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Responsible Research Conduct at Stellenbosch University: Policy

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29 November 2022

Responsible Research Conduct at Stellenbosch University: Policy

Type of document:	Policy
Purpose:	To promote and ensure research integrity and ethical research conduct at Stellenbosch University
Approved by:	Council
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Validity:	The English version of this regulation is the operative version, and the Afrikaans version is the translation.

[1] Rules Owner: Head(s) of Responsibility Centre(s) in which the rules functions.
[2] Rules Curator: Administrative head of the division responsible for the implementation and maintenance of the rules

POLICY FOR RESPONSIBLE RESEARCH CONDUCT AT STELLENBOSCH UNIVERSITY

Document reference number	BEL-001E-2013
Purpose	To promote and ensure research integrity and ethical research conduct at Stellenbosch University
Type of document	Policy
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Revision history	V1 approved March 2009
	V2 approved by SU Council on 24 June 2013
Policy owner	Vice-Rector: Research, Innovation and Postgraduate Studies
Institutional curator of this policy	Senior Director: Research and Innovation, Division for Research Development
Responsible for policy development and revision	Senior Director: Research and Innovation, Division for Research Development
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Date of approval	SU Council: 28 November 2022
Approval by	SREC, Rector's Management Team, Stellenbosch University Council, Institutional Forum and Senate
Key terms	research ethics, research integrity, accountability, stewardship, supervision, mentoring, animal research, animal care, research ethics committee, human participant, environmental safety, biosafety

DESCRIPTION OF ANNEXURES PROVIDED IN SUPPORT OF THIS POLICY	
ANNEXURE 1	Singapore Statement on Research Integrity
ANNEXURE 2	Global Code of Conduct for Research in Resource-poor Settings
ANNEXURE 3	Organogram: structures supporting the promotion of responsible research at SU
ANNEXURE 4	Infographic: Ethics at SU - Navigating the ethics approval process
ANNEXURE 5	Authorization or registration with the South African Veterinary Council
ANNEXURE 6	Related SU policies, procedures, codes and guidelines
ANNEXURE 7	Key Texts: national and international research ethics and integrity guidelines, regulations and Acts

1. INTRODUCTION

Stellenbosch University (SU) is committed to applying the values of excellence, compassion, equity, respect and accountability in all its activities.[1] This includes, by definition, all the research conducted at the

[1] Stellenbosch University's Code 2040 (Code of Conduct)

University. This document serves as a broad policy framework, which must be interpreted in the context of the other relevant policy and procedural documents, referred to below. SU is of the view that good science assumes ethical accountability according to internationally acceptable norms and that the responsibility for this lies with every person conducting research under the auspices of SU.

2. APPLICATION OF THIS POLICY

This policy applies to all those conducting research under the auspices of Stellenbosch University, irrespective of whether they are employees, students or visiting researchers at the University and irrespective of the source of their funding, the field in which they conduct their research or the site where the research is conducted.

3. DEFINITIONS

3.1 **'Animal'** refers to a live, non-human vertebrate, including fertilized eggs, foetuses and embryos, i.e. fish, amphibians, reptiles, birds and mammals, and encompassing domestic animals, feral animals, purpose-bred animals, farm animals, wildlife and higher invertebrates, such as the advanced members from the Cephalopoda and Decapoda (for example, octopus, squid, cuttlefish) (SANS10386:2021)

3.2 **'Biological and environmental safety'** is the application of knowledge, techniques and equipment to prevent personal, laboratory and environmental exposure to potentially infectious or hazardous agents. Biosafety defines the ethically responsible handling and containment conditions under which infectious microorganisms and hazardous biological materials can be safely manipulated and disposed of.[2]

3.3 **'Data subject'** is any individual person who can be identified, directly or indirectly, via an identifier such as a name, an ID number, location data, or via factors specific to the person's physical, physiological, genetic, mental, economic, cultural or social identity. Data subjects may include but are not limited to: prospective students; applicants; students; alumni; research participants; employees; employment candidates; visitors; and members of the public (POPIA, 2013).

3.4 **'Health research'** includes but is not limited to research that contributes to knowledge of: biological, clinical, psychological, or social welfare matters including processes as regards humans; the causes and effects of and responses to disease; effects of the environment on humans; methods to improve health care service delivery; new pharmaceuticals, medicines, interventions and devices; new technologies to improve health and health care (NHA, 2003).

[2] SU's Policy for Responsible Research Conduct refers in this instance only to the handling and disposal of biological waste. It does not refer to the handling of hazards outside of biological hazards such as, radiation or radioactive waste disposal. These are dealt with separately under Occupational Health and Safety.

3.5 '**Human participant'** is generally a living person who voluntarily takes part in a research study where a researcher obtains data through intervention or interaction with the person or their identifiable information. However, where applicable this definition may be extended, for the purposes of this policy to include deceased persons or foetuses.

3.6 **'Personal information'** for the purposes of this policy is the same as the defined term in the Protection of Personal Information Act (2013).

3.7 **'Research'** is any systematic, scholarly and/or creative enquiry aimed at producing new and generalisable knowledge, new meaning or a deeper understanding of meaning.

3.8 **'Research data'** means recorded information, obtained during a research process, regardless of form or the media on which it may be recorded. The term includes computer software (computer programmes, databases and documentation thereof), and records of scientific or technical nature. The term does not include information incidental to research administration such as financial, administrative, cost or pricing, or management information. In practice scientific data include both intangible data (statistics, findings, conclusions) and tangible data. Tangible data include, but are not limited to notes, printouts, electronic storage, photographs, slides, negatives, films, scans, images, autoradiograms, electro-physical recordings, gels, blots, spectra, cell lines, reagents, modified organisms, specimens, consent forms, case report forms, collected organisms and other materials that are relevant to the research project.[3]

4. PURPOSE OF THE POLICY

The purpose of this policy framework is to establish the fundamental principles for the promotion of responsible conduct of all research undertaken at this university.

5. OBJECTIVES OF THE POLICY

The objective of this policy is to provide a framework for the promotion of scientific integrity and ethically responsible research at the University, and, amongst others:

5.1 To formally endorse the Singapore Statement of Research Integrity (see Annexure 1) and the Global Code of Conduct for Research in Resource-Poor Settings (see Annexure 2)

5.2 To establish principles and responsibilities for research with human participants, animal care and use for scientific purposes, and biological and environmental safety

5.3 To establish principles and responsibilities for research collaboration, supervision, mentorship and authorship

[3] Stellenbosch University Research Data Management Regulations (2021). Available at: http://www.sun.ac.za/english/research-innovation/Research-Development/policies-guidelines

5.4 To establish principles and responsibilities for data acquisition and management

5.5 To ensure compliance with this policy and other applicable legislation, research related norms, standards and regulations

5.6 To address other research related issues such as financial management, management of conflict of interest, intellectual property, research data management and the investigation of scientific misconduct, by referring to other relevant SU policy or procedural documents

This policy is published in support of the existing value system of Stellenbosch University as an ethically responsible institution.

