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**FACULTY OF HEALTH SCIENCES**
RESEARCH ETHICS COMMITTEE

# RESEARCH ETHICS APPLICATION
(REC 2.1)

*Boxed words/abbreviations are defined at the end of the document. * indicates required fields (other fields may also be required depending on responses).*

| **Section 1: Application Details** | | |
|---|---|---|
| 1.1 | Research Title * | |
| 1.2 | Application Date (ddmmyyyy) * | |
| 1.3 | Research/Application Type * | Qualification ○ Non-qualification ○ External ○ |
| ↳ | If the answer to 1.3 is [Qualification] please complete sections 1.4 - 1.10. | |
| ↳ | If the answer to 1.3 is [Non-qualification] please complete sections 1.5, 1.11 - 1.14 and 1.16. | |
| ↳ | If the answer to 1.3 is [External] please complete sections 1.11 - 1.12, 1.14 and 1.15. | |
| 1.4 | Qualification Category | Undergraduate/Honours ○ Masters ○ Doctoral ○ |
| 1.5 | Department | Choose |
| 1.6 | Student First Name<br>List all names for group projects | |
| 1.7 | Student Last Name<br>List all names for group projects | |
| 1.8 | Student Number<br>List all numbers for group projects | |
| 1.9 | Supervisor<br>Title, Initials & Last Name | |
| 1.10 | Co-supervisor(s)<br>Title, Initials & Last Name | |
| 1.11 | PI First Name | |
| 1.12 | PI Last Name | |
| 1.13 | Supervisor (if PDRF)<br>Title, Initials & Last Name | |
| 1.14 | Other Researchers<br>Title, Initials & Last Name | |
| 1.15 | Affiliation | |
| 1.16 | PI Staff Number | |

| **Section 2: Research** | | |
|---|---|---|
| ⚠ | If the research is qualitative, please go to 2.4. If the research is mixed methods, please select applicable options in 2.1 and 2.4. | |
| 2.1 | Research design [quantitative] | Survey ☐ Record Review ☐ Analytical ☐ Quasi-experimental ☐<br>Experimental ☐ Laboratory ☐ Clinical Trial ☐ Other ☐ |
| ↳ | If the answer to 2.1 is [Other], please provide details below. | |
| | | |
| ↳ | If the answer to 2.1 is [Clinical Trial], please complete sections 2.2 - 2.3. | |

| | | |
|---|---|---|
| 2.2 | Is the intervention registerable with the South African Health Product Registration Authority? | Yes ◯ No ◯ |
| ↳ | If the answer to 2.2 is [Yes], please provide the SAHPRA registration number below. | |
| | | |
| 2.3 | Is the trial registered with the South African Clinical Trials Register or the Pan African Clinical Trials Register? | Yes ◯ No ◯ |
| ↳ | If the answer to 2.3 is [Yes], please provide the registration number below. | |
| | | |
| ↳ | If the answer to 2.3 is [No], please attach evidence to the research proposal of an application having been submitted. | |
| 2.4 | Research design [qualitative] | Qualitative Descriptive ☐ Phenomenology ☐ Ethnographic ☐ Case Study ☐ Model ☐ Other ☐ |
| ↳ | If the answer to 2.4 is [Other], please provide details below. | |
| | | |
| 2.5 | Type of data to be collected * | Text/Numerical ☐ Voice Recordings ☐ Instrument Output ☐ Blood/tissue ☐ Images ☐ Video ☐ Other ☐ |
| ↳ | If the answer to 2.5 is [Other], please provide details below. | |
| | | |
| 2.6 | If the research involves a survey or interview(s), will sensitive questions be asked? | Yes ◯ No ◯ |
| ↳ | If the answer to 2.6 is [Yes], please provide of summary of the subjects the questions will cover below. | |
| | | |
| 2.7 | Does the research involve deception, concealment or covert data collection? * | Yes ◯ No ◯ |
| ↳ | If the answer to 2.7. is [Yes], please provide details and a justification below. | |
| | | |
| 2.8 | Please provide a summary of the (i) data collection, (ii) data processing and (iii) data analysis methods below. | |
| | | |

