FPDREC

SOP and GUIDELINES for RESEARCH ETHICS EVALUATION

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CONTENTS

PART 1

GENERAL GUIDELINES FOR ETHICAL RESEARCH

1. INTRODUCING FPD AND FPDREC

1.1 FPD is committed to

• Building a better society through education.

• Undertaking and promoting research that will benefit 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 FPDREC is a Level 1 REC, and has the capacity to assess research designs that involve minimal risk to human participants. These include research proposals that do not involve drug research, biomedical research involving human tissues, high-budget research (more than R250 000 per annum) or studies that are longer than one year.

• In the execution of its responsibilities in evaluating the ethics of research protocols, FPDREC is guided by the relevant South African law, ethics guidelines, professional standards, international standards and guidelines and codes of practice.

• FPDREC follows the standards adopted by the latest version of Guidelines for Good Clinical Practice; and conforms to the guidelines laid down by the World Medical Association, in particular, the Declaration of Helsinki, the Belmont Report, the National Department of Health and the SA Medical Research Council.

• FPDREC promotes high standards of scientific work and strives for excellence in research that can withstand public scrutiny.

• FPDREC espouses the constitutional values of human dignity, equality, social justice and fairness.

• FPDREC affirms the constitutional principles of academic freedom and freedom of scientific research.

2. FPDREC SOP AND GUIDELINE RATIONALE

The FPDREC SOP and Guidelines on Ethics Evaluation 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.

• The guidance of the Research Ethics Board: Faculty or Health Sciences Research Ethics committee, University of Pretoria, or the College of Agriculture and Environmental Sciences, University of Pretoria, for example, should be sought for all research projects involving animals or other living organisms.

• Research is ethical in increasingly diverse research areas; examples include qualitative[1] and quantitative[2] research, and collaborative research between 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.

The FPDREC should consider the following issues when reviewing a proposal for a research study:

• The scientific relevance of the study.

• the suitability of the investigator(s) for the proposed study in terms of his/her availability, qualifications, experience, supporting staff and available facilities.

• The relevance of the study rationale and the appropriateness of the inclusion / exclusion criteria to the South African context.

• The suitability of the study application in relation to the objectives of the study; i.e. the potential for reaching sound conclusions with the smallest possible exposure to risk of participants, and the justification of predictable risks and **inconveniences** weighed against the anticipated benefits for the participants and/or others.

• The suitability of study population, whether they constitute a vulnerable group, if so whether justified and whether sufficient measures to protect their interest are in place.

• If applicable, that the number of participants to be recruited is adequate to demonstrate the predicted effect.

• The risk-benefit analysis takes full cognisance of benefits and harms beyond the life of the study itself, particularly in relation to chronic life-threatening conditions.

• That by their participation in a study the participants or other persons in the establishment or clinical centre are not denied timely access to medical personnel, investigations, equipment or procedures.

• The means by which initial recruitment is to be conducted and by which full information is to be given and informed consent is to be obtained. All written information for the participant and/or legal representative must be submitted in its final form.

• The adequacy and completeness of the written information to be given to the participants, their relatives, guardians and legal representatives, if necessary.

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.

• That the application allows the participants and/or their representatives' adequate time to consider the patient information document before informed consent is sought.

• The content of any advertisements or public notices which will be used to recruit participants to a study.

• That the study protects participants' rights to privacy.

• The extent to which investigator(s) and participants are to be compensated for participation.

• The demographic information available to assess whether the patient population is adequate to support the study.

• Whether any restrictions will be placed on the publication of results; (i.e. ensure there is a written commitment from investigators to publish the results and there is no contractual clause which reserves the right of publication to the sponsor only).

• The adequacy of the statistical methods proposed to evaluate the data generated.

• Whether the study is advancing knowledge in the research field.

3. APPLICATION OF THE SOP/GUIDELINE

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

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

3.3 The policy does not apply retrospectively. However, researchers carrying out research involving human participants, should report to the relevant Research Ethics Committee on the extent to which their current research complies with the policy.

