Trinity Policy on Good Research Practice

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Context

"A working definition of research in College is what constitutes the discovery, creation or critical development of new facts, ideas, theories or processes that advance knowledge in the relevant discipline or field of study or result in works of artistic accomplishment". Scholarly research has been conducted at Trinity College, Dublin for over four centuries. In that time, there has been no indication other than that this research has been carried out to the highest international standards. However, in many areas, research has become very competitive and more complex in its collaborative links.

In 2002, to bring College into line with best international practice the Board adopted a policy on Good Research Practice, which was revised in 2009, and again in 2014. The 2021 revision incorporated changes in the legislation and practice of the key areas encompassed by this policy: research ethics, data management protection and research integrity. In contrast to previous editions of this policy, it presents an overview of the concepts with detail available through links to the policies of the key areas, allowing this information to be as up to date as possible.

Purpose

Good research practice cannot be policed. Rather it must be inculcated in the research ethos of the College at the level of the individual executor of research, and through wide dissemination of this policy both publicly, online, and in the induction of new staff and students. We undertake to inform all concerned about their rights and responsibilities as laid out in this document.

Scope

The guidelines outlined in this policy apply to all staff and students conducting research, including all staff categories, all students - undergraduate and postgraduate - and all others in the research community, including visitors and adjunct staff, and staff involved in research in College's affiliated teaching hospitals and other institutions.

Principles

Good research practice may, in certain cases, place some limits on the nature of research being carried out. However, the principle of academic freedom must at all times be defended. In so doing, the policy guides and protects the researcher, facilitating them to "work on their own challenging ideas, to be disruptive in their thinking, to do great research as individuals and collectively, and to excel at what they do". In all cases where research is carried out under the auspices of College within or without the defined campus properties, the College requires compliance with the policies as set out in this document and related links and additional compliance with the policies of the relevant body of the organization

wherein any external research is conducted. Failure to comply with the policies may result in disciplinary action under the College's disciplinary procedures.

The principles outlined in this document are the College adaptations and implementation strategies of national and international guidelines.

Policy

1. Research Integrity

Policies in College relating to research integrity are guided by the national policy statement Ensuring Research Integrity in Ireland.

This policy advocates that "research shall be conducted ethically and with integrity, and shall be founded upon the principles of honesty, reliability, objectivity, impartiality, independence, fairness, respect, accountability, open communication, compliance with duties of care, and responsibility for future generations of researchers. It is imperative that the principles of sound research design/ methodology be applied in the seeking of new knowledge, so as to ensure trust in the accuracy of the data collected and facilitate correct interpretation of the data" (p.8).

By adhering to this document College makes the following commitments:

1. We are committed to ensuring the highest standards of integrity in all aspects of our research, founded on basic principles of good research practice to be observed by all researchers and research organisations.
2. Education and promotion of good research practice are the foundations of research integrity. We are committed to maintaining a research environment that is founded upon a culture of integrity, embracing internationally recognised good practice and a positive, proactive approach to promoting research integrity. This will include support for the development of our researchers through education and promotion of good research practices.
3. We are committed to working together to reinforce and safeguard the integrity of the Irish research system and to reviewing progress regularly.
4. We are committed to using transparent, robust and fair processes to deal with allegations of research misconduct when they arise.

Research Integrity covers many issues, including good research practice, research misconduct and conflict of interest.

1.1 General Guidelines

The European Code of Conduct for Research Integrity (2017, revised edition) specifies eight basic principles that underpin all research integrity and good practice in carrying out research: (1) honesty, (2) reliability, (3) objectivity, (4) impartiality and independence, (5) open communication, (6) duty of care, (7) fairness, and (8) responsibility for future science

generations. These principles, which all researchers must adhere to, are summarised as follows in the European Code (2017, p.4):

- Reliability in ensuring the quality of research, reflected in the design, the methodology, the analysis and the use of resources.
- Honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair, full and unbiased way.
- Respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment.
- Accountability for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts.

1.2 Inclusivity in Research

Trinity's Strategy 2020-25 articulates College's fundamental commitment to promote equality and inclusivity in all that we do. A commitment to inclusivity in research must be embedded in standard research practice in all areas of the University. We actively seek to promote a research culture that includes, rather than excludes, under-represented groups at all levels and strands of research activity, namely within research design, on research teams, and among research leadership.

Our research culture and our individual researchers should espouse the principal that inclusive research can add value to our research outcomes and quality by ensuring that research is informed by the lived experience of individuals and groups traditionally under-represented in this context. It is the responsibility of all members of the community to uphold a positive research culture that is free from bullying and harassment of any kind.

Trinity's Equality Policy outlines in full our commitment to equality in all aspects of activity.

1.3 Gender in Research

College currently holds an institutional Bronze Athena Swan award and many schools have also secured individual bronze awards in recognition of their support and development of gender equality. The College's gender action plan has identified and actioned plans to further optimise equality in the field of recruitment, promotion and support of researchers. This organisational level of gender equality planning is a requirement for hosting Horizon Europe grants. In line with College's action plan, and applicable to not only Horizon Europe projects but all college research, projects should promote equal opportunities between men and women, and at all levels, including managerial and supervisory, to the extent possible. In addition, unless inapplicable, projects should seek to avoid gender bias within the project and seek to utilise gender-sensitive research, where gender is consistently integrated into the research from the development of the initial hypothesis to dissemination.

1.4 Research Misconduct

Research Misconduct is any intentional, knowing or reckless misconduct which affects the integrity of any aspect of the process of research, including the research itself, research records, and research publication. It is defined as, but is not limited to, fabrication, falsification or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It includes questionable research practice including misquotation or misrepresentation relating to matters such as attribution of authorship, publication, record keeping, conflicts of interest, breach of confidentiality, ethical approval, interests, qualifications or failing to meet ethical, legal, professional, privacy or data protection responsibilities.

