## School of Nursing and Midwifery Research Ethics Committee application form

Important questions to answer before filling in this form:

1. Have you checked that you are applying to the correct ethics committee?
2. Have you checked that you need to complete this form in its entirety or just the shortened version which is needed for some Chair approvals?

**PLEASE NOTE THE FOLLOWING;**

* **Incomplete and/or late applications will not be processed and will be returned by post to the applicants.**
* **Forms without the following signatures will not be processed: Applicant(s) signature, Research Supervisor signature (applicable in student application), all researchers named on the form.**
* **Forms without the checklist completed will not be processed. (Please see checklist on next page)**

|  |  |  |
| --- | --- | --- |
| **Applicant NAME:** | |  |
| **Applicant email address:**  **Please ensure this is correct. The decision will be sent to this email address** | |  |
| **Supervisor NAME:** | |  |
| **Supervisor email address:**  **Please ensure this is correct. The decision will be sent to this email address** | |  |
| **Staff MEMBER** | | YES / NO ID NUMBER |
| **STUDENT MEMBER** | | YES / NO ID Number |
| **Working title of proposed study:**  **Please ensure to use the same working title of your study throughout the document and appendices** | | |
| **TO BE REVIEWED AT WHICH ETHICS COMMITTEE MEETING? please provide month of meeting.** |  | |
| **PLEASE IDENTIFY WHICH OF THE FOLLOWING APPLIES:** | AN ELEMENT OF A TAUGHT POST -GRADUATE COURSE  A FULL TIME POST-GRADUATE RESEARCH PROJECT  STAFF RESEARCH PROJECTS | |

**MAKE SURE YOU FILL IN ALL THESE sections**

**do not skip any questions in the form School of Nursing and midwifery research ethics committee**

**application FORM**

RESEARCH APPLICATION INDEX

**Section 1: Applicants Details**

**Section 2: Details of Research Study and Participant Selection**

**Section 3: Consent and Confidentiality (incl. Data protection)**

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**Section 5: Funding and Payment**

**Section 6: Ethical Approval from Other Committees**

**Section 7: Declaration of Approval and Signatures**

**Please complete the application form and return one signed hard copy to**

**Mrs Caroline Rooney, School of Nursing and Midwifery, Trinity College Dublin, 24 D’Olier St., Dublin 2. When collating please staple documents**

**Please also email your application in full to caroline.rooney@tcd.ie**

**If you have any queries regarding the completion of this application form please email SNMEthics.com@tcd.ie or phone (01) 896 3943**

**To process your application form efficiently you are required to fill in the checklist below. Do not leave any blanks. If this checklist is not completed, your application will not be processed.**

**CHECKLIST BELOW MUST BE COMPLETED:**

|  |  |  |
| --- | --- | --- |
| Please TICK THE APPROPRIATE BOX | **Yes** | **No** |
| Are you undertaking the proposed research study in your capacity as:  (a) a student of the School of Nursing and Midwifery? Or |  |  |
| (b) a staff member of the School of Nursing and Midwifery |  |  |
| 1. Does the proposed research involve current students and / or staff of the School of Nursing and Midwifery as research participants? |  |  |
| 1. If you are a student, has your supervisor endorsed the completed form? |  |  |
| 1. Have you checked the criteria to ensure that this application is suitable for this committee ( please not applicants who have forwarded submissions that are not covered by this ethics committee are at risk of serious delays ) |  |  |
| **IF APPROPRIATE TO THE STUDY YOU SHOULD ATTACH THE FOLLOWING:** |  |  |
| * 1. the consent form you propose using   2. the letter(s) and/ or participant information leaflet you propose to prospective participants seeking their co-operation with the study   3. for the purpose of your proposed study, if you require access to: a site outside your home department/School, and/or   (ii) the person who is responsible for the welfare of your proposed participants please attach the letter seeking access, please attach the proposed access letter   * 1. If relevant to this study please attach a copy of the   tool(s) of data collection you propose using (Questionnaire / interview schedule / observation schedule/other). |  | |