3.4 This policy may be reviewed by the FPD Research Ethics Committee when the need arises.

4. RIGHTS AND RESPONSIBILITIES OF FPDREC

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

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

4.3 FPDREC should promote the observance of the SOP and Guidelines for Research Ethics Evaluation and take appropriate steps for protection against pressures inimical to the observance of the policy.

4.4 FPDREC may require the payment of review fees for externally funded research. The particulars are contained in Part 2.

4.5 As a general rule, all intellectual property resulting from research which was conducted with FPDREC funds, or use of its facilities, vests in FPDREC. 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 must have ethics clearance (from an appropriate Research Ethics Committee before it may commence). It includes research which

• is undertaken on FPD premises or in any of its units or uses any of its facilities

• involves FPD employees or students in various capacities, including collaborative or multi-institutional or multi-country studies, or

• is or will be funded from FPD funds or where funding was obtained through FPD.

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

4.6.2 FPDREC has the right to monitor research that has been approved by its Research Ethics Committee 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 organization is jeopardized.

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

4.6.4 FPDREC is accountable only for research which has been approved by its Research Ethics Committee.

4.6.5 The particulars of the ethics review system are contained in Part 2.

5. RIGHTS AND RESPONSIBILITIES OF RESEARCHERS AT FPD

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 SOP and Guidelines for Research Ethics Evaluation, 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 FPDREC (the particulars are contained in Part 2). 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 as has been approved by an appropriate Research Ethics 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 undertaken 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 Research Ethics Committee and the findings reported to FPD or the research sponsor. See Part 2.

5.2.11 Researchers undertaking research involving humans may be requested to report regularly to the Research Ethics 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 SOP and Guidelines for Research Ethics Evaluation.

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 FPD who may have access to data or identifying information, should be briefed on ethical issues

and the SOP and Guidelines for Research Ethics Evaluation, including the participants' right to confidentiality.

5.4. Relationship between researchers and participants

5.4.1 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.

5.4.2 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.

5.4.3 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. 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.

5.4.4 The criteria for selecting research participants should be fair. Repeat studies should not be undertaken 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.

5.4.5 Unless consent on a mutually beneficial arrangement is obtained, FPD 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.

5.4.6 The relevant social, cultural and historical background of participants should be taken into consideration in the planning and conduct of research.

5.4.7 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.

5.4.8 Researchers should ensure that reimbursements or compensation to participants does not cause conflict in the group or community.

5.4.9 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.

5.4.10 Participants are autonomous agents who have the right to choose whether or not to be part of the research.

5.4.11 Participants should be informed of the existence of the FDPREC SOP and Guidelines for Research Ethics Evaluation. The policy should be made available to them if it can help them make an informed decision regarding their participation.

6. INFORMED CONSENT

6.1 Personal information (i.e. information[3] about an identifiable, natural person)[4] 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.

6.2 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[5], or if it is in the public domain or contained in a public record.

6.3 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.

6.4 Participants should give their consent in writing. They, in turn, should be given written information containing adequate details of the research.

6.5 Consent for participation in research is freely given and informed if

(i) it is given without any direct/indirect coercion or inducement.

(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

6.6 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 behaviour. Where research may affect communities they should be informed and consulted on possible long-term effects for them.

3 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.
4 In so far as it is applicable, it also includes information about an identifiable juristic person.
5 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

• 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 Research Ethics 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.

• 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.

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

7. 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 undertaken:

(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.

8. 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.

9. VULNERABLE PARICIPANTS

(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.[6]

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

(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 experimentation[7] 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 experimentation[8] 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.[9] The Minister may not give consent if the research or experimentation poses a significant risk to the health of the child.[10]

10. PRIVACY, ANONYMITY AND CONFIDENTIATLIY[11]

10.1 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).

10.2 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.

10.3 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.

10.4 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 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).

10.5 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.

10.6 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.

10.7 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.

