New Protocol Applications — Pointers for Reviewers

This guidance is offered to remind reviewers about important ethical issues in research. Where a reviewer makes a comment about a methodological issue, please indicate whether the change is required or merely recommended.

1. Aims, Background and Significance

* Are the study aims and objectives clearly specified?
* Are there adequate preliminary data to justify the research?
* Are adequate references provided? (where possible, the literature review should include pertinent references to local research in the proposed field of study)
* Why is this research important to conduct? Will it add important knowledge to the field?
* Why is it worth doing in this particular setting?
* Is there a mechanism for those affected by the study to express their views, clarify their needs and contribute to the research?

Comments or Questions for Researchers

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1. Scientific Design

* Is the scientific design adequate to answer the study’s questions?
* Is the scientific design adequately described and justified?
* Does the study involve a placebo?
* If so, why is a placebo needed?
* Could the study be done without a placebo?
* Is there a persuasive justification for using 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?
* In the case of qualitative research, does the researcher:
* Demonstrate an understanding of the qualitative paradigm and method chosen?
* Have experience in conducting qualitative research?

Comments or Questions for Researchers

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1. Inclusion and Exclusion Criteria

* Is the selection of participants appropriate for the question being asked?
* Is the rationale for the proposed number of participants reasonable?
* Are inclusion and exclusion criteria clearly stated and reasonable?
* Does the study include vulnerable groups such as children, psychiatric patients, individuals with impaired decision-making capacity?
* If yes, are adequate safeguards included to protect their rights and welfare?
* Is the inclusion of vulnerable populations justified?
* Can the study be done without involving vulnerable populations?
* Will the study target or exclude a particular ethnic or language group?
* In the case of qualitative research:
* Is the method of sample selection appropriate and clear as to how the researcher will determine when adequate sampling has occurred?
* If the sample size cannot be delineated before the study begins, are a rationale and plan provided?

Comments or Questions for Researchers

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1. Recruitment and Enrolment

* How and by whom will individuals be identified for recruitment into the study?
* Are the location, setting, and timing of recruitment acceptable?
* What recruitment methods materials will be used e.g. flyers, posters, advertisements?
* Are procedures for screening participants prior to recruitment acceptable?
* Will any potential participants be in a dependent relationship with the researchers or persons recruiting for the study, e.g. student/lecturer, doctor/patient, and employer/employee? If so, has the researcher taken steps to ensure that the participants’ decision to enrol will not be influenced by the 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)

Comments or Questions for Researchers

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Research Procedures

* Are the rationale and details of research procedures adequately described and acceptable?
* Is there a clear differentiation between research procedures and standard of care?
* Are the proposed tests or measurements appropriate, valid and reliable to answer the scientific question in the local context?
* Are there adequate plans to inform participants about specific research results, e.g. incidental findings, clinically relevant findings?
* Are individuals who are performing procedures adequately trained? For example, in research with children, only research staff with paediatric expertise and/or experience should perform research-related procedures.

Comments or Questions for Researchers

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1. Risks and Benefits

* Are risks and benefits adequately identified, evaluated, and described, including physical, psychological, social, and economic?
* Are risks to the community or a particular group of individuals, e.g. Stigmatisation, adequately identified?
* Are there any specific risks to the researcher (e.g. safety concerns)?
* Do risks stated in the protocol match the risks described in the informed consent form?
* Are risks reasonable in relation to anticipated benefits?
* Are risks reasonable in relation importance of knowledge to be gained?
* Are risks minimised to extent possible, e.g. study procedures are already being performed on participants for diagnostic or treatment purposes.
* 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)?
* Will counselling or support services be available, if required?
* Is the population from which study participants will be drawn likely to benefit from the research?

Comments or Questions for Researchers

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1. Process of Obtaining Informed Consent and Assent

* Is the process well-defined?
* Does the process minimise the possibility of undue influence?
* Does the process provide sufficient time, privacy and an adequate setting for participants to decide?
* 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 enrol 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?
* Is the language used in the assent and consent forms appropriate for participants’ level of understanding?
* 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 protocol state if consent forms will be translated into other languages?
* 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?

Comments or Questions for Researchers

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1. Privacy and Confidentiality

* Does the protocol describe site-specific measures to protect participants’ privacy?
* Are provisions to protect confidentiality of data during and after research adequate?
* Does the protocol describe how written records, video or audiotapes will be secured, for how long and who will be responsible for storage or final disposal?
* In the case of focus groups, are participants told that confidentiality cannot be guaranteed as group members may disclose what was discussed outside the research setting?
* Are activities that could potentially result in notification (e.g. deliberate abuse or neglect, diagnosis of TB) addressed in the protocol and consent form?

Comments or Questions for Researchers

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1. 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 UCT or at an external site?

Comments or Questions for Researchers

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1. Data Analysis and Monitoring

* Are the plans for data and statistical analysis defined and justified?
* Are there adequate plans for monitoring data, e.g. stopping rules?
* Is a data safety monitoring board part of the study? Is it independent?
* In the case of non-interventional or qualitative research is there a mechanism, such as a reference or event monitoring group, to provide ongoing oversight and impartial analysis of unanticipated incidents?

Comments or Questions for Researchers

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1. Reimbursement

* Are there adequate plans to avoid out-of-pockets expenses and costs incurred by participants (e.g. travel expenses, parking costs, and lost wages? Participants cannot be expected to carry any study-related expenses)?
* Is the compensation to participants reasonable?
* If the participant does not complete the study, will compensation be pro-rated?
* If children or adolescents are involved, who receives the compensation? Is this appropriate?

Comments or Questions for Researchers

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1. 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 UCT’s no-fault insurance policy?

Comments or Questions for Researchers

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* ***What Happens at the End of the Study?***
* ***Will post-trial treatment be available?***
* ***Who will supply this treatment and for how long?***
* ***How will participants and communities be informed of important findings?***
* ***How will findings be disseminated to the wider research community (e.g. peer-reviewed scientific journals, conference presentation, and internal report)?***

Comments or Questions for Researchers

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1. Conflicts 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?

Comments or Questions for Researchers

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Additional Comments or Questions for Researchers

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Reviewer’s Final Assessment (check🗙)

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|  | Approved: No changes. There is an acceptable risk: benefit ratio and the protocol is acceptable as submitted. |
|  | Conditional approval ⎯ minor changes: Minor changes needed to consent form or other study materials; minor clarifications regarding specific aspect(s) of study or additional information requested from PI. Chair or designee will approve revisions. |
|  | Conditional approval ⎯major changes: Major changes needed as protocol is poorly written, lacking information relating to scientific and/ or ethical aspects, needs to be rewritten and resubmitted. Please state whether:  ⬜ Chair or designee can approve revisions  ⬜ Revised protocol must be tabled at a full committee meeting |
|  | Disapproved: Risks significantly outweigh the benefit or value of the knowledge to be gained; there are significant ethical concerns or questions that make the study unacceptable. |