

Rhodes University

Ethical Standards Committee

Handbook

www.ru.ac.za/research/ethics/

The protection of the rights and dignity of humans and animals is a top priority for all activities at Rhodes University. In order to ensure that appropriate practices are applied, particularly in research and teaching, Rhodes University has established a Policy on Ethics that is binding throughout the University.

This Handbook is a compilation of the Rhodes University Policy on Ethics, the Protocols for Research and Teaching involving Humans and Animals, and all supplementary information for applying ethics at Rhodes University.

All University research and teaching involving human participants, human biological material or vertebrate animals must have prior approval of the University Ethical Standards Committee or one of its authorised sub-committees. Full details are presented in this document.

Senior Management, Heads of Department, new committee members, researchers and all interested parties are encouraged to use this handbook for questions with regards to ethics.

This Handbook is available to the public.

Last updated on 21 November 2014

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Preamble

Research involving humans, animals or human biological material is essential for the advancement of knowledge in the sphere of human and animal welfare and for society at large. Protecting the rights and dignity of humans and, minimally, the welfare of animals involved in research is thus of utmost importance for all activities under the auspices of Rhodes University. Research and teaching must be conducted with maximum care in order to respect those rights and the welfare of the individuals who are involved in research and teaching. In this regard, staff members conducting and supervising research and who are involved in teaching have the primary responsibility to ensure that those rights are met. The university and its institutes, under whose auspice research and teaching are conducted, have the responsibility of supporting researchers for ethically sound conduct towards participants and the public.

Ethical considerations are further subject to legal liability and public perception.

These rights shall be protected by conscientious scrutiny of each University research and teaching project in order to identify and minimise all foreseeable risks and to ensure that human rights of privacy and an informed and voluntary participation are met.

A policy statement of Ethical Standards and Procedures is important to ensure that this responsibility is fulfilled. It is further important for researchers and teachers to have guidelines on how these rights are respected in research and teaching. The policy described herein shall define and reinforce ethical standards, and to provide the formal procedures for endorsement of teaching and research projects utilizing human participants, animals or other biological material at or in conjunction with Rhodes University.

For this Handbook the following documents and standards were considered (amongst others):

Primary legislation:

National Health Act (No 61 of 2003)

Children's Act (No 38 of 2005)

Regulations and standards in terms of primary legislation:

National Health Act (Act No. 61 of 2003): R719 Regulations Relating to Research with Human Participants (from 19 Sep 2014).

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

Department of Health (2004): Research Ethics Guidelines.

Department of Health (2006): Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa. Second Edition. [<http://www.kznhealth.gov.za/research/guideline2.pdf>]

NHREC (2012): Payment of trial participants in South Africa: Ethical considerations for Research Ethics Committees (RECs). National Research Ethics Committee.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1978): Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.

South African Medical Research Council (2004): Guidelines on Ethics in Medical Research: General Principles.

International standards:

WMA (1965-2013): Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

I. Rhodes University Policy on Ethics

1. POLICY PARTICULARS

DATE OF APPROVAL BY RELEVANT COMMITTEE STRUCTURE: Rhodes University Ethical Standards Committee 03 Nov 2014	
DATE OF APPROVAL BY SENATE:	21 November 2014
DATE OF APPROVAL BY COUNCIL:	4 December 2014 (scheduled)
COMMENCEMENT DATE:	2 November 1984
REVISION HISTORY:	1 st revision 26 November 1986 2 nd revision (informal) March 2008
REVIEW DATE:	Every three years or as necessary
POLICY LEVEL:	All academic staff and students
RESPONSIBILITY [Person/Division/Committee accountable for]:	
- IMPLEMENTATION & MONITORING:	Rhodes University Ethical Standards Committee
- REVIEW AND REVISION:	Rhodes University Ethical Standards Committee
REPORTING STRUCTURE: Rhodes University Ethical Standards Committee → Senate → Council	

2. POLICY STATEMENT

2.1 Policy declaration

- (1) Human dignity and animal welfare deserve the highest respect. Ethically correct conduct is thus of utmost importance for all activities under the auspices of Rhodes University.
- (2) In establishing this policy, Rhodes University, a university which measures itself against the highest international standards of academic and professional practice, sets a clear statement for the consideration of ethical requirements, and corresponding procedures to meet those requirements, across the whole University.
- (3) This policy succeeds previous policies to establish a Rhodes University Ethics committee from 2 November 1984, and guidelines approved by Senate on 26 November 1986.

2.2 Policy objectives

- (1) Rhodes University Ethical Standards Committee aims to provide uniform and effective protection of humans and animals that are associated with Rhodes University and any

of its activities. Ethical considerations include (not exclusively) the minimisation of physical, psychological, social or financial risks as well as the fulfilment of moral and legal standards.

- (2) This policy concentrates on ethical considerations in research and teaching activities. Further aspects of institutional ethics, ethical conduct, and ethics as an academic discipline or part of thereof are not covered by this policy.
- (3) It is incumbent upon the whole University to make staff, students and any other parties involved in University activities aware of this policy. The University must ascertain that, where applicable, all involved individuals are competent to maintain the standards outlined in this policy and the relevant protocols on ethics.
- (4) Ethical considerations are universal, and have to be prioritised against any other interest.
- (5) Nothing in this policy document should be interpreted as relieving a University member or associate of any obligations acquired as a result of membership of a professional or other association. However, adherence to a professional code of ethics does not in itself override the obligation to observe this policy and the relevant protocols on ethics.

3. POLICY DEFINITIONS

3.1 Glossary

Ethics application: The document or set of documents describing the research or teaching activity requested for ethical approval. The ethics application normally consists of a form and appendices. Some other sources use the term 'research proposal' or 'teaching proposal' indirectly for an ethics application.

Ethical approval: The support of an ethics committee to undertake the activity proposed in the Ethics application, normally expressed in form of a letter. Some other sources use the term 'ethical clearance' synonymously to 'ethical approval'.

Ethics review: The process of reviewing an ethics application aimed to obtain approval by an ethics committee.

Principal Investigator: The Principal Investigator (PI) heads the research project and takes the responsibility for conducting the research. (See section 4.3.1(3) for the role of students as Principal Investigators and section 4.3.1(4) for the role of the Principal Investigator in teaching.)

Researcher: The term 'researcher' encompasses all individuals who are actively involved in research.

Methodology and protocol: A theoretical underpinning or justification for the choice of methods or approach and a set of rules for the processes applied in the research. Different disciplines do, however, have very different definitions on the details and the structures of a 'methodology' or a 'protocol'. This policy uses the term 'methodology' as a broad understanding of the conceptual and the empirical setup of the research and the term 'protocol' for the processes applied, particularly with respect to the collection of data. In this

understanding a 'protocol' forms part of the 'methodology'. (Please note the difference between a research protocol and the protocol appended to a policy.)

Teaching: Any class activity, such as lecture demonstrations, laboratory practicals, and student projects. (Note that only activities that fall under the scope of this policy shall be considered in this context, see section 3.2.)

Teacher and lecturer: The person conducting teaching. For this policy 'teacher' will be used synonymously for 'lecturer'.

(Human) Participant: A living person about whom a researcher obtains data or specimens or identifiable private information through intervention or interaction with that person.

Vertebrate animal: Any member of the phylum Chordata (animals with backbones, viz. fish, amphibians, reptiles, birds and mammals) and including cephalopods (octopus and squid) and decapods (crabs). (See Protocol for research and teaching involving vertebrate animals, section 1(6)). Please note that primates are not within the scope of this policy, and special rights and duties apply to those species. Researchers that plan to conduct research involving primates shall liaise with the Rhodes University Ethics Standards Committee as early as possible.)

Minimal risk: The probability and magnitude of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in daily life in a stable society or in routine medical, dental, educational or psychological tests or examinations.

3.2 Scope

- (1) A formal ethical consideration (with approval of the University Ethics Standards Committee or one of its sub-committees) is required for:
 - a) research involving human participants,
 - b) research involving vertebrate animals,
 - c) research using human biological material,
 - d) research that might compromise individual, institutional or public integrity when being performed or published¹,
 - e) teaching involving humans for study or demonstration purposes beyond what can be reasonably assumed as part of their normal life routine,
 - f) teaching involving vertebrate animals for study or demonstration purposes, and
 - g) research and teaching that may cause health and safety risks for the involved individuals beyond what is covered by legal or professional standards.
- (2) Ethical aspects have to be considered for all kinds of research or teaching activities that
 - a) are conducted by Rhodes University staff, and students, and/or
 - b) use infrastructure of Rhodes University, and/or
 - c) use participants from Rhodes University, and/or

¹ Research of this kind is welcome, but requires careful consideration of unintended or possibly inappropriate consequences.

- d) are conducted on behalf of or affiliated to Rhodes University.
- (3) The Rhodes University Policy on Ethics and the relevant protocols are binding upon all Rhodes University staff and students as well as externals falling under the scope of this policy.

4. POLICY IMPLEMENTATION

4.1 The actions and processes by which the objectives of the policy will be achieved

4.1.1 Committees

- (1) Rhodes University establishes an independent standing committee, the 'Rhodes University Ethical Standards Committee' (RUESC).
- (2) RUESC aims to ensure that all activities on campus are performed in a responsible way and meet contemporary ethical standards. This is particularly relevant for research and teaching involving humans or vertebrate animals.
- (3) In order to act in itself ethically, RUESC is an independent committee, not controlled by any superior instance. RUESC commits itself to national and international ethical principles and standards, to its policy and protocols on ethics and to Rhodes University rules and standards for all administrative issues.
- (4) RUESC reports to Rhodes University Senate and is administratively supported by Research Office. In case of conflicts of interest or other ethical concerns arising with the Senate of Rhodes University, RUESC shall report to Rhodes University Council.
- (5) RUESC is the official RU body for ethical considerations, and no other internal or external body (apart from its own sub-committees) may be applied in its place. However, the RUESC may appoint other internal or external expertise for facilitation.
- (6) The decisions of the RUESC are binding for the University.
- (7) RUESC is assisted by two standing sub-committees for human ethics (RUESC-HE) and for animal ethics (RUESC-AE), both under the auspices of RUESC and reporting to RUESC.
- (8) The Human Ethics and Animal Ethics sub-committees may be assisted by individual departmental or faculty sub-committees. The departmental committees report to the corresponding Human or Animal Ethics committee. If a departmental committee cannot be associated with either the Human Ethics or the Animal Ethics sub-committee, it shall report directly to RUESC.

² In order to facilitate the terminology, the term 'departmental ethics committee' shall stand equally for faculty ethics committees from hereon.

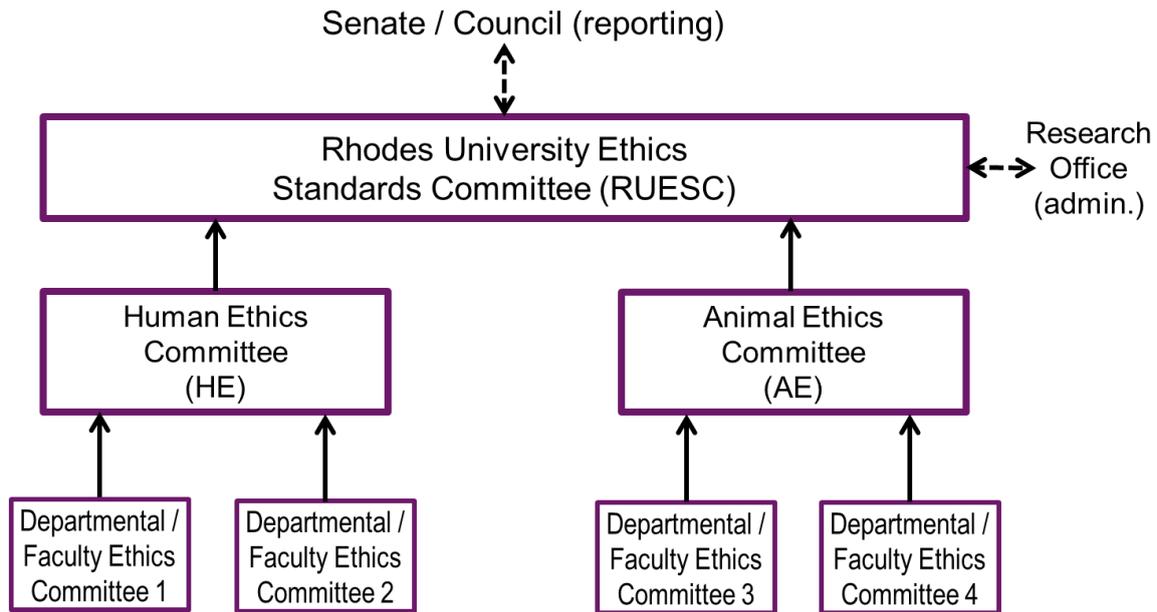


Figure 1: Reporting structure of RUESC and its sub-committees.

