

POLICY FOR RESPONSIBLE RESEARCH CONDUCT AT STELLENBOSCH UNIVERSITY

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DESCRIPTION OF ANNEXURES PROVIDED IN SUPPORT OF THIS POLICY	
ANNEXURE 1	Singapore Statement on Research Integrity
ANNEXURE 2	Organogram
ANNEXURE 3	SU related policies, procedures and guidelines
ANNEXURE 4	Key Texts used in the development of this policy.

1. INTRODUCTION

Stellenbosch University (SU) is committed to applying the values of equity, participation, transparency, service, tolerance and mutual respect, dedication, scholarship, responsibility and academic freedom in all its activities. This includes, by definition, all the research conducted at the University.

The 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 or the field in which they conduct their research or the site where the research is conducted.

3. DEFINITIONS

- 3.1 'Animals'** refers to all non-human living beings having the power of sense perception or sensation (SANS10386:2008).
- 3.2 'Human participant'** is generally a living person about whom 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.
- 3.3 'Research'** is any systematic enquiry aimed at producing new and generalisable knowledge, new meaning or a deeper understanding of meaning.
- 3.4 '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.¹

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:

¹ University of Pittsburgh guidelines on research data management.

- 5.1 To formally endorse the Singapore Statement of Research Integrity
- 5.2 To establish principles and responsibilities for research involving humans, animals and risks to society and the broader physical environment
- 5.3 To establish principles and responsibilities for research collaboration, mentorship and authorship
- 5.4 To establish principles and responsibilities for data acquisition and management
- 5.5 To ensure compliance with this policy and other applicable 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 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 Integrity².** This internationally accepted statement promotes four core principles and 14 responsibilities (See Annexure 1)

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 and is of particular relevance when research involves human participants.

6.3 Academic freedom and dissemination of research results

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. Any specific or explicit decision to withhold or delay the publication of research results 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 ethics review committee or research committee that originally approved the research or InnovUS, whichever is most appropriate. This ethics committee (in the case of sensitive or harmful results) or InnovUS (in the case of patents or intellectual property and/or corporate claims) must place a balance on the dissemination of results and the placement of

² <http://www.singaporestatement.org/>

moratoriums on the dissemination of certain data.

6.4 Ethics approval of research

It is the responsibility of all researchers (including students) to ensure that they obtain ethics approval for their research 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. Details of these committees and their standard operating procedures are provided at the end of this policy.

6.5 Responsibility for future science generations

The education of young scientists and scholars is a priority for Stellenbosch University and requires established researchers to provide leadership and acceptable standards for mentorship and supervision.

7. RESEARCH INVOLVING HUMAN PARTICIPANTS

7.1 Health Research

All health research, as defined by the National Health Act, must be reviewed and approved by a research ethics committee registered with the National Health Research Ethics Council. Thus all health related research involving:

7.1.1 any direct interaction with or observation of human participants

7.1.2 the use of potentially identifiable personal health records, information or tissue specimens, and/or

7.1.3 human progenitor or stem cells

requires the approval of 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 subjects, or information linked to human subjects, or research involving groups of individuals, or organisations must go through a process of ethical screening and clearance. Investigators are responsible for ensuring that they obtain ethics approval for their research where applicable. If an investigator (students included) is unsure if ethics approval is required for a specific project, it is the responsibility of that investigator to seek and obtain clarification from a reliable resource.

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

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

7.3.2 Have a valid scientific methodology

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 Be preceded by a thorough risk-benefit analysis
- 7.3.7 Thorough care must be taken to ensure that research in communities is effectively coordinated and does not place an unwarranted burden on such communities

8. RESEARCH INVOLVING ANIMALS

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 subject. All research and teaching involving animals must be approved by a SU research ethics committee before the research 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).

All animal research conducted under the auspices of this university should uphold the "Three R" principles for humane animal research, namely:

- 8.1 Replacement** of so-called "sentient" animals wherever possible, with "non-sentient" research models or systems in order to eliminate the use of animals that can experience unpleasant sensations.
- 8.2 Reduction** of the numbers of animals in experiments by design strategies that facilitate use of the smallest number that will allow valid information to be obtained from the study.
- 8.3 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.

9. RESEARCH INVOLVING ENVIRONMENTAL AND BIO-SAFETY CONCERNS

Care should be taken to ensure that all research that could potentially harm the environment, including research with genetically modified organisms (GMOs), 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 material including GMOs that could potentially cause harm to the researcher and supporting staff, or other humans, animals or the environment must familiarise themselves with appropriate bio-safety and containment procedures. This research must be submitted for ethical review and approval before the research commences.

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 in order 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 ethical 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**.

11.3 Intellectual Property

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

12. COLLABORATION, MENTORSHIP AND AUTHORSHIP

12.1 Collaboration

The University supports and encourages research collaboration. Researchers (including visiting students) 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. Faculties and/or departments should develop their own guidelines for effective research collaboration in consultation with the Research Contracts Office.