Research misconduct does not include honest error or honest differences of opinion in interpretations or judgements of data. In particular, the analysis of either old or new material and subsequent drawing of new conclusions is not considered to be research misconduct. The section below provides good insight for all researchers into establishing good practices, improving their scholarship and keeping up to date, and in so doing avoiding research misconduct. In particular, Principal Investigators from students to multi-site researchers, must take all reasonable measures to ensure that accuracy and completeness of information is contained in applications for funding, and to ensure compliance with sponsor, institutional, legal, ethical and moral obligations in managing projects. Financial fraud or misuse of research funds or research equipment may constitute research misconduct as defined above, and it may also be dealt with under the College's Financial Regulations and Fraud Policy.

College takes any allegations of Research Misconduct seriously and will investigate them in accordance with established disciplinary procedures. Plagiarism by undergraduate and postgraduate students is subject to College Academic Integrity Plagiarism Policy.

1.4.1 Key Roles involved in the Research Integrity Process

The Senior Dean is the College Research Integrity Officer (RIO). The RIO delegates the Dean of Research to manage allegations of Research Misconduct from any source and implement an investigation process. If the Dean of Research and all Associate Deans of Research are sufficiently involved in the matter that their investigating could not objectively be regarded as independent, the matter shall be investigated by the Research Integrity Officer. The Research Ethics and Integrity Administrator within the Office of the Dean of Research is the designated administrator responsible for all research ethics and integrity matters in College. This person will manage and document all research misconduct allegations raised and facilitate and support the research of any investigation undertaken. The Dean of Research will report the outcome of any investigation to the RIO.

If allegations are deemed legitimate the Senior Dean will address disciplinary proceedings for staff members as necessary. In the event allegations relating to students are deemed legitimate, the Junior Dean (undergraduate) or Dean of Graduate Studies (postgraduate) will address disciplinary proceedings.

1.4.2 The Research Integrity Process

A concern may be reported to any individual in College. However, all matters involving issues of Research Integrity must be referred to the Dean of Research - see 1.4.3 for how to raise a concern.

On receiving the referral, the Office of the Dean of Research begins the coordination of informal preliminary enquiries to get familiar with the facts and whether College Research procedures were infringed (2010 Consolidated Statutes of Trinity College Dublin). Where the allegations are serious, and in particular where possible criminal conduct is involved, it will usually be inappropriate to deal with the matter informally.

As part of this informal enquiry the Dean of Research may:

- delegate responsibility for the review to an Associate Dean of Research depending on the nature of the enquiry
- contact the person raising the allegation to have them articulate it in more detail, thereby ensuring that they have fully expressed it and that the Dean of Research fully understands the allegation so that they can address each of the points raised
- gather information pertaining to the allegation from various other individuals who have responsibility, such as Head of School or Faculty Dean, and can address points raised.

NB. Every effort is made to resolve matters informally with the aforementioned panel

Where the allegation appears to be ill-founded, no further action is taken.

Where informal resolution is not possible, or if the allegation appears serious or of a criminal nature, then the Dean of Research will report preliminary findings to the RIO. On analysis of the report from the Office of the Dean of Research, if there is a case to answer, the RIO can instigate the DoR to undertake a formal investigation. The DoR may seek such assistance from external experts as is necessary.

- The RIO is informed of the outcome of the formal investigation by the DoR. If the allegation is upheld the matter is subject to the disciplinary process and will be carried out by the relevant College Officer according to College procedures:
    - the office of the Senior Dean if an academic or research staff member is at the centre of a case
    - the office of the Junior Dean if a undergraduate student is at the centre of a case
    - the office of the Dean of Graduate Studies if a postgraduate student is at the centre of a case

NB. Undergraduate and/or post graduate students will be disciplined as per Academic Integrity procedures.

Appeals can be made on the outcome of the informal or formal process and should be addressed in writing to the RIO

1.4.3 How to Raise a Concern

Any member of college or external party may raise a concern on Research Integrity/Misconduct as follows:

- Please outline the nature of your concern to the designated email research.integrity@tcd.ie.
- In your email, you should include the following information:
    - your contact details
    - the name of the Trinity School, Discipline or other affiliation your concern is about
    - the specific nature of the concern and what precipitated it
    - when event occurred
    - include details of the alleged research integrity breach/ misconduct and relevant supporting documentation

Regarding allegations of research misconduct:

a) No person should suffer any penalty for making an allegation of research misconduct in good faith.
b) The making in bad faith of allegations of research misconduct shall itself constitute research misconduct.
c) Improper dealing with allegations of research misconduct – such as failing to address possible infringements, attempts to cover up misconduct, and reprisals against anyone who has made an allegation or complaint of research misconduct pursuant to the relevant Statute Chapter and Schedule shall itself constitute research misconduct.

The majority of instances are covered by the general misconduct regulations. See Schedule 1 to the Chapter on Academic Staff Conduct; Schedule 1 to the Chapter on Administrative, Technical and Support Staff Conduct; Schedule 2 to the Chapter on Student Conduct and Capacity.

Complaints in relation to dignity and respect issues will be dealt with under the College Dignity and Respect Procedures. Complaints that are upheld will be dealt with under the College Disciplinary Procedure as appropriate.

The University also has in place a Protected Disclosures (Whistleblowing) Policy.

1.5 Conflict of Interest

Where interests exist that could present a real or perceived conflict of interest, these should be declared and managed appropriately (IUA 2019, p.8). Conflict of interest is a key concept in the conduct of all research for all projects and should be examined at the outset of all research projects. Declaration of interest extends to the researcher or their partner and/or members of their family or the research grouping, with which the researcher has an employment relationship, has an interest. The primary purpose of seeking declarations of interest is one of transparency.