7 The aim of therapeutic research is to benefit the individual research participants by treating or curing their condition.
8 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.
9 S 71(2) of the National Health Act 61 of 2003
10 S 71(2) of the National Health Act
11 See notes 5 and 7 and text to these notes.

10.8 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.

10.9 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.

10.10 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.

10.11 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).

10.12 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).

10.13 The obligation to maintain privacy, anonymity and confidentiality extends to the entire research team, other researchers at FPD, FPD administrative employees, and all those (from or outside FPD) not directly associated with the research who may possibly have access to the information.

11 DATA SHARING

11.1 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.

11.2 Data which do not identify participants and which are in the form of anonymous[4] 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.

11.3 As far as possible, researchers should ensure that relevant findings of the research are taken back to the research participants or communities in a form and manner that they can understand, and which will not cause them harm.

12 REPORTING AND PUBLICATION OF RESEARCH

12.1 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.

12.2 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.

12.3 If a client/sponsor/funder requires nonpublication of results carried out on humans, or that it must give prior approval for the manner and content of reporting, such research proposal may be disapproved by the Research Ethics 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 division/institute/centre should be sought where there is a request not to publish. See Part 2.

12.4 The results should be reported irrespective of whether they support or contradict the expected outcome(s).

12.5 Researchers should disclose in their publications the source(s) of funding and sponsors, if any.

12.6 Researchers should in their publications explain the methodology used, as well as how ethical dilemmas encountered were resolved.

12.7 Aspects regarding authorship should be determined as the earliest possible phase of a study. 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.

12.8 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.

13. INTERNATIONAL COLLABORATIVE RESEARCH

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

13.2 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 undertaken in a host country that could just as easily be done in a collaborating country.

13.3 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).

13.4 Research involving human participants may not commence without ethics approval by the Ethics Review Committees of all collaborating institutions, including national or provincial governments.

13.5 Research may not commence without informed consent from participants and/or communities.

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13.6 There may be no exploitation of institutions, researchers, research participants or communities.

13.7 Funders, sponsors and clients may accept responsibility for payment of compensation for research injury, if agreed to in writing.

13.8 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.

13.9 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.

13.10 Before submission of a collaborative research proposal to a Research Ethics 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.

13.11 Intellectual property rights of parties should be respected and acknowledged as agreed on before the research commenced.

13.12 Research may not be carried out in a host country without local research collaboration in the design and conduct of that research.

13.13 Research undertaken in communities needs clearance from an appropriate community representative.

13.14 If research is undertaken in collaboration with another institution, their ethical clearance will be needed.

14. RIGHTS AND RESPONSIBILITIES OF FUNDERS, CLIENTS AND SPONSORS

14.1 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).

14.2 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.

14.3 The position with regard to the dissemination and publication of findings from the research study should be clarified.

14.4 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 FPD to cancel the cooperation.

14.5 Clients/funders/sponsors should be made aware of the FPDREC SOP and Guidelines for Ethics Evalutation. 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 FPDREC contains the necessary information on ethical issues and complies with the policy.

14.6 Clients/funders/sponsors should respect the FPDREC SOP and Guidelines for Ethics Evaluation and should not expect researchers or FPDREC to undertake research or conduct which is in any way contrary to the policy.

15.7 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.

PART 2
PROCEDURES AND ADMINISTRATIVE GUIDELINES FOR RESEARCH INVOLVING HUMAN PARTICIPANTS

1. INTRODUCTION

1.1 The research ethics review system in FPD aims to protect potential human participants, and contribute to the highest attainable quality of scientific and ethical research.

1.2 FPD having committed itself to safeguarding the rights of potential and actual human research participants, undertakes to provide administrative, financial and other forms of support for the ethics review system.

1.3 The Managing Director: FPD takes ultimate responsibility for the proper application of ethics review at FPD. He/she ensures that the FPDREC SOP and Guidelines for Research Ethics Evaluation are publicly available and registers all research that has obtained ethics clearance.

