Standard Operating Procedure (SOP)

FOUNDATION FOR PROFESSIONAL DEVELOPMENT RESEARCH ETHICS COMMITTEE (FPDREC)

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AUTHORITY

The Foundation for Professional Development Research Ethics Committee (FPDREC) was established by Foundation for Professional Development (FPD) as set out in the Terms of Reference. Its authority has been conferred upon it by the Board of FPD.

The FPDREC is registered with the National Health Research Ethics Council (NHREC) in accordance with the National Health Act, Act 61/2003. Its registration number is REC-030711-033.

The FPDREC does not, as a general rule, review research studies that are longer in duration than one year or review research proposals that involve clinical trials, drug research, bio-medical research involving human tissue or studies involving animals or plants. Where appropriate the FPDREC will refer such applications to an external ethics review committee.

The FPDREC will accept, for ethics review, applications of research protocols submitted to it by researchers from other institutions and persons who are not FPD staff members or students, provided the research falls within the scope of the studies the committee generally reviews as set out in the previous paragraph. Such reviews will be done at a prescribed fee.

All FPDREC SOPs should be read in conjunction with the contents of the National Department of Health Guidelines “South African Ethics in Health Research: Principles, Processes and Structures” Third Edition 2024. (NHREC Guidelines)

ROLE OF THE FPDREC

The FPDREC functions as the official Research Ethics Committee of FPD. The main role of the FPDREC is to promote the conduct of ethical research by FPD staff and students as well as external research conducted by institutions and persons not affiliated with FPD. In particular, to contribute to safeguarding the dignity, rights, safety, and well-being 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 FPDREC functions independently and is not attached to or based in a single cluster or division in FPD. The FPD Deputy CEO acts as the custodian of the Committee and appoints the members on recommendation of the Committee.

The FPDREC aims to ensure that:

- An ethical and scientific intellectual culture prevails among FPD employees, its students and external researchers.
- The rights and interests of human participants are protected. This is particularly important where gathered information 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.
- Ethical and scientific soundness of research is not compromised where lack of funding limits opportunities for research and force cost-saving procedures.

The objective of the Committee, in reviewing research involving human research participants, is to contribute to safeguarding the dignity, rights, safety, and well-being of all research participants and to ensure that the goals of research do not override the best interests of the research participants. The FPDREC is committed to ensuring high-quality scientific and ethical research and aims to provide independent, comprehensive, and timely review of the ethics of proposed studies. Monitoring of approved studies is conducted by requesting ongoing reporting and a final closing report.

COMPOSITION OF THE FPDREC

Membership

Research Ethics Committees should consist of members who collectively have the qualifications and experience to review and evaluate the health aspects and ethics of proposed research. It should be independent, multi-disciplinary, multi-sectoral and pluralistic.

The composition of the FPDREC should comply with the prescriptions of the NHREC Guidelines and should consist of at least nine (9), but not more than fifteen (15) members of which at least one member: -

- is a layperson;
- has knowledge of, and current experience in the professional care, counselling, or health-related treatment of people. Such a member might be e.g., a medical practitioner, psychologist, social worker, or nurse;
- has had professional training and is experienced in qualitative and quantitative research methodologies;

- has expertise in biostatistics; ● has expertise in research ethics;
- who is legally qualified.

The FPDREC should strive for proportional representation in terms of gender, race, and discipline. The Committee should look regularly at the renewal of its membership. The size of the Committee could be increased to accommodate new members. The portfolios of members could also be changed to allow for new and diverse perspectives in order to guard against functions to become static as this could impact decision-making processes leading to affect participants and the research community adversely. The FPDREC should endeavour to reflect the demographic profile of the population of the Republic of South Africa as best and reasonably as possible.

Members of the FPDREC, irrespective of the fact that they are employed by FPD or not, are indemnified by FPD from personal liability against claims that may arise in the course of ordinary business of the FPDREC.

Co-opted Membership

If indicated the FPDREC may co-opt persons on an ad hoc basis to provide the Committee 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 as co-opted members must be based on the need of the Committee for their special expertise.

If, in the view of the FPDREC, human populations will be affected by particular research, the Committee should exert efforts to include a representative of the population which will be studied. If this is not possible, the Committee must invite persons who are knowledgeable about the culture, language, history, social dynamics, and vulnerabilities of a particular population and who can speak on their behalf.

Consideration should be given to invite students and other interested parties to attend meetings as observers with a view to join the Committee as members some time in future.