6. FUNDAMENTAL PRINCIPLES OF RESEARCH ETHICS AND SCIENTIFIC INTEGRITY

6.1 Stellenbosch University endorses the Singapore Statement on Research Integrity[4] and the Global Code of Conduct for Research in Resource-Poor Settings[5]. The Singapore statement promotes four core principles and 14 responsibilities (see Annexure 1). The Global Code of Conduct promotes four core principles and 23 related articles (see Annexure 2).

In addition the following principles are also important:

6.2 Justice

The principle of justice ensures the fair distribution of both the burdens and benefits of research. Justice ensures the application of fairness and equity in the selection of research participants. This is of particular relevance when research involves vulnerable communities and individuals, such as children, prisoners, pregnant women, intellectually impaired persons, or economically or educationally disadvantaged persons. The application of justice also works to ensure equitable partnerships in research.

6.3 Academic freedom and dissemination of research data and findings

Stellenbosch University supports the principle of academic and intellectual freedom. Researchers have an obligation to report research results accurately and transparently in the public domain (also where appropriate to the target group of the study) and should not allow funders or other stakeholders to influence research publications and dissemination of research data and findings. Any specific or explicit decision to withhold or delay the publication of research results that is not in agreement with the contractual terms, e.g. because the publication of results could produce some harm or because of issues regarding patents or intellectual property and/or certain corporate claims, should be reviewed and accepted by the research ethics committee or research committee that originally approved the research or the Division for Research Development (DRD), whichever is most

[4] http://www.singaporestatement.org/
[5] http://www.globalcodeofconduct.org/

appropriate (see *Section 6.13 Embargo of sensitive dissertations and theses*, General Yearbook). DRD and the research ethics committee must balance the scientific imperative to disseminate research results and the placement of moratoriums on the dissemination of certain data in a number of cases, including but not limited to: (a) the case of sensitive or harmful results; (b) the case of research misconduct; and (c) the case of patents or intellectual property and/or corporate claims. DRD will liaise with appropriate internal stakeholders (such as InnovUS or Corporate Communication, etc.) as required by the specific case. DRD reviews and negotiates all research- and research related contracts and ensure that Stellenbosch University's academic and intellectual freedom is protected within the context of the specific research collaboration and research contract.

6.4 Ethics approval of research

It is the responsibility of all researchers (including students and supervisors) to ensure that they obtain ethics approval for their research, **prior** to the initiation of research activities, when required to do so by this policy, or by generally accepted norms and standards for ethical research. Stellenbosch University has established various research ethics committees to review, provide ethics approval and monitor research. Retrospective review and approval of research by RECs is not permitted.[6] Details of these committees and their standard operating procedures are provided at the end of this policy (see Annexures 3 and 4).

6.5 Respect for communities and individuals

Stellenbosch University expects both consultation with, and respect for, communities and individuals involved in research. There should be appropriate community consultation, for example, discussions with Community Advisory Boards (CABs) and/or other community representatives before, during and after the research; as well as adequate provisions to respect the autonomy of communities and individuals and to maintain the confidentiality and security of their data. By engaging, where practicable, non-academic stakeholders as partners as early as possible in the research process SU will advance the concept of knowledge exchange (KE), which could increase the visibility and accessibility of research outcomes. Communities and individual research participants should be informed of research results. Research participants must be informed of the intention to disseminate findings as part of the informed consent process.[7]

6.6 Responsibility for future science generations

The education of young scientists and scholars is a priority for Stellenbosch University and requires all researchers to provide leadership and acceptable standards for mentorship and supervision. This responsibility includes training in and adherence to ethical principles in research conduct, Codes of

[6] See South African National Department of Health (2015). Ethics in Health Research: Principles, Processes and Structures (2nd Ed).
[7] See also Section 9.7 of Stellenbosch University's Research Data Management Regulations which talks further to cultural sensitivities and indigenous knowledge and that some indigenous peoples and local communities can and have developed their own ethical guidelines for external researchers.

Ethics, Codes of Behaviour and any other existing or future directives or Codes of Conduct, as applicable to the training and mentoring of those under research supervision.

7. RESEARCH INVOLVING HUMAN PARTICIPANTS

7.1 Health Research

7.1.1 All health research, as defined by the National Health Act (NHA), must be reviewed and approved by a research ethics committee registered with the National Health Research Ethics Council (NHREC), prior to initiation of research activities.

7.1.2 All health-related research involving any direct interaction with or observation of human participants, the use of potentially identifiable personal health records, information or tissue specimens, and/or human progenitor or stem cells requires review and approval by a SU Research Ethics Committee (REC) before the research study commences.

7.2 Social, Behavioural and Educational Research

At SU all research involving interaction with or observation of human participants, or information linked to human participants, or research involving groups of individuals, or organisations must go through a process of ethics review and approval, prior to the initiation of the research. Researchers are responsible for ensuring that they obtain ethics approval for their research where applicable. If a researcher (students included) is unsure if ethics approval is required for a specific project, it is the responsibility of that researcher to seek and obtain clarification from a REC.

7.3 All research involving human participants must comply with the following principles:

7.3.1 Be relevant and responsive to the needs and interests of the broader community and the advancement of knowledge. Furthermore biomedical research should be directly relevant to the community in which the research is conducted

7.3.2 Have scientific integrity with sound design and methodology that are likely to result in reliable and valid data and outcomes that address the research objectives

7.3.3 Ensure research participants are well informed about the purpose of the research and how the research results will be disseminated and have consented to participate, where applicable

7.3.4 Ensure research participants' rights to privacy and confidentiality are protected

7.3.5 Ensure the fair selection of research participants

7.3.6 Ensure that participants are adequately compensated for their time and inconvenience, where appropriate, according to national guidelines and reimbursed for their research-related expenses, with an amount and method of compensation that does not present an undue influence

7.3.7 Recognise that human categories such as race, ethnicity and gender are social constructs, adequately justify their use in research and follow best practice in collecting, documenting, analysing, reporting and discussing race, ethnicity and gender.

7.3.8 Be preceded by an appropriate risk-benefit analysis

7.3.9 Have respect for communities by appropriate community interaction, working with gatekeepers in a responsible manner, and feedback of results

7.3.10 Ensure that research in communities is effectively coordinated and does not place an unwarranted burden on such communities

8. ANIMAL CARE AND USE FOR SCIENTIFIC PURPOSES

8.1 Harm/benefit evaluation

The care and use of animals for scientific purposes can only be justified if the benefits to both humans and/or animals outweigh the potential harm to the animal. All research, teaching and testing activities involving live animals or tissue or specimens collected from animals euthanized for a purpose other than research or teaching, animals that died of natural causes, animals euthanized under another ethics approval or animals not included in the SANS10386:2021 must be approved by the Research Ethics Committee: Animal Care and Use (REC: ACU) before it commences, so that a formal evaluation of the potential harm/benefit equation can be undertaken. "Justification for causing psychological or physical distress, illness or pain to animals should not be based on any explicit or implicit assumption that non-human animals experience these conditions in qualitatively different ways to humans" (MRC Guidelines).