**TRINITY COLLEGE**

**School of Nursing and Midwifery Research Ethics Committee**

**CONFIDENTIAL**

*Please complete all information relevant to your application*

SECTION 1 – APPLICANTS’ DETAILS

**1.1 Name, qualification and position of each person associated with this research project.**

*List details of all personnel involved with the research (excluding participants)*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Investigator**  **Title / First name / Surname** | **Title of Study** | **Postal Address *(approval will be posted to this address)*** | **Email address** | **Tel No**  **Work / Home** | **Role in research** | **Primary Employer (Hospital / University / Other)** | **Current Occupation** |
|  |  |  |  |  |  | **Be explicit here as to the unit you work in and your job. The reviewers will be looking for evidence that you are not working or caring for your potential participants** | |
| **Supervisor (if investigator is a student)** |  | **Postal Address *(Please note that approval will be posted to this address)*** | **Email address** | **Tel No**  **Work / Home** | **Role in research** | **Primary Employer (Hospital / University / Other)** | **Current Occupation** |
|  |  |  |  |  |  |  |  |

SECTION 2 – DETAILS OF RESEARCH STUDY & PARTICIPANT SELECTION

**At this point if you have not done so already scan the document in its entirety to assess what information is required in each of the sections and jot done some notes.**

2.1 Working title of proposed study

|  |
| --- |
| As mentioned earlier keep consistent throughout |

**2.2 Dates & Duration of Study**

|  |  |  |  |
| --- | --- | --- | --- |
| Proposed Start Date: | Do not be over ambitious. At the very best put in a date that is 14 days after the ethics meeting and under no circumstances arrange interviews etc. until final ethical approval is received | Proposed End Date: | Give yourself a bit of extra time here in case something delays you , put in at the earliest the date of submission of your masters rather than the date you expect to stop collecting data |

* 1. **What are the primary location(s) for data collection? (e.g. classroom, participant’s home,**

**hospital/clinic, laboratory, place of convenience for participant)**

|  |
| --- |
| Again be specific here, location of interviews should protect the identities of the participants, in other words, colleagues should not be able to see participants arriving/leaving interview location. Be specific if you are collecting data from other units that you do not work on.  If you are interviewing alone off site or in a person’s home you must note that you will adhere to the Lone researchers’ policy. <http://www.nursing-midwifery.tcd.ie/research/assets/pdf/Lone-Worker-Guidelines.pdf> |

* 1. **State research aim(s) and objective(s), research question or hypothesis (as appropriate)**

|  |
| --- |
| Your aims and objectives should be achievable and reflected in your research design.  If you have a study that has several phases, and particularly if phase 1, for example, will inform phase 2, you are advised to submit a separate application for the two different phases. |

* 1. **Provide brief outline of the project** (**maximum 400 words**, must include background, research approach, design, data collection methods, sampling, indicate the method of sampling you intend to use and the sample size

|  |
| --- |
| This is the section where many errors ambiguities and omissions occur. Ensure you address each of the elements outlined in the instructions above.  **Do not include appendices such as your academic research proposal.**  **Background:** Provide brief but sufficient background to justify the proposed study. There is no need to include references.  **Research approach**: outline your research approach and design.  **Data collection methods**: Clearly specify how you are intending to collect the data e.g. questionnaire, interview, case notes etc. Access and recruitment is addressed in 2.6.  **Sampling** Outline the method of sampling you intend to use (random, purposive, convenience) and justify its choice.  **Sample size:** Many applicants do not give attention to the size of the population from which you draw your sample. The study is unlikely to achieve its objectives if the sampling is unrealistic, i.e. looking to recruit 6 out of a population of 7 and would therefore be considered unethical. |

* 1. If appropriate please identify how participants will be recruited and what steps you will take to access the sample, specifying details of people who will be contacted during this process:

|  |
| --- |
| **This is the section where most researchers have difficulty in terms of gaining ethical approval. Many applications have major errors, inconsistencies and often omit to give a detailed description of the process of recruitment.** Compared to the academic research proposal this section needs to be well developed and include considerable detail to meet the required ethical standards.  -Access: How will access to the sample be obtained i.e. who will you have to ask for access to the sample?  It is important to remember that information such as names and addresses, case notes to which you have access to in your current role you cannot be accessed/used in your research without asking specific permission.  Gatekeepers should not have a care responsibility for the participant  Gatekeepers should not have a power relationship with the potential participants  Gatekeepers are usually selected from the administration staff.  If you cannot get a gatekeeper that meets these criteria you will need to consider an alternative recruitment method such as use of a poster. Only in rare cases ( action research) will you be permitted to deviate from the above recommendations  Name the current role of the gatekeeper e.g. the ward clerk to Primrose ward. Detail what the gatekeeper will do e.g. address and send out information packs to potential participants who meet the inclusion criteria, send e-mail to potential participants who meet the inclusion criteria, send reminder letter etc. You must consider if the gatekeeper will be able to determine who should receive the information packs. If the inclusion criteria are complicated or involve a particular criterion e.g. mini-mental health score then it may be necessary to consider an alternative method of recruitment.  Studies that use posters to recruit do not need gatekeepers.  Consent is not usually addressed in this section.  **Please refer to the Operating Procedures for the Gatekeeper role section.** |

* 1. **List your exclusion/inclusion criteria for participant selection:**

|  |
| --- |
| Inclusion criteria:  Exclusion criteria: |

**SECTION 3 – CONSENT, CONFIDENTIALITY (INCLUDING DATA PROTECTION)**

**3.1** **Will informed consent be obtained from the research participants?**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| YES |  |  | NO |  |  |
|  |  |  |  |  |  |

If yes, please give details of **who** will take consent and **how** it will be done.

(Please attach a copy of letter, consent form (if required) and information leaflet. See guidelines on how to prepare these documents in Appendices and adapt examples accordingly to suit your study and participants)

|  |
| --- |
| Consent is not required for anonymous questionnaires consent is implied by return of the questionnaire  The process for obtaining consent must be outlined. The researcher must obtain consent in person. Consent must be taken before data collection begins e.g. before an interview commences and in person. Written consent is expected, when written consent is not possible i.e. telephone interviews it is recommended that verbal consent is taken and recorded. It is essential when taking verbal consent to address all the elements that are usually in a consent form so it is required that you create an appendix outlining these consent elements in this case. |

* 1. **What is the time interval between giving information and seeking consent?**

*(It is recommended that a period of seven days be provided for reflection. If less than this, please justify).*

|  |
| --- |
| In the case of interview etc. allow 7 days between giving them the participant information leaflet and arranging interviews.  If you are distributing questionnaires (by hand, post, email , online) you must outline here how long the participants have to complete the questionnaire to address this question |

3.3 During and after the study, what steps will you take to protect the confidentiality of:

|  |
| --- |
| Complete each section below separately if they apply and if not put in Not applicable N/A  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.  Confidentiality is about protecting the identity of a participant whose identity is known or the site     1. participant identities? 2. data collected and patient/client records?   (c) hardcopy records?  Do not forget to detail how you are going to manage audio or other recordings  **Please refer to the Operating Procedures, Section 6 (D)** |

* 1. Is there any potential confidentiality issue through identification of the study location?

|  |
| --- |
| It is important that you consider this if you are undertaking a study within a population, setting or service, that is unusual or has unusually small numbers. In these instances it may be easy to identify individuals. |

* 1. If your data is to be held on computer, how will it be protected?

|  |
| --- |
| Password protection is an important aspect to discuss here. Sensitive data should not be kept in publically accessible clouds i.e. dropbox/iCloud  **Please refer to Operating Procedures Section 6 (F)** |

* 1. **What other person(s) other than the researcher/team as listed will have access to the data collected and what steps will be done to protect confidentiality?**

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| --- |
| Do not forget to list the other members of your team, your supervisor and include anyone who will be transcribing data if applicable.  **N.B. If using a professional transcriber, s/he should be asked to sign a confidentiality form.** |

* 1. Accepted best practice recommends secure retention of data for 5 years. Will you be adhering to this guideline

|  |  |  |
| --- | --- | --- |
| **YES** | **NO** | If No, please explain and justify |
|  |  |  |

* 1. **If identifiable data or material will be retained after the study is completed, is it stated on the informed consent form that this will be done and that material will not be used in future unrelated studies without further specific permission being obtained?**

|  |  |  |
| --- | --- | --- |
| **YES** | **NO** | If No, please explain Why |
|  |  |  |