Observers must declare at meetings that they will observe the confidentiality of the deliberations of the Committee.

Mentoring

Mentoring is defined as a developmental relationship in which a more experienced or knowledgeable person provides guidance, support, advice and encouragement to someone with less experience or expertise, often referred to as a mentee or protégé. If the FPDREC is of the opinion that newly appointed members could benefit from being mentored by a retired member, it may appoint such a retired member to the Committee as a mentor on terms as determined by the Committee at the time. Such mentor may attend meetings of the Committee, but will have no voting rights. Although newly appointed members will receive induction training, one of the best ways of training a new member on the ethos and processes of an ethics research committee, is through observation and participating in the activities of the committee. Mentors will be able to provide any guidance that maybe required by any of the newly appointed members.

Appointment of Members

The processes by which FPDREC members are appointed, and membership is renewed should be transparent and fair. The process should be free of partisanship that might hamper the independence of the committee. Members are appointed as individuals for their expertise, knowledge, and qualities, rather than in a representative capacity. They are not appointed as representatives of any organisation, community, or opinion.

In the case of a vacancy on the Committee, suitable candidates for members of the FPDREC, including those who do not have appointments as employees of FPD, may be proposed by members and/or the FPD Deputy CEO. Committee members consider the candidates' suitability for members at a committee meeting and vote for candidates they want to recommend to be appointed to the FPDREC by the FPD Deputy CEO. Successful candidates have a term of office of three to five years with possible reappointment for a further term of three to five years.

In order to comply with the provisions of the NHREC Guidelines and to keep a balance between bringing younger and new members into the committee while not jeopardising the collective wisdom built up over time and requirements of NHREC, members should stand down for at least one term before being eligible to serve again on the committee.

Newly elected members will be provided with a letter of appointment by the FPD Deputy CEO which will, inter alia, include details of the term of office; where to find the necessary information for new members; and the assurance that members are indemnified from personal liability against claims that may arise in the course of ordinary business of the FPDREC. Appointments to the FPDREC will allow for continuity, the development of expertise and the regular input of fresh ideas and approaches.

Conditions of Appointment

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

Members will sign a confidentiality agreement regarding meetings, deliberations, applications, and related matters. Members will also sign a conflict of interest statement. In addition, at each meeting of the committee members must reaffirm verbally their confidentiality agreement and also declare any conflict of interest at each committee meeting. These confirmations and declarations must be recorded in the minutes of meetings.

Members must take cognisance of the contents of the Code of Conduct applicable to members and perform their duties and responsibilities accordingly. Members are required to sign annually an acknowledgement that they have received a copy of the Code of Conduct.

Training

According to the NHREC Guidelines it is expected that all REC members and REC administrators should ensure they complete theoretical research ethics training to ensure they are familiar with expectations. FPDREC members should, therefore, participate in appropriate, independent, initial and continuing training relevant to their roles in the committee. In addition to general training for all members, training courses should be adapted to individual members' needs and the specific needs of the FPDREC. Health research ethics training is additional to discipline- or profession-specific training. It should include an assessment to provide evidence of more than mere attendance at training. However, additional training courses or learning opportunities, such as conferences, workshops, informal training at REC meetings, continuing professional development, peer reviewed publications, and other learning opportunities that are not assessed, can be valuable.

FPD should provide the necessary support and resources to enable and empower FPDREC members to undergo assessed ethics education and training to achieve the required competence.

Training should lead in particular to a good understanding of:

- Ethical principles and their application in biomedical research;
- Research design and methods, socio-cultural and public health implications, as well as scientific integrity
- The principles of research integrity and the practicalities of responsible conduct of research, consequences of non-compliance and misconduct, available structures for complaints and whistle blowing processes;
- The interdependence of scientific integrity, research ethics, social values and legal compliance
- The governance principles, structures, documentation, composition, functions, roles, responsibilities and oversight of the FPDREC.
- The induction and other training of REC members
- FPD administrative support, FPDREC procedures, study and resource management, confidentiality agreements, management of conflicts of interest, Code of Conduct for members, Committee meetings, review and expedited processes as well as monitoring by the Committee.
- Recruiting Participants

- Obtaining Informed Consent;
- The protection of the Rights of Participants, especially vulnerable groups
- Information Governance (incorporating data protection and data management);
- Quality Control Systems and Quality Assurance; and
- The role of the National Health Research Ethics Council and the relationship of FPDREC with the Council.

The acquisition of the required knowledge and skills is meant to be an interactive learning experience. Learning activities should be facilitated by the Secretariat with the support of FPD.

