School of Nursing and Midwifery Research Ethics Committee (SNMREC)
Operating Procedures

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1. Introduction

Since May 2018, there have been significant changes in the regulations as to how we collect, store and destroy personal data - General Data Protection Regulations (GDPR) (https://www.tcd.ie/info_compliance/data-protection/gdpr/), for all purposes including research. Particular care must be taken in regard to these aspects and evidenced in the researcher’s application for ethical approval for which you are responsible. Another major change arising from these changes are the penalties and sanctions that will be applied in the event of non-adherence to GDPR. The responsibility lies with the researcher(s) to ensure that regulations are addressed as indicated in this document.

The School of Nursing and Midwifery Research Ethics Committee (SNMREC) is a granting ethics committee for “low risk projects” carried out by the School’s staff and students. Researchers should be aware of TCD’s Policy on Good Research Practice (https://www.tcd.ie/research/dean/assets/pdf/FINAL_Good%20Research%20Practice%20Policy%20COUNCIL%20APPROVEDandminutedgg.pdf)

GRPR training and related documents https://www.tcd.ie/itservices/vle/kb/overview-GDPRtraining.php

It is the responsibility of the researcher to determine which research ethics committee/committees are correct for their proposal, which form to use and whether the application is committee or for Chair approval (Figure 1).

**FIGURE 1:** Association between the common ethics committees that staff and students apply to from the School of Nursing and Midwifery

- **SNMREC School of Nursing and Midwifery Research ethics Committee Chair Approval**
  - Examples of types of projects (list not exhaustive):
    - Audit material of standard practice
    - Quality assurance

- **SNMREC School of Nursing and Midwifery Research ethics Committee Committee Approval**
  - Examples of types of projects (list not exhaustive):
    1. Research involving non-vulnerable adults
    2. Surveys, anonymous or otherwise, of a non-intrusive personal nature
    3. Qualitative/mixed methods studies using interviews/focus groups/other qualitative methods of a non-intrusive personal nature

- **JREC Joint Research Ethics Committee**
  - Projects involving patients and their families attending St James or Tallaght Hospitals

- **Other Ethics Committees**
  - Students applying to other ethics committees must also apply for SNMREC Chair approval

- **FREC Faculty research Ethics Committee**
  - Examples of types of projects (list not exhaustive):
    1. Surveys, anonymous or otherwise, asking questions of a sensitive or private nature
    2. Non-anonymous questionnaires involving children or adults
    3. Observational studies involving children or vulnerable adults

- **Moderate – High Risk**
The primary task of the SNMREC is to protect the welfare and rights of research participants in the first instance. In addition, the committee aims to facilitate and support the progress that the research community seeks to achieve (Irish Council of Bioethics 2004).

**Common terms used in ethics applications and their interpretation for the School of Nursing and Midwifery research ethics committee:**
For the purposes of all guidelines, applications and correspondence, the following interpretations will be used:

- **“Anonymise”** the term anonymise is only used when all links to identifiable data has been erased, the term is usually reserved for post-analysis and publication purposes.

- **“Anonymity”** is only achieved when there is no possible way the data can be linked back to the identity of the participant e.g. anonymous questionnaire.

- **“Anonymous”** data from whom the personal identity of the person who gave the data is unknown and the data cannot be identified or linked to personal information.

- **“Children or minor”** A person who has not attained full age (18 years) or has never been/is married prior to attaining full age , is a minor

- **“Confidentiality”** is where the identity of a participant or site is known and the methods we put in place to protect it from being revealed.

- **“Deception”** means misinforming participants for the purposes of research. The School will not accept the submission of projects for ethical approval that involve a degree of deception.

- **“External Publication”**, from a data protection point of view, this refers to data that is intended for publication outside the institution from which it was originally collected, this includes theses.

- **“Gatekeeper”** from an ethics point of view, the primary role of a gatekeeper is to protect the study population for the most part and to maintain the objectivity of the research.

A study gatekeeper may therefore act as a medium for recruitment of the study population, e.g. distribute questionnaires, send out an e-mail inviting recruitment. This is required by GDPR, it prevents personal contact data from released to a study personnel without the participants’ consent (Figure 2).