| **Section 3: Research Participants** | | |
|---|---|---|
| 3.1 | Does the research involve prospective recruiting of human participants? * | Yes ◯ No ◯ |
| ↳ | If the answer to 3.1 is [Yes], please complete sections 3.2 – 3.6 below. | |
| 3.2 | Are any research participants adults lacking capacity to give informed consent? | Yes ◯ No ◯ |
| ↳ | If the answer to 3.2 is [Yes], please provide details and justification for their inclusion below. | |
| | | |
| 3.3 | Are any research participants considered to be vulnerable? | Yes ◯ No ◯ |
| ↳ | If the answer to 3.3 is [Yes], please describe the type/source of vulnerability below. | |
| | | |
| ↳ | If the answer to 3.3 is [Yes], please describe steps that will be taken to protect these participants below. | |
| | | |

| | | |
|---|---|---|
| 3.4 | Are any research participants prisoners or in any other form of detention? | Yes ○ No ○ |
| ↳ | If the answer to 3.4 is [Yes], please provide details and justification for their inclusion below. | |
| | | |
| 3.5 | Will any of the research participants be in a dependent relationship with the researcher(s)? | Yes ○ No ○ |
| ↳ | If the answer to 3.5 is [Yes], please provide details below. | |
| | | |
| 3.6 | Are any research participants < 18 years of age? | Yes ○ No ○ |
| ↳ | If the answer to 3.6 is [Yes], please provide details and justification for their inclusion below. | |
| | | |
| ⚠ | *A REC 5.0 form must be completed and attached if the research is non-therapeutic and includes participants < 18 years of age. If appropriate for participant age ranges, please also attach an assent form to the research proposal. | |

| **Section 4: Sampling & Recruiting** | | |
|---|---|---|
| 4.1 | Does the research involve prospective recruiting of human participants? * | Yes ○ No ○ |
| ↳ | If the answer to 4.1 is [Yes], please complete sections 4.2 – 4.10 below. | |
| 4.2 | Please provide the estimated number of participants in the research. | |
| 4.3 | What is the estimated duration of the research (in months)? | |
| 4.4 | Please briefly describe where the research will take place (i.e. where data will be collected) below. | |
| | | |
| 4.5 | Please briefly describe the population that the sample will be drawn from below. | |
| | | |
| 4.6 | Sampling method used in the research | Random ☐ Cluster ☐ Convenience ☐ Purposive ☐ Snowball ☐ Other ☐ |
| ↳ | If the answer to 4.6 is [Other], please provide details below. | |
| | | |
| 4.7 | Please give the sample (i) inclusion and (ii) exclusion criteria below. | |
| | | |
| 4.8 | Is the research quantitative and does it test one or more hypotheses? | Yes ○ No ○ |
| ↳ | If the answer to 4.8 is [Yes], please give the page number in the research proposal where a sample size determination/calculation can be found. | page(s): |
| 4.9 | Please give a brief summary of how participants will be recruited, including how contact will be made with them and by whom. | |
| | | |
| 4.10 | Will participants whose home language is not English be recruited? | Yes ○ No ○ |
| ↳ | If the answer to 4.10 is [Yes], please describe how information about the research will be communicated to these participants in a way that they can understand below. | |
| | | |

| Section 5: Informed Consent | | |
|---|---|---|
| 5.1 | Does the research involve prospective recruiting of human participants? * | Yes ◯ No ◯ |
| ↳ | If the answer to 5.1. is [Yes], please complete sections 5.2 - 5.3 below. | |
| ↳ | If the answer to 5.1 is [No], please go to 5.4. | |
| 5.2 | Please give a detailed description of how the informed consent process will be conducted below (including how, where and by whom prospective participants will be informed of the research, what documentation will be provided as part of this process and how voluntariness of consent will be addressed). | |
| | | |
| 5.3 | Please describe how withdrawal of informed consent will be managed below (differentiate between processes where data are anonymous vs. not anonymous at the point of collection). | |
| | | |
| 5.4 | Does the research involve secondary use of existing data? * | Yes ◯ No ◯ |
| ↳ | If the answer to 5.4. is [Yes], please complete section 5.5 - 5.6 below. | |
| ↳ | If the answer to 5.4 is [No], please go to 5.7. | |
| ⚠ | Please be sure to complete 9.1 further down if the answer to 5.4 was [Yes]. | |
| 5.5 | Please describe the source of data to be used and whether individuals from whom the data was collected have given informed consent for the use of their data for research purposes (please provide details of how and by whom informed consent was obtained if applicable). | |
| | | |
| 5.6 | Is a waiver of the requirement of informed consent for secondary use of data requested? | Yes ◯ No ◯ |
| ⚠ | *A REC 15.0 form must be completed and attached to the research proposal if retrospective access is required to existing data and a waiver of the requirement of informed consent for secondary use is being requested. | |
| 5.7 | Does the research involve use of stored human tissue (including commercial cell lines)? * | Yes ◯ No ◯ |
| ↳ | If the answer to 5.7. is [Yes], please complete section 5.8 below. | |
| 5.8 | Please describe below how informed consent was originally obtained from tissue donors. Attach any relevant documents to the research proposal and refer to these below. | |
| | | |