1.5.1 Definition of conflict of interest

For the purposes of this policy, the definition of Conflict of Interest shall include, but not be limited to, the following:

- When a person's judgement concerning a primary interest could be unduly influenced by a secondary interest;
- Apart from financial interests (including benefit in kind), conflicts might, for example, be personal, academic or political;
- Conflicts of interest can occur at any stage of the research endeavour. For example, submitting the same proposal to different grant bodies may be acceptable, whereas accepting more than one source of funding for exactly the same proposal may not be acceptable;
- There is nothing inherently unethical in finding oneself in a position of conflict of interest; what is required is to recognise the fact and deal with it accordingly.

1.5.2 Disclosure of potential conflict of interest

The College and society as a whole has the right to know if a recognised expert in a given area has an interest, material or otherwise, which could be seen to pose a conflict. Declaring such interests is one way of indicating that the declared interest is perfectly ethical and need not interfere in the researcher's capacity to conduct independent research. Disclosure of any potential conflict of interest is essential for the responsible conduct of research. This should cover disclosure of such interests to the persons responsible for institutional research management, to the editors of journals to which papers are submitted and to bodies from which funds are sought.

An obligation is placed on the recipients of all research grants to declare any interest that would interfere with or compromise the performance of research supported by the grantor. This is to ensure the technical integrity and impartiality of the researcher's work. This will involve completing a Declaration of Interest document that is to be signed at contract signature stage. The absence of, or an official declaration of interest for all participants or proposed participants in research, must be disclosed at the point of research contract acceptance (or earlier if required by research sponsors). Every researcher should exercise responsibility when applying to and/or accepting money from a sponsor. Intentionally failing to reveal a known interest may be regarded as research misconduct and may be subject to disciplinary action. When circumstances may exist (at research contract acceptance stage or during the course of any research project) which could lead to a conflict of interest or be

seen to do so, the investigator is required to divulge sufficient such information in writing to the College.

If a researcher working with an organisation is approached by a competing entity, the onus is on the researcher to inform the latter entity that he/she is already conducting some work for the former entity provided there is a substantial overlap in the research endeavour. Similarly, the researcher should only accept a contract with the latter entity if he/she has informed the former entity of this new contract (if there is a substantial overlap in the research endeavour).

Given that documents relating to the Declaration of Interest will be accessible to any who may request it under the Freedom of Information Act 2014 (or any amendments thereto), the onus is on a researcher to think carefully about their position before filling in the Declaration of Interest form.

2. Training, supervision and mentoring of research

College has an institutional responsibility to ensure integrity and ethical practice in the conduct of research. This responsibility devolves to those in faculties, institutes, schools and disciplines, research centres, and to those affiliates leading research. In the case of all researchers it includes training and mentoring. Training and mentoring vary significantly depending on the research and the researchers. All PhD students are required to complete research integrity training. All College personnel (including researchers and supervisors) must complete GDPR training annually. In the case of graduate and undergraduate research, responsibility devolves to the supervisor in overseeing student research projects. The supervisor has a duty of care to ensure integrity and ethical practice in research as well as a pedagogical responsibility to help develop the new researcher's understanding of appropriate research practices. A code of responsibilities is available for supervisors, indicating the frequency of contact, responsibilities regarding scrutiny of primary data, the broader development needs of research trainees and so on. Guidance regarding these regulations and eligibility to supervise research students is available via the Office of the Dean of Graduate Studies20.

It is mandatory that supervisors supervise all stages of the research process, including outlining or drawing up a hypothesis, preparing applications for funding, protocol design, data recording and data analysis. The supervisor is expected to ensure that students and new researchers understand and adopt best practice as quickly as possible. Supervisors should facilitate their researchers in undertaking appropriate training, for example in research design, regulatory and ethics approvals and consents, equipment use, confidentiality, data management, record keeping and data protection.

3. Ethics

Dignity is the foundation of the ethical conduct of research at Trinity College Dublin, in accordance with the principles of beneficence, non-maleficence, autonomy, justice, and truthfulness. As some types of research have the potential to infringe upon these principles, ethical approval may be required before it is permitted to commence. Research that most frequently requires ethical approval includes that involving humans or the use of human biological material, or that which requires the processing of data derived from humans, the use of genetically modified organisms, or that which is conducted using certain animal species (primarily vertebrates and cephalopods). Not all research requires ethical approval. Examples of types of research that may not require ethical approval can be found here. Research that does not require ethical approval may however be subject to the application of data protection law, necessitating advice on best practice from the College Data Protection Office before it can commence.

In some circumstances, the identification of risks associated with the conduct of research, and the implementation of mitigation strategies to deal with any such risks, will be undertaken separately from scrutiny to ensure that there is adherence to ethical principles. That is, research that does not require ethical approval may demand risk assessment and risk mitigation.

It is an expectation that all research activities will be lawful, and in compliance with all relevant legislation and regulations. It cannot however be assumed that research activities which are lawful will also be deemed to be ethical.

In line with IUA research integrity guidelines, College advocates that all research must be planned and carried out with adequate safeguards that protect the welfare and rights of all connected to the research and their data and incorporates the principle of sustainability and sustainable development insofar as possible;

Researchers from the outset should identify and establish mitigation plans against potential harms and risks relating to their research.

In addition, attention must be paid to intrusive, personal or sensitive topics and data, vulnerable groups and personal data.

To assure the protection of human subjects of research in both biomedical and behavioural research involving human participants, College adopts the guidelines detailed in the National Institutes of Health Belmont Report (1978) and the Helsinki Declaration (revised 2013) Declaration of Helsinki.

In all research, in addition to the Law of the Land, the over-arching ethical principles College adheres to can be summarised as:

- **Respect** for the individual subject or population;
- **Beneficence** and the **absence of maleficence** (research should have the maximum benefit with minimal harm);
- **Justice** (all research subjects and populations should be treated fairly and equally).

It is essential that research is conducted in an ethical manner. All individuals conducting research have a role to play in facilitating and making sure that research is carried out ethically.