Within ethics applications, it is important to state:
- the normal role of the study gatekeeper
- their role within the research
- the relationship of the study/gatekeeper/s to the researcher and the study participants

The study gatekeeper is:
- not involved in the study or the care of the potential participants
- not involved in the direct teaching of the student participants
- not a line manager of the potential participants
If a study is unable to utilise this type of neutral/non-involved study gatekeeper, the researcher must be even more explicit as to who they will use, their current role and relationship to the potential participants, and develop a recruitment methodology to promote voluntary participation, so that potential coercion is prevented and freedom to participate/not participate, or to later withdraw from the study, is not seen as a threat to participants, their care or progress.

**FIGURE 2:** Example gatekeeper role

![Diagram showing gatekeeper role](image)

N.B. While the gatekeeper distributes information about and/or invitations to participate in the study, s/he should not know who has expressed interest in or has agreed to participate.

“**Intrusive**” Studies of any kind asking questions of a sensitive or private nature (e.g. eliciting responses to a questionnaire about bullying, questioning abuse.

"**Participant**" means human participant, interviewee, respondent, subject, client, or informant.

"**Personal information**" means personal information about an individual that could make them identifiable; the most obvious of these are: name, address, age, medical record number, contact details.

"**Research**" means any data-gathering activity involving human participants, conducted by any student or staff member of the school, during his or her study or employment with the University of Dublin Trinity College, including research carried out by students as part of course requirements (e.g. projects or assignments the assessment of which requires the student to undertake a research study) or thesis requirements.

“**Pseudonymisation**” When data collection is not anonymous, personal information such as names used in the analysis and publication etc., are not used and are replaced with pseudo names are a process called - Pseudonymisation. Where pseudonymisation methods are used, it is recommended that extra efforts, beyond use of initials, be incorporated.
“Vulnerable groups” The ethics committee chosen within TCD is dependent on the project participants and the relationship of the participants to the researcher/s. Projects that have participants that fall within the following categories cannot apply to the School of Nursing and Midwifery Ethics Committee and will have to apply to the Faculty Research Ethics Committee. The School of Nursing and Midwifery categorise the following as vulnerable groups.

1. Children
2. Participants who cannot give consent
3. Participants who have a care relationship with the researcher/s
4. Participants who have a working relationship with the participants. Masters students in particular should avoid doing research with their colleagues, the exception to this are anonymous questionnaire type studies of a reasonable size.

1. General introduction to processes

Researchers should review all criteria below and the relevant ethics application forms and websites before selecting the appropriate committee or committee and mode of application (Chair approval application or committee approval application). It is the responsibility of the researcher to determine the appropriate committees to apply for. **Researchers who select the incorrect pathway are at risk of experiencing significant delays in their ethical approval.**

Projects reviewed by the School of Nursing and Midwifery Research Ethics Committee are of a no or low risk status, indicating that little or no risk or discomfort will be encountered by the participant greater than is experienced in normal daily life (detailed descriptions of the criteria that determine a project’s risk status later in documentation (See Page 7).

The School will not usually accept submissions from staff/students from outside the School, e.g. other Schools in the College or other universities (except in the case where no other suitable ethics committee is available, and ethics is required to access staff and students within the school for research).

Currently, most hospitals, services and HSEs have their own ethics application route and, in cases where these do not exist, then students can apply to the relevant TCD ethics committee (Faculty research ethics Committee (FREC) or the School of Nursing and Midwifery Research Ethics Committee (SNMREC)), with consent from the Director of the service.

In the case of hospitals, services and HSEs having their own ethics application the following apply:

- Research of any kind involving patients, their families or their data need to apply to the sites own ethics application route in the first instance.
- In most cases research of any kind involving staff requires ethics through their own ethics application route. Some hospitals e.g. Tallaght and St James Hospital Dublin do not accept applications from projects with staff as participants, therefore these projects will have to go to the relevant ethics committee within TCD (FREC or SNMREC) only.
- **Student and staff** projects that have ethics approval from an external site/s have also to apply to the relevant ethics committee within TCD (FREC or SNMREC). The exception to this is projects that have received ethical approval from JREC in which case this is the only ethics application/approval that is required.
• Staff and student projects with ethics from JREC, FREC or other college ethics must inform the school ethics committee SNM.Ethics.com@tcd.ie of these applications.

