

UNIVERSITY OF THE
FREE STATE
UNIVERSITEIT VAN DIE
VRYSTAAT
YUNIVESITHI YA
FREISTATA



| | | | | |
|---|--|---|------------|--|
| Policy Name/Title: University of the Free State Research Integrity and Ethics Policy | | | | |
| Policy Group(s): | Support Service Policies : Research | | | |
| Type: | Policy | X | Guideline | |
| Tick document category | Procedure | | Regulation | |
| UFS Statute and/or regulation reference number and date: | UFS Statute, Government Gazette, No 41399, 26 January 2018 UFS Statute, Government Gazette, No 42337, 29 January 2019 | | | |
| Relevant legislation and/or policy, codes of practice, professional authorities: | <ol style="list-style-type: none"> 1. Animal Diseases Act 35 of 1984 2. Animal Health Act 7 of 2002 3. Animal Protection Act 71 of 1962 4. Basic Conditions of Employment Act 75 of 1997 5. Cartagena Protocol on Biosafety, May 2000 6. Child Justice Act 75 of 2008 7. Children's Act 38 of 2005 8. Choice on Termination of Pregnancy Act 92 of 1996 9. Constitution of the Republic of South Africa, 1996 10. Convention on Biological Diversity 11. Criminal Law (Sexual Offences and Related Matters) Amendment Act 32 of 2007 12. Domestic Violence Act 116 of 1998 13. Employment Equity Act 55 of 1998 14. Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies Act 36 of 1947 15. Genetically Modified Organisms Act, Act No 15 of 1997 16. Hazardous Substances Act 15 of 1973 17. Health Professions Act 56 of 1974 18. Labour Relations Act 66 of 1995 19. Medical Schemes Act 131 of 1998 20. Medicines and Related Substances Control Act 101 of 1965 21. Mental Health Care Act 17 of 2002 22. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits (5) 23. National Environmental Management: Biodiversity Act 10 of 2004 24. National Health Laboratory Service Act 37 of 2000 | | | |

| | |
|---|---|
| | <ul style="list-style-type: none"> 25. Patents Act 57 of 1978 26. Performing Animals Protection Act 24 of 1935 27. Promotion of Access to Information Act 2 of 2000 28. Promotion of Equality and Prevention of Unfair Discrimination Act 4 of 2000 29. Protected Disclosures Act 26 of 2000 30. Protection of Personal Information Act 4 of 2013 31. Provincial Nature Conservation Acts or Ordinances 32. Rules Relating to the Practising of the Para-Veterinary Profession of Laboratory Animal Technologist, Department of Agriculture (1997) GN 1445 of 3 October 1997 33. Rules Relating to the Practising of the Profession of Veterinary Nurse, Department of Agriculture (1991) GN 1065 of 17 May 1991 34. Societies for the Prevention of Cruelty to Animals Act 169 of 1993 35. Sterilisation Act 44 of 1998 36. Veterinary and Para-veterinary Professions Act 19 of 1982 |
| Relevant institutional policies/manuals | <ul style="list-style-type: none"> 1. Department of Health (DoH), 2015: Ethics in Health Research – Principles, Processes and Structures 2. Singapore Statement on Research Integrity 3. The Norwegian National Research Ethics Committees, General Guidelines for Research Ethics (2014) and Guidelines for Research Ethics in the Social Sciences, Humanities, Law and Theology (2015) 4. South African National Standard: care and use of animals : SANS 10386: 2021 5. Policy on Preventing and Dealing with Academic Writing Misconduct 6. Policy on Research Data Management 7. Policy on Preventing and Dealing with Academic Writing Misconduct 8. Policy on the Protection, Exploitation and Commercialisation of Intellectual Property 9. University of the Free State: Research Strategy 2015 – 2022 (Updated January 2019) 10. Relevant Documents and Texts related to Research Ethics 11. Biosafety South Africa: Relevant Acts, Regulations & Guidelines |
| Consultation process To be verified and signed off before approval | |
| Status | Approved by Council as per Minute nr: 8.2.2 |
| Coordinating UMC owner | Senior Director: Research Development |
| Contact person | RIMS Project Manager and Research Ethics Adviser |
| Certification of due process: To be verified and signed once approved by the relevant authority | <div style="display: flex; justify-content: space-between;"> <div style="text-align: center;"> <u>Prof FW Petersen</u> Rector and Vice-Chancellor </div> <div style="text-align: center;"> <u>18 July 2022</u> Date </div> </div> |

| | | | | | |
|--|----------------------------|--------------------------|--|---|---|
| Approval date | To be inserted | Commencement date | To be inserted | Review date | To be inserted |
| | 24 June 2022 | | 24 June 2022 | | 24 June 2025 |
| REVISION HISTORY: Only applicable to amended or reviewed policies. Record details of amendments/revision. | | | | | |
| Version number | Approved/ Rescinded | Date | Approving Authority | Resolution Number (minutes number) | Date for next review (start date for review process) |
| V.1 | Approved | 18 June 2021 | Council | 9.2.4 | 18 June 2024 |
| | | | | | |
| | | | | | |
| For office use only | | | | | |
| Policy Group (broad policy field) | | | Academic Policies: Teaching and Learning, Research | | |
| Subject (policy subfield) | | | Policy | | |
| Reference Number | | | RES700/P/1.6/22.1 | | |
| Version Number | | | V.2 | | |
| Keywords for Search Engine: | | | Research, Integrity, Ethics, RES 700 | | |

| POLICY STATEMENT | |
|------------------------------------|---|
| 1. Preamble/ background | <p>1.1 Research is a fundamental cornerstone of the UFS's endeavour to become a leading research-led institution in South Africa, and an institution recognised worldwide for academic excellence.</p> <p>1.2 The overall aim of the Policy is to enhance ethical research practices in all aspects of research.</p> <p>1.3 The UFS is committed to intellectual freedom and research excellence, and, in pursuit of these goals, has established a research strategy and framework of policies and structures that govern and promote ethical research conduct at the university.</p> <p>1.4 The UFS research ethics framework acknowledges the multidisciplinary academic contexts and multiplicity of research contexts, and, various methodological approaches and practices, etc.</p> <p>1.5 This is an overarching document that outlines the standards and practices of responsible research conduct as it relates to various aspects of research integrity, including authorship practices, collaboration, conflict of interest and commitment, research misconduct, data management, mentoring, a research ethics code for research involving humans, a code for the use of animals in research and teaching and a code of conduct for environment and biosafety research.</p> <p>1.6 This overarching policy document describes requirements for ethical research in broad terms. Academic disciplines also maintain specific ethical frameworks, shaped by research contexts that are specific to them. It follows that each faculty can formulate discipline or research-stream specific position statements concerning how to implement the principles promoted in this overarching university policy.</p> |
| 2. Purpose | <p>2.1 The purpose of this Policy is to highlight the fundamental principles of research ethics and scientific integrity in research and related relationships, and to provide procedures to guide decision-makers or people who are engaged in, or affected by, research at the UFS.</p> <p>2.2 The Policy further establishes a procedural framework promoting the application of basic principles and values to conduct ethically sound research. The procedures instituted in pursuit of this Policy are intended to facilitate (not hinder) research, and to promote a culture within the UFS where researchers conscientiously reflect on ethical implications of their research.</p> |

| | |
|---|--|
| 3. Scope | <p>3.1 The policy framework relates to ethics in research but also largely to Research Integrity. For the purposes of this Policy, the term ‘researcher’ includes members of the UFS in academic research fields and non- academic research fields, contract researchers, and postgraduate and undergraduate researchers. It also relates to external researchers who wish to conduct research activities at the UFS.</p> <p>3.2 All research conducted under the auspices of the UFS is bound by the principles stipulated in this Policy, irrespective of whether the researchers are employees, students, or visiting researchers at the UFS. This is applicable regardless of the source of their funding, the field in which the research is conducted, or the site where the research is conducted.</p> <p>3.3 Researchers have responsibilities to society at large, those who fund their research, the institutions that employ them or at which they study, their colleagues and wider academic and research community, the people who take part in their research, and themselves (i.e., their own safety and well-being). Reconciling these responsibilities can be difficult and may require ethical judgement. The intention of this policy statement is to provide a framework to assist staff and students in exercising such judgement.</p> |
| 4. Definitions and abbreviations | <p>Terms as indicated in DoH, 2015: Ethics in Health Research: Principles, Processes and Structures, if not stated otherwise.</p> <p>Academic freedom – the collective freedom of researchers, including students, to conduct research and to disseminate ideas or findings without religious, political, or institutional restrictions; it includes freedom of inquiry and freedom to challenge conventional thought. Academic freedom does not mean freedom to ignore ethical issues.</p> <p>AREC – Animal Research Ethics Committee registered by the NHREC as Interfaculty Animal Ethics Committee (IAEC)</p> <p>Biosafety – the application of safety precautions to reduce the risk of exposure to a potentially dangerous and infectious material and to limit contamination of the environment and ultimately the community. (ASSAf, 2018. Proceedings Report)</p> <p>Collaborative research – involves co-operation of research, institutions, organisations, or communities, each contributing distinct expertise, characterised by respectful relationships.</p> <p>Community – a group of people with a shared identity or interest that has the capacity to act or express itself as a collective; it may be territorial, organisational or a community of interest.</p> <p>Confidentiality – the responsibility to protect information entrusted to researchers for research purposes from unauthorised access, use, disclosure, modification, loss of theft.</p> |

