UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

Health Sciences Research Ethics Committee

REVIEW FORM

CRITERIA FOR APPROVAL

REVIEW CRITERIA – to be used by reviewers			
1. Introduction, specific aims, literature review	**YES**	**NO**	**N/A**
Is the literature review adequate?	☐	☐	☐
Are the study aims and objectives clearly specified?	☐	☐	☐
Is there adequate preliminary data to justify the study?	☐	☐	☐
Are adequate references provided?	☐	☐	☐
Is there appropriate justification for this study protocol?	☐	☐	☐
Why is it important to conduct this study? Will it add important knowledge to the field?	☐	☐	☐
Is this study worth doing in this particular setting?	☐	☐	☐
2. Scientific design	**YES**	**NO**	**N/A**
Is the scientific design adequate to answer the study question(s)?	☐	☐	☐
Is the scientific design adequately described and justified?	☐	☐	☐
Does the study involve a placebo? If so, is the need for placebo adequately justified? Could the study be done without a placebo?	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Are study aims and objectives achievable in the given time frame?	☐	☐	☐
Do the principal and co-investigators have appropriate academic and clinical credentials and experience to conduct this study?	☐	☐	☐
2.1 Qualitative research: ☐ **N/A**			
Does the researcher have experience in conducting qualitative research?	☐	☐	☐
Does the researcher demonstrate an understanding of the qualitative paradigm and method chosen?	☐	☐	☐
3. Selection of participants ☐ **N/A**	**YES**	**NO**	**N/A**
Is the choice of participants appropriate for the study question?	☐	☐	☐
Is the rationale for the proposed number of participants reasonable?	☐	☐	☐
Is participant selection equitable?	☐	☐	☐
Are inclusion and exclusion criteria clearly stated and reasonable?	☐	☐	☐
Is the inclusion of children, pregnant women or other vulnerable groups adequately justified?	☐	☐	☐
Are adequate safeguards in place to protect the rights and welfare of these vulnerable groups?	☐	☐	☐
Can the study be done without involving vulnerable populations?	☐	☐	☐
Will the study target or exclude a particular ethnic or language group?	☐	☐	☐
3.1 Qualitative research: ☐ **N/A**			
Is the method of sample selection appropriate and clear?	☐	☐	☐
If the sample size cannot be delineated before the study begins, are a rationale and plan provided?	☐	☐	☐
Has the researcher clearly described how they will determine when adequate sampling (saturation) has occurred?	☐	☐	☐

Has the study population been involved in previous research and/or is the study population currently involved in research to the extent that the current study may present a significant additional burden?	☐	☐	☐
4. Recruitment strategy ☐ **N/A**	**YES**	**NO**	**N/A**
Are the methods for recruiting participants clearly explained and appropriate?	☐	☐	☐
Is the location, setting and timing of recruitment acceptable?	☐	☐	☐
Are screening procedures prior to recruitment acceptable?	☐	☐	☐
Will any potential participants be in a dependent relationship with the researcher/recruiter? (e.g. Student/lecturer, employee/employer, patient/doctor)	☐	☐	☐
Has the researcher taken steps to ensure that the participant's decision to enrol will not be inappropriately influenced by this relationship?	☐	☐	☐
5. Research procedures ☐ **N/A**	**YES**	**NO**	**N/A**
Are the rationale and details of research procedures described in sufficient detail?	☐	☐	☐
Are the research procedures acceptable and in keeping with study aims and objectives?	☐	☐	☐
Is there a clear distinction between research procedures and standard clinical practice and/or standard care?	☐	☐	☐
Are the proposed tests/measurements appropriate, valid and reliable to answer the study question in the local context?	☐	☐	☐
Is there a clear description of plans to inform participants of specific research results e.g. Incidental findings, clinically relevant findings?	☐	☐	☐
Are those performing the research procedures adequately trained?	☐	☐	☐
6.Risk-benefit assessment ☐ **N/A**	**YES**	**NO**	**N/A**
Are risks (Physical, psychological, social, and economic) and benefits (to individuals and/or community) adequately: • Identified; • Evaluated; and • Described?	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Do risks and benefits stated in the protocol match those described in the informed consent form?	☐	☐	☐
Are potential risks minimised?	☐	☐	☐
Are potential benefits maximised?	☐	☐	☐
Will counselling or support services be available, if required?	☐	☐	☐
Are potential benefits realistically described and not over emphasized?	☐	☐	☐
Are risks reasonable in relation to anticipated benefits?	☐	☐	☐
Are risks reasonable in relation to importance of anticipated knowledge gained?	☐	☐	☐
Is the risk/benefit ratio acceptable for proceeding with the research?	☐	☐	☐
Is the population from which study participants are drawn likely to benefit from the research?	☐	☐	☐
7. Clinical drug/device trial ☐ **N/A**	**YES**	**NO**	**N/A**
Has the national drug regulatory authority approval been obtained, if required?	☐	☐	☐
Are the drug or device safety and efficacy data sufficient to warrant the proposed phase of testing?	☐	☐	☐
Is the use of placebo adequately justified from both a scientific and an ethical perspective?	☐	☐	☐
Are there adequate provisions for safety monitoring including a DSMB?	☐	☐	☐
8. Data analysis and statistical analysis ☐ **N/A**	**YES**	**NO**	**N/A**
Are the plans for data and statistical analysis defined and justified?	☐	☐	☐