| Section 6: Biohazards | | |
|---|---|---|
| 6.1 | Are there possible biohazards associated with the research? * | Yes ◯ No ◯ |
| ↳ | If the answer to 6.1. is [Yes], please describe the nature of possible biohazards and safety precautions below. | |
| 6.2 | | |

| Section 7: Data Management | |
|---|---|
| 7.1 | Please describe where and how data (both hard copy and electronic) will be stored, secured and backed up below (please be specific about the level of authentication and use of features such as encryption etc.). * |
| | |

| | | |
|---|---|---|
| 7.2 | Please describe how it is planned that data will be archived and preserved after it has been analysed (refer to the platform that will be used for archiving). * | |
| | | |
| 7.3 | Is there any intention to make any raw research data accessible to others at any point (e.g. as part of the publication process where a supplementary dataset may be made openly accessible or via any other open data sharing platform)? * | Yes ○ No ○ |
| ↳ | If the answer to 7.3 is [Yes], please describe measures to be taken to de-identify the data prior to sharing/open access. | |
| | | |

**Section 8: Privacy and Confidentiality**

| | | |
|---|---|---|
| ⚠ | *A completed Personal Information Impact Assessment (PIIA, REC 20.0) must be attached to every application. | |
| ↳ | If the answer to 2.1 in the PIIA form (REC 20.0) was [No], please complete sections 8.1 - 8.2. Help | |
| 8.1 | Please describe how confidentiality will be addressed for the research data below (even if no personal information is being processed, it is still the case that data must be treated as confidential). | |
| | | |
| 8.2 | Are there any entities with a legitimate reason to access research data (other than the researcher(s) and participant)? Help | Yes ○ No ○ |
| ↳ | If the answer to 8.2 is [Yes], please provide details and justification below. | |
| | | |

**Section 9: External Gatekeeper Permissions**

| | | |
|---|---|---|
| 9.1 | Please list the name(s) of any external (i.e. outside of the University of Johannesburg) gatekeepers whose permission will be necessary for access to participants or data below. | |
| | | |

**Section 10: Faculty Gatekeeper Permission**

| | | |
|---|---|---|
| 10.1 | Will the research require access to Faculty students, staff or resources? * | Yes ○ No ○ |
| ↳ | If the answer to 10.1 is [Yes], please complete sections 10.2 - 10.3. | |
| 10.2 | Please indicate below which apply. | |
| 10.2a | Faculty students (either undergraduate or postgraduate). | Yes ○ No ○ |
| 10.2b | Faculty staff. | Yes ○ No ○ |
| 10.2c | Faculty resources (i.e. equipment or other resources managed by the Faculty). | Yes ○ No ○ |
| 10.2d | One of the Faculty Campus Health Clinics. | Yes ○ No ○ |
| ↳ | If the answer to 10.2a was [Yes], please provide details and justification for wanting to include students in the research as participants below. | |
| | | |

| | | |
|---|---|---|
| 10.3 | Please list the Department(s) (or if not Academic Departments other organisational units) from which access is required below. | |
| | | |
| ⚠ | A letter from the Head of Department (or if not an Academic Department, the operational head) of all items listed in 10.3 confirming that the required access is provisionally approved (pending ethical clearance) must be attached to the research proposal. The letter must contain the title of the research, the researcher's names and must not be dated more than two months before the date of this application. | |

