Code of Practice for the School of Social Work and Social Policy (SWSP) Research Ethics Committee, Trinity College Dublin

TCD has a new platform (Research Ethics Application Management system REAMS) developed for processing research ethics applications. Before submitting an application, please read the following information carefully.

From January 2023: all applications from Staff researchers or PhD students should be made through the Research Ethics Application Management system (REAMs). REAMs is a new platform developed for processing research ethics applications.

From September 2023: all applications – including applications from taught and research masters students and undergraduate students – should be made through REAMs.

To access the Research Ethics Application Management System click access REAMS.

To access information about REAMS and support using it, please click REAMS information and support.

This Code of Practice provides guidance on applications submitted via REAMS and applications using the ethics application form submitted via email. Where alternative guidance applies to REAMS, this has been noted and relevant links provided.

1. Requirements for ethical approval

All research in the *School of Social Work and Social Policy* should be conducted in a manner that respects the rights of all participants (including to privacy, confidentiality and anonymity as appropriate), causes no harm to participants or researchers, and requires the active, informed consent of all participants and where appropriate their parents, guardians or relevant responsible others. See TCD Good Research Practice Guide for a full account of guidelines and legislation that govern research in the College.

The University requires **all** research activity to be subjected to ethical scrutiny. Ethical approval is not granted until a formal response has been issued to the researcher by the School of Social Work and Social Policy Research Ethics Committee. Data collection on the project can only proceed following receipt of this formal response (see section 3 below).

Ethical approval can be sought at Level 0, Level 1 or Level 2. This must be clearly indicated on the ethical approval application form. **Please note that the levels of risk have been changed to 1, 2, and 3 in REAMS. If you are submitting your application via REAMS, please see section 2 of this document "Submission" and read the Guidance for using REAMS.**

Level 0 ethical approval

Research activity is classified as Level 0 if the research does not involve human (or animal) participants. This research is confined to publically available data[1]. Level 0 approval quires the applicant to complete this short checklist. Here are some examples:

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[1] Data Protection Impact Assessment and Data Protection Officer's review may be required (section 4).

1. Organisational/policy analysis
2. Literature reviews
3. Research on publicly available information, documents or data sets

Level 1 ethical approval

This is no risk to relatively low risk research – i.e. research carrying little or no risks or discomfort greater than usually encountered during normal daily life, for example:

1. Anonymous surveys of a non-intrusive personal nature.
2. Unrecorded and anonymous observation of individuals in public areas.
3. Analysis of irrevocably anonymised and appropriately collected data.
4. Interviews (consensual) with adults at no risk of vulnerability.
5. Action research (Research initiated to solve an immediate problem or a reflective process of progressive problem solving by individuals on their own practice or by individuals working in teams or as part of a "community of practice" to improve the way they address issues and solve problems [participatory action research]).
6. Surveys where respondents can be identified and where respondents have given appropriate consent.

Level 2 ethical approval

Moderate to high-risk research (i.e. risk or discomfort is greater than that usually encountered during normal daily life). This includes all research *with children* (i.e. under 18 years of age) and adults at risk of *vulnerability* (e.g. participants with an intellectual disability) and *all research conducted outside ireland*[2].

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 and usually submit to Level 2 research ethics committees for approval. One area that could impact the vulnerability of participants is the sensitivity of the research and the potential for harm. In studies which include groups at risk of vulnerability (e.g. such as people with a communication disability), and where the potential for harm is low, researchers should consult with their local Level 1 ethics committee to confirm which research ethics committee would be most appropriate for their application. Applicants should provide a rationale in their application if a deviation from this general policy is being sought. However, all groups that require assistance with consent (see section 4.2.1. of the TCD Policy on Good Research Practice) must submit to Level 2 committee (the school of Social Work and Social Policy REC is a level 2 committee).

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[2] Potentially harmful research conducted outside Ireland must be reviewed at Level 2. Projects conducted outside Ireland that are based on publicly available materials may be reviewed at level 1. It does not apply to materials publicly available in another jurisdiction.