Newly appointed members should undergo induction training soon after their appointment. Such induction training may be provided by a suitable qualified member or facilitator assisted by the FPDREC Secretariat. Induction training will provide an opportunity for members to familiarise themselves with all the FPDREC documentation as well as national and international research ethics guidelines. **A copy of the FPDREC SOP "INDUCTION PROGRAMME FOR NEWLY APPOINTED MEMBERS" is attached for ease of reference.**

FPDREC, with the support of FPD, will arrange for members to attend research ethics training courses and refresher courses at least once during a term of appointment. FPDREC will record such training as documented proof of such familiarity and training courses.

OFFICE BEARERS OF THE COMMITTEE

Chairperson

The Chairperson of the FPDREC is appointed by the FPD Deputy CEO for a period of three to five (3 - 5) years. If the Chairperson is an external appointee, FPD must provide the chairperson with the necessary support and authority to perform the role. The Chairperson is assisted by a Deputy Chairperson with responsibilities and inter-meeting matters. The Deputy Chairperson is elected by the members from among themselves and has a term of three to five years. In the absence of the Chairperson, the Deputy Chairperson shall perform the role and duties of the Chairperson.

The Chairperson is the presiding officer and overall administrator of the work of the FPDREC.

The roles and responsibilities of the Chairperson are to:

- Chair the meetings of the Committee.

- Ensure matters referred to the Committee are addressed, and that outcomes and decisions are accurately recorded.
- Ensure the guidelines for the operation of the Committee are adhered to.
- Ensure research proposals are considered in an effective and timely manner.
- Provide information for briefings and other advice as indicated
- Be the signatory for ethics approval letters.
- Ensure that the records and documents of the committee are secure and, in appropriate cases, kept confidential;
- Oversee adequate documentation in a timely manner pertaining to all committee meetings and deliberations;
- Verify recording of receipts of applications, documents submitted and other transactions of the FPDREC with the support of the Secretariat; and
- Report annually to the FPD Deputy CEO on the activities of the committee as well as funds received and all disbursements.

Secretariat

FPD is responsible for providing FPDREC with adequate secretarial and administrative support as well as resources. This support is provided for FPDREC to conduct its functions in compliance with the minimum standards as described in the guidelines and the statutory governance framework. In this regard FPD will appoint trained administrative personnel (or support an online application that will incorporate and streamline many of these tasks of the secretariat) to manage the office administration required to process research ethics applications, organise and service FPDREC meetings, including agendas, minutes and the other regular record keeping and reporting tasks. FPD will also provide offices and other administrative infrastructure if and as required.

The Secretariat is responsible for:

- Preparing communications regarding the listing of each received and approved document, the frequency of continuing review, responding to queries directly or if necessary after consultation with the chair/deputy-chair and other obligations relating to the investigator or researcher;
- Stamping approval and expiry date on every page of the consent form;
- Obtaining signatures of the chairperson or deputy chairperson;
- Keeping records and receipts;
- Organising and maintaining a registry of research proposals reviewed by the FPDREC;

- Keeping record of all research proposals that obtained ethics clearance;
- Signing a confidentiality agreement; arranging that all committee members have signed the required documentation on acceptance of membership and yearly thereafter;
- Preparing the committee meeting agendas and minutes, as well as distributing relevant documentation to FPDREC members timeously in preparation for meetings or otherwise.

Executive Committee (EXCO)

If indicated and to assist with the well-functioning of the Committee, it may establish an EXCO to deal with matters duly authorised by the Committee. The EXCO consists of the Chairperson, Deputy Chairperson and one other member of the Committee elected by the Committee. The EXCO may deal with renewals, final approvals after receipt of further input by the investigators as requested by the Committee at a previous meeting or matters as directed by the Committee.

RESEARCH REQUIRING RESEARCH ETHICS COMMITTEE (REC) APPROVAL

Researchers may not undertake research involving humans without the prior approval of the FPDREC. This refers to research by FPD employees or students, in various capacities including collaborative or multi-institutional or multi-country studies, as well as research undertaken by external researchers. Prior approval of the FPDREC is also needed for research conducted at or on the premises of FPD, or in any of the FPD clinical sites, or at clinics/hospitals associated with FPD in terms of academic support, or if it uses FPD facilities, or is to be funded from FPD funds or if funding for it was acquired through FPD.

Under no circumstances will retrospective research approval be granted by FPDREC.

