

CENTRAL UNIVERSITY OF TECHNOLOGY RESEARCH ETHICS AND INTEGRITY POLICY FRAMEWORK

Purpose

Central University of Technology (CUT) is committed to the core values of customer service, integrity, diversity, innovation and excellence. As part of the core values it is important for the university to promote responsible conduct of research in line with internationally acceptable norms and standards. The document serves as a policy framework, which must be interpreted in the context of and in line with other relevant policies and guidelines relating to research and academic ethics and integrity matters.

Preamble

The study in and the application of research ethics are not new to the scientific community. This is evident from the large number of ethical codes and best practices that exist around the world.

Research integrity can be defined as the trustworthiness of research due to the soundness of its methods and the honesty and accuracy of its presentation. *Draft Singapore Statement (2010)*.

Research Ethics and Integrity outlines expectations that set standards that can be used to define Responsible Conduct of Research (RCR). RCR is simply conducting research in ways that fulfil the professional responsibilities of researchers, as defined by their professional organizations, the institutions for which they work and, when relevant, the government and public.

The former reasonably falls under Research Ethics (RE) and can be defined as the critical study of the moral problems associated with or that arise in the course of pursuing research. Research integrity (RI) is defined as possessing and steadfastly adhering to professional standards, as outlined by professional organizations, research institutions and, when relevant, the government and public.

Research ethics is of utmost importance as it portrays an institution and individual's credibility and integrity. The IAP (InterAcademy Panel) and the IAC (InterAcademy Council) stress that the **accountability for ethical research does not fall solely with authors**. They declare that **all those involved in research should be bound by the principles of scientific integrity**. Institutes are also considered to have a vital **role in raising the standards** of research integrity- it is their duty to **educate** staff in ethical research practices, and to **facilitate a supportive and effective environment** whistle-blowers. *Promoting Research Integrity: A New Global Effort*. The Lancet. October 2012.

Research today is international, inter-disciplinary, team oriented, technology-intensive, and should be non-manipulative and free from error or distortion. Following from literature and policy review, debates and applications, it is evident that the challenge is not limited to a conceptual understanding of ethics only. Another challenge is the concern that although an enabling ethical climate can be created, it is no guarantee that researchers will be “ethical” or behave according to ethical expectations.

Hence the question remains if one can teach or train researchers to be ethical? The question therefore is how can ‘n research community become more responsive to those norms and values associated with a responsible research community?

The characteristics of research community is built on universally accepted ethical values such as honesty, integrity, loyalty, respect for life, care for the environment, accountability of public funding expenditure, research outputs supportive of human capital development, value for money, responsibility, trustworthy, no conflict of interest, non-hazardous activities or results, etc.

Responsibilities of institutions and researchers towards research ethics and integrity

Institution – facilitate, establish, promote monitoring, provide support and ensure safe research environment

Researcher – respect research participation, reporting research misconduct; maintain a high standard, report research responsibility, respect research environment.

Currently the CUT has the following written documents that officially touch on ethical matters:

- a) Policy and Procedures on Academic Integrity at the Central University Technology Free State
- b) The CUT Yearbook that explains disciplinary rules for students in terms of behavioural conduct and registration procedures, (but contains no explicit guidelines for research integrity, e.g. it does not list plagiarism),
- c) The automatic protection as set out in the Copyright Act 98 of 1978
- d) Policy regarding Copyright- including the spectrum of literary resources at CUT,
- e) A Code of Ethics for employees that underlines the responsibility of staff members to focus their professional efforts and objectives,
- f) Student Assessment Manual that stipulates plagiarism explicitly in all its possible forms under a heading: Student Misconduct,
- g) The Intellectual Property Policy that that aligns Intellectual Property strategy with CUT objectives and protects intellectual property within our innovation parameters,
- h) Most CUT programme study guides in fostering awareness of responsible conduct in research matters such as plagiarism or copyright are mentioned in learner guides.

The question to our current research community CUT culture is: How do we foster awareness, and how do we implement more drastic measures to ensure integrity is upheld in the high standards of our institution? In an attempt to provide a solution to the question, specifically in the domain of research at the CUT, we propose the following policy framework for responsible research conduct which contains the following sections:

- A. RESEARCH ETHICS AND INTEGRITY CODE OF CONDUCT FOR RESEARCHERS AT THE CENTRAL UNIVERSITY OF TECHNOLOGY, FREE STATE
- B. ETHICS COMMITTEES: STRUCTURES AND ROLES (RESEARCH INVOLVING HUMANS, ANIMALS AND THE ENVIRONMENT)
- C. CUT ETHICAL APPROVAL FLOW DIAGRAM
- D. ANNEX – REIC CONSTITUTION AND FORMS

A. RESEARCH ETHICS AND INTEGRITY CODE OF CONDUCT FOR RESEARCHERS AT THE CENTRAL UNIVERSITY OF TECHNOLOGY, FREE STATE

The Central University of Technology, Free State is committed to an ethical research environment expressed through the universal core functions of a university, namely teaching and learning, research and innovation and community engagement. The university expects that its staff and students will carry out the academic assignment with the highest ethical and scientific standards of academic integrity and performance. Staff and students should adhere to those values that are universally recognized by the scientific community. Staff and students are also expected to live up to the institutional values of the university and the constitution.

The code is based on a broad understanding of research integrity:

- honesty and integrity
- respect for human research participants, animals and the environment
- good stewardship of public resources used to conduct research
- appropriate acknowledgement of the role of others in research
- responsible communication of research results” (Australian Research Council, 2007 p. 1.3)

To give effect to this orientation, the following ethical principles are adopted:

1. **Dictum of do no harm:** The university commits itself to the ethical dictum of “do no harm” in all its research activities. The university further commits to the universal accepted ethical values associated with the protection of human life, responsibility towards animal life, preservation of the environment, contribution to safety, security and sustainable development, integrity in human interactions and relations and the association with the common good.
2. **Paradigmatic choices:** Researchers should be free to select the paradigm for their academic work and to form their own findings and conclusions based on scientific evidence. These findings and conclusions should be available for scrutiny and criticism as required by the university and scientific community’s principles of fairness, openness, transparency and academic dialogue. It is expected from researchers to conduct scholarly work in a way that advances knowledge while maintaining high ethical standards.