3.1 General Guidelines

Researchers are responsible for minimising risk in the research process by ensuring they comply with core ethical principles: gathering informed consent, protecting the confidentiality and privacy of the information and ensuring the well-being of participants, animals, plants and the environment of their research. In addition, researchers in certain areas need to take particular care and adhere to additional specific regulations.

3.2 Research on participants at risk of vulnerability

The definition of vulnerability in Irish law while clearly defined, is not defined relevant to research. Participants who are at risk of vulnerability are not always vulnerable - their vulnerability may change with their situation and environment, and this should be considered in our research to manage the balance between protection and risk. Research policy within College gives special consideration to protecting the wellbeing of individuals at risk of vulnerability such as the following (this is not an exclusive list):

- Children;
- Prisoners;
- Asylum seekers;
- Persons who require support to give consent, e.g. adults with mental health problems, learning disability, literacy difficulties, cognitive impairment, communication disability or who are terminally ill. Please note that not all the people in these groups may require support to provide consent. Please be aware that this is not an exclusive list;
- Participants who have an unequal power relationship with the researcher, i.e. student/ lecturer, employee/ manager.

Conducting research with groups of people at risk of vulnerability is the exception rather than the norm. Research that is ethical should not deliberately exclude groups of the population who are at risk of vulnerability unless this exclusion is consistent with the research question and aims of the study. Existing guidance on conducting ethical research with people at risk of vulnerability is available from the National Disability Authority. Local College policies offer further specific guidelines in this regard.

While extra supports may be needed and different processes may be used with populations at risk of vulnerability, research with a vulnerable group is important when it is responsive to the needs or priorities of these populations. Considerations related to the well- being of the participant always take precedence over the interests of science and society. While respect for basic pillars such as autonomy and confidentiality are implicit in all research involving human subjects, they are especially pertinent in situations where the people

concerned are at risk of vulnerability or already marginalised or stigmatized. In the latter situations there can be danger of exacerbating or further entrenching negative social stereotypes, thereby further marginalizing the individual or group and further contributing to inequity.

It is usual practice that studies that specifically aim to recruit groups at risk of vulnerability as research participants are considered medium/higher risk projects.

Participants in research under the age of 18 are considered as children. Parental/ guardian consent is required for research participation of any child or children, and good research practice also requires the child's agreement or assent.

3.3 Research of an intrusive personal or sensitive nature or with potential to cause harm

Types of potential harm that must be recognized and addressed in research include but are not limited to: psychological harm (e.g. recalling a traumatic event), physical harm (e.g. reduction in wellness and health), social stigma (e.g. loss of reputation), cultural effects (e.g. going against existing cultural norms), political effects (e.g. disturbing existing power relationships) and economic repercussions (e.g. loss of employment).

Research projects may, in some cases, also collect intrusive personal or sensitive data, i.e. data which relates to racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data, data concerning health, sexual behaviours, sexual orientation, abuse and illegal activities. Research that could cause harm or uses intrusive, personal or sensitive data is generally considered to be of a higher risk.

3.4 Clinical trials of Investigational Medicinal Products (CTIMPs) and Clinical Investigations of Medical Devices.

For research which comes under the remit of the Clinical trials Regulation EU 536/2014 or the Medical Device Regulations (MDR and IVDR), Trinity follows EU and best practice legislation including ICH Good Clinical Practice (ICH-GCP) and ISO14155 (good Clinical Practice for Medical Devices). As with all sponsors of Clinical trials, Trinity must comply with national and applicable EU legislation, including the Medical Device Regulations, GDPR and S.I. No 41/99/2022 (implementing CTR) S.I. 260/261 of 2021 (implementing MDR) and S.I. No 257/2022 (implementing IVDR), the GDPR and Health Research Regulations 2018 (as amended in 2021).

3.5 Research using plants and ecosystems

There is no definite national or international research ethics policy developed to date with regard to plant and ecosystem research, however there are several policies and directives that both inform and govern research in this area. There are detailed policies on plant movement and on agricultural related plant genetic development and research. It is an

offence to interfere with the 68 rare plant species in Ireland that are covered by the Flora Protection Order (1999) and the 56 wild plant species in Northern Ireland i.e. one cannot collect, pick or uproot without a licence. There is also much relevant legislation internationally, including the Convention on Biological Diversity and the Convention on Trade in Endangered Species CITES which inform research in this area. Wildlife legislation in both parts of the island also provides for the protection of habitats as well as species, and the Natural Heritage Area programme operated by NPWS and the Area of Scientific Interest programme operated by NIEA aim to protect those sites which are of national and regional significance. Furthermore, as a European Union Member, Ireland has adopted the Habitats Directive 92/43/EEC.

3.6 Research using animals

Research involving animals by College researchers both on campus and in the wild, is governed by Directive 2010/63/EU & S.I No 543 of 2012 on the protection of animals used for scientific purposes. The Animal Research Ethics Committee reviews all projects involving animals in the wild and the laboratory and provides oversight over every protected species under this directive proposed for use in teaching and research at College. The external regulator for animal research in Ireland is the Health Products Regulatory Authority (HPRA).

Animal research is College is based on the internationally used 3R principals:

- Replacement: using alternative methods that do not require live animals;
- Reduction: using the most appropriate number for each animal project;
- Refinement: minimizing suffering and improving animal welfare.

3.7 Research using genetically modified organisms

For guidelines on research involving genetically modified organisms (GMOs) and genetically modified (GM) products, College adopts the guidelines of the Environmental Protection Agency (EPA). This is the authority in Ireland which implements GMO Regulations, including research consents, on:

- The contained use of Genetically Modified Organisms;
- The deliberate release of Genetically Modified Organisms into the environment;
- The transboundary movement of Genetically Modified Organisms.

College researchers are legally obliged to submit a notification to the EPA in accordance with the requirements of the Contained Use legislation, seeking the agency's consent before commencing work with GMOs.