Has the sample size and selection been adequately justified?	☐	☐	☐
8.1 Qualitative research: ☐ **N/A**	**YES**	**NO**	**N/A**
Is it clear and well-motivated why or how qualitative data collection methods are the most appropriate for analysis?	☐	☐	☐
Is there clarity in the analytic approach?	☐	☐	☐
Does the description of the analytic approach indicate how this will allow the researcher to pursue their objectives?	☐	☐	☐
Has the researcher adequately described how they intend to go about coding and analysis?	☐	☐	☐
9. Compensation and costs for subjects ☐ **N/A**	**YES**	**NO**	**N/A**
Are there adequate plans to avoid out-of-pocket expenses and costs to participants?	☐	☐	☐
Is the amount or type of compensation or reimbursement reasonable and well justified?	☐	☐	☐
If children or adolescents are involved who receives compensation and is this appropriate?	☐	☐	☐
10. Privacy and confidentiality ☐ **N/A**	**YES**	**NO**	**N/A**
Are there adequate measures to protect the privacy and ensure the confidentiality of the research subjects?	☐	☐	☐
Does the protocol describe site-specific measure to protect privacy?	☐	☐	☐
Does the protocol describe how written records, audio or videotapes, and digital recordings will be secured, for how long, and whose responsibility?	☐	☐	☐
For focus groups, are participants informed that confidentiality cannot be guaranteed as group members may disclose what we discussed outside the research setting?	☐	☐	☐
Are activities that could potentially result in notification e.g. Abuse, neglect, potential for harming self or others, addressed in the protocol and IC form?	☐	☐	☐
11. Process of obtaining informed consent and assent ☐ **N/A**	**YES**	**NO**	**N/A**
Is the process adequately described? Or has a waiver of informed consent or waiver of documentation of informed consent been requested and adequately justified?	☐	☐	☐
Are all required elements of informed consent contained in the ICF?	☐	☐	☐
Is the language level appropriate?	☐	☐	☐
Does the process minimise the potential for undue influence?	☐	☐	☐
Does the process provide sufficient time, privacy and an adequate setting for participants to decide?	☐	☐	☐
Will the ICF be translated into all required languages?	☐	☐	☐
Is assent required?	☐	☐	☐
12. Other ☐ **N/A**	**YES**	**NO**	**N/A**
Is the investigator and research team adequately qualified to carry out/supervise the research?	☐	☐	☐
Does the PI have 'human subjects protection training' /GCP?	☐	☐	☐
Is the budget adequate?	☐	☐	☐
Are there any administrative deficiencies with the application, such as missing documents?	☐	☐	☐
Has a material/data transfer agreement been submitted if required?	☐	☐	☐
13. At the end of the study ☐ **N/A**	**YES**	**NO**	**N/A**
Will post trial treatment be available?	☐	☐	☐
Will communities and participants be informed of significant findings?	☐	☐	☐
Will findings be disseminated more broadly e.g. publishing, presenting etc?	☐	☐	☐