## School of Nursing and Midwifery Research Ethics Committee Application Form

**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).**

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| --- | --- | --- | --- |
| **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 |
| **Student member** | | | YES / NO |
| **Working title of proposed study:** | | | |
| **To be reviewed at which ethics committee meeting?** | | Please provide month of meeting (if applicable) | |
| **Please identify which of the following applies:** | An element of a taught postgraduate course  A full time postgraduate research project  Staff research project | | |
| **Type of application** | Committee application  Chair application utilising SNMREC form  Chair application utilising other standard application form | | |
| **Check list** | Proposal participants are not “ vulnerable” as outlined  in the operating instructions  Data collection does not involve asking questions of a “sensitive or personal nature” as outlined in the operating procedures  Application form signed by applicant  Application form signed by supervisor ( if applicable )  All documents merged into one document | | |

RESEARCH APPLICATION INDEX

**Section 1: Applicants Details**

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**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**

**School of Nursing and Midwifery Research Ethics Committee, School of Nursing and Midwifery, Trinity College Dublin, 24 D’Olier St., Dublin 2.**

**Please also email your application in full to** [**snm.ethics.com@tcd.ie**](mailto:snm.ethics.com@tcd.ie)

**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:**

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| 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 note applicants who have forwarded submissions that are not eligible for review by this ethics committee are at risk of significant 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** |
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| **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** |
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SECTION 2 – DETAILS OF RESEARCH STUDY & PARTICIPANT SELECTION

2.1 Working title of proposed study

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**2.2 Dates & Duration of Study**

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| --- | --- | --- | --- |
| Proposed Start Date: |  | Proposed End Date: |  |

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

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

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

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* 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

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* 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:

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

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

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

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

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

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* 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).*

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

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| 1. participant identities? 2. data collected and patient/client records?   (c) hardcopy records? |

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

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

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* 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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* 1. Accepted best practice recommends secure retention of data for 5 years. If there is any reason to apply for variation from these guidelines, please give details and justify.

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* 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?**

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

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| --- | --- | --- | --- |
| **YES** | **NO** | **N/A** | **If No, please explain Why** |
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###### 4 - RISK, BENEFIT AND HARM

* 1. **Are there ethical issues or problems which may arise with the proposed study, and what steps will be taken to address these?**

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* 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.**

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* 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: snm.ethics.com@tcd.ie

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* 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***

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

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

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#### 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?**

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

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

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

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| --- | --- | --- |
| 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?**

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

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#### 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. In the case of the end of project report the report 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.

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| --- | --- | --- | --- |
| 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.**

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

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

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| 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:**  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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Office Use Only:**

|  |  |
| --- | --- |
| Reference Number |  |
| ***School of Nursing and Midwifery Ethics Committee Meeting Date*** |  |
| ***Approved*** |  |
| ***Date*** |  |
| ***Amendments*** |  |
| ***Date amendments submitted*** |  |
| ***To be resubmitted*** |  |
| ***Date of resubmission*** |  |
| ***Mid-term progress report due date*** |  |
| ***End of project report due date*** |  |
| ***Project adverse events and complaints*** |  |