3. **Unfair benefit:** Staff and students should at all times avoid situations that could contribute to an unfair benefit for the individual or behavior characterized by greed. Although the notion of individualism is respected and entrepreneurship is promoted by the university, individualism and entrepreneurship can never be to the expense of other staff and students.
4. **Creation of knowledge:** Researchers should be committed to the creation of new knowledge that can enhance the Vision statement of the university. The creation of new knowledge should promote the technology and innovation agenda of the university. It should by no means contribute to any situation where the safety and security of society is under threat.
5. **Postgraduate supervision:** Teaching and learning at the postgraduate level should be driven from the perspective that the supervisor plays a supportive role in the student's discovery of new scientific knowledge. The supportive role should be informed by assisting the student to delineate the research topic, to formulate appropriate research questions, to identify an appropriate research design and to develop the scientific and scholarly skills of the student. The supportive role implies that the different roles and responsibilities are well-defined. This relationship depends on mutual commitment to the project and assignment, clear roles and responsibilities in the supervisory relationship and regular interaction on the basis of formative assessment.
6. **Research teams:** Research teams should behave at all times according to the ethos of their professions, live up to the expressed values of the professional and academic organisations and express collegiality and team work in the research that they are collectively and individually worked on.
7. **Use of information and data:** To preserve the integrity of research, researchers are obliged to report honestly, objectively, avoid error and disclose all important information. Objectivity in research gives researchers trustworthiness. This applies to both the *a priori* tasks of setting up the research and gathering the data and in the *posteriori* tasks of interpreting and publishing the results. This is critical so that future work built on the research will continue in an objective fashion.
8. **Obligations of Authorship:** It is a researcher's obligation to publish results of research so that readers may be informed and are able to build on the reported findings. The methods and results should be sufficiently and accurately detailed with an objective discussion of its significance, so as to allow replication. Authorship should be in line with the Vancouver Code.
9. **Responsible dissemination of research findings:** All reasonable steps must be taken to ensure that published reports and public statements about research activities are complete, accurate and unambiguous. If researchers become aware of inaccurate statements about their work they must correct the record as soon as possible.

- 10. Stewardship:** The Principal investigator (PI) of the research is the custodian of the sponsored research funds. In exercising this custodianship, the following principles must be adhered to:
- i. **Justification:** The reason for transactions out of research funds must support the project's goals and adhere to the guidelines of the Funding Agencies as well as the University.
 - ii. **Documentation:** Each transaction must be supported by sufficient documentation. The documentation must be retained, organised and complete enough to stand up to an audit.
 - iii. **Timeliness:** Transactions must be handled within a reasonable period of time consistent with the time frames outlined by Funding Agencies and the University.
 - iv. **Certification:** Transactions must be approved by the relevant authorising signatories.
- 11. Risk:** Key issues associated with the research on and with human participants are evaluation of the risks and benefits of the research, informed consent, privacy and confidentiality, coercion and rewards. An evaluation of risk should take a participant centered approach, with the establishment of a threshold for normally acceptable risk. This threshold is generally set by determining the normal range of risk a participant encounter in everyday life. If the risk inherent in research participation does not exceed this standard, then the risk of participation is seen as being within the threshold of normal acceptance.
- 12. Informed consent:** Although partial disclosure and deception run contrary to the principles of informed consent, their use is acceptable as long as sufficient justification is provided. This justification must include the: (a) identification of partial disclosure/deception as the only feasible method for achieving the research objectives; (b) none of the information that is withheld would cause the participant to refuse participation if the information was provided; and (c) the level of risk involved in participation is not withheld.
- 13. Privacy:** Privacy involves the right to decide the extent to which personal data that is not already in the public domain may be disseminated. Confidentiality involves the preservation of a participant's right to anonymity. Every step must be taken to ensure privacy and confidentiality in all personal information. If privacy and confidentiality cannot be maintained, it is important that this situation be identified during the process of informed consent. It is also important that privacy must be treated within the boundaries of existing legislation. A guiding principle for involving participants in research and/or research-related activities is that of voluntariness. A participant's involvement in research and/or research-related activities must be through their own free will.
- 14. Conflict of interest:** Staff and students have the obligation to avoid ethical, legal, financial or other conflicts of interest. Care should also be taken to ensure that research activities do not conflict with their obligations to the University or Funding Agency. If any real or apparent conflict of interests arises, this must be disclosed to the relevant Faculty Research Committee.

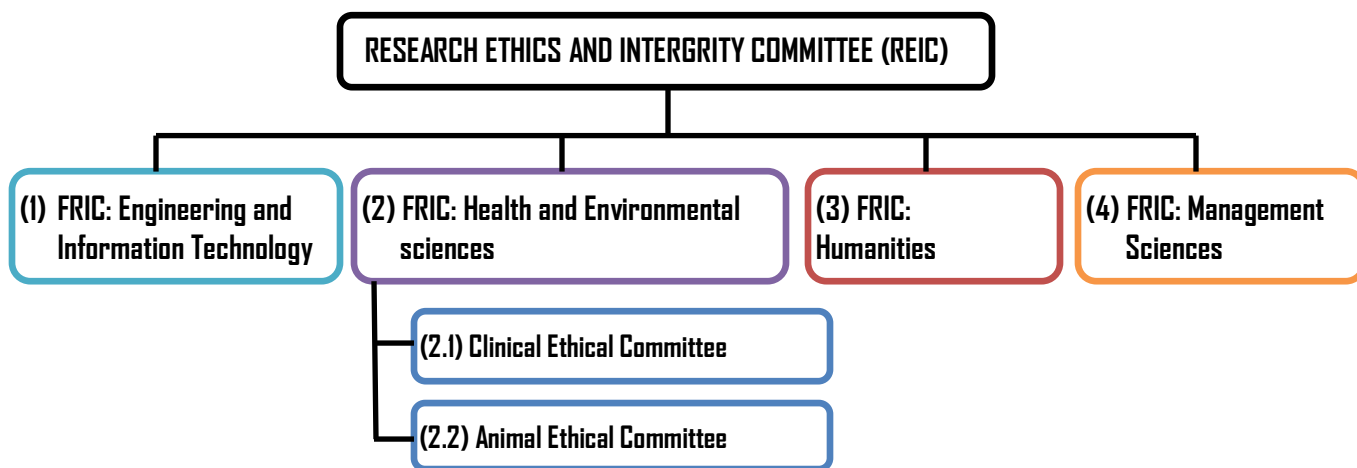
15. Execution of discipline: Direct relationships between staff/staff and staff/students must be avoided in the context where discipline must be exercised. In cases where such relationships do exist, the information must be put in a public record. Situations where a spouse and/or child are supervised must be discouraged. Where such cases do exist, an independent staff member must be in charge of executing discipline.