1.4 The FPDREC SOP and Guidelines for Research Ethics Evaluation serves as the fundamental guide for ethics review. Other local and international guidelines may be used by the FPDREC.

1.5 Revision of the Guidelines for Research Ethics Evaluation may be initiated by the FPDREC. Revision must be undertaken through the broadest and most transparent process possible, and any changes must be disseminated widely. The secretary is the officer responsible for revision.

2. RESEARCH REQUIRING RESEARCH ETHICS COMMITTEE (REC) APPROVAL

Researchers may not undertake research involving humans without the prior approval of the REC, if the research

• is undertaken on the premises of FPD or in any of its clinics or if it uses FPD facilities.

• involves FPD employees or students, in various capacities including collaborative or multi-institutional or multi-country studies, or

• is or will be funded from FPD funds or if funding for it was acquired through FPD.

3. BODY OF FPD RESEARCH ETHICS COMMITTEE (FPDREC)

3.1 The FPDREC is an independent body comprising members who have the ability to undertake thorough, competent and timely reviews of research proposals. They must be independent from political, institutional, professional and market pressure.

3.2 The FPDREC is different from a scientific or technical review committee. While the FPDREC examines the adherence of the research to ethical principles, scientific or technical review committees look at scientific and technical quality. Membership in committees may overlap but the ethics review must be independent of any scientific review.

3.2.1 It is beneficial for the work of the FPDREC to maintain active links with scientific or technical experts, especially because some methodologies or research designs while technically sound,

could involve ethical dilemmas. The FPDREC may seek the advice of experts of the scientific or technical field when in their view this will help them in the discharge of their functions.

4. TERMS OF REFERENCE OF ETHICS REVIEW COMMITTEES

4.1 The main role of the FPDREC is to promote the conduct of ethical research in FPD. In particular, to contribute to the safeguarding the dignity, rights, safety, and wellbeing of all actual or potential research participants and communities, while taking into account the interests and needs of researchers and the integrity of FPD.

• The FPDERC has institution-wide jurisdiction and is not attached to or based in a single Cluster in FPD.

4.2 The FPDREC

4.2.1 Provides guidance to Clusters.

4.2.2 Reviews research protocols and ongoing research that require its action, including complaints from researchers and matters not resolved at Cluster level.

4.2.3 Provides guidance to researchers on the ethical aspects of their work.

4.2.4 Develops mechanisms in consultation with Clusters for the promotion of cooperation between the FPDREC and among Clusters.

4.2.5 Develops and proposes policies to enhance and facilitate ethical research and ethics review in FPD, including those which are necessary for building capacity in ethical research and ethics review.

4.2.6 Reviews the FPDREC SOP and Guidelines for Research Ethics Evaluation as the need arises.

4.2.7 Provides advice to the Managing Director: FPD on matters pertinent to research ethics.

4.2.8 Reviews research which:

• is elevated to it for action or opinion from Clusters, researchers, research participants or other stakeholders in research, or

• involves several Clusters. Such cases must first have the approval of the pertinent Cluster/s before review by the FPDREC. Where there is inconsistency in the response to the research proposal between the Cluster and the FPDREC, steps must be taken to resolve the issues involved. If the issue cannot be resolved in this way, the FPDREC decision takes precedence. Basic ethical principles for research remain the basis for resolving issues.

4.3 Multi-institutional research

Research involving external bodies (e.g. laboratories/institutions/universities)

South Africa, or in other countries must have the approval of the FPDREC. To facilitate the review process, parallel or simultaneous reviews may be conducted among the ethics committees of the institutions involved. In no case however may the approval by ethics committees of external institutions replace the review and action by the FPDREC.

5. COMPOSITION OF REVIEW ETHICS COMMITTEE

Research ethics committees must consist of members who collectively have the qualifications and experience to review and evaluate the science, health aspects and ethics of proposed research. Committees must be independent, multi-disciplinary, multi-sectorial and pluralistic. The composition of the FPDREC complies with the prescriptions of the Department of Health Guidelines for Ethics in Health Research.