**3.9 If the study involves audio taping interviews, you must allow the participant access to the transcript, if they so wish. This must be included in the Informed Consent Form and Information Leaflet (if these forms are being used). Will the participant be given access to a transcript of the audio tape interview?**

|  |  |  |  |
| --- | --- | --- | --- |
| **YES** | **NO** | **N/A** | ***If No, please explain Why*** |
|  |  |  |  |

###### 4 - RISK, BENEFIT AND HARM

* 1. **Are there ethical issues or problems that may arise with the proposed study, list the potential problems and how they will be addressed?**

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| --- |
| This is not a theoretical section. Be specific in the points you put here.  If there are no foreseen ethical issues say so.  Look at the next subsection to insure you are not duplicating information that should be in the later sections  Examples : participant revealing their identity, discussing health related problems. |

* 1. **What is the potential for an adverse outcome (for example, illness, pain, discomfort, distress, inconvenience) for research participants? NOTE: for the protection of both the investigator and the participant, this list must be comprehensive and must also appear in full in the participant information leaflet.**

|  |
| --- |
| If there are no foreseen adverse outcomes say so. In most instances at this ethics level the most likely adverse effect is inconvenience, try to establish a protocol that will prevent this.  **Please refer to Operating Procedures, Section 6 (E)** |

* 1. If there is potential for an adverse outcome, please indicate what steps you will take in the case of an adverse outcome/results for participants.

\*\* Please note that any substantive adverse events *must*  be reported to The School of Nursing and Midwifery Research Ethics Committee via Caroline Rooney , [caroline.rooney@tcd.ie](mailto:caroline.rooney@tcd.ie) – 01-8963943

|  |
| --- |
| The host organization and/or professional requirements /procedures for addressing an adverse outcome must be addressed where appropriate.  **Please refer to Operating Procedures, Section 6 (E), No. 7** |

* 1. **Will individual or group interviews/questionnaires discuss any topics or issues that might be**

**sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could take place during the study (e.g. during interviews/group discussions, or use of screening tests for drugs)?**

***If Yes, give details of procedures in place to deal with these issues***

|  |
| --- |
| For this section think of the worst-case scenario of your data collection i.e. participants recollecting a bad experience.  Criminal, child protection and bad practice revelations need to be discussed here and in the participant information leaflet. If there is the potential for these to be revealed by this study you must explain what you would do in that situation i.e. stop the interview and who you would report the information to. You need to be specific as to who this information will be reported to i.e. the Gardaí, the Director of Nursing and the participant’s line manager, both here and in the participant information leaflet.  This is the one time when you have to breach confidentiality, so it is best to insert this information into the confidentiality section of the Participant Information leaflet.  **Please refer to Operating Procedures, Section 6 (E)** |

**4.6 What is the potential for benefit for research participants?**

|  |
| --- |
| Only list direct and indirect effects to the participant i.e. more knowledge with regard to their disorder. Do not talk about benefit to other patients or practice in the future. |

* 1. **Are there elements of genetic testing involved in the proposed project? If Yes please explain.**

|  |
| --- |
|  |

#### SECTION 5 - FUNDING & PAYMENT

* 1. **Outline sources of funding for the study if applicable and how you will manage any possible conflict between the funders of the study and the aims and results of the study if applicable?**

|  |
| --- |
|  |

* 1. **Will payment be made to research participants?**

|  |  |  |
| --- | --- | --- |
| **YES** | **NONE OTHER THAN MINIMAL EXPENSES TO COVER TRAVEL COSTS ETC** | **NO** |
|  |  |  |

**5.3** **If you answered YES to question 5.2, please specify for what purpose the payment will be made and the amount per participant.**

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|  |

**SECTION 6 – ETHICAL APPROVAL FROM OTHER COMMITTEES**

Ethical approval from the School of Nursing and Midwifery Committee, if granted, does not supersede any requirements that outside bodies may have that similar applications be made to local ethical approval bodies in advance of the study commencing.

This section needs to be carefully considered as we get several applications a year who apply to the **wrong** ethics committee or use the wrong form or application procedures. If you are a student, discuss in depth with your supervisor.

If you are collecting data from participants who come under the jurisdiction of another ethics

committee such as an HSE or hospital site you must apply to this committee as well as the School of Nursing and Midwifery Ethics committee. Reminder if they use the standard ethics application form you may use that form in your application to the School of nursing and Midwifery by chair approval see procedures for details.

