

**FACULTY OF HEALTH SCIENCES**

RESEARCH ETHICS COMMITTEE

**ETHICAL REVIEW FORM**

(REC 4.0)

|  |  |  |  |
| --- | --- | --- | --- |
| Student Name |  | Student Number |  |
| Supervisor Name |  | Co-Supervisor Name |  |
| Department |  | | |
| Research Title |  | | |
| Date Submitted |  | Version |  |

**Notes:**

* If the research under ethical review is a clinical trial, please complete this review form and the addendum for clinical trials (REC 4a.0).
* Add comments to the far right column for **No** responses to add further detail, if necessary.
* Add mandatory changes at the end of the form only if these are not covered by **No** responses to any of the items below.

|  | Criteria | | Yes | No | N/A | Comments |
| --- | --- | --- | --- | --- | --- | --- |
| **1. Research Proposal: Design, Methodology & Research Procedures** | | | | | | |
| 1.1 | The research procedure risks to the participants are minimised by using procedures that are consistent with sound research design. | |  |  |  |  |
| 1.2 | The chosen research design and method is likely to produce a meaningful result and thus justify the time, effort and possible risks that participants will be exposed to. | |  |  |  |  |
| 1.3 | If the research is quantitative and tests a hypothesis, the sample size is large enough to produce a meaningful result and avoid a Type II error and thus justify the time, effort and possible risks that participants will be exposed to. | |  |  |  |  |
| If any response to 1.1 - 1.3 is **No**, then the final decision may not be 01. | | | | | | |
| **2. Research Proposal: Participant Selection & Sampling** | | | | | | |
| 2.1 | The selection of participants is equitable, i.e. based on fair and justifiable inclusion and exclusion criteria that do not expose the participants to unfair discrimination and/or stigmatisation. | |  |  |  |  |
| 2.2 | The sampling strategy and/or procedure ensures that potential participants can freely (i.e. without coercion) exercise their autonomy. | |  |  |  |  |
| 2.3 | The selection of participants based on age, gender, minority status, pregnancy status or other criteria is scientifically justifiable. | |  |  |  |  |
| If any response to 2.1 - 2.3 is **No**, then the final decision may not be 01. | | | | | | |
| **3. Research Proposal: Vulnerable Groups** | | | | | | |
| 3.1 | Are some or all participants (e.g., children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged or students) vulnerable to coercion or undue influence during the sampling or data collection phases? | |  |  |  |  |
| 3.2 | If **Yes**, there are additional and sufficient safeguards described in the proposal to protect the rights and welfare of these participants. | |  |  |  |  |
| If the response to 3.2 is **No**, then the final decision may not be 01. | | | | | | |
| **4. Research Proposal: Informed Consent** | | | | | | |
| 4.1 | Informed consent is sought from each prospective participant or the participant’s legally authorised representative where applicable. | |  |  |  |  |
| 4.2 | Steps are taken to ensure that informed consent is voluntary, particularly if the answer to 4.1 was **Yes**. | |  |  |  |  |
| 4.3 | The method of obtaining informed consent prospectively from participants is explained. | |  |  |  |  |
| 4.4 | Is the research anonymous? | |  |  |  |  |
| 4.5 | If **No**, it is clearly explained that participants may withdraw their consent at any time without any consequences. | |  |  |  |  |
| 4.6 | If **No**, measures to be taken with regard to confidentiality are adequate and clearly explained. | |  |  |  |  |
| 4.7 | If **Yes**, it is clearly explained that participants may withdraw their consent prior to submission of data, however beyond this point withdrawal of consent is not possible due to the anonymous nature of the research. | |  |  |  |  |
| 4.8 | Are any participants younger than **18 years of age**? | |  |  |  |  |
| 4.9 | If **Yes**, there is a clear, detailed and logical explanation justifying the participation of minors in the research (i.e. defending the position that minor participation in indispensable). | |  |  |  |  |
| 4.10 | If **Yes**, and if participants may reasonably be expected to be of sufficient age and maturity to understand this, assent will be obtained for each minor participant. | |  |  |  |  |
| 4.11 | If **Yes**, and if the research is non-therapeutic in nature, **Form A** (REC 5.0) applying for delegated Ministerial consent from the REC is attached and adequately completed. | |  |  |  |  |
| If any response to 4.1 - 4.3, 4.5 - 4.7 and 4.9 - 4.11 is **No**, then the final decision may not be 01. | | | | | | |
| **5. Research Proposal: Risks & Benefits** | | | | | | |
| 5.1 | The risks and benefits of the research are clearly explained (in the research proposal) and are balanced in an acceptable ratio so as to maximise benefit (if applicable) and avoid harm. | |  |  |  |  |
| If the response to 5.1 is **No**, then the final decision may not be 01. | | | | | | |
| **6. Research Proposal: Privacy, Confidentiality & Anonymity** | | | | | | |
| 6.1 | There is a clear distinction between confidentiality and anonymity and it is clear which applies. | |  |  |  |  |
| 6.2 | Steps to uphold prospective participant’s right to privacy are clearly explained and are appropriate. | |  |  |  |  |
| 6.3 | Circumstances under with confidentiality may be breached are clearly explained. | |  |  |  |  |
| If any response to 6.1 – 6.3 is **No**, then the final decision may not be 01. | | | | | | |
| **7. Research Proposal: Permissions** | | | | | | |