3.8 Research using stem cells

In the area of utility of stem cells derived from human embryos in research, in the absence of a national framework or legislation on this matter, College subscribes to an ethical code

of practice on the use of established human embryonic stem cell lines (hES cells) in research. Any transfer of established human embryonic derived cell lines to College for use in research must be accompanied by a full materials transfer agreement, including details of the ethical compliance of the transferring institution for the derivation of the line in accordance with International Society for Stem cell Research (ISSCR) guidelines. College formally limits the permitted range of experimentation involving hES cells to those defined as category 1 and category 2 of the ISSCR Guidelines. This policy makes a clear distinction between the study of non-human primates and common laboratory animals such as mice and rats. College researchers will not be able to create new hES cell lines under this policy. Researchers wishing to employ stem cells derived from human embryos in their research in College are required to have their proposed use of such materials reviewed by an appropriate Level 2 College research ethics committee in the context of compliance with international ISSCR ethical guidelines.

3.9 College Research Ethics Structures

All researchers are required to conduct their research to the highest ethical standards and each individual researcher is responsible for ensuring good ethical practice. Research in College is categorised into three levels depending on the subject matter, the participants, and the likelihood that it may infringe upon ethical principles, as defined broadly below.

- **Level 1**: Very low likelihood
- **Level 2**: Relatively low likelihood, i.e. research carrying little or no risks or discomfort to a human participant greater than usually encountered during normal daily life;
- **Level 3**: Moderate and high likelihood: research risk or discomfort is greater than that usually encountered during normal daily life. This also usually includes research on intrusive personal or sensitive topics and with populations at risk of vulnerability.

In order to support maximum flexibility and efficiency for research, College currently has a policy committee, the Research Policy Ethics Committee, which reports to the Research Committee, and 24 Research Ethics Committees that review research proposals across College.
Note: some RECs deal with Level 1, 2 and Level 3 applications.

3.9.1 Research ethics policy committee (REPC)

This committee reports to the College Research Committee. The REPC serves as the over-arching institutional research ethics body and is mandated to develop appropriate policy

governing all research conducted under the auspices of College. This committee functions independently of, but in co-ordination with, Faculty, School or unit-level research ethics committees.

3.9.2 College research ethics committees (RECs)

All Schools/units are required to have a research ethics approval process in place. Usually each School should have its own REC that has the authority to review what are deemed to be low-risk projects (a Level 1/2 committee). Schools/units that routinely engage in moderate to high risk research generally have or have access to a Level 3 REC.

The appropriate, usually Faculty, Level 3 REC acts as the appeal committee for Level 1/2 committees. The Research Policy Ethics Committee (REPC) acts as the appeal committee for Level 3 RECs.

3.9.3 College's position on reciprocity of ethical approvals from third party collaborating institutions

College recognizes that our collaborating institutions worldwide conduct research under established ethical procedures and policies. It is, however, a requirement that an appropriate level of scrutiny is undertaken by a Trinity REC i.e., in addition to that which may have been given by an external institution (except in the case of JREC-see below).

JREC is the Joint REC for St James' and Tallaght hospitals and is responsible for the ethical approval of all research involving hospital patients, patients' relatives and any research conducted based on accessing medical records. Trinity representatives sit on the JREC and as such College affords JREC special status and as a result, any Trinity researcher carrying out research for which they have received JREC approval does not require a further ethical approval from Trinity.

Ireland's health ethics review system is currently made up of some 80 research ethics committees operating at a local or institutional level. This is largely regarded as disjointed and inefficient. A national Research Ethics Committee (NREC) is in place to give approvals for all Clinical trials of Investigational Medicinal Products (CTIMPS) which come under the remit of the Clinical Trial Regulation EU536/2014 (CTR) and Clinical Investigations of Medical Devices coming under the Medical Device Regulation EU2017/745 (MDR) and in Vitro Medical Device regulation EU 2017/746 (IVDR).

Only NREC can give an opinion on CTIMPS and Clinical Investigations. Local NREs are not involved in approving CTIMPS and Device Investigations and cannot ask for changes to NREC opinion.

For other types of trials/clinical studies (observational, interventions other than IMP or medical device) the HSE is currently reforming the REC landscape in Ireland and is in the

process of setting up six 'reference RECs' across the country which will work in a coordinated fashion with existing RECs in voluntary hospitals. A single REC review process will also be established for national studies, and studies which involve multiple sites within the scope of health research in the HSE.

All interventional trials carried out at Trinity or by Trinity Personnel should follow ICH-GCP guidelines as this is best practice.

3.10 How to Apply for Ethical Approval

REAMs is Trinity's Research Ethics Application Management System, an online platform that channels research ethics applications from the applicant (and in some case via a supervisor and/or principle investigator) to the relevant research ethics committee (REC). Key features of the platform are:

- It comprises a responsive application form which automatically opens up sections, depending on answers to specific queries, so that an applicant only has to answer questions relevant to their specific application.
- It determines the designation of an application (Level 1-3) depending on the answers to certain trigger questions and routes the application to the appropriate faculty or school REC.
- The answers to some trigger questions may mark the application as requiring a data protection review, in which case the applicant will be directed to the DPO's office. The applicant must complete any process deemed necessary by the DPO's office before the application can be given full consideration by a REC.

Reviews of the application are logged on the system, and feedback is returned to the applicant by the REC. If necessary, the applicant will be required to make revisions (i.e., within the REAMS system) and resubmit. In most cases, iterations of submission, review and revision continue until approval is granted.

4. Research Data and its Management

There are many definitions of research data, but for the purposes of this policy, the Consortia Advancing Standards in Research Administration Information (CASRAI) definition is adopted:

"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".