| | |
|--|--|
| | <p>Conflict of interest – incompatibility of duties, responsibilities, or interests (personal or professional) of a person or an institution as regards ethical conduct of research so that one cannot fulfilled without compromising another.</p> <p>Consent – indication of agreement to participate in research, based on adequate knowledge and understanding of relevant information, and freely given</p> <p>EBREC – Environment and Biosafety Ethics Committee</p> <p>Environmental Ethics – Environmental ethics is a branch of applied philosophy that studies the conceptual foundations of environmental values as well as more concrete issues surrounding societal attitudes, actions, and policies to protect and sustain biodiversity and ecological systems.</p> <p>Environmental Research Ethics - Environmentally sensitive and protected areas provide benchmarks for research. Research in turn provides information for the conservation, Management and understanding of these areas. It is important to sustain this interdependent relationship between protected areas and science. At the same time, we must acknowledge community values and the need for the research approval process to be efficient and transparent. (ASTEC, 1998: Environmental Research Ethics)</p> <p>Ethics review – review of research proposals or protocols by RECs prior to commencement of the research.</p> <p>GHREC – General / Human Research Ethics Committee</p> <p>Harm – anything that has a negative effect on participants' welfare, broadly construed; its nature may be physical, emotional, psychological, financial loss, social, or legal.</p> <p>Health research – contributes to knowledge of biological, clinical, psychological, or social welfare matters including processes; causes and effects of and responses to diseases; effects of environment on humans; methods to improve health care delivery; new pharmaceuticals, medicines, interventions and devices; new technologies to improve health and health care.</p> <p>HSREC – Health Sciences Research Ethics Committee</p> <p>Identifiable information – reasonably expected to identify an individual alone or in combination with other information.</p> <p>Low risk research – where the only foreseeable risk is one of discomfort and is referred to as 'negligible risk' in some guidelines</p> <p>Laboratory biosafety – The containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents and toxins, or their accidental release (WHO, 2004 and European Commission for Standardisation, 2008)</p> |
|--|--|

| | |
|------------------------------|--|
| | <p>Minimal risk research – where probability and magnitude of possible harms implied by participation are no greater than those posed by daily life in a stable society or routine medical, dental, educational, or psychological tests or examinations.</p> <p>Observational research – study of behavior in a natural environment where people involved in their usual activities are observed with or without their knowledge; observational research also occurs in clinical research e.g., when a researcher observes individuals or measures particular outcomes, without intervention, e.g., no treatment is given;</p> <p>an observational study describes a wide range of study designs including prospective and retrospective cohort studies, case-control studies, and cross-sectional studies, a defining feature of which is that any intervention studied is determined by clinical practice and not the protocol.</p> <p>Protocol – document that provides background, rationale and objectives of research; describes its design, methodology, organization and conditions under which it is to be conducted and managed.</p> <p>Qualitative research – involves studies use of empirical materials such as case studies, personal experience, life stories, interviews, observations and cultural texts.</p> <p>Repository – a collection, storage and distribution system for human biological materials for research purposes including blood, urine, faeces, bone marrow, cell aspirates, diagnostic specimens, pathology specimens and so on. Usually demographic and medical information about the donors is included in the repository as are codes that link the material to the donors.</p> <p>Research – includes a range of activities conducted by many different disciplines that may use different methodologies and explanatory frameworks to extend knowledge through disciplined inquiry or systematic investigation.</p> <p>Research project – refers to any project that parties may undertake that involves research or teaching activities, and in respect of which a researcher will submit a research proposal in order to obtain ethical clearance to undertake such research. This includes, but is not limited to, any publication pursuant to the research activities conducted.</p> <p>Risk – function of the magnitude of harm and the probability that it will occur.</p> <p>Vulnerability – diminished ability to fully safeguard one's own interests in the context of a specific research project; may be caused by limited capacity or limited access to social goods like rights, opportunities and power.</p> |
| 5. Guiding principles | <p>5.1 Codes, guidelines, and standards governing research ethics and scientific integrity</p> |

| | |
|--|---|
| | <p>5.1.1 The UFS endorses the Singapore Statement on Research Integrity of 2010, which is an internationally accepted statement that promotes four core principles and fourteen responsibilities. (Annexure A: http://www.singaporestatement.org). The UFS also acknowledges the importance of recognising human research participants' agency, as reflected in the Norwegian National Research Ethics Committee 2014 and 2015 research ethics guidelines (Annexure B: https://www.etikkom.no/en/ethical-guidelines-for-research/general-guidelines-for-research-ethics/).</p> <p>Nationally, the Department of Health's (DoH) Ethics in Health Research: Principles, Processes and Structures (2015) is the leading document for research ethics in South Africa, and the UFS recognises this document as providing national guidelines for conducting research responsibly and ethically within the South African context.</p> <p>5.1.2 The UFS also recognises the South African National Standard (SANS) 10386 guide containing principles and regulations for animal welfare in research (Annexure C: SANS 10386).</p> <p>5.1.3 The Environment and Biosafety Committee (EBREC) complies with the principles and norms of the NIH (National Institute of Health in the USA). EBREC is a NIH registered committee.</p> <p>5.1.4 The UFS recognises the Cartagena Protocol on Biosafety, an international agreement that aims to ensure the safe handling, transport and use of living and genetically modified organisms (LMOs & GMOs) that may have adverse effects on biological diversity. This UN initiative is legally binding and in 2010, the Nagoya-Kuala Lumpur Supplementary Protocol supplemented it.</p> <p>5.1.5 In addition to the above guidelines, researchers are expected to observe the norms and standards, legislation and guidelines specific to their particular field of research, and ensure compliance.</p> <p>5.2 Fundamental principles of research ethics and research integrity</p> <p>Research integrity refers to the commitment to the trustworthiness of the research process by the scientific community. It requires active adherence to ethical principles and professional standards essential for the responsible practice of research. Active adherence means the adoption of principles and practices as personal credo, not simply accepting them as impositions by policy-makers.</p> <p>Research integrity requires honesty, accountability, and professional courtesy in promoting fair, transparent, and ethical research conduct.</p> |
|--|---|

| | |
|--|--|
| | <p>5.2.1 Avoidance of research misconduct: Any form of academic dishonesty will be considered a serious offence. (Annexure D: The Policy on Preventing and Dealing with Academic Writing Misconduct was approved by Senate in 2018.)</p> <p>5.2.2 A scientifically sound study design and methodology is important for research integrity and reliability of data. Research proposals benefit from scientific review by experts.</p> <p>5.2.3 Data management: The integrity of research depends on integrity in all aspects of data management, including collection, use, storage, sharing, protection, and archiving. (Annexure E: Policy on Research Data Management)</p> <p>5.2.4 Open access to stored data / Data sharing and open access: The sharing of data and results produced by research is recognised as an essential part of the research process. A key imperative in research is how to achieve a balance between maintaining respect for individual autonomy and ensuring that society benefits from research findings, when applicable.</p> <p>5.2.5 Data ownership and rights to data: In practice <i>both the principal investigator and the university have responsibilities</i> regarding access, usage and maintenance of original research data, notwithstanding that the UFS is the custodian of the research data. (Annexure F: Policy on the Protection, Exploitation and Commercialisation of Intellectual Property.)</p> <p>5.2.6 Collaboration: The multi-disciplinary nature of research requires the cooperation of different researchers in different disciplines and/or institutions. The UFS supports responsible inter-faculty, national and international collaborations, including collaborative partnerships with communities. Researchers should formalise their research collaborations with a memorandum of understanding' at the start of a collaboration. Collaboration agreements are finalized at the institutional level through the Directorate of Research Development (DRD).</p> <p>5.2.7 Academic freedom and dissemination of research results: The UFS supports the principle of academic and intellectual freedom. Researchers have an obligation to report research results accurately and transparently in the public domain (and, where applicable, to the target group of the study). Funders or other stakeholders should not influence the research publications. The ethics committee (in the case of sensitive or harmful results) must consider the dissemination of results versus moratoriums on the dissemination of certain data.</p> <p>5.2.8 Authorship: Researchers are expected to make a reasonable effort to publish the results of their research in some form of recognised academic media. Authorship credit should be</p> |
|--|--|