• In cases where students/staff have applied to their sites own ethics application route and are conducting research of low risk, within TCD they can then apply to the SNMREC chair approval route. Please note in the case of Chair approval, students must submit the ethics form that they submitted to the hospital and an additional short information form.

2. Research not requiring ethics approval
   • Research on publicly available information, documents or data
   • Projects from external researchers (with ethics approval) utilising our own students or staff (these researchers will request access approval rather than ethics approval from the Director of Research).
   • Quality assurance studies that are in line with GDPR regulation being utilised for the purpose it was collected (e.g. assessment of teaching practice) (NB please check next category also)
   • Audits of standard practice that are in line with GDPR regulation, being utilised for the purpose it was collected and not involving identifiable records) (NB please check next category also)

3. Criteria for submission to the School of Nursing and Midwifery Research Ethics Committee (SNMREC)

3.1 Research requiring SNMREC Chairperson Approval
   • Quality assurance studies (e.g. assessment of teaching practice) (for thesis or external publication)
   • Audit material of standard practice (for external publication non-student projects, see next section also)
     o Material to which the researcher has access due to their position and that will involve data extraction, leading to non-identifiable records i.e. patient notes. These studies will be the only type of research to which retrospective research ethical approval will be given for the data collection.
   • Projects eligible for level 1 ethics from staff or student that have received ethical approval from an approved ethics committee (not JREC or FREC) and therefore need TCD ethics approval
   • Projects that need college ethical approval for additional sites that do not have their own ethics application route
   • Projects for additional site/s for a study that has already been received committee approval (SNMREC) for sites that do not have their own ethics application route

3.2 Research requiring SNMREC committee approval (Level 1 committee)
   • Audit material of standard practice (for postgraduate qualifications) – material to which the researcher has access due to their position and that will involve data extraction, leading to non-identifiable records.
• Surveys of a non-intrusive personal nature of non-vulnerable adults.
• Unrecorded and anonymous observation of non-vulnerable adults in public areas.
• Analysis of irrevocably anonymised and appropriately collected data.
• Interviews (consensual) with non-vulnerable adults.
• Collection of non-invasive biological samples from non-vulnerable adults (e.g. hair, nails, saliva, semen, urine, buccal epithelial cells) for research studies that have no prospect of impacting on the healthcare of the participant (controls in particular). An example of an unacceptable protocol is interrogation of BRCA status or any genetic investigation that might have relevance for future treatment.
• Collection of specific biological samples using minimally invasive techniques (e.g. blood) from non-vulnerable adults. Sample collection must be performed by a suitably qualified and competent person and will typically involve the collection of a single vial of <10ml of blood.
• Action research (research initiated to solve an immediate problem, or a reflective process of progressive problem solving, conducted either by individuals on their own practice or by individuals working with others in teams, or as part of a “community practice”, to improve the way they address issues and solve problems (participatory action research) in settings where the individuals are non-vulnerable adults.
• Observational studies of non-vulnerable adults.
• St James’s and Tallaght University Hospital low risk projects with staff as participants.
• Projects eligible for level 2 ethics from staff or student that have received ethical approval from an approved ethics committee (not JREC or FREC) and therefore need TCD ethics approval

4. Criteria for submission to the Faculty of Health Sciences Research Ethics Committee

Moderate to high risk research – i.e. risk or discomfort is greater than that usually encountered during normal daily life).

Please note: Researchers must not apply for approval to FREC if their project falls under the remit of the SNMREC.

Moderate Risk
• Surveys, anonymous or otherwise, asking questions of an intrusive/ sensitive or private nature (e.g. eliciting responses to a questionnaire about bullying, questioning abuse)
• Anonymous and non-anonymous questionnaires involving children or vulnerable adults
• Observational studies involving children or vulnerable adults
• 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; patient/clinician)
• Projects involving a justifiable degree of deception (Deception means misinforming participants for the purposes of research)
• Analysis of archival irrevocably anonymised human tissue samples for which consent for research was not originally given and was not acquired in the course of clinical treatment. (Archived samples taken for a previous research study must always get new ethical approval)
• St James’s and Tallaght University Hospitals’ moderate risk projects with staff as participants.