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MODERATE RISK

1. Surveys asking questions of a sensitive or private nature.
2. Questionnaires or observational studies involving children or adults at risk of vulnerability.
3. Research where there is a risk of a participant feeling undue pressure to participate by virtue of his/her relationship with the researcher (e.g. student/supervisor; social worker/service user).
4. Projects involving a justifiable degree of deception.

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HIGH RISK

1. Research involving children and adults at risk of vulnerability.
2. Research where identifiable information obtained may have legal, economic or social consequences for research subjects.
3. Research that may identify illegal activity.
4. Projects where each subject is paid (over and above token gestures).
5. Research that may potentially endanger the subjects, and/or researchers, and/or 3rd parties, and/or the environment.
6. Research that may have a direct military role.
7. Research conducted outside Ireland.
8. Research involving psychological intervention.
9. Research where a potentially beneficial or harmful treatment, information or learning method may be withheld from some participants.

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2. Submission

TCD has a new platform (REAMS) developed for processing research ethics applications. Before submitting an application, please read the following information carefully.

From January 2023: all applications from Staff researchers or PhD students should be made through the Research Ethics Application Management system (REAMs). REAMs is a new platform developed for processing research ethics applications.

From September 2023: all applications – including applications from taught and research masters students and undergraduate students – should be made through REAMs.

To access the Research Ethics Application Management System click access REAMS.

Until September 2023
Applications from taught and research masters students and undergraduate students should be submitted using the ethical approval application form.

Applications submitted using the ethical approval form must be typed and submitted as a single PDF file containing the application form and all application materials, and must be submitted by email to Swsp.Ethics@tcd.ie.

Electronic signatures are accepted on all applications.

Applications must name all researchers involved in the project and must be signed by the study lead researcher or Principal Investigator.

In the case of collaborative projects involving researchers from outside the School, where ethical approval has been obtained from an external research ethics body, the project must still come before the REC for review. Such projects will be fast-tracked for approval.

3. Review and approval process

Ethical approval is not granted until a formal response has been issued to the researcher(s) by the *School of Social Work and Social Policy* Research Ethics Committee. Data collection on the project can only proceed following receipt of this formal response.

Applications can be dealt with as a matter of priority upon request.

Applications from students being supervised by a member of the School Research Ethics Committee will be reviewed by another member (or members) of the Committee.

Where two members of the Committee are reviewing an application, one primary assessor will collate the outcome and feedback from both reviewers.

If the Committee cannot reach a consensus in relation to a decision on an application, the application will be referred to the Faculty Research Ethics Committee.

If an application is unsuccessful, required changes will be outlined for the applicant in a timely manner.

Resubmissions should address all points outlined in the feedback provided by the reviewer(s). The feedback and the changes made to the application should be listed at the start of the resubmission. All changes to the original submission must be clearly tracked using track changes or highlighting. If changes are not clearly indicated, the resubmission will be returned without review.

Resubmissions will be reviewed by 1 member of the ethics committee unless the reviewer requests a second reviewer.

4. Referrals and Appeals Process
Referral to FREC (Faculty of Arts Humanities And Social Sciences Research Ethics Committee)

Some Level 2 ethical approval applications may need to be referred to the FREC or the Trinity Research Ethics Policy Committee (REPC) where proposals:

- have the potential to cause harm to participants or researchers, directly physical or psychological;

- may give rise to situations in which the researchers have to make statutory disclosure of illegal activity, whether on the part of participants or others;

- seek to deceive participants for any reason;

- may give rise to situations that may put the participants or researchers in any form of jeopardy.

Referral to Data Protection Officer (Research)

The Research Ethics Committee may refer applications for review to the Research Data Protection Officer.

The REC may require the applicant to contact research DPO@tcd.ie to complete a Data Protection Impact Assessment (DPIA) in instances where there are questions in relation to data protection or processing.

The purpose of a DPIA is to assess and demonstrate compliance with data protection legislation. The DPIA also provides evidence that the risks to individuals have been considered and sufficient measures have been taken to protect those individuals. The DPIA should assess the activity to be carried out against all the principles of data protection and determine whether the processing of personal data is both necessary and proportionate or whether changes to the process or additional controls are required.