| 7.1 | All required permissions are identified, including any institutional permissions, and draft letters requesting these permissions are attached as annexures. | |  |  |  |  |
| 7.2 | If applicable, in principle letters of permission are attached. | |  |  |  |  |
| If any response to 7.1 – 7.2 is **No,** then the final decision may not be 01. | | | | | | |
| **8. Research Proposal: Biohazards** | | | | | | |
| 8.1 | | Are there possible biohazards associated with the proposed research? |  |  |  |  |
| 8.2 | | If **Yes**, safety precautions are explained and adequate for the risk level. |  |  |  |  |
| 8.3 | | If **Yes**, any required certificates or other biohazard safety documents are attached. |  |  |  |  |
| If any response to 8.2 - 8.3 is **No,** then the final decision may not be 01. | | | | | | |
| **9. Information Letter: Informed Consent** | | | | | | |
| 9.1 | In the **Information Letter**, the purpose of the research is clear and communicated in understandable language. | |  |  |  |  |
| 9.2 | In the **Information Letter**, the expected duration of the prospective participant’s participation in the study is clearly described. | |  |  |  |  |
| 9.3 | In the **Information Letter**, the research procedures (i.e. what the prospective participants will be expected to do if the they participate) are explained adequately yet in simple and understandable language written at a reasonable level (Grade 8 level) and without use of technical terms and jargon. | |  |  |  |  |
| 9.4 | In the **Information Letter**, the risks and benefits of the research are clearly explained in simple and understandable language. | |  |  |  |  |
| 9.5 | In the **Information Letter**, is the research anonymous? | |  |  |  |  |
| 9.6 | If **No**, it is clearly explained that participants may withdraw their consent at any time without any consequences. | |  |  |  |  |
| 9.7 | If **No**, measures to be taken with regard to confidentiality are adequate and clearly explained. | |  |  |  |  |
| 9.8 | If **Yes**, it is clearly explained that participants may withdraw their consent prior to submission of data, however beyond this point withdrawal of consent is not possible due to the anonymous nature of the research. | |  |  |  |  |
| 9.9 | In the **Information Letter**, there is information about the availability of medical or psychological treatment or compensation if injuries occur in the case of research involving more than minimal risk [*if applicable*]. | |  |  |  |  |
| 9.10 | In the **Information Letter**, there is contact information of the researcher/s, supervisor/s and Research Ethics Committee Chairperson (or Vice-Chairperson) should questions or concerns arise about the research and the research participant’s rights. | |  |  |  |  |
| If any response to 9.1 - 9.4, 9.6 – 9.10 and 9.12 is **No,** then the final decision may not be 01. | | | | | | |
| **10. Assent Form: If Applicable** | | | | | | |
| 10.1 | The assent form is generally written in a way that is appropriate for the prospective participant age range. | |  |  |  |  |
| 10.2 | The assent form gives a simple and understandable explanation of the purpose of the research and what is expected of the prospective participant if they agree to participate. | |  |  |  |  |
| 10.3 | The assent form gives a simple and understandable explanation of the risks and benefits associated with participation, including possible pain, discomfort or distress. | |  |  |  |  |
| 10.4 | The assent form gives a simple and understandable explanation of measures to be taken in relation to confidentiality and the prospective participant’s right to privacy. | |  |  |  |  |
| 10.5 | The assent form gives a simple and understandable explanation of the prospective participant’s right to withdraw their assent without any consequences. | |  |  |  |  |
| 10.6 | The assent form gives a simple and understandable explanation that the decision to participate is the prospective participant’s decision and is not only dependent on parental consent. | |  |  |  |  |
| 10.7 | The assent form clearly identifies the researcher and supervisor (if applicable) and contains contact details for both, as well as for the Chairperson of the REC. | |  |  |  |  |
| If any response to 10.1 - 10.7 is **No,** then the final decision may not be 01. | | | | | | |
| **11. Material Transfer Agreement (MTA): If Applicable** | | | | | | |
| 11.1 | The MTA is completed correctly, and signed by both the provider and recipient. | |  |  |  |  |
| If the response to 11.1 is **No,** then the final decision may not be 01. | | | | | | |

**11. Other Comments:**

Click here to enter any other comments not covered in the list above. Push the [Enter] key at the end of each comment to create a numbered list.

**12. Decision:**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 01 |  | 02a |  | 02b |  | 03 |  | 04 |  |

**13. List of Mandatory Changes:**

Click here to enter any mandatory changes that are not covered in the list above. Push the [Enter] key at the end of each change to create a numbered list.

*Please sign on next page…*

|  |  |  |  |
| --- | --- | --- | --- |
| Reviewer Name |  | Reviewer Signature |  |
| Date (dd/mm/yy) |  |  |  |

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| --- |
| **FOR STUDENTS, SUPERVISORS & RESEARCHERS**  Research proposal revisions should address (i) the items above marked as **No** (with the exception of branching questions – marked in yellow) and (ii) **mandatory changes**. Use forms REC 7.0 (for 02a decisions) or REC 6.0 (for 02b or 03 decisions) when submitting your revised research proposals. |