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Health Research Ethics Committee (HREC)

NEW APPLICATION – HREC RECIPROCAL REVIEW
Guidance and instructions for researchers

Instructions

New Reciprocal Review Application

The DoH guidelines (2015) allow for reciprocity of reviews (section 4.5.1.4) as follows: "4.5.1.4 Reciprocal recognition of review decisions:

- RECs may, at their own discretion, recognize prior review and approval of a research proposal by another registered REC to avoid duplication of effort.
- Reciprocal recognition means that two or more registered RECs decide to recognize each other's prior review.
- RECs that recognize prior review in this manner must determine the nature of the documents to be filed locally, which must, at minimum, include a copy of the approval letter from the other REC".

Stellenbosch University (SU) currently uses a reciprocal review system where SU HREC may consider acknowledging ethics clearance by other South African RECs registered with and accredited by the National Health Research Ethics Council (NHREC).

GENERAL CONDITIONS FOR CONSIDERATION OF A RECIPROCAL REVIEW:

- Where a research study will be undertaken at multiple sites (e.g., a multi-centre study or clinical trial), a simplified and mutually acknowledging HREC review process may be considered. This means that the HREC of Record's review report will be considered under a reciprocal agreement by the relevant HRECs. Such an agreement should be in writing and detail the extent of and/or limits to such agreement, for example, responsibility for future review of study materials (for example, protocol amendments, adverse events, etc.).
- The local Principal Investigator will be required to complete the online **HREC Reciprocal Review Application form**.
- To access the electronic submission platform for your HREC application, you need to click the link https://applyethics.sun.ac.za and login using your SU credentials, e.g., test123@sun.ac.za
- Once login is Successful, select the "Create Project'' Tile 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 are able to enter the full project title and then select the appropriate form; in this case it is the **HREC Reciprocal Review Application** Form and press the create button.
- Once this has been done, Under the HREC **Reciprocal Review Application** you can now start the application by clicking on Page 1 and completing all the questions.

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What needs to be submitted?

Clinical trials:		**Health and student research:**
Please submit through *Infonetica*© **and**		Please submit through *Infonetica*© **only**
Please submit 1 hard copy of your full submission pack to the HREC office		No hard copies are required

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 **(Word doc) including** signed agreement by local PI and lead PI as per HREC SoPs on reciprocal reviews		1. Cover letter listing all submitted docs with version numbers and version dates **(Word doc), including** signed agreement by local PI and lead PI as per HREC SoPs on reciprocal reviews
2. Approval letter from Primary REC/HREC of record		2. Approval letter from Primary REC/HREC of record
3. Primary REC/HREC of record Review Report (if available)		3. Primary REC/HREC of record Review Report (if available to PI)
4. Site-specific Protocol Synopsis – **2 Pages** (if the submission pertains to a multi-site study kindly ensure synopsis is site-specific)		4. Site-specific Protocol Synopsis – **2 Pages** (if the submission pertains to a multi-site study kindly ensure synopsis is site-specific)
5. Site-specific local Research Protocol - **Clean copy** (In the case of multi-site studies this needs to pertain specifically to the site for which SU HREC approval is sought; the main protocol/sponsor protocol can be uploaded as supporting documentation)		5. Site-specific Research Protocol – **Clean copy** (in the case of multi-site studies this needs to pertain specifically to the site for which SU HREC approval is sought)
Appendices (as applicable)		*Appendices (as applicable)*
6. Site-specific Consent and assent forms (English versions) with a statement in site specific protocol regarding translations into local languages, where applicable		6. Site-specific Consent and assent forms (English versions) with a statement in site specific protocol regarding translations into local languages, where applicable
7. Recruitment materials (e.g., advert, flyer, poster)		7. Recruitment materials (adverts, flyers, posters)
8. Data collection tools (e.g., survey, questionnaire, interview guide)		8. Data collection tools (e.g., survey, questionnaire, interview guide)
9. Materials for participants (e.g., diaries, patient identification cards)		9. Materials for participants (e.g., diaries, patient identification cards)
10. Letters of authorisation from institutions (e.g., hospital, clinic, school)		10. Letters of authorisation from institutions (e.g., hospital, clinic, school)
11. Budget (and financial contract if external funding)		11. Budget (and financial contract if external funding)
12. 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)

13. Two-page CV for PI, **all investigators** listed on the application, and research supervisor		13. Two-page CV for PI, **all investigators** listed on the application, and research supervisor
14. Signed Investigator Declaration for PI, **all investigators** listed on the application and research supervisor		14. Signed Investigator Declaration for PI, **all investigators** listed on the application and research supervisor
15. Proof of GCP training for PI and **all investigators** listed on the application		15. HREC Reciprocal Payment instruction form and Proof of payment
16. Proof of trial insurance		16. Proof of insurance (where applicable)
17. HREC Reciprocal Payment Instruction Form and proof of payment		17. Approved Primary REC/HREC of Record documents • Main study Protocol • Main study consent/assent forms
18. Approved Primary REC/HREC of Record documents • Main study Protocol • Main study consent/assent forms		19. Reciprocal review agreement between Primary REC/HREC of Record (if available to PI)
19. Reciprocal review agreement between Primary REC/HREC of Record (if available to PI)		20. Other relevant documentation
20. Other relevant documentation		

POST SUBMISSION - HREC CONSIDERATION OF REQUEST FOR RECIPROCAL REVIEW:

- The HREC Chair will consider the application and the relevant reciprocal review documentation and decide on the most appropriate way forward. This may include:
  a. A fully-fledged local HREC full committee review depending on amongst other factors, the risk level of the project, impact on the local community etc. *or*
  b. An expedited or rapid HREC review (for example, in the time of Research in Emergencies) *or*
  c. Deferral of an expedited or rapid review to a full committee review.
- The outcome of the review will be communicated to the local SU investigator using standard HREC communication (HREC outcome letter).
- The Chair of the relevant HREC will report to the full HREC meeting the process and outcome of the reciprocal review for ratification.

OVERSIGHT OF STUDY

Whilst general oversight of the study remains the responsibility of the HREC of Record (Primary REC), the management and oversight of the local site remains the purview of SU HREC. The local PI is therefore responsible for reporting site-related matters to SU HREC. Such reporting will include, but is not limited to:

- Any adverse events
- Protocol amendments and deviations approved by the HREC of Record
- Amendments to recruitment materials and informed consent forms, data collection tools/materials etc.
- Submission of annual progress reports in respect of local site
- Submission of final study report or study termination report (where applicable).