HREC / UREC review criteria guide

1. INTRODUCTION, SPECIFIC AIMS, LITERATURE REVIEW
Is the literature review adequate? Are the study aims and objectives clearly specified? Is there appropriate justification for this study protocol? Is there adequate preliminary data to justify the study? Why is it important to conduct this study? Will it add important knowledge to the field? Why is this study worth doing in this particular setting? Are adequate references provided? (Where possible, the literature review should include pertinent references to local research in the proposed field of study). Is there a mechanism for those affected by the study to express their views, clarify their needs and contribute to the research?
2. SCIENTIFIC DESIGN
Is the selected scientific design appropriate to answer the study question(s)? Is the scientific design adequately described and justified? Does the study involve a placebo? If so, is there a persuasive justification for using a placebo? 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? **Qualitative research:** Is the selected scientific design appropriate to answer the study question(s)? Is the scientific design adequately described and justified? Are study aims and objectives achievable in the given time frame? Does the researcher and/or their supervisor/co-investigators have experience in conducting qualitative research? Does the researcher demonstrate an understanding of the qualitative paradigm and method chosen?
3. SELECTION OF PARTICIPANTS
Is the selection of participants appropriate for the study question being asked? 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? 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? **Qualitative research:** 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?
4. RECRUITMENT STRATEGY
Are the methods for recruiting participants clearly explained and appropriate? How and by whom will individuals be identified for recruitment? 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? Has the study population been involved in previous research to the extent that the proposed research may present a significant additional burden? (e.g. an existing cohort of participants already in research).
5. RESEARCH PROCEDURES

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 patient 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? For example, in research with children, only research staff with paediatric expertise and/or experience should perform research-related procedures.

6. RISK-BENEFIT ASSESSMENT

Are risks and benefits (to individuals and/or community) adequately identified, evaluated and described? (physical, psychological, social, and economic)
Do risks and benefits stated in the protocol match those described in the Informed Consent form?
Are potential risks minimised?
Are there any specific risks to the researcher (e.g. safety concerns)?
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?
Is the location of the study adequate to assure participants' safety and comfort (e.g. appropriate equipment for monitoring and emergencies, a child-friendly setting for paediatric research)?

7. CLINICAL DRUG/DEVICE TRIAL

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

Are the plans for data and statistical analysis defined and justified?
Has the sample size and selection been adequately justified?
Qualitative research:
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?
Is there evidence and detail of a conceptual framework?
Is there a mechanism, such as a reference or event monitoring group, to provide ongoing oversight and impartial analysis of unanticipated incidents?

9. COMPENSATION AND COSTS FOR SUBJECTS

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 the participant does not complete the study, will compensation be pro-rated?
If children or adolescents are involved who receives compensation and is this appropriate?

10. PRIVACY AND CONFIDENTIALITY

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

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 information contained in the informed consent form?
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 informed consent form be translated into all required languages?
Is Assent required?
Who will obtain consent or assent? Is the individual obtaining consent or assent adequately trained?
Is the setting where individuals are being recruited or would report for research-related activities the same as where they are seen for clinical care? If so, is it likely to cause confusion about what is research activity and what is standard care?
Are issues relating to participants' comprehension considered?
How will a researcher decide if a participant has decision-making capacity to choose to enroll in a study?
Is there appropriate justification for the use of proxy consent in the event that the researcher cannot obtain direct consent from the participant?
Are jargon, acronyms and abbreviations explained or defined?
Are terms such as 'randomisation' clearly defined and illustrated (e.g. like flipping a coin)?
Will an interpreter be necessary to obtain assent or consent?
Does the consent form state that participants can contact the Human Research Ethics Committee if they have a complaint or questions about their rights and welfare as research subjects?
Does the consent process meet South African legal and regulatory requirements?
In general, is the consent form consistent with the protocol?

12. OTHER

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?
Other comments related to the budget?
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

Will post trial treatment be available?
Who will provide this treatment and for how long?
How will communities and participants be informed of significant findings?
How will findings be disseminated more broadly e.g. publishing, presenting etc?

14. STORAGE OF BIOLOGICAL SPECIMENS

Will biological specimens be stored for future use?
In the case of uniquely identified specimens, especially those containing genetic material, do the participant and family understand where and how their genetic material will be stored and protected and who will have access and why?
Where appropriate, does the consent form spell-out specific provisions for future use of participants stored biological material?
If samples will be stored for future use, does the consent form include opt-in or opt-out options?
Will samples be stored at Stellenbosch University or at an external site?

15. INSURANCE

Is there provision for insurance for research-related injuries, if applicable?
In the case of drug trials, does the insurance cover comply with ABPI Guidelines for commercially sponsored research?
In the case of investigator-initiated research, is there cover in terms of SU's no-fault insurance policy?

16. CONFLICT OF INTEREST

Will any research staff receive incentives for recruiting participants or for any other purpose directly related to the study?
Do any personnel involved in the design, conduct or analysis of the research have any proprietary interests (e.g. royalties, patents, trademarks, copyrights or licensing agreements) involving any agent, device or software being evaluated in the study?

RECOMMENDATION by HREC reviewer:

☐ **APPROVED**

☐ **APPROVED WITH STIPULATIONS** (research can begin subject to certain set pre-conditions – the onus rests with the research applicant to fulfil these)

☐ **MODIFICATIONS REQUIRED** (Approval will be finalised by the 1st reviewer and Chairperson once satisfied with changes/clarifications)

☐ **DEFERRED or "REFERRED BACK"** (NB: the project must serve before the committee again before it can be given "Final Approval" Status.)

PROVISIONS

Describe reason(s) for above recommendation and detail any modifications required

This content will be communicated to the research applicant in the HREC letter