



POLICY ON RESEARCH ETHICS

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PART 1

GENERAL GUIDELINES FOR ETHICAL RESEARCH

1. PREAMBLE

- 1.1 Unisa is committed to
- becoming the African university in the service of humanity
 - undertaking and promoting research that will benefit all the people of South Africa
 - being guided by integrity, accountability and rigour in research
 - promoting an institutional ethos that is conducive to critical discourse, intellectual curiosity, tolerance and a diversity of views
 - maintaining an environment for researchers in which they may be autonomous and ethical in their work
- 1.2 Unisa promotes high standards of scientific work and strives for excellence in research that can withstand public scrutiny.
- 1.3 Unisa espouses the constitutional values of human dignity, equality, social justice and fairness.
- 1.4 Unisa affirms the constitutional principles of academic freedom and freedom of scientific research.

2. RATIONALE

The Unisa Policy on Research Ethics aims to ensure that

- an ethical and scientific intellectual culture prevails among its employees and students
- the rights and interests of human participants are protected. This is particularly important where information gathered has the potential to invade the privacy and dignity of participants, and where participants are vulnerable owing to their youth, age, poverty, disease, ignorance or powerlessness.
- research is ethical where the following are involved: animals, genetic material, agriculture, living organisms, and genetically modified organisms which may negatively affect humans, animals, plants or the environment.
- research is ethical in increasingly diverse research areas. Examples are qualitative¹ and quantitative² research, and collaborative research between

¹ This is research that attempts to understand phenomena in their entirety. It comprises research to understand social and cultural problems, and focuses on interactive processes to collect subjective information that is not structured numerically, but intuitively. It attempts to understand human experience and analyses thematic and narrative information. The investigator interacts with people in a sustained manner. See MRC *Guidelines on Ethics for Medical Research: General Principles* Ch 8 on ethics issues in qualitative research.

² This is research that focuses on concise concepts as well as on variables. It collects information under controlled conditions, and uses structured and established procedures to do so. It uses objectivity in the analysis of information. It analyses numerical information using statistical procedures, it involves logistic and deductive reasoning, and the investigator does not interact with the event being researched.

international researchers and host country institutions. Such collaboration raises particular ethical issues, which include the possible exploitation of vulnerable populations, intellectual property rights of indigenous people and benefit for the host country.

- ethical and scientific soundness of research is not compromised where lack of funding limits opportunities for research and force cost-saving procedures

3. OBJECTIVES

3.1 The Policy on Research Ethics is not intended to restrict or discourage research at Unisa. On the contrary, this policy aims to

- enable researchers to
 - enhance their capability to undertake ethical research
 - maintain their independence, especially when confronted with undue influence or pressure which may compromise their integrity or that of their research
- discourage unethical research practice
- serve as a basis for policymakers and to provide an enabling environment for the practice of ethical research
- provide an additional resource for the teaching and training of students in research
- make ethics an integral part of the planning and methodology of research
- preserve and promote the autonomy, quality, legitimacy and credibility of research
- protect and promote the rights of research participants³ and honour their trust in researchers and research
- strengthen the research ethics review system in the University where research involves human participants, animals, or other living or genetically modified organisms

3.2 Application of the policy

3.2.1 The policy covers all activities through which research information is gathered, interpreted, processed and disseminated, for example surveys, interviews, data processing and the reporting of research findings.

3.2.2 The policy applies to all parties in research, including Unisa, researchers, students, research participants, peer reviewers, consultants, clients, funders and sponsors.

3.2.3 The policy does not apply retrospectively. However, researchers carrying out research involving human participants, animals, or other living or genetically modified organisms should report to the relevant Ethics Review Committee on the extent to which their current research complies with the policy.

3.3 This policy should be read in conjunction with the following Unisa guidelines and policies:

3 That is, the human beings who are studied.

- Research Policy
- Policy on Grants from Research Funds
- Research and Development Leave Policy
- Policy on Copyright Infringement and Plagiarism
- Policy on the Publishing of Journals.

3.4 This policy may be reviewed by the Unisa Ethics Review Committee when the need arises.

4. RIGHTS AND RESPONSIBILITIES OF UNISA

4.1 Unisa should respect the autonomy and academic freedom of researchers.

4.2 Unisa should create and maintain an enabling environment in which researchers may conduct ethical research.

4.3 Unisa should promote the observance of the Policy on Research Ethics and take appropriate steps for protection against pressures inimical to the observance of the policy.

4.4 Unisa may require the payment of review fees for externally funded research. The particulars are contained in [Annexure "A"](#).

4.5 As a general rule, all intellectual property resulting from research which was conducted with Unisa funds, or use of its facilities, vests in Unisa. However, agreements may be entered into according to which the outcomes and benefits of research are shared with the researchers, funders and/or participants or communities involved. These include intellectual property ownership, data, technologies and instruments developed in the research, such as questionnaires and analytic designs or methods.

4.6 All research involving human participants, animals, or other living or genetically modified organisms must have ethics clearance (from an appropriate Ethics Review Committee before it may commence. It includes research which

- is done on Unisa premises or in any of its units or uses any of its facilities
- involves Unisa employees or students in various capacities, including collaborative or multi-institutional or multi-country studies, or
- is or will be funded from Unisa funds or where funding was obtained through Unisa

4.6.1 Class approval for student research projects may be obtained in certain circumstances.

4.6.2 Unisa has the right to monitor research that has been approved by any of its Ethics Review Committees and to require submission of regular reports or other information about the research. It may impose disciplinary measures or stop research when ethical principles are violated or the integrity of the University is jeopardised.

4.6.3 In pursuance of this right, the Unisa Research Directorate registers all research that obtained ethics clearance.

4.6.4 Unisa is accountable only for research which has been approved by any of its Ethics Review Committees.

4.6.5 The particulars of the ethics review system are contained in [Annexure "A"](#).

5. RIGHTS AND RESPONSIBILITIES OF RESEARCHERS AT UNISA

5.1 Researchers have the fundamental right to academic freedom and freedom of scientific research.

5.2 Integrity in research

5.2.1 Researchers should be competent and accountable. They should act in a responsible manner and strive to achieve the highest possible level of excellence, integrity and scientific quality in their research.

5.2.2 Researchers have a right, as well as a duty, to refrain from undertaking or continuing any research that contravenes the Policy on Research Ethics, violates the integrity and/or validity of research and/or compromises their autonomy in research. If they feel that the policy or ethical principles are being violated, or that the study is unethical, they should make all possible efforts to make corrections. These would include reporting to the relevant Unit Ethics Review Committee. (The particulars are contained in [Annexure "A"](#).) In the event of failure of remedial measures they should terminate the study or end their involvement in it.

5.2.3 Researchers may undertake only such research involving human participants, animals, other living or genetically modified organisms as has been approved by an appropriate Ethics Review Committee.