5.1 The chairperson serves ex officio on the FPDREC.

5.2 Regular membership of an REC is between 5 - 12 members. The regular members of REC should come from different academic disciplines and sectors. These are

• scientists or researchers

• person(s) with competence in law

• person(s) with competence in research ethics

• lay person(s) including representatives of interest groups such as groups for human rights, HIV / AIDS advocates, indigenous peoples' rights and environmentalists.

5.3 Membership on *ad hoc* basis

5.3.1 In addition to the regular members, members may be appointed on an ad hoc basis by the chairperson: FPDREC to provide the REC with special expertise or guidance not adequately available in its regular membership, e.g. representatives of special groups or communities. The duration of their membership in the committee must be based on the need of the REC for their special expertise.

5.3.2 The REC must exert efforts to include a representative of the population which will be studied. If this is not possible, the REC must invite persons who are knowledgeable about the culture, history, social dynamics and vulnerabilities of this population and who can speak on their behalf.

5.3.3 If, in the view of the REC, human populations will be affected by particular research, the committee must exert efforts to include a representative of the populations that will be potentially affected. If this is not possible, the REC must invite persons who are knowledgeable of the culture, history, social dynamics and vulnerabilities of this population and who can speak on their behalf.

5.3.4 Where appropriate, e.g. where human tissue, animals or plants are involved, the FPDREC must refer the application to an external review committee, e.g., the Research Ethics Board: Faculty or Health Sciences Research Ethics committee, University of Pretoria, or the College of Agriculture and Environmental Sciences, University of Pretoria.

5.4 The FPDREC should strive for balanced representation in terms of gender, race, and discipline.

6. OFFICE BEARERS OF THE COMMITTEE

6.1 Chairperson

The chairperson of the REC is elected by the members from among themselves and has a term of three years.

6.2 Secretary

The REC is provided with secretarial and administrative assistance, as well as a secure office, by FPD.

7. FUNCTIONS OF OFFICE BEARERS

7.1 Chairperson

7.1.1 The chairperson is the presiding officer and overall administrator of the work of the REC.

7.1.2 The chairperson is responsible for:

• ensuring that the records and documents of the committee are secure and, in appropriate cases, kept confidential;

• documenting adequately and in a timely manner all documentation of committee meetings and deliberations;

• the recording of receipts of applications, documents submitted and other transactions of the REC; and

• reporting annually to the FPD Managing Director on funds received and disbursed.

7.2 Secretary

The secretariat is responsible for:

7.2.1 preparing communications regarding the listing of each received and approved document, the frequency of continuing review, and other obligations of the investigator or researcher;

7.2.2 stamping approval and expiry date on every page of the consent form;

7.2.3 obtaining signature of chairperson;

7.2.4 keeping records and receipts;

7.2.5 organising and maintaining a registry of research proposals reviewed by the REC;

7.2.6 submitting all research that obtained ethics clearance to the Research Unit for registration;

7.2.7 signing a confidentiality agreement;

7.2.8 preparing the meeting agenda and minutes, as well as distributing relevant documentation to REC member a week in advance before meetings.

7.2.8 executing other tasks assigned by the chairperson.

8. MEMBERSHIP OF FPDREC

8.1 Appointment

8.1.1 Members of the FPDREC, including those who do not have appointments as employees of FPD, are appointed by the FPD Managing Director and have a term of office of three years with possible reappointment.

8.1.2 To ensure continuity in the workings of the FPDREC, as well as utilise accumulated experience and wisdom, the term of office of regular members of the FPDREC is rotated. The first FPDREC membership tenure rotation is broken down as follows:

- No more than 50% of the members serve for two years, the remainder for three years.

- The succeeding members serve the full three-year term.

8.2 Conditions of appointment

8.2.1 FPDREC members should be willing to have their names and affiliations made publicly available.

8.2.2 FPDREC members should sign a confidentiality agreement regarding meetings, deliberations, applications and related matters.