| | |
|--|--|
| | <p>based on substantial contributions to conception and design, acquisition or analysis and interpretation of data, drafting the article or revising it critically for important intellectual content, and final approval for publishing. Authors should meet all the above conditions. Acquisition of funding, administrative relationship to the researcher, collection of data or general supervision of the research team alone do not justify authorship. The UFS endorses the guidelines on authorship by the International Committee of Medical Journal Editors.</p> <p>5.2.9 Mentorship: Proper mentoring is an ethical issue as it determines the quality of the research, minimises research misconduct, minimises harm to research participants and promotes capacity building. Mentors/supervisors are expected to provide proper mentoring to students with clearly outlined responsibilities for both mentors and mentees. Issues with publication and authorship are best discussed at the onset of research. Mentors or supervisors should apply the principles of authorship cited above to publications of research where a student has made a significant contribution.</p> <p>5.2.10 Conflict of interest and commitment: Conflict of interest occurs when professional judgement regarding a primary interest, e.g., research, welfare of research participants and validity of research, is unduly influenced by another interest, e.g., financial gain or personal status, relationships, or academic competition. All researchers are expected to declare and manage conflict or potential/perceived conflict of interest at all times. Researchers must familiarise themselves and comply with the UFS Policy on Conflict of Interest.</p> <p>5.2.11 Ethics review and approval of research: It is the responsibility of all researchers (including students) to ensure that they obtain ethics approval before their empirical data collection commences. The UFS has established four independent research ethics committees to review, approve, and monitor research. Details of these committees and their standard operating procedures are available on the university website.</p> <p>5.3 Research involving human participants</p> <p>5.3.1 All research as well as teaching practices with a clear research component, involving human participants, at the UFS must be reviewed and approved by a research ethics committee registered with the National Health Research Ethics Council (NHREC). In this regard, the Policy outlines the broad principles underpinning research that informs the norms and standards in all research disciplines that involve human participants. Best practice, standards, discipline- and paradigm-specific ethical frameworks and expectations that may exist in the different disciplines must be considered. However, the moral standards by which we judge the acceptability of planned research do not differ. The following principles are, therefore, relevant to all research disciplines</p> |
|--|--|

| | |
|--|---|
| | <p>involving human participants:</p> <p>5.3.2 Respect for people (dignity and autonomy): It requires that people are always treated with respect and permitted to exercise self-determination.</p> <p>5.3.3 Protection of research participants: The UFS recognises that dignity, well-being and safety interests of all participants are of primary concern in research. The process of informed consent should show both comprehension and voluntariness. A researcher should observe additional requirements for the protection of vulnerable groups.</p> <p>5.3.4 Beneficence and non-maleficence (do no harm): It is an ethical obligation to minimise risk of harm. A risk assessment of harm based on severity, probability, and magnitude of harm should provide evidence that harm posed by research is reasonable in light of the anticipated benefits. Harm comprehensively includes physical, psychological, reputational and financial harm.</p> <p>5.3.5 Distributive justice (equity): There should be a fair balance of burdens and benefits of research among all role-players, including participants and participating communities. A researcher should therefore provide adequate justification for selection of a particular segment of the population.</p> <p>5.4 Human Health Research – Health Sciences Research Ethics Committee (HSREC) - All health sciences research requires the approval of the Health Sciences Research Ethics Committee (HSREC) before it commences. This includes health-related research involving:</p> <p>5.4.1 Any direct interaction with or observation of human participants;</p> <p>5.4.2 The use of potentially identifiable personal health records, information or tissue specimens; and/or</p> <p>5.4.3 Human progenitor or stem cells or cell lines.</p> <p>5.5 Social, behavioural and educational research – General Human Research Ethics Committee (GHREC) - Research involving interaction with or observation of humans, or information linked to humans, groups of individuals or organisations must go through a process of ethical screening and clearance. Investigators are responsible for ensuring that they obtain ethical approval for their research.</p> <p>Teaching practice only requires ethical clearance if there is a clear research component involved. If an investigator, a supervisor, lecturer or student is unsure whether ethics approval is required, they can obtain clarification from the Research Ethics Office at the Directorate of Research Development.</p> |
|--|---|

| | |
|-----|---|
| | <p>All research ethics reviews must comply with the principles indicated in the DoH's 2015 Ethics in Health Research document.</p> |
| 5.6 | <p>Research involving animals – Animal Research Ethics Committee (AREC). Registered at the NHREC as Interfaculty Animal Ethics Committee (IAEC) - The use of animals in scientific research can only be justified if the benefits to both humans and/or animals outweigh the potential harm to the animal subjects. The Animal Research Ethics Committee must approve all research and teaching involving animals before the research commences so that a formal evaluation of the potential harm/benefit equation can be undertaken. The latest South African National Standard (SANS) 10386: 2021 for the Care and Use of Animals for Scientific Purposes and the South African Medical Research Council's Guidelines on Ethics for Medical Research provide the minimum benchmark to ensure ethical and humane care of animals used for scientific purposes and teaching activities.</p> <p>International and foreign codes for animal research include the Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes and the Australian Code for the Care and Use of Animals for Scientific Purposes (8th Edition) 2013.</p> <p>All animal research conducted under the auspices of the UFS should uphold the following fundamental "five R" principles for humane animal research:</p> <p>5.6.1 Replacement of animals, wherever possible, with 'non-sentient' research models or systems in order to eliminate the use of animals that can experience unpleasant sensations.</p> <p>5.6.2 Reduction of animals in experiments by design strategies that facilitate the use of the smallest number that will allow valid information to be obtained from the study.</p> <p>5.6.3 Refinement of animal sourcing, animal care practices and experimental procedures to eliminate physical and psychological distress within limitations imposed by the objectives of the research.</p> <p>In addition, the following two principles should be considered:</p> <p>5.6.4 Relevance: Animal-based teaching and research must address an important question relevant to the advancement of knowledge, education, science, and human and animal welfare through research.</p> <p>5.6.5 Responsibility: It is the responsibility of everyone using animals for research and education purposes to ensure that the animals are afforded the highest levels of welfare and</p> |

| | |
|----------------------------|--|
| | <p>protection from abuse.</p> <p>5.7 Research involving environmental and biosafety concerns – Environment and Biosafety Research Ethics Committee (EBREC)</p> <p>5.7.1 It is becoming generally accepted that the traditional anthropocentric approach to the environment is no longer valid and that the principles of environmental ethics and biosafety should be an integral part of the planning and execution of research and teaching, which may affect the environment. Therefore, the UFS should, in accordance with the recommendation of the Rio Declaration on Biosafety, review and oversee all research, teaching and testing activities utilising biohazardous materials, recombinant DNA, genetically modified organisms (GMOs), nanomaterials and any other sample for which a permit is needed for collection of the sample. It includes thus any action that could exert a negative impact on the biological, physical, or spatial environment. All researchers undertaking such research must submit research protocols for ethical review and approval in accordance with the governing policies and rules of the UFS.</p> <p>5.7.2 In order to realise the above-mentioned approach to environmental and biosafety research ethics, the following two core principles are applied to govern ethical research in this regard.</p> <p>5.7.2.1 The principle of precaution</p> <p>5.7.2.2 The principle of proportionality</p> <p>In addition to the application of the above principles and norms, researchers and parties engaging in any research activities should be familiar with all applicable and relevant legislation and other binding instruments</p> |
| 6. Policy/procedure | <p>6.1 In keeping with the emphasis on excellence in research, the UFS has a research strategy to ensure excellence and impact through transformative research. This is a framework to promote ethical research conduct and integrity in research and related relationships.</p> <p>6.2 The UFS confirms the requirement that research must undergo ethical clearance. This includes projects for teaching and learning with a clear research component, where the research involves human participants or animal use, or projects that involve the use of biohazardous materials and projects that can have an impact.</p> <p>6.3 The administrative offices, Health Sciences Research Ethics Office and the Research Ethics Office at the Directorate Research Development (DRD), work collaboratively with the</p> |