16. Hazardous material: The use and disposal of hazardous materials for teaching and learning, research, demonstration, or other purposes whether on or off the premises of the university, but whose activities are associated with the university, will be subjected to the provisions of existing legislation and must be complied with.

17. Disputes: Should any dispute arise out of the above mentioned principles or the application thereof, the CUT will have the choice/jurisdiction to determine how the matter will be dealt with internally or externally.

B. ETHICS COMMITTEES: STRUCTURES AND ROLES (RESEARCH INVOLVING HUMANS, ANIMALS AND THE ENVIRONMENT)

Research ethics and integrity at CUT is managed by the Research Ethics and Integrity Committee (REIC) and the Faculty Research and Innovation Committees. The REIC reports to the University Research and Innovation Committee (URIC) and is mandated to provide broad leadership on research ethics and integrity and oversight function of the four FRICs. The diagram below illustrates the research ethics and integrity structure at CUT. The Faculty of Health and Environmental Sciences based the approval of their research with humans and animals on ethical clearance by a legally approved Clinical Ethical Committee and Animal Ethical Committee.



B1. Research Ethics and Integrity Committee (REIC)

The Research Ethics and Integrity Committee (REIC) in reviewing research, will contribute to the safeguarding the dignity, rights, safety, and well-being of all actual or potential participants in social, behavioural, economic and educational research conducted by the University¹.

The purpose of this committee is to:

- 1.1 Develop policies and/or offer opinions on on-going ethical issues in research.
- 1.2 Monitor the compliance of approved studies
- 1.3 Facilitate training and capacity building on research ethics and integrity related issues.

The research ethics committee includes individuals with scientific, medical expertise and non-scientific members, particularly those related to social, economic, legal or cultural considerations.

Deputy Vice-Chancellor: Research, Innovation and Engagement (Ex Officio)

Director: Research Development and Post-Grad Studies

Chairs: Faculty Research and Innovation Committees

Representative: Environment and Sustainability

Representative: Animal Research

Representative: Clinical Research

Representative: Information and Data Protection

Representative: Editor of University Journal

Representative: Research based on human engagements and interaction

Head of Research Development and Post-Grad Studies will be the Chairperson and the office of Research Development and Post-Grad Studies will provide secretariat support.

Generally the functions of research ethics committees include identifying and weighing up the risks and potential benefits of research, evaluating the process and materials (printed documents and other tools) that will be used for seeking participants' informed consent, assessing the recruitment process and any incentives that will be given to participants, evaluating risks to participants' confidentiality (and the related risk of discrimination) and the adequacy of confidentiality protections, and examining any other issues that may affect the ethical acceptability of the research.

¹ Refer to Annex 1 on the CUT REIC Constitution

The REIC is mandated to:

- to develop appropriate research ethics and integrity policies that comply with national and international regulations and norms for the ethical conduct of research,
- to oversee the implementation and compliance with the University's research ethics and integrity policy in all the research activities undertaken by the University,
- to establish procedures to ensure research ethics and integrity, and alter when appropriate, the structure, composition and function of the research ethics committees and to approve the appointment of members to these committees,
- to put a procedure in place, according to acceptable norms and standards, for dealing with appeals,
- to facilitate training and capacity building on research ethics and integrity related issues, and
- to coordinate, monitor and evaluate the integrity of research ethics in all research activities undertaken by the University.

The committees listed below have been mandated to function as independent research ethics committees for the purpose of reviewing and approving research.

B2. Faculty Research and Innovation Committees

International guidelines for the need for ethics approval of non-health related research e.g. social science research involving interviews/engagements/observations of human/animals/environment participants is less prescriptive. However, **non-legislated** research involving direct interaction with human subjects or the capturing of any personal information should go through a process of ethical clearance.

Research Involving Human Participants

Research involving human participants must comply with the following principles:

- be relevant to the needs and interests of the community in which the research is conducted
- have a valid scientific methodology
- have a South African resident researcher as a Principal or Co-Researcher, if the research is health related
- ensure research participants are well informed on the purpose of the research and how the research results will be disseminated and have consented to participate, where applicable
- ensure research participants' rights to privacy and confidentiality are protected
- ensure the fair selection of research participants
- be preceded by a thorough risk benefit analysis
- thorough care must be taken that research in communities are effectively coordinated

Research Involving Environment- And Bio-Safety

Care should be taken to ensure that all research 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 that could potentially cause harm to humans, animals or the environment or the researcher and supporting staff must familiarise themselves with appropriate bio-safety and containment procedures. All research involving genetically modified organisms or research that poses a risk to the natural environment or the researcher and supporting staff, must be submitted to for review and approval.

This includes the following:

- all research involving recombinant DNA techniques or genetically modified organisms
- research involving organisms that are pathogenic to humans and/or animals (Risk Group 2 or Bio-safety Level 2 and above)
- research involving radiation, and
- research which may potentially cause harm to the natural environment.

Procedure/Process

Supervisor/s identifies ethical considerations and indicates such on form after consultation with proposal panel. In case of doubt supervisors may consult with the FRC and formulate a resolution. If FRC has a problem, then the Ethics and Integrity Committee can attend with a recommendation to the URIC.

The **researcher** is ultimately responsible to apply for ethics approval for a given project and should make this decision after discussion with supervisor, the Head of Department, and the FRC, which will refer the matter to the chairperson of the REIC and URIC for a decision, if necessary.