8.2 Competence, authorisation, and registration of persons involved in the care and use of animals for scientific purposes

8.2.1 All personnel involved in the care, use and breeding of animals for scientific purposes, including researchers, students, and staff, should be adequately educated and trained before they perform any of the following: tissue or specimen collection from animals, carrying out procedures on animals, capture or restraint of animals; designing procedures or projects (or both) involving animals; taking care of animals; or killing animals.

8.2.2 The requirements for education, training and competence apply to all animal species, to all types of scientific institutions or facilities and to all types of housing enclosure or study area, including laboratory-housed, domestic, agricultural, feral and wildlife animal populations.

8.2.3 Performing procedures or working with or on animals remains subject to authorisation or registration with the relevant national council. (See Annexure 5). There are some procedures on animals e.g., taking samples from wild animals, which do not require SAVC authorisation

8.3 The care and use of animals for scientific purposes must comply with the following principles:

This policy promotes the implementation of the principles of the four Rs, that is to Replace, Reduce, Refine and to take Responsibility for animal care and use for scientific purposes. All animal research,

teaching and testing conducted under the auspices of this university should uphold these “Four R" principles for humane animal care and use, namely:

8.3.1 **Replacement** of so-called “sentient” animals wherever possible, with “non-sentient” research models or systems to eliminate the use of animals that can experience unpleasant sensations.

8.3.2 **Reduction** of the numbers of animals in experiments by design strategies that facilitate use of the smallest number that will allow statistically valid information to be obtained from the study.

8.3.3 **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.

8.3.4 **Responsibility** - The institutions, the Research Ethics Committee: Animal Care and Use, and the people involved in any aspect of the care and use of animals for scientific purposes shall be aware of and accept their responsibilities, and act in accordance with this standard, and be held accountable for this.

9 RESEARCH INVOLVING ENVIRONMENTAL AND BIO-SAFETY CONCERNS

9.1 Biological and Environmental Safety

9.1.1 Care should be taken to ensure that all research that could potentially harm the environment, including research with genetically modified organisms (GMOs) and manufactured nanomaterials, is carried out with the necessary respect for the impact that it could have on the physical, biological and spatial environment. All researchers undertaking research with bio-hazardous materials that could potentially cause harm to the researcher and supporting staff, or other humans, animals or the environment must familiarise themselves with appropriate national legislation and standards, and bio-safety and containment procedures. This research must be submitted for ethics review and approval before the research commences.

9.1.2 The Research Ethics Committee: Biological and Environmental Safety (REC: BES) has been instituted to: (a) to protect the interests of researchers, the community and the environment and ensure that all research, teaching and testing involving biohazardous organisms and materials (including those of biological origin and nanomaterials), comply with accepted international and national guidelines on biological and environmental safety. (b) to prevent and reduce exposure of laboratory workers, other persons and the environment to potentially biohazardous agents**.**

9.2 Facility Registration with REC: BES

9.2.1 Each SU facility which houses research, teaching and/or testing activities involving recombinant DNA, GMOs, infectious agents, select agents, biological toxins and cultured cell lines that fall into Hazard group 2-4 and are NOT classified as exempt in section III-F and Appendix C of the NIH Guidelines, or that in any other way can pose a risk to the physical and biological environment, and individuals, must be registered with the REC: BES.

9.2.2 Registration will be contingent on REC: BES assessment and inspection of: 1) laboratory design, physical facilities, and containment levels (based on Hazard group), 2) the facility's procedures and practices, and 3) the training and expertise of the Principal Investigator (PI) and all personnel involved.

9.3 Project Review by REC: BES

9.3.1 Specific protocols for research, teaching and testing activities utilizing recombinant DNA, biohazardous materials, genetically modified organisms (GMOs) and nanomaterials that have the potential to negatively impact the physical, biological or spatial environment must be reviewed and approved by SU's Research Ethics Committee: Biological and Environmental Safety (REC: BES) *prior to* the initiation of the activity.

9.3.2 Protocol approval is contingent on Facilities registration.

10 RESEARCH INVOLVING OTHER ETHICAL CONCERNS

Certain research projects may not fall under any of the three categories mentioned above but may still be regarded as ethically sensitive such as research involving deceased persons, certain historical archives or research that needs to be 'covert' in some respect to fulfil its objectives. It remains the responsibility of the researcher to conduct a self-critical ethical appraisal of their own research and to obtain ethics approval from an appropriate university research ethics committee if necessary. However formal ethics review and approval is mandatory in all instances where obtaining prior informed consent from individuals or permission from organisations or institutions would be an obstacle to fulfilling the objectives of the research.

11 FINANCIAL ASPECTS, CONFLICT OF INTEREST AND INTELLECTUAL PROPERTY

11.1 Financial Aspects

All research projects involve some financial cost and require sound financial management. Stellenbosch University expects all researchers to uphold the highest standards of financial integrity and transparency when dealing with all financial, budget related and contractual aspects of research. Researchers are required to familiarise themselves with and comply with applicable institutional and funder-specific policies.

11.2 Conflict of Interest

A conflict of interest occurs when professional judgement regarding an interest e.g., research, is unduly influenced by another interest e.g. financial gain or gain in personal status.

Conflicts of interests are an inherent and unavoidable part of the academic research environment and can be effectively managed by disclosure and transparency. Researcher conflicts of interests are

of particular importance when an unacknowledged or undisclosed interest, financial or otherwise, may negatively affect the well-being of human research participants, or the results of the research. Researchers must familiarise themselves with and comply with the **Stellenbosch University Policy on Conflict of Interest.** In addition to following the stipulated declaration as outlined in SU's Policy on Conflict of Interest, it is imperative that conflicts of interest be declared to an ethics committee at the time of submission for review, and that if conflicts of interest emerge (or change) during the course of a research project this should be reported to the ethics committee that approved the initial project.

11.3 Intellectual Property

Researchers must familiarise themselves with Stellenbosch University's **Protection and commercialization of Intellectual Property Policy** and ensure that all research related activities that may give rise to issues surrounding intellectual property are in compliance with this policy.

12 COLLABORATION, VISITING STUDENTS, RESEARCH SUPERVISION, MENTORSHIP AND AUTHORSHIP

12.1 Collaboration

The University supports and encourages research collaboration. Researchers (including visiting students and Postdoctoral Research Fellows) have a responsibility to ensure that a clear understanding of respective roles and responsibilities is developed at the beginning of the research collaboration and a duty to adequately fulfil their respective research obligations. Researchers should formalize their research collaborations with a 'Memorandum of Understanding' at the initiation of the collaboration and should obtain research ethics committee (REC) approval for their research from their home institution and from SU. They must also comply with any specific requirements for research oversight as determined by the SU REC that reviews and approves the research. Faculties and/or departments should develop their own guidelines for effective research collaboration in consultation with the Research Contracts Office.