Where applicants have changed data protection aspects of the TCD consent substantially, the Research Ethics Committee may refer the application to be reviewed by Deputy DPO for Research.

Appeals Process

Applicants whose projects are rejected will receive feedback from the School REC. An amended project may be submitted to the REC for the next or subsequent deadlines. Where a dispute cannot be resolved, the input of another REC or the FREC will be sought.

5. Changes to Research Projects

For the purpose of this document a "study" may be understood to involve a potentially staged series of data collection/analysis processes to be conducted over a period of time. Any changes to a study require approval before data collection can proceed.

Non-Substantive Changes

Researcher submits an addendum to an original application (a copy of the original application and any supplementary materials such as consent forms with any changes clearly noted) for:

i.   Changes to project personnel (e.g new Research Assistant or collaborator who will have access to the data)

ii.   Changes to data collection methods (e.g. additional data collection instrument, audio to video recording)

iii.   Another phase of data collection from the same participants (e.g. collecting data in year 2 from the same students as year 1)

iv.   Same data collection methods from a new set of participants (e.g. the next student year cohort)

v.   Changes to data collection instruments and new participant groups (e.g. data collection with parents of a student cohort) where the ethics risk level of the study has not increased

Substantive Changes

Researcher submits a new application:

b.   Change of ethics risk level (e.g. Level 1 to Level 2)

6. Informed Consent: Information sheets and consent forms

Best and common ethical practice involves ensuring informed consent is obtained from the research participants. All research ethics applications with human participants require participant information sheets and consent forms for each group of research participants to be included as appendices, whether approval is sought at Level 1 or at Level 2. The TCD consent templates should be used and only stylistic modifications should be made to these (see templates here).

The information sheets and consent forms should:

- be intelligible in language that is accessible to the target audience (e.g. children, young people, etc);

- describe the nature and duration of participation in the study;

- describe the research instrument(s)/methodology with indicative questions where appropriate;

- clearly state the purpose(s) or phases of processing and request explicit consent for each;

- explain how participant data in all its forms (e.g. paper forms, recordings, etc) will be protected, including how it will be stored and for how long and how it will be ultimately destroyed

- state the planned avenues for dissemination of results of the study;

- clearly inform possible participants that participation is voluntary, that the participant has the right to cease participation at any time without giving a reason and without prejudice;

- clearly state up to what point a participant can withdraw their data from a study, e.g. up until the data is irrevocably anonymised or until analysis or publication of the data findings.

Who is required to provide consent and how?

As per College's Policy on Good Research Practice, consent forms should be designed on an opt-in basis where consent is freely given and affirmative. Participants should be given sufficient time (e.g. 2-7 days) to consider the participant information sheet prior to providing consent to participate in the study.

Opt-out designs are not acceptable for research participants of any kind, for their parents/guardians, or for school management.

As per College's Policy on Good Research Practice, consent is usually indicated by participants with an original signature.

Online questionnaires must require active consent, i.e. participants must tick consent in order to proceed to the questionnaire. The first page of the questionnaire must repeat the content of the information sheet, followed by the consent form. If the participant does not agree to the consent, they must automatically be exited from the questionnaire. Participants must be asked to indicate that they are over 18 unless prior parental consent has been sought.

For the distribution of questionnaires for anonymous return, as long as the circumstances guarantee anonymity, return of the questionnaire itself implies consent and no separate form needs to be used.

If using a paper-based questionnaire, the following opt-out clause should be included on the top of each page of the questionnaire: "Each question is optional. Feel free to omit a response to any question; however the researcher would be grateful if all questions are responded to."

For an on-line questionnaire, each question must be optional. The participant must have the option to 'exit without submitting' at the final submission point on the questionnaire.

For research to take place in pre-school, primary school, secondary school, or equivalents, the application must include the letter requesting consent from the principal and/or board of management. This must be sought on an opt-in basis.

Research with minors requires signed parental/guardian consent. It is accepted by the Irish courts and international guidelines that minors have independent rights. All minors regardless of age should therefore be informed as fully as is practicable about the research and agree to be involved. If they do not wish to do so, then this must take precedence over any consent given by a responsible adult. For older children, they should provide signed consent. For research with very young children the researcher must seek assent from the children by discussing clearly with them what the participation in the research involved and explaining that they can absent themselves at any time without giving a reason.