It is important that FPDREC has SOPs that clarify the expectations about their review responsibilities. Operational expectations should be advertised and adhered to, e.g., review turnaround times, prompt completion of meeting minutes, feedback correspondence to applicants, etc. In general terms, RECs are encouraged to strive for improvements in efficiencies, e.g., streamlining review processes, considering use of new technologies to improve review and approval cycles.

MEETINGS

The FPDREC will endeavour to meet at least ten (10) times annually or more frequently if the need arises. Although a hybrid meeting format is permissible, a balance should be maintained between virtual and face-to-face meetings. For high-risk or sensitive protocols, as well as for initial REC member training, or with regard to protocols requiring complex deliberations involving community stakeholders, face-to-face meetings are critically important and should be held. Committee meetings could, therefore, be face-to-face (physical) meetings or virtually using online communication tools.

The NHREC advised that the following key elements in the Agenda of meetings, irrespective of the format, should be incorporated, requiring quorate meeting decisions or ratifications:

- Conflict of interest declaration
- Confirmation of confidentiality agreements
- Attendance register
- Establishment of quorum
- Confirmation of previous minutes
- SAE and SI reports and outcome ratifications (handled by SAE committee in between meetings)
- EXCO committee decision ratifications / notifications
- Passive monitoring ratifications for renewal, or final reports for ending of studies
- Active monitoring report ratifications
- Minor amendment request ratifications, or approval of major amendments
- Ethics application reviewer reports, deliberations and decisions (narrative style of discussions)
- Any membership decisions as per SOPs
- Reporting on ethics training status, or the provision of additional ethics training of members if and as necessary, as per SOP
- Open discussions if and as necessary/required

Poor meeting attendance impacts on the quorum and can result in a meeting being cancelled. To ensure timely and efficient review of research proposals, committee members are expected to attend meetings punctually and regularly.

Committee members and members of the Secretariat shall confirm their adherence to their confidential agreements at the start of the meeting. At the same time committee members must declare any conflict of interests with any of the items on the agenda.

Where one of the members is absent from a meeting, the meeting may consider the member's views on a particular protocol, provided it is in writing. Such input will, however, not make up a quorum.

In dealing with any matter directed by the Committee, EXCO may meet in order to discharge of its duties.

In general, committee meetings will be held on the second Tuesday of a month. A schedule of the meeting dates will be available from the FPDREC Secretariat and on the FPD website.

A simple majority will constitute a quorum.

As indicated above the Agenda of a meeting should list the protocols, reviews by members, major amendments, annual status reports, other reports and responses to queries to be considered, and will be sent to the members, together with the study documents. Members should be furnished with all documents in sufficient time for individual member review prior to the Committee meeting.

At the discretion of the Chairperson, and subject to their observing the confidentiality of the meeting, applicants may attend meetings to clarify points of issue but will not be present during the decision-making phase.

FPD INTERNAL SCIENTIFIC COMMITTEE

FPD has established an Internal Scientific Committee to review research proposals for scientific soundness before the application is submitted to the FPDREC for ethics review. The Internal Scientific Committee is reviewing the scientific merit of the proposed study allowing the FPDREC to focus on the ethics of the study. This would build towards higher standards in the proposals that are on par with acceptable scientific norms which is essential for the protection of the well-being of participants.

The internal scientific reviews are conducted according to a set review form. The scientific reviewers need to approve any changes requested or recommended by them before the application is submitted for ethics review to the Committee. **A copy of the FPDREC SOP on Scientific Review is attached for ease of reference.**

PROCEDURE FOR ETHICS REVIEW

According to the NHREC Guidelines research protocols should be reviewed prospectively to ensure that they meet the accepted ethical norms and standards before research commences. The NHREC Guidelines should be used as a minimum benchmark for the review of protocols. Research protocols must stand up to scientific and ethical scrutiny. The review process should entail an independent and objective assessment of the potential effect of the proposed research on potential participants, the environment, and on the general day-to-day functioning of the infrastructure that provides the site or context for the research.

The review should ensure that the ethical and appropriate scientific standards are maintained to:

- protect participants from harm by minimising risks of harm to the extent possible and then balancing the risk of harm against the likelihood of benefit
- hold researchers accountable for the research activities and, where appropriate, expect them to provide adequate and suitable support, including referral to appropriate free support services when potential harm might result from participation in the research activity
- promote important social and ethical values.

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 the 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, 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.