12.2 Visiting students

Research activities involving visiting students must have sufficient oversight to ensure compliance with the principles established in this policy particularly with respect to the protection of human or animal research participants. In addition, visiting students conducting research in affiliation with Stellenbosch University, but who are registered at another institution should obtain ethics approval for their research from their home institution **and** from SU[8,9]. Visiting students and their supervisors

[8] Some international academic institutions do not have established processes for ethics review of research involving human participants outside of a biomedical context. In such cases students must provide a formal letter from their home institution confirming this.

should comply with the *Guideline for visiting students wishing to conduct research while at SU*.[10] They must also comply with any specific requirements for research oversight as determined by the SU research ethics committee that reviews and approves the research. Furthermore if the research involves SU staff or students as research participants additional approval is required from the Stellenbosch University Division for Information Governance.[11] Faculties and Departments hosting visiting students thus have the responsibility to ensure that students complete all necessary approval processes, **prior to** the initiation of their research projects.

12.3 Supervision and mentorship

Supervisors and mentors should:

12.3.1 Ensure that the research relationship or project is begun with a clear understanding of mutual responsibilities, a commitment to maintain a supportive research environment, effective supervision and review and an understanding that the main purpose of the relationship is to prepare trainees to become successful researchers.

12.3.2 Actively supervise and train students in research, including research ethics.

12.3.3 Be responsible for mentoring their students in, and modelling to their students, responsible research practices. These include ensuring familiarity with, and adherence to, the established standards of responsible research conduct set out in national ethics guidance documents and regulations as well as the familiarity with, and adherence to, the research ethics processes and requirements of SU's research ethics committees (RECs).

12.3.4 Be actively involved in supporting students during the complex process of protocol development and research ethics committee (REC) review of research involving human participants, animal care and use and/or biological and environmental safety.

12.3.5 In the case of transdisciplinary research requiring REC review, where students from a particular discipline are not familiar with the ethics and regulatory framework of South Africa - be responsible for supervising students with the necessary multi-disciplinary expertise involved and/or link up with experts in the field to ensure good scientific rigor, validity of the protocol, as well as adherence to relevant ethics requirements.

12.3.6 Mentors or supervisors should apply the principles of authorship described in Section 12.3 below to publications of research, where a student has made a significant contribution.

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[9] Stellenbosch University (2022). Student and Supervisor Guidelines: Ethics clearance(s) for research in the context of a joint doctoral degree under a partnership agreement with an international institution. Available at: http://www.sun.ac.za/english/research-innovation/Research-Development/postgraduate-office

[10] Stellenbosch University (2013). Guideline for Visiting Students Wishing to Conduct Research While at Stellenbosch University. Available at: http://www.sun.ac.za/english/research-innovation/Research-Development/postgraduate-office

[11] SU Division for Information Governance: http://www.sun.ac.za/english/InformationGovernance

12.3.7 Junior researchers in turn have a responsibility to complete assigned work conscientiously, respect the authority of others working in the research setting, follow research regulations and protocols and abide by agreements established for authorship and ownership.

12.4 Authorship

Researchers are expected to make a reasonable effort to publish the results of their research in legitimate scholarly journals and should avoid predatory journals at all costs. Researchers have the responsibility to publish/disseminate/and interpret findings accurately and in line with the research aims and objectives. Where relevant, publication content must be in line with the research protocol and dissemination plan approved by the REC. The following principles apply to authorship:

12.4.1 Authorship should be discussed and agreed upon during the planning phase of research, and expectations of authors clearly outlined;

12.4.2 Authorship credit should be based on substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; drafting the article or revising it critically for important intellectual content; and final approval of the version to be published. Authors should meet all the above conditions;

12.4.3 Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship;

12.4.4 An administrative relationship to the investigation does not of itself qualify a person for co-authorship;

12.4.5 The order of the names in a publication is decided according to the quality of the contribution, the extent of the responsibility and accountability for the results, and the custom of the discipline;

12.4.6 The attribution of authorship is not affected by whether researchers were paid for their contributions or by their employment status;

12.4.7 An author who submits a manuscript for publication accepts the responsibility of having included as co-authors all persons who are entitled to co-authorship, and none who are inappropriate;

12.4.8 The submitting author should send each co-author a draft copy of the manuscript and should make a reasonable attempt to obtain consent to co-authorship, including the order of names; other contributions should be indicated in a footnote or an "Acknowledgements" section, in accordance with the standards of the discipline and the publisher.

13 DATA ACQUISITION AND MANAGEMENT[12]

The acquisition and management of research data particularly within an international collaborative research environment is often very complex. Researchers should familiarise themselves with the

[12] Adapted in part from the ORI publication *Introduction to the Responsible Conduct of Research* Chapter 6, Data Management Practices

Stellenbosch University Research Data Management Regulations as well as the *Stellenbosch University Data Privacy Regulations* that clarify the principles of national and international data protection and privacy legislation[13]. Each Faculty and/or department and/or institute, school or centre must ensure that it has developed its own specific procedures to supplement the points below, where appropriate.

13.1 Data collection and recording

Researchers must collect data, using appropriate methodology and recording practices, and apply appropriate quality assurance mechanisms. Where personal information will be collected the *Stellenbosch University Privacy Impact Assessment* must be considered as per the *Stellenbosch University Data Privacy Regulation*. Raw data must be recorded in hard copy or electronically as appropriate for each research field and with due consideration given to the advantages and disadvantages of different methods.

13.2 Data storage and protection

Data must be properly stored and protected to allow for the validation of research findings, to establish priority of the data, allow for reanalysis if necessary (and consented to by research participants), comply with requirements of funders etcetera. Processes should be established to safeguard data from unauthorised access, accidental loss, damage or theft. The duration of appropriate data storage must be determined by each research environment, giving due consideration to requirements of all stakeholders, including funders, collaborators and legal requirements. In the absence of specific requirements, the default period for research data retention is ten years from date of last requested access, publication or public release.

13.3 Data ownership and access

Both the researcher and the University have responsibilities and rights regarding access, usage and maintenance of primary research data. Research data belong to Stellenbosch University, unless there are specific terms regarding intellectual property rights in the funding agreement. Before research is initiated, it is important to delineate the rights, obligations, expectations, and roles played by all interested parties. The University can be held accountable for the integrity of the data even after the researchers have left the university. The primary responsibility for the management of primary research data remains with the laboratory or department or research environment where it was created. However, in accordance with principles of academic freedom and intellectual integrity a researcher may be allowed to retain copies of the research records and portions of materials created by him/her in the course of the research. Samples of materials or data created or collected during research may be transferred to another institution. However, in all cases, the transfer shall be subject to the terms of a material/data transfer agreement negotiated by the Research Contracts Office,

[13] POPIA and the European Union's General Data Protection Regulation (GDPR)

Division of Research Development, and signed by the authorised representatives of the relevant parties. These rights to access research data also apply to students, research fellows, postdocs and visiting academics who are an integral part of the research project. Researchers must familiarise themselves with **SU's Protection and commercialization of Intellectual Property Policy** which is also applicable to the context of data ownership, sharing and dissemination.

