HSREC
Terms of Reference
&
Member
Code of Conduct

Health Sciences Research Ethics Committee

Version 01

03 December 2021

HEALTH SCIENCES
UFS

ABREVIATIONS

DOH	Department of Health
HSREC	Health Sciences Research Ethics Committee
FHS	Faculty of Health Sciences
NHA	National Health Act
NHREC	National Health Research Ethics Council
REC	Research Ethics Committee
RIMS	Research Information Management System
SOP	Standard Operating Procedure
SREC	Senate Research Ethics Committee
TOR	Terms of Reference
UFS	University of the Free State

1. TERMS OF REFERENCE

1.1 INTRODUCTION

1.1.1 The University of the Free State Faculty of Health Sciences Research Ethics Committee (UFS HSREC) is tasked with health research related ethical standard adherence.

1.1.2 Health Ethics Committees are registered by the National Health Research Ethics Council (NHREC) after an assessment of eligibility and compliance with the governing legal and ethical framework. The HSREC is nationally accredited by the NHREC as mandated by the National Health Act 61/2003 (NHA) with registration number REC-230408-011.

1.1.3 The HSREC Terms of Reference are aligned with the UFS Research Ethics Policy, the NHA and the Department of Health's 'Ethics in Health Research' Guidelines (March 2015).

1.2 PURPOSE

1.2.1 The purpose of the Terms of Reference is to describe the formal character of the committee as well as institutional and statutory requirements for the committee.

1.2.2 The TOR shall also determine the responsibilities of the HSREC, the HSREC relationship to non-affiliated researchers, the HSRECs accountability responsibilities, mechanisms for reporting as well as remuneration for members.

1.2.3 The purpose of the UFS HSREC is prescribed by section 73(2) of the NHA as to review research proposals and protocols in order to ensure that research conducted under the auspices of the relevant institution will promote health, contribute to the prevention of communicable or non-communicable diseases or disability or result in cures for communicable or non-communicable diseases; and grant approval for research by the relevant institution in instances where research proposals and protocol meet the ethical standards of that health research ethics committee. Section 73(2) finds application as:

1.2.4 The aim of the UFS HSREC is to ensure the safety, dignity, rights and well-being of all research participants and researchers involved in any health-related research undertaken by the UFS, its students and affiliates in accordance to the ethical principles of beneficence, non-maleficence, distributive justice and respect for persons

1.2.5 The objectives of the UFS HSREC are to protect human participants in research; acknowledge human rights in health research; maintain high ethical standards in health research; foster an awareness of ethical aspects in the health sciences and prevent impermissible research and research practices.

1.2.6 Note that the TOR should be read in conjunction with all the other SOPs of the HSREC as well as appropriate national and international guidelines.

1.3 CHARACTER OF THE HSREC

1.3.1 The HSREC of the Faculty of Health Sciences (UFS) must always be a NHREC registered committee.

1.3.2 See detail for HSREC composition and membership (SOP 01)

1.4 INSTITUTIONAL REQUIREMENTS

1.4.1 Members should be approved by the Faculty Board (Faculty of Health Sciences, UFS).

1.4.2 The HSREC reports to the Faculty Board (Faculty of Health Sciences, UFS) on administrative matters.

1.4.3 The HSREC shall report annually to the Faculty Board (Faculty of Health Sciences, UFS)

1.4.4 The HSREC should review all health and health-related research at the UFS.

1.5 STATUTORY REQUIREMENTS

1.5.1 The NHREC-registered RECs function within the legislative framework of Section 73 of the National Health Act No. 61 of 2003.

1.5.2 This Act requires that a University at which health and health-related research is conducted should have an NHREC-registered REC.

1.5.3 The HSREC is the single body vested with the explicit authority and legal accountability for the final determination regarding the ethical acceptability of protocols involving health and health-related research at the University of the Free State.

1.5.4 The main responsibility of the HSREC is to conduct rigorous ethics reviews of all health or health-related research protocols involving human participants to ensure that the welfare and other interests of participants and researchers are properly protected and that the research will be conducted in accordance with the required ethical norms and standards.

1.6 AUTHORITY

1.6.1 The UFS HSREC derives statutory authority from section 73(1) of the NHA which creates a legal mandate in terms of which all institutions, health agencies or health establishments at which health research is conducted, must establish or have access to a health research ethics committee, registered with the NHREC.