High risk
• Research involving invasive procedures (other than those listed above)
• Research involving vulnerable persons (where assent is needed from another party)
• Research where identifiable information obtained may have legal, economic or social consequences for research subjects
• Research that is likely to identify illegal activity on the part of the participant
• Projects where each subject is paid (except for expenses and nominal gratuity)
• Research that may potentially endanger the subjects, and/or researchers, and/or 3rd parties, and/or the environment
• Research involving the collection of human tissue
• Research that may have a direct military role
• Potentially harmful research involving humans conducted outside Ireland
• Research involving psychological intervention
• Research where a potentially beneficial or harmful treatment, information or learning method may be withheld from some participants
• St James’s and Tallaght University Hospitals’ with staff as participants in high risk projects as cited above
• Research not included in this document should be reviewed by an appropriate Level 2 REC

5. General Points regarding an application for ethical approval to the School of Nursing and Midwifery Research Ethics Committee
a. All applicants must be aware of the current College Policy on Good Research Practice (http://www.tcd.ie/about/policies/assets/pdf/TCDGoodResearchPractice.pdf)

b. Midwives and nurses must be aware of the NMBI guidance document for conducting research (https://www.nmbi.ie/Standards-Guidance/More-Standards-Guidance/Ethical-Conduct-In-Research) and the 'The Code of Professional Conduct for each Nurse and Midwifery (An Bord Altranais 2014), which states that in their work, nurses and midwives should conduct themselves in a professional manner;
‘In taking part in research, the principles of confidentiality and the provision of appropriate information, to enable an informed judgement to be made by the patient, must be safeguarded. The nurse or midwife has an obligation to ascertain that the research is sanctioned by the appropriate body and to ensure that the rights of the patient are protected at all times. The nurse or midwife should be aware of ethical policies and procedures in his/her area of practice’.

c. Researchers should be explicit about their role and position in the research (e.g. ‘Second year masters student...’). ‘Doctorate student working ... on project funded by ...’ principal investigator etc.)

d. In the case of student researchers, the supervisor must sign the declaration in Section 7. It is the responsibility of the student researcher to ensure that their application is forwarded in time to their supervisor, giving the supervisor enough time to read and recommend changes before submission. **Supervisors must not sign applications that they have not read in full.** Incomplete, unsigned or late submissions will not be reviewed.

e. Researchers must be explicit as to their role and area in an organisation, hospital and unit that they work in in order to identify any possible relationship between the researcher and the participants.

f. Applicants are responsible for informing the Committee if their project changes significantly during the period for which approval has been given. In such cases, the Committee will determine if a new application for approval is necessary, or if only amendments to the conditions of the approval are required.

g. Researchers should not claim to have competencies that they do not have.

h. Researchers should be aware that they may not use data, access staff or other participants that they have access to routinely in their normal role for research without ethical permission.

i. Account should be taken of the organisation’s (study site/location) own procedures and guidelines for ethical approval of research and, in particular, for working with vulnerable groups. It should be the responsibility of the researcher to ascertain whether or not these exist.

j. It is the responsibility of the researcher to determine if application to this Ethics Committee is appropriate.

k. Submission to the SNMREC does not preclude the requirement for approval from other Ethics Committee

l. Where researchers have doubts about any of the guidelines, they should contact the SNMREC

SNM.Ethics.com@tcd.ie.

m. Participants should be given as much information as possible prior to participation.

n. Researchers must offer transcripts or cumulative findings to all participants.

o. In the case of research in the community, hospitals, care centres, and other similar contexts, researchers not employed within the study location/site/organisation should be aware that participants may think they are staff or other similar people with authority. Researchers should take reasonable steps to assure participants that this is not the case.

p. There is a relationship and some dependency between ethics approval and access. Ethics approval does not confer access to research sites. Access to research sites may sometimes be dependent on obtaining ethics permission. Ethics approval is contingent on access being granted.

q. Minor changes required to the research project must be sent to the SNMREC for approval before these changes are instigated.

r. The project start date should not predate the timeframe spanning the approval process. This would normally imply a start date no earlier than 14 days following the relevant SNMREC meeting but
usually a month is advisable. Where amendments are required, the start date should be changed to no earlier than 10 days following submission of amendments. Projects may not extend beyond their nominated end date without SNMREC approval and researchers need to submit to the Chair of the SNMREC for this to be amended on their original submission.

s. When completing an SNMREC application form, it is best to avoid using the passive voice, e.g. an email will be sent to potential participants. It is better to be specific and state who will email the potential participants.