8.2.3 Only members who are not appointed as employees of FPDFPD may receive honoraria for work on the REC, and all reimbursements and payments received in relation to their work in the FPDREC must be recorded.

8.3 Resignation

8.3.1 A member who can no longer serve on the committee must resign in writing. No reason for the resignation need be stated.

8.3.2 A vacancy should be filled as soon as possible. The chairperson of an FPDREC recommends people to fill vacancies to the FPD Managing Director.

9. MEETINGS

9.1 The FPDREC meets once a month or more frequently if the need arises.

9.2 It may decide to meet regularly *en banc* or as subcommittees. However, in instances where there is disagreement among members regarding action on applications, or whenever the need arises, the chairperson may call for an *en banc* meeting.

9.3 Sixty percent (60%) of regular and ad hoc members constitutes a quorum.

9.4 Members must be furnished well ahead of time with all documents which will be deliberated on at the meeting.

9.5 The FPDREC may decide to divide the members into subcommittees to review research proposals. This is particularly pertinent there is considerable volume of proposals and/or a diversity of research fields to review. Alternatively, it may decide to review the research proposals en banc.

9.6 Voting

9.6.1 When a vote is required to arrive at a decision, a simple majority of members present suffices. However, any dissenting opinion must be adequately recorded and kept. A quorum is set according to the number of members in the committee.

9.6.2 All regular and ad hoc members are entitled to vote. Each member has one vote.

9.6.3 The chairperson votes only when there is a tie.

9.6.4 No member who has not reviewed the application can vote on that application.

9.7 Timely decisions

9.7.1 To ensure complete and correctly accomplished applications the FPDREC must communicate to applicant(s) its action or decision within two weeks after the meeting where the application was decided on.

9.7.2 Applications with incomplete or incorrect documents must be returned no later than two weeks after receipt of the application. Inadequacies in the application must be clearly identified in the communication of researchers.

9.8 Possible decisions

The REC can make any of the following decisions on applications:

• Approved

• Require modifications

• Request further information or clarification

• Disapproved, with reasons

9.9 Conflict of interest on ethics review committee

9.9.1 Only members without conflict of interest with the research under review may participate in the deliberations and vote.

9.9.2 There is conflict of interest when a reviewer has an interest relative to a specific application for review and such interest can compromise his/her ability to make a free and independent evaluation. Conflicts of interest may arise, for instance, when the reviewer has financial ties to the project.

10. PROCEDURE FOR ETHICS REVIEW

10.1 Submissions required for ethics review

A copy in English of the following must be submitted electronically to the FPDREC:

(i) Complete research proposal. The proposal which is submitted for scientific or technical review must be the same as that submitted for ethics review.

(ii) Completed application for review form.

(iii) Documents related to the proposal.

10.2 The application for review form must contain the following information:

(i) Researchers' names, affiliations, addresses and contact numbers

(ii) Organisation(s) or institution(s) involved in the study

(iii) Sponsors or funders

(iv) Other pertinent information such a conflict of interests. There is conflict of interest when the researcher has an interest in the research that may jeopardise his/her ability to undertake the research in a scientific and ethical manner.

10.3 The proposal-related documents must include the following:

(i) Participant information sheet (if applicable).

(ii) Description of the process for obtaining informed consent.

(iii) Informed consent form in English and in the language of the potential participants. The language should be understandable to a lay person.

(iv) Description and/or amounts of compensation including reimbursements, gifts or services to be provided to participants (if applicable)

(v) Description for arrangement for indemnity (if applicable)

(vi) Description of any financial costs to participants (if applicable)

(vii) Description of provision of insurance coverage to participants (if applicable)

(viii) Description of steps to be undertaken in case of adverse event or when injury or harm is experienced by the participants attributable to their participation in the study.