1.6.2 In terms of section 1 of the NHA, *health research* is defined as: any research which contributes to knowledge of- the biological, clinical, psychological or social processes in human beings; improved methods for the provision of health services; human pathology; causes of the diseases; the effects of the environment on the human body; the development or new application of pharmaceuticals, medicines and the development of new applications of health technology."

1.6.3 The UFS HSREC was established as a Faculty Committee of the University of the Free State (UFS) and derives its authority from the Faculty Management.

1.6.4 Administrative support is provided by the Faculty of Health Sciences.

1.6.5 In addition to section 73 of the NHA, the UFS HSREC derives power and is bound to the following sections of the NHA:

1.6.5.1 Section 71 which provides for research on or experimentation with human subjects

1.6.5.2 Section 72 which provides for the establishment of the NHREC.

1.6.6 The UFS HSREC is bound by section 12 of the Constitution of the Republic of South Africa, 1996 (the Constitution) which provides for bodily and psychological integrity of every person, which right includes to not be subjected to medical or scientific experiments without their informed consent.

1.6.7 The UFS HSREC is further bound to respect and protect the following rights as enshrined in the Constitution: equality – section 9; human dignity – section 10; life – section 11; privacy – section 14; freedom of religion, belief and opinion – section 15; freedom of expression – section 16; freedom of trade, occupation and profession – section 22; health care – section 27; children – section 28.

1.6.8 The UFS HSREC adheres to the guidelines and principles of the various relevant regulatory bodies connected to the field of health sciences.

1.6.9 In addition to the above, the UFS HSREC honours and respects current national and international ethical norms, standards and principles in compliance with, but not limited to, the following documents and guidelines:

1.6.9.1 Department of Health, 2015.

1.6.9.2 Ethics in Health Research: Principles, Processes and Structures. Department of Health: Pretoria, South Africa; Department of Health, 2006.

1.6.9.3 Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa. Department of Health: Pretoria, South Africa;

1.6.9.4 Declaration of Helsinki;

1.6.9.5 The Belmont Report;

1.6.9.6 The Singapore Statement on Research Integrity; H3Africa (2013).

1.6.9.7 Guidelines for Informed Consent. H3Africa Working Group on Ethics and Regulatory Issues for the Human Heredity and Health (H3Africa) Consortium; CIOMS (2002).

1.6.9.8 International Ethical Guidelines for Biomedical Research Involving Human Subjects. Council for International Organisations of Medical Sciences and WHO: Geneva;

1.6.9.9 ICH Harmonised Tripartite Guideline: Guideline for Good Clinical Practice E6 (R2) 2018;

1.6.9.10 ICH Harmonised Tripartite Guideline: Clinical Investigation of Medicinal Products in the Paediatric Population E11 2000;

1.6.9.11 The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite); Final Framework for African genomics and biobanking (2017);

1.6.9.12 Guidelines of the South African Health Products Regulatory Authority (SAHPRA) as well as Laws and Regulations with regard to the Control of Medicines.

1.7 SCOPE AND MANDATE

1.7.1 The UFS HSREC is mandated to fulfil its functions in accordance to the NHA as outlined in the Department of Health 'Ethics in Health Research' guidelines (2015). It reports annually to the National Research Ethics Council (NHREC) and to the University of the Free State Faculty of Health Faculty Board. The HSREC may be requested to report to the NHREC occasionally on specific matters.

1.7.2 The UFS HSREC founds all approval decisions on the ethical norms and standards of relevance and value, scientific integrity, role-player engagement, fair selection of participants, fair balance of risks and benefits, informed consent, ongoing respect for participants which includes privacy and confidentiality, researcher competence and expertise.

1.7.3 The HSREC shall use the document *Ethics in Health Research: Principles, Processes and* Structures (2015) as a minimum benchmark

1.7.4 The mandate of the UFS HSREC is the following:

1.7.4.1 Conduct rigorous prior ethical review of all health or health related research proposals to ensure that welfare and other interests of participants, and researchers are properly protected and that the proposed research is compliant with ethical norms and standards (retrospective review is not permitted);

1.7.4.2 Ensure that research proposals are scientifically sound and feasible;

1.7.4.3 Decide whether to approve, to require amendments or to reject the proposals for lack of compliance with scientific or ethics norms and standards; and

1.7.4.4 Ensure appropriate reporting occurs to fulfil the oversight obligation of the UFS HSREC to monitor welfare interests of participants.