13.4 Data Sharing

Validated research data can be shared where appropriate once researchers have had the opportunity to establish the priority for their work through publication. Data sharing must comply with ethics principles for fair data sharing, data rights as well as intellectual property considerations. Researchers are expected to adhere to FAIR data principles to optimise the reuse of data. This entails that research data should be *Findable, Accessible, Interoperable* and *Reusable* to optimise sharing.[14] Certain funders such as the USA National Institutes of Health (NIH) specifically require data sharing and researchers should acquaint themselves fully with such requirements and comply where applicable. As stated above the conditions for transfer of data or materials to other institutions must be stipulated in an agreement, signed by authorised representatives of the relevant parties, to ensure that all the appropriate legislative and regulatory considerations as well as the requirement of informed consent from research participants for data sharing are correctly addressed. Collaborative research databases or repositories should be managed according to the principles set out above for managing research collaborations. Where appropriate collaborative data repositories should be formally managed by the appointment of a steering committee and the development of written operating procedures that set out the conditions for the use and transfer of data.

14 BREACH OF RESEARCH NORMS AND STANDARDS

Allegations of breach of research norms and standards (including research misconduct) and the investigation thereof, is covered in detail in the *SU Procedure for the investigation of allegations of breach of research norms and standards*. All researchers should familiarise themselves with this document. Researchers are expected to maintain the highest standards of honesty and integrity. Researchers must always function within an ethically acceptable methodological framework. Any form of academic dishonesty will be regarded as a serious offence.

15 POLICY GOVERNANCE

15.1 The **owner** of this policy is the **Deputy Vice-Chancellor (Research, Innovation and Postgraduate Studies),** as line head of the research function of the University. They are responsible for the

[14] See Wilkinson et al. (2016). The FAIR Guiding Principles for scientific data management and stewardship. *Scientific Data*, 3. Available at: https://www.nature.com/articles/sdata201618

existence, updating and implementation of the policy and for ensuring that a curator and related structures and roles are appointed and function effectively.

15.2 The **curator** of this policy is the **Senior Director: Research and innovation** and they are responsible to ensure the formulation, approval, revision, communication and release of this policy. The curator is also responsible for the interpretation and implementation of the policy.

15.3 The owner of this policy is accountable and the curator is responsible for the creation of the necessary controls for **monitoring and reporting** on this policy and to report to the **Senate Research Ethics Committee** on an annual basis, or more frequently if required.

15.4 Management of all affected areas are responsible for the implementation of the policy and specific control in their own areas.

16 ACTIONS FOR NON-COMPLIANCE

The University may take the necessary steps, in accordance with the provisions of its disciplinary code, against any person who is found to be in breach of the requirements of this policy. Such a person may be found guilty of research misconduct and may be censured in accordance with the provisions of the University's disciplinary codes.

ANNEXURE 1

SINGAPORE STATEMENT ON RESEARCH INTEGRITY

http://www.singaporestatement.org/

PRINCIPLES

- ***Honesty*** *in all aspects of research*
- ***Accountability*** *in the conduct of research*
- ***Professional courtesy and fairness*** *in working with others*
- ***Good stewardship*** *of research on behalf of others*

RESPONSIBILITIES

1. ***Integrity:*** *Researchers should take responsibility for the trustworthiness of their research.*
2. ***Adherence to Regulations:*** *Researchers should be aware of and adhere to regulations and policies related to research.*
3. ***Research Methods:*** *Researchers should employ appropriate research methods, base conclusions on critical analysis of the evidence and report findings and interpretations fully and objectively.*
4. ***Research Records:*** *Researchers should keep clear, accurate records of all research in ways that will allow verification and replication of their work by others.*
5. ***Research Findings:*** *Researchers should share data and findings openly and promptly, as soon as they have had an opportunity to establish priority and ownership claims.*
6. ***Authorship:*** *Researchers should take responsibility for their contributions to all publications, funding applications, reports and other representations of their research. Lists of authors should include all those and only those who meet applicable authorship criteria.*
7. ***Publication Acknowledgement:*** *Researchers should acknowledge in publications the names and roles of those who made significant contributions to the research, including writers, funders, sponsors, and others, but do not meet authorship criteria.*
8. ***Peer Review:*** *Researchers should provide fair, prompt and rigorous evaluations and respect confidentiality when reviewing others' work.*
9. ***Conflict of Interest:*** *Researchers should disclose financial and other conflicts of interest that could compromise the trustworthiness of their work in research proposals, publications and public communications as well as in all review activities.*
10. ***Public Communication:*** *Researchers should limit professional comments to their recognized expertise when engaged in public discussions about the application and importance of research findings and clearly distinguish professional comments from opinions based on personal views.*
11. ***Reporting Irresponsible Research Practices:*** *Researchers should report to the appropriate authorities any suspected research misconduct, including fabrication, falsification or plagiarism, and other irresponsible research practices that undermine the trustworthiness of research, such as carelessness, improperly listing authors, failing to report conflicting data, or the use of misleading analytical methods.*

12. ***Responding to Irresponsible Research Practices:*** *Research institutions, as well as journals, professional organizations and agencies that have commitments to research, should have procedures for responding to allegations of misconduct and other irresponsible research practices and for protecting those who report such behavior in good faith. When misconduct or other irresponsible research practice is confirmed, appropriate actions should be taken promptly, including correcting the research record.*
13. ***Research Environments:*** *Research institutions should create and sustain environments that encourage integrity through education, clear policies, and reasonable standards for advancement, while fostering work environments that support research integrity.*
14. ***Societal Considerations:*** *Researchers and research institutions should recognize that they have an ethical obligation to weigh societal benefits against risks inherent in their work.*

ANNEXURE 2

GLOBAL CODE OF CONDUCT FOR RESEARCH IN RESOURCE-POOR SETTINGS

http://www.globalcodeofconduct.org/

FAIRNESS

Article 1: *Local relevance of research is essential and should be determined in collaboration with local partners. Research that is not relevant in the location where it is undertaken imposes burdens without benefits.*

Article 2: *Local communities and research participants should be included throughout the research process, wherever possible, from planning through to post-study feedback and evaluation, to ensure that their perspectives are fairly represented. This approach represents Good Participatory Practice.*

Article 3: *Feedback about the findings of the research must be given to local communities and research participants. It should be provided in a way that is meaningful, appropriate and readily comprehended.*

Article 4: *Local researchers should be included, wherever possible, throughout the research process, including in study design, study implementation, data ownership, intellectual property and authorship of publications.*

Article 5: *Access by researchers to any biological or agricultural resources, human biological materials, traditional knowledge, cultural artefacts or non-renewable resources such as minerals should be subject to the free and prior informed consent of the owners or custodians. Formal agreements should govern the transfer of any material or knowledge to researchers, on terms that are co-developed with resource custodians or knowledge holders.*

Article 6: *Any research that uses biological materials and associated information such as traditional knowledge or genetic sequence data should clarify to participants the potential monetary and non-monetary benefits that might arise. A culturally appropriate plan to share benefits should be agreed to by all relevant stakeholders, and reviewed regularly as the research evolves. Researchers from high-income settings need to be aware of the power and resource differentials in benefit-sharing discussions, with sustained efforts to bring lower-capacity parties into the dialogue.*

Article 7: *It is essential to compensate local research support systems, for instance translators, interpreters or local coordinators, fairly for their contribution to research projects.*