4.1.2 Responsibilities

- (1) Primary responsibility for ensuring that the Policy and Protocols on Ethics are adhered to rests with the Principal Investigator.
- (2) Supervisors and superiors on all levels are requested to develop awareness and to provide support to their students and co-workers for ethical considerations, as part of their guiding responsibility.
- (3) RUESC and its sub-committees shall provide
 - a) ethics policies and guidelines,
 - b) education and information dissemination on ethics,
 - c) critical review of all institutional research and teaching practices with respect to ethics,
 - d) review and approval of research projects and teaching with respect to ethics, and
 - e) any other service to support ethical considerations within the scope of RUESC to all members of the Rhodes University community and for all activities that fall under the ethical responsibility of Rhodes University.
- (4) The Rhodes University community at large is requested to critically reflect on ethical issues within the University and communicate these to RUESC or to either of its sub-committees for consideration.
- (5) RUESC has discretion in applying the Policy and the Protocols on Ethics where exceptional circumstances or common sense dictate, provided that the basic principles underlying the policy are not compromised.
- (6) RUESC and its sub-committees provide support for further ethical questions as far as expertise is available, e.g. with respect to institutional ethics, ethical conduct, and Ethics as part of an academic discipline.

4.1.3 Processes

- (1) Researchers who intend to perform research involving human participants or vertebrate animals or research that requires any other ethical consideration shall obtain ethical approval prior to data collection.
- (2) Teachers preparing teaching or any class projects that require ethical approval shall seek approval from RUESC or the appropriate sub-committee.
- (3) This policy shall be made available to all members of staff of Rhodes University, and shall be considered by Heads of Departments, Deans and Senior Management.

4.2 Constitution of ethics committees

The overall committee structure is outlined in Figure 1 of this policy.

4.2.1 Rhodes University Ethical Standards Committee

- (1) Rhodes University Ethical Standards Committee (RUESC) is the principal ethics committee at Rhodes University, dealing with strategic aspects, information dissemination and guidance, such as
 - a) guidelines and policies,
 - b) external representation,
 - c) gatekeeping for external and internal enquiries,
 - d) guidance of Human Ethics and Animal Ethics sub-committees,
 - e) accreditation and audit of departmental sub-committees, and
 - f) provision of education and training.
- (2) RUESC is further responsible for decision making with respect to queries that have been escalated and could not be finalised by one of its sub-committees.
- (3) RUESC may request external assessment or expertise for queries or approvals beyond its own scope and legal competency. However, the decision making and final responsibility remains with RUESC.
- (4) Membership:
 - a) Nominated representatives
 - one representative of each Faculty
 - one representative of Senate
 - one representative of the Community Engagement Division
 - one representative of the students (nominated by SRC)
 - one representative of Postgraduate Liaison Sub-Committee
 - one representative of Human Resource Division
 - one external representative of a welfare organisation or NGO
 - b) Ex-officio members
 - Director of Research Office or representative
 - Director of Student Affairs or nominee

- Human Ethics sub-committee: Chairperson
 - Animal Ethics sub-committee: Chairperson
- c) RUESC reserves the right to co-opt members when necessary, i.e. in instances where specific expertise is identified or to represent the community and its demographics.
- (5) RUESC elects one chairperson amongst its members by a simple majority of votes. Either chairperson of the Human Ethics or Animal Ethics sub-committee may chair such an election.
- (6) The Chairperson of RUESC and all committee members that are not nominated or ex-officio members, are elected for a two year period initially. Re-election is possible. Chairpersons should not be re-elected for more than two consecutive terms.
- (7) The Chairperson shall notify the Deputy Vice-Chancellor: Research and Development of changes of the committee chair-ship.
- (8) One third of the appointed members shall constitute a quorum.
- (9) Decisions of the RUESC shall be majority decisions.
- (10) The RUESC schedules 4 meetings per annum, and further ad hoc meetings if required.
- (11) One joint meeting of RUESC and the Human and Animal Ethics sub-committee shall be held for training purposes and to discuss cases and aspects of broader interest.

For further operational procedures valid for all ethics (sub-) committees see section 4.2.5 of this policy (page 14).

4.2.2 Human Ethics sub-committee

- (1) The Human Ethics sub-committee (RUESC-HE) is a sub-committee of RUESC and reports to RUESC.
- (2) The main scope of the RUESC-HE is to:
- a) advise RUESC on all matters pertaining to the ethics involving humans
 - b) ensure that research involving human participants undergoes an informed ethical review process,
 - c) investigate, and take appropriate actions, in the event of allegations of unethical conduct,
 - d) provide education and training specific for Human Ethics,
 - e) review and support the auditing of Departmental sub-committees, and to
 - f) review and revise the specific guidelines for Human Ethics.
- (3) Membership:
- a) A minimum of 9 members including one representative of each departmental sub-committee associated with the RUESC-HE.
 - b) The members should represent the community and its demographics according to the scope of the committee and have appropriate experience, further being independent and multi-disciplinary.

- c) Membership is voluntary and is representative of diverse disciplines within the University community.
 - d) The Chairperson of the RUEESC-HE shall be free to invite ad hoc members to deal with particular ethics applications.
- (4) The RUEESC-HE elects one Chairperson and a Deputy Chairperson from among its members by a simple majority of votes.
 - (5) The Chairperson and members that are not nominated or ex-officio members are elected for a two year period. Re-election is possible. Chairpersons should not be re-elected for more than two consecutive terms.
 - (6) The Chairperson shall notify the Chairperson of RUEESC of changes in the RUEESC-HE membership.
 - (7) One third of the appointed members shall constitute a quorum.
 - (8) Decisions of the RUEESC-HE shall be majority decisions.
 - (9) The RUEESC-HE processes applications and queries electronically, and if required, ad hoc meetings are arranged to discuss. One or two meetings per annum shall be scheduled for general issues.
 - (10) Cases that cannot be resolved by the RUEESC-HE shall be escalated to RUEESC.

For further operational procedures valid for all ethics (sub-) committees see section 4.2.5 of this policy (page 14).

4.2.3 Animal Ethics sub-committee

- (1) The Animal Ethics sub-committee (RUEESC-AE) is a sub-committee of RUEESC and reports to RUEESC.
- (2) The main scope of the RUEESC-AE is to:
 - a) ensure that scientific research and teaching activities involving vertebrate animals) at Rhodes University comply with legislative norms and the relevant provisions of the South African National Standard SANS 10386:2008 (The care and use of animals for scientific purposes), international wildlife biology best practice guidelines and animal care policies,
 - b) approve or withhold research or teaching activities relating to the care, husbandry and use of vertebrate animals,
 - c) ensure that research involving the use of vertebrate animals undergoes rigorous, scientifically-informed ethical review processes,
 - d) ensure that animal usage takes place only where scientifically and ethically justifiable (see section 2 for details),
 - e) authorise experimental treatments or the humane killing of any animal used in research or teaching,
 - f) investigate, and take appropriate actions, in the event of deviations from approved protocols, and violations or allegations of unethical conduct concerning the use of vertebrate animals in teaching and research,

- g) confirm that researchers and teachers are adequately qualified and/or trained to perform the research or teaching involving vertebrate animals,
 - h) confirm that applicants have (or will obtain) necessary permits from the relevant authorities to capture, transport and/or work on any of the animals involved,
 - i) ensure that the particulars of the species, number and origin of the vertebrate animals in each category of experiment are recorded,
 - j) monitor, at its discretion, the housing, care, treatment, euthanasia and disposal of vertebrate animals in scientific studies and teaching activities,
 - k) review and support the auditing of departmental sub-committees,
 - l) advise the RUEESC on all matters pertaining to the ethics of research and teaching involving vertebrate animals, and to
 - m) review and revise the specific guidelines for Animal Ethics at Rhodes University.
- (3) Membership-categories: RUEESC-AE members will be from the following four categories³:
- A. Veterinarians and/or suitably qualified wildlife biologists.
 - B. Scientists experienced in animal use for research and/or teaching.
 - C. Animal welfare organisation representatives.
 - D. Academic staff representatives from within the University, who is not involved in vertebrate animal experimentation, and not from the Faculty of Science.
- (4) Committee members: The composition of the RUEESC-AE is as follows:
- a) one veterinarian or academic staff member with appropriate qualifications and experience in wildlife biology (Category A),
 - b) up to six academic staff members with substantial and recent experience in the use of vertebrate animals for teaching and/or research (Category B),
 - c) two representatives or nominees of animal welfare organization(s) or NGO, appointed by mutual agreement between the University and the organisation(s) (Category C),
 - d) two academic staff not involved in vertebrate animal research, both of whom should be from outside the Science Faculty (Category D), and
 - e) where appropriate, specialists and other advisers may be invited to attend meeting and/or give input (without being eligible to vote).
- (5) The RUEESC-AE elects one Chairperson and a Deputy Chairperson from amongst its members by a simple majority of votes.
- (6) The Chairperson and committee members that are not nominated or ex-officio members are elected for a two year period⁴. Re-election is possible. Chairpersons should not be re-elected for more than two consecutive periods.

³ This follows international and national standards including the SANS Code 10386.

⁴ Note that SANS 10386 permits a maximum term of office of three years.

- (7) The Chairperson shall notify the Chairperson of RUESC of changes in the committee membership.
- (8) Four members, including at least one member from each category A, B, C, and D shall constitute a quorum⁵.
- (9) Decisions of the RUESC-AE shall be majority decisions.
- (10) The RUESC-AE processes applications and queries electronically, and, if required, ad hoc meetings are arranged to discuss applications. One or two meetings per annum shall be scheduled for general issues.
- (11) Applications for ethical approval are circulated to at least three committee members. Unambiguous decisions will be made after the reviews have been completed, otherwise final decisions on the approval of applications can only be made at meetings of the RUESC-AE⁶. These full meetings will take place on published dates.
- (12) Cases that cannot be resolved by the RUESC-AE shall be escalated to RUESC.

For further operational procedures valid for all ethics (sub-) committees see section 4.2.5 of this policy (page 14).

4.2.4 Departmental ethics sub-committees

- (1) Where there is a substantial number of research or teaching projects in a Department or a Faculty that require ethical approval, that department or faculty should establish a departmental ethics sub-committee.
- (2) A departmental ethics sub-committee shall be established at Departmental or Faculty level in order to facilitate Human Ethics or Animal Ethics sub-committee by
 - a) screening the departmental application for ethical approval, particularly for student research, and
 - b) developing departmental and faculty expertise on the ethics pertaining to a specific discipline.
- (3) Any departmental ethics sub-committee must be accredited by and report to the corresponding Human or Animal Ethics sub-committee (or to RUESC).
- (4) A departmental ethics sub-committee may be integrated into broader committees (like Higher Degrees Committees), but must fulfil all structural and procedural requirements as outlined for departmental ethics sub-committees.
- (5) Applications for ethical approval need to be referred to the appropriate Human or Animal Ethics sub-committee when:
 - a) the project involves an application for funding to an external research sponsor or to a grant administered by the University,
 - b) the departmental ethics sub-committee is unable to deal with the ethical issues of the application,

⁵ As described in SANS 10386.

⁶ As requested by SANS 10386.

- c) a conflict of interest exists between reviewers and researchers. This is typically the case for the review of staff research projects in which the reviewers are formally or informally involved, e.g. by having provided advice to the research being reviewed,
 - d) the Principal Investigator is unable to agree to alterations suggested by the departmental ethics sub-committee, and wishes the decision of that committee to be reviewed,
 - e) a minority of the committee wishes to register dissent from the approval of an application given by that committee, or
 - f) the project involves human participants who are below 18 years old or a members of a vulnerable group and require particular attention (see section 3.3, page 26).
- (6) Membership: A minimum of 3 academic staff members with reasonable experience in research and ethics, appointed by the Head of Department or Dean after consultation with staff or heads of departments, respectively.
- (7) A departmental ethics sub-committee elects a chairperson from amongst its members by a simple majority of votes.
- (8) The chairperson and members are elected for a two-year period. Re-election is possible. Chairpersons should not be re-elected for more than two consecutive terms.
- (9) The Chairperson shall notify the Chairperson of the associated Human or Animal Ethics sub-committee of any changes in departmental ethics sub-committee membership.
- (10) One third of the appointed members, but at least two members, shall constitute a quorum.
- (11) Decisions of the departmental ethics sub-committee shall be majority decisions.
- (12) Members of the departmental ethics sub-committee shall not participate in any decision making where a conflict of interest exists, e.g. acting as supervisor for research proposals to be reviewed.
- (13) Departmental ethics sub-committees have the option to co-opt additional members if required.
- (14) Constitution of new departmental ethics sub-committees:
- a) Each Department or Faculty wishing to establish a departmental ethics sub-committee has to request accreditation by RUEHC-HE or RUEHC-AE (or RUEHC if a department does not clearly relate either to human or to animal ethics).
 - b) The request for accreditation shall include documentation on:
 - i. Terms of reference (topics and level of research processed by the departmental ethics sub-committee),
 - ii. Subject-specific policies (if applicable),
 - iii. (Specific) Procedures that the departmental ethics sub-committee will follow (if applicable),
 - iv. Templates used (e.g. application form), and
 - v. Initial members and chairpersons of the departmental ethics sub-committee.