1.7.5 The UFS HSREC may establish an Executive Committee (EXCO) to deal with matters arising between meetings, duly authorised by the full committee.

1.7.6 The UFS HSREC may establish sub-committees to deal with specific aspects of the work of the REC, including but not limited to undergraduate student ethics review applications. The subcommittee should be authorised to approve the applications and to report to the full committee to be noted.

1.7.7 The UFS HSREC must establish a Code of Conduct for its members that describes the responsibilities of members, a Confidentiality Agreement and a Conflict-of-Interest Declaration.

1.7.8 The UFS HSREC must ensure a transparent and inclusive recruitment and appointment process for members of the HSREC.

1.7.9 The UFS HSREC must establish Standard Operating Procedures (SOPs) that systematically describe all the processes and procedures involved in its work including its institutional arrangements and reporting obligations. It must ensure that the SOPs

are systematically reviewed every three to four years or more frequently as necessitated by research ethics changes.

1.7.10 The UFS HSREC must establish appropriate documentation, including but not limited to application forms, guidance documents, review guidance, information & consent document guidance as well as report templates amongst others, to facilitate appropriate processing of applications and to assist researchers to comply with requirements.

1.7.11 It is the responsibility of the HSREC to:

- **1.7.11.1** receive applications for ethics review from researchers via RIMS
- **1.7.11.2** consider applications at regular meetings
- **1.7.11.3** ensure that each review evaluates and maintains ethical and scientific standards to:
  - **1.7.11.3.1** protect participants from harm by weighing the risk of harm against the likelihood of benefit;
  - **1.7.11.3.2** ensure that harm to research participants is prevented or at least minimised and balanced against the likelihood of benefit
  - **1.7.11.3.3** promote health, contribute to prevention of communicable or non-communicable diseases or disability or result in cures or alleviation of suffering
  - **1.7.11.3.4** promote the highest scientific standards and best available techniques or approaches for optimal use of participants;
  - **1.7.11.3.5** hold researchers accountable for their research activities;
  - **1.7.11.3.6** promote important social and ethical values;
  - **1.7.11.3.7** always give precedence to the interest of the participant over the scientific interest of the research study;
  - **1.7.11.3.8** decide whether the proposed research study adequately protects the interests of participants and upholds exemplary standards
- **1.7.11.4** ensure that researchers who submit protocols have a proper understanding of research ethics as applicable to the specific research conducted
- **1.7.11.5** ensure that all applications are accompanied by a valid signed investigator declaration
- **1.7.11.6** minute discussions and decisions and communicate the HSREC decisions to applicants according to time lines;
- **1.7.11.7** provide ethics approval letters to researchers (valid for 1-year after date of issue)
- **1.7.11.8** consider and approve amendments to original approved research protocols;
- **1.7.11.9** manage a system that:
  - **1.7.11.9.1** follows up on projects that are in either “modifications required” or “conditional approval” status within 60 days of last communication with the investigators;
  - **1.7.11.9.2** follows up on approved projects that includes a reminder to researchers that continuation reports are due and to provide written approval for continuation of research activities upon receipt and approval of such continuation reports;
  - **1.7.11.9.3** follows up on and closes projects for which final notifications have been provided
- **1.7.11.10** ensure confidentiality of all information revealed to it
- **1.7.11.11** ensure that members of the HSREC function according to a code of conduct (below);
- **1.7.11.12** consider and act appropriately in cases of ethical misconduct by researchers;
- **1.7.11.13** report all ethical matters to the Vice-Dean Research, Transformation and Marketing via the HSREC office

1.8 RELATIONSHIP TO NON_AFFILIATED RESEARCHERS

1.8.1 The UFS HSREC reviews health or health related research proposals for members of the Faculty or elsewhere in the UFS.