| | |
|--------------------------|--|
| | <p>respective research ethics committees and individual researchers under the auspices of the Senate Research Ethics Committee to promote responsible research conduct and, in particular, foster ethics in research.</p> <p>6.4 The Senate Research Ethics Committee (SREC) establishes/provides the appropriate structures, resources and training opportunities to ensure that the principles, norms and standards captured in this Policy are realised.</p> <p>6.5 All individuals involved in research, must assume direct and primary responsibility for the intellectual and ethical quality of their research activities and academic work. Where guidelines and legislation are published by scientific and professional associations or by other relevant professional bodies, statutory councils and government institutions, the UFS expects all researchers to ensure that they are familiar and comply with applicable norms, policies and legislation.</p> <p>6.6 By upholding the highest ethical standards, the UFS can build public support for the pursuit of scientific knowledge garnered in an ethically sound research environment. Such an environment encompasses a great emphasis on ethics in research, which is why it is essential to obtain ethical clearance for all research projects at the UFS. Pursuant to the aforementioned, the UFS prioritises the refinement of ethical guidelines and the establishment of research ethics committees, such as the Senate Research Ethics Committee (“SREC”) and specialised RECs.</p> <p>6.7 The UFS is of the view that good science assumes ethical accountability according to nationally and internationally accepted norms, and that the responsibility for this lies with every person conducting research under the auspices of the UFS.</p> <p>6.8 All staff and students are expected to act ethically when engaging in any research conduct affiliated with the UFS. Any research involving animals, human participants, the environment, human tissue or the collection of data on individuals requires ethical clearance. This includes creative research in the arts.</p> <p>6.9 The UFS aligns its activities to ensure that transformation is promoted in research through a process of understanding and reconciliation, which includes adherence to the highest ethical standards and avoiding an environment of distrust and segregation within the participating communities.</p> |
| 7. Responsibility | <p>NHREC: Registration Body for RECs and REC audits. Sets the norms and standards for health and health related research involving humans and animals, as well as for conducting clinical trials. Determines the guidelines to facilitate the best practices for RECs</p> <p>DRD: Custodian of the Policy</p> |

| | |
|--|--|
| | <p>Provide the system and processes to support Research Ethics at the UFS. Provide updates on legislative requirements. Manage research and ethics information. Provide annual reporting to Management</p> <p>SREC: Institutional Governance Body over research ethics; processes and structures</p> <p>RECs: HSREC, GHREC, IAEC/AREC & EBREC review research applications and handles research ethics related complaints</p> <p>Faculties: HODs, Supervisors and Researchers to ensure well-formulated research applications</p> <p>Other: Research Ethics Administrators, University Meeting Administration Department, Faculty Representatives, Chairs of the Ethics Committees</p> |
|--|--|

| | |
|---|---|
| 8. Accountability and Authority: | |
| 8.1 Implementation: | DRD, SREC , HSREC, GHREC, IAEC (AREC) and EBREC |
| 8.2 Compliance: | DRD, SREC , HSREC, GHREC, IAEC (AREC) and EBREC Researchers, Students, Research Administrators |
| 8.3 Monitoring and evaluation: | Vice Rector: Research and Internationalisation Senior Director: Research and Development |
| 8.4 Development/review: | DRD and SREC. |
| 8.5 Approval authority: | Council |
| 8.6 Interpretation and advice: | NHREC; DRD and RECs |

| | |
|---|--|
| 9. Who should know this policy? | |
| Anybody involved in any form of data collection and research at the UFS | |

| | |
|---|--|
| 10. Policy/procedure implementation plan | <p>10.1. At the UFS, research ethics are coordinated by the SREC and managed by specific interfaculty RECs. The SREC is mandated by the Senate to provide broad leadership on research ethics and ensure the effective functioning of individual RECs. The SREC has Senate-delegated responsibility for developing, monitoring, and maintaining all UFS research ethics procedures and research ethics committees.</p> <p>10.2. The SREC acts as an advisory and governance structure. The committee reports to the Senate and its operations are determined by its Terms of Reference and Standard Operating Procedures.</p> <p>10.3. The Research Ethics Offices at DRD and Health Sciences work collaboratively with research ethics committees, as well as individual researchers, under the auspices of the SREC, to promote responsible conduct of research and, in particular, foster ethics in research.</p> |
| 11. Resources required | 11.1 Training Workshops |

| | |
|----------------------------|---|
| 12. Answers to FAQs | |
| | List questions asked by participants in the development of the policy. Provide answers that will help direct action within the relevant departments. |
| | |

| EFFECTIVENESS OF THE POLICY | |
|------------------------------------|--|
| Performance Indicator(s): | To be completed on review by the person responsible for implementation, monitoring and evaluation. |

UNIVERSITY OF THE
FREE STATE
UNIVERSITEIT VAN DIE
VRYSTAAT
YUNIVESITHI YA
FREISTATA



Policy Name/Title: University of the Free State Research Integrity and Ethics Policy

Policy Group(s): Support Service Policies : Research

Type:

Tick document category

Policy

Guideline

Plan

X

Standard

Procedure

Regulation

Remit

SOP

**UFS Statute and/or
regulation reference
number and date:**

UFS Statute, Government Gazette, No 41399, 26 January 2018
UFS Statute, Government Gazette, No 42337, 29 January 2019

**Relevant legislation
and/or policy, codes of
practice, professional
authorities:**

1. Animal Diseases Act 35 of 1984
2. Animal Health Act 7 of 2002
3. Animal Protection Act 71 of 1962
4. Basic Conditions of Employment Act 75 of 1997
5. Cartagena Protocol on Biosafety, May 2000
6. Child Justice Act 75 of 2008
7. Children's Act 38 of 2005
8. Choice on Termination of Pregnancy Act 92 of 1996
9. Constitution of the Republic of South Africa, 1996
10. Convention on Biological Diversity
11. Criminal Law (Sexual Offences and Related Matters) Amendment Act 32 of 2007
12. Domestic Violence Act 116 of 1998
13. Employment Equity Act 55 of 1998
14. Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies Act 36 of 1947
15. Genetically Modified Organisms Act, Act No 15 of 1997
16. Hazardous Substances Act 15 of 1973
17. Health Professions Act 56 of 1974
18. Labour Relations Act 66 of 1995
19. Medical Schemes Act 131 of 1998
20. Medicines and Related Substances Control Act 101 of 1965
21. Mental Health Care Act 17 of 2002
22. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits (5)
23. National Environmental Management: Biodiversity Act 10 of 2004
24. National Health Laboratory Service Act 37 of 2000
25. Patents Act 57 of 1978
26. Performing Animals Protection Act 24 of 1935

| | |
|--|--|
| | <ul style="list-style-type: none"> 27. Promotion of Access to Information Act 2 of 2000 28. Promotion of Equality and Prevention of Unfair Discrimination Act 4 of 2000 29. Protected Disclosures Act 26 of 2000 30. Protection of Personal Information Act 4 of 2013 31. Provincial Nature Conservation Acts or Ordinances 32. Rules Relating to the Practising of the Para-Veterinary Profession of Laboratory Animal Technologist, Department of Agriculture (1997) GN 1445 of 3 October 1997 33. Rules Relating to the Practising of the Profession of Veterinary Nurse, Department of Agriculture (1991) GN 1065 of 17 May 1991 34. Societies for the Prevention of Cruelty to Animals Act 169 of 1993 35. Sterilisation Act 44 of 1998 36. Veterinary and Para-veterinary Professions Act 19 of 1982 |
| Relevant institutional policies/manuals | <ul style="list-style-type: none"> 1. Department of Health (DoH), 2015: Ethics in Health Research – Principles, Processes and Structures 2. Singapore Statement on Research Integrity 3. The Norwegian National Research Ethics Committees, General Guidelines for Research Ethics (2014) and Guidelines for Research Ethics in the Social Sciences, Humanities, Law and Theology (2015) 4. SANS 10386 5. Policy on Preventing and Dealing with Academic Writing Misconduct 6. Policy on Research Data Management 7. Policy on Preventing and Dealing with Academic Writing Misconduct 8. Policy on the Protection, Exploitation and Commercialisation of Intellectual Property 9. University of the Free State: Research Strategy 2015 – 2022 (Updated January 2019) 10. Relevant Documents and Texts related to Research Ethics 11. Biosafety South Africa: Relevant Acts, Regulations & Guidelines |
| Consultation process To be verified and signed off before approval | |
| Status | Approved by Council as per Minute nr: 8.2 |
| Coordinating UMC Owner | Senior Director: Research Development |
| Contact person | RIMS Project Manager and Research Ethics Adviser |