(ix) Statement agreeing to comply with ethical principles set out in the FPD Policy on Research Ethics

(x) Disclosure of any previous ethics review action by other ethics review bodies (if applicable)

(xi) Research instruments such as questionnaires, interview guides and similar documents

(xii) Research budget

(xiii) Project agreement (e.g. MOA)

(xiv) CVs of principal investigators

(xv) Letter(s) of permission from relevant bodies (if applicable)

10.4 Steps for reviewing proposals

10.4.1 Proposals for review must be distributed to REC members at least a week in advance of REC meetings, together with other relevant documents (minutes, agenda etc).

10.4.2 After members have reviewed the proposal and related documents they make a summary of the proposal and documents using the Assessment Form/Checklist.

10.4.3 They then write their decision on the appropriate page of the Assessment Form/Checklist. If the decision is 'disapproved' they must write the reasons for the disapproval. If the decision is "modify" the items for revision must be clearly indicated in the Assessment Form/Checklist.

10.4.4 Reviewers should as far as possible provide researchers with suggestions for meeting the ethical requirements for the research, especially if the research is deemed to be significantly beneficial to society or has strong social justice merits. However, the justice merit of the research cannot on its own be used to approve an ethically defective proposal.

10.4.5 The members' views are discussed at the meeting and a decision reached in accordance with 10.4.2 above.

10.4.6 Any member can request the chair to invite the investigators and/or funders to elaborate or explain certain aspects of the proposal.

10.4.7 The chairperson must communicate the decision of the FPDREC to the applicant in writing. This must include a clear explanation if the decision is negative or if revisions are required.

10.4.8 Research which involves external institutions must be reviewed and acted on by the REC(s) to which the students belong.

10.5 Expedited review

10.5.1 Expedited review is possible for proposals that pose no significant risks (Category 1 research) or need only minor revisions after previous conditional approval.

10.5.2 The chairperson may nominate two or more members to review the proposal. If it is a resubmission, previous reviewers should be nominated. The reviewers examine the proposal and documents.

10.5.3 The chairperson circulates the reviewers' decision and comments to the rest of the members for their decision. If a consensus cannot be reached or a member expresses some concerns, the proposal must be given a full review. An en banc meeting of the FPDREC may be required.

10.5.4 The chairperson then communicates the decision to the researchers.

10.6 Ongoing monitoring/review

10.6.1 The FPDREC evaluates ongoing research that it has previously approved.

10.6.2 Principal investigators must submit in writing the following to the FPDREC:

(i) Report of any adverse event [1] including a detailed description of the event, measures taken to address it and the outcomes. This report must be submitted as soon as possible, but not later than two weeks after occurrence of the event.

(ii) Report of any ethical problems encountered including a description of how these were addressed. This report must be submitted every two months after commencement of the research.

(iii) Any changes in the research design including methodology.

(iv) A terminal report describing the actual procedures for taking informed consent and any other ethics-related procedures, including the steps taken to ensure that participants are informed of the findings and consulted on how the findings can benefit them or others.

(v) For long-term research and highly sensitive research the FPDREC can require a progress report on a regular basis for renewal of approval.

Relevant to (iii), any envisaged change in the study design or methodology that has potential or actual ethical repercussions must first be approved by the FPDREC.

10.6.3 It is the duty of researchers to inform the FPDREC in writing as soon as possible in the case of premature termination of the study. The information should include an explanation for the premature termination, including an explanation of measures taken to protect the participants against any adverse effects of the premature termination. The REC documents all terminations of approved research projects

10.7 Review fees

10.7.1 A standard review fee, the amount to be set by the FPDREC, may be charged for exclusively external research or research which is externally funded. The fee is payable upon submission of the proposal for review.

10.7.2 Monies thus collected may be spent on the operation of the FPDREC.

10.8 Vulnerability and risks

10.8.1 It is the duty of reviewers to identify whether or not the research will involve vulnerable persons or groups and to ensure that adequate protective measures are provided for.

