The **SAMRC Human Research Ethics Committee (HREC)** wishes to process applications for clearance as speedily as possible. To help us do this applicants need to provide a clear and comprehensive protocol for assessment.

**Please note that all applications will be checked for completeness by the administration before submission to the Committee. All incomplete proposals will be returned to the applicant for updating which could result in unfortunate delays in the review process.**

**Below is a checklist to help achieve this.   
Please complete and attach the checklist to your submission**

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| --- | --- | --- | --- |
|  |  | **Yes** | **No** |
| 1 | **Is the application labelled?** Give project title, unit. | |  | | --- | |  | | |  | | --- | |  | |
|  |  |  |  |
| 2 | **Are details of the investigators provided?** Name, title, full mailing address, telephone and fax numbers, e-mail address of principal investigator and co-investigators from each collaborating organisation. | |  | | --- | |  | | |  | | --- | |  | |
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| 3 | **Have key words been given?** Up to six scientific descriptors (key words) for the project. | |  | | --- | |  | | |  | | --- | |  | |
|  |  |  |  |
| 4 | **Is the following declaration provided, dated and signed?** I, - ***name of principal investigator***- have read the Department of Health: *Ethics in health research: principles, processes and structures, second edition*, 2015, the *Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa,* Second Edition, 2006, Department of Health, Pretoria, South Africa (where applicable), and the Declaration of Helsinki (2013) and have prepared this proposal with due cognisance of its content. Furthermore, I will adhere to the principles expressed when conducting this proposed research project.  Did you have any difficulty with any specific provision in the guidelines concerning your proposal?   If so, please provide details. This will be very helpful to the HREC.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  What type of study is it: feasibility, preliminary, pilot, exploratory, versus full, confirmatory?  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  | | --- | |  | | |  | | --- | |  | |
|  | **Please give a statement of the research problem.**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
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| 5 | **Has the application been approved through the HREC’s scientific review process?**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  | | --- | |  | | |  | | --- | |  | |
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| 6 | **Has the application been checked for content, grammar and spelling?** If yes, by whom?  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  | | --- | |  | | |  | | --- | |  | |
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| 7 | **Are the ethics issues identified, and is it stated how they will be addressed?**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  | | --- | |  | | |  | | --- | |  | |
| 8 | **Are the copies of the following attached? [N/A = not applicable]**   * An Executive Summary, stating the AIM, METHODS, OUTCOME and INTENDED FEEDBACK of the study. | **Yes**   |  | | --- | |  | | **N/A**   |  | | --- | |  | |
|  | * Participant information sheet | |  | | --- | |  | | |  | | --- | |  | |
|  | * Informed consent form | |  | | --- | |  | | |  | | --- | |  | |
|  | Are the technical terms in the above forms explained in lay terms? | |  | | --- | |  | | |  | | --- | |  | |
|  | Are the contact details of the SAMRC Human Research Ethics Committee given with a statement that participants can contact the Chairperson when they have queries or problems? (Adri Labuschagne, tel. (021) 938 0687; e-mail: [adri.labuschagne@mrc.ac.za](mailto:adri.labuschagne@mrc.ac.za)) | |  | | --- | |  | | |  | | --- | |  | |
|  | * Translations into languages relevant to the study area.  If yes, which language(s)?   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  | | --- | |  | | |  | | --- | |  | |
|  | If consent will be verbal or informed consent is not necessary, please explain why not  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  | | --- | |  | | |  | | --- | |  | |
|  |  |  |  |
| 9 | **Is any questionnaire to be used provided?** | |  | | --- | |  | | |  | | --- | |  | |
|  |  |  |  |
| 10 | **Is confidentiality clarified?** | |  | | --- | |  | | |  | | --- | |  | |
|  |  |  |  |
| 11 | **Has consent from minors been explained?** If participants are under age (less than 18 years) from whom will consent be obtained, e.g. parent, guardian, etc.?  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  | | --- | |  | | |  | | --- | |  | |
|  | If minors will be included, is the application form for non-therapeutic research with minors included? | |  | | --- | |  | | |  | | --- | |  | |
| 12 | **Has blood sampling been clarified?** Venous or arterial, the amount and frequency and by whom? | |  | | --- | |  | | |  | | --- | |  | |
|  |  |  |  |
| 13 | **Has any drugs administration been specified?** If yes, have the drug, dose, frequency, and who will administer it been clarified? | |  | | --- | |  | | |  | | --- | |  | |
|  |  |  |  |
| 14 | **Have drug side-effects been specified?** | |  | | --- | |  | | |  | | --- | |  | |
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| 15 | **Have the following protocol details been provided?** | |  | | --- | |  | | |  | | --- | |  | |
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| **Table of Contents** | | |  | | --- | |  | | |  | | --- | |  | |
|  | Number the pages in the proposal and include page numbers in the contents. |  |  |
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| --- | --- | --- | --- | --- | --- |
| **Methodology details: are these included in the protocol?** | | |  | | --- | |  | | |  | | --- | |  | |
| 1 | Overall aim and specific objectives. |  |  |
| 2 | *Background and rationale:* This must be substantial and include references to or details of similar studies, and allow for thorough technical peer review by experts in your field. |  |  |
| 3 | *Technical work plan:* Describe in considerable detail your overall experimental design, methods and research protocols. Discuss research alternatives if your original assumptions/hypotheses prove incorrect. |  |  |
| 4 | *Statistical planning:* Has there been consultation with a statistician? If NO, please provide reasons. If YES, please give details including randomisation, sample size and proposed methods of analysis. |  |  |
| 5 | *Time chart:* Critical path analysis identifying when each activity is to take place. Identify points at which timing is critical (e.g. a season when a particular field study would need to be done). |  |  |
| 6 | References cited. |  |  |
| 7 | Description of methods applied. |  |  |
| 8 | Has this study been approved by the research group you operate in, or by any other peer group, for scientific validity; including a statistician?  If yes, name the group. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  | | --- | |  | | |  | | --- | |  | |
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| **Management details: are these included in the protocol?** | | |  | | --- | |  | | |  | | --- | |  | |
| 1 | Management approach: Discuss the overall management of the project. Where is managerial responsibility? Consider specific functions such as reporting, financial management, procurement of equipment and research supplies, and management of field activities. |  |  |
| 2 | Staff and scientific collaboration: Who will do what, when and where? (one page). |  |  |
| 3 | Facilities: Describe the facilities and resources available for the proposed research. |  |  |
|  |  |  |  |
| **Budget details: are these included in the protocol?** | | |  | | --- | |  | | |  | | --- | |  | |
| 1 | *Budget:* full detailed budget for each year. The following headings can act as a guide: Salaries, equipment, its repair and maintenance, materials and supplies, training, consultation, travel, other, indirect costs/overheads. |  |  |
| 2 | *Budget justification:* Explain how the individual items of the budget were calculated. Justify major or unusual expenses. |  |  |
| 3 | Budget summary. |  |  |
| 4 | Has your research group reviewed and accepted the budget? |  |  |
| 5 | Do you believe the budget is fully sufficient to conduct the study ethically and scientifically? |  |  |
| 6 | Has the name of the sponsor of the study (if applicable) been indicated on the participant information sheet? |  |  |
|  |  |  |  |
| **Details of researchers** | | |  | | --- | |  | | |  | | --- | |  | |
|  | CVs ([Health Professionals](http://www.samrc.ac.za/sites/default/files/attachments/2016-06-29/cvhealthprofessional.doc)) ([non-Health Professionals](http://www.samrc.ac.za/sites/default/files/attachments/2016-06-29/cvresearchers.doc)) and publication lists of all senior personnel involved in the project.  **NOTE:** Only provide qualifications and scientific experience, e.g. publications, projects, presentations. A one-page biosketch with the ten most important references will suffice. |  |  |
|  |  |  |  |
| **Other details: are these included in the protocol?** | | |  | | --- | |  | | |  | | --- | |  | |
| 1 | *Ethical considerations:* This must address all relevant ethical issues including: details of possible negative consequences to the study animals/participants, information to be given to participants, reporting back procedures to the community/authorities and an example of the consent form to be used. |  |  |
| 2 | *Additional review bodies:* does this protocol need to be reviewed by another institution or Ethics Committee? If so, has it been submitted and what was the outcome? Please provide copies of relevant documentation. |  |  |
| 3 | *Similar studies:* Please list titles of any similar studies previously approved. |  |  |
| 4 | *Research translation:* Summary details of the implementation of research results and outputs, e.g. |  |  |
|  | policy briefs, new research techniques, diagnostic tools, therapies; health policy development, etc. |  |  |

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| 5 | Please declare which of the following interests you may have in the study, such as: |  |  |
|  | * resources paid directly to you or your research account; | |  | | --- | |  | | |  | | --- | |  | |
|  | * potential financial benefits from the outcome of the study; | |  | | --- | |  | | |  | | --- | |  | |
|  | * direct financial interest in the company; | |  | | --- | |  | | |  | | --- | |  | |
|  | * any others; | |  | | --- | |  | | |  | | --- | |  | |
|  | * any gains to your family; | |  | | --- | |  | | |  | | --- | |  | |
|  | * travel sponsorship. | |  | | --- | |  | | |  | | --- | |  | |
| 6 | Name the possible (both positive and negative) short- and long-term consequences of the study. |  |  |
| 7 | Does the study have insurance for research-related injury? Are participants informed accordingly in the information sheet? | |  | | --- | |  | | |  | | --- | |  | |
| 8 | If applicable, has the application been submitted to the South African Health Products Regulatory Authority (SAHPRA) for approval? | |  | | --- | |  | | |  | | --- | |  | |
| 9 | Has the following statement in terms of the POPI Act been added to the informed consent?  In accordance with the provisions of the **Protection of Personal Information Act 4 of 2013** (as amended), I hereby consent:  a. To my personal information (hereinafter 'data') being collected, processed, shared and stored in accordance with the research protocol as approved by the South African Medical Research Council's Human Research Ethics Committee (SAMRC HREC);  b. To my anonymised data being shared, processed and transferred by third parties and between third parties, and where relevant beyond the jurisdictional borders of South Africa;  c. To all findings and results flowing from my anonymised data being broadly shared and published on the conclusion of the research. | |  | | --- | |  | | |  | | --- | |  | |