

**FACULTY OF HEALTH SCIENCES**

RESEARCH ETHICS COMMITTEE

**RESEARCH PROPOSAL COVER SUMMARY**

(REC 2.0)

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

|  | Criteria | Yes | No |
| --- | --- | --- | --- |
| **Section 1: Specific Risk Factors & Type of Research** | | | |
| 1.1 | Will this research include any of the following?:   * Adults who cannot give informed consent due to the influence of alterations in consciousness brought about by their condition. * Adults with factual incapacity to give informed consent. * Prisoners. * Deception, concealment or covert data collection. |  |  |
| 1.2 | Is this research a clinical trial?[[1]](#footnote-1) |  |  |
| 1.3 | Is this research a clinical observational study?[[2]](#footnote-2) |  |  |
| If you answered **Yes** to any of the questions above in **Section 1**, you do not need to proceed any further with this form. | | | |
|  | | | |
| **Section 2: Survey/Interview** *This research involves a survey or interview (yes or no)* → | |  |  |
| 2.1 | If yes, will this research include participants younger than 18 years of age? |  |  |
| 2.2 | If yes, will any of the participants be in a dependent relationship with any of the researchers or a supervisor?[[3]](#footnote-3) |  |  |
| 2.3 | If yes, will any sensitive questions be asked in the survey or during interviews?[[4]](#footnote-4) |  |  |
|  |  | | |
| **Section 3: Retrospective Research Designs** *This research is a retrospective design (yes or no)* → | |  |  |
| 3.1 | If yes, has the proposed data source been ethically cleared, or is it clear that the data in the data source is intended for research purposes? |  |  |
| 3.2 | If yes, will the data from the data source that will be used for the research be de-identified? |  |  |
| 3.3 | If yes, has consent been prospectively obtained to utilise the data in the data source for research purposes? |  |  |
|  |  | | |
| **Section 4: Laboratory Research** *This research involves laboratory work (yes or no)* → | |  |  |
| 4.1 | If yes, will biobanked tissue be used in the research? |  |  |
| 4.2 | If yes, will tissue be collected from participants in this research? |  |  |

I/we, the researcher/supervisor and student (if applicable) declare that the answers provided by me/us above are a true reflection of the proposed research, as set out in the research proposal.

|  |  |  |  |
| --- | --- | --- | --- |
| Supervisor/Researcher Signature |  | Student Signature |  |
| Date |  | Date |  |

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|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **OFFICE USE ONLY**  Risk Level:   |  |  |  |  | | --- | --- | --- | --- | | Low Risk |  | > Low Risk |  | |

1. *Clinical Trial* means any research that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. [↑](#footnote-ref-1)
2. *Clinical Observational Study* means any non-experimental clinical research where there is no manipulation of variables by the researcher and excludes retrospective research designs. [↑](#footnote-ref-2)
3. *Dependent Relationship* means a relationship characterised by a power or influence differential in a hierarchically structured group, where an individual (in this context the research participant) is in a subordinate position to another individual (in this context the researcher). [↑](#footnote-ref-3)
4. *Sensitive Questions* means questions, asked either verbally in an interview or as part of a questionnaire, that enquire about a participant’s racial or ethnic origin, political opinions, physical or mental health condition, sexual life or practices, religious beliefs, criminal activity or law-breaking behaviour. [↑](#footnote-ref-4)