10.8.2 Special attention should be given to evaluating the risks of participants in relation to benefits.

10.8.3 Research can be classified on the basis of the degree of risk:

'Category 1' Research involving negligible or minimal risk

'Category 2' Research involving greater than minimal risk but presenting the prospect of direct benefit to participants

[1] That is, **h**arm or injury suffered by participants that is attributable to the research such as physical harm, psychological or emotional stress, financial loss and social ostracism or stigma.

'Category 3' Research involving a minor increase in minimum risk and presenting no prospect of direct benefit to participants

'Category 4' Research that does not fit the above categories

10.8.4 While all research involving human subjects should be approved by an FPDREC and subjected to scrutiny, research involving reviews of administrative records which contain names of

people may require a lower level of scrutiny, while research involving solely aggregated data and literature reviews needs the lowest scrutiny (if any).

11. ASSESSMENT FORM/CHECKLIST

11.1 Code number

11.2 Title of research proposal

11.3 Proponent(s)

11.4 College or Institute

11.5 Sponsor or funder

No N/A Yes

(i) Demonstrated that potential benefit outweighs potential harm

(ii) Justification for risk

(iii) Protective measures for vulnerable participants

(iv) Informed consent form in language familiar to participant

(v) Information in consent form clear and comprehensible to participant

(vi) Consent form contains the following basic information:

• purposes of research

• expected duration of participation

• participant's actual role in the study

• procedures for selection of participants

• foreseeable risks and discomforts

• procedures or measures in case of adverse event

• how privacy of participants will be ensured

• benefits to the participant

• benefits to others

• how confidentiality will be maintained

• compensation/gifts/services to participants

• reimbursements

• indemnity

• insurance

• approximate number of participants

• additional information required by local laws

• names of contact person for research-related inquiry

• statement that participation is voluntary and no penalty or loss of benefit for nonparticipation

• measures that will be taken if injury or harm attributable to study occurs

• statement that participant can withdraw any time without obligation to explain

(ix) Procedure for taking prior informed consent ensures that potential participants understand the implications of their participation and are able to make an autonomous decision.

(x) Security of data storage

(ix) Information and consultation with participants on findings or results

(xi) Participants' access to products developed by study

(xii) Sharing of benefits from products developed by study

(xiii) Reporting to ERC after approval

(xiv) Qualifications of investigators and staff

(xv) Disclosure of conflict of interest

(xvi) Benefit to local community

(xvii) Benefit to larger society

(xviii) Community participation

(xix) Possible adverse impact on the community

(xx) Manner of sharing or disseminating findings or results

(xxi) Prior informed consent

Acknowledgements

The South African Medical Association Research Ethics Committee (SAMAREC). *Standard Operating Procedures and Guidelines for the Ethics Evaluation of Clinical Trials in Humans.* (2011).

South African Human Sciences Research Council. *HSRC Code of Research Ethics.* (2011).

National Committee for Ethics in Social Science Research in Health (NCESSRH). (2003).

South African Medical Research Council. *Guidelines on Ethics for Medical Research: General Principles (Book 1).* (2002).

University of South Africa. *Policy on Research Ethics.* (2007).

South African Good Clinical Practice Guidelines (2nd edition). (2006). *Guidelines for good clinical practice in the conduct of clinical trials with human participants in South Africa*. Department of Health, South Africa.

Hospice Palliative Care Association of South Africa (HPCA) Research Ethics Committee. Standard Operating Procedures. (2011)

The FPDREC SOP and guidelines are based on

- the Declaration of Helsinki,
- the Council for International Organizations of Medical Sciences (CIOMS),
- International Ethical Guidelines for Biomedical Research Involving Human Subjects,
- World Health Organisation. *Operational Guidelines for Ethics Committees that Review Biomedical Research* (2000) Geneva,
- Belmont Report. *Ethical Principles and Guidelines for the Protection of Human Subjects of Research.*

It is further based on principles contained in applicable UN declarations such as:

- the Universal Declaration of Human Rights,
- the Convention for Biological Diversity,
- the Declaration on the Elimination of Discrimination against Women,
- the Declaration of the Rights of the Child, and
- the Rights and Protection of Indigenous Peoples.