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Health Research Ethics Committee (HREC)

NEW PROTOCOL APPLICATION:
Guidance and instructions for researchers

Instructions

New protocol application

The Health Research Ethics Committee (HREC) uses an electronic ethics review management system, *Infonetica*©, to manage the application and review process.
» This is a new system and we recommend that you consult the **APPLICANT MANUAL** for guidance
» To access the electronic submission platform for your HREC application, please click here: **APPLY HERE**

What needs to be submitted?

Clinical trials:		**Health and student research:**
Please submit through *Infonetica*© **and**		Please submit through *Infonetica*© **only**
Please submit 2 hard copies of your full submission pack to the HREC office		No hard copies are required

Definition of a Clinical Trial: Research study or investigation intended to test safety (not harmful or dangerous to human health), quality (ingredients are of good quality), effectiveness (working to diagnose, treat, prevent or cure a disease condition) and efficacy (better/ best when compared with other treatment or medicine for a similar condition) of new and/or existing or old medicines, medical devices and/or treatment options, using human participants (*South African National Clinical Trials Register, South African Department of Health, see:http://www.sanctr.gov.za/Resources/Whatisaclinicaltrial/tabid/175/Default.aspx)*

How to prepare your submission pack

Please prepare the following supporting documentation which you will be asked to upload during the electronic application process.

Clinical trial		**Health and student research**
1. Cover letter listing all submitted docs with version numbers and version dates		
2. PI-Generated Protocol Synopsis		1. PI Generated Protocol Synopsis
3. Sponsor's Synopsis (if applicable)		
4. Sponsor's Research Protocol		2. Research Protocol
5. PI-Generated Protocol Addendum for Local Site – this addendum should detail the specifics of participant selection, any risks and benefits that might be unique to local participants, and the local recruitment and informed consent process that will take place at your site and should indicate, where necessary, how this might be different from what is stated in the international protocol.		
Appendices (as applicable)		*Appendices (as applicable)*
6. Consent and assent forms (English versions) – if this is a multi-site trial the consent and/or assent forms should be adapted by the PI for the local site. Submit only those forms relevant to your site.		3. Consent and assent forms (English versions)
7. Recruitment materials (e.g. advert, flyer, poster)		4. Recruitment materials (adverts, flyers, posters)

8. Data collection tools (e.g. survey, questionnaire, interview guide)		5. Data collection tools (e.g. survey, questionnaire, interview guide)
9. Materials for participants (e.g. diaries, patient identification cards)		6. Materials for participants (e.g. diaries, patient identification cards)
10. Letters of authorisation from institutions (e.g. hospital, clinic, school)		7. Letters of authorisation from institutions (e.g. hospital, clinic, school)
11. Budget (and financial contract, if external funding)		8. Budget (and financial contract, if external funding)
12. Post-trial care/Care after research justification		9. Post-trial care/Care after research justification
13. For multi-site studies, a description of the *local* study site, including the available infrastructure and the roles and responsibilities of study staff		10. For multi-site studies, a description of the *local* study site, including the available infrastructure and the roles and responsibilities of study staff
14. For multi-site studies, a description of the recruitment and consent processes proposed for the *local* site		11. For multi-site studies, a description of the recruitment and consent processes proposed for the *local* site
15. For studies that intend to send/receive data or samples to/from another location, a Draft Data/Material Transfer Agreement (DTA/MTA)		12. For studies that intend to send/receive data or samples to/from another location, a Draft Data/Material Transfer Agreement (DTA/MTA)
16. Proof of insurance for participants		13. Proof of insurance for participants
17. Two-page CV for each investigator and research supervisor		14. Two-page CV for each investigator and research supervisor
18. Signed Investigator Declaration for each investigator and research supervisor		15. Signed Investigator Declaration for each investigator and research supervisor
19. Proof of GCP training for investigators		
20. Investigator's brochure		
21. SA approved package insert(s) of registered comparators		
22. A summary of Phase III efficacy and safety data if this is an application for an open label or extension study		
23. SAHPRA letter of approval, or proof of application		
24. If an application has been submitted to SAHPRA, a copy of Section 13 (Ethical Issues) extracted from the CTF1 application form		
25. NHREC approval or proof of application		
26. HREC Payment instruction form		16. HREC Payment instruction form and Proof of payment
27. Other relevant documentation		17. Other relevant documentation

Post Submission Guidance

Responding to the HREC's feedback

- Address all points and queries in a cover letter, using examples, references and data where necessary.
- Copy or restate the question or concern raised by HREC and then provide a detailed and thoughtful response. Incomplete responses are likely to trigger a repeat query from the reviewer.
- If a reviewer's feedback is unclear or ambiguous, contact the HREC staff and request clarification. If you disagree with a comment or recommended change, provide your rationale.
- If the response requires a change in study procedures or design, revise the protocol, recruitment materials and information sheets/ consent forms accordingly.
- If your response requires revisions to the protocol and consent documents, submit copies with changes highlighted in track changes so the reviewer can immediately determine where and what changes have been made.
- Proofread the final versions for grammatical, typographical and formatting errors.

Annual Progress Reports (Continuing Review of Ongoing Research)

International and national regulatory and ethical requirements require the HREC to review active research at least annually. The PI is responsible for submitting an annual progress report to the HREC in a timely manner before the approval period for the study expires. The HREC has the authority to suspend or terminate research which does not comply with annual reporting requirements.

Active Protocols

All changes or amendments to research protocols, including for example information/consent documents, advertisements, addition of investigators and study instruments must have HREC approval prior to implementation except where necessary to eliminate immediate risk of harm to enrolled participants.