- c) RUEESC-HE or RUEESC-AE will constitute an audit sub-committee that operates according to the audit process outlined in section 4.2.4(15).
 - d) All policies and/or Guidelines for departmental ethics sub-committees shall be published by the relevant department via departmental handbooks, departmental instructions, internet, intranet etc.
- (15) Auditing of departmental ethics sub-committees:
- a) Internal audit forms an important part of quality assurance to ensure that appropriate ethical standards are followed. The aim of the audit is to standardise processes and practices which would ultimately improve the overall quality function of departmental ethics sub-committees. During the process of audit, the adherence to the guidelines and regulations stipulated by the Rhodes University Ethical Standards Committee are reviewed.
 - b) Departmental ethics sub-committees may be subject to internal audits from time to time. As such departmental ethics sub-committees are required to store all ethics applications and supporting documentation for the period stipulated in the main policy document.
 - c) Audits will be carried out by an audit sub-committee recruited from RUEESC, RUEESC-HE and RUEESC-AE comprising the Audit Chairperson, one subject specialist and one other member as deemed appropriate. Auditors will meet with representatives from the departmental ethics sub-committee.
 - d) The following documents would typically be examined:
 - i. overview on the departmental ethics sub-committee (membership etc.),
 - ii. annual list of applications (incl. research level and outcome),
 - iii. brief report on specific experiences from the applications,
 - iv. critical review of the policy and work of the departmental ethics sub-committee,
 - v. training material and instructions, and
 - vi. a random sample of applications and corresponding reviews.
 - e) Auditors will produce an audit report that will reflect the findings of the audit. If needed, the auditors will provide supportive guidance to the departmental ethics sub-committee on how to address any identified concerns.
 - f) In case of a non-successful audit (and after attempts have been made to address the corresponding concerns) the matter has to be escalated to RUEESC for a final decision on the re-accreditation of a departmental ethics sub-committee.
 - g) Any departmental ethics sub-committee shall be audited at least once every three years.

4.2.5 General operational procedures for all ethics committees

- (1) The committee members' names are disclosed to the public.
- (2) Committee meetings normally shall be held *in camera*.
- (3) Attendance of applicants and advocacy for specific applications is only permitted by invitation and for a specific application and the non-confidential discussion of this application.

- (4) Committee business is confidential to protect intellectual property, researchers' interests, and to permit committee members to speak freely and frankly, and to protect the public image of the University. This policy is affirmed by signing a statement on the attendance register at every meeting. Concerns about breaches of confidentiality should be raised with the Chairperson of the corresponding committee in the first instance and, if not addressed to the satisfaction of the complainant, thereafter with the Chairperson of the RUESC.
- (5) Each ethics committee will retain a copy of each application reviewed by it, with amendments if any, and a record of the decision taken by the committee immediately after the review is completed. If ad hoc members were consulted in the course of making the decision, that fact should be noted.
- (6) Members of the committee shall disclose, withdraw from voting and recuse themselves in any case of actual, perceived or potential conflict of interest. This might be in a conflict of interest for affiliation, adversity, project sponsoring or any financial reward according to a proposal to be approved. In cases where the Chairperson has a conflict of interest, a Deputy Chair is to be appointed by the committee for the specific application and the Chairperson must recuse her-/himself.
- (7) Where any objection to an ongoing or complete application is raised, it is the responsibility of the Chairperson of the appropriate committee to investigate the matter, and to attempt to resolve the problem in consultation with the applicant. Where the objection cannot be resolved, the committee will refer the matter to the next higher level committee.
- (8) Reporting: The Chairperson of each committee shall provide an annual report to the next higher level committee. RUESC shall report to Senate.
- (9) The committee has to keep records of any correspondence.
- (10) The committee, in conjunction with the University administration, has to ensure that all documents are kept confidential and stored in a secure way.
- (11) All documents with respect to ethics applications have to be stored for a minimum period of five years after the research or the teaching has been completed. For research involving children this period should be seven years.⁷

4.3 Ethical approval process

This section rules the general process of ethical approval. Details with respect to specific forms of research and teaching are outlined in the corresponding protocols.

4.3.1 Application for ethical approval

- (1) Any intended research, teaching or other activity that falls under the scope of this policy (see section 3.2) has to be approved by the Rhodes University Ethics Standards Committee or one of its sub-committees.

⁷ Those time periods are basically set by law for possible liability claims.

- (2) A written application for ethical approval, signed by the Principal Investigator, has to be submitted to RUESC or the relevant sub-committee. RUESC and its sub-committees will help to identify the relevant sub-committee if clarification is needed.
- (3) In student research students cannot take the role of a Principal Investigator. This is normally the Supervisor or another senior researcher. Sufficiently mature students (such as Masters and PhD students) are however encouraged to act as Co-Principal Investigators.
- (4) In teaching, the course-coordinator normally takes the role of the Principal Investigator and the individual lecturers act as Co-Principal Investigators.
- (5) In order to facilitate the review process the application should use the standard application form of the corresponding sub-committee, the research or teaching methodology and the required appendices.
- (6) It is expected that all research and teaching, respectively, will adhere to acceptable standards of practice.
- (7) The basic ethical objectives are (1.) minimising the risks associated with an activity and (2.) the benefits must expectedly outweigh the risks. The application must provide clear information for evaluating both objectives.
- (8) A research/teaching methodology or protocol is required to review an application in order to evaluate risks and benefits of the proposed activity as well as to consider if risks are minimal with respect to what can be achieved (e.g. by remedial measures) without significantly compromising the outcome.
- (9) Principal Investigators have to ensure that occupational safety and health safety requirements are met for all involved staff, researchers, facilitators and participants. Particular attention has to be given to processes and conditions that do not fall under set categories and where occupational and safety standards have to be applied in analogy to existing rules and regulations.
- (10) The University projects of concern must be approved before commencement of the project. Research that has been initiated elsewhere, but shall be continued under the auspices of Rhodes University must undergo a full review process prior to any continuation at Rhodes University.
- (11) No external ethics committees might be approached for ethical approval by the applicant instead of RUESC or one of its sub-committees.

4.3.2 Review of applications

- (1) Applications are processed as they are submitted.
- (2) The committee Chairperson checks if the application is complete, whether the application falls under the scope of the committee, which type of review shall be applied (see following clause) and appoints reviewers.
- (3) Types of reviews:

- a) Query review: A primary review is performed by the Chairperson or one reviewer in order to formally check whether ethical approval is required for the proposed research.
 - b) Primary review: An expedited review is performed by two reviewers who each provide a written review with a suggestion for decision. Applications for expedited review are however available to all committee members for consideration and commenting.
 - c) Full committee review: An application is reviewed by all committee members from which at least two reviewers will provide a written review.
- (4) Decision making: applications are approved on the basis of consensus at quorate meetings. If consensus cannot be achieved, the decision of the majority of committee members shall be accepted.
 - (5) Depending on the review outcome an application can be
 - a) Decided by Chairperson (only for expedited review and if suggestions of the reviewers are consistent),
 - b) Further discussed and decided in an internal ad-hoc meeting of the committee,
 - c) Referred for a full committee review, or
 - d) Referred to a higher committee (except on RUESC level).
 - (6) Applicants and advocacy may be invited to meetings of the ethics committee if this is deemed to facilitate the approval process.
 - (7) Outcome: The acting ethics committee may confer an application as
 - a) Approved (with or without stipulations)
 - b) Disapproved
 - c) Modifications required
 - d) No ethics approval required
 - (8) In case of an application being approved with stipulations, the application will not be re-reviewed, thus the stipulations should concern only very minor aspects.
 - (9) The ethics committee may suggest amendments to the methodology/protocol, particularly where a discrepancy is perceived between the methodology/protocol and the policy and relevant protocols on ethics.
 - (10) The ethics committee may require a project to be monitored in such a manner as deemed appropriate, particularly for student projects under supervision.
 - (11) Should an applicant be dissatisfied with an ethics committee decision she/he may appeal this decision.
 - (12) A committee will refer a matter to the next higher level committee (RUESC will consult the Senate) when:
 - a) the Principal Investigator is not prepared to alter the application in order to conform to the suggestions of the committee, and the Principal Investigator wishes the decision of the committee to be reviewed, or

- b) a minority of the committee wishes to register dissent from the approval given by the committee.
- (13) When a Principal Investigator contemplates altering or amending substantially any element of an application which was approved, either before or after commencement of the project, the Principal Investigator shall consult with the Chairperson of the relevant committee about the alteration. The Chairperson may at her/his discretion refer the matter for the opinion of the committee, or to approve it on her/his own authority. The Principal Investigator must exercise professional discretion in determining whether a contemplated alteration is substantial; however, any change which imports deception or risk, or reduced protection of the participant's anonymity, or the confidentiality of data collected, is deemed to be substantial for the purposes of this policy.
- (14) Appeals:
- a) On appeal by the Principal Investigator, the relevant ethics (sub-) committee shall invite the Principal Investigator to explain and discuss the critical aspects of the application.
 - b) The (following) deliberations of the relevant ethics (sub-) committee will be held *in camera*. The committee shall record the written reasons for the decision under appeal.
 - c) Where any objection to an ongoing or completed University research project is not resolved, the matter may be taken on appeal to the next higher level committee (see Figure 1).
 - d) When a matter is taken to the next higher level committee, this committee may confirm or modify the decision previously taken. The committee may impose its own conditions for approval of the project. The committee may further halt an ongoing project pending recourse through other channels.
- (15) Once an ethics committee has approved an application project, the Principal Investigator must:
- a) conduct the research/teaching in accordance with what is documented in the application,
 - b) inform the ethics committee if amendments to the methodology/protocol become necessary, detailing – with rationale – the changes required, and seeking approval to incorporate them in the research/teaching, and
 - c) inform the relevant ethics (sub-) committee of the occurrence of serious or unexpected adverse effects that are likely to affect the safety of the participants, the welfare of animals or the conduct of the research.

4.3.3 Sponsoring

- (1) It is recognised that researchers have the right to receive an explicit research mandate from a sponsor/client. However, the following applies.
- (2) Interference by sponsors or clients that may jeopardize the scientific integrity of the study, or prejudice the interests, health or dignity of the participants is not acceptable.

- (3) Information that may reveal the identity of the human participants may not be supplied to the sponsors/client unless this was included in the research methodology and was part of the informed consent given by the participants.

4.3.4 Reporting

- (1) Any adverse effects, changes, discontinuation and unforeseen events must be immediately reported to relevant (sub-) committee.
- (2) Any (sub-) committee will investigate, and attempt to satisfy, objections or concerns that were raised with respect to ethical standards in any ongoing or completed project. Where a dispute cannot be resolved, the committee will refer the matter to the next higher level committee.
- (4) The relevant (sub-) committee may withdraw approval. In this case it has to inform the Principal Investigator and the hosting institution about the decision made and the reasons. The project or the teaching unit, respectively, must then be discontinued immediately.
- (5) A brief report must be submitted to the relevant committee on the completion of every research programme that has been granted ethical approval. The report should include a very brief summary of results and conclusions obtained; importantly, whether there were any unforeseen and undesirable consequences and if so, the steps that were taken to rectify them.
- (6) The report will be kept with the application and the committee reserves the right to access the research findings.

4.3.5 Publications

- (1) Results must not be exaggerated or filtered so as to make funding more likely or a submission more attractive to editors.
- (2) Results should be published if they have academic merit. Withholding, changing or toning down the content are not acceptable practices. Sponsors should not be allowed to comment on results prior to publication. They may not veto, change conclusions or delay publication. Such aspects should be formalised in a written contract. Publication should proceed regardless of outcomes of the research.
- (3) Authorship and acknowledgements: All persons who have contributed to the originality of the publication shall be listed as authors. Individuals or institutions that have actively supported the research shall be acknowledged in the paper. Individuals or institutions that have supported the research financially must be acknowledged in the publication in order to provide transparency with respect to possible conflicts of interest.
- (4) It is advised to mention in the publication that ethics approval has been obtained and from which committee this was issued.

5. POLICY REVIEW PROCEDURE

- (1) The RUEESC reconsiders the appropriateness of the Ethics Policy every three years, or as necessary.

- (2) All Rhodes University standing committees and individuals are welcome to suggest revisions of the policy.
- (3) The RUEESC's recommendations are submitted to Senate and Council for discussion and notification. RUEESC will carefully consider any feedback from Senate and Council. All revisions that are approved by RUEESC will be included in a revised copy of policy which will be distributed amongst the University via Internet. Senior Management, Deans and all Heads of Departments will be notified of the revision.

II. Protocol for Research and Teaching involving Human Participants

This protocol specifies and complements the Rhodes University Policy on Ethics.

1. TERMS OF REFERENCE

1.1 Research on Human Participants

- (1) Research on Human Participants includes:
 - a) humans partaking in data collections of an individual or a community through methods such as observation, surveys, interviews or focus groups,
 - b) collecting of personal information from or about a human participant, including use of personal documents or personal records of an institution,
 - c) humans undergoing experimental psychological, physiological or medical testing or treatment,
 - d) humans providing identifiable tissue or other personal matter for the purpose of research,
 - e) humans whose information (in individually identifiable, re-identifiable or non-identifiable form) is accessible as part of a published or unpublished source or database, whether data is collected directly from individuals or data of individuals or collectives has been aggregated previously, or
 - f) humans participating in Health Research (see section 1.2).

1.2 Health Research

- (1) Health Research is a subcategory of Research on Human Participants (see section 1.1), however specific (legal) requirements may apply to Health Research. According to the National Health Act (2003:12), "health research includes any research which contributes to knowledge of:
 - a) the biological, clinical, psychological or social processes in human beings,
 - b) improved methods for the provision of health services,
 - c) human pathology,
 - d) the causes of disease,
 - e) the effects of the environment on the human body,
 - f) the development or new application of pharmaceuticals, medicines and related substances, and
 - g) the development of new applications of health technology".
- (2) Level One and Level Two Health Research
According to the Department of Health document on Ethics in Human Research

(2004:12) Health Research is assigned on two levels, considering the probabilities of risk for those participating in Health Research.