Unless otherwise noted, research involving adults assumes adults have the capacity to consent. The *Assisted Decision Making (Capacity) Act, 2015* sets out for all people to be assumed to have capacity until proven otherwise and that assessment of capacity will no longer be a blanket functional assessment, in that, capacity can shift and change depending on the context. Therefore, all practicable supports should be provided to enable the adult to make an informed decision about participation in the study. When assistance from another person is required to provide consent, the application must be submitted to a level 2 committee.

Participants must be informed at the point of data collection at the latest regarding disclosing illicit activity: "In the extremely unlikely event that illicit activity is reported I will be obliged to report it to appropriate authorities."

Best practice for projects that involve a justifiable degree of deception require consent both before submitting the data and afterwards for participants to be aware what the data will be used for in compliance with GRPR.

Consent options

1. A paper signed consent form
2. A scanned copy of a signed consent form by email
3. A digitally signed consent form (image of signature) by email
4. A completed consent form with typed name from a verified email address (without signature)
5. Consent provided via a Qualtrics survey or MS Forms assuming a link is sent to a verified email account
6. A signature could also be captured using the file upload feature: https://www.qualtrics.com/support/survey-platform/survey-module/editing-questions/question-types-guide/advanced/file-upload/
7. In very exceptional circumstances where written consent is not possible, verbal consent is also acceptable, once a record is provided, written or video recorded, of when and how consent was taken, and any questions posed etc. The application for ethical approval must provide a clear justification for why only verbal consent is possible in these circumstances.

7. Research instruments

The research instruments/methodology employed by the applicant should be described in precise detail in Section 1 of the application form.

It is the policy of the *School of Social Work and Social Policy* Research Ethics Committee that applicants are not ordinarily required to submit research instruments for review.

It should be noted in light of this, however, that the description of the research instruments and/or the methodological approach in the application form should be highly detailed.

In certain circumstances (e.g., level two applications that involve research of a sensitive nature, conducted with children or adults at risk of vulnerability), the Research Ethics Committee may request that (at least advanced draft) copies of research instruments (e.g., questionnaires, interview schedules, introductory and debriefing materials) be submitted for consideration as part of the application for approval.

8. Participants and location of data collection

Where known, application forms for ethical approval should name the locations at which data will be collected (i.e. name the school, or the youth centre, or the area). This information will be dealt with in strictest confidence.

The approximate number of participants, their ages, year group etc. should be described in the application form as well as the sampling method adopted in the study.

Research with participants at risk of vulnerability

Special consideration must be given to protecting the welfare of potentially vulnerable research participants. 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 may 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;

- Participants who have an unequal power relationship with the researcher, i.e. student/ lecturer, employee/ manager;

- Additional social factors, such as poverty and lack of access to health care, can also make individuals vulnerable to coercion, exploitation or other risks and need to be considered in reviewing applications.

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 (i.e., people with disabilities) and from the Department of Children and Youth Affairs (i.e., children). Local College policies offer further specific guidelines in this regard[3]. See the section on research with vulnerable participants in the TCD Good Research Practice Guide.

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[3] See Accessible Information Policy & Guidelines and the College policy on provision of/ working with Irish Sign Language Interpreters.

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 wellbeing 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.

9. Garda Vetting

Where the participants include children or adults at risk of vulnerability, research cannot proceed unless **all** researchers involved have obtained Garda vetting or equivalent.

10. Research outside of the Republic of Ireland

Research undertaken outside Ireland must adhere to the same ethical standards as research in Ireland. Any additional regulations (e.g. police clearance or equivalent, mandatory disclosure regulations) and cultural sensitivities of the host country must also be observed. The requirement for a project to obtain ethical approval in the host country also will be assessed on a case by case basis with reference to the risk level of the project to participants and researchers.

11. Data storage, retention and destruction

Data storage and access

In line with College's Policy on Good Research Practice and policy for retention and with Irish Data Protection Legislation and the General Data Protection Regulation (GDPR) applicants should describe in detail the process for data storage (including encryption, if applicable) and destruction.