5.2.4 Researchers should undertake only such research as, according to their understanding, will benefit society and contribute to knowledge on the subject. They are advised to use resources judiciously and to avoid the unnecessary duplication of research.

5.2.5 Researchers have a right and a duty to make all necessary efforts to bring the research and its findings to the public domain in an appropriate manner and at an appropriate time. The publishing of research findings should be done in a manner which will not harm research participants or their communities.

5.2.6 Researchers should not undertake secret or classified research, any secret assignment under the guise of research or research whose findings are to remain confidential. They should endeavour to convince their client(s)/sponsor(s)/funder(s) of the importance of publishing research findings in scientific journals.

5.2.7 Researchers have a responsibility towards those involved in or affected by their work. They should make reasonable efforts to anticipate and to guard against the possible undesirable or harmful consequences of research. They should take reasonable corrective steps when they come across misuse or misrepresentation of their work.

5.2.8 Researchers should be honest in respect of their own actions in research and in their responses to the actions of other researchers. This applies to the whole range of research, including generating and analysing data, publishing results, and acknowledging the direct and indirect contributions of colleagues, collaborators and others.

5.2.9 Researchers may not commit plagiarism, piracy, falsification or the fabrication of results at any stage of the research. The findings of research should be reported accurately and truthfully, and historical records and study material should be preserved and protected.

- 5.2.10 Plagiarism, falsification, the fabrication of results, and scientific misconduct in general are regarded as serious disciplinary offences. These will be investigated by the relevant Ethics Review Committee and the findings reported to Unisa or the research sponsor. See [Annexure "A"](#), the Disciplinary Code for Employees and the Student Disciplinary Code.
- 5.2.11 Researchers undertaking research involving humans, animals, other living or genetically modified organisms may be requested to report regularly to the relevant Ethics Review Committee. They should inform this committee immediately about any unexpected adverse events.

5.3 Relationship among researchers

- 5.3.1 Principal researchers are responsible for the ethical conduct of research by juniors, assistants, students and trainees under their supervision. At the same time juniors, assistants, students and trainees have a responsibility to act ethically and to observe the Policy on Research Ethics.
- 5.3.2 Juniors, assistants, students and trainees have a right to receive, and principal researchers have a responsibility to provide, proper training and guidance on all aspects of research, including ethical conduct. The principal researchers should delegate to juniors, assistants, students and trainees only those responsibilities that they are reasonably capable of performing on the basis of their education, training or experience, either independently or under supervision.
- 5.3.3 Researchers should not engage in discriminatory, harmful or exploitative practices or harassment. They should not impose their views or beliefs on or try to seek personal, sexual or economic gain from anybody, including other researchers, juniors, assistants, trainees or students.
- 5.3.4 Researchers should not deceive or coerce other researchers, including juniors, assistants, trainees and students into serving as research participants. Students, either as research participants or as research assistants, have the right to end involvement in the research without having to face adverse consequences.
- 5.3.5 Students working on research as a tuition requirement should not be exploited by advisors or mentors, nor used as cheap labour.
- 5.3.6 In addition to researchers and students, other individuals such as administrative employees of Unisa who may have access to data or identifying information, should be briefed on ethical issues and the Policy on Research Ethics, including the participants' right to confidentiality.

5.4 Data sharing

- 5.4.1 Researchers should ensure the protection of the interests of co-researchers and participants, including participants' right to confidentiality, when sharing or making public available data in any form.
- 5.4.2 Data which do not identify participants and which are in the form of anonymous⁴ or abstracted facts may be commonly shared, if necessary even before publication of the study, among researchers and peer reviewers, and may be made available to the public.
- 5.4.3 As far as possible, researchers should ensure that relevant findings of the research are taken back to the research participants or communities in a

4 That is, the assurance that information will not be traceable to individuals or specific organisations or institutions

form and manner that they can understand, and which will not cause them harm.

5.5 Reporting and publication of research

- 5.5.1 Reporting of research findings advances scientific knowledge. Researchers who conducted the study have the right and the duty to publish research findings in scientific journals, books or other media. When they agree to delegate this responsibility to other individual(s) or organisation(s) they should do so only if they have received a mutually agreed commitment to publish or disseminate the results within an agreed period, with an agreed content and in an agreed manner.
- 5.5.2 Where there is a conflict between the advance of scientific knowledge and the protection of intellectual property (e.g. by way of patents) researchers should endeavour to convince the patent holder of the importance of publishing research findings.
- 5.5.3 If a client/sponsor/funder requires nonpublication of results carried out on humans, animals, or other living or genetically modified organisms, or that it must give prior approval for the manner and content of reporting, such research proposal may be disapproved by the relevant Ethics Review Committee. If the request not to publish is based on strategic or other reasonable grounds, the committee may consider nonpublication of results for no more than one year following the completion of research. Input from the relevant college/institute/centre should be sought where there is a request not to publish. See [Annexure "A"](#).
- 5.5.4 The results should be reported irrespective of whether they support or contradict the expected outcome(s).
- 5.5.5 Researchers should disclose in their publications the source(s) of funding and sponsors, if any, unless there is a compelling reason not to do so.
- 5.5.6 Researchers should in their publications explain the methodology used, as well as how ethical dilemmas encountered were resolved.
- 5.5.7 The following guidelines should be followed for giving authorship credit while reporting the research in any form:
- Authorship, and its sequence in case of more than one author, should be based on the quantum of contribution made in terms of ideas, conceptualisation, and actual performance of the research, analysis and writing of the report or any publication based on the research. Authorship and its sequence should not be based on the status of the individual in the institution or elsewhere.
 - All other individuals not satisfying the criteria for authorship but whose contribution made the conduct and completion of research or publication possible should be properly acknowledged.
 - A student should be listed as principal or first author on any multiple-authored publication that substantially derives from the student's dissertation or thesis.
 - When data or information from other studies or publications is quoted or included, appropriate credit should be given.
- 5.5.8 When results are disseminated through the popular media, researchers should endeavour to ensure that media people comprehend the limitations

and implications of research results, and that distortions and misrepresentations in media reporting are minimised.

5.6 Peer review

- 5.6.1 Apart from ethical review, peer (scientific) review is an essential part of research. The purpose of peer review is to improve and advance research, and to facilitate observance of ethics. Researchers should be encouraged to subject their own work to such a process.
- 5.6.2 Researchers should be encouraged to make themselves available as peer reviewers for research in the fields in which they have adequate knowledge and expertise.
- 5.6.3 Peer reviewers should be aware of the ethical aspects of research and publication. They have to act objectively, impartially and constructively.
- 5.6.4 If peer reviewers have any actual or potential conflicts of personal or professional interest with the work under review which could jeopardise their ability to undertake the review in a scientific and ethical manner, they should either disclose the same or decline to review the work concerned. In such situations, their role should be decided on the basis of the type and severity of the conflict of interest.
- 5.6.5 When scientific misconduct or violation of ethics is discovered, the peer reviewer should take appropriate steps to report it to the relevant Ethics Review Committee. See [Annexure "A"](#).