1.8.2 Researchers with no affiliation to the UFS may approach the UFS HSREC to review research proposals.

1.8.3 The UFS HSREC may exercise its discretion on a case-by-case basis to decide whether to review the proposal or whether to refer the applicant elsewhere to access appropriate expertise and capacity to evaluate the application.

1.8.4 A fee may be levied for such a service.

1.9 RELATIONSHIP WITH AD HOC REVIEWERS, OBSERVERS, GUESTS AND NON-VOTING-MEMBERS

1.9.1 Consultants or ad hoc reviewers might, from time to time, be called upon to assist with research proposal reviews. The obligation to maintain confidentiality according to Faculty guidelines, should be made known to these reviewers, unless otherwise necessitated.

1.9.2 Observers or guests may attend committee meetings at the Chair's discretion or invitation.

1.9.3 Such persons have an interest in research ethics and the review process but are not committee members. Observers and guests must maintain confidentiality according to HSREC guidelines, regarding the business of the committee, unless otherwise necessitated.

1.9.4 All persons who attend HSREC meetings are free to make observations and ask questions but only HSREC members may vote on decisions. Anyone without a vote who disagrees with the resolution of the issues under discussion and/or the outcome of the vote should take the matter up with the Chair of the HSREC in the first instance. The Chair may call a special meeting to discuss the substance of the disagreement or to debate more fully issues raised in this way.

1.10 MECHANISMS FOR REMUNERATION

1.10.1 Any HSREC member who is appointed on the joint-staff establishment (Free State Department of Health and UFS) or who is on the payroll of the UFS shall not be remunerated for their services on the HSREC. This is in order to reduce conflict of interest and increase independence.

1.10.2 Laypeople and legal advisors who are not on the payroll of the UFS should view their services as part of service delivery to their community. However, they may be remunerated according to an honorarium negotiated before their appointment to compensate for time, inconvenience and expenses. The honorarium will only be paid if they are:

1.10.2.1 Not employed and may lose the opportunity to earn income in the period that they attend HSREC meetings;

1.10.2.2 Employed but have to work additional hours to their workday to serve on the HSREC;

1.10.2.3 In a private practice and their involvement in the HSREC will lead to a loss of income.

1.11 MECHANISMS FOR REPORTING

1.11.1 The HSREC, managed and supported by the Faculty of Health Sciences HSREC office functions directly under the Vice-Dean Research, Marketing and Transfusion of the Faculty of Health Sciences.

1.11.2 The HSREC Office consists of a Head of Administration and support staff members.

1.11.3 The HSREC works in close collaboration with the following stakeholders:

1.11.3.1 Research Committees of the Faculty of Health Sciences

1.11.3.2 Faculty structures involved with health-related research

1.11.3.3 The Faculty Management

1.11.3.4 The Faculty Board
1.11.3.5 General/Human Research Ethics Committee (GHREC)
1.11.3.6 Animal Research Ethics Committee (AREC)
1.11.3.7 Environmental and Bio-Safety Research Ethics Committee (EBREC)
1.11.3.8 Research Information Management System (RIMS) managers and administrators
1.11.3.9 Senate Research Ethics Committee
1.11.3.10 Vice-rector: Research, Innovation and Internationalisation
1.11.3.11 The Directorate of Research Development
1.11.3.12 Directorate for Institutional Research and Academic Planning
1.11.3.13 The Free State Department of Health
1.11.3.14 Director-Health System Research and Development (Free State Department of Health)
1.11.3.15 The National Health Research Ethics Council (NHREC)

1.11.4 The Faculty Management and Senate Research Ethics Committee (SREC) may from time to time perform internal audits on the HSREC in terms of their operational mandate, standard operating procedures, and where applicable, ratify the HSRECs decisions.

2. TERMINATION OF HSREC MEMBERSHIP

2.1 The validity of membership of the HSREC will be re-assessed if the member:
- 2.1.1 has failed to do any of the following on two occasions in a 6-month period:
  - 2.1.1.1 provide a rational reason for HSREC meeting non-attendance,
  - 2.1.1.2 refused to accept reviews,
  - 2.1.1.3 failed to timeously review accepted reviews
- 2.1.2 failed to produce documentation or certification required for a member to be a functional member of the HSREC despite being asked for the documents in writing three times over a three-month period

2.2 The membership re-assessment process that will be implemented are:
- 2.2.1 HSREC admin office will contact the member when any of the criteria mentioned above are met and require an explanation from the member. The member's response will be submitted to the Chair of the HSREC.