**6.1 Has ethical approval been sought from any other organisation(s) in which the study will take place?**

|  |  |  |
| --- | --- | --- |
| YES |  | (If you answer YES go to question 6.2) |
| NO |  | (If you answer NO go to question 6.3) |
| N/A |  | (If N/A please explain why below) |

* 1. **If you have answered YES to question 6.1, where has approval been sought from and has ethical approval been given?**

|  |  |  |  |
| --- | --- | --- | --- |
|  | | | |
| **YES** | **Awaiting Reply** | **NO** | If No, please explain Why |
|  |  |  |  |

* 1. **If you have answered NO to question 6.1, is it your intention to seek ethical approval from the organisation(s) in which the study will take place?**

|  |  |  |
| --- | --- | --- |
| YES | NO | **If No, please explain Why** |
|  |  |  |

**SECTION 7 - DECLARATION OF APPROVAL AND SIGNATURES**

#### LEAD INVESTIGATOR

**The lead investigator must provide all data below and sign:**

* 1. **If applicable please state briefly what preparatory work you will need to undertake to become competent in your chosen method of data collection (e.g. training in the use of a standardised schedule/test, clinical procedures, or practice in conducting an interview)**

|  |
| --- |
| Needs only a brief outline |

#### LEAD INVESTIGATOR DECLARATION:

**7.2** I confirm that the information provided in this protocol is correct, that I am not aware of any other ethical issue not addressed within this form and that I understand the obligations to and the rights of participants (particularly concerning their safety and welfare, the obligation to provide information sufficient to give informed consent, the obligation to respect confidentiality and all the obligations as set out in the Declaration of Helsinki (appendix attached) governing the conduct of research involving human participants) and/or other relevant guidelines (please refer to your Head of Department/School)

I undertake to provide an annual report within twelve months of the date of approval, yearly thereafter and a final project report within 6 months of the completion of the study to the School of Nursing and Midwifery Research Ethics Committee with details of the number of participants who have been recruited, the number who have completed the study and details of any adverse effects or complaints. The end of project report this must also include where the data is to be stored and who will be responsible for it destruction. Any serious adverse effects will be reported immediately to the School of Nursing and Midwifery Research Ethics committee.

|  |  |  |  |
| --- | --- | --- | --- |
| NAME:(BLOCK CAPITALS) |  | | |
| STAFF / STUDENT I.D. No. |  | | |
| SCHOOL / DEPARTMENT: |  | | |
| COURSE OF STUDY: **(if appropriate)** |  | **YEAR** |  |
| SIGNATURE: |  | **DATE:** |  |

**PLEASE NOTE THAT IF THERE IS MORE THEN ONE APPLICANT, ALL APPLICANTS MUST SIGN THE APPLICATION FORM.**

|  |  |  |  |
| --- | --- | --- | --- |
| NAME:(BLOCK CAPITALS) |  | | |
| STAFF / STUDENT I.D. No. |  | | |
| SCHOOL / DEPARTMENT: |  | | |
| COURSE OF STUDY: **(if appropriate)** |  | **YEAR** |  |
| SIGNATURE: |  | **DATE:** |  |

|  |
| --- |
| 7.3 RESEARCH SUPERVISOR Student applicants are required to have their Research Supervisor complete this section.  **The Supervisor must sign the statement and accept responsibility as per College policy.**  Name of Supervisor:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (BLOCK CAPITALS)  Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  State the educational value of this research:  If you are a student, make sure you get this section completed by your supervisor. It does not have to be long a short outline of the benefit is sufficient  I confirm that I have reviewed this application and I am not aware of any other ethical issue not addressed within this form.  I undertake to insure that the student provides an annual report within twelve months of the date of approval, yearly thereafter and a final project report within 6 months of the completion of the study , to the School of Nursing and Midwifery Research Ethics committee with details of the number of participants who have been recruited, the number who have completed the study and details of any adverse effects, complaints and the date of completion of the project .  Any serious adverse effects must also l be reported immediately to the School of Nursing and Midwifery Research Ethics committee.  The final report must also include details of where the data will be stored and who will be responsible for its destruction.  I accept responsibility for the ethical conduct of this project:  Signature of the Supervisor:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |