



## 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](#)
- » Once login is Successful, select the “Create Project” Tile on the second row on the left hand side under the actions drop down list
- » Should log in be unsuccessful please verify your Sun ID account with your home department and try again at a later stage.
- » After the “create project” tile has been clicked a “create project” box should appear whereby you should enter the full project title and then select the appropriate form; in this case it’s the HREC New Application Form and press the create button
- » Once this has been done, Under the HREC New Application Form you can now start the application by clicking on Page 1 in line with Section 1 marked “Filter Questions “

For further information please consult the Applicant Manual.

#### What needs to be submitted?

Clinical trials:	Health and student research:
Please submit through <i>Infonetica</i> ® and	Please submit through <i>Infonetica</i> ® only
Please submit <b>one</b> hard copy 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. Research Protocol	2. Research Protocol

<i>Appendices (as applicable)</i>		<i>Appendices (as applicable)</i>
5. Consent and assent forms (English versions)		3. Consent and assent forms (English versions)
6. Recruitment materials (e.g. advert, flyer, poster)		4. Recruitment materials (adverts, flyers, posters)
7. Data collection tools (e.g. survey, questionnaire, interview guide)		5. Data collection tools (e.g. survey, questionnaire, interview guide)
8. Materials for participants (e.g. diaries, patient identification cards)		6. Materials for participants (e.g. diaries, patient identification cards)
9. Letters of authorisation from institutions (e.g. hospital, clinic, school)		7. Letters of authorisation from institutions (e.g. hospital, clinic, school)
10. Budget (and financial contract, if external funding)		8. Budget (and financial contract, if external funding)
11. Post-trial care/Care after research justification		9. Post-trial care/Care after research justification
12. For multi-site studies, a description of the <i>local</i> study site, including the available infrastructure and the roles and responsibilities of study staff		10. For multi-site studies, a description of the <i>local</i> study site, including the available infrastructure and the roles and responsibilities of study staff
13. For multi-site studies, a description of the recruitment and consent processes proposed for the <i>local</i> site		11. For multi-site studies, a description of the recruitment and consent processes proposed for the <i>local</i> site
14. 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)
15. Proof of insurance for participants		13. Proof of insurance for participants
16. Two-page CV for each investigator and research supervisor		14. Two-page CV for each investigator and research supervisor
17. Signed Investigator Declaration for each investigator and research supervisor		15. Signed Investigator Declaration for each investigator and research supervisor
18. Proof of GCP training for investigators		
19. Investigator's brochure		
20. SA approved package insert(s) of registered comparators		
21. A summary of Phase III efficacy and safety data if this is an application for an open label or extension study		
22. MCC letter of approval, or proof of application		
23. If an application has been submitted to the MCC, a copy of Section 13 (Ethical Issues) extracted from the CTF1 application form		
24. NHREC approval or proof of application		
25. HREC Payment instruction form		16. HREC Payment instruction form and Proof of payment
26. 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.