

**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
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| 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
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| 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
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| 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
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| 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
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| 9 | Has a risk-benefit ratio analyses been done? * Risks identified
* Precautions mentioned
* Direct and indirect benefit stated
* Risk benefit ratio analyses favourable
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| 10 | Will the participants be appropriately reimbursement? * Time
* Inconvenience
* Expenses
* No coercion or undue influence
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| 11 | Is the participant’s privacy and confidentiality protected?* Personal information and records protected
* Identity protected
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| 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
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| 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
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| 14 | Is respect for participants clear throughout? * Dignity
* Voluntary
* Safety
* Well-being
* Interest of the participant
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| 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?
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| 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?
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| 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.)
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| 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?
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| 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?
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| 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?
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**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**