- a) Level One Health Research involves “*minimal risk* to human participants”,
 - b) Level Two Health Research specifically involves “drug research, biomedical research involving human tissues, high-budget research, and high-technology research (invasive, radiological, radio-active, and other research requiring substantial equipment)”.
- (3) RUESC may provide approval certificates for Level One Health Research. For Level Two Health Research RUESC provides guidance and approval after involving an external committee that is accredited for Level Two Health research.
 - (4) The Rhodes University Policy on Ethics and the relevant protocols may not sufficiently outline all requirements for approval of Level Two Health Research, thus appropriate further sources must be considered.

1.3 Clinical Trials

- (1) A Clinical Trial is a study involving humans to find out if a treatment or diagnostic procedure, which is believed to benefit a patient, actually does so. A Clinical Trial may involve testing a drug, a surgical or other procedure, or a therapeutic or diagnostic device. In pharmaceutical trials there are established codes of good clinical research practice that define clearly what is meant by a Clinical Trial. This section has principal application in the context of clinical drug trials but should also apply to other interventions claiming therapeutic benefit, wherever provided or conducted.
- (2) The Rhodes University Policy on Ethics and the relevant protocols may not sufficiently outline all requirements for approval Clinical Trials, thus appropriate further sources must be considered. (See section 4 on Protocol for Clinical Trials for more details).

1.4 Research using Human Biological Material

- (1) Human biological material are physical samples extracted from the human body or its secretions, such as blood, blood plasma, tissue, stem or cancer cells etc.
- (2) Donation of human biological material that requires invasive measures and/or treatment will apply clinical processes that cannot be performed under the auspices of Rhodes University. Further, specific legal standards apply (e.g. Chapter 8 of the NHA 2004).
- (3) Research using human biological material in the context of the current guidelines concentrates on researching human biological material in a laboratory using scientific principles and technical processes. Any referral of human biological material back to humans must be considered as Clinical Trial and thus will require extensive risk management.
- (4) As human biological material carries personal information in the form of its DNA, storage and handling require particular attention in order to respect anonymity and privacy of information (see sections 2 and 5).

2. GUIDING ETHICAL PRINCIPLES

- (1) Participants should be accorded the respect and dignity that is due to them. For this to be achieved, researchers and teachers should adhere to the principles of respect and dignity, transparency, accountability and integrity as outlined in the following.
- (2) Respect and dignity includes:
 - a) To respect the autonomy and welfare of participants,
 - b) To protect the privacy and confidentiality of participants, and
 - c) To respect the right of individuals to refuse or withdraw from participation.
- (3) Transparency and honesty includes:
 - a) To analyse and disclose potential risks and benefits to participants,
 - b) To obtain informed consent from participants by briefing participants about the aims and implications for the research, and
 - c) To practice the principles of honesty, transparency and scrutiny, when communicating the research findings to the public and their peers.
 - d) In cases where the methodology/protocol necessitates concealment of information, the Principal Investigator should
 - i. ensure that the prospective academic, educational or applied value of the research project justifies this methodology/protocol,
 - ii. investigate alternative methodologies that do not require the concealment of information instead, and
 - iii. ensure participants are informed of the reasons for such concealment as soon as is practically possible.
- (4) Accountability and responsibility
 - a) Researchers should conduct their research in accordance with the Rhodes University Policy on Ethics and the relevant protocols, and in accordance with codes of ethics of the disciplinary contexts and professional associations to which they are related.
 - b) Researchers should disclose any conflicts of interest.
 - c) Research should not be misused for personal power or gain.
 - d) Special attention should be paid to research which includes vulnerable participants.
 - e) Attention should be paid to investigator and supervisor competence and responsibilities.
- (5) Integrity and academic professionalism
 - a) Researchers should attempt to practice non-partisanship and independence, conducting research that is either free from or explicitly discloses any political, racial, gendered, religious or other bias.
 - b) Researchers should ensure that the methodology of their research project is thorough and academically sound in terms of relevance and scientific integrity.

3. PROTOCOL FOR INVOLVING HUMAN PARTICIPANTS

3.1 Information to participants

- (1) All researchers and teachers interacting with human participants will identify themselves to their participants. They will identify their association with the University, and their status as staff member, student or research assistant.
- (2) All participants will receive the following information necessary to facilitate their giving fully informed consent:
 - a) the nature of the research/teaching, its purpose and usefulness,
 - b) a precise description of the procedures in which the participant will be asked to participate,
 - c) the anticipated personal risks, including direct physical, psychological or social harm,
 - d) the expected benefits of the research,
 - e) the methods for protection of confidentiality and anonymity which will be observed by the project supervisor and colleagues in respect of the participant's participation as well as the legal limitations to anonymity and confidentiality (see sections 3.5 and 3.6),
 - f) the fact that the participant is free to withdraw from the project at any time without penalty or reason,
 - g) the details of the contact person in the event of a query or research related harm or injury, and
 - h) the ethics committee which approved the research/teaching project, and contact information of this committee to whom comments on the project may be directed.
- (3) Where applicable information has to be provided to the participant on:
 - a) reimbursement and/or incentive given for participation,
 - b) information about the sponsor,
 - c) potential conflicts of interests,
 - d) the anticipated personal benefits derived from this participation,
 - e) what social benefits are anticipated, and to whom they accrue,
 - f) the anticipated risks to a larger social group or a third party,
 - g) the extent to which risks in the project have been pretested, and whether the project the participant will participate in differs from pre-tested practice,
 - h) the possibility that the data from this research project may be stored and used for a different purpose in future without obtaining a new consent from the participant,
 - i) whether the results of the project will be available from the project supervisor when they are published, and
 - j) for more than *minimal risk* research: insurance in the event of research related injury.

- (4) Except where the Principal Investigator justifies an alternative method, the information set out in 3.1 (2) and 3.1 (3) will be presented to the participant in writing, as part of the consent form.
- (5) Where the project supervisor justifies presenting the information set out in 3.1 (2) and 3.1 (3) to the participant verbally, the person who presents the information will refer to a printed copy of the information.
- (6) Documents must be understandable in the participant's language. In case of an interpreter being involved for this purpose, she/he must be independent and present at all discussions with participants. In case of no significant risk imposed to the participant, friends or family members of the participant will be allowed for this role.
- (7) Special precautions should be taken to ensure that participants understand the information provided as part of informed consent, especially when research is conducted in cross-cultural settings, or in vulnerable communities.
- (8) All documents given to participants must be approved by the ethics committee.

3.2 Informed consent of participants

- (1) A person must give express consent to participate in any teaching or research as a human participant, free of coercion, constraint or inducement, with information adequate to evaluate the anticipated risks and benefits inherent in personal participation in the project.
- (2) Persons are under a legal disability where they cannot be legally bound by their own actions, as with a person under 18 years of age, or a person of limited capacity because of mental illness or any other recognised disorder. In cases where the participant is under a legal disability section 3.3 for consent requirements.
- (3) Unless the Principal Investigator has justified the use of verbal consent in the methodology/protocol, consent shall be given in writing.
- (4) It is preferable that the information and consent forms be integrated; where this is not possible, the following elements of information must appear on the consent form:
 - a) the name of the University and name of the project supervisor,
 - b) a brief but explicit description of the procedures the participant personally will participate in,
 - c) an explanation that the participant is free to withdraw from the project at any time, even after having given consent and the project has commenced,
 - d) when the research exposes participants to more than *minimal risk* (see Glossary, page 4), the consent form shall include an acknowledgement by the participant of the risk(s) involved in the research and the provisions made for compensation of injury or a waiver of claims arising from those risks.⁸
- (5) It is recommended that the consent form contains general words indicating that participants understand that the nature of the variables being considered may make it

⁸ This does not waive claims resulting from negligent behaviour of the researchers and facilitators.

impossible to be informed completely of the nature and purpose of the procedures to be followed, but that they will be fully informed when their participation has been completed.

- (6) Remuneration for participation as a participant, if any, shall be based on the time required of the participant and the inconvenience caused, and shall not be sufficient to induce the participant to disregard any risks inherent in participation.
- (7) The provision of incentives (e.g. payment for participation) should not cause undue influence. It should be ensured that the participant is able to make an independent decision regarding consent. Payments to participants should be in the spirit of the National Guidelines on Payment of Trial Participants in South Africa.⁹
- (8) Provision of informed consent is understood to include consent to publish findings subject to the requirements in respect of participant confidentiality and anonymity. Even though consent may be given by a participant, the researcher must consider whether the publication will stigmatise a group or groups to which the participant belongs. Research should not exploit the vulnerability of a community but should rather reduce such vulnerability. (See section 3.8 for more details on publication of results.)

3.3 Activities involving participants that require additional attention

- (1) Researchers and teachers must pay special attention to protecting the welfare of certain classes of participants, such as
 - a) Children (persons under 18 years of age),
 - b) Women and particularly pregnant women,
 - c) Individuals from vulnerable communities.
 - d) Individuals participating as groups,
 - e) Individuals in dependent relationships,
 - f) Prisoners,
 - g) Individuals with intellectual or mental impairment or other disabilities,
 - h) Individuals for whom English is not a first language, and
 - i) Research involving persons highly dependent on medical care.
- (2) Research must involve participants of one of the above-mentioned classes only when other participants are not appropriate for inclusion.
- (3) Research must not systematically avoid inclusion of participants of one of the above-mentioned classes if no compelling reasons for exclusion apply.¹⁰

⁹ The National Guidelines on Payment of Trial Participants in South Africa be downloaded via the Rhodes University Ethics website.

¹⁰ This clause refers to National Health (Act No 61 of 2003), Notice 719, 4(b) in order to avoid unfair discrimination.

3.3.1 Activities involving children

- (1) For purposes of these guidelines 'child' means a person under the age of 18 years.
- (2) Children under the age of 12 years old should participate in research and teaching only where their participation is indispensable to the research and where participation is not contrary to the individual child's best interests. In all cases, the ethics application must provide sufficient information to justify clearly why children under 12 years should be included as participants.
- (3) Research and teaching activities involving a child under and over 12 years should be approved only if:
 - a) the activity, including observational research, places the child at no more than *minimal risk* (see Glossary), or
 - b) the activity involves more than *minimal risk* but provides possible benefit for the child participant. The degree of risk must be justified by the potential benefit, or
 - c) the activity, including observational research, involves greater than *minimal risk*, with no prospect of direct benefit to the child participant, but has a high probability of providing significantly generalisable knowledge; that is the risk should be justified by the risk-knowledge ratio. The risks must represent no more than a child increase over *minimal risk*.
- (4) Consent for children to participate in research or teaching must be obtained from:
 - a) the child, where the child is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the research, and
 - b) the parents or legal guardian, and
 - c) if applicable, any organization or person required by law.

The researcher/teacher must ensure adequate steps to obtain the child's assent when the child is capable of providing such assent. The application must also document whether and how such assent shall be given. No other caregiver can act on behalf of a child in providing consent to participate.

A child's refusal to participate must be respected.
- (5) Parental permission: Where the research does not involve greater than *minimal risk* to the child, or involves greater than *minimal risk* but presents the likelihood of direct benefit to the child, the permission of one parent is sufficient. Permission from both parents is necessary where the research involves greater than *minimal risk*, is of no direct benefit to the child but is likely to produce generalisable knowledge. Where only one parent is available for reasons including the death, incompetence or disappearance of the other, or where a court has placed the child in the sole care and contact of one parent, then the permission of that one parent is sufficient for participation in the latter type of research. In the event of conflicting views between the parents, the child's best interest settles the matter.
- (6) Unmarried mothers who are under the age of 18 years may not consent to the participation of their children in research investigations. Their guardians (usually their parents) are also the guardians of her child and must thus consent to the child's participation as set out above.

- (7) 'Non-therapeutic research' with children (that means research that does not hold out the prospect of direct benefit to the participant) must obtain consent of the Minister of Health after being approved by RUESC.¹¹

3.3.2 Activities involving women

- (1) Researchers and teachers have ethical obligations to conduct their activities in such way that it does not perpetuate negative discrimination against women. However, the special need to protect women may justify or even require a positive discrimination.
- (2) Researchers must give extra attention to research that involves women who are, or may become pregnant, because of the additional health concerns during pregnancy and the need to avoid unnecessary risk to the foetus. Reasons for excluding women from research should be adequately justified both from the point of protecting the health of a foetus and from the perspective of whether such exclusion is scientifically supportable.
- (3) No pregnant woman may be involved as a participant in any research or teaching activity unless:
 - a) The purpose of the activity is to meet the health needs of the mother and the foetus will be placed at risk only to the minimum extent necessary to meet such needs, or
 - b) The risk to the foetus is minimal.
- (4) No research activities involving pregnant women and foetuses may be undertaken unless:
 - a) appropriate studies on animals and non-pregnant individuals have been completed (if applicable), and
 - b) the purpose of the activity is to meet the health needs of the mother of the particular foetus, the risk to the foetus is minimal and, in all cases, presents the least possible risk for achieving the objectives of the activity.
- (5) Any activity permitted above may be conducted only if the mother is legally competent and has given informed consent after having been fully informed about the possible impact on the foetus. The father's informed consent need not be secured if:
 - a) the purpose of the activity is to meet the health needs of the mother,
 - b) his identity or whereabouts cannot reasonably be ascertained, or
 - c) he is not reasonably available.