2.3 Failure to provide a rational explanation, or further HSREC meeting non-attendance, refusal to accept reviews, or failure to timeously review accepted reviews will automatically result in membership termination. The member will be notified in this regard by the HSREC chair.

3. CODE OF CONDUCT FOR HSREC MEMBERS:

3.1 Each member of the HSREC is obliged to abide by the essential purpose of a research ethics committee, which is to protect the dignity, rights, safety and well-being of all human participants in health and health-related research.

3.2 All Health Sciences Research Ethics Committee (HSREC) members of the University of the Free State have a fiduciary responsibility to serve the interests of the university and of the public in general. In accordance with UFS Conflict of Interest Policy, all decisions are to be made solely on the basis of a desire to promote the best interests of the university and the public and, in the case of research ethics-related matters, the interests of research participants and researchers must be protected.

3.3 Members of the HSREC are expected to:

- **3.3.1** agree to a term of office of three years;
- **3.3.2** familiarise themselves with the institutional policies and standard operating procedures as well as national and international research ethics guidelines;
- **3.3.3** acknowledge that HSREC meetings take priority over any other academic and administrative responsibilities;
- **3.3.4** keep up to date with national research ethics and regulatory guidance by attending ethics training sessions and reading;
- **3.3.5** to provide proof of such training at least once every three years;
- **3.3.6** contribute to ethics-related continuing education and training;
- **3.3.7** perform their official duties timeously and arrange their private affairs in a manner that will bear the closest public scrutiny; to act ethically and with integrity, within the law and always in manner that will withstand the closest public scrutiny in all realms of their professional, official, and private lives.

3.4 In carrying out their duties, members of the HSREC must:

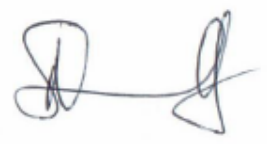
- **3.4.1** uphold ethical standards by fostering public confidence in the HSREC's ability to act in the public interest and in accordance to long term public good, to ensure that the integrity of the HSREC is maintained, and to promote the HSREC's objectives;
- **3.4.2** demonstrate integrity, honesty, good judgement and professionalism;
- **3.4.3** perform their duties to the HSREC diligently;
- **3.4.4** perform all responsibilities in compliance with national and international ethical and regulatory requirements;
- **3.4.5** make decisions in the interest of the HSREC, with a view to the public interest, and with regard to the merits of each case;
- **3.4.6** attend meetings punctually and on a regular basis and, as far as possible, to remain until the meeting is adjourned;
- **3.4.7** maintain confidentiality according to Faculty of Health Sciences HSREC guidelines, regarding research proposal or protocol information, reviews and decisions and all matters discussed at committee meetings, unless otherwise necessitated;
- **3.4.8** disclose all conflicting interests, including any personal involvement or participation in the research or in competing research, and, in the event of such a conflict with respect to a proposal, not to review the proposal and to recuse him or herself during the discussion and decision-making process;
- **3.4.9** serve as a reviewer of research proposals and protocols according to operational needs of the HSREC.
- **3.4.10** review independently, impartially, and objectively whether the proposed design and conduct of research is likely to protect participants' safety, rights and welfare.
- **3.4.11** present and discuss comments made regarding review of research proposals and protocols at HSREC meetings
- **3.4.12** use HSREC property of any kind, directly or indirectly, only for official approved HSREC activities.

3.5 All HSREC members are expected to sign the HSREC code of conduct for members annually at the first meeting of each calendar year.

4. REFERENCE DOCUMENTS

4.1 The National Health Act, No. 61 of 2003.
4.2 Regulations Relating to Research with Human Participants, 19 September 2014.
4.3 Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
4.4 The Declaration of Helsinki, 2013.
4.5 The Belmont Report, 1979.
4.6 The Singapore Statement on Research Integrity, 2010.
4.7 The Code of Federal Regulations of the USA (Title 45 Part 46).
4.8 The International Conference on Harmonization – Good Clinical Practice (ICH-GCP), 1997.
4.9 Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (Department of Health, 2006).

APPROVAL



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03 December 2021