Research data are generated by research efforts or projects but the data (generally) persists after the research project is complete. The data may be reused by the original researcher or shared with others to be reused, subject to College policies. This requires that data be

correctly managed during and after the research phase and subsequently shared in a manner that permits reuse by other researchers in the long term.

4.1 General Policy

Throughout their work, researchers are required to keep clear and accurate records of the research procedures followed and of the results obtained, including interim results. This is necessary not only as a means of demonstrating proper research practice but also in case questions are subsequently asked about either the conduct of the research or the results obtained. For similar reasons, data generated in the course of research must be retained securely in paper, electronic or other form, as appropriate to the task and the type of research undertaken.

4.2 Guidelines

These guidelines are taken from the Policy Statement on Ensuring Research Integrity in Ireland:

- Primary responsibility for observing good practice in the use, storage, retention and preservation of data sits with the individual researcher, supported by College;
- College acknowledges data as legitimate and citable products of research;
- Research data should be recorded in a clear and accurate format. Particular attention should be paid to the completeness, integrity and security of these records;
- Research data should be stored in secure and accessible form and must be retained for a length of time in accordance with national, institutional, funder and/or publisher requirements;
- Researchers should publish results and interpretations of research in an open, honest, transparent and accurate manner, and respect confidentiality of data or findings when legitimately required to do so;
- Research data and records may be discoverable in the event of legal proceedings. This means that the research data and records can be accessed by the higher education institution (or other research performing institution) and its legal advisers, to determine their relevance to any legal proceeding;
- Data access arrangements should consider the applicability of data protection and intellectual property regulations. Clear governance and protocols should be developed on how such sensitive data may be accessed;
- College recommends the use of Data Management Plans by researchers and research teams.

4.3 Research Data Management

From a single student's individual scholarly endeavour, through to large multi-institutional research collaborations with industry, researchers must ensure that at least one named individual, referred to as the Principal Investigator (PI), is responsible for ensuring that

appropriate data management processes are created and adhered to both for the duration of the project and for the full lifecycle of the data generated during the project.

The PI should put in place a research Data Management Plan (DMP) before commencing the research activity. The core elements in DMP include general administrative data, data capture, documentation and metadata production, ethics and legal compliance, storage, back up, preservation and sharing. Data Management Plans are a compulsory requirement of many institutions and funding bodies.

In line with the Science Europe Practical Guide to the International Alignment of Research Data Management it is recommended that the PI consider a Data Management Plan under the following headings:

- Data Description and Collection;
- Documentation and Data Quality;
- Storage and Backup during the research process;
- Legal and Ethical Requirements, Codes of Conduct;
- Data Sharing and Long-Term Preservation.

A PI should also consider the resources needed for data management both during and after the project and should assign and roles and responsibilities for data management. Best practice management of research data may require input from multiple actors across College. These actors include the following units:

- IT Services
- The Library
- Procurement
- Data compliance
- Trinity Innovation and Enterprise The PI must ensure that:
- Third parties subcontracted to participate in the project and handle data be included in and adhere to the data management plan;
- Adequate training should be provided to ensure that all members of the project team understand the data management plan, any standard operating procedures, and their roles and responsibilities in respect of data management;
- All members of the project team, as defined in the data management plan should formally sign off that they have read, understood, have received adequate training if appropriate, and agreed to abide by the plan and any standard operating procedures developed for data handling.

The DMP should conform to the general principles of the College's Record Management Policy.

There are templates available to support preparation of data management plans, including funder-specific templates. Further guidelines related to Research Data Management are not yet available but will be made available in due course.

4.4 Data Storage and Retention

Research data should be classified based on the College's data and information classification. Classification of data is particularly important where personal, sensitive, politically or commercially sensitive data are being collected, processed and/or stored. College provides managed storage options for each class of data and these storage options should be used to store research data whenever practical. Other acceptable storage options may include school/ unit/ institute storage and cloud storage services provided they comply with all College IT policies. Each PI should ensure that an acceptable data backup solution is in place so that all data can be recovered in the event that the primary data source becomes unavailable.

It is not recommended that data be stored on:

- Personal laptops;
- Stand-alone hard drives;
- External storage devices such as USB sticks, SD cards, DVD and similar;
- Personal public cloud storage.

When it is necessary to temporarily store data on a laptop, the laptop should be owned by College, the laptop disk(s) must be encrypted, and data should be safely transferred onto an acceptable storage solution as soon as practical.

Non-digital research data which cannot be digitised should be:

- Stored securely according to its classification and level of sensitivity. Non-digital data should be stored on College premises where possible;
- Labelled, indexed or categorised appropriately in order to find the research data. Adequate data documentation and metadata should be provided so that the data can be identified, accessed and reused where appropriate.

Researcher data must be managed in accordance with College's records management policy.

Retention periods for the different classes of research records arising from a project differ depending on the record type. In the main, records are retained within the relevant School/ Institute/ centre/ group and the compulsory retention period varies from two years (unsuccessful applications) to an indefinite period (anonymised data) and are outlined in the college's records retention schedule.

4.5 Codes of Practice

Where the nature of a person's/ team's / Discipline's/ Institute's research involves primary data, the PI is required to adopt a code of practice for the retention of this data in their School/ Institute. The code shall take into account the nature of the research concerned and any special factors affecting the environment for research in their School/ Institute. This code must be publicly available and published on the School's/ Institute's. website.

The retention of different types of primary data raises a range of issues and may require different procedures. Factors affecting the precise codes adopted by Schools/ Institutes include the nature of the primary material, which may be problematic, such as degradable specimens, toxic specimens, voluminous source material, awkward material, records needing special readers or in electronic formats no longer current, etc. Limitations on storage arising from costs of storage, staff resources required, physical problems of storage, accessibility in the context of changing technology, etc. may require a School to adopt the nearest practical alternative to retaining original source material.
Researchers are required to adhere to the School/ Institute's code on the retention of research data. Heads of School, or those appointed to act on behalf of the Head, will ensure that the code adopted for their researchers is implemented by those concerned.