RESPECT

Article 8: *Potential cultural sensitivities should be explored in advance of research with local communities, research participants and local researchers to avoid violating customary practices. Research is a voluntary exercise for research participants. It is not a mission-driven exercise to impose different ethical values. If researchers from high-income settings cannot agree on a way of undertaking the research that is acceptable to local stakeholders, it should not take place.*

Article 9: *Community assent should be obtained through recognized local structures, if required locally. While individual consent must not be compromised, assent from the community may be an ethical prerequisite and a sign of respect for the entire community. It is the responsibility of the researcher to find out local requirements.*

Article 10: *Local ethics review should be sought wherever possible. It is of vital importance that research projects are approved by a research ethics committee in the host country, wherever this exists, even if ethics approval has already been obtained in the high-income setting.*

Article 11: *Researchers from high-income settings should show respect to host country research ethics committees.*

CARE

Article 12: *Informed consent procedures should be tailored to local requirements to achieve genuine understanding and well-founded decision-making.*

Article 13: *A clear procedure for feedback, complaints or allegations of misconduct must be offered that gives genuine and appropriate access to all research participants and local partners to express any concerns they may have with the research process. This procedure must be agreed with local partners at the outset of the research.*

Article 14: *Research that would be severely restricted or prohibited in a high-income setting should not be carried out in a lower-income setting. Exceptions might be permissible in the context of specific local conditions (e.g. diseases not prevalent in high-income countries). If and when such exceptions are dealt with, the internationally acknowledged compliance commandment "comply or explain" must be used, i.e. exceptions agreed upon by the local stakeholders and researchers must be explicitly and transparently justified and made easily accessible to interested parties.*

Article 15: *Where research involvement could lead to stigmatization (e.g. research on sexually transmitted diseases), incrimination (e.g. sex work), discrimination or indeterminate personal risk (e.g. research on political beliefs), special measures to ensure the safety and wellbeing of research participants need to be agreed with local partners.*

Article 16: *Ahead of the research it should be determined whether local resources will be depleted to provide staff or other resources for the new project (e.g. nurses or laboratory staff). If so, the implications should be discussed in detail with local communities, partners and authorities and monitored during the study.*

Article 17: *In situations where animal welfare regulations are inadequate or non-existent in the local setting compared with the country of origin of the researcher, animal experimentation should always be undertaken in line with the higher standards of protection for animals.*

Article 18: *In situations where environmental protection and biorisk-related regulations are inadequate or non-existent in the local setting compared with the country of origin of the researcher, research should always be undertaken in line with the higher standards of environmental protection.*

Article 19: *Where research may involve health, safety or security risks for researchers or expose researchers to conflicts of conscience, tailored risk management plans should be agreed in advance of the research between the research team, local partners and employers.*

HONESTY

Article 20: *A clear understanding should be reached among collaborators with regard to their roles, responsibilities and conduct throughout the research cycle, from study design through to study implementation, review and dissemination. Capacity-building plans for local researchers should be part of these discussions.*

Article 21: *Lower educational standards, illiteracy or language barriers can never be an excuse for hiding information or providing it incompletely. Information must always be presented honestly and as clearly as possible. Plain language and a non-patronising style in the appropriate local languages should be adopted in communication with research participants who may have difficulties comprehending the research process and requirements.*

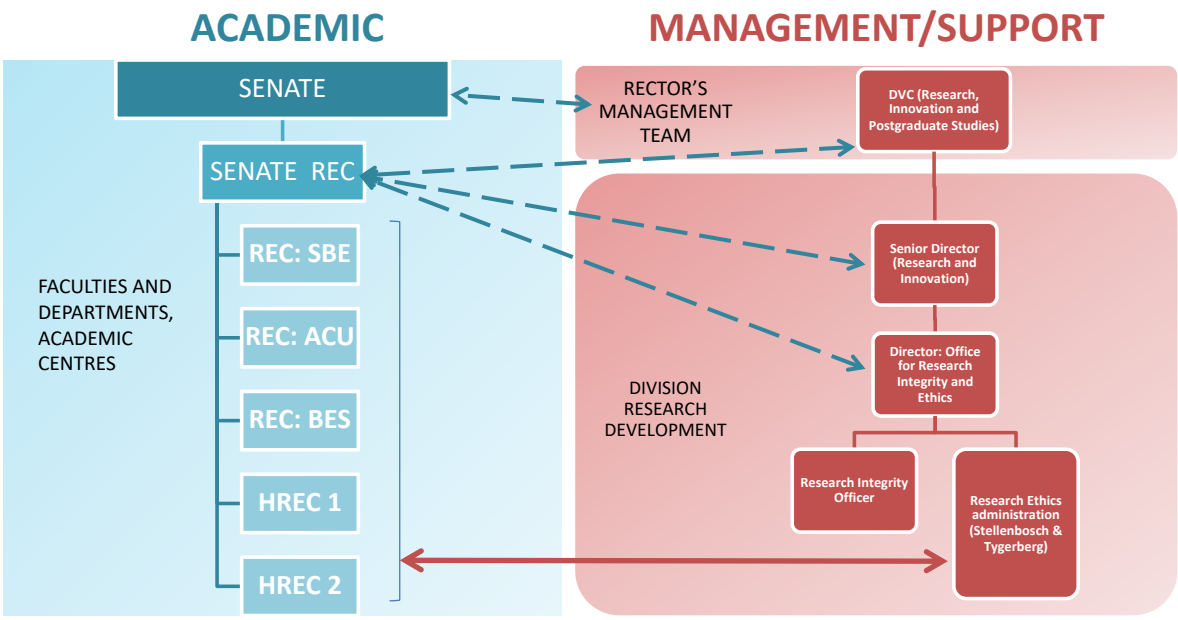
Article 22: *Corruption and bribery of any kind cannot be accepted or supported by researchers from any countries.*

Article 23: *Lower local data protection standards or compliance procedures can never be an excuse to tolerate the potential for privacy breaches. Special attention must be paid to research participants who are at risk of stigmatization, discrimination or incrimination through the research participation.*

