

GUIDANCE FOR EXTERNAL APPLICANTS APPLYING FOR ETHICAL REVIEW BY THE HSRC 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 and has US OHRP FWA accreditation FWA 00006347, IRB No. 00003962) 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 Audits or quality control surveys done purely for an organisational reasons (e.g. internal performance audits not for publication) does not need ethics review.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.

Certain 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 an academic who is not from the HSRC, your protocol will have to be reviewed by the REC associated with that person's academic institution);
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, and 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 Principal Investigator's CV must be attached to the application**
6. **the HSRC's REC levies a management fee for reviewing external proposals** (an amount of R2500 is applicable to grants and R7000 for commercially funded research).
7. **any other points raised by REC members and the HSRC's CEO and executive must be taken into account.** *This includes but is 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 ethical clearance from RECs in the other 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 Child Act or Health Act.

- c. Applicants are strongly advised to use and modify as required the HSRC sample generic information sheets and consent forms available at http://www.hsrc.ac.za/Corporate_Information-49.phtml
8. All applicants must be familiar with the HSRC ethics guidance and the South African Department of Health Ethics Guidance available at <http://www.doh.gov.za/docs/factsheets/guidelines/ethnics/index.html>

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