3.3.3 Activities involving vulnerable communities

- (1) South Africa is home to a number of vulnerable communities. Where factors relating to vulnerability are an aspect of the research, the researchers should demonstrate how

¹¹ This refers to National Health Act, Notice 719(7). The details for the application to the Minister of Health are outlined in the aforementioned Health Act Notice, including an application form. The document can be downloaded via the Rhodes University Ethics website. Due to the impact of this regulation on research with children, Principal Investigators are advised to contact RUESC in advance in order to clarify the need for a ministerial consent.

they will seek to redress that vulnerability. Particular caution must be exercised before undertaking research involving participants in such communities ensuring that:

- a) persons in these communities will not ordinarily be involved in research that could be carried out in non-vulnerable communities,
- b) the research is relevant to the needs and priorities of the community in which it is to be carried out,
- c) research participants should know that they are taking part in research and this research should be carried out only with their consent. This requires that particular attention be paid to the content, languages and procedures used to obtain informed consent.
- d) The research should not adversely affect the routine treatment of patients, nor should it disrupt routine management protocols.

3.3.4 Activities involving persons participating as groups

- (1) A collectivity is an expression used to distinguish some distinct groups from informal communities, commercial or social groups. Collectivities are groups distinguished by:
 - a) common beliefs, values, social structures and other features that identify them as a separate group,
 - b) customary collective decision-making according to tradition and beliefs,
 - c) the custom of leaders expressing a collective view, and
 - d) members of the collectivity being aware of common activities and common interests.
- (2) Researchers must seek the ethical approval for research involving a collectivity when any of the following conditions apply:
 - a) property or information private to the group as a whole is studied or used, or
 - b) the research requires the permission of people occupying positions of authority, whether formal or informal, or involves the participation of members acknowledged as representatives.
- (3) Arrangements to address these issues should follow a process of respectful negotiation, and may include:
 - a) the manner in which anticipated or actual disagreements between the researcher and the collectivity will be resolved,
 - b) the seeking of informed consent from both the collectivity and individual participants,
 - c) resolution of the ownership of data and the rights of publication of research findings, and
 - d) the fair distribution of direct benefits and harms of the research among affected participants.

3.3.5 Activities involving persons in dependent relationships

- (1) Persons whose proposed involvement in research arises from dependent or comparable relationships need additional attention. It is not possible to define such

relationships exhaustively, but they include persons who are in junior or subordinate positions in hierarchically structured groups and may include relationships between:

- a) older persons and their caregivers,
 - b) persons with chronic conditions or disabilities and their caregivers,
 - c) wards of State and guardians,
 - d) patients and health-care professionals,
 - e) school children, students and teachers,
 - f) prisoners and prison authorities,
 - g) persons with life-threatening illnesses,
 - h) employees and employers, including farm workers and their employers, including members of the uniformed services and hospital laboratory staff and their employers.
- (2) Where the participant is part of such a “captive population”, provision may be required in the methodology/protocol for receiving the consents of the institutional authority and the individual participants and/or their legal guardians or curators.

3.3.6 Activities involving prisoners

- (1) Ethical review must take cognisance of the impact of a prisoner's incarceration on their ability to make a voluntary decision, without coercion, about their participation in research.
- (2) Prisoners as participants may be involved only for:
 - a) study of the possible causes, effects, and processes of incarceration, and of criminal behaviour, provided that the study presents no more than *minimal risk* and no more than inconvenience to the participants,
 - b) study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than *minimal risk* and no more than inconvenience to the participants,
 - c) research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on diseases that may be more prevalent in prisons and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) only after appropriate experts have been consulted, or
 - d) research on practices, both innovative and accepted, that have the intent and probability of improving the health or wellbeing of prisoners. Where some prisoners may be assigned to control groups that may not benefit from the research, the research may proceed only after appropriate experts have been consulted.
- (3) Research that could be conducted on a population other than prisoners should not be permitted, unless cogent motivation is presented, and the ethics committee is satisfied that the motivation does not represent exploitative research. The ethics committee should take into consideration the extent to which research facilitates the empowerment of prisoners as a vulnerable group.

- (4) Researchers have to follow the procedures and guidelines issued by the Department of Correctional Services.
- (5) When reviewing research involving prisoners, the ethics committee must meet the following requirements:
 - a) A majority of the research ethics committee, other than prison members, shall have no association with the prison(s) involved, apart from their membership of the research ethics committee.
 - b) At least one member of the ethics committee shall be a prisoner, or a prisoners' representative with appropriate background and experience to serve in that capacity.

3.3.7 Activities involving persons highly dependent on medical care

The involvement of participants who are highly dependent on medical care raises ethical issues that deserve special attention. The gravity of their medical condition may require invasive measures carrying increased risk. Researchers and teachers need to acknowledge that informed consent may be compromised by the effect of the medical condition on the participant's capacity to form an opinion or to communicate. Additionally, there may be a perception of coercion if a participant is reluctant to refuse consent for fear that it may compromise his or her medical treatment. Researchers and teachers need to consider whether an unfair burden of participation is being placed on groups such as these.

3.3.8 Other special groups

The discussion on special groups should not be limited to those already mentioned. Other special groups include: traumatised and comatose patients, terminally ill patients, elderly or aged patients, minorities, students, and employees. Ethics committees must ensure special consideration is given to all these groups, especially with regard to informed consent.

3.4 Activities that requires particular attention

Certain types of research also require special attention. These include:

- a) research involving deception of participants, concealment or covert observation,
- b) research that exposes participants to more than *minimal risks*,
- c) research on innovative therapy or interventions, and
- d) research involving indigenous medical systems

3.4.1 Activities involving deception, concealment or covert observation

- (1) As a general principle, deception of identifiable participants, concealment of the purposes of research or covert observation are not considered ethical because they are contrary to the principle of respect for persons and the obtaining of informed consent. In studies of human behaviour there may be exceptional circumstances when studies cannot be conducted without deception, concealment or covert observation of participants. Before approving research that involves any degree of deception, concealment or covert observation, an ethics committee must be satisfied that:

- a) the provision of detailed information to prospective participants about the purpose, methods and procedures of the research would compromise the scientific validity of that research,
 - b) the precise extent of deception, concealment or covert observation is defined,
 - c) there are no suitable alternative methods, not involving deception, concealment or covert observation, by which the desired information can be obtained,
 - d) participants are not exposed to an increased risk of harm as a result of the deception, concealment or covert observation,
 - e) adequate and prompt disclosure will be made and de-briefing provided to each participant as soon as practicable after the participant's participation is completed,
 - f) participants will have the opportunity to withdraw data that was obtained from them during the research without their knowledge or consent, and
 - g) activities will not corrupt the relationship between researchers and research in general, with the community at large.
- (2) Where it is necessary to withhold or to misrepresent significant facts in informing the participant, such deception must be expressly justified in the methodology/protocol. In particular, it must be demonstrated:
- a) that the deception is indispensable to the effectiveness of the project,
 - b) that the deception must extend to all the elements as proposed,
 - c) that all alternative investigative methods are unsatisfactory,
 - d) that the deception will not invalidate the informed consent of the participant, and
 - e) that the participant will be fully informed of all elements of the programme which were withheld or misrepresented as soon as possible after participation in the project has been completed.
- (3) No application will be approved where deception disguises or misinforms the participant of the risks, or in itself creates a substantial risk to the participant's self-esteem and dignity.

3.4.2 Research exposing participants to more than minimal risks

Principal Investigators must make provision for compensation for research-related injury in case of more than *minimal risks* (see Glossary, page 4).

3.4.3 Research involving innovative therapy or intervention

- (1) Research which must be considered for ethical compliance includes the use of any innovative therapy or intervention that is being tested on one or more patients. The researcher must ensure that appropriate provision is made for the long-term care and observation of participants and for the maintenance and security of records, before commencing new therapeutic or innovative procedure.
- (2) In terms of section 129(2) of the Children's Act 74 of 2005 and in the absence of specific legislative provisions to the contrary, children who have attained the age of 12 years, and are of sufficient maturity and have the mental capacity to understand the benefits, risks, social and other implications of the treatment are legally capable of

consenting to their own medical treatment as well as those of their children. Conversely, the consent of a parent or legal guardian is required for a surgical operation if the child is under the age 18 years. (See section 3.3.1 for details on consenting for children.)

3.4.4 Research involving indigenous medical systems

Researchers must respect the cultures and traditional values of all communities. Participants involved in research of indigenous medical systems must be accorded the same degree of respect and protection from harm as participants in scientific medical research. The research must be submitted for ethics review. Any substance that is used on participants must be subjected to stringent toxicology testing. Researchers should furnish proof of safety to the ethics committee.

3.5 Privacy of participants

- (1) The University recognizes and supports the freedom of persons and communities to reveal or withhold all information about themselves not already in the public domain, by deliberate, fully informed decision, and with the assurance that the participant's anonymity will be protected and all records of participation will be kept confidential.
- (2) The Principal Investigator must account for differing sensibilities among participant groups in the matter of invasion of privacy especially if the participant group is a particularly vulnerable one, or of a background radically different from that of the researcher.
- (3) The use of institutional records in a project requires obtaining consent from the individuals involved as well as from the institutional authorities. The use of aggregated data that is sufficiently aggregated to disable backtracking to individual information may be exempted from the need of individual consent by the ethics committee, provided that the individual information remains with the authorities that have right of accessing this data and that the ethics application clearly outlines the handling of the data.
- (4) Consideration must be taken for the privacy of third parties where the participant is asked to disclose information or opinions about such third parties.
- (5) Mechanical methods of observation, such as TV cameras, microphones, tape recorders, and one-way mirrors, may be used only with the consent of participants and/or their legal guardians. Where the participant has been recorded, the participant must be given the opportunity to call for erasure of the recording when such participation is complete. Any disclosure of a mechanical recording to persons who are not involved in carrying out the project (for instance, as an audio-visual demonstration) must be expressly consented to by the participant.
- (6) Location of research or teaching on private property must be disclosed in the application and approved in advance by the property owner. Shopping centres and commercial businesses are private property.
- (7) A researcher who is given access to a government or community institution or agency has a responsibility not to make public exposure of conditions or practices with which

the researcher disagrees without first reporting them to the responsible authority and giving reasonable time for an investigation to be made and a decision reached.

3.6 Anonymity of participants and confidentiality of data

- (1) The participant's anonymity must be strictly protected and all data collected must remain absolutely confidential. Where the participant has given written consent,
 - a) information may be disclosed only within the strict limits of the terms of the consent, and
 - b) the participant must be explicitly informed about risks associated with disclosing personal information.¹²
- (2) The responsibility is on the Principal Investigator to describe positive measures to be taken to preserve the anonymity of the research participant, both in the published results of the project, and in the records retained by the project supervisor.
- (3) Where confidential data will be stored for possible re-use, the method of recording and storing the data must be strictly designed to confer anonymity on the participant.
- (4) No consent from participants needs to be sought for re-use only if:
 - a) this may cause unnecessary anxiety to the participant or prejudice the validity of study,
 - b) there is no disadvantage to participant's rights (e.g., anonymity) and dignity, and
 - c) it is practically impossible to obtain such permission.
- (5) All persons having access to confidential data must be briefed by the Principal Investigator on the duty to observe the rules of anonymity and confidentiality.
- (6) In certain circumstances a researcher may acquire information on illegal activities or information relevant to a criminal investigation. A researcher who acquires information about illegal activities may be called as a witness in court proceedings and can be compelled to make full disclosure of such information received. It is recommended that the Principal Investigator appraises all co-researchers associated with the project of the legal implications in this connection.
- (7) Computer files (including back-up copies) should only be stored in on-site computers and files should be stored in locked cabinets. People with access rights should sign a secrecy promise and should only access data for legitimate purposes.
- (8) Electronic communication of confidential information should be carried out in encrypted form.

¹² This rule might appear as very strict and even as impairing research at some stage. However, researchers and participants have to bear in mind what irreversible (and possibly unintended) consequences a disclosure of a single bit of personal information may have with today's possibilities of political persecution, DNA tracking or public access through Internet.

3.7 Risks and benefits

Apart from the formal requirements of ethical conduct, the evaluation of risks and benefits of a research or teaching project is crucial for its justification and, hence, for its ethical approval.

- (1) The Principal Investigator must demonstrate in the application documents, where appropriate:
 - a) That a careful analysis of the direct and indirect risks to human participants of the proposed activity, however remote, has been made. This shall include physical, psychological and social risks to the participants, and further economical risks, if present. Particular vulnerabilities by reason of factors such as age or mental capacity must be considered.
 - b) That consideration has been given to the risk of damage or offence to third parties who may identify with participant individuals and groups for racial, cultural or sexual reasons, and to public sensitivity at large.
 - c) That attempts have been made to minimize the potential harm to participants, including the consideration of remedial measures, if applicable.
 - d) That, whenever the research or teaching activity creates foreseeable risk, the Principal Investigator and his co-researchers do have sufficient experience with application of the methodology/protocol.
 - e) An outline of the benefits of the research to the participant and to the society at large.
 - f) A methodology or a protocol that allows reviewers to clearly identify that the research is functional¹³ and no other than the identified risks were associated with the research.
 - g) An outline of the intended results that shall be published in order to allow reviewing the risks associated with providing the results to the public (e.g. for possible misinterpretations).
- (2) The review and approval decision will be made according to the following criteria:
 - a) whether the risk factors were explored sufficiently,
 - b) whether the benefits to the participant personally and the benefit of the knowledge gained will likely outweigh the risks inherent to the research,
 - c) whether risks have been minimized and provision made to remedy any harm,
 - d) the extent to which the publications of results may put the participants at risk with respect to their privacy and anonymity,
 - e) the extent to which the publication of results may put the institution hosting the research and/or the participants at risk, and
 - f) whether the consent the participant will give will encompass all foreseeable risk factors.