ANNEXURE 3

ORGANOGRAM: STRUCTURES SUPPORTING THE PROMOTION OF RESPONSIBLE RESEARCH AT STELLENBOSCH UNIVERSITY

STRUCTURES SUPPORTING THE PROMOTION OF RESPONSIBLE RESEARCH AT STELLENBOSCH UNIVERSITY

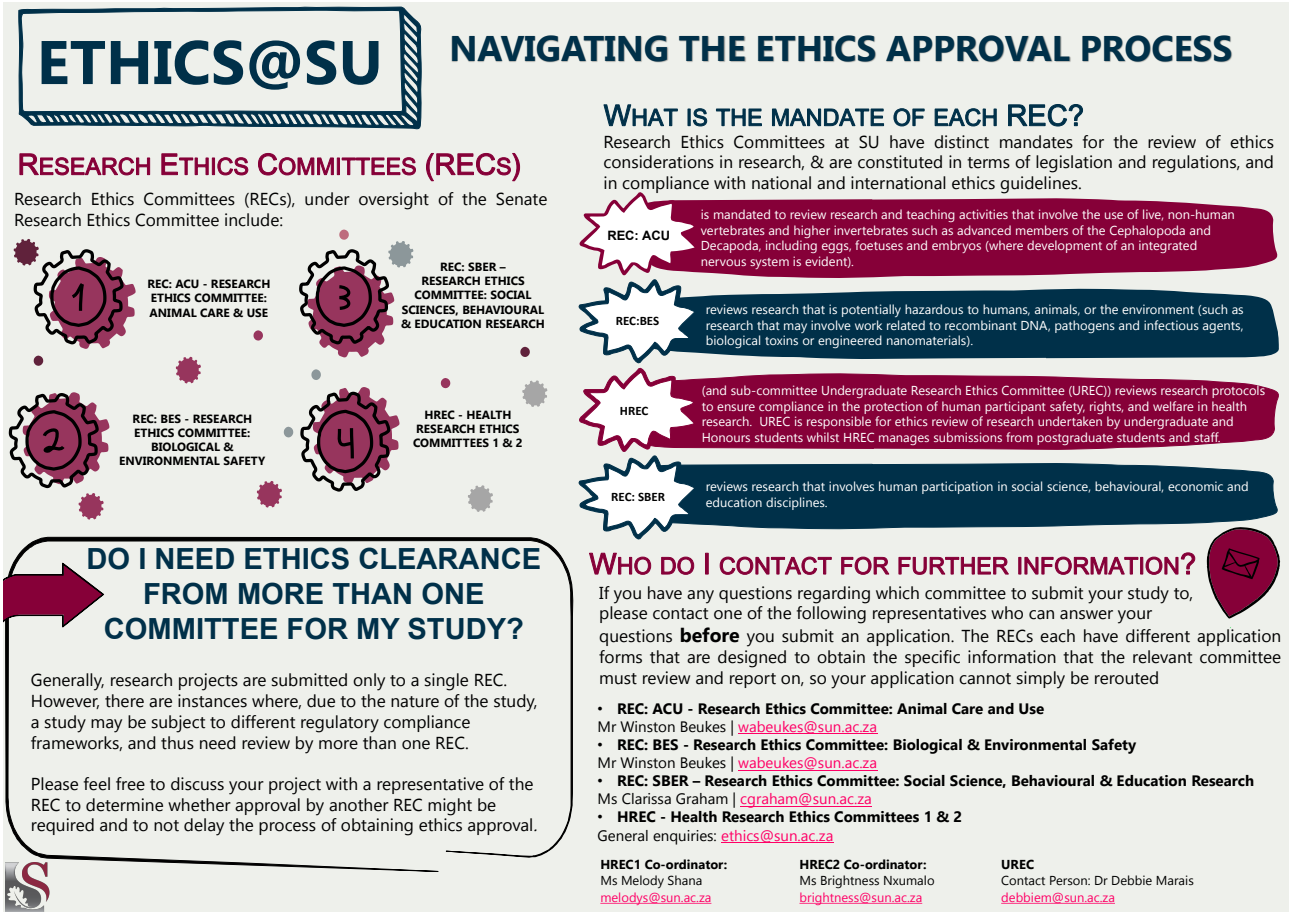


SU has five Research Ethics Committees that function under the Senate Research Ethics Committee (SREC). Terms of Reference and Standard Operating Procedures for each REC can be found on their respective websites. Please see links below.

1. Research Ethics Committee: Social, Behavioural and Education Research (REC: SBE)
2. Health Research Ethics Committee 1 (HREC 1)
3. Health Research Ethics Committee 2 (HREC 2)
4. Research Ethics Committee: Animal Care and Use (REC: ACU)
5. Research Ethics Committee: Biological and Environmental Safety (REC: BES)

ANNEXURE 4

INFOGRAPHIC: ETHICS AT SU - NAVIGATING THE ETHICS APPROVAL PROCESS



Infographic available at: http://www.sun.ac.za/english/research-innovation/Research-Development/integrity-ethics

ANNEXURE 5

AUTHORIZATION OR REGISTRATION WITH THE SOUTH AFRICAN VETERINARY COUNCIL

The practising of a veterinary or para-veterinary profession means the rendering of any service deemed by the rules to relate specially to the veterinary or relevant para-veterinary profession or the prescribing and supplying or of any veterinary medicine, as regulated by the Veterinary and Para-Veterinary Professions Act (Act 19 of 1982), as well as the Medicines and Related Substances Control Act, Act 101 of 1965. Specific attention is particularly given to the performing of any act aimed at the diagnosing, treating, or preventing of any pathological or physiological condition in any animal or which constitutes a surgical procedure on any animal. As outlined in the Act such professionals are **registered** with the South African Veterinary Council based on prescribed qualifications, formal examination, or both.

Section 23 of the Act prohibits unregistered persons from practising any of the professions referred to in the Act or performing any of the procedures referred to in the Act. SECTION 23(1)(c) permits the Veterinary Council to **authorise** a non-registered person in writing to render FOR GAIN a service deemed to pertain specially to a veterinary or para-veterinary profession. Gain is indirect within the scope of employment with any employer, including the State, and includes professional experience gained because of such employment. The authority granted is subject to such conditions as the Council may determine. **Authorisation** in terms of SECTION 23(1)(c) of the Act will be considered for persons in temporary or full-time employment of academic institutions, research institutions, industrial institutions, service organisations, animal welfare organisations and/or private employers. In all instances, authorisation will only be considered if the applicant has a firm offer of employment from a specific institution/organisation or private employer or is placed in an accredited academic/training/research programme. Authorisation may be sought based on the below outlined categories:

A. CATEGORIES OF ACTIVITIES IN WHICH PERSONS WITH VETERINARY QUALIFICATIONS NOT RECOGNISED BY COUNCIL WILL BE CONSIDERED FOR AUTHORISATION 1. Industry 2. Research 3. Service-rendering (animal welfare, embryo transfer, state veterinary service, etc.) 4. Training (Educational)
B. CATEGORIES OF ACTIVITIES IN WHICH PERSONS WITHOUT VETERINARY AND/OR PARAVETERINARY QUALIFICATIONS WILL BE CONSIDERED BY COUNCIL FOR AUTHORISATION 1. Service rendering (animal welfare, embryo transfer) 2. Industry 3. Research 4. Training (Educational)

Authorisation in both categories A and B will be considered in relation/with specific reference to: 1. A specific employer or institution; 2. A specific duration; 3. The scope of procedures to be performed and the proven competency of the applicant; 4. Specific requirements/limitations which may be imposed on the applicant; and 5. A suitably registered supervising professional.

GUIDELINES FOR UNIVERSITIES IN RESPECT OF APPLICANTS IN CATEGORY B4 [TRAINING] 1. Authorisation will be restricted to those activities relating to teaching, research, service-rendering and/or professional development which would normally involve the practising of a veterinary or paraveterinary profession as defined in the Act and performed on behalf of and whilst in the employ of or placed in a specific academic/research programme of the academic institution; 2. Authorisation will be valid for a maximum period of 2 years. Renewal of authorisation may be considered at Council's discretion. The possibility of long-term authorisation as a result of fixed employment with the specific employer may be considered at Council's discretion; and 3. Renewal of authorisation will only be considered for individuals in fixed employment on receipt of a satisfactory status report submitted by the institution and person under whose supervision the candidate performs his or her duties.