| Implementation Plan | | |
|------------------------------------|-----|---|
| 1. Preamble/ background | 1.1 | This is an overarching document that outlines the standards and practices of responsible research conduct as it relates to various aspects of research integrity, including authorship practices, collaboration, conflict of interest and commitment, research misconduct, data management, mentoring, a research ethics code for research involving humans, a code for the use of animals in research and teaching and a code of conduct for environment and biosafety research. |
| | 1.2 | This overarching policy document describes requirements for ethical research in broad terms. Disciplines also maintain specific ethical frameworks shaped by research contexts that are specific to any given discipline. It follows that each faculty should formulate discipline or research-stream specific position statements concerning how to implement the principles promoted in this overarching university policy. |
| 2. Purpose | 2.1 | The policy on responsible research conduct is not intended to restrict or discourage research at the UFS, but on the contrary, the policy aims to inform the researcher of his/her responsibility in the conduct of ethical research and to understand and promote adherence to all applicable procedures and to protect the rights of all stakeholders. |
| 3. The Work plan | 3.1 | At the UFS, research ethics are coordinated by the SREC and managed by specific interfaculty RECs. |
| | 3.2 | The SREC is mandated by the Senate to provide broad leadership on research ethics and ensure the effective functioning of individual RECs. The SREC has Senate- delegated responsibility for developing, monitoring, and maintaining all UFS research ethics procedures and research ethics committees. |
| | 3.3 | The SREC acts as an advisory and governance structure. The committee reports to the Senate and its operations are determined by its Terms of Reference and Standard Operating Procedures. |
| | 3.4 | In principle, the SREC at the UFS recognizes reciprocity of ethics review. It acknowledges that ethics approval obtained from a NHREC- registered committee (NHREC-registered committees must adhere to the same stringent criteria) will be accepted by the UFS. However, the UFS RECs may conduct an expedited review of the research ethics application, or a full review should there be ethical concerns. |
| | 3.5 | The detailed Management of research ethics relevant to the circumstances of the specific research environment will be managed by the specialised interfaculty RECs as indicated. |
| | 3.6 | The Research Ethics Offices at DRD and Health Sciences work collaboratively with research ethics committees and individual |

| | |
|--|--|
| | <p>researchers, under the auspices of the SREC, to promote responsible conduct of research and, in particular, foster ethics in research.</p> <p>3.7 Failure to review the ethical implications of research or comply with any other aspect of this policy, or failure to apply reasonable care in assessing the likely ethical implications of a research project, may constitute research misconduct according to the UFS research misconduct policy and procedures.</p> |
| 4. Identify stakeholders (people or groups) | 4.1 All parties that are engaging and are involving in any research activities undertaken at the UFS. |
| 5. Indicate current and needed levels of commitment | <p>5.1 The policy should be communicated through the different available university channels to every person involved in research activities to explain and emphasise the importance.</p> <p>5.2 It needs to be integrated into the UFS practices and need an enforcement backup plan.</p> |
| 6. Potential reasons for resistance and mitigating strategies | <p>6.1 Researchers have the fundamental right to academic freedom and freedom of scientific research, but it is the researcher's responsibility to ensure that no research is undertaken without ethical clearance from an applicable REC. Researchers may be reluctant to comply with all aspects of the policy, based on different research methodological approaches.</p> <p>6.2 This policy provides mitigating strategies to enforce ethical conduct of research. This policy is an overarching document providing broad statements and concepts that support ethical conduct of research. Various disciplines can adopt the key principles and provide additional guidance aligned to the norms and standards in their discipline. Researchers should be competent and accountable and should act responsibly and strive to achieve the highest possible level of excellence, integrity, and scientific quality in their research.</p> <p>6.3 Researchers have a right, as well as an obligation, to refrain from undertaking or continuing any research that contradicts the policy violates the integrity and/or validity of research and/or compromises their autonomy in research.</p> |
| 7. Stakeholder engagement | 7.1 A meaningful and enforceable research ethics policy, linked to systemic practices and procedures, based on legislation and ethical guidelines and backed up by management and ethics committees, as well as high-level commitment and ongoing training, is essential for all research engagement. |
| 8. Communication of policy | <p>8.1 The UFS sets out to make this policy accessible and available to all parties engaging in research and any third parties affected by research activities undertaken at the UFS.</p> <p>8.2 The policy needs to be embedded into the university's culture and should be a 'living' document to guide and create ethical</p> |

| | | |
|---|---|--|
| | | behaviour in all research activities. This will happen through communication and training, monitoring, auditing and reporting. |
| 9. Resources and budget | <p>9.1 Research ethics committees need trained reviewers and funding to support their operations. The policy provides for appropriate fees when reviewing external ethical applications. RECs should receive training on the international and local ethical and legal standards governing research and the standard operating processes of the REC. Training is necessary for members to understand terminology and research methodology sufficient to participate in the committee's discussions intelligently. Good knowledge of the social and cultural context is also essential. Training should not be a single occurrence but instead should be an ongoing process in which all committee members participate.</p> <p>9.2 Some committees may need to undergo a formal accreditation process with national or international organisations. Other oversight mechanisms include regional or national meetings to exchange information about best practices or partnerships between committees from different countries. These activities require funding.</p> <p>9.3 Committee might need to conduct active monitoring by sending representatives to study sites to see if the committee's guidance to investigators is being followed.</p> | |
| 10. Strategies for successful implementation of policy/guideline | 10.1 The DRD will be responsible for guiding, communicating, and training the research community about the policy. Explain the importance of the policy. Reinforce ethical behaviour. Strengthen the moral compass. Identify and deal with ethical dilemmas and provide guidance on how to implement the policy more effectively. Different ways will be used, such as workshops, group discussions, a helpline to assist everybody involved in research activities. | |
| 11. Risk assessment | <p>11.1 The policy provides for different factors in research such as social risk, legal risk, economic harm, reputational risk and health and safety risk. The potential hazards and risk in research can be many and varied. The policy assists to identify whether existing resources and facilities are adequate to ensure risk control.</p> <p>11.2 Each REC should do risk assessment of research as part of the evaluation process.</p> | |
| 12. Monitoring and evaluation of the | <p>12.1 Effective implementation requires ethical leadership and support, training, continuous reinforcement, and updates to keep the policy current.</p> <p>12.2 Ongoing administration and the reinforcement of standards to stimulate ethical action and encourage compliance also to be aware of the actions as stipulated in the policy regarding unethical and unacceptable research behaviour.</p> | |

STANDARD OPERATING PROCEDURE OF THE SENATE RESEARCH ETHICS COMMITTEE

1. BACKGROUND

The establishment and operation of the Senate Research Ethics Committee (SREC) is guided by various framework documents that have been approved by the Senate of the UFS. These framework documents include but are not limited to the following, and should be read in conjunction with one another if the context so requires:

- 1.1 Policy pertaining to the responsible conduct of research at the UFS (“Policy”)
- 1.2 Terms of Reference for the SREC (“TOR”)
- 1.3 The Standard Operating Procedures for the SREC (“SOP”)

Guidelines and procedures applicable to all researches are contained in the Policy document, which is easily accessible and available to any party engaging in research activities.

2. THE SOP AND FRAMEWORK FOR GOVERNANCE OF ETHICAL RESEARCH CONDUCT AT THE UFS

- 2.1 The SREC serves as the governing body for all research ethics committees (RECs), as stipulated in the TOR of the SREC.
- 2.2 As the governing body responsible for oversight, the SREC does not review research proposals and does not, therefore, have the authority to issue ethical clearance numbers in respect of research proposals submitted to RECs. The RECs have the mandate to review all research proposals, and, if all standards are met, the REC may approve proposals with or without additional conditions.

- 2.3 In accordance with international ethical research codes and regulations as well as South African legislation, all research to be conducted must be reviewed and approved by research ethics committees registered with the National Health Research Ethics Council. This does not apply to the Environmental and Biosafety Research Ethics Committee (EBREC), which is registered with the National Institute of Health (NIH) in the USA. The NIH registration takes place in accordance with international environmental and biosafety research codes and regulations.
- 2.4 The NIH registration takes place in accordance with international environmental and biosafety research codes and regulations.
- 2.5 A research-specific approach, as opposed to a faculty-specific approach, is followed by RECs, and therefore, be regarded as interfaculty committees of the UFS.