Approved Forms:

- LS 262 - application for approval of master's doctoral, post-doctoral and staff research projects; and application for funding from CUT research grant scheme.
- NSPCA Research Ethics review checklist and comments

B3. Clinical Ethical Committee – Health related or clinical research

All **health related** or **clinical** research is **legislated** and in terms of the *South African Health Act No 61.2003* must be approved by an accredited research ethics committee. Thus all health related research involving:

- a. interaction with human participants
- b. the use of potentially identifiable personal records, information or tissue specimens, and/or
- c. human progenitor or stem cells

Requires the approval of a legally approved **Clinical Ethical Committee** before the research study commences.

B4. Animal Ethical Committee - Research Involving Animals

Due to the specialist knowledge required the services of a legally approved **Animal Ethical Committee** is required for the purpose of reviewing and approving research and teaching involving animals. The term “Animals” in this framework policy refers to all animals having the power of sense perception or sensation (SANS10386:200X).

The use of animals in scientific research can only be justified if the benefits to both humans and animals outweigh the potential harm to the animal subject. All research and teaching involving animals must be approved by a 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.” (*Medical Research Council Guidelines*).

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

- **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.
- **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.
- **Refinement** of animal sourcing, animal care practices and experimental procedures to eliminate physical and psychological distress within limitation imposed by the objectives of the research.

All research and teaching programmes involving animals that will be conducted at CUT and other sites must be submitted to the Committee for review and approval. The committee also has a responsibility to oversee and monitor the care and use of all laboratory and other animals kept for teaching and research purposes at, or under the auspices of the University.

B5. Research Information Management Systems (RIMS)

The University is a member of the South African Universities and Science Councils Consortium which participates in the National Research Foundation (NRF) project for establishing a Research Information Management System. This is a web-based tool that captures statistical data and produces reports on institutional research inputs and outputs. The system will play an important role in research management with advanced data collection and provision for the institutions of higher learning in South Africa.

The system consists of the following research management modules:

- Expertise Management
 - Grants and Contracts
 - Human Studies
 - Animal Studies and Facilities
 - Clinical Trials
 - Environmental Safety
 - Intellectual Property
- } **Research Ethics & Integrity**
(Responsible Conduct of Research)

RIMS will in future play an important role in research management including research ethics, providing advanced data collection and provision for the institutions of higher learning. The official link to the RIMS Information Website is <https://info.rims.ac.za>

Administration of RIMS is the responsibility of the Research Officer: NRF Activities

B6. Gate Keeper Approval

Social science research often depends on gaining access to either people or data. That means you need the cooperation of the ‘gatekeepers’ to the data you want to access, or to the people you want to talk with – before you can get to the stage of asking permission from potential research participants themselves. In practice, that means you may need to secure permission or approval from different organisations or bodies before you can go ahead with your research.

Gatekeeper approval is responsibility of Office of the Registrar or Academic Planning: Deputy Director Institutional Research.

B7. Misconduct

Academic dishonesty or misconduct hampering responsible conduct of research will be dealt in line with the Policy and Procedures on Academic Integrity at the Central University Technology Free State and/or other applicable policy.

B8. Legislation

South African National Standard (SANS 10386:2008). The care and use of animals for scientific purposes.

MRC Guidelines on Ethics for Medical Research, Revised Edition, 1993

National Health Act No: 61 of 2003

Code of Conduct for Nanoscience and Nanotechnology Research and Development in South Africa

Protection of Personal Information (POPI) Act and Promotion of Access to Information Act (PAIA)

Implications of the PAIA and POPIA Legislation for Research Managers in South Africa

The two legislations Protection of Personal Information (POPI) Act and Promotion of Access to Information Act (PAIA) which impact on the research ethics and integrity within institutions.

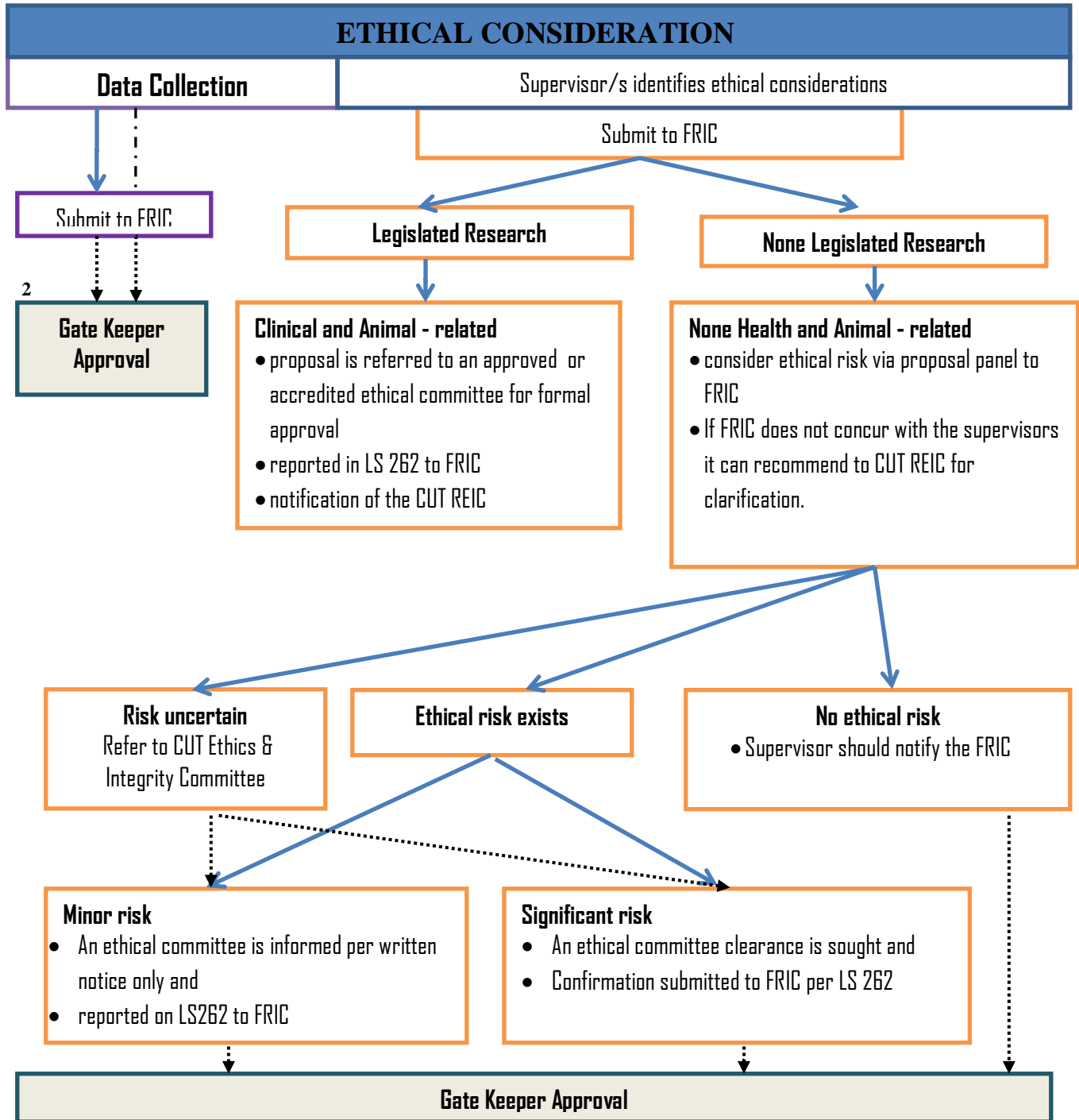
- Whether the administration of ethics is centralized or decentralized depends on the size of the institution.
- In principle – all research must be submitted and given exemption or reviewed.
- The legislation is not only limited to animal and human but extends to researchers who do desktop research – socio-economic and environmental issues.