While working remotely it is important to ensure that we maintain the College's high standards of data management to ensure that all data is handled in a reliable, secure and compliant manner as per the College's Working Remotely with Research Data guidance.

4.6 Data ownership

College claims ownership for all intellectual property (IP) devised, made, or created by staff in the course of their employment. Likewise, College claims ownership of research IP of students or visitors in College when the research was conducted during or was incidental to their studies or activities in College.

Researchers/ students who are leaving College must make sure a copy of the source/ original data is retained by College. Researchers who wish to retain data, or copies of data, must get permission from their Head of School/ Institute and (if appropriate) the PI to do so. Where personal data are involved, the request should be refused unless it is clear that future use will be consistent with the terms of the original consent given and in line with ethics approval. Source data must continue to be held by the College following the departure of the researcher in order to fulfil the commitment to good research practice. Publication of the data (including in theses) does not negate the need to retain source/ original data. All copyright and licensing issues with data must be documented and defined.

4.7 Legal and Regulatory Obligations regarding Data

All research data must be lawfully processed.

4.7.1 Freedom of Information

Researchers should be aware that under the Freedom of Information Act 2014 (or any amendments thereto) a university or other research performing institution (where subject to freedom of information legislation), may be subject to a request for records or information in respect of documents or records which are in the institution's possession, under defined circumstances, as set out in the Freedom of Information Act 2014 (or any amendments thereto).

4.7.2 Data Protection

Researchers must at all times be aware of the provisions of, and operate in accordance with data protection legislation, specifically the EU General Data Protection Regulation 2016 (GDPR) and Data Protection Acts 1988-2018 (or any amendments thereto). Researchers processing personal data for the purposes of health research should be especially mindful of the requirements of the Health Research Regulations 2018 (or amendments to same).

Researchers must familiarise themselves with and adhere to College's Data Protection Policy, procedures and guidance. Researchers should note that the College's Data Protection Policy applies to any use of personal data (including pseudonymised personal data) for research purposes, including but not limited to: its collection, use, storage, analysis, alteration, retrieval, disclosure by transmission, dissemination, anonymisation, erasure or destruction.

Trinity promotes a privacy by design based approach to any research project which uses personal data, commencing at the design stage and applicable through all phases of the data's lifespan. Researchers are encouraged to carry out data protection risk assessments, and/or to create data management plans, for any research which uses personal data. This will ensure that the entire research journey from access/collection to deletion/archival has been considered from a data protection perspective. Adoption of this approach should minimise the risk of a data breach or non-compliance with data protection legislation.

4.8 Data Sharing and Long-Term Preservation

The "National Framework on the Transition to an Open Research Environment" (NORF) underlines the importance of making research data "as open as possible, as closed as necessary". Open access to research data should lead to greater integrity in the gathering, analysis and presentation of data as it may be open to scrutiny by peers, globally. It should also facilitate reuse of data for further research, contribute to public knowledge and inform policy and practice. In line with the Irish National Open Research Forum (NORF) and the principles of FAIR research (Findable, Accessible, Interoperable, and Reusable), College adopts the practice of Open Scholarship with regard to research. Research publications, data, lab notes and other scholarly objects, unless restricted for justifiable reasons, are made available under appropriate license to enable reuse, redistribution and reproduction of the work and its underlying data and methods in such a way that others can collaborate and contribute.

Where possible, research data should be suitably prepared and uploaded to appropriate domain specific repositories or archives for long term preservation. If a domain specific repository does not exist, research data may be uploaded to institutional or appropriate third party repositories. Data repositories should fulfil minimum criteria to allow data to be reliably found, used and cited:

- Data uploaded to a repository must be associated with a globally unique, persistent and resolvable identifier (Persistent Identifier -- PID). An example of a PID is a Digital Object Identifier (DOI);
- Data uploaded to a repository must be associated with standardised descriptive data (metadata) rich and detailed enough to enable them to be found and used.

College provides open access solutions for data and publications through the Research Support System (including the TARA repository). This also allows researchers to comply with publicly funded requirements for open access. In addition, the European Commission is currently establishing an open publication platform for Horizon funded projects.

5. Good Publication Practice

Researchers have a fundamental right to publish their findings. This right must be taken into consideration when contractual agreements are made with funding partners. An individual researcher's right in this context must be within the framework of any collaboration with other participants, having respect for agreements made and for other participants' rights.

Researchers should publish their findings in good time and should not unnecessarily withhold data that may be of interest to the public or to the advancement of knowledge.

Research findings should be disseminated in such a way that the researcher's peers and/or the public can make objective assessments of the results. Suitable vectors include peer-reviewed or similarly reputable publications in journals, books, software, policy statements, specialist conferences or expert reports.

The quality of the results of a project must provide the sole reason for the decision to publish. Therefore, finished research results should be presented for publication even when results differ from previous expectations and selective reporting – "p-hacking" should be avoided. Deviations from this principle result in biased reporting.

Supervisors of undergraduate and postgraduate students should firmly protect the students' rights in terms of publication and authorship.

While many studies warrant several publications, plans to do so should be set out at the outset to avoid poor publication practice. The contributor roles taxonomy (CRediT) is a helpful tool in this regard which can support open dialogue on authorship within research groups while projects are still in the research phase and increase transparency relating to researcher contributions to scholarly publications.

Publication ethics generally disallow duplicate publication of results from the same study in different journals even for different audiences. While separate publications are warranted in some cases, literature/ systematic review, methodological papers, separate, distinct objectives or baseline/ initial data, caution must be taken to avoid piecemeal publication - the excessive publication of limited elements of a study or self-plagiarism - publication of previously published text.

In all research, College expects that authors do not publish libellous or defamatory material and that standard codes of political, ethnic or moral ethics are not breached.

