NWU-EMELTEN-REC

The Faculty of Health Sciences Ethics Office of the North-West University is acknowledged for the use of their document with minor adjustments made by the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC).

REVIEWER REPORT

Title of the study	
Ethics Application no.	**NWU-**
Applicant's Name **(Principal Investigator)**	
Reviewer Code	
Date of Review	

	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?		

Recommendation for status of the application

Approved	
Approved with minimal changes	
Approved with several changes	
Deferred	
Disapproved	

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

No risk	
Minimal risk	
Medium risk	
High risk	

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

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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Reviewer signature

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Date

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