¹³ This is due to the fact, that a dysfunctional research cannot provide benefits. Hence, the review will focus on possible obstacles that will disable the research to produce an acceptable result.

- (3) Procedures involving physiological intrusions of clear medical concern will be performed by a medically authorized person.
- (4) No methodology will be approved whose object is long-term behavioural change to the participant, unless such change is evidently beneficial to that participant.
- (5) The committee reviewing the application will observe caution in approving any methodology which stimulates negative behaviour, such as anger, aggression, and racial antagonism.

3.8 Publications

- (1) Provision of informed consent is understood to include consent to publish findings subject to the requirements in respect of participant confidentiality and anonymity. Even though consent may be given by a participant, the Principal Investigator must consider whether the publication will stigmatise a group or groups to which the participant belongs. Research should not exploit the vulnerability of a community but should rather reduce such vulnerability.
- (2) Findings should not be published unless peer-reviewed. If a formal peer review is not prescribed by the publisher, the authors shall seek peers to review their paper in order to ensure that anonymity and privacy of participants is ensured.
- (3) Participants who waived the right for privacy and anonymity, even if this is true only for parts of their data, must be given the opportunity to review a publication before it is made accessible to the public and to withdraw from waiving this right if the publication entails identifiable information of this participant.

4. PROTOCOL FOR CLINICAL TRIALS

- (1) Clinical Trials research is Health Research (see section 1.2), and thus the according rules for Health Research Level One or Level Two apply.
- (2) For Clinical Trials the aforementioned Protocol for Involving Human Participants apply (see section 3), and further the following rules of this section.
- (3) The research methodology/protocol must be conform to the spirit of the following guidelines and international documents:
 - a) Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (Department of Health, 2006),
 - b) the World Medical Association Declaration of Helsinki,
 - c) the International Conference for Harmonisation Guideline for Good Clinical Practice (ICH Guideline for GCP), and
 - d) the Association of the British Pharmaceutical Industry (ABPI) Guidelines for Medical Experiments in healthy volunteers if the study intends involving such volunteers.
- (4) An ethics committee must consider all aspects of the design of the trial and be satisfied that:

- a) the Clinical Trial is directed to answering a specific question, that the hypothesis is scientifically valid and that the trial medication offers a realistic possibility of benefit over standard treatment,
 - b) the research methodology/protocol provides a rationale for the selection of appropriate participants, an appropriate method of recruitment, adequate understandable information for the purpose of obtaining participants' informed consent, a clear description of the interventions and observations to be conducted, and statistical validation of sample size and outcome, and
 - c) that participants are fully informed about benefits and risks of treatments, including the possibility of adverse effects. Participants should receive written information about such risks, either as part of informed-consent documents or as information leaflets specifically designed to inform participants.
- (5) Every Clinical Trial must be conducted by competent researchers with suitable experience and qualifications.
 - (6) The use of a placebo in a Clinical Trial is ethically unacceptable where the use of a therapy or intervention is available, which has been demonstrated to be effective for a particular condition.
 - (7) An ethics committee should examine the aspects of the budget of a Clinical Trial with respect to capitation fees, payments to researchers or institutions or organizations involved in the research, current and consequential institutional or organisational costs, and costs that may be incurred by participants. In particular,
 - a) no payments in money or kind must influence the findings of the research, and
 - b) there will be proper disclosure of the above aspects to the research participants.
 - (8) Arrangements must exist to ensure adequate compensation to participants for injury suffered as a result of participation in the trial.
 - (9) Payments to participants should be in the spirit of the National Guidelines on Payment of Trial Participants in South Africa.¹⁴ ()
 - (10) Clinical trials must be registered with the South African National Clinical Trials Register (<http://www.sanctr.gov.za/>).
 - (11) Researchers are required to report promptly to the relevant ethics committee:
 - a) deviations from the research methodology/protocol, so that immediate hazards to trial participants may be eliminated,
 - b) changes that increase the risk to participants or affect significantly the conduct of the trial,
 - c) all adverse drug reactions that are serious or unexpected, and
 - d) new information that may adversely affect the safety of all participants of the trial.
 - (12) A Clinical Trial has to be stopped immediately if
 - a) side effects of an unexpected type or frequency are encountered, or if

¹⁴ The National Guidelines on Payment of Trial Participants in South Africa be downloaded via the Rhodes University Ethics website.

- b) as the trial progresses, one of several treatments or procedures being compared proves to be so much better, or worse, than others that adherence to the approved research methodology/protocol disadvantages some of the participants.
- (13) Adverse reactions have to be reported (if possible anonymously) to a competent authority, as the safety of products is yet to be established. The Principal Investigator shall identify an appropriate authority, if applicable, in the ethics application.

5. PROTOCOL FOR USING HUMAN BIOLOGICAL MATERIAL

The Protocol for Involving Human Participants (see section 3) apply accordingly for using human biological material.

5.1 Donation of human biological material

- (1) Invasive donation of human biological material falls under the category of Level Two Health Research (see section 1.2(2)) and corresponding requirements apply. Further, only medical professionals are permitted to take samples.
- (2) Specific legislation and particular ethics considerations have to be considered for human stem cells and in particular for human embryonic cells in terms of consent of the donor/parents and permission by the Minister of Health.¹⁵
- (3) Non-invasive donation of human biological material falls under the category of Level One Health Research (see section 1.2(2)) and requires the corresponding standards to be considered.
- (4) Donation of human biological material must be performed in accordance to the legal and hygienic standards and legislation.
- (5) Human biological material carries the DNA of the donor. Thus the protection of anonymity of the donor must be ensured under all circumstances, and it must be ensured that the donor is aware of this fact.
- (6) Informed consent of the donor must consider the protection of the anonymity while specifying the research and the destruction of the samples.

5.2 Use of human biological material

- (1) In case of using human biological material from an external source (such as a co-operating hospital or a commercial provider) the Principal Investigator must make sure, that the donation was done according to the national standards, and that the donation has had local ethical approval.
- (2) Particular attention must be paid to ensure anonymity and confidentiality of the data associated with the biological material. However Principal Investigators should be

¹⁵ As the controversial issues surrounding the creation, use and destruction of embryonic stem cells are not yet clear.

aware of the challenge (or impossibility) to obtain further personal information or altering the scope of the research retrospectively.

- (3) The transfer of human biological material and associated information must be clearly documented in a materials transfer document.
- (4) The use of scarce biological material must be justified to the ethics committee by evidencing that no other biological material might be used for the purpose of the research and by provision of plausibility that the use of that material in the proposed research is sufficiently beneficial with respect to the other individuals in need of this material.
- (5) The Principal Investigator must specify for how long the human biological material will be kept and how it will be destroyed and disposed. This must be in line with the appropriate legal and hygienic standards.

III. Protocol for Research and Teaching involving Vertebrate Animals

This protocol specifies and complements the Rhodes University Policy on Ethics.

Please consider the working paper on the Moral Standing of Animals (see Appendix 5.1, page 50).

1. TERMS OF REFERENCE

- (1) Ethical approval is required to use the remains of a vertebrate animal that is specifically killed for a scientific purpose. Remains include cadavers, tissue samples, genetic material, body fluids, excreta, bones etc.
- (2) Ethical approval is not required to use the remains of a vertebrate animal if no aspect of the animal's life and death were altered for the scientific purpose, i.e. if the animal's life and death would have been exactly the same whether or not the scientific purpose occurred. The RUEESC-AE encourages the sharing of tissues or remains of vertebrate animals in additional activities, providing the initial use and death of the animal was approved as required, as this maximises the potential benefit from the original use of the animal with no additional welfare impact. Ethical approval is not required for example for:
 - a) use of organs or other material from vertebrate animals killed as part of routine commercial food and fibre production; e.g. sourced from butchers, fish shops or abattoirs,
 - b) use of carcasses or samples from vertebrate animals killed at veterinary clinics, animal shelters or game reserves for other (veterinary or management) reasons,
 - c) use of samples from vertebrate animals killed as part of a routine, unmodified pest control programme,
 - d) use of carcasses or samples from vertebrate animals found dead (e.g. roadkill),
 - e) use of tissue samples stored in laboratories from vertebrate animals whose care and euthanasia has already been approved and monitored as part of an earlier RUEESC-AE-approved activity, and
 - f) use of specimens housed in museums and research collections.
- (3) Ethical approval and relevant authorization from conservation agencies and/or landowners is required for observation activities that involve the interference of vertebrate animal populations, such as:
 - a) close physical proximity to vertebrate animals such that the animals may suffer stress (e.g. monitoring of seabird nesting sites or cave-dwelling bat populations),
 - b) spotlighting or using light sources more powerful than a domestic torch for the purposes of visual observation to collect scientific data,
 - c) trapping of vertebrate animals (Elliot, pitfall, cage/box traps, foot-loops, nets etc.),

- d) catching and banding birds or bats for scientific use or as part of ecological research programmes or surveys,
 - e) using call playback to stimulate responses by vertebrate animals,
 - f) identifying vertebrate animals by means of physical marking or placing on or in the animal any form of identifying mark or object, e.g. includes paint or other external marker, micro-chipping, trimming hair, banding and tagging, toe clipping, ear punching etc., or
 - g) conducting surveys where vertebrate animals are caught by hand, examined and released.
- (4) No Ethical approval is required for observational activities like:
- a) observing visually, not including spotlighting, e.g. bird watching and whale watching from a public beach using the naked eye or binoculars, providing that such observation will not stress the animals,
 - b) recording observations, note taking,
 - c) making photographic, sound or digital recordings,
 - d) collecting faeces (scats) and shed feathers,
 - e) searching for and recording vertebrate animal tracks,
 - f) recording vertebrate animal tracks through the use of shallow sand pans, or
 - g) using hair tubes to detect presence of vertebrate animals.
- (5) Ethical approval is required for displaying or demonstrating a vertebrate animal 'using' the animal, and animals may suffer discomfort and stress from this situation. This is for example the case for wildlife displays at schools, open days and school outreach activities in the field. Displays of vertebrate animals that are for purposes other than scientific or teaching purposes do not require ethical approval (e.g. fish tank in a departmental foyer).
- (6) Additional ethical approval is required from the RUEESC for using Non-Human Primates. Only after the RUEESC has ratified the pre-authorisation by the RUEESC-AE may the research be initiated.

2. GUIDING ETHICAL PRINCIPLES

- (1) In line with SANS Code 10386), the use of vertebrate animals must incorporate the core ethical principles of
- a) Replacement of the use of vertebrate animals with alternative models where appropriate
 - b) Reduction of the number of individual vertebrate animals used
 - c) Refinement of experimental design, procedures, care and husbandry, to minimise or eliminate the impact on individual vertebrate animals in terms of actual or potential pain, suffering, stress, and lasting harm.
- (2) Only activities for which vertebrate animal usage is essential, and that are scientifically and ethically justifiable, are approved after due consideration of both animal ethical/welfare aspects and the scientific and/or educational value of the proposed research.

3. PROPOSAL OUTLINE

- (1) In the research proposal the Principal Investigator must
 - a) ensure that experimentation takes place only where scientifically and ethically justifiable;
 - b) confirm that researchers/teachers are adequately qualified/trained to perform the research or teaching activities involving vertebrate animals, and that these activities are legal under South African law, and
 - c) assess the benefits (scientific / educational quality and outcomes) of the proposed vertebrate animal usage activity against the costs (stress / discomfort that target animals will suffer).

4. APPROVAL

- (1) Any RUESC-AE approval is applicable only to the number and types of vertebrate animals, and the proposed activities that are detailed in a research proposal. Approval is valid for the specified duration of a project or for the time period specified on the relevant permit(s) from conservation authorities, with a maximum of three years, after which a new application (listing the original approval number) must be submitted.
- (2) RUESC-AE's approval is also subject to the submission of relevant permits from conservation authorities within 60 days, if not already provided. Should any permits expire and be renewed during the execution of the project, Principal Investigators are required to submit a copy thereof to the RUESC-AE. Should there be any changes to the numbers and types of vertebrate animals to be used and/or procedures to be followed, Principal Investigators must obtain further written approval from the RUESC-AE.

5. REPORTING

Reports may include details of vertebrate animal usage, animal welfare observations, adherence to outlined procedures, achieved results compared to animal usage, details of non-utilized vertebrate animals, and any other relevant details deemed necessary by the RUESC-AE.

IV. Conceptual and Practical Considerations

This section discusses some practical aspects of applying the Rhodes University Policy on Ethics and the Protocols on Research Involving Human Participants and Vertebrate Animals. It does not entail further clauses.

1. FORMAL PROCEDURES ASSOCIATED WITH ETHICS

1.1 Ethical approval for research that is performed outside of Rhodes University

Basically, ethical approval from RUESC or one of its sub-committees is required, if the Principal Investigator is affiliated with Rhodes University. However, the hosting institution may additionally require ethical approval by its own authorities. This is typically the case for hospitals, schools etc.

Researchers are strongly suggested to enquire the need for additional ethical approval from another institution in advance (as this may take extra time). Furthermore, external institutions often will require ethics approval of Rhodes University prior to the application to their ethics committee and accept only approvals from RUESC, and not from sub-committees. RUESC is willing to support researchers in liaising with other ethics committees and bodies, but the onus is on the Principal Investigator to initiate those processes.