Authors must ensure that they are not guilty of plagiarism in their publication. Thus, they should provide a complete reference list of all sources of information used in the preparation of their article or talk. They should fully cite the sources of tables, diagrams, quotations, paraphrases, etc. that are included in the article and they should obtain permission from holders of copyright where necessary.

Before dissemination, authors should familiarise themselves with published ethical guidelines. Examples of such guidelines in the scientific area are the Committee on Publication Ethics (COPE) guidelines or the Vancouver Requirements for health publications. Authorship rights and responsibilities of researchers working as part of a research group within College should be decided at the development stage of the project. College adheres to the general guidelines listed above and researchers may also have to adhere to the specific guideline of the journal regarding the rights to authorship, the principles of which include:

- Contribute substantially to at least one of the following areas: the creation, design, collection analysis or interpretation of data;
- Contribute substantially to the preparation of the article;
- Be prepared to take public responsibility for the content.

Researchers participating in a collaborative research project should not prepare separate publications or deliver presentations without prior consent of the collaborators.

6. Evaluating Research: the DORA Principles

The San Francisco Declaration on Research Assessment (DORA) is a set of recommendations that seek to improve the ways in which the output of scientific research is evaluated by funding agencies, academic institutions, and other parties.

The main themes in the document include:

- The need to eliminate the use of journal-based metrics, such as Journal Impact Factors (JIF), in funding, appointment, and promotion considerations;
- The need to assess research on its own merits rather than on the basis of the journal in which the research is published; the need to capitalize on the opportunities provided by online publication (such as relaxing unnecessary limits on the number of words, figures, and references in articles, and exploring new indicators of significance and impact).

In addition, DORA advocates that researchers use and teach a range of metrics and indicators to assess research on its own merits that focus on its specific value and influence and to cite primary research rather than reviews when appropriate, so that credit is given for original authorship.

Irish funding agencies (SFI, HRB, RIA and the IRC) have all become signatories to the San Francisco Declaration of Research Assessment, making a formal commitment to assessing the quality and impact of research through means other than journal impact factors. Further, in 2019, the cOAlition S group, of which both SFI and Wellcome are members, confirmed their commitment to assess research outputs based on their intrinsic merit. The cOAlition S open access policy comes into force on 1st January 2021. This requires funded organisations to publicly commit to the two core DORA principles and this may be assessed as part of regular audits.

In responding to this, we in College commit to implementing the DORA principles as part of a fair and responsible approach to research assessment. In doing so, we commit to assessing research outputs and other research contributions based on their intrinsic merit and to discouraging the inappropriate use of proxies or metrics – such as the title or impact factor of the journal in which the work was published.

Responsibility and Implementation

The Dean of Research is responsible for monitoring the implementation of this policy.

More broadly, it is the responsibility of all Trinity staff who conduct research to be familiar with the policy, the principles and guidance contained within, and to ensure that they

Related Documents

This section outlines any documents or guidance material that relates to the policy and provides context and/or additional information to assist readers understand or implement the policy. Any related policies impacted by the policy should also be listed.

Research Policy Page: https://www.tcd.ie/about/policies/research-policies/

Advice from Data Protection Office on retention of personal data
https://www.tcd.ie/dataprotection/retention/

Embassy of Good Science (Platform for Research Integrity and Ethics)
https://embassy.science/

European Commission Ethics and Data Protection November 2018:
https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-data-protection_en.pdf

Explanatory Guidelines and Related Policies for the Financial Management of Research

Gift Voucher Policy: https://www.tcd.ie/media/tcd/about/policies/pdfs/Small_Gifts_and_Benefits_Policy.pdf

Grants and Contracts https://www.tcd.ie/media/tcd/about/policies/pdfs/Guidelines_Policies_Research_Grants_and_Contracts.pdf

Guidance on Health Research https://www.hrb.ie/funding/gdpr-guidance-for-researchers/health-research-regulations-2018/health-research-regulations-2018-faq/

Guidelines on Health Research January 2021 Amendments:https://www.gov.ie/en/publication/b46c2-amendments-to-health-research-regulations/?s=09

Guidelines on Scientific Research and GDPR: https://edps.europa.eu/sites/edp/files/publication/20-01-06_opinion_research_en.pdf

Health Research Consent Declaration Committee: https://hrcdc.ie/about-us/

Hospitality and Entertainment Policy: https://www.tcd.ie/media/tcd/about/policies/pdfs/hospitality-entertainment-policy.pdf

Innovation and Industrial Engagement Policy: https://www.tcd.ie/innovation/for-trinity-innovators/collaborating-with-industry/

Legal Frequently Asked Questions (FAQs): https://www.tcd.ie/secretary/compliance-and-legislation/legal-faq/

Policy on Access to Trinity College Staff and Students for Research Purposes by External Organisations: https://www.tcd.ie/media/tcd/about/policies/pdfs/Policy-on-external-research-access-1.0.pdf

Preferred Supplies List: https://www.tcd.ie/financial-services/procurement/suppliers/preferred-supplier-cat/index.php

Research Excellence Strategy: https://www.tcd.ie/research/assets/pdf/Research%20Excellence%20Strategy.pdf

Social Networking and Social Media Policy: https://www.tcd.ie/media/tcd/about/policies/pdfs/Policy-on-Social-Networking-and-Social-Media.pdf

Students Charter: https://www.tcd.ie/students/assets/pdf/student-charter-2009.pdf

Students Complaints: https://www.tcd.ie/about/policies/university-policies/complaints-procedure/

Trademarks Policy: https://www.tcd.ie/media/tcd/about/policies/pdfs/trademarks.pdf

Travel Policy: https://www.tcd.ie/media/tcd/about/policies/pdfs/Travel_Policy.pdf

Trinity Institutes: https://www.tcd.ie/media/tcd/about/policies/pdfs/Trinity-Research-Institute-Policy-2018-final.pdf

Document Control for Revised Policies

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