3. PURPOSE OF THE SOP

- 3.1 The UFS aims to create an environment for researchers that allows for freedom of inquiry, academic competitiveness, creativity, and sound ethical research that meets national and international ethical norms and standards.
- 3.2 The purpose of this SOP is to guide the activities of the SREC in a systematic and consistent manner. This applies especially to the governing and coordination of ethics-related activities and principles in research and related structures to ensure compliance with applicable national and international standards.

4. STRUCTURAL PROCEDURES OF THE SREC AND THE RECS

- 4.1 Research ethics are governed by the SREC and managed by the RECs.
- 4.2 The individual RECs report directly to the SREC.
- 4.3 The SREC reports to the Executive Committee of the Senate when necessary.

5. PROCEDURES OVERSEEN BY THE SREC

5.1 Procedure to lodge an appeal

- 5.1.1 Researchers will be entitled to appeal decisions made by the RECs following the RECs SOPs for appeal, or voice any concerns about the administrative processes of the relevant REC.
- 5.1.2 The principal investigator must submit the appeal to the chairperson of the SREC.
- 5.1.3 The chairperson requests nominations for two suitably qualified independent and/or external reviewers from the SREC and asks the administrator of the Central Research Ethics Office to start the online appeal process. The two independent reviewers and make recommendations online.
- 5.1.4 The SREC makes the final decision, taking into account the reviewers' recommendations.
- 5.1.5 A final decision can be made by means of an SREC member vote.
- 5.1.6 After the final decision, no further decisions or discussions will be allowed. The chairperson of the SREC communicates the outcome of the appeal to the complainant in writing.

5.2 Complaints brought against RECs by complainants

- 5.2.1 In the event that the SREC receives complaints about the review processes of the RECs (concerning, for example, the manner in which researchers and their research projects have been considered and dealt with, the rejection or delayed consideration of a research proposal, or any other relevant matter), the Central Research Ethics Office will attempt to facilitate communication between the RECs and the relevant parties in an attempt to settle the complaint without formal investigation, if possible. Should this fail, the aforementioned complaint(s) shall be considered as a formal complaint lodged with the SREC.
- 5.2.2 SREC procedure on how to deal with a formal complaint:
 - 5.2.2.1 The SREC will ascertain whether there has been adequate communication between the complainant and the REC and that all relevant RECs SOPs have been followed.
 - 5.2.2.2 The chairperson of the SREC may convene a meeting between the complainant and the Chair of the REC if the complainant is not anonymous. The chairperson of the SREC may invite members of the SREC and/or an expert in the subject under discussion to the meeting.

5.2.2.3 The SREC may also consult relevant academic structures, e.g. heads of departments, heads of schools, deans, etc., if necessary.

5.2.2.4 The SREC will inform the complainant about the outcome of the deliberations and possible recommendations. The complainant will also be informed of the possibility of escalating the complaints to the NHREC should he/she find the outcome of deliberations by the SREC unsatisfactory.

5.3 Procedures for the investigation of complaints in respect of the conduct of an initially approved research project

5.3.1 In instances where a study is conducted after initial ethical clearance was granted by any of the RECs, but a complaint reveals that further investigation and review will be required, the following procedure is recommended:

5.3.1.1 Invite the principal researcher and other relevant parties or colleagues of the researcher, if applicable, to a meeting with the SREC and provide them with the opportunity to tender reasons as to why the research project should not be discontinued or why ethical clearance should not be withdrawn.

5.3.1.2 Reconsider the initial research proposal and offer the principal researcher the opportunity to provide further information about the research that is being conducted.

5.3.1.3 The SREC will, upon conclusion of the investigation as indicated above, arrive at a final decision, which may either revise or corroborate the ethical clearance that was initially granted for the research project. This decision may include any of the following:

5.3.1.3.1 The withdrawal of approval, resulting in the suspension of the research project.

5.3.1.3.2 Setting out amendments to be made to the original research proposal or the conduct of the research.

5.3.1.3.3 Allow the research project to continue without any amendments. The ethical clearance remains unchanged.

5.3.1.3.4 The SREC will inform the principal researcher and the REC in writing of the

decision of the SREC and will explain the reasons for any recommendations.

5.3.1.3.5 In certain instances, it may be necessary to inform research participants that the research they have been participating in has been modified or discontinued.

5.3.1.3.6 It is the responsibility of the principal investigator to send a notification to inform the research participants of any new developments, and to send proof of such notifications to the Central Research Ethics Office.

5.4 Suspension of a research study

5.4.1 The SREC, under the guidance of its chairperson, will issue an urgent response if there is the possibility of harm to researchers, participants or any other person.

5.4.2 In extreme circumstances, an immediate demand to suspend a study may be necessary while concerns are being adequately investigated. In other cases, prompt action may be required to rectify or remove the cause of concern. The SREC will oversee the process to ensure that steps are taken in accordance with the procedures as prescribed in (DoH 2015: 4.5.11).

5.4.3 Having determined the urgency of the need for action, the chairperson, in consultation with members of the SREC, should take any, and possibly all, of the following steps in accordance with the circumstances present in respect of each complaint:

5.4.3.1 Compile a clear record, which fully sets out the origin and nature of the complaint.

5.4.3.2 Lodge an enquiry in order to collect further information from all parties involved.

5.4.3.3 Convene an urgent meeting of the SREC, if necessary.

5.4.3.4 Confer with the highest level of management and authority at the UFS, if necessary.

5.5 Procedure pertaining to the handling of complaints and allegations of serious research misconduct.

5.5.1 The following may be reported to the SREC: complaints and concerns about the manner in which researchers conduct research or fulfil their responsibilities; questions about culpability for misconduct and misleading reports published by researchers; and allegations of misconduct or fraud.

5.5.2 The following actions constitute serious research misconduct:

5.5.2.1 The fabrication, falsification and plagiarism of any research, or any kind of deception in proposing, carrying out, or reporting the results of any research.

5.5.2.2 Deliberate, dangerous, or negligent deviations from accepted practice in carrying out research. This includes the failure to follow approved protocols, resulting in unreasonable risk or harm to participants, animals or the environment, and also the facilitating of misconduct through collusion in or concealment of such actions by others.

5.5.2.3 Failure to obtain informed consent from all research participants.

5.5.2.4 Any breach of confidentiality as the context may require.

5.5.2.5 Participating in deceptive research which is not in line with the DOH 2015 guide on deceptive research (***DOH 2015: 3.4.5 – Research involving deception or withholding information***)

5.5.2.6 Misrepresentation or falsification of credentials.

5.5.2.7 It is specifically recorded that misconduct does not include honest error or honest differences in the design, execution, interpretation, judgment and/or evaluation of research methods, or misconduct (including gross misconduct) unrelated to the research process.

5.5.3 In the event that the SREC receives a complaint or an allegation amounting to serious misconduct as indicated in the UFS Policy for Ethical Research Conduct, the SREC and, therefore, the UFS should ensure the following:

5.5.3.1 That all research participants receive extensive protection.

5.5.3.2 That the particulars linked to a complaint or an allegation shall be kept confidential should it prove to be without any grounds.

5.5.3.3 That whistle-blowers receive appropriate protection and anonymity, if so required, according to the whistleblowing policy of the UFS.

5.5.3.4 That appropriate action is taken in respect of those who are the subject of any complaints or allegations.

5.5.3.5 That the confidentiality and protection of complainants and justice for the person being accused of serious misconduct will be ensured by applying the following

review process:

5.5.3.5.1 Determine whether the allegation falls within the ambit of scientific misconduct

5.5.3.5.2 Determine whether there is prima facie evidence of scientific misconduct

5.5.3.5.3 Institute a formal investigation to evaluate all relevant facts to determine whether scientific misconduct has been committed and if so, by whom, as well as the degree of the misconduct. The integrity of the research data must be evaluated, and all appropriate groups advised if inaccurate, misleading or invalid data has been published or submitted to funding bodies or other agencies such as NRF.

5.5.4 Any party, such as researchers, UFS staff, or other third parties, may address a complaint to the SREC.

5.5.5 Complaints will be handled promptly and sensitively, with due regard to the specific nature of such complaints. These complaints may concern technical deviations from approved protocols or allegations of scientific misconduct or fraud, among other things.

5.5.6 Complaints should be submitted directly to the chairperson of the SREC if not resolved at REC level.

5.5.7 The SREC, under the guidance of its chairperson, will attend to the complaint. This may include consideration of the original protocol, contact with researchers, and contact with the complainant.

5.5.8 Depending on the nature and complexity of the complaint, the chairperson may table the complaint at the next SREC meeting, or proactively take action.

5.5.9 In the event that complaints are actionable, steps may be taken. This could include the implementation of a full-scale investigation, if so warranted. The chairperson may delegate to a member of the SREC or external body/persons the responsibility to further investigate the complaint.