6. General principles in considering applications for ethical approval

A. The following principles will guide the SNMREC in considering applications for ethical approval. There must be:
   a. informed consent free of coercion
   b. respect for rights of privacy and confidentiality
   c. minimization of risk of harm to the participant
   d. social and cultural sensitivity
   e. research and/or learning merit
   f. avoidance of conflict of interest
   g. respect for property rights

B. Scientific merit

Hospitals, care centres, etc. receive very many requests from students and other researchers who wish to carry out research. It is important that researchers consider whether the potential scientific outcome of the research justifies approaching the organisation and participants. Researchers should consider whether there are any realistic potential outcomes for the organisation, what use the research will be put to, and who will benefit from it. These concerns particularly apply to student projects.

C. Consent and withdrawal

1. Informed consent:
   a. Written informed consent should be obtained from all participants in all cases, with the exception of anonymous questionnaires. In the case of anonymous questionnaires return of the questionnaires is taken as consent and insertion of a line at the beginning of the questionnaire informing the participant of the above is good practice.
   b. Must be obtained prior to participant participation.
   c. In the first instance must be in writing and signed.
   d. Must include a line that indicates that the participant has had the study explained to them and that they understand what they are committing to.
   e. Forms must be signed by the participant and the researcher

2. In research that involves several points of data collection additional ongoing consent is the preferred ethical option.

3. Consent forms should clearly indicate:
   a. All procedures that the participant is committing.
   b. If the study intends to access other data regarding the participant i.e. exam results or clinical records.
c. If quotations, pictures, drawings or any other recordings in any media taken during the data collection process will be used in publication.

4. Participants have the right to withdraw
   a. Care should be taken to ensure that all participants are aware that they may withdraw from the research at any time or to the point where it is possible in terms of data extraction and analysis. If the latter applies participant information leaflets should include an estimate of the date this is likely to be. At the point of withdrawal, participants can ask that all data pertaining to them can be destroyed.

5. All participants should have the opportunity to ask questions prior to participation and be given a contact address and number of the researcher to facilitate any further queries.

D. Confidentiality
   1. Researchers should note that any data that can be traced back through any means is not anonymous but should be referred to as confidential.
   2. Researchers have to take reasonable steps to preserve the confidentiality of participants, their families, other associated individuals and personal information.
   3. In the case of the identity of the research site, the identity of the site will not be revealed in any publication (including theses) unless prior informed consent is given.

E. Protection from harm
   1. Researchers have a fundamental responsibility to protect participants from physical and mental harm.
   2. Inconvenience and discomfort to participants must be balanced against the benefit to the participant and/or society, and the importance of the knowledge to be gained.
   3. Researchers must use their best endeavours to ensure that they are adequately aware of the participants’ ability to understand the purpose of the research.
   4. Researchers within the field of education have a responsibility not to intervene in the teaching and learning process in a way that has the potential for disadvantaging participants.
   5. Researchers should check whether participants who become distressed during an interview/experiment wish to postpone the interview/experiment or withdraw from the research. If in the course of a procedure a participant is uneasy about undertaking any tasks, etc., (s)he should be reassured, and if (s)he is still uneasy or upset the procedure should be stopped.
   6. Participants must be made aware of how to contact the researcher within a reasonable time period following the procedure should stress, potential harm, or related questions of concern arise.
   7. In the ethics application forms and participation information leaflets appropriate contact numbers for participants to avail of supports must generally be included even in projects when the chances of requiring this support this occurring are low.
   8. Researchers must make clear what steps will be taken in the event of disclosure of unsafe or criminal practice. In the case of anonymous questionnaires, researchers should state what actions will be taken arising from findings in relation to unsafe or criminal practice, such as informing the senior manager of the service.
   9. Researchers must take all necessary steps to ensure that they do nothing to introduce or reinforce any form of social prejudice.
   10. Researchers must be mindful of cultural, religious, linguistic, gender, and other differences within participants in the reporting of their research process.
   11. Participants and other involved parties should have information on how to contact the researcher. They should also be made aware that they are able to do this for a prescribed period after the research has been completed.
F. Storage, security and destruction of data

1. Personal information should be handled in a way that protects the confidentiality of the participant and ensures the safe custody of data in line with GDPR.