6. INTERNATIONAL COLLABORATIVE RESEARCH

- 6.1 Before submission of a collaborative research proposal to an Ethics Review Committee, agreement should be reached between the host research institution and the collaborating institution on all aspects of the research. These include sharing of intellectual property rights, management of the research process, data management, the fate of data and research specimens, division of responsibilities, finances, research output, publication strategy, sharing of benefits and burdens, development of infrastructure and research capacity in the host country, and an ombudsman to settle disputes.
- 6.2 Intellectual property rights of parties should be respected and acknowledged as agreed on before the research commenced.
- 6.3 Research may not be carried out in a host country without local research collaboration in the design and conduct of that research.

7. RIGHTS AND RESPONSIBILITIES OF FUNDERS, CLIENTS AND SPONSORS

- 7.1 Researchers should ensure that they have an explicit written research mandate from the client/sponsor/funders in which the conditions and terms of the research are set out clearly (e.g. research problem, expected deliverables, financial commitments and time frames).
- 7.2 The acceptance of a mandate should be sealed by a legally binding, written contract between the parties. This contract should specify the terms agreed on, including the rights and obligations of the parties involved, and the sharing of intellectual property rights and benefits.
- 7.3 The position with regard to the dissemination and publication of findings from the research study should be clarified.

- 7.4 Researchers should recognise the right of the client/sponsor/funder to request information from them at any stage in the course of the research. However, interference that may jeopardise the scientific integrity of the study or the interests of the research participants may oblige Unisa to cancel the cooperation.
- 7.5 Clients/funders/sponsors should be made aware of the Unisa Policy on Research Ethics. They have the right to receive a copy of the policy and to expect that the research proposal submitted for funding or sponsorship by researchers and Unisa contains the necessary information on ethical issues and complies with the policy.
- 7.6 Clients/funders/sponsors should respect the Unisa Policy on Research Ethics and should not expect researchers or Unisa to undertake research or conduct which is in any way contrary to the policy.
- 7.7 Where clients/sponsors/funders act, directly or indirectly, as gatekeepers and control access to the participants, researchers should not devolve onto the gatekeepers their responsibility to obtain separate and informed consent from participants and to protect their rights.

Acknowledgements and works consulted

1. South African Human Sciences Research Council *Draft Code of Research Ethics* (http://www.hsrc.ac.za/Corporate_information-6.html)
2. National Committee for Ethics in Social Science Research in Health (NCESSRH) (2003) (http://www.hsph.harvard.edu/bioethics/guidelines/ethical_1.html)
(<http://www.gal.ac.uk/R-E/pub/policies/goodpractice>)
3. South African Medical Research Council *Guidelines on Ethics for Medical Research: General Principles (Book 1)* (2002)
4. Access and benefit sharing: good practice for academic research on genetic resources website: <http://abs.scnat.ch>

PART 2

GUIDELINES FOR RESEARCH INVOLVING HUMAN PARTICIPANTS

1. BASIC PRINCIPLES FOR RESEARCH

1.1 Moral principles

Unisa promotes the following four internationally established and accepted moral principles of ethics as bases for research:

- autonomy (research should respect the autonomy, rights and dignity of research participants)
- beneficence (research should make a positive contribution towards the welfare of people)
- nonmaleficence (research should not cause harm to the research participant(s) in particular or to people in general)
- justice (the benefits and risks of research should be fairly distributed among people)

These principles are not ranked in any order of preference. In disputes a balance between the four principles should be pursued.

1.2 General ethics principles

In addition to, and expanding on, the above moral principles, the following ten general ethics principles should be adhered to by researchers. Again, the ethical principles may not, by themselves, resolve all ethical problems and dilemmas which confront researchers. Researchers may be required to balance the demands made by moral principles of research and to privilege one principle over another, depending on the context and circumstances of the research involved.

(i) ESSENTIALITY AND RELEVANCE

Before undertaking research adequate consideration should be given to existing literature on the subject or issue under study, and to alternatives available. In view of the scarcity of resources in South Africa, it should be clearly demonstrated that the research is essential to the pursuit of knowledge and/or the public good.

(ii) MAXIMISATION OF PUBLIC INTEREST AND OF SOCIAL JUSTICE

Research should be carried out for the benefit of society, and with the motive of maximising public interest and social justice. All efforts should be made to make public in an appropriate manner and form, and at an appropriate time, information on the research undertaken, as well as the results and implications of the completed research.

(iii) COMPETENCE, ABILITY AND COMMITMENT TO RESEARCH

Researchers should be professionally and personally qualified for the research. Commitment to research in general and to the relevant subject in particular is an essential prerequisite for good and ethical research.

(iv) RESPECT FOR AND PROTECTION OF PARTICIPANTS' RIGHTS

Researchers should respect and protect the dignity, privacy and confidentiality⁵ of participants and should never expose them to procedures or risks not directly attached to the research project or its methodology. Research and the pursuit of knowledge should not be regarded as the supreme goal at the expense of participants' rights.

(v) INFORMED AND NON-COERCED CONSENT

Autonomy requires that individuals' participation should be freely given, specific and based on informed consent. Direct or indirect coercion, as well as undue inducement of people in the name of research should be avoided. These act as barriers to autonomous decision making and may result in people consenting against their better judgment to participate in studies involving risks.

(vi) RESPECT FOR CULTURAL DIFFERENCES

Researchers should treat research participants as unique human beings within the context of their community systems, and should respect what is sacred and secret by tradition. Research should preferably be undertaken with, and not merely on, an identified community. In some situations the consent of "gatekeepers" may have to be obtained in addition to that of research participants.

(vii) JUSTICE, FAIRNESS AND OBJECTIVITY

Criteria for the selection of participants of research should be fair, besides being scientific. Easily accessible individuals or groups should not be inordinately burdened with research being carried out repeatedly on them.

(viii) INTEGRITY, TRANSPARENCY AND ACCOUNTABILITY

The conduct of research should be honest, fair and transparent. Researchers should be honest about their own limitations, competence, belief systems, values and needs. The contribution of other researchers or members of the research team should be properly acknowledged. Researchers should not abuse their positions or knowledge for personal power or gain.

(ix) RISK MINIMISATION

Researchers should ensure that the actual benefits to be derived by the participants or society from the research clearly outweigh possible risks, and that participants are subjected to only those risks that are clearly necessary for the conduct of the research. Researchers should ensure that the risks are assessed and that adequate precautions are taken to minimise and mitigate risks.

