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Overview of REAMS

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

All applications from Staff researchers, PhD students and M.Litt. students should be made through the Research Ethics Application Management system (REAMs). REAMs is a new platform developed for processing research ethics applications.

Applications from taught postgraduate students and undergraduate students should be submitted using the ethical.approval.application.com to swsp.ethics@tcd.ie.

To access the Research Ethics Application Management System click <u>access REAMS</u>.

To access information about REAMS and support using it, please click <u>REAMS information</u> 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.

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 <u>all</u> 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 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 Research

Research activity is classified as Level 0 if the research does not involve human (or animal) participants. This research is confined to publicly available or irrevocably anonymised data¹. Undergraduate and postgraduate taught students conducting Level 0 Research do not have to submit an ethics application form. PhD students and staff submitting their applications through REAMS should get familiar with Level 1 research requirements here. Level 0 research conducted by undergraduate and postgraduate taught students is recorded by the REC through the respective course directors including: name of the student conducting research, title of the study, beginning and end dates of the study, and data sources (e.g., library databases, research databases, etc.). Here are some examples: Non-anonymised or pseudo-anonymized data: students using non-anonymized or pseudo-anonymized data must provide a written account of how they will ensure that data is protected at all times and that no individual is identifiable. If the student must detail these issues as part of the process of getting access to the data (e.g. accessing GUI AMF data through the CSO) they can submit this documentation and approval letter to the REC and ethical approval can be granted on this basis. If there is no such process for gaining access to the data, then the student must detail how they will handle these issues on a bespoke basis.

- 1. Organisational policy analysis
- 2. Literature reviews
- 3. Research on publicly available information, documents or data sets
- 4. Analysis of irrevocably anonymised and appropriately collected data.

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. Interviews (consensual) with adults atno risk of vulnerability.
- 4. 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]).
- 5. Surveys where respondents can be identified and where respondents have given appropriate consent on a non-intrusive topic.

¹ Data Protection Impact Assessment, Data Protection Officer's review may be required (section 4)

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 Ireland². 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 3.2. of the <u>TCD Good Research Practice Guide</u>) must submit to Level 2 committee (the school of Social Work and Social Policy REC is a level 2 committee).

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.

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.

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.
- Research where a potentially beneficial or harmful treatment, information or learning method may be withheld from some participants.

Submission

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

All applications from Staff researchers, PhD students and M.Litt. students should be made through the Research Ethics Application Management system (REAMs). REAMs is a new platform developed for processing research ethics applications.

Applications from taught postgraduate students and undergraduate students should be submitted using the ethical approval application form to swsp.ethics@tcd.ie.

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

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.

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.

If the application is approved with recommendations or comments, the supervisor of the research will be asked to sign a supervisor agreement/adherence letter. A template letter will be sent with the decision letter, data collection on the project can only proceed following submission by the supervisor of this adherence letter.

The minimum turnaround time for an ethics application is 10 working days. This allows for the logging of the application and the assignment of the application to members of the REC. Any expected delay in processing an application will be highlighted upon receipt of the application. Each year, the Chair of the REC will issue details of a pre-defined period during the Summer months that the REC will not be processing applications. Applications, where possible can be dealt with as a matter of priority.

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 Chair of the SEC to determine the outcome. If a decision cannot be made at this stage, the application will be referred to the Faculty REC.

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 upless the reviewer requests.

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

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)

For applications submitted via REAMS. Applicants submitting ethics applications via REAMS might be prompted to seek ethical approval by the Data Protection Officer.

For applications submitted via the ethics application form via email. 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.

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)

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 [add link to gatekeeper information form]).

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 <u>TCD Good Research Practice Guide</u>, consent forms should be designed on an optin 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 <u>TCD Good Research Practice Guide</u>, 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,

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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.

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.

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 <u>National Disability Authority</u> (i.e., people with disabilities) and from the <u>Department of Children and Youth Affairs</u> (i.e., children). Local College policies offer further specific guidelines in this regard³. See the section on research with vulnerable participants in the <u>TCD Good Research Practice Guide</u>.

