



GUIDANCE FOR EXTERNAL APPLICANTS APPLYING FOR ETHICAL REVIEW BY THE HSRC RESEARCH ETHICS COMMITTEE (REC)

Provided there is no more suitable or eligible REC in South Africa and subject to certain terms and conditions, the HSRC's REC (which is registered with the SA DoH NHREC no REC-290808-015 and has US OHRP FWA accreditation FWA 00006347, IRB No. 00009534) ethically reviews external proposals submitted by researchers not employed by or contracted to the HSRC.

Before submitting your protocol, please check that it meets the following criteria:

1. *There is scholarly intent.* That is, you intend to publish the results in the academic literature. Audits or quality control surveys done purely for organisational reasons (e.g. internal performance audits not for publication) do not need ethics review.
2. *Human participants are involved.* That is, you are interviewing people or reviewing records that contain private information about people.
3. If your research is a desk study involving a review of published literature that is *all in the public domain* rather than engaging human participants, a fast-track exemption process is available. Please enquire prior to submitting an application if you think this route might be more suitable.

Conditions apply to applications for ethical review of external proposals:

1. **there is no more suitable or eligible REC in South Africa** (if your project team includes a South African academic who is not from the HSRC, your protocol may have to be reviewed by the REC associated with that person's academic institution unless reciprocity is granted to HSRC REC).
2. **the applicant's home institution must agree in writing to ethical review by the HSRC's REC** (approval to be solicited by the applicant);
3. **the HSRC's REC has the resources to take on occasional, additional work. The HSRC REC might decline requests depending on workload, capacity etc;**
4. **the application is submitted on current HSRC ethics application forms with full supporting documentation** (Please ensure that all parts of the application form are completed in full and that full protocols, consent forms and instruments are attached);
5. **the HSRC's REC levies a review management fee, payable on application, for reviewing external proposals. The review fee is revised annually.** Different amounts apply for grants and for commercially funded research. The REC administrator will advise on the current review fee.
6. **External applications must include the following, failing which an application will not be placed on the next meeting agenda:**

- a. TRREE Research Ethics Certificate (see <https://elearning.tree.org/>) for lead applicant and any co-investigators
 - b. Current CV for lead applicant and any co-investigators
 - c. Study instruments (questionnaires, In-depth Interviews or Focus Group Discussions schedules, etc.)
 - d. Information sheets and consent forms based on HSRC templates but without HSRC logos if external projects
 - e. Application form to be signed by applicant's line manager
 - f. Proof of host university ethics review (if a foreign student)
 - g. Proof of payment of review fee after the application has been vetted by the REC
7. **Any other points raised by REC members and the HSRC's CEO and executive must be taken into account.** *These include but are not limited to:*
- a. The HSRC REC cannot approve research conducted on human participants beyond our national jurisdiction. If the project involves countries other than South Africa, the applicant will need to seek concurrent ethics approval from RECs in the other host countries. Inventories of RECs in other countries in Africa are available on the internet; see [Health Research Web's](#) ethics section.
 - b. Research conducted on minors, and on some vulnerable populations, requires extra care and specific reference to legislative restrictions such as The Children's Act 38 of 2005 or The National Health Act 61 of 2003. See also <http://www.nhrec.org.za/index.php/grids-preview>.
 - c. Applicants are strongly advised to use and modify as required the HSRC sample generic information sheets and consent forms available at http://www.hsrb.ac.za/Corporate_Information-49.phtml. These contain all legally required elements for informed consent and must be adapted to purpose.
8. All applicants must be familiar with the HSRC ethics guidance (see <http://www.hsrb.ac.za/en/about/research-ethics/code-of-research-ethics>) and the South African Department of Health Research Ethics Guidance (DoH, 2015) available at <http://www.nhrec.org.za/index.php/grids-preview>