| **Section 11: Benefits & Risks** | | |
|---|---|---|
| 11.1 | Does the research reasonably hold the prospect of any benefits for participants? *<br>Note: Completing a survey questionnaire or participating in an individual or focus group interview does not confer any benefits to participants. | Yes ○ No ○ |
| ↳ | If the answer to 11.1 is [Yes], please describe the benefits below. | |
| | | |
| 11.2 | Does the research reasonably hold the prospect of any other benefits? *<br>Note: A benefit in the ethical sense is not the same as academic merit. | Yes ○ No ○ |
| ↳ | If the answer to 11.2 is [Yes], please describe the benefits below. | |
| | | |
| 11.3 | Please give a summary of risks associated with the research below. * | |
| | | |

| **Section 12: Attachments** |
|---|
| All applications must have a research proposal attached (compiled in accordance with the Faculty of Health Sciences Guidelines for Writing Research Proposals), along with any other required forms as indicated above. |

| **Section 13: Conflicts of Interest** | | |
|---|---|---|
| 13.1 | Do any of the research team (PI, other researchers, student(s), supervisor(s) – whichever is applicable) declare a conflict of interests? * | Yes ○ No ○ |
| ↳ | If the answer to 13.1 is [Yes], please provide details of the conflict of interests and how this conflict could be managed below. | |
| | | |

**Section 13: Declaration & Signatures**

- We confirm that all information selected/entered above is true and correct.
- We understand that this research (i.e. any interactions with prospective participants or participants or data collection of any other description) may not begin until a signed ethical clearance letter is received.
- We confirm understanding of the Faculty of Health Sciences Research Ethics Standard Operating Procedures, including procedures related to renewal of ethical clearance, amendments, deviations and reporting of adverse events. We will conduct the research in line with these procedures.
- We take full responsibility for the conduct of this research (once ethical clearance has been granted) and for protecting the interests, rights and welfare of research participants including the protection of their personal information.

| Validate | Please validate this form by clicking the [Validate] button to the left **before the form is signed (below)**. The results of validation will be displayed below this text box. If errors exist in the form, these will be highlighted in an error message and should be corrected, followed by re-validation (clicking the button again). Only validated forms (where the validation outcome is "Validated") should be signed. **Only signed and validated forms will be accepted when uploaded to the REC SharePoint site (unsigned/unvalidated forms will be returned)**. |
|---|---|

| Risk Category: | Undetermined | Validation Outcome: | Not Yet Validated |
|---|---|---|---|

**NB:** *The risk category assigned above is preliminary. Each application is screened again for risk afer upload to SharePoint.*

| If the research is for a qualification: | |
|---|---|
| Title, Initial and Surname of Student(s) * | Date * |
| | |
| Signature of Student(s) * | |
| | For group research projects please list all student names in the Title, Initial and Signature box. One student in the group must sign on behalf of the group. Help - How to Sign |
| Title, Initial and Surname of Supervisor * | Date * |
| | |
| Signature of Supervisor * | |
| | Help - How to Sign |
| If the research is not for a qualification or is an external application: | |
| Title, Initial and Surname of PI * | Date * |
| | |
| Signature of PI * | |
| | The PI accepts the declaration and signs on behalf of the research team identified in 1.14. Help - How to Sign |

**Definitions:**

1. PI = Principal Investigator.
2. PDRF = Postdoctoral Research Fellow.
3. *Analytical research designs* (sometimes called observational designs) involve inferences about causation without the manipulation of an independent variable and includes research designs such as case-control studies and cohort studies.
4. *Quasi-experimental research designs* involve inferences about causation based on comparative analysis of outcomes between groups where assignment is without any randomisation.
5. *Vulnerable* refers to research participants who are considered to be unable to protect their own interests and are therefore at risk of exploitation. Conventionally, vulnerability is thought of as being operative at the group level (e.g. marginalised groups based on socio-economic status, patients highly dependent on care, those lacking capacity for consent etc.) however it is not necessarily the case that all members of an identity group associated with vulnerability are, in fact, vulnerable.
6. *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. Research that studies some other kind of outcome (e.g. an educational/learning outcome) using a randomised design is not included in the definition of a clinical trial.
7. *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.
8. *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).