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.

Garda Vetting

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

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.

Data Storage, Retention and Destruction

Data storage and access

In line with College's TCD Good Research Practice Guide 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.

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

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 <u>research</u> <u>team</u> and, potentially, the <u>examiners</u>.

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 <u>Irish Data Protection Legislation</u>, the General Data Protection Regulation (GDPR) and <u>TCD Good Research Practice Guide</u>, 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). DPO guidance on retention of personal data for research projects is also available in Appendix D.

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/. DPO guidance on retention of personal data for research projects is also available in Appendix D

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.

Appendices

Appendix A. Trinity Policy on Good Research Practice.

https://www.tcd.ie/about/policies/Good Research Practice June2021.pdf

Appendix B: Data Protection Legislation:

<u>Data Protection - Information Compliance : Trinity College Dublin (tcd.ie)</u>

Appendix C: GDPR Regulations:

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

Appendix D: DPO Guidance on Retention of Personal Data for Research Projects:

For any research project which uses personal data, the motto "as long as necessary, as short as possible," is important. The Principal Investigator should periodically review their research data set/s to assess whether personal data is still required.

When planning and designing a research project, the Principal Investigator should establish at what stage personal data will be: pseudonymised (de-identified), archived, anonymised, and/or securely deleted as applicable. This ensures that the retention period for personal data is appropriate to the requirements of the research project. Irrevocably anonymised data¹ can be stored indefinitely.

In line with the principle of transparency, the retention period or the criteria used to calculate that retention period should be shared with the research participant in your project specific Privacy Notice or Information Leaflet.

Determining the retention period for research projects using personal data

Research data should be retained in a secure manner by the University for as long as it is of continuing use to the University. If the research data may be of value to the University (in terms of secondary analysis), consider this at the outset, so that participants are informed at the time of data collection of any possible future use of their data. This practice not only reflects the ethical principle of informed consent, but the principle of fair and lawful use of data, transparency, purpose limitation and storage limitation under Article 5 GDPR.

The following is a non-exhaustive list of the criteria to consider when calculating the retention period. Please note this is guidance only, and ultimately the Principal Investigator is responsible for justifying the retention period.

¹ https://www.dataprotection.ie/en/dpc-guidance/anonymisation-and-pseudonymisation

Criteria	Term	Rationale
·		This is to allow sufficient time for verification of results or appeal by the student. This retention period can be longer for any undergraduate or postgraduate programmes which also fall under the criteria listed below.
Research project is funded.	Retain for the period required by the funder or Coordinator (if a collaboration).	-
Publication requirements (follow up, verification).		To comply with publication requirements
		requirements

Subject to a contract (research services etc.).	Retain for the period of time specified within the contract.	To comply with the contract terms and conditions
Evidence novel IP etc.	Retain indefinitely.	To comply with IP law
Poses a higher risk to the participant.	Retain for the duration of the project plus 7 years	In case of any potential legal claims
Any other legislative or regulatory reason.	Retain in line with that requirement (for example, 25 years minimum after the trial has ended for clinical trials).	
Data is required for follow up (longitudinal studies) or biobanks.		Best practice for longitudinal studies or biobanks
Personal data provided by a third- party for secondary use	Retain for the duration agreed with the provider under contract.	To comply with the contract

Individuals' rights in relation to the retention of their personal data may override the retention periods indicated above. If any request is received from a research participant to remove their personal data from a research project, contact the College Research DPO for advice without delay at researchdpo@tcd.ie Each request will be assessed on a case-by-case basis.

Retention of consent-related documentation

Consent Forms are a form of personal data, often containing contact details, and the participants unique identifier. They should only be stored for as long as you are processing the participant's personal data for research purposes (to evidence the ethical principle of informed consent, or compliance with the Health Research Regulations, if health research).

Please be aware of any other retention requirements regarding consent which may be imposed by the funder, publisher, law, regulation or best practice in your particular area of research.

If you are unclear about how long you should retain personal data, the College Research DPO can be contacted for advice, at researchDPO@tcd.ie.