(x) NON-EXPLOITATION

There may be no exploitation of research participants, researchers (including student and junior members), communities, institutions or vulnerable people. There should be benefit to a community in which research is conducted. As far as possible, communities should receive feed-back on research carried out on them.

⁵ That is, the nondisclosure of personal information (e.g. direct quotations or identifiable images) to others. Participants may consent to disclosure, preferably in writing.

2. RELATIONSHIP BETWEEN RESEARCHERS AND PARTICIPANTS

- 2.1 Participants should be seen as indispensable and worthy partners in research. Researchers should respect and protect the rights and interests of participants at every stage and level of research.
- 2.2 The risks and benefits of the research to the prospective participants should be fully weighed. Research that could lead to unnecessary physical, social and/or psychological harm should not be undertaken. Researchers should identify potential risks to participants and make provision for their avoidance. When risks form part of the conduct of the study, efforts should be made for mitigation or protection.
- 2.3 In case harm, injury or loss of opportunity is incurred by participants, provision should be made for compensation or payment for treatment with clear guidelines on how to obtain this.⁶ In the event of significant harm, participants should be entitled to claim compensation regardless of whether or not there was negligence or legal liability on any other basis.
- 2.4 The criteria for selecting research participants should be fair. Repeat studies should not be done on the same group because of their easy accessibility, as this will make them bear an unfair share of the burden of participation. At the same time, it should be borne in mind that no particular group(s) should be unfairly excluded from research, as this could result in their unfair exclusion from the direct, indirect or potential benefits of research.
- 2.5 Unless consent on a mutually beneficial arrangement is obtained, Unisa and its students should not use a community or research setting as a constant and long-term resource for data collection for curricular research or training.
- 2.6 The relevant social, cultural and historical background of participants should be taken into consideration in the planning and conduct of research.
- 2.7 Researchers should not infringe the autonomy of participants by resorting to coercion, undue influence or the promise of unrealistic benefits. Coercion may include taking undue advantage of individuals or abusing the authority and influence of research. Inducement may include a promise of material or financial rewards, services or opportunities. No financial or other inducement should be offered to participants, whether children or adults, parents or guardians of children taking part in research. Reimbursement of expenses (e.g. transport costs, meals) or compensation for time or effort expended or opportunity lost is allowed, on condition that all participants are offered similar rewards and that such rewards are aimed at recompensing only.
- 2.8 Researchers should ensure that reimbursements or compensation to participants does not cause conflict in the group or community.
- 2.9 Research should not unreasonably burden or exploit participants or communities, and should not unnecessarily consume their time or make them incur loss of resources, opportunities or income.
- 2.10 Participants are autonomous agents who have the right to choose whether or not to be part of the research.
- 2.11 Participants should be informed of the existence of the Unisa Policy on Research Ethics. The policy should be made available to them if it can help them make an informed decision regarding their participation.

⁶ See e.g. the *Guidelines for Good Clinical Practice in the Conduct of Trials in Human Participants in South Africa* Pretoria, Department of Health (1999).

3. INFORMED CONSENT

- 3.1 Personal information (i.e. information⁷ about an identifiable, natural person)⁸ may only be collected and processed with the specific informed consent of the individual(s) involved. Only information that is relevant and necessary (i.e. not excessive) may be collected.
- 3.2 Consent need not be obtained where personal information is involved which has been de-identified to the extent that it cannot be re-identified again, if it is about a natural person who has been dead for more than 20 years,⁹ or if it is in the public domain or contained in a public record.
- 3.3 The participation of individuals should be based on their freely given, specific and informed consent. Researchers should respect their right to refuse to participate in research and to change their decision or withdraw their informed consent given earlier, at any stage of the research without giving any reason and without any penalty.
- 3.4 Participants should give their consent in writing. They, in turn, should be given written information containing adequate details of the research.
- 3.5 Consent for participation in research is freely given and informed if
- (i) it is given without any direct/indirect coercion or inducement. See paragraph 2.7 above.
 - (ii) prospective participants have been informed on the details of the intended research
 - (iii) prospective participants have understood this information
 - (iv) the researcher has answered any question(s) about the research and their participation
 - (v) it is given before research commences
- 3.6 The information in (ii) and (iii) should include the following:
- Purpose of research

The aims, implications (including commercial ones) and possible outcomes of the intended research should be stated in understandable language.
 - Risks and benefits

The possible, anticipated and potential benefits and the potential risks (direct/indirect, immediate/long term) of the research should be explained. These include discomfort and unpleasant emotional experiences. Where questionnaires or interviews are involved, participants should be informed of the nature of questions posed, for example that they are sensitive or emotionally disturbing, or that they cover personal issues such as health, sex life or criminal

⁷ This includes information relating to race, gender, sex, pregnancy, sexual orientation, religion, culture, physical or mental health, disability, education, criminal history, and address, name of a person together with other identifying information, fingerprints, and personal opinions. See Draft Bill on the Protection of Personal Information October 2005.

⁸ In so far as it is applicable, it also includes information about an identifiable juristic person.

⁹ Researchers should take note of the provisions of the Protection of Personal Information Act once this Act comes into operation. The Information Protection Commission, which will be established in terms of this Act, may authorise a responsible party to collect, record, organise, store and disseminate personal information without informed consent if the Commission is satisfied that the public interest in such processing outweighs any interference with the privacy of the individual(s) concerned. The public interest includes scientific research.

behaviour. Where research may affect communities (e.g. when genetically modified organisms are studied) they should be informed and consulted on possible long-term effects for them.

- Methods of study and participants' actual role in research

Where questionnaires or interviews are involved, participants should be informed of the estimated time these will take.

- Identity of the researchers

The name, address and telephone number of researcher(s), the institution(s) and the chairperson of the relevant Ethics Review Committee who may be contacted, should be provided.

- Identity of others associated with the research

The name(s), address and telephone number of chief consultant(s), funder(s) or sponsor(s) if any, should be provided.

- Why selected

The reasons or method for selecting the particular locality, community, group and/or individual for participation in the study should be explained.

- Privacy, anonymity and confidentiality

Measures to ensure privacy, anonymity and confidentiality of participants, as well as any risk of breach of confidentiality and anonymity should be explained. If data and identity provided by participants in group discussions cannot be kept anonymous and confidential, this should also be disclosed. See paragraph 4.8 below.

- Future use of information

Participants should be informed of any possible future use of the information obtained, including publication of research findings, use as a database, archival research, recordings for educational purposes, and use as secondary data (i.e. anonymous or abstracted information which does not violate the privacy, anonymity and confidentiality of participants).

- Right not to participate and to withdraw

Participants should be informed that they have the right to decline their consent outright, or to withdraw their given consent at any time without any penalty or prejudice. They are free to refuse to answer certain questions which form part of an interview or questionnaire, and to object to the use of data gathering devices, such as camera, tape recorder, and so forth.

