

**HREC RESEARCH ETHICS REVIEW REPORT**

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| **Title of the study** |  |
| **Ethics Application nr.** | **NWU-** |
| **Applicant’s Name** |  |
| **Reviewer Code** | **#** |
| **Date of Review** |  |

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| **Element** | | **Yes**  **No**  **NA** | **Comment** |
| 1 | Is the title appropriate to the content of the research? |  |  |
| 2 | Has the research proposal been evaluated by a scientific/research proposal committee? |  |  |
| 3 | Is the study relevant and of value?   * Responsive * Contributes to knowledge * Worth doing |  |  |
| 4 | Does the study show scientific integrity?   * Knowledge of relevant literature * Sound and valid design and methodology * Was open to peer review and scrutiny * The ethical implications of the design and method clearly stated * Rationale of methodology |  |  |
| 5 | Are the aims and/or objectives achievable and will it produce outcomes? |  |  |
| 6 | Is the selection of the study population fair and just?   * Method clear and complete * Fair distribution of burden and likelihood of benefit * No groups are deprived of an opportunity |  |  |
| 7 | Are the inclusion and exclusion criteria clearly stated, appropriate and justified?   * Rationale for the planned number reasonable * Rationale for inclusion and exclusion criteria clear and reasonable * Inclusion of vulnerable participants is justified |  |  |
| 8 | Is the process of recruitment and enrolment clear and in detail?   * Recruitment strategies neutral * Recruitment method (including screening) clear * Roles of gatekeepers and mediators clear * Recruitment materials appropriate (e.g. advertisement) * Done by an independent person * Location, context and timing appropriate and privacy and confidentiality protected * Participants not over researched |  |  |
| 9 | Has a risk-benefit ratio analyses been done?   * Risks identified * Precautions mentioned * Direct and indirect benefit stated * Risk benefit ratio analyses favourable |  |  |
| 10 | Will the participants be appropriately reimbursement?   * Time * Inconvenience * Expenses * No coercion or undue influence |  |  |
| 11 | Is the participant’s privacy and confidentiality protected?   * Personal information and records protected * Identity protected |  |  |
| 12 | Is the process of obtaining informed consent/permission/assent clear?   * Informed and voluntary * Written and verbal * Obtained by an independent person * Confirmed by the researcher * Sufficient time given to consult and make an informed decision before signing * Can withdraw * Without coercion, undue influence or inappropriate incentives * Understandable and valid informed consent form * Need for translation |  |  |
| 13 | Are the researchers professionally competent?   * Academic qualifications suitable * Scientific and technical competence adequate * Proof of research competence (education, knowledge and experience) * Appropriate skills * Mentoring |  |  |
| 14 | Is respect for participants clear throughout?   * Dignity * Voluntary * Safety * Well-being * Interest of the participant |  |  |
| 15 | Are the facilities where the research will be conducted appropriate and suitably resourced? |  |  |
| 16 | Is data-collection well managed?   * What data is being collected? * Why is the data being collected? * What will happen to the data? * How long will data be retained? * Will the data identify the participant? * Will it be shared with others and why? * Will it leave the country? |  |  |
| 17 | Is the process of sample storage clear (if applicable)?   * For how long? * Where will it be stored? * Is there informed consent for the analyses? * Who will manage it? * Will it be shared with others and why? * Will it leave the country? |  |  |
| 18 | Was a statistician included or consulted/proof of expertise? |  |  |
| 19 | Are all the additional legal documents/requirements applicable, included and correctly completed?   * What is the current status thereof? * To what extent has it been operationalized? * International contractual agreements/sub agreements * National contractual agreements/sub agreements * Collaboration agreements (other universities, individuals etc.) * Written permission (National/provincial Departments, hospitals, clinics, universities etc.) * Written goodwill permission (Traditional leaders, managers etc.) * Confidentiality agreements (fieldworkers, mediators, participating clinicians or professionals etc.) * Export/import permits * Sponsorship agreements * Service agreements (with sponsors, other entities etc.) |  |  |
| 20 | Is the researcher and project covered by insurance? |  |  |
| 21 | Is it clear how results will be disseminated?   * How will participants be informed? * Is there a sure dissemination plan? * Will it be done in an ethical manner? |  |  |
| 22 | Is conflict of interest clearly stated and how it will be handled? |  |  |
| 23 | Is the process of data management and storage clear?   * How will electronic data and hard copies be stored? * How will audio and video data be stored? * Who will store the data? * Who will have access? * How will the data be protected? * For how long will data be stored? * How will it finally be disposed of? |  |  |
| 24 | Are there clear monitoring and safety measures in place? |  |  |
| 25 | Is it a realistic time schedule? |  |  |
| 26 | Has a budget been included and has it been stated how it will be covered? |  |  |
| 27 | Specifically for secondary use of data or samples (if applicable):   * Is there a permission letter from the project head stating what can be done? * Is the documentation of the original study included (e.g. proposal, ethics certificate etc.)? * Does the sub-study match the larger study? * Was permission given in the signed informed consent for the planned sub-study? * Is it clear that the initial data set or samples were collected in an ethical manner? * Is it clear how data/sample integrity was ensured through safe storage? * Has a clear methodology been presented on how the data/samples will be used in the present sub-study? |  |  |

**Conditions to approval (if applicable)**

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**Recommendation for status of the application**

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| Approved |  |
| Minor changes required for approval |  |
| Several changes required for approval |  |
| Deferred |  |
| Disapproved |  |

**Recommendation for potential risk level of the application in the case of adult participants**

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| No risk |  |
| Minimal risk |  |
| Medium risk |  |
| High risk |  |

**Recommendation for potential risk level of the application in case of children or incapacitated adults**

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| No risk |  |
| No more that minimal risk of harm |  |
| Greater than minimal risk but provides prospect of direct benefit |  |
| Greater that minimal risk with no prospect of direct benefit |  |

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**Date**