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| **NWU-HREC** – North-West University Health Research Ethics Committee *(REC-130913-037)***NWU HEALTH RESEARCH ETHICS COMMITTEE REVIEWER REPORT*****9.1.5.2.1\_NWU-HREC\_RR\_Sept2019, Version: September 2019*** |
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| **SUMMARY OF STUDY** |
| **Title of the study** | Enter the Title here |
| **Ethics Application number** | NWU-?????-??-S? |
| **Project Leader/Principle Investigator/Study Supervisor:** | Enter Initials & Surname here |
| **Student Details:*(Initials & Surname)*** | Enter Initials & Surname here |
| **Reviewer Code** | **#** Enter Reviewer Number here |
| **Date of Review** | Select the date of the review |

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| ***Note:*** *In your review, please refer to the applicable document and page number* |

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| **ELEMENTS OF REVIEW** |

# Has the research proposal been evaluated by a scientific/research proposal committee?

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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# Is the title appropriate to the content of the research?

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| --- | --- | --- |
| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# Is the study relevant and of value?

* Responsive to needs
* Contributes to knowledge
* Worth doing

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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# Does the study show scientific integrity/validity?

* Covers relevant literature
* The aims and/or objectives achievable and will produce outcomes
* Sound and valid design and methodology

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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# 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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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# 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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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# 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)
* Location, context and timing appropriate and privacy and confidentiality protected
* Participants not over researched

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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# Has a risk-benefit ratio analyses been done?

* Risks identified
* Precautionary measures for each risk described
* Direct benefits to participants stated
* Indirect benefits to scientific community & community at large stated
* Risk benefit ratio analyses favourable

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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# Will the participants be appropriately reimbursement?

Taking into consideration:

* Time
* Inconvenience
* Expenses
* Without coercion, undue influence or inappropriate incentives

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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# Is the participant’s privacy protected doing data-gathering?

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| --- | --- | --- |
| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# Is the participant’s confidentiality protected after data-gathering?

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| --- | --- | --- |
| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# Is the process of obtaining informed consent/permission/assent clear?

* Informed and voluntary
* Written and verbal
* Witness included if illiterate participants
* Obtained by an independent person
* Confirmed by the researcher
* Sufficient time given to consult and make an informed decision before signing
* Can withdraw
* Understandable and valid informed consent form
* Need for translation

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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# Are the researchers professionally competent with the necessary expertise?

* Academic qualifications suitable
* Scientific and technical competence adequate
* Proof of research competence (education, knowledge and experience)
* Supervisory mentoring skills
* Proof of research ethics training in the past year

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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# Is respect for participants clear throughout?

* Dignity
* Safety
* Well-being
* Justice
* Interest of the participant

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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# Are the facilities where the research will be conducted appropriate and suitably resourced?

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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# 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?
* Do they have participant permission to share and leave the country?

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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# 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?
* Do they have participant permission to share and leave the country?

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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# 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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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# Are there clear monitoring and safety measures in place?

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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# Was a statistician included or consulted/proof of expertise?

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| --- | --- | --- |
| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# Are all the additional legal documents/requirements applicable, included and correctly completed?

* What is the current status thereof?
* To what extend has it been operationalised?
	+ 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.)
	+ 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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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# Is the researcher and project covered by insurance?

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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# 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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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# Is conflict of interest (types) clearly stated and how it will be handled?

|  |  |  |
| --- | --- | --- |
| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# Is it a realistic time set for the study?

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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# Has a budget been included and has it been stated how it will be covered?

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| --- | --- | --- |
| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

# Specifically, for secondary use of data or samples (if applicable):

* Is there a permission letter form the primary investigator stating what can be done?
* Is the documentation of the original study included (e.g. proposal ethics certificate etc.)?
* Does the sub-study/affiliated study match the larger study?
* Was permission given in the signed informed consent for the planned sub-study/affiliated study?

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| **Yes** |[ ]  **No** |[ ]  **Not Applicable** |[ ]
| Click or tap here to enter text. |

**Any additional comments that could not be handled within the prior questions (if applicable):**

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| Click or tap here to enter text. |

**Any documents to be submitted before approval (if applicable):**

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| Click or tap here to enter text. |

**In-process requirements (if applicable):**

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| Click or tap here to enter text. |

**Recommendation for status of the application**

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| --- | --- | --- | --- | --- | --- |
| **Approved** |[ ]  **Changes required for approval** |[ ]   |  | **Deferred** |[ ]  **Disapproved** |[ ]

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

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| --- | --- | --- |
| **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 more than minimal risk of harm |[ ]
| Greater than minimal risk but provides prospect of direct benefit |[ ]
| Greater than minimal risk with no prospect of direct benefit |[ ]

File Reference: 9.1.5.5.2

Current details: (13210572) G:\My Drive\NWU-HREC\NWU-HREC\_Reviewer Report\9.1.5.2.1\_RR00\_NWU-00000-23-S1\_2023mmdd.docx
15 November 2022