- Right to get help

Researchers should help participant(s) in cases of adverse consequence resulting from their participation in research. These include psychological trauma, distress, and loss of job, social hostility or retaliation against the participant(s). When, in the course of the research, researchers come to know of a need of participants that is not connected to the research but which may improve their lives (e.g. medical treatment), they should endeavour to get the help needed.

- Additional information should be given to which a reasonable person in the prospective participant's position is likely to attach significance in his/her decision whether to participate.

3.7 If the data collection from the participant(s) is done in more than one sitting and there is a long time period between the sittings/contacts, informed consent should be sought each time.

3.8 Nondisclosure of all information

In some situations the methodology or practicalities of a research project may necessitate the concealment of information. This may be due to the possibility that behaviour changes may result or responses be affected when such details are revealed to participants. In such a case the researcher should, before conducting the study, determine

- (a) whether the use of such a methodology is justified by the scientific, educational or applied benefits
- (b) whether alternative procedures which do not require the concealment of information could be used instead

If the use of such methodology is deemed justified by the researcher, the following should be done:

- (i) A detailed justification for not revealing all necessary information and obtaining informed consent should be provided in the research proposal and methodology and it should be subject to scientific and ethical reviews. Only after approval in both reviews, should such research be undertaken.
- (ii) The participants' right to privacy, anonymity and confidentiality gains additional importance in such cases as they do not know the real purpose or objective for which they provide information.
- (iii) Even if both scientific and ethical reviews would allow that some of the information about the study need not be revealed, participants should be provided the rest of the information. In no case, however, should researchers withhold information regarding risks, discomfort, unpleasant emotional experiences, or any such aspect that would be material in making the decision to participate.
- (iv) Participants should be given the reasons for not providing full information as soon as is possible after completion of the research. Where needed, services such as counselling and referral should be offered.

3.9 Consent where gatekeepers are involved

In some situations there may be a need to obtain permission of the "gatekeeper" to access the participants for research. The following care should be taken in such a situation:

- (i) Permission obtained from the gatekeeper may not be substituted for the need to obtain separate and informed consent from the participants. The rights of participants in such a situation are the same as in all other cases.
- (ii) In obtaining the gatekeeper's permission, no precondition made by the gatekeeper for access to information or data obtained should be accepted without the consent of the participants.

- (iii) In the process of research or data collection, care should be taken to ensure that the relationship between the gatekeeper and the participants is not jeopardised.

3.10 Vulnerable participants

- (i) Researchers should be concerned particularly about the rights and interests of vulnerable participants, such as children (i.e. those individuals under the age of 18 years), the elderly, pregnant women, people with mental impairment, prisoners, students and persons in dependent relationships, the disabled, indigenous people and indigents.¹⁰
- (ii) Research results that can be obtained if carried out on adults should never be done with children. Children should participate only when their participation is indispensable to the research. The protection and best interests of children are of prime importance.
- (iii) Therapeutic research or experimentation¹¹ on a child under the age of 18 years may be conducted only if it is in the best interests of the child, and if the consent of both the child (if he or she is capable of understanding) and of his or her parent or guardian, has been obtained.
- (iv) Nontherapeutic research or experimentation¹² may only be conducted on a child under the age of 18 years with the consent of the following persons: the Minister responsible for social development, the parent or guardian of the child, and the child if he or she is capable of understanding.¹³ The Minister may not give consent if the research or experimentation poses a significant risk to the health of the child.¹⁴

4. PRIVACY, ANONYMITY AND CONFIDENTIALITY¹⁵

- 4.1 All research participants have the right to privacy to the extent permitted by law (e.g. child abuse cases should be reported to the appropriate authorities in terms of the law).
- 4.2 Privacy includes autonomy over personal information, anonymity and confidentiality, especially if the research deals with stigmatising, sensitive or potentially damaging issues or information. When deciding on what information should be regarded as private and confidential, the perspective of the participant(s) on the matter should be respected.
- 4.3 All personal information and records provided by participants should remain confidential. When conducting interviews it should be made clear that confidentiality and anonymity will be safeguarded. Whenever it is methodologically feasible, participants should be allowed to respond anonymously or under a pseudonym to protect their privacy.
- 4.4 All personal information obtained directly or indirectly on or about the participants (e.g. names obtained by researchers from hospital and school records), as well as information obtained in the course of research which may reveal the identity of participants, should remain confidential and anonymous. This guarantee should also

¹⁰ See MRC *Guidelines on Ethics for Medical Research: General Principles* Ch 7 on vulnerable research participants.

¹¹ The aim of therapeutic research is to benefit the individual research participants by treating or curing their condition.

¹² The aim of nontherapeutic research is to benefit people other than the research participant. The acquisition of knowledge may be of no immediate benefit to the participant, but he /she may unexpectedly become a direct or indirect beneficiary of such research.

¹³ S 71(2) of the National Health Act 61 of 2003

¹⁴ S 71(2) of the National Health Act

¹⁵ See notes 5 and 7 and text to these notes.

be given when researchers ask consent to use data which is not already available within the public domain (e.g. classified data on prisoners held by the Department of Correctional Services).

- 4.5 In the case of covert observation (e.g. of a public scene) steps should be taken to ensure that the information will not be used or published in a form in which the individuals could be identified.
- 4.6 Researchers should maintain privacy, anonymity, and confidentiality of information in collecting, creating, storing, accessing, transferring and disposing of personal records and data under their control, whether these are written, automated or recorded in any other medium, including computer equipment, graphs, drawings, photographs, films or other devices in which visual images are embodied.
- 4.7 Researchers should make appropriate arrangements for the preservation and confidentiality of research records for one year after the submission of the report or the results.
- 4.8 Risk minimisation should be applied to research records. The possibility of a breach of confidentiality and anonymity should be anticipated, addressed and explained to the participants as an attendant risk.
- 4.9 Codes or other identifiers should be used to break obvious connections between data and individuals/organisations/institutions where possible. Where there is a mixture of information obtained from the public domain and information obtained with the participants' informed consent, no traceable link should be left between the two sets of information.
- 4.10 Confidentiality and anonymity of participants and their localities should be maintained when reporting to clients/sponsors/funders. Participants should not be identified or made identifiable in the report unless there are clear reasons for doing so. If the researcher or institution intends to identify participants or communities in the report, their informed consent allowing such disclosure should be obtained, preferably in writing.
- 4.11 Research findings published in the public domain (e.g. theses and articles) which relate to specific participants (e.g. organisations or communities) should protect their privacy. Identifiers which could be traced back to the participants in the study should be removed. However, public interest may outweigh the right to privacy, and may require that participants be named in reports (e.g. when child labour is used by a firm).
- 4.12 Participants' consent should be sought where data identifying them are to be shared with individuals or organisations not in the research team. They should be provided with information about such individuals or organisations (their names, addresses etc).
- 4.13 The obligation to maintain privacy, anonymity and confidentiality extends to the entire research team, other researchers at Unisa, Unisa administrative employees, and all those (from or outside Unisa) not directly associated with the research who may possibly have access to the information.