Legal ramifications - implications for academic institutions:

- Registration and Records/Information Management Accountability – implications for Libraries in terms of data management and data life cycle. There should be procedures in place on the storage of data in a secured manner.
- The RIMS must be compliant with the POPI Act. Transmission of data is secured in a secured server not connected to the internet.
- Ethics committees have a legal duty of compliance to the POPI Act.
- Access to information and mitigation against liability
- Procedures should include withdrawal of consent and how to withdraw the data from the database.
- Challenge of students who are doing desktop research, how going to unite an ethics approval from the POPI Act. Possible solutions:
 - More general consent forms
 - More engagement with respondents
 - More planning and explaining research in information sheets
 - Security- routine encryption, off email and drop box for research data – not good practice

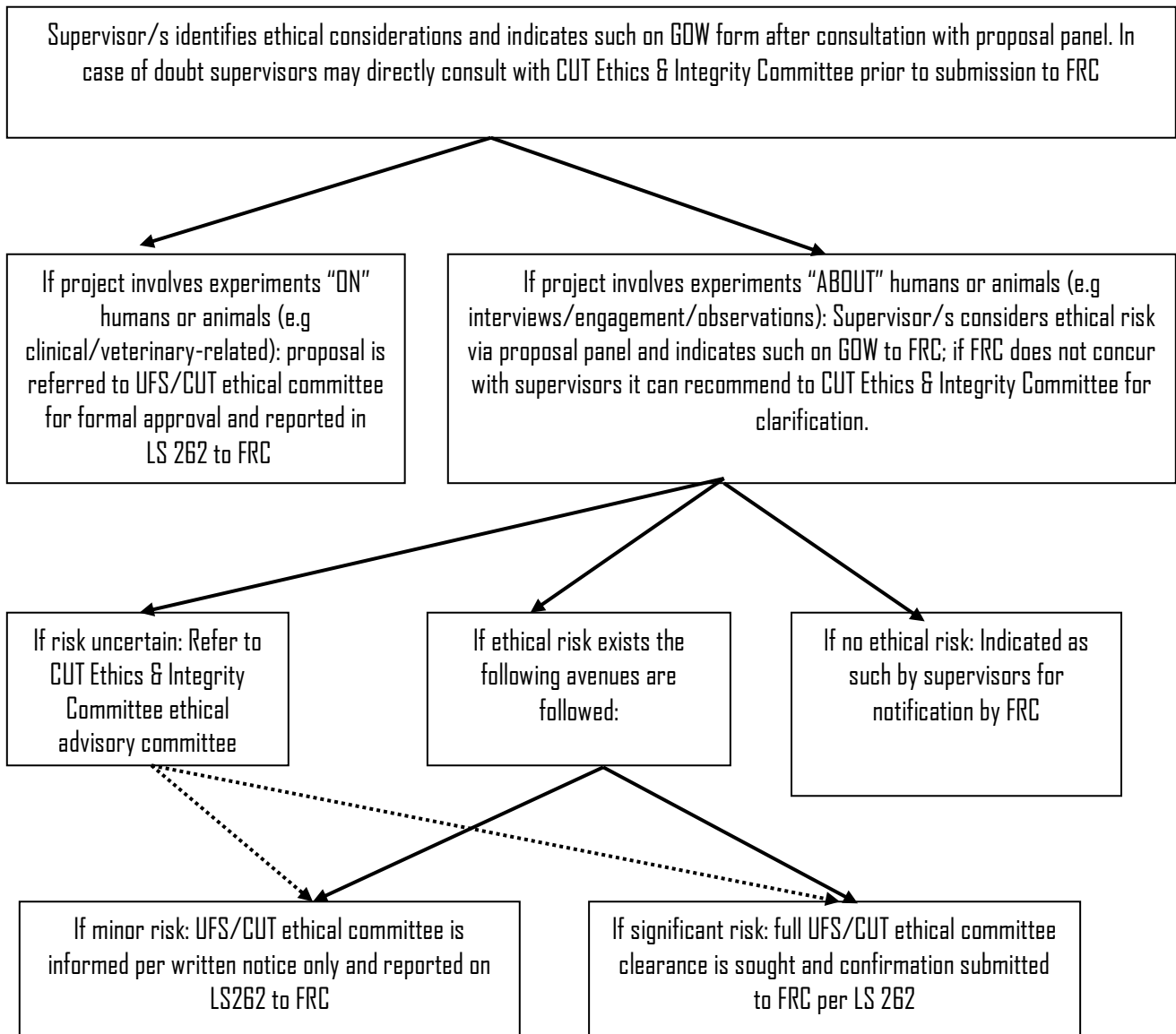
C. CUT ETHICAL APPROVAL FLOW DIAGRAM

C.1 Proposed Ethical Approval Flow Diagram



² **Gate Keeper Approval** - Social science research often depends on gaining access to either people or data. That means you need the cooperation of the 'gatekeepers' to the data you want to access, or to the people you want to talk with – before you can get to the stage of asking permission from potential research participants themselves. In practice, that means you may need to secure permission or approval from different organisations or bodies before you can go ahead with your research