1.2 Research involving students, staff or infrastructure from Rhodes University

Any research of this kind must have ethical approval of the relevant ethics committee. Further, the approval of the following bodies will be required:

- Head of Department, if all required resources stem from one department only, and staff are only involved in tasks covered by their job profile
otherwise
- Director of Student Affairs, if students from Rhodes University are involved,
- Director of Human Resources, if Rhodes University staff are involved,
- Registrar of Rhodes University, and
- Head of Department, if specific equipment or infrastructure is to be used.

Any information sheets (posters, hand-outs) need to have a written indication or footnote that the research was ethically approved and the name of the relevant ethics (sub-) committee.

Further, permission from the responsible unit must be obtained for displaying or disseminating such information. For public spaces the responsible party is the Registrar of Rhodes University.

1.3 Exemption Letter for ethical approval

Funders may request an exemption letter from the university ethics committee stating that no ethics approval is required for a proposed research. Researchers in need of such a statement should complete the Ethics Application Form for Human Participants, and, after giving some basic particulars, answer the initial four questions:

- Does the research involve sentient vertebrate animals?
- Does the research involve humans as participants?
- Does the research make use of human matter, such as blood samples or stem cells?
- Are the safety and health regulations for the professionals involved in the study known and have they been properly considered?

If the research deals with neither humans nor animals, the applicant may choose to receive an exemption letter stating that no ethical approval is required. However, the research proposal has to be uploaded and screened before an exemption letter can be issued. Although RUEESC aims to respond as quickly as possible, researchers should allocate one week time for such a request being processed.

1.4 Research at Rhodes University beyond the mandate of RUEESC

RUEESC cannot process applications for Clinical Trials and Level Two Health Research on its own. RUEESC is however responsible for all ethical approvals at Rhodes University, and, hence, RUEESC has to be addressed. In case ethical applications go beyond the mandate of RUEESC, RUEESC will appoint external bodies that are competent in approving the requested type of research, and RUEESC will refer to this body for the aspects that go beyond its own scope. Under any circumstances, RUEESC will have to approve the research.

The applicant (or her/his hosting department) will, however, have to budget for the cost of the external consultation and possibly required insurances.

1.5 Using information from student or staff records

Student and staff statistics in aggregated form (from which it is impossible to identify individuals) can be used without ethical approval, provided permission of the relevant department or division has been obtained.

Individual student and staff data can only be made available to researchers if individual permission of each student or staff member was obtained.

Individual student and staff data can be used without individual permission if the research falls under the mandate of Rhodes University (e.g. for surveys studying teaching quality). However, personal data cannot be made available to researchers directly. For such research the Information and Technology Service Division may process the data in the role of a trustee and hand over only anonymous data (the results) to the researcher.

It is strongly suggested to consult RUEESC or one of its subcommittees during the conceptual phase of research using data from students or staff.

1.6 Transferral of ongoing research to Rhodes University

Information that has been gained or produced during research outside the responsibility of Rhodes University can be used for research at Rhodes University only if the same ethical standards were applied as for internally conducted research. Thus, ethical approval must be obtained for any kind of previous research before transferring it to Rhodes University.

In cases where ethical approval was obtained from another institution and the research objectives and methodology remain, the approval process at Rhodes may be facilitated by attaching the approval documents. The documentation must, however, include all information that is required by the application form, even if it was not part of the original application. Ethical approval obtained by a nationally accredited ethics committee will normally be conferred for Rhodes University as a formal process.

As generally no ex post ratifications may be issued at Rhodes University, ethical approval must be obtained prior to the start or continuation of the research at Rhodes University.

2. SPECIFIC ASPECTS OF ETHICAL CONSIDERATIONS

2.1 Risk assessment

2.1.1 Probability and level of harm

Occasionally Principal Investigators argue that the average risk for a participant would be very low. Even if this might be true, the individual risk may still be very high, despite the very low probability of this happening. For example, while exercising the risk of collapsing is rather low, provided the exercise level is appropriate for the age and fitness status of the participant, and the participant is healthy, suitably recovered and had a proper warm-up phase. However, in case of a collapse there is a substantial risk of fatality or chronic impairment.

A risk assessment from an ethics point of view must, hence, take the individual risk into consideration as well. For the above-mentioned example, low-level exercise is unproblematic, while the demands of controlling the conditions, selecting the participants and providing first aid will increase dramatically with increased exercise effort required for the study. Even if the risk of a fatality would be 1 out of 100,000 and the study would be applied to 100 participants, the statistical chance of a fatality during the study in question would be 0.1%. Should an ethics committee accept this? However, there is no study without any risk of harm at all or injury to participants.

2.1.2 Reputational risks

Reputational interests must be sacrificed for the sake of academic integrity, if need be. However, as any reputation, whether of an individual, a group or an institution, is difficult and lengthy to reinstate, a risk of reputational loss must be seriously considered and minimized as far as reasonably possible.

In one example, a postgraduate student researcher wanted to perform a survey on lifestyle, well-being and performance of students in different South African Universities. The topics

suggested an interesting study. However, one part of the survey focused on sexual behaviour of students, and the researcher wanted, as it is common practice, to correlate the responses from the different questions. Apart from the problem of possible intimidation of participants being asking explicit questions on their sexual behaviour, two reputational risks would have occurred if approving this research:

First, sexual behaviour would be compared amongst different universities. This could motivate student, parents, and other members of the society to make decisions in favour of a University according to the sexual practices of their student body. From a broader perspective one might question, whether such information is useful to make a decision in favour of one university against another one, or whether such information is distracting. An ethics committee would have to weigh up, amongst many other factors, the benefit of having such information against the risk of its misinterpretation.

Secondly, sexual behaviour would be correlated with performance data. As a consequence, students and their families, and the public at large could conclude a relation between both factors from the results of this study. A significant correlation between particular sexual practices and a higher performance could therefore be interpreted in a way that a student following such sexual practice would have a better chance of achieving good marks.

From a scientific point of view, it is questionable that a correlation between sexual practice and performance, even if this can be mathematically evidenced, would represent a cause-effect relationship. More likely there will be several hidden factors affecting sexual behaviour and affecting performance. Without a proper and scientifically underpinned model, the simple empirical correlation would very likely lead to a misinterpretation, which again might have an effect on institutional reputation.

2.2 The consulting aspect of an ethics review

The process of reviewing an application is of a formal nature, but in itself it aims at supporting the researcher(s) to meet ethical principles to a maximum extent. Thus, for the approval of a research proposal the formal minimum requirements have to be met, and, beyond this, an ethics committee has to consider the feasibility of protecting the human rights of the participants to a maximum extent. The latter aspect is very much an individual consideration, and very different options might be discussed to achieve this. In this regard, the ethics committee takes the role of a consultant to the applicant, in addition to the role on an approving body. Applicants are welcome to discuss a verdict with the relevant ethics committee if deemed helpful.

2.3 Decision making in ethics committees

Whereas decision making in business and in most other committees would take place as majority decisions after reasonable consideration of arguments, the Chairperson of an ethics committee would not act ethically by ending a discussion as per 'time is over' directive and approving an application (if need be by a 51:49 vote) despite serious concerns still remaining. On the other hand, it is not practical, and often even not possible, to discuss all arguments until all committee members are willing to decide unanimously. Hence it has to be at the discretion of a chairperson to sufficiently consider all ethically relevant concerns, and to ask for an approval decision after reasonable consideration.

2.4 Anonymity and confidentiality

Normally, research would strive for a thorough protection of the anonymity of participant in a way that the outcome of the research cannot be tracked back to an individual. However, in certain circumstances this cannot be ensured without substantially compromising the research outcome. For example, if a survey amongst the academic community of a university were to be performed, and the different academic Faculties, academic ranks and gender shall be compared, depending on the composition of the Faculty, the responses may identify or suggest the identification of an individual who responded. Skipping one of these categories would, however, compromise the results, as Faculty, academic ranks and gender may be relevant for distinction.

The only way out of this dilemma would be accepting a compromised anonymity for the data collection (compromised in a way that individuals can be tracked back in some cases) but ensuring confidentiality for the collected data and anonymity for the published results. More precisely, data storage and data processing would have to be performed via a trustee, keeping the data strictly enclosed (and, ideally processing the data electronically so that no human individual needs to spot the individual questionnaire). The results would then be compressed in a way that only two of the three categories would be distinguished at a time (e.g. only Faculty by academic rank or academic rank by gender; this would be indicated for statistical reasons anyway). So all categories would be processed, but none of the results would identify a single individual.

Another option to resolve the conflict would be to ask the individuals that can be identified to approve the publications of the results. Apart from the anonymity problem that contact data of the individuals must be stored, those individuals must however be protected not to make unwise decisions of indirectly disclosing their identity. Further, one participant refusing to publish data that could be tracked back to her/him would disable the corresponding part of the survey outcome from being published. However, in qualitative surveys this strategy can make sense, as no other alternatives would exist.

2.5 Internet surveys

Internet surveys that do not ask for identifiable information may still be tracked back for the user logged in to a computer when filling out the survey. This is particularly the case when the survey provider is identical with or linked to the institution a user is logged in to.¹⁶

In order to provide anonymity, it must be explained to the participants (and the ethics committee) which identifiable information other than what the user has entered will be stored with the survey data. Similarly, it must be explained to the participants how voluntarily entered personal information is stored, if applicable.

If no personal data is stored, the informed consent may be given anonymously, in order to avoid a participant identifying herself/himself.

¹⁶ Strictly speaking any user can be tracked back, as this is prescribed by South African law for crime prevention. However, the identity information is normally not available to the survey provider.

Often the survey itself is anonymous, but a lucky draw incentive is associated with participation. In such cases, contact information needs to be entered and stored to allow addressing the winner(s). In order to avoid personal information being linked to the survey data, two separate databases should be used in a way that first the survey is filled out, and after its submission an optional link is opened to the lucky draw part where participants can enter contact information on a voluntary basis (or withdraw from the lucky draw part by not using the link or not entering contact data). The contact information should be the minimal information required to contact a winner, e.g. an email address.

2.6 Cross-cultural research

Ethical principles on humans need to be applied with respect to the context, as humans are different. This is particularly the case for different cultures. For example, informed consent should be given in writing, if possible. This would, however, be highly inappropriate for illiterate participants. In such a case, a set protocol for oral information and a witness signing that the participant consented would apply the spirit of ethical consent.

Taking this example further to other cultures, it might be considered as highly disrespectful to request a personal agreement being settled in writing (or to present a request in writing before a personal consultation). Particularly honourable persons (e.g. directors) would consider it as an offense not to accept their word as sufficient to rely on.

Another example addresses the relationship of a participant to her/his superiors, as both would have to consent for acquiring information from a business context. Depending on the cultural background of those relationships, it might be ethically more appropriate to address a participation request first to the superior or first to the participant.

2.7 Research involving employees

Employees are dependent on and requested to be reasonably loyal to their employers. This normally includes to support the interests of the employing company or institution (as long as this does not in itself cause legal or ethical conflicts). Research involving employees has to consider possible conflicts of interest which may, for example, arise from a discrepancy between a personal opinion and a company's position or by asking to disclose potentially confidential information.

Researchers have to demonstrate awareness of possible conflicts of interest and apply means to minimise the risk of such conflicts arising. Therefore it is imperative to obtain consent from the employee and her/his superiors. Further no questions should be asked that could provoke a conflict of interest, or such questions should be agreed upon with the employer beforehand.

2.8 Can illegal actions be ethically approved?

Normally, only legal actions can be ethically approved, as otherwise social rules would be undermined and fair interaction likely compromised. Apart from the fact, that legal rules are not per se ethically sound, there are cases that may justify legal conflicts from an ethical perspective. However, crime that is to be reported by law cannot be approved by an ethics committee.

The principle question that the committee would need to ask when considering an application would be: is the committee acting unethically by approving illegal actions or the observation of illegal actions? The committee would need to ask the ancillary question: would the sake of an important research output justify accepting (minor) deviations from the law, from an ethics point of view?

In addition, the committee would need to satisfy itself that the researcher is aware of any legal duty to intervene. A legal duty would exist where the law attaches it to a person for some reason. So if the researcher observed someone abusing a child he or she would have a duty to report that action. But if the researcher observed people using drugs (see the example below), that same duty would not arise.

Legal implications of research of this nature may result in a legal order to compel disclosure of information required by a researcher (there is no privilege that attaches to the relationship between researcher and participant). In this instance then, the researcher should explain to participants as clearly as possible: the extent to which the researcher will keep confidential any information about illegal activity by participants, and the response the researcher will make to any order to disclose information.

A first example stems from the Fine Arts discipline: A student planned a presentation for his postgraduate degree, in which an artist should perform naked in the botanical garden. From a legal perspective this would be a public indecency, which is a legal offence. Stipulating a dressed performance would however take away a core element of this artwork. The ethics committee, in this case, stipulated that safety officers would have to be present far enough from the performance to inform approaching visitors about the risk of being offended by a naked artist and to suggest keeping sufficient distant if not prepared for this. So there was no risk of offence to visitors, despite the fact that a naked performance in a public space would not be legally accepted.