5. INTERNATIONAL COLLABORATIVE RESEARCH INVOLVING HUMAN PARTICIPANTS

- 5.1 In international collaborative research the parties are host country institutions, collaborating country institutions, researchers from both, research participants and/or communities.

- 5.2 There should be clear justification for collaborative research and why it needs to be carried out in a particular community. Unless there is clear justification, no research should be done in a host country that could just as easily be done in a collaborating country.
- 5.3 There should be clear potential benefit to the community being researched (e.g. access to the best proven methods or treatment identified by the study).
- 5.4 Research involving human participants may not commence without ethics approval by the Ethics Review Committees of all collaborating institutions.
- 5.5 Research may not commence without informed consent from participants and/or communities.
- 5.6 There may be no exploitation of institutions, researchers, research participants or communities.
- 5.7 Funders, sponsors and clients may accept responsibility for payment of compensation for research injury, if agreed to in writing.
- 5.8 Institutions and researchers should assist indigenous communities and traditional societies to protect their knowledge and resources, and should respect what is sacred and secret by tradition.
- 5.9 Those involved in international collaborative research should have some understanding of, and be sensitive to, the social, economic and political conditions in which the research is carried out. This will alert them to the need to protect research participants who are, for example, subject to deprivations through poverty.

Acknowledgements and works consulted

1. South African Human Sciences Research Council *Draft Code of Research Ethics* (<http://www.hsrc.ac.za/about/researchEthics/draftCode.html>)
2. National Committee for Ethics in Social Science Research in Health (NCESSRH) (2003) (http://www.hsph.harvard.edu/bioethics/guidelines/ethical_1.html)
<http://www.gal.ac.uk/R-E/pub/policies/goodpractice>
3. South African Medical Research Council *Guidelines on Ethics for Medical Research: General Principles (Book 1)* (2002)
4. Access and benefit sharing: good practice for academic research on genetic resources website: <http://abs.scnat.ch>

PART 3

GUIDELINES FOR RESEARCH INVOLVING ANIMALS, OTHER LIVING ORGANISMS AND GENETICALLY MODIFIED ORGANISMS¹⁶

1. INTRODUCTION

Unisa's commitment to ethical research applies to all aspects of the use and care of, and the interaction with, animals for research purposes in the field of medicine, biology, agriculture, nature conservation, animal health and other disciplines within Unisa and in collaboration with other institutions. It also includes the development, production, use and application of genetically modified organisms in research.

2. DEFINITIONS

Animal	means any live nonhuman vertebrate, that is fish, amphibians, reptiles, birds and mammals including domestic animals, purpose-bred animals, livestock, wildlife and cephalopods like octopus and squid.
Animal welfare	refers to an animal's quality of life based on an assessment of an animal's physical and psychological state as an indication of how the animal is coping with the ongoing situation as well as a judgment about how the animal feels.
Animal wellbeing	refers to an animal's present state with regard to all aspects of its environment, both internal and external. It implies a positive mental state, impaired physiological and biological functioning, positive experiences and freedom from any adverse condition.
Death as an end-point	is the deliberate and intended measure used to evaluate biological or chemical processes, responses or effects. In those cases the animal will not be killed humanely before death occurs in the course of a scientific activity.
Distress	indicates the state of an animal which is not able to completely adapt to stressors and that results in abnormal physiological and/or behavioural responses. Distress can be chronic or acute and may result in pathological conditions.
Ethics	applies to considerations whether actions are regarded as good or bad, right or wrong. Ethical considerations are applied in the evaluation of what should or should not be done when animals are proposed for use, or are used, for scientific and teaching purposes.
Euthanasia	is the humane killing of an animal consistent with veterinary recommendations and practice. Euthanasia is applied in the interest of an animal's welfare to lessen pain and distress.
Genetically modified organism	means "an organism the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both, and 'genetic modification' shall have a corresponding meaning" (Genetically Modified

¹⁶ Definitions used in these guidelines are adapted from the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*.

Organisms Act 15 of 1997).

Humane killing	is the killing of an animal with minimal pain and distress.
Livestock	is animals that are used in agriculture and aquaculture.
Pain	means an unpleasant sensory and/or emotional experience associated with actual or potential tissue damage. It may provoke protective actions and result in avoidance and distress and may modify behaviour.
Wildlife	refers to free-living animals of native, non-indigenous or feral species including captive-bred animals and those captured from free-living populations.

3. USE OF ANIMALS IN RESEARCH

3.1 General principles for the care and use of animals in research

- (i) All vertebrate animals are protected in South Africa by the Animal Protection Act 71 of 1962, and the use of animals for research has to adhere to this Act. Therefore, these guidelines emphasise the responsibilities of researchers to
 - ensure that the use of animals is justified,
 - ensure that optimal standards in terms of animal health, care and welfare are observed,
 - only use animals when alternative techniques and research methods for a certain project do not exist,
 - only use the number of animals absolutely required by the study, and
 - refine methods and procedures to minimise or avoid pain or distress in animals used in research projects.
- (ii) The guidelines require that researchers adhere to the "3 R" principles of Replacement, Reduction and Refinement when planning and conducting research studies involving animals. An Animal Ethics Review Committee (ERC) should determine for each research project using animals whether the rules of these guidelines are adhered to before approving such projects. See paragraphs 3.4, 3.5 and 3.6 below on the "3 R" principles.
- (iii) These guidelines apply to all live nonhuman vertebrates and higher-order invertebrates, that is fish, amphibians, reptiles, birds and mammals including domestic animals, purpose-bred animals, livestock and wildlife as well as cephalopods such as octopus and squid. Early stages of development, such like embryonic, foetal and larval forms are also included. As different species develop differently, the experience of pain and distress in those developmental stages varies. Decisions with regard to the welfare of those animals and their developmental stages should therefore be made for each case individually based on specific knowledge and evidence of the neurobiological development.
- (iv) Researchers must be committed to the welfare of the animals used and must respect the contribution those animals make to research.
- (v) Researchers must ensure that procedures which will cause hunger, thirst, injury, disease, discomfort, fear, distress, deprivation or pain to the animals involved in the studies are limited to the absolute minimum. The elimination or

reduction of the total of those conditions experienced by an animal will be achieved by the application of the '3 R' principles. See paragraphs 3.4, 3.5 and 3.6 below.