All data must be stored securely on encrypted devices or drives. All data must be stored in compliance with GDPR. That is, it should be stored within the EEA or it can be stored outside the EEA if specific legal conditions are in place e.g. a contract with the third party containing the EU standard contractual clauses or an adequacy ruling and once you advise individuals that their data will be stored outside the EEA.

Any cloud storage solutions used must state full compliance with GDPR in their contract or terms and conditions. Currently free versions of DropBox, iCloud, etc may not be compliant. Any breach of data protection must be notified to the College within 72 hours of occurrence. See http://www.tcd.ie/ITSecurity/gdpr/checklist.php for storage requirements under GDPR.

The application should indicate who will have access to the data e.g. the members of the research team and, potentially, the examiners.

Application forms, and the information sheets, should detail what plans there are for dissemination of the research, if any.

Data Retention and Destruction

As per Irish Data Protection Legislation, the General Data Protection Regulation (GDPR) and College's Policy on Good Research Practice, a timeframe for when data will be destroyed must be provided. This refers to all copies, electronic and 'hard' copies alike, including signed consent forms.

Data shall not be kept for longer than is necessary for the purpose(s) stated. Current legislation

does not specify any minimum or maximum retention periods. It is the responsibility of the researcher to determine the retention period for their research data. (See https://www.dataprotection.ie/docs/Data-Protection-Rule-7/31.htm).

For taught postgraduate students at the School of Social Work and Social Policy all raw data must be kept until exam boards confirm a student's results for a dissertation. Anonymised interview transcripts are to be retained for two years from the date of the exam board. If a student requires an extension to retain data beyond two years then the student must seek the approval of the Research Ethics Committee.

For research postgraduate students and staff research projects at the School of Social Work and Social Policy, research students and staff will normally plan to keep their data for longer periods, in consultation with their supervisors/PIs or research teams. The principle must be adhered to that this is done with clear and informed consent from all participants in the study. This requires an explicit data retention / storage / destruction policy to be developed for each individual Research Ethics Committee application and to be included in all participant and agency information sheets and consent forms. They will also need to inform participants of their rights to access their personal data at any time (under Freedom of Information legislation).

For as long as **personal data** are held, Data Protection requirements hold. It may be sufficient in some cases to retain only de-identified (i.e. anonymised) data. After the retention period, the data must be destroyed as appropriate to the medium of storage.

A description of how data, in both electronic and 'hard' copies, will be destroyed should be provided in the application form.

The following line may be inserted in the participant information leaflet to specify this:

"Data will be retained for no longer than is necessary. All records where you can be identified (e.g. recordings, etc) will be destroyed after all phases of data collection are complete and the data have been fully anonymised. At this point, your data can no longer be withdrawn from the study as it is no longer identifiable. "

Data Protection Impact Assessment (DPIA)

A DPIA aims to ensure that privacy and data protection is embedded in project by design. This is a requirement for projects that may have high risk for participants or require high volume processing of personal data.
If you are unsure whether you need a DPIA you can contact dataprotection@tcd.ie.
For more information see https://www.tcd.ie/info_compliance/data-protection/dpias/.

12. Recording, Monitoring and Archiving

The ethics administrator maintains the list of all staff ethics applications and application status

Every staff application that is received by the Administrator will be logged on the spreadsheet database, showing the following as a minimum:

- Name of Lead Researcher
- TCD e-mail
- Project Title
- Estimated start date of survey/research
- Date received by Administrator
- Committee decision and date of Committee decision
- Amendments submitted and
- Committee decision on amendments and date of Committee decision on amendments

13. Appendices

i) Appendix A. Trinity Pollicy on Good Research Practice.
   https://www.tcd.ie/about/policies/Good_Research_Practice_June2021.pdf

ii) Appendix B: Data Protection Legislation: Data Protection - Information Compliance : Trinity College Dublin (tcd.ie)

iii) Appendix C: GDPR Regulations: General Data Protection Regulation (GDPR) – Official Legal Text (gdpr-info.eu) and https://gdpr.eu