12.1.1 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 SU³. 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 additional approval is required from the Office for Institutional Research and Planning. 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.

12.2 Mentorship

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

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.

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

12.3 Authorship

Researchers are expected to make a reasonable effort to publish the results of their research in some form of recognised academic media. The following principles apply to authorship:

12.3.1 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;

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

³ 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.

- 12.3.3 An administrative relationship to the investigation does not of itself qualify a person for co-authorship;
- 12.3.4 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;
- 12.3.5 The attribution of authorship is not affected by whether researchers were paid for their contributions or by their employment status;
- 12.3.6 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;
- 12.3.7 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 MANAGEMENT⁴

The acquisition and management of data particularly within an international collaborative research environment is often very complex. Each Faculty and/or department and/or center must ensure that it has developed its own specific policies and/or 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. 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 in order to allow for the validation of research findings, to establish priority of the data, allow for reanalysis if necessary, comply with requirements of funders etcetera. Processes should be established to protect data from 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.

13.3 Data ownership and access⁵

Both the principal investigator and the University have responsibilities and rights regarding access, usage and maintenance of original research data. Research data belong to Stellenbosch University, which can be held accountable for the integrity of the data even after the researchers have left the

⁴ Adapted in part from the ORI publication *Introduction to the Responsible Conduct of Research* Chapter 6, Data Management Practices

⁵ This section is a slightly modified version of that found in ⁵ University of Pittsburgh guidelines on research data management.

university. The original data should remain in the laboratory or department or research site where it was created i.e. at Stellenbosch University. However in accordance with principles of academic freedom and intellectual integrity an investigator 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 in the course of 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, Division of Research Development. These rights to access data also apply to students, research fellows and visiting academics who are an integral part of the research project.

Researchers must familiarize themselves with the **SU's Policy in Respect of Exploitation of Intellectual Property** which is also applicable to the context of data ownership and sharing.

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. 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 all relevant parties. 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. SCIENTIFIC MISCONDUCT

Scientific misconduct and the investigation thereof, is covered in detail in the *Procedure for the Investigation of Research Misconduct at Stellenbosch University*. All researchers should familiarise themselves with this document. Researchers are expected to maintain the highest standards of honesty and integrity. Researchers must at all times 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 **Vice-Rector (Research and Innovation)**, as line head of the research function of the University. He/she is responsible for the 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 he/she is 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.
- 15.5** **Actions for non-compliance:** Disciplinary steps may be instituted against any person who is found to be in breach of any requirement of this policy. Such a person may be found guilty of research misconduct and may be censured in accordance with the provisions of 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.

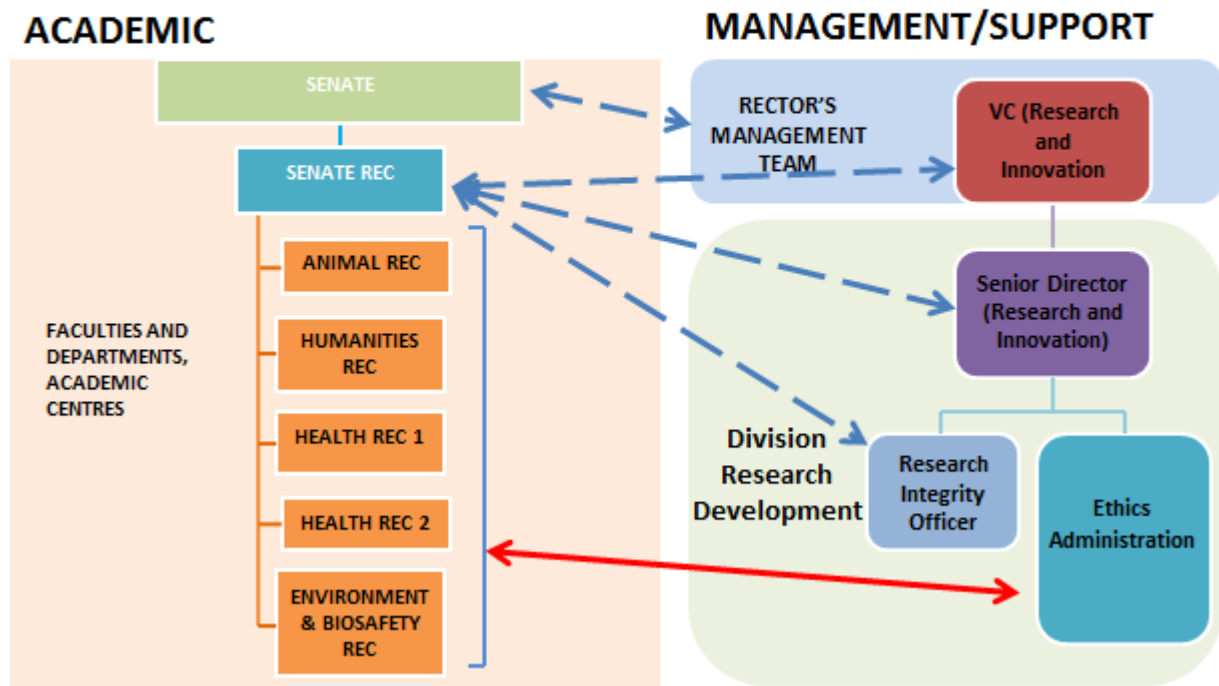
13. Research Environments: Research institutions should create and sustain environments that encourage integrity through education, clear policies, and reasonable standards for advancement, while fostering work environments that support research integrity.