A second example touches the grey zone of witnessing or even participating in illegal drug consumption: An anthropologist wanted to study a specific indigenous population, e.g. Rasta men. In such a community the consumption of marihuana is a common practice. The researcher would therefore possibly being exposed to witness illegal practice. Furthermore, a close interaction with such populations often requires some form of fraternisation prior to the inquiry of personal information. Should the ethics committee approve that a researcher may smoke marihuana for this purpose, in order to be welcomed by such a community for data collection? Seeing that such research can be highly beneficial, e.g. with respect to medical or social practices and its impact on the distribution of infectious diseases like HIV/Aids, ethical approval in some cases can neither be clearly granted nor clearly denied.

A third example deals with the study of child pregnancies. As engagement in sexual conduct with a child below 16 years age is unlawful and must be reported, any research of a child pregnancy would duly require the researcher to report to police. From an ethical point of view participants would, during recruitment, have to be informed about the duty of reporting. Hence, it would be almost impossible to find volunteers for participation without specific exemption permission of a legal body.

3. GUIDELINES FOR PREPARATION OF AN ETHICS APPLICATION

To be outlined

4. GUIDELINES FOR REVIEWING AN ETHICS APPLICATION

To be outlined

5. DISCUSSION PAPERS

5.1 Moral Standing of Animals

This section stems from a working paper adopted in principle by the Rhodes University Ethical Standards Committee and the Rhodes University Animal Ethics Committee on 25 August, 2010.

Most fundamentally, Rhodes University Ethical Standards Committee on Animal Ethics (RUESC-AE) recognises that non-human animals have moral status. This means that they are part of the moral community, and that it matters morally how animals are treated by humans. It makes sense to ask whether they are being treated in ways that are harmful or beneficial, respectful or disrespectful. The committee recognises that animals have a welfare: their lives can go better or worse for them. Whether their lives are going well or badly matters for the sake of the animal itself, not the sake of humans. To acknowledge this is to bring them into the moral sphere and to recognise that we ought to be concerned about their welfare for their own sakes.

Acknowledging that animals have moral status need not depend on any controversial assumptions about their abilities or their possession of rights. In order to be part of the moral community, creatures need not possess complex rational capacities like the ability for self-reflection or a sense of self; certainly they need not be moral agents in the sense of knowing right from wrong, being properly held responsible for their actions, or being able to speak for themselves within the moral community. Young children, after all, are assumed to possess none of these capacities and yet they are clearly members of our moral community. What is required for any creature to enter the moral community as a bearer of moral status is sentience – the capacity to feel pain, stress and pleasure, the capacity to be harmed and benefited. Sentience is a minimal requirement, and if it is deemed controversial no ethically-based interventions – human or otherwise – would be acceptable. Consistency then requires that any creature possessing sentience be granted moral status; moral status cannot, for instance, be granted along species lines. If it is sentience that matters morally, then it is morally irrelevant if the sentient creature is from another species to our own.

The RUESC-AE therefore accepts that sentient creatures have moral status and are part of the moral community. It accepts that they are the fitting subjects of moral discourse and concern and that any complete conversation about morality must include them. And it follows from this that human agents have a moral duty to take into account the potential suffering and stress of animals affected by their actions. Acknowledging this duty means we can be

held morally responsible for failing in it and be appropriately censured. We fail morally if we fail in our duties towards animals.

Certain consequences follow from recognising that animals have moral status and that human beings have duties regarding them. First, human behaviour that adversely affects the welfare of animals requires justification. We cannot act in ways that are harmful to animals without providing reasons that explain and justify the action. Just as it is with human beings, the burden of proof lies with those who intend to act in ways that are harmful. Second, not just any kind of reason and justification is permissible. We cannot cite pleasure or sporting activities or brute curiosity as justifying reasons for harming animals. Permissible reasons are more difficult to establish non-controversially.

One possible reason is the envisioned benefits of the action for other animals – for instance, the general knowledge that research on an individual would bring about habitats and populations; or about the distribution, prevention, treatment and cure of diseases. In these cases, harm to individual animals is thought justified by the increase in knowledge that could help to protect particular species or populations in the future. The conclusions of RUEESC-AE to date suggest its acceptance of the view that the protection of groups of animals outweighs individual welfare when they come into conflict, though this is a controversial matter.

Another reason, and one that is particularly pressing in the context of university teaching and learning, is that of the envisioned benefits for human beings, which we concentrate on here.

Currently, research and teaching with animal subjects at Rhodes University is justified by the benefits for human beings directly, or by the benefits expected in the future. The benefits are weighed against the harms to the animals, including capture, confinement, stress and pain (and the memory of them) and death. If the benefits are thought not to outweigh the harms, the research and teaching is not approved or given approval. Note that this assumes that animals can be harmed, that these harms matter morally and that in some circumstances the harms can outweigh benefits to humans and so be unjustifiable. Human welfare is therefore not without qualification a sufficient reason for imposing harms on animals. Certain kinds of benefits are relevant and others not. For example, benefits that do not further the basic interests of human beings will be weighted far less than those affecting basic interests. Treatment that adversely affects the basic interests of animals for benefits to humans which are not fundamental will similarly be difficult to justify.

This approach is Consequentialist. The moral action, considering all factors, is that which brings about the greatest amount of benefit over harm for all affected by the action. In using this approach, some amount of harm to animals is justified by the amount of significant benefits to the fundamental interests of human beings. The morality of each decision regarding the use of animals must be decided on a case by case basis, by calculating the expected benefits and burdens to both animals and humans. If it turns out the harms imposed on animals would be greater than any benefits humans can be expected to receive, the proposed use of animals is impermissible. Like any Consequentialist approach, this faces the objection that there are no in principle limits on what can be done to animals, or humans for that matter. No intervention is ruled out as immoral from the start, in principle; any action could be justified if the calculations reveal greater expected benefits over harms.

At present, Consequentialism is the de facto approach of RUEESC-AE. An issue to be considered in the future is whether we ought to propose any in principle limits to what can be

done to animals. This would be to recognise that animals have certain rights which place limits on what can be done to them in the name of the greater good. We are familiar with this utility-restricting role of rights in the human domain (as humans we have certain rights that can never be infringed no matter the benefits to others); it is however still controversial in the animal domain. Consider the kinds of in principle limits to what can be done to humans. No matter the benefits, no-one thinks it permissible to perform arbitrary experiments on human beings without their consent (or even with their consent). No-one thinks that a good reason for experimenting on and ultimately killing a human being is that it would bring benefits to other human beings, let alone another species. Human beings have rights that can never be infringed in the name of maximising overall utility. Yet most people do not extend these considerations to animals. There is at least a *prima facie* double standard at work here if one accepts that it is sentience that grounds moral status.

However, RUEESC-AE does not think its work or moral commitments need wait upon a resolution to this complex and probably intractable debate. It is important to note that regardless of whether one accepts that animals have rights, their sentience brings them into the sphere of moral concern. The moral status of animals is not hostage to a resolution of the debate about whether they have rights. What that debate does affect, however, is the extent or weight of their status, and whether or not it could ever be considered from the start inadmissible to harm them, as we think it inadmissible to harm human beings. Grounding moral status in sentience can provide a crucial framework/guideline, though it cannot do all the work we might think necessary to fully bring animals into the moral community.

In practice, the committee recognises the moral status of animals in the very fact that harms to them require justification in any research or teaching. The committee does not simply require justification in order to obey the rules or avoid prosecution, but because it thinks it is right to do so. The aim of the committee is to ensure that research and teaching that uses animals is adequately justified and that the guidelines for animal care are followed. We follow the guidelines and standards of care prescribed by the South African National Standard SANS 10386:2008 as a minimum, but strive, wherever possible to exceed these prescriptions to the benefit of non-human animals.

Furthermore, the committee is committed to the 'three Rs' approach: the reduction, refinement, and replacement of animals in teaching and learning. It is committed to reducing the number of animals used and using subjects more efficiently, to improving the way animals are treated and housed, and – as knowledge and technology realistically make it possible – to replacing the use of animals with alternative techniques. At present reduction and refinement are the most viable options and a challenge for the future is to actively find ways of further reducing and refining the use of animals in teaching and research.

RUEESC-AE realises that a mark of integrity and moral commitment lies in treatment of those one has in one's power. Animals fall into the group of vulnerable subjects, along with conscripts, prisoners, children or the mentally ill. Having power over such groups increases rather decreases our responsibility to care for their wellbeing and to take it into account when making decisions that affect them. As our knowledge of the complexity, intelligence and sensitivity of animal life increases, so does our commitment to bringing animals more completely into the moral community. RUEESC-AE pledges itself to ensuring that this commitment is honoured.

Appendices

Last updated 13.11.2014. As this information is subject to frequent changes, please consult the Rhodes University ethics website for most recent information.

1. ADMINISTRATION

1.1 Contact

Management and Resources:

Jaine Roberts (Research Office, j.roberts@ru.ac.za, phone: 8756, mobile: 083 460 9477)

Administration and Electronic Data Management:

Noelle Obers (Project Officer & PA to DVC, n.obers@ru.ac.za, phone: 8055)

Electronic Data Management System:

For Management: <https://ru.rims.ac.za>

For applications: <https://ru.rims.ac.za>

Intranet: <http://ruconnected.ru.ac.za/course/enrol.php?id=1058>

(Enrolment key: <RUEESC>)

1.2 Information Dissemination

Information on Ethics is provided for:

- Ethics website (from Rhodes homepage)
- Departmental/Faculty websites
- HoD Handbook
- Academic orientation program
- Lecturers introduction course
- Postgraduate training
- Doctoral supervision training
- Rhodes University Calendar

2. COMMITTEES

2.1 Rhodes University Ethics Standards Committee (RUEESC)

Email distribution list: EthStd@lists.ru.ac.za (this list is moderated)

Minutes and organisation of meetings:

Rita Ferreira (Committee's Officer in Registrar's Division, rita.ferreira@ru.ac.za, phone 8748)

Current members:

Name	Department	Role
Prof M. Göbel	Human Kinetics and Ergonomics	chair
Prof R Dowse	Pharmacy	Pharmacy Faculty representative
n.n.	Pharmacy	Pharmacy Faculty representative
Dr Patricia Henderson	Anthropology	Humanities Faculty representative
Dr Mareli Stolp	Musicology	Humanities Faculty representative
Dr D Parker	Zoology and Entomology	Science Faculty representative
Ms H Kruuse	Law	Law Faculty representative
Prof M Schafer	Education	Education Faculty representative
Prof G Foster	Information Systems	Commerce Faculty representative
Prof C Young	Psychology	
Prof C Boughey	CHERTL	
Ms S Paphritis	Community Engagement	
Dr C Knox	(Biochemistry, Microbiology & Biotechnology)	
Prof C de Wet	Institute of Water Research	
Dr S Zschemack	Human Kinetics and Ergonomics	
Ms M Mattison	Human Kinetics and Ergonomics)	
Prof A Craig	Zoology and Entomology	
Prof H Kaiser	Ichthyology	
Ms H van Zyl	Psychology	
Jaine Roberts	Research Office	Research Office representative

2.2 Human Ethics Sub-committee

Name	Department	Role
Prof M. Göbel	Human Kinetics and Ergonomics	chair
Prof R Dowse	Pharmacy	Pharmacy Faculty representative
Dr Patricia Henderson	Anthropology	Humanities Faculty representative
Dr Mareli Stolp	Musicology	Humanities Faculty representative
Ms H Kruuse	Law	Law Faculty representative
Prof M Schafer	Education	Education Faculty representative
Prof G Foster	Information Systems	Commerce Faculty representative
Prof C Young	Psychology	
Prof C Boughey	CHERTL	
Ms S Paphritis	Community Engagement	
Dr C Knox	Biochemistry, Microbiology & Biotechnology	
Prof C de Wet	Institute of Water Research	
Dr S Zschemack	Human Kinetics and Ergonomics	
Ms M Mattison	Human Kinetics and Ergonomics)	
Ms H van Zyl	Psychology	

2.3 Animal Ethics Sub-committee

Name	Department	Category
Dr. D. Parker	Zoology and Entomology	Category A
Prof. A. Craig	Zoology and Entomology	Category B

Prof. H. Kaiser	Ichthyology	Category B
Ms H. van Zyl	PGLSC representative	Category D

2.4 Departmental ethics sub-committees

Department	Chairperson(s)	No of members
Accounting	John Williams	5
CHERTL	Sioux McKenna	3
Economics	Gavin Keeton and Jen Snowball	2
Education	Marc Schafer	3
HKE	Miriam Mattison	8
Information Systems	Caro Waktins	2
Humanities Higher Degrees Committee	Tom Martin	>15
Journalism and Media Studies	Herman Wasserman	5
Law	Helen Kruuse	4
Management	Mark Maritz	2
Pharmacy	Carmen Oltmann	4
Political and international studies	Louise Vincent	3
Psychology	Charles Young	5
Sociology	Kirk Helliker	3
Zoology & Entomology	Dan Parker	3

3. SPECIAL AGREEMENTS

3.1 Research performed by the Biopharmaceutical Research Institute

The Biopharmaceutical Research Institute of Rhodes University (BRI) performs repeated pharmaceutical studies on skin blanching. In order to comply with the Rhodes University Policy on Ethics and the corresponding protocols, BRI will require approval from RUEESC, and an external ethics committee for the specific issues related to pharmaceutical studies. In the meeting of RUEESC on 9 November 2012 it was agreed, that the BRI will prepare a framing application for all studies of this kind to RUEESC, and, having this approved, obtain clearance for the pharmaceutical aspects of each single study by an external committee. BRI will have to report any single study to RUEESC and BRI will have to budget for the cost of an external ethics committee and possible insurance and liability costs.