5.5.10 In the event that consideration of complaints requires independent assistance, the SREC may approach or appoint applicable persons to assist.

5.5.11 The chairperson will consider the recommendations of the investigating person/committee and inform the complainant about the outcome of the investigation.

- 5.5.12 A report will be issued at the next committee meeting of the SREC, and complaints as well as outcomes will be discussed and recorded in the committee meeting minutes of the SREC.

6. CONFLICT OF INTEREST

- 6.1 A conflict of interest may arise when committee members' private or personal interests and professional obligations diverge to such an extent that an independent observer may regard it as possible that personal, financial or other considerations could influence professional actions.
- 6.2 Any conflict of interests should be avoided, and any potential conflict of interests must be disclosed.
- 6.3 Procedure for dealing with a conflict of interest:
- 6.3.1 Members of the SREC should make decisions and fulfil their oversight-related responsibilities in an independent manner, free from bias and undue influence.
- 6.3.2 Members who have a conflict of interest related to any research protocols or issues to be considered should refrain from participating in the discussion. This recusal will be minuted.
- 6.3.3 If the conflict of interest involves the chairperson, the vice-chairperson will act as the chairperson for the remainder of the discussion of the item/issue in question. This will be minuted.

7. CONFIDENTIALITY

Senate Research Ethics Committee members and support staff sign a standard confidentiality and non-disclosure agreement upon appointment.

8. FEES TO BE CHARGED FOR THE REVIEW OF RESEARCH PROPOSALS SUBMITTED FOR ETHICS APPROVAL BY EXTERNAL BODIES

- 8.1 The SREC, with the approval of the Senate of the UFS, will levy a schedule of fees for the review of external research proposals from entities other than academic

institutions. The fees received should be paid into a cost center of the university and may be used for expenses related to the operation of the RECs, continuous professional development, or specific ethics training.

- 8.2 RECs that depend on external funding for their operations cannot function independently; it is a conflict of interest. If a fee is charged, it should be paid into a 'Central Ethics Fund', which can be used for staff development and committee-related functions.
- 8.3 Academic institutions that do not have their own RECs may enter into an agreement with the UFS for an ethics review of research projects.
- 8.4 All staff and students registered at the UFS will be exempt from paying the fees as outlined above.

9. MEETING PROCEDURES AND DECISION-MAKING

- 9.1 Standard meeting procedures will apply.
- 9.2 The committee shall meet at least once per quarter.
- 9.3 The University Secretariat administers the meeting.
- 9.4 Members of the committee shall be reminded about the next meeting at least two weeks before the meeting date, and they will be advised to submit items for the agenda.
- 9.5 The meeting agenda and other applicable documents shall be circulated to members at least one week in advance of a scheduled meeting.
- 9.6 The meeting is quorate if at least 50% plus one of the members are present.
- 9.7 The committee may appoint individuals or task teams to attend to special assignments.
- 9.8 The chairperson of the SREC may call an extraordinary or emergency meeting, if necessary
- 9.9 The chairperson may invite field experts who are not committee members in an advisory capacity to attend meetings. These individuals may participate in discussions but they may not vote.
- 9.10 A quarterly report is submitted to the Senate for noting, ratification or consideration of matters.
- 9.11 All members have one vote, except the chairperson, who has a casting vote.
- 9.12 Decision-making is primarily based on the principle of consensus and/or sufficient consensus.

- 9.13 If consensus cannot be reached, a motion is put to the vote, and it is carried if a simple majority vote of those present at the meeting has been obtained.
- 9.14 The chairperson has on any matter, a deliberative vote and, in the event of inequality of votes a casting vote.
- 9.15 A yearly report is submitted to the Senate for noting, ratification or consideration of matters of the different RECs.

UNIVERSITY OF THE
FREE STATE
UNIVERSITEIT VAN DIE
VRYSTAAT
YUNIVESITHI YA
FREISTATA



| | |
|---------------------------------|--|
| Document name: | Senate Research Ethics Committee Terms of Reference |
| Co-ordinating Rectorate member: | Vice-Rector: Research and Internationalisation |
| Recommended by: | Senate Research Ethics Committee : 17 May 2022 |
| Approved by: | Senate : 24 May 2022 Council: 24 June 2022 |
| Implementation date: | Date of approval by Council: 24 June 2022 |

INTRODUCTION

The Terms of Reference of the UFS Senate Research Ethics Committee (SREC) are aligned with the university's Policy on Research Ethics. The National Health Act, 63 of 2003, requires that institutions establish RECs, and that research projects undergo prior ethics review by a research ethics committee registered with the National Health Research Council (NHREC).

The SREC is the structure that governs the establishment and functioning of RECs as well as their continued registration with the NHREC.

1. SREC ESTABLISHMENT AND STATUS

The Senate Research Ethics Committee (SREC) is an independent body established as a standing committee of the Senate in terms of Section 32 of Higher Education Act 101 of 1997 (Institutional Statute: University of the Free State).

The **SREC** is the advisory and governing committee of research ethics.

2. SREC OBJECTIVES AND FUNCTIONING

- 2.1 The SREC's general functions are to advise the Senate on issues pertaining to research, finalise matters related to research ethics on behalf of the Senate, and govern and coordinate ethical research and research ethics committees. The jurisdiction and functioning of the SREC are determined in accordance with these Terms of Reference as well as the Standard Operating Procedures (SOPs) approved and adopted by the Senate.
- 2.2 The SREC contributes towards promoting the university's reputation as a research-driven institution and an important role-player in research, and it ensures that research development opportunities and possibilities are created and maintained.
- 2.3 One of the UFS's main objectives is to promote ethically sound research. In order to achieve and maintain this objective, strategies and structures should be implemented to ensure that:
 - 2.3.1 Ethical standards of practice in research conduct, as prescribed by the relevant acts, regulations, standards and guidelines applicable to the specific REC, are maintained.
 - 2.3.2 Research participants, the environment, animals, and researchers are protected from harm and exploitation.
 - 2.3.3 The research is sound and scientifically acceptable, and systems promoting and supporting research,

are in place.

2.3.4 Reassurance is provided to society that the above-mentioned objectives are observed and promoted.

2.4 The SREC's purposes include, but are not limited to:

2.4.1 Advising the Senate on research-related policy issues and issues pertaining to the general control function of the committee.

2.4.2 Ensuring the effective functioning and coordination of the RECs.

2.4.3 Acting as an advisory and governance structure of the RECs.

2.4.4 Acting as an appeal and advisory board tasked to hear complaints and issue recommendations.

2.5 The SREC coordinates ethical research while the implementation of the policy pertaining to ethical research ("**policy**") is facilitated by the relevant registered interfaculty Research Ethics Committee (**REC**). The committees are:

2.5.1 General Human Research (**GHREC**)

2.5.2 Health Sciences Research (**HSREC**)

2.5.3 Animal Research Ethics (**IAEC**)

2.5.4 Environment and Biosafety (**EBREC**)

2.6 The RECs will, in accordance with national and international research ethics codes and guidelines, review and approve or reject research proposals submitted by parties conducting research at the UFS, and monitor the ethical compliance of the research.

3. SREC AUTHORITY

3.1 The SREC, as mandated by the Senate of the UFS, has the authority to action the following:

3.1.1 Finalise and review the research policy and recommend approval thereof to the Senate

3.1.2 Develop, review and approve the relevant ethical guidelines of RECs in accordance with national and international regulations and norms and standards for ethically sound research.

3.1.3 Oversee the implementation of, and compliance with, the policy in all research activities undertaken at the UFS.

3.1.4 Decide on procedures where special ethical clearance is required, which may include research on a topic of a secret or criminal nature.

3.1.5 Oversee the establishment of the RECs and alter, when appropriate, their structure, composition

and functioning.

- 3.1.6 Draft and finalise procedures, according to acceptable norms and standards, for dealing with researchers' appeals regarding the review and determination of the ethical clearance of their research proposals by relevant RECs (REC appeal procedure).
- 3.1.7 Implement procedures, according to acceptable norms and standards, to facilitate whistleblowing.
- 3.1.8 Implement procedures, according to acceptable norms and standards, to deal with research misconduct, which will be outlined in the policy in order to ensure accessibility to all relevant parties.
- 3.1.9 Appoint standing or ad-hoc subcommittees to investigate certain matters under its jurisdiction, establish the functions and rights of such subcommittees, and advise on the execution thereof.
- 3.1.10 Implement procedures to monitor ethical aspects relating to all research activities.
- 3.1.11 Implement strategies to ensure that all procedures as indicated above have been implemented and are functional.
- 3.1.12 Remain abreast of all developments in the implementation of national and international guidelines on ethical research, and advise the Senate and senior management of the UFS accordingly.