Please note that if your research, requires a risk assessment or Data Protection Impact Assessment (DPIA), the DPO's office will provide tailored advice on retention specific to your project.

Further guidance

- 1. Data Protection Commission guidance on the principles of GDPR. Please see here.
- 2. Trinity's current records retention schedule. Please see here.
- 3. Guidance on data management CESSDA Data Management Expert Guide. Please see https://www.cessda.eu/Training/Training-Resources/Library/Data-Management-Expert-Guide.
- 4. Guidance on data anonymisation. Please see here.

5. HSE Policy for Consent in Health and Social Care Research. Please see here.

Appendix E: Guidance for applicants submitting an ethics application.

- 1. Gate Keepers What are their function.
- a. Information available on REAMS manual Gate Keeper (p. 39 and below)
- b. Information/consent form available through the SWSP Research Ethics website
- 2. Services available and support.
- a. Support Mental Health Ireland
- i. The Samaritans Samaritans Ireland Contact Us | Samaritans
- ii. Aware www.aware.ie
- iii. Pieta House www.pieta.ie
- iv. Turn2me www.turn2me.ie
- v. Childine www.childline.ie
- vi. Parent line <u>www.parentline.ie</u>
- vii. Women's Aid <u>www.womensaid.ie</u>
- viii. Men's Aid Home Men's Aid (mensaid.ie)
- ix. Aoibhneas Women and Children's Refuge www.aoibhneas.ie
- x. The Dublin Rape Crisis Centre https://www.drcc.ie/
- xi. LGBT Ireland www.lgbt.ie
- xii. National Advocacy Service Contact Us National Advocacy Service

3. TCD counselling

- i. Services Available Student Counselling Trinity College Dublin (tcd.ie)
- ii. After Hours Support Student Counselling Trinity College Dublin (tcd.ie)
- iii. Text about it text TCD 50808
- iv. Home NiteLine
- b. TUSLA report a concern
- c. HIQA Report a Concern or Give Feedback | HIQA
- 4. Minor v's Major Revisions.
- a. Review outcomes are: approve, reject and make revisions. <u>REAMS manual</u> (Section 3.3.3 Review Outcomes, p. 66 and below)
- 5. Checklist for applicants to ensure they have attached all information with their application.
- a. Added to the ethics approval application form (new version on the website) and required to submit through REAMS.
- 6. Plain English Guidance on GDPR:
- a. TCD Data Protection Handbook
- b. Data Protection Basics | Data Protection Commission
- c. Overview of the General Data Protection Regulation (GDPR) (citizensinformation.ie)
- 7. Recording. A list of approved devices and methods of storage.
- a. GDPR IT Checklist IT Security Trinity College Dublin (tcd.ie)

b. Research-Data-Collection-and-Storage-30-03-2020.pdf (tcd.ie)

8. Gate Keeper (REAMS manual p. 39)

Some projects require gatekeepers. The role of the gatekeeper is usually to assist the researcher in the recruitment or screening of participants for the study. Gatekeepers may be individuals affiliated with a specific organisation. In this instance, their role in the project might include giving / sending letters, emails to eligible participants. One benefit of this approach is that the researchers need not have access to personal contact data. It may also serve to reduce any feeling of pressure to participate. This is particularly important if the participants have known the researcher in another role. Organisations themselves may act in a gatekeeping role by posting an email or a social media announcement about a project. As the precise role played by gatekeepers varies across disciplines and projects, you should refer to the literature that is relevant in your area, and/or consult experienced researchers. Be specific with regards to the role of the gatekeeper in relation to the project, and the position of the gatekeeper within their organisation. Will the gatekeeper be distributing flyers, posting social media advertising, handing out participant information leaflets, screening a database to select suitable potential participants and/or contacting potential participants on your behalf? Does the gatekeeper have a position of authority within the organisation or are potential participants dependent on them in any way?

9. Review Outcomes (REAMS manual p. 66)

- Approve: the application has been successful, and approval granted
- Reject: the application has been refused
- Make Revisions: the application has been reset to draft enabling you to do minor or major corrections