3.2 Justification

- (i) The use of animals for research purposes must be justified by assuring that the outcomes of the studies will essentially contribute to
- the understanding of humans and/or animals,
 - the maintenance and improvement of human and/or animal health or welfare,
 - the improvement of animal management or production,
 - the understanding, maintenance or improvement of the natural environment,
- and that the potential benefits outweigh the potential harm to the animals used.
- (ii) Approval for each research project involving animals must be based on considerations whether the project is justified and whether the potential benefit outweighs the potential harmful effects on the welfare of the animals used.
- (iii) Researchers must submit written proposals to the Animal ERC for all projects involving animals. These proposals must address the expected value of knowledge to be gained, the justification of the project and an ethical analysis regarding the animal welfare aspects under consideration of the "3 R" principles.

3.3 Responsibilities

3.3.1 Responsibilities of researchers

The adherence of researchers to these guidelines will ensure a transparency which results in high quality ethical and scientific screening of proposals and monitoring of research studies. Researchers are responsible for all matters relating to the welfare of the animals they use. They should respect the animals and their demands and should not treat animals as mere objects. Research objectives should be subordinate to the humane treatment of animals.

- (i) The responsibility of researchers for the welfare of animals involved in their studies begins with the design of a project and ends with the completion of the project unless unforeseen long-term negative effects result from the experiments. Under those circumstances the responsibility of the researcher extends until those issues have been addressed satisfactorily. It is essential when invasive procedures are to be used that a veterinarian is consulted during the protocol design.
- (ii) When applying for approval for a research project, researchers must inform the Animal ERC of other institutions that plan to participate in the project.
- (iii) Unisa's Animal ERC needs to be informed in writing if a researcher plans to participate in a research project performed at another institution.

- (iv) Researchers are requested to keep complete record of all matters related to the animals used during a research project.
- (v) Researchers must choose a species appropriate for their research purpose.
- (vi) When livestock is used in research projects, standard husbandry procedures that are carried out for research purposes need approval by the Animal ERC. Approval is also required for the use of livestock for the production of any biological products other than food or fibre. Approval is not required for regulatory inspection measures like control of external parasites or disease surveillance carried out by qualified personnel.
- (vii) In their proposals submitted to the Animal ERC for approval, researchers must indicate the category of experiments according to Table 1. The qualifications, experience and specific knowledge of researchers and employees with regard to the performance of experimental procedures on the animals used must be stated in detail. Those researchers and employees must be competent in terms of the relevant South African legislation and the Rules for Veterinary and Para-veterinary Professionals as stipulated by the South African Veterinary Council. The qualification and experience of employees responsible or involved in the care and husbandry of the animals used must also to be addressed clearly in the proposal. A veterinarian must be affiliated to the project so that he/she may be called in during an emergency and is aware of the project and its outcomes.
- (viii) In the case where privately owned animals are used in a research project, and where those animals remain under the responsibility of the owners, their staff or other personnel attend to the day-to-day tasks of treatment, care and welfare. The various responsibilities of the owner and the researcher in this regard must be stated clearly in the proposal.
- (ix) Researchers are requested to report regularly to the Animal ERC. They need to inform the Animal ERC immediately about any unexpected adverse effects impacting on the animals resulting from the procedures and advice when a project is completed or discontinued.
- (x) Research activities may not be performed before written approval has been granted by the Animal ERC.
- (xi) The acquisition, care and use of animals for research purposes in South Africa must be done in accordance with the relevant legislation of South Africa including the National Environmental Management: Biodiversity Act 101 of 2004, which aims to prevent bio-piracy of indigenous biological resources.

3.3.2 Responsibilities of the institution

Unisa should ensure through the Animal ERC and the Executive Director: Research that all research projects making use of animals adhere to the standards and requirements of these guidelines.

3.4 Replacement

Techniques, models or systems that can replace the use of animals totally or partially must be investigated, developed and used.

3.5 Reduction

- (i) Reduction of the number of animals used in research studies means the following: Only the minimum number of animals necessary to obtain valid information or results must be used.
- (ii) The minimum number of animals should not be obtained at the expense of fewer animals suffering more.
- (iii) An animal should not be exposed to repeated procedures unless it is essential for the purpose of the project.
- (iv) The killing of healthy animals should be kept to the absolute minimum number required by the study.

3.6 Refinement

Refinement of animal sourcing, animal care and procedures means to minimise or eliminate physical or psychological distress imposed on the animals by the requirements of the research study.

- (i) Animals selected for a research project must be suitable for the specific purpose.
- (ii) The care for animals should be according to the species-specific needs in terms of behavioural and biological requirements.
- (iii) Animals bred in captivity should be used for projects involving wildlife species where possible.
- (iv) Researchers must be competent in the procedures their projects require or they must make use of a person competent in the procedures.
- (v) Project design must be aimed at the avoidance or minimisation of pain and distress.
- (vi) Pain and distress in animals must be evaluated on the basis of relevant species-specific knowledge. In principle it must be assumed that animals experience pain and distress in a manner similar to humans and decisions regarding the animals' welfare should be based on this assumption.
- (vii) Unpredicted pain or distress in animals should be alleviated immediately irrespective of the effect on the project. If alleviation is not possible, the animal should be euthanised without delay.
- (viii) Any procedure that is carried out under anaesthesia or sedation in medical or veterinary practice must be carried out using anaesthesia appropriate to the species and the procedure.
- (ix) Appropriate pain management must be applied.
- (x) If the purpose of a procedure inhibits the use of anaesthetic or analgesic drugs to alleviate pain or distress, the procedures must be carried out in such a way as to minimise the degree of pain and distress and the duration thereof that the animal is exposed to.
- (xi) Death as an end-point, that is, when the death of an animal is a deliberate measure used to evaluate biological or chemical processes, responses or effects, must be avoided as much as possible. If death as an end-point is

unavoidable, distress should be minimised by choosing the earliest end-point that is compatible with the scientific objectives of the research study.

- (xii) The duration time of exposure of animals to procedures for research purposes must be kept to a minimum

3.7 Wildlife studies

This section refers to free-living vertebrates, native, non-indigenous or feral species including captive-bred animals and those captured from free-living populations. All research projects and scientific studies involving wildlife are subject to Animal ERC approval. In addition to the requirements and responsibilities listed above, the following is applicable to research involving wildlife:

- (i) As many wildlife species are protected by national and/or international laws, conservation authorities need to be consulted when those species are involved in the research, and permits must be obtained if required.
- (ii) Observational studies of free-living animals must be designed in a way that any impact on the animal wellbeing is minimised.
- (iii) Field studies may cause disturbances of the environment or habitat and subsequently adversely affect target and nontarget species, and must therefore be minimised.
- (iv) Studies and research projects must not be repeated unnecessarily. When repeated studies are proposed, the Animal ERC must decide whether the repetition is scientifically justified for the specific research purpose. Animal ERC approval is required every time a study is to be repeated.
- (v) Capturing, holding, transporting, handling and releasing free-living animals must be in accordance with the following:
 - a) researchers must be aware that the effects of numerous stressors can be accumulative
 - b) potential sources of stress must be identified and the measures to be taken to minimise those must be addressed in the proposal
 - c) materials and equipment that are used during the capturing, holding, handling and transport of animals must be maintained in good condition and kept clean to avoid injuries of animals or personnel handling them and to minimise the risk of disease transmission.
- (vi) When wildlife is captured any distress caused to the captured animals and the populations from which they are taken must be minimised.
- (vii) When capturing is applied for, the proposal must include details about the capturing method and about the skills of people involved in the process.
- (viii) Handling, restraining and transportation of captured free-living animals must be appropriate to the species and be done in such a way as to minimise the risk of injury and/or stress-induced disease.
- (ix) The holding time for captured animals must be as short as possible to achieve the envisaged scientific objectives. Holding of an animal must be done in such a way as to minimise stress and the risk of injuries.
- (x) Animals should be released at the site of capture unless an alternative site is reasoned for in the proposal and approved by the Animal ERC.

- (xi) Identification of individual animals must be done by using a method that causes the least distress and interference with the normal functioning of the animal without hindering the research outcome. Identification done for routine husbandry purposes does not require Animal ERC approval.
- (xii) Research on wildlife interaction and behaviour includes interaction between species (e.g. predator-prey), within a species (e.g. competition) and between species and habitat. Ethical considerations with these studies are the degree of manipulation required and the effect of the researcher on the interaction. Proposals should address the wellbeing of the animals primarily targeted in the project, as well as the other species that may be affected adversely by the research.

4. GENETICALLY MODIFIED ORGANISMS

In South Africa, the development, production, use and application of genetically modified organisms including viruses and bacteriophages is regulated by the Genetically Modified Organisms Act 15 of 1997.

The Act defines a *genetically modified organism* as "an organism the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both, and 'genetic modification' shall have a corresponding meaning".

In order to comply with the provisions of the Act, research projects and scientific studies need to adhere to the following conditions:

- (i) Any institution or laboratory or similar facility where genetically modified organisms will be developed, produced, used or applied must be registered in terms of the Act.
- (ii) A permit in terms of the Act has to be obtained in the case of importing, exporting, producing, using, applying, releasing and distributing genetically modified organisms.
- (iii) Institutions, laboratories or similar facilities may be authorised for use of genetically modified organisms in a contained manner or in a trial release.
- (iv) The researcher or supervisor of the study must prove the necessary qualifications and experience in using genetically modified organisms.
- (v) The proposal must contain a risk assessment in terms of a possible impact on humans and/or the environment. In the event of an accident involving genetically modified organisms, a copy of the written notification to the Registrar in terms of the Act must be submitted to the relevant ERC.
- (vi) The liability for any possible damage caused by the use or release of genetically modified organisms needs to be addressed in the proposal.
- (vii) The public must be notified adequately about the trial release or release of genetically modified organisms if this forms part of the study.
- (viii) Waste management and disposal procedures must be included in the proposal as part of the study.

TABLE 1: CATEGORIES OF BIOMEDICAL EXPERIMENTS¹⁸

Category	Examples and Comments
Category A: Experiments involving either no living materials or use of plants, bacteria, protozoa or invertebrate animal species	Biochemical, botanical, bacteriological, microbiological or invertebrate animal studies, tissue cultures, studies on tissues obtained from autopsies or from slaughterhouses, studies on embryonated eggs. Invertebrate animals have nervous systems and respond to noxious stimuli, and therefore must also be treated humanely.
Category B: Experiments on vertebrate animal species that are expected to produce little or no discomfort	Mere holding of animals captive for experimental purposes; simple procedures such as injections of relatively harmless substances and blood sampling, physical examinations, experiments on completely anaesthetised animals which do not regain consciousness; food/water deprivation for short periods (a few hours); standard methods of euthanasia that induce rapid unconsciousness, such as anaesthetic overdose or decapitation preceded by sedation of light anaesthesia.
Category C: Experiments that involve some minor stress or pain (short duration pain) to animal species	Exposure of blood vessels or immolation of chronic catheters with anaesthesia; behavioural experiments on awake animals that involve short-term stressful vertebrate restraint; immunisation employing Freund's adjuvant; noxious stimuli from which escape is possible, surgical procedures under anaesthesia that may result in some minor post-operational discomfort. Category C procedures incur additional concern in proportion to the degree and duration of unavoidable stress or discomfort.
Category D: Experiments that involve significant but unavoidable stress or pain to vertebrate species.	Deliberate induction of behavioural stress in order to test its effect; major surgical procedures under anaesthesia that result in significant post-operational discomfort; induction of an anatomical or physiological deficit that will result in pain or distress; application of noxious stimuli from which escape is impossible; prolonged periods (up to several hours or more) of physical restraint; maternal deprivation with substitution of punitive surrogates; induction of aggressive behaviour leading to self-mutilation or intra-species aggression; procedures that produce pain in which anaesthetics are not used, such as toxicity testing with death as an end-point; production of radiation sickness; certain injections, and stress and shock research that would result in pain, approaching the pain tolerance threshold, i.e. the point at which intense emotional reactions occur. Category D experiments present explicit responsibility and the investigator has to explore alternative designs to ensure that animal distress is minimised or eliminated.

Category E:

Procedures that involve severe pain near, at, or above the pain tolerance threshold of unanaesthetised conscious animals

Use of muscle relaxants or paralytic drugs such as succinyl choline or other inflicting curariform drugs used alone for surgical restraint without the use of anaesthetics; severe burn or trauma infliction on unanaesthetised animals; attempts to induce psychotic-like behaviour; killing by use of microwave ovens designed for domestic kitchens or by strychnine; inescapable severe stress or terminal stress. Category E experiments are considered highly questionable or unacceptable irrespective of the significance of anticipated results. Many of these procedures are specifically prohibited in some countries (e.g. the USA) in national policies, and therefore may result in the withdrawal of funds and/or registration.

- 18 Adapted from: Consensus recommendations on effective animal care and use committees, *Laboratory Animal Science Special Issue*, January 1987

5. IMPLEMENTATION OF POLICY

Related policies of the former institutions that were in force prior to the commencement of this Policy are replaced with effect from the date on which Council approves this Policy.

Acknowledgement and works consulted

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2. South African Veterinary Council *Policies: Animal Experimentation* <http://savc.co.za/policies.htm>
3. The ethics of research involving animals, Chapter 3 *Ethical Issues Raised by Animal Research*, publisher: Nuffield council on bioethics, London (2005)
4. Australian Government: National Health and Medical Research Council *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*, 7th edition (2004) <http://www.nhmrc.gov.au/publications/eahom.htm>
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10. National Environmental Management: Biodiversity Act 10 of 2004