ANNEXURE 6

SU RELATED POLICIES, PROCEDURES, CODES AND GUIDELINES

The latest published version of Stellenbosch University policies, procedures and guidelines are available at: http://www.sun.ac.za/english/research-innovation/Research-Development/policies-guidelines

Policies, procedures and guidelines must be accessed only directly through the DRD website to ensure the correct version is used. NOTE: Do not "Google Search" as older, incorrect versions of the policy, procedure or guideline document may appear in search results. The onus is on researchers to ensure they are working to the correct version of any policy, procedure, code or guideline.

TITLE	TYPE	STATUS	POLICY CUSTODIAN
Policies			
Policy on Conflict of Interest	Policy	Approved by Council	Division for Research Development
Policy on Contract Research Management at SU	Policy		Division for Research Development
SU Policy on Plagiarism (in support of academic integrity)	Policy	Approved by Council	Division for Research Development
Stellenbosch University Financial Guidelines	Policy	Approved	Finance Division
SU Risk Management Committee Regulations	Policy	Approved	Risk and Security Services
SU Protection and commercialization of Intellectual Property Policy	Policy	Approved	InnovUS
SU Media/ Information Policy	Policy	Pending	Communication and Liaison
SU Procedure for the investigation of allegations of breach of research norms and standards	Procedure	Approved by Senate Research Ethics Committee (SREC)	Division for Research Development (DRD)
SU Procedure for the investigation and management of allegations of plagiarism	Procedure	Approved by SREC and Committee for Learning and Teaching (CLT)	Division for Research Development (DRD)
Health Research Ethics Committee Terms of Reference and Standard Operating Procedures	Procedure	Approved by SREC	Research Development and Support Division, Faculty Medicine and Health Sciences
Research Ethics Committee: Social, Behavioural and Education Research Standard Operating Procedure	Procedure	Approved by SREC	Division for Research Development
Research Ethics Committee:	Procedure	Approved by SREC	Division for Research

Animal Care and Use Standard Operating Procedures and Guidelines			Development
Research Ethics Committee: Biological and Environmental Safety Standard Operating Procedures and Guidelines	Procedure	Approved by SREC	Division for Research Development
Departmental Ethics Screening Committee (DESC) Guideline	Guideline	Approved	Division for Research Development
Research Collaboration	Guideline	Under development	Division for Research Development
Guideline for Visiting Students[1] Wishing to Conduct Research while at Stellenbosch University	Guideline	Approved	Division for Research Development
Guideline Joint Degrees (Dorothy)	Guideline	Approved	Division for Research Development
Code of Conduct for the Relationship Between Supervisor / Promoter and Research-based Postgraduate Student			
Framework for the governance of personal information at Stellenbosch University.	Guidelines	Active	Division for Information Governance
Stellenbosch University Code of Ethics	Code	Under development	Council
Stellenbosch University Code of Ethics: Code of Conduct	Code of conduct	Under development	Council
Stellenbosch University Research Data Management Regulations	Regulations	Approved by Senate	Division for Research Development (DRD) and Library and Information Services (LIS)

ANNEXURE 7

KEY TEXTS

HUMAN PARTICIPANT RESEARCH

1. World Medical Association (2013). **Declaration of Helsinki: Ethical Principles For Medical Research Involving Human Subjects.** *JAMA*, 310(20): 2191-4. doi: 10.1001/jama. Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

2. **National Health Act 61. 2003 Chapters 2, 8, 9 and supporting regulations.**

3. Department of Health (2015). **Ethics in Health Research: Principles, Structures and Processes.** (2nd edition). Pretoria, South Africa. Available at: http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics/SOP.aspx (you can also search for this document on the Department of Health web site at http://www.doh.gov.za/search/index.html)

4. Department of Health (2020). **South African Good Clinical Practice. Clinical Trial Guidelines** (3rd edition). Pretoria, South Africa. Available at: https://www.sahpra.org.za/wp-content/uploads/2021/06/SA-GCP-2020_Final.pdf

5. Protection of Personal Information Act (**POPIA**, Act 4, 2013**). Pretoria,** South Africa (effective date 1 July 2020). Available at https://popia.co.za/

6. **Guidelines on Ethics for Medical Research. Books 1-5. MRC SA** (refer http://www.sahealthinfo.org/ethics/ethics.htm)

7. **ICH- GCP** (for clinical trials – refer http://www.fda.gov/cder/guidance/959fnl.pdf)

8. **CIOMS (2016)**. International Ethical Guidelines for Biomedical Research involving Human Subjects (refer https://cioms.ch/publications/product/international-ethical-guidelines-for-health-related-research-involving-humans/)

9. The Belmont Report can be found at http://ohsr.od.nih.gov/guidelines/belmont.html

10. **Social Research Association**. Ethical Guidelines. Dec.2003 Available at www.the-sra.org.uk (downloaded 20.01.2008)

ANIMAL CARE AND USE FOR SCIENTIFIC PURPOSES

11. Department of Health (2015). **Ethics in Health Research: Principles, Structures and Processes.** (2nd edition). Pretoria, South Africa. Available at: http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics/SOP.aspx (you can also

search for this document on the Department of Health web site at http://www.doh.gov.za/search/index.html)

12. **South African National Standard: The Care and Use of Experimental Animals** Standards SA. SANS 10386:2021
13. the Animals Protection Act, 1962 (Act No. 71 of 1962);
14. the Animal Diseases Act, 1984 (Act No. 35 of 1984);
15. the Veterinary and Para-veterinary Professions Act, 1982 (Act No. 19 of 1982);
16. the Animal Health Act, 2002 (Act No. 7 of 2002);
17. the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965);
18. the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947);
19. EUs Directive 2010/63/EU on the protection of animals used for scientific purposes;
20. the Genetically Modified Act, 1997 (Act No. 15 of 1997);
21. the Animal Identification Act, 2002 (Act No. 6 of 2002);
22. the National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004) on Threatened Or Protected Species Regulations.
23. Institute for Laboratory Animal Research **(2011). Guide for the Care and Use of Laboratory Animals: Eighth Edition**. National Research Council of the National Academies, National Academies Press 2011
24. South African Medical Research Council (2004). **Guidelines on Ethics for Medical Research: Use of Animals in Research and Training** (Book 3)

BIOLOGICAL AND ENVIRONMENTAL SAFETY IN RESEARCH

25. **Guidelines on Ethics for Medical Research: Use Of Biohazards and Radiation** South African Medical Research Council 2002
26. **NIH Guidelines for Research Involving Recombinant DNA Molecules** www4.od.nih.gov/oba/IBC/nihguidelines.htm

AUTHORSHIP

27. International Committee for Medical Journal Editors (ICMJE, 2019). **Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals.** Available at: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html