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

ORGANOGRAM:

STRUCTURES SUPPORTING THE PROMOTION OF RESPONSIBLE RESEARCH AT STELLENBOSCH UNIVERSITY



ANNEXURE 3

SU RELATED POLICIES, PROCEDURES AND GUIDELINES

TITLE	DOCUMENT TYPE	STATUS	POLICY CUSTODIAN
Policy on Conflict of Interest	Policy	Approved	Division for Research Development
Policy on Contract Research Management at Stellenbosch University	Policy	Approved	Division for Research Development
SU Policy on Academic Integrity: The Prevention and Handling of Plagiarism	Policy	Approved	Division for Research Development
Stellenbosch University Financial Guidelines	Policy	Approved	Finance Division
SU Risk Management Committee Regulations	Policy	Approved	Risk and Security Services
SU Policy in Respect of Exploitation of Intellectual Property	Policy	Approved	InnovUS
SU Media/ Information Policy	Policy	Pending	Communication and Liaison
Procedure for the Investigation of Research Misconduct at Stellenbosch University	Procedure	Approved	Division for Research Development
Health Research Ethics Committees Human Research: Standard Operating Procedures and Guidelines	Procedure	Approved	Division Research Development and Support, Faculty Medicine and Health Sciences
Research Ethics Committee: Human Research (Humanities) Standard Operating Procedure	Procedure	Approved	Division for Research Development
Research Ethics Committee: Animal Care and Use Standard Operating Procedures and Guidelines	Procedure	Approved	Division for Research Development
Research Ethics Committee: Biosafety and Environmental Ethics Standard Operating Procedures and Guidelines	Procedure	Under development	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

ANNEXURE 4

KEY TEXTS:

HUMAN SUBJECT RESEARCH

1. The **Declaration of Helsinki** can be found at www.wma.net/e/policy/b3.html
2. **National Health Act 61. 2003 Chapters 2, 8, 9 and supporting regulations.**
3. **Ethics in Health Research: Principles, Structures and Processes.** (Department of Health) Published April 2005 (you can search for this document on the Department of Health web site at <http://www.doh.gov.za/search/index.html>)
4. **SA GCP. Clinical Trials 2006.** Department of Health (you can search for this document on the Department of Health web site at <http://www.doh.gov.za/search/index.html>)
5. **Guidelines on Ethics for Medical Research. Books 1-5. MRC SA** (refer <http://www.sahealthinfo.org/ethics/ethics.htm>)
6. **ICH- GCP** (for clinical trials – refer <http://www.fda.gov/cder/guidance/959fnl.pdf>)
7. **CIOMS 2002.** International Ethical Guidelines for Biomedical Research involving Human Subjects (refer http://www.cioms.ch/frame_guidelines_nov_2002.htm)
8. **CIOMS 2008.** International Ethical Guidelines for Epidemiological Studies (Available at http://www.cioms.ch/080221feb_2008.pdf)
9. **Social Research Association.** Ethical Guidelines. Dec.2003 Available at www.the-sra.org.uk (downloaded 20.01.2008)

ANIMAL RESEARCH

10. **Guidelines on Ethics For Medical Research: Use of Animals in Research and Training** (Book 3) South African MRC 2004
11. **South African National Standard: The Care and Use of Experimental Animals** Standards SA. SANS 10386:2008
12. **Guide for the Care and Use of Laboratory Animals: Eighth Edition,** Institute for Laboratory Animal Research, National Research Council of the National Academies, National Academies Press 2011

BIOSAFETY RESEARCH

13. **Guidelines on Ethics for Medical Research: Use Of Biohazards and Radiation** South African Medical Research Council 2002

14. NIH Guidelines for Research Involving Recombinant DNA Molecules
www4.od.nih.gov/oba/IBC/nihguidelines.htm

OTHER REFERENCES

15. The Belmont Report can be found at <http://ohsr.od.nih.gov/guidelines/belmont.html>
16. ORI Introduction to the Responsible Conduct of Research. Nicholas H Steneck. Department of Health and Human Services Office of Research Integrity. 2003
17. McGill University Policy on Research Ethics
18. International Committee for Medical Journal Editors: Guide to Authorship.
<http://www.icmje.org/index.html#author>