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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** |

# 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. | | | | | | |

# 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. | | | | | | |

# 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. | | | | | | |

# 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. | | | | | | |

# 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. | | | | | | |

**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 |  |

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File Reference: 9.1.5.5.2

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