C.2 Proposed Ethical Approval Flow Diagram: Health And Environmental Sciences



D. ANNEX - FORMS

INTERFACULTY ANIMAL ETHICS COMMITTEE OF THE CUT

RESEARCH PROTOCOL FOR THE USE OF LIVE VERTABRATES

FOR OFFICE USE ONLY	ANIMAL EXPERIMENT NR.
Date received:	Date to Control Committee:
Progress report:	Final report:

PLEASE COMPLETE AS COMPREHENSIVELY AS POSSIBLE, THUS EXPEDIATING THE CONCLUSION HEREOF. COMPLETED DOCUMENTS MUST BE SUBMITTED TO THE ADMINISTRATION OFFICE OF THE DEAN OF RESEARCH, CUT. (ATTENTION....., TEL. (051) E-mail address

Project title:

Project leader:

Title:	Initials:	Surname:
Department:	Qualifications:	
Telephone (Home):	Telephone (Work): N/A	
Registration Authority: CUT		

Collaborators:

NAME	DEPT	RESPONSIBILITIES	TEL	SIGNATURE

1. Type of research (Mark with an X)

- (i) Basic research
- (ii) Contract research
- (iii) Training

2. Background and objective:

Main objectives

Specific objectives

3. Aim

4. **Experimental animals required:**

Species	Phylum	Sex	Age/mass	Number

Are the abovementioned animals available at the Animal Experimentation Unit?

YES	NO
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5. **Drugs:**

Drug/compound	Route Dosage Frequency

Legal regulations require that either a medical practitioner or a dental practitioner, or a veterinarian should exercise control over the use of drugs.

6. **Explanation of experimental design:**

- a. *Kindly explain abbreviations e.g. FCR in brackets only once, when it is mentioned in the application form and protocol.*
- b. *Provide a detailed explanation where animals will be divided into groups.*

7. **Duration of study:** The maximum continuous period that will be allocated to projects is twelve months. Renewals, extensions and amendment of existing projects must be submitted for approval.

<i>Date of commencement</i>	<i>Date of completion</i>

The period any animal or treatment group will be subjected to the procedure:

8. **Conducted where:** (Indicate the venue where this experimental/training procedure will be conducted.)

9. **After-care:** Could normal veterinary services be utilised if you or your collaborators cannot be reached during an emergency?
Please note that the costs associated with this service will be for your own account.

May the personnel of the Animal Experimentation Unit administer analgesics if deemed necessary?

10. a) **Anaesthesia:** Drug as well as route and dose.
N/A

YES	NO
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b) **Euthanasia:** Please indicate the method of euthanasia that will be used on completion of your study or during your training experiment, e.g. CO₂ inhalation, i.v./i.p. injection of a recognised agent, cervical paratopia, exsanguination under anaesthetic. If an alternative method is used, please motivate in full the reason for using the method concerned.

11. **Researcher's own judgment of severity of the procedure: (Slight/Moderate/Severe).**
12. Motivate please: Moderate, at slaughter they will be killed instantly to avoid pain and suffering.

13. **How has the three R's (Replacement/Reduction/Refinement) been addressed?**

Please indicate ownership of the animals concerned. Are all applicable permits (where necessary) available? Please attach.

N/A

Ownership of animals:

14. **Radio Isotopes:** Does this study require the use of Radio Isotopes?

If **YES**, the approval of the Radio Isotope Control Committee must be appended

15. **Statement**

- 15.1 I, the undersigned hereby certify that the conducting hereof will occur according to existing University regulations regarding the use of experimental animals, and that
- 15.2 I am appropriately qualified to conduct this study or to supervise the conducting thereof;
- 15.3 this study may result in the broadening of biological knowledge or is essential for the training of students;
- 15.4 this study is not a replication of similar research of which the results are known;
- 15.5 this study is designed in such a way that no animals are wasted;
- 15.6 This study is designed in such a way that for the animal's discomfort, stress and anxiety are restricted to the absolute minimum.
- 15.7 all alternative methods have been investigated and that it would be impossible to achieve the goal of this study without making use of experimental animals;
- 15.8 I am familiar with the regulations contained in the NATIONAL CODE FOR THE HANDLING OF ANIMALS FOR RESEARCH, TRAINING, and DIAGNOSIS AND TESTING OF AGENTS AND RELATED SUBSTANCES IN SOUTH AFRICA.
- 15.9 I will comply with any restrictions or changes recommended by the Control Committee for Animal Experimentation with regard to this study;
- 15.10 I undertake to report in writing to this body on a regular basis, as recommended by the Interfaculty Animal Ethics Committee of the CUT, with regard to the progress that has been made with this project, and furthermore that on completion of this study I will without delay provide the committee with copies of all publications proceeding from this study; and
- 15.11 if according to the personnel of the Experimental Animal Unit any animal involved in this study has endured unnecessary pain and they have been unable to reach me telephonically, or if I am unable to react to their call immediately, they hereby receive my authorisation to terminate the life of the animal(s) concerned as soon as possible and in an humane manner. **(NB. In such a case only one telephone call will be made to your office and if you fail to act within 1 hour of the call, the life of the animal(s) will be terminated).**

16. **Declaration by Head of Department on the scientific merit of the research:**

SIGNATURE OF APPLICANT

DATE

SIGNATURE OF SUPERVISOR

DATE

ANIMAL ETHICS COMMITTEE OF THE CUT

ANIMAL EXPERIMENT NR:

Name of applicant:

Department:

Project title:

Classification of study:

Research

Contract research

Training

ANIMAL SPECIES	NUMBER	EXPIRY DATE

.....
CHAIRMAN:
INTERFACULTY ANIMAL ETHICS COMMITTEE OF THE CUT

.....
DATE

INFORMATION: BEFORE ANIMALS WILL BE SUPPLIED TO HIM/HER, THE RESEARCHER MUST PROVIDE THE ANIMAL EXPERIMENTATION UNIT WITH A COPY OF THIS. PLEASE STATE THE ABOVEMENTIONED NUMBER IN ALL CORRESPONDENCE AND ENSURE THAT THIS IS FILLED IN ON THE INTERNAL ORDER FORM WHENEVER ANIMALS ARE REQUESTED FOR THIS SPECIFIC PROJECT. PLEASE NOTE THAT THIS APPROVAL IS ONLY VALID FOR A LIMITED PERIOD. IN THE CASE OF ANY EXTENSION OF OR AMENDMENT TO THIS STUDY, AS EXPLAINED IN YOUR APPLICATION, THE RENEWAL OR AMENDMENT FORM HAS TO BE COMPLETED AND SUBMITTED TO THE ADMINISTRATION OFFICE OF THE INTERFACULTY ANIMAL ETHICS COMMITTEE OF THE UFS, BLOCK D, ROOM 115, FRANCOIS RETIEF BUILDING, DEAN'S DIVISION, FACULTY OF HEALTH SCIENCES. FAILURE TO COMPLY WITH THE GUIDELINES OUTLINED ABOVE WILL RESULT IN THE SUMMARY SUSPENSION OF THIS PROJECT

NSPCA: RESEARCH ETHICS REVIEWER'S CHECKLIST AND COMMENTS

APPLICATION NO:

TITLE:

SPECIES	TOTAL	SEVERITY CATEGORY	FATE OF ANIMALS @ END OF STUDY

	N/A	YES	UNSURE	NO
1. Is there sufficient justification for the proposed research?				
2. Are the specific aims, hypotheses and research questions clearly identified?				
3. Is the experimental design of the project in keeping with the aims of the proposal?				
4. Does the protocol adequately justify the use of live animals?				
5. Does the proposed animal model make sense for the research project?				
6. Is there adequate statistical or technical justification for the number of animals requested?				
7. Have the "Three Rs" (replacement, reduction and refinement) been adequately addressed?				
8. Have all surgical and non-surgical procedures been clearly and completely described, consistent with the experimental design outline?				
9. Has pain, discomfort and distress to the animal(s) been minimized or avoided to the fullest extent possible?				
10. Is there any appropriate plan for monitoring animals for pain, discomfort and distress, including criteria for determining early euthanasia (humane endpoint)?				
11. Are the members of the research team qualified and experienced in the procedures to be performed?				
12. Is the harm to animal interest reasonable in relation to potential benefits of the proposal?				

NSPCA RECOMMENDATION:

Approved without changes:		Rejected, but may be resubmitted following substantial changes:	
Conditionally approved subjected to required changes:		Rejected:	

GENERAL COMMENTS:

REVIEWED BY:

DATE:

Guideline Research Ethics Checklist

This code applies to all research carried out in the CUT, whether by staff or students. The checklist should be completed by the Principal Investigator, leader of the research group, or supervisor of the student(s) involved. Those completing the checklist should ensure, wherever possible, that appropriate training and induction in research skills and ethics has been given to researchers involved prior to completion of the checklist, including reading the University's Code of Research Ethics.

This is particularly important in the case of student research projects.

If the answer to any of the questions below is 'yes', please give details of how this issue is being/will be addressed to ensure that ethical standards are maintained.	
1 THE RESEARCHERS	
Your name and position	
Proposed title of research	
Funding body	
Time scale for research	
List those who will be involved in conducting the research, including names and positions (e.g. 'PhD/Dtech student')	
2 RISKS TO, AND SAFETY OF, RESEARCHERS	
Those named above need appropriate training to enable them to conduct the proposed research safely and in accordance with the ethical principles	Yes/No
Researchers are likely to be sent or go to any areas where their safety may be compromised	Yes/No
Could researchers have any conflicts of interest?	Yes/No
3 RISKS TO, AND SAFETY OF, PARTICIPANTS	
Could the research induce any psychological stress or discomfort?	Yes/No
Physically invasive or potentially physically harmful procedures?	Yes/No
Could this research adversely affect participants in any other way?	Yes/No
4 DATA PROTECTION	
Will any part of the research involve audio, film or video recording of individuals?	Yes/No
Will the research require collection of personal information from any persons without their direct consent?	Yes/No
How will the confidentiality of data, including the identity of participants (whether specifically recruited for the research or not) be ensured?	
Who will be entitled to have access to the raw data?	
How and where will the data be stored, in what format, and for how long?	
What steps have been taken to ensure that only entitled persons will have access to the data?	
How will the data be disposed of?	
How will the results of the research be used?	
What feedback of findings will be given to participants?	

Is any information likely to be passed on to external companies or organisations in the course of the research?	Yes/No
Will the project involve the transfer of personal data to countries outside the South African Area?	Yes/No
5 RESEARCH	
The research involves living human subjects specifically recruited for this research project? <i>If 'no', go to section 6</i>	Yes/No
How many participants will be involved in the study?	
What criteria will be used in deciding on inclusion/exclusion of participants?	
How will the sample be recruited?	
Will the study involve groups or individuals who are in custody or care, such as students at school, self-help groups, and residents of nursing home?	Yes/No
Will there be a control group?	Yes/No
What information will be provided to participants prior to their consent? (e.g. information leaflet, briefing session)	
Participants have a right to withdraw from the study at any time. Please tick to confirm that participants will be advised of their rights.	
Will it be necessary for participants to take part in the study without their knowledge and consent? (e.g. covert observation of people in non-public places)	Yes/No
Where consent is obtained, what steps will be taken to ensure that a written record is maintained?	
In the case of participants whose first language is not English, what arrangements are being made to ensure informed consent?	
Other benefit from their participation?	Yes/No
Are any of the participants likely to be particularly vulnerable, such as elderly or disabled people, adults with incapacity, your own students, members of ethnic minorities, or in a professional or client relationship with the researcher?	Yes/No
Will any of the participants be under 18 years of age?	Yes/No
Do the researchers named above need to be cleared through the Disclosure/Enhanced Disclosure procedures?	Yes/No
Will any of the participants be interviewed in situations which will compromise their ability to give informed consent, such as in prison, residential care, or the care of the local authority?	Yes/No
6 EXTERNAL PROFESSIONAL BODIES	
Scrutiny by any external body concerned with ethical approval?	Yes/No
If so, which body?	
Date approval sought	
Outcome, if known <i>or</i>	
Date outcome expected	
7 ISSUES ARISING FROM THE PROPOSAL	
In my view, ethical issues have been satisfactorily addressed. OR In my view, the ethical issues listed below arise and the following steps are being taken to address them:	
<i>P.S The guideline does not replace any existing Faculty guidelines or requirements.</i>	