4. SREC MEMBER COMPOSITION

Members of the SREC should have the appropriate qualifications and experience to evaluate the ethical aspects of research. The SREC membership should be independent, interfaculty-oriented and multidisciplinary.

4.1 The SREC is composed of the following members:

- 4.1.1 The Vice-Rector: Research and Internationalisation acts as the chair (ex officio).
 - 4.1.2 The Senior Director: Directorate of Research Development acts as the vice-chairperson (ex officio).
 - 4.1.3 Seven (7) members of the Senate (elected by the Senate), composed of:
 - 4.1.4 Two (2) members from the Humaniora (Faculties of the Humanities, Economic and Management Sciences, Education and Theology).
 - 4.1.4.1 Two(2) members from the Faculty of Natural and Agricultural Sciences.
 - 4.1.4.2 Two(2) members from the Faculty of Health Sciences
 - 4.1.4.3 One(1) member from the Faculty of Law
 - 4.1.5 The chairpersons from each of the respective RECs.
 - 4.1.6 A faculty-elected representative from each faculty.
 - 4.1.7 Additional ad-hoc members as required.
- 4.2 Membership of the SREC must represent the community it serves and reflect the demographic profile of the UFS staff and student body.
- 4.3 The SREC may seek assistance from experts where appropriate, but it must be satisfied that such experts

have no conflicts of interest in the matter under consideration.

- 4.4 The Senate appoints the SREC members. Members are required to sign a non-disclosure agreement to ensure that knowledge and information obtained by a SREC member remains confidential.
- 4.5 The appointed members must receive formal notice of appointment and assurance that the UFS will provide legal protection for any liability that might arise in the course of bona fide fulfilment of their duties as SREC members. In this regard, the UFS will obtain professional liability insurance to cover both affiliated and non-affiliated members in carrying out their functions and duties.
- 4.6 The SREC must ensure that both SREC and REC members receive initial and continued training in the evaluation of ethical research and that they are kept aware of current issues and developments in research ethics in general. Conversely, each SREC member is obliged to ensure that he/she remains adequately informed on all aspects of research ethics.

5 ELECTION PROCEDURE

The Registrar facilitates the election and nomination of qualifying members of the Senate.

6 OFFICE TERM

- 6.1 A member is appointed to serve a three-year term from the date of appointment.
- 6.2 Members may be re-elected at the end of a term, subject thereto that a member may not serve more than three (3) consecutive three-year terms.
- 6.3 A member of the SREC may resign and subsequently be replaced by the nominating entity to serve the remaining time of the vacancy created by the departing member.
- 6.4 The SREC may suspend or terminate someone's membership, if so decided by the SREC, due to the member's conduct or failure to attend three (3) consecutive scheduled meetings without tendering an apology or good reason for his/her absence.
- 6.5 A member who has resigned or whose membership has been terminated will be replaced by nomination and selection by the Senate.

7 MEETINGS AND REPORTING

- 7.1 The SREC will have four (4) scheduled general meetings per year.
- 7.2 The chairperson may schedule special meetings if needed.
- 7.3 All documents for discussion at a meeting must be submitted to the secretariat ten (10) working days before the scheduled meeting.
- 7.4 The secretariat will distribute the agenda of the meeting to all members at least seven (7) working days before the meeting.

- 7.5 The SREC will submit annual reports to the Council or Senate (as applicable) on the operations of the SREC and RECs.

8 COMMITTEE MEETING PROCEDURES

The SREC determines its own meeting procedure with due observance of the accepted norms of fair administrative process and generally accepted principles for conducting meetings.

9 DECISION-MAKING

- 9.1 Where consensus cannot be reached, the SREC takes a decision by at least 50% (FIFTY PERCENT) of the members present at a duly constituted meeting voting in favour of the matter at hand.
- 9.2 50% (FIFTY PERCENT) of the voting members of the SREC plus one (1) constitutes a quorum for purposes of decision-making.
- 9.3 Each member has one (1) vote, except the chairperson of the SREC who has a casting vote.
- 9.4 Observers or advisors to the SREC may not vote on any matter.
- 9.5 The secretariat may not vote on any matter.

10 SECRETARIAT

The university's Meeting Administration Department is responsible for secretarial services.

| | |
|----------------------------|---|
| Document Name | University of the Free State Research Integrity and Ethics policy |
| Document Version | Final Draft pending submission and approval |
| Coordinating UMC Members | Dr Glen Taylor |
| Policy Initiator/Custodian | Maricel van Rooyen |
| Status | Final Draft pending submission and approval |

| Stakeholders | Comments/Concerns | Date |
|---------------------------------|--|------|
| 2017 – 2018 – Development Phase | | |
| | Training session with Prof Anne Pope; Dr Mamello Sekhoacha; Dr Bert Mohr; Prof Braam Hoffmann | |
| | Discussions with National Institutions: SU, UCT, Wits, UP, UNISA, TUT | |
| | Discussions with International Institutions: Brown University (USA), NIH, UNESCO; Colorado University (Anschutz Medical Campus) System development Process development | |
| | Change from Faculty Committees to Independent University Committees as per national and international frameworks and rules assessment of other institutions Policies Draft documentation | |

| 2019 – Start with UFS Policy Documents | | |
|--|---|--|
| | Elna van Pletzen: Deputy Registrar: Governance | 4 April 2019 |
| | Phatshoane Henney Attorneys: Official consultation session May – December 2019 Several informal consultation sessions to assist during the development of the Policy | 24 April 2019 – 8:00 |
| | Prof Anne Pope: NHREC Chair UFS visit and formal consultations session | 23 Aug 2019 |
| | Online sessions | 3 Sept 2019 12 Sept 2019 |
| | USAF Engagement | 27 Sept 2019 |
| | Dr Mamello Sekhoacha: NHREC Vice Chair Several sessions and assistance with the development to ensure national compliance | 3,4 April 2019 10,26 June 2019 3,13,25 Sept 2019: 3,9,14,15,16,22,23 Oct 2019: 12,25,26 Nov 2019 2 Dec 2019 16 Jan 2020 Feb 2020 (Final Check) April 2022 Finalisation after audit report |
| | Ingrid Kluyts: Language Edited | 12 Dec 2019 |
| | Deans of all the Faculties notification | 28 July 2020 |
| | SREC Meetings/ Email / Round Robin Consultations SREC Members: SREC Meeting: SREC Meeting: SREC Meeting: SREC Meeting: Approved for Senate SREC Meeting: Final Round Robin email to all the SREC Members and Faculty Representatives | 25 June 2019 25 July 2019 24 Oct 2019 6 Feb 2020 23 July 2020 28 July 2020 |

| | | |
|--|---|---|
| | | |
| | <p>Tabled at Rectorate Meeting</p> <p>Recommended for Approval at Senate Meeting</p> | <p>12 Aug 2020</p> <p>18 Aug 2020</p> |
| | <p>Prof Heidi Hudson raised a concern at Senate Meeting. A new round of discussions with Humanities followed.</p> | <p>24 Aug 2020</p> <p>22 Nov 2020</p> <p>4 March 2021</p> <p>24 March 2021 – Final Feedback Meeting</p> |
| | <p>Prof Mamello Sekhoacha: Response and discussion to Humanities concerns</p> <p>Revision and final check</p> | <p>31 Aug 2020</p> <p>14 Sept 2020</p> <p>7 Oct 2020 (Prof Anne Pope advise)</p> <p>22 Oct 2020</p> <p>11 Nov 2020</p> <p>2, 5 and 9 Feb 2021</p> <p>Final check</p> |
| | <p>NHREC Audit Report with requested ratifications</p> | <p>17 March 2022</p> |
| | <p>Prof Mamello Sekhoacha: NHREC Chairperson</p> <p>Final feedback from NHREC Chair Prof Mamello Sekhoacha</p> <p>Final comments after the Audit Report and the NHREC Recommendations</p> <p>Policy Management and Template Assistance: Angelique Koeberg</p> | <p>April 2022: Finalisation after audit report</p> <p>21 April – 21 May 2021</p> |
| | <p>SREC Approval</p> <p>Ratification Approval</p> | <p>8 May 2021</p> <p>17 May 2022</p> |
| | <p>Senate Approval</p> <p>Final Senate Approval after ratification</p> | <p>1 June 2021</p> <p>May 2022</p> |