2. Researchers, supervisors and instructors must ensure that personal information is protected by reasonable security safeguards against loss, unauthorised access, use, modification or disclosure and other misuse. Where a project involves the collection of personal information, the researcher should set out clearly who is entitled to have access to that information and under what conditions, and whether personal information will be used in the writing up or other means of completion of the project.

3. Confidential research information that includes personal data needs to be kept and stored in line with the GDPR, see these acts, the Good Research Practice Guidelines and course lecture material if appropriate for further detail.
   a. Confidential data in paper format or other hard copy formats needs to be kept in a locked cupboard.
   b. Electronic confidential data including codes need to be stored on password protected computer, USB keys or other storage media.
   c. Secure approved cloud storage is the only form of cloud storage that should be utilised. i.e. free data storage is not secure enough for personal data.
   d. Codes relating anonymised data to confidential data should not be stored in the same place as the anonymised data.

4. Research information collected for one purpose shall not be used, without the written consent of any person who is the subject of that information, for another purpose unless it is in the public arena or is available in a non-identifying manner.

5. The written consent form presented to the participant should clearly indicate what will happen to collected data when the research has been completed.

6. Personal information should not be kept for longer than is necessary to complete the particular project. Personal data must be kept for 5 years after the completion date of the project subsequent to this date only anonymised data can be retained.

7. Please be aware that under the new GDPR regulations you may be requested to submit annual, end of project, data storage and destruction reports.

7. Application procedures for Chair approval

1. Applications and queries may then send to SNM.Ethics.com@tcd.ie.

2. Applicants submitting an ethics approval form used by another organisation must also complete the short additional chair information form that includes the cover and signature sheets of the standard SNMREC application form and submit the data collections tools, questionnaire, interview schedule etc. These documents should be collated into a single file. Failure to do so will result in return of the documentation to the applicant and may result in delay in reviewing.

3. Application forms will be reviewed from the start of Michaelmas term each year until the end of the academic year.

4. Application forms will be reviewed by the Chair of the committee and a response will be sent usually within 10 working days of receipt.

5. The applicants will receive their feedback in one of the following formats.
   i. Approved
   ii. Amendments to be made
iii. Submission not reviewed due to: not eligible for submission to this committee or in this format.

8. Application procedures for committee approval

The procedure for submission to the SNMREC committee approval is as follows:

1. Submission

Applicants are required to complete the application form and develop the consent form, participant information leaflet, questionnaires, interview schedule etc. All of these documents are to be compiled into a single document for electronic submission to snm.ethics.com@tcd.ie by 5.00pm on the published deadline dates.

Applicants are also required to submit one signed paper copy of the entire application (application form, consent form, participant information leaflet, questionnaires etc.) by 5.00pm on the published deadline marked for the attention of:

- The Ethics Committee
- School of Nursing and Midwifery
- Trinity College Dublin
- 24 D’Olier St
- Dublin 2

2. Review

a. Application forms will be reviewed by the Chair and two other members of the committee.

b. Within 10 working days of the date of the meeting the applicants will receive their feedback in one of the following formats.
   i. Approved
   ii. Amendments required
   iii. Resubmission required
   iv. Submission not reviewed due to late/ incomplete/ incorrect form/ not eligible for submission to this committee.

3. Queries for both chair and committee applications

All queries with regard to any aspect of a submission or amendments/ feedback should be sent to snm.ethics.com@tcd.ie. There is no facility for queries in person or by phone. Queries will be responded to within 10 days during term time.

In the unlikely event of the applicant not agreeing with the outcome of the process their submission will be forwarded to the FREC to undergo review within their processes and timeframes.

4. Submission of amendments for both chair and committee applications

a. Amendments will be reviewed within 10 working days of receipt during term time

b. Required amendments to the application form must be in red to facilitate review, do not use track changes or the form will be returned to you. All files must be collated into a single file again including those that there were no amendments required, failure to do any of the above so will
result in return of the documentation to the applicant and may result in delay in reviewing. If subsequent amendments are requirement a different colour is then required for each round of amendments.

c. Once all amendments have been approved by the Chair, a formal letter confirming ethical approval of the study will be issued to the student and the supervisor.