Singapore Statement on Research Integrity

Preamble. The value and benefits of research are vitally dependent on the integrity of research. While there can be and are national and disciplinary differences in the way research is organized and conducted, there are also principles and professional responsibilities that are fundamental to the integrity of research wherever it is undertaken.

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.

The Singapore Statement on Research Integrity was developed as part of the 2nd World Conference on Research Integrity, 21-24 July 2010, in Singapore, as a global guide to the responsible conduct of research. It is not a regulatory document and does not represent the official policies of the countries and organizations that funded and/or participated in the Conference. For official policies, guidance, and regulations relating to research integrity, appropriate national bodies and organizations should be consulted. Available at: www.singaporestatement.org

Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations

Preamble. Research collaborations that cross national, institutional, disciplinary and sector boundaries are important to the advancement of knowledge worldwide. Such collaborations present special challenges for the responsible conduct of research, because they may involve substantial differences in regulatory and legal systems, organizational and funding structures, research cultures, and approaches to training. It is critically important, therefore, that researchers be aware of and able to address such differences, as well as issues related to integrity that might arise in cross-boundary research collaborations. Researchers should adhere to the professional responsibilities set forth in the *Singapore Statement on Research Integrity*. In addition, the following responsibilities are particularly relevant to collaborating partners at the individual and institutional levels and fundamental to the integrity of collaborative research. Fostering the integrity of collaborative research is the responsibility of all individual and institutional partners.

Responsibilities of Individual and Institutional Partners in Cross-Boundary Research Collaborations

General Collaborative Responsibilities

- 1. Integrity.** Collaborating partners should take collective responsibility for the trustworthiness of the overall collaborative research and individual responsibility for the trustworthiness of their own contributions.
- 2. Trust.** The behavior of each collaborating partner should be worthy of the trust of all other partners. Responsibility for establishing and maintaining this level of trust lies with all collaborating partners.
- 3. Purpose.** Collaborative research should be initiated and conducted for purposes that advance knowledge to the benefit of humankind.
- 4. Goals.** Collaborating partners should agree at the outset on the goals of the research. Changes in goals should be negotiated and agreed to by all partners.

Responsibilities in Managing the Collaboration

- 5. Communication.** Collaborating partners should communicate with each other as frequently and openly as necessary to foster full, mutual understanding of the research.
- 6. Agreements.** Agreements that govern collaborative research should be understood and ratified by all collaborating partners. Agreements that unduly or unnecessarily restrict dissemination of data, findings or other research products should be avoided.
- 7. Compliance with Laws, Policies and Regulations.** The collaboration as a whole should be in compliance with all laws, policies and regulations to which it is subject. Collaborating partners should promptly determine how to address conflicting laws, policies or regulations that apply to the research.
- 8. Costs and Rewards.** The costs and rewards of collaborative research should be distributed fairly among collaborating partners.
- 9. Transparency.** Collaborative research should be conducted and its results disseminated transparently and honestly, with as much openness as possible under existing agreements. Sources of funding should be fully and openly declared.
- 10. Resource Management.** Collaborating partners should use human, animal, financial and other resources responsibly.
- 11. Monitoring.** Collaborating partners should monitor the progress of research projects to foster the integrity and the timely completion and dissemination of the work.

Responsibilities in Collaborative Relationships

- 12. Roles and Responsibilities.** Collaborating partners should come to mutual understandings about their roles and responsibilities in the planning, conduct and dissemination of research. Such understandings should be renegotiated when roles or responsibilities change.
- 13. Customary Practices and Assumptions.** Collaborating partners should openly discuss their customary practices and assumptions related to the research. Diversity of perspectives, expertise and methods, and differences in customary practices, standards and assumptions that could compromise the integrity of the research should be addressed openly.
- 14. Conflict.** Collaborating partners should seek prompt resolution of conflicts, disagreements and misunderstandings at the individual or institutional level.
- 15. Authority of Representation.** Collaborating partners should come to agreement on who has authority to speak on behalf of the collaboration.

Responsibilities for Outcomes of Research

- 16. Data, Intellectual Property and Research Records.** Collaborating partners should come to agreement, at the outset and later as needed, on the use, management, sharing and ownership of data, intellectual property, and research records.
- 17. Publication.** Collaborating partners should come to agreement, at the outset and later as needed, on how publication and other dissemination decisions will be made.
- 18. Authorship and Acknowledgement.** Collaborating partners should come to agreement, at the outset and later as needed, on standards for authorship and acknowledgement of joint research products. The contributions of all partners, especially junior partners, should receive full and appropriate recognition. Publications and other products should state the contributions of all contributing parties.
- 19. Responding to Irresponsible Research Practices.** The collaboration as a whole should have procedures in place for responding to allegations of misconduct or other irresponsible research practice by any of its members. Collaborating partners should promptly take appropriate action when misconduct or other irresponsible research practice by any partner is suspected or confirmed.
- 20. Accountability.** Collaborating partners should be accountable to each other, to funders and to other stakeholders in the accomplishment of the research.

The Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations was developed as part of the 3rd World Conference on Research Integrity, 5-8 May 2013, in Montréal, as a global guide to the responsible conduct of research. It is not a regulatory document and does not represent the official policies of the countries or organizations that funded or participated in the Conference.