



Guidance Points for External Applicants Applying for Ethical Review by the HSRC Research Ethics Committee (REC)

NHREC registration no: REC-290808-015

OHRP registration details:

FWA No: 00006347

IRB: 00009534

1. Research conducted in South Africa poses unique and complex ethical challenges. Each country has different cultures, values, and socioeconomic contexts. It is crucial that researchers understand the local context in which research is being conducted.

2. **The HSRC REC expects an applicant to acknowledge and understand the following:**
 - a. For health or social science research to be conducted in South Africa, the study needs to receive ethical clearance from the National Health Research Ethics Council (NHREC) registered REC. In the case of international applicants, the researcher should obtain ethical approval from the home country prior to applying for ethical approval at the HSRC REC, noting that the HSRC REC cannot approve research conducted beyond the national jurisdiction.
 - b. If an application is a study for degree purposes, then ethics must first be approved by the host university before it comes to the HSRC REC.
 - c. The HSRC REC will, at the discretion of the chairperson accept for review, research protocols submitted to it by researchers from other institutions at a prescribed fee to cover administrative costs.
 - d. The research must be in line with the HREC Standard Operating Procedures which is available at https://www.hsrc.ac.za/uploads/pageContent/5498/HSRC%20SOP%20_2022.pdf?_ga=2.141665650.1149590686.1661355889.1814782318.1661355889&_gl=1*1cgn2zn*_ga*MTgxNDc4MjMxOC4xNjYxMzU1ODg5*_ga_8T91XDZ2CX*MTY2MTQxMjExNC4yLjEuMTY2MTQxMjQ0NS4wLjAuMA.. Researchers should be familiar with the legislation and other binding instruments relevant to research.
 - e. In terms of s2.3.8 of the NHREC Guidelines, “Researchers must be suitably qualified and technically competent to carry out the proposed research. The principal investigator (PI) or research leader has the primary responsibility to ensure the safety and well-being of participants, the scientific integrity of the protocol, and the responsible implementation of that protocol. For international multi-center research, at least one (co-) PI must be South Africa-based.”
 - f. For all postgraduate studies being conducted outside South Africa a co-supervisor from a recognised tertiary institution in South Africa is necessary.
 - g. The ethics application will proceed more smoothly and quickly if researchers clarify what they intend to do and clearly respond to the questions asked in the HSRC REC application form. Furthermore, while researchers may prefer their own consent forms, they need to ensure that they meet the minimum requirements of the HSRC Consent and study explanation form.

- h. All applicants should be familiar with the South African Department of Health (2015) *Ethics in Health Research: Principles, Processes & Structures* 2nd edition. See <https://www.sun.ac.za/english/faculty/healthsciences/rdsd/Documents/Ethics/DoH%202015%20Ethics%20in%20Health%20Research%20-%20Principles,%20Processes%20and%20Structures%202nd%20Ed.pdf>

3. 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.trree.org/>) for the lead applicant and any co-investigators.
- b. Current CV for the lead applicant and any co-investigators.
- c. Study instruments (questionnaires, In-depth Interviews or FocusGroup 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.

VERSION CONTROL

Version	Date	Author	Details
Version 1	May 2010	Ms Khutso Sithole and Professor Douglas Wassenaar	Approved by REC
Version 2	January 2018	Ms Khutso Sithole and Professor Theresa Rossouw	Approved by REC
Version 3	August 2022	Ms Khutso Sithole, Mbalenhle Mphake, and Professor Ames Dhai	Approved by REC