practice).(see Figure 1 below)

- The applicant completes an appeals form and submits it to the email of the REC to which the application was made. In the case of some Level 1 applications submitted by students, the appeal should be directed to the supervisor in the first instance.
- On the appeal form the applicant should state clearly the grounds for appeal.
- If the applicant is a student (for appeals originally submitted to Level 2 or 3) or someone other than the PI, the appeal form must be countersigned by the relevant parties (i.e., supervisor or PI).

- The chair of the REC to which the application was made (or supervisor in the case of Level 1 appeals), will scrutinise the application, the outcome, feedback and the appeal documentation and decide whether the outcome they have given is justified and that therefore the applicant has to make a formal appeal. This is a common practice in ethics appeal processes to identify if the decision or elements of the feedback are erroneous and can be corrected without escalation. If the Chair of the REC (or supervisor in the case of Level 1 appeals) deems that the decision or elements of the feedback were erroneous, this finding and a modified decision/ outcome/ feedback will be communicated to the applicant. In such instances, if this satisfies the applicant an Appeal Committee will not be formed.
- If the Chair of the REC (or supervisor in the case of Level 1 appeals), affirms the original decision, the full application, original review documentation, and the appeal documentation will be made available to the appropriate REC appeal committee for review.
- The Chair of the REC designated to deal with the appeal will set up an appeal committee, which they will chair. In addition to the chair, the appeal committee will include at least one reviewer with specialist knowledge relating to the subject matter of the application, and three additional reviewers (i.e., a total of five members). If necessary, members of the appeals committee may be co-opted from other RECs within the Faculty. Members of the appeal committee cannot however be members of the original reviewing REC. All members of the appeals committee are to review the documentation.
- With the exception of the original review documentation, the appeal committee will work independently of the original committee to make a decision in relation to the application and provide feedback outside the REAMS system.
- The outcome of the appeal will be communicated to the applicant, Chair of original REC, and if applicable the PI and supervisor.
- In the event that the applicant does not accept the decision of the appeals committee, further appeal mechanisms are available (detail under development).

Figure 1: Flow Diagram of appeal process

Appendix 1. Abbreviations & Terminology

Abbreviations

AREC: Animal Research Ethics Committee

DPIA: Data Protection Impact Assessment

DPO: Data Protection Office

DPRA: Data Protection Risk Assessment

GDPR: General Data Protection Regulation

HPRA: Health Products Regulatory Authority

PI: Principal Investigator

PIL: Participant Information Leaflet

REAMS: Research Ethics Administration Management System

REC: Research Ethics Committee

RSS: Research Support System

RPAMS: Research Proposal and Application Management System

TR&I: Trinity Research & Innovation

Terminology

Given a diversity of research domains, it is inevitable that several different terms can be used to convey approximately the same meaning. Within the REAMS systems, and in this manual, only one term is used to convey a particular meaning. The specific terms were selected based on adequacy, and the manner of their current use across Trinity in the context of ethics applications. In this section, the main terms are defined.

- **Adverse Event:** is any event that causes harm or distress in the context of research involving animal or human participants. The risk section in the application form requires that applicants to identify the potential for adverse events and indicate the steps to be taken to mitigate against any such events. It is requirement when ethical approval has been granted that adverse events are reported to the approving ethics committee. Details of adverse event reporting policy currently under development.
- **Amendment:** Changes made to an ethics application after receiving approval.
- **Applicant**: The applicant is the **one** named researcher who has primary responsibility for the ethics application. This person will receive official correspondence concerning the application, including the outcome of review. It is expected that this person will respond to any requirements arising from review. In most cases (including submissions by students), the applicant will also be Principal Investigator (PI) for the project (see below for PI definition). In some large projects, the role of applicant may be delegated to another member of the research team, who is not the PI. In such cases, the PI must tick the appropriate declaration, and approve the application, as part of the submission process (See PI below for more information).
- **Attachment:** An attachment is any additional document required to be submitted with the application. For example, when the answer is yes to the question: *Will consent be taken from the participant?* the system will register that an attachment of the consent form is required. An attachment tab will appear at the top of the page. When the application form is otherwise complete, opening the attachment tab will reveal a list of all the attachments that are required and an interface for their uploading. Submission of the application will only be possible when all the attachments on this list have been uploaded. (See section 3.5 below for further detail on the attachments that may be required).

- **Collaborator:** The term collaborator is the generic term used in the application for all other members of the project's research team. This term is synonymous with investigator, co-investigator, co-applicant and includes Academic/ Clinical/Professional/ Industrial Collaborator and Public or Participant Collaborator
- **Committee Review:** This is the term used in the present document for the traditional means of evaluation by a research ethics committee, see also expedited review and Section 4 below for further detail).
- **Expedited Review**: In line with the Policy on Good Research Practice all research ethics committee have a pathway that permits certain projects to be reviewed in a fast-track manner for example those that have ethics approval from other recognised research ethics committees (see Section 4below for further detail).
- **Principal Investigator:** Principal investigator (PI) is the term used to identify the person responsible for the preparation, conduct and administration of a project and (if applicable) of a corresponding research grant. This person will usually also be the one responsible for the ethics application (i.e., the Applicant). Most students will be both the PI and the Applicant. In such cases, a supervisor declaration section will be generated. For the application to proceed, this must be completed by the primary supervisor. In some large projects, the role of applicant may be delegated to another member of the research team, who is not the PI. In such cases, the PI must sign the appropriate declaration, and approve the application, as part of the submission process (See also Applicant entry above).
- **Project:** Throughout this documentation, the term project applies to the research that is related to an ethics application. In most cases synonymous with study, thesis, proposal.
- **Participant/ potential participants**: This term is used synonymously for subject, data subjects, individuals, animals.
- **Administrative Data**: This is administrative information collected through the course of the project which is not directly related to the aims and objectives of the study. It is not research data (see below Research Data). It may include Personal Data (as defined under the General Data Protection Regulation and are subject to being processed, retained and destroyed in line with Trinity policies. These data may include schedules, contact details. You will be asked to identify data of this nature in your application.
- **Research Data:** "Research data are data that are used as primary sources to support technical or scientific enquiry, research, scholarship, or artistic activity, and that are used as evidence

in the research process and/or are commonly accepted in the research community as necessary to validate research findings and results. All other digital and non-digital content have the potential of becoming research data. Research data may be experimental data, observational data, operational data, third party data, public sector data, monitoring data, processed data, or repurposed data" (Policy on Good Research Practice) . It also includes the codes linking the original data to the pseudonymised data.

- **Revision:** This is a version of the application that has been amended to satisfy changes requested by the REC, and which must be provided before ethics approval can be granted.
- **Supervisor:** All students conducting research will have at least one supervisor. The main or singular supervisor is called the primary supervisor. In line with Trinity policies, the primary supervisor for Post Graduate students is generally a member of Trinity academic staff. All supervisors, both Trinity and non-Trinity, must be named as collaborators within the ethics application. For all student applications, the primary supervisor will be required to complete a declaration before submission can proceed. Applicants who have a primary supervisor that is external to Trinity, must contact the relevant research ethics committee they are applying to, to facilitate this.