Protocol applications for approval must be submitted in English electronically to the FPDREC Secretariat fifteen (15) working days before a meeting date and must contain the following:

- The Complete research proposal. The proposal which is submitted for scientific or technical review must be the same as that submitted for ethics review. A statement of the ethics considerations involved in the proposed research must be included. The Committee must be satisfied that the research protocol gives adequate consideration to participants' welfare, rights, beliefs, values, customs and cultural heritage. A clear community engagement plan outlining how stakeholders and community members will be consulted and involved in the research lifecycle process. It is recommended that researchers follow the SA Community Advisory Board guidelines. The process of obtaining informed consent and assessing understanding of the consent information should be included in the protocol. Special attention should be paid to participants' understanding and appreciation of the information provided prior to making decisions to join the research.
- Completed application for review form containing the following:
  - Researchers' names, affiliations, addresses and contact numbers ○ Organisation(s) or institution(s) involved in the study ○ Sponsors or funders ○ A summary, synopsis, or diagrammatic representation (flowchart) of the protocol.
  - A summary of the data management programme for the study.
  - Other pertinent information such as 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.
  - A declaration by the researcher agreeing to comply with and adhere to ethical principles, standards and guidelines as per FPDREC SOP's.

  - A statement agreeing that all research activities will commence only after a certificate of approval has been issued by FPDREC.
  - Evidence of ethics training such as TRREE - module 1-3 for researchers.
- Documents related to the proposal must include the following:
  - Participant recruitment procedures, educational material (e.g., advertisements) and any other written information to be provided to participants.
  - Description of the process for obtaining informed consent. Identity documents should be used for age determination of participants. If ID's are not available other means of determining age such as SASSA documentation could be used.
  - Written Informed Consent Form in English and in the language of the potential participant.
  - Written version of the Verbal Informed Consent Form (if applicable). The language should be understandable to a lay person.
  - A list of site details, including the site address and names of the PI, subinvestigators, study coordinators and all other research team members.
  - Description and/or amounts of compensation including reimbursements, gifts, or services to be provided to participants (if applicable). This includes any refreshments, tokens of appreciation, or incentives for retention. Reimbursement for participants is now regarded equivalent to what an unskilled labourer in the marketplace, whether employed or not, would earn. However, the NHREC Guidelines on reimbursement should be used as a guideline.
  - Description for arrangement for indemnity (if applicable) ○ Description of any financial costs to participants (if applicable) ○ Description of provision of insurance coverage to participants and a copy of the insurance certificate covering the protocol (if applicable) ○ Description of steps to be undertaken in case of an adverse event or when injury or harm is experienced by the participants attributable to their participation in the study.
  - Disclosure of any previous ethics review action by other ethics review bodies (if applicable) ○ Research instruments such as questionnaires, interview guides, diary cards, computer-based surveys intended for research participants and similar documents.

- Research budget and details of other financial agreements with investigators signed and dated. ○ Project agreement (e.g., MOA) ○ Principal Investigator’s and Co-/Sub-investigator’s current Curricula Vitae ○ Letter(s) of permission from relevant bodies (if applicable)

The Secretariat will screen the application for completeness and ensure that the correct documentation accompanies the application. Applications with incomplete or incorrect documents must be returned no later than one week after receipt of the application by the Secretariat. Inadequacies in the application must be clearly identified in the communication to researchers.

If an approved study is not initiated for whatever reason, the Committee must be informed forthwith.

RISK DETERMINATION

Introduction

The NHREC Guidelines state that the ratio of risk of harm to likelihood of benefit should be favourable, i.e., the likelihood of benefit, at least to the category of person involved, should outweigh the risk of harm to the participants. In weighing risk of harm against likelihood of benefit, the analysis is concerned not only with the participants themselves, but also with community or societal interests. The ratio may be analysed by considering whether:

- the harms and benefits are adequately identified, evaluated and described;
- the harms stated in the protocol match those stated in the informed consent documentation;
- the risk of harm is reasonable in relation to anticipated benefit;
- the risk of harm is reasonable in relation to the importance of the anticipated knowledge to be gained;
- counselling and support services will be made available, e.g., if emotional distress is a likely side effect of research procedures, arrangements to facilitate access to assistance should be made. Counselling and support services should be free to participants who need them, locally accessible and where necessary, immediately accessible to the participants who need these services. Where the referral pathway is to a public health centre, this must be negotiated carefully with the centre, because the referral presents an example of risk of harm (being introduced by research), which must be offset by the use of public health resources and funds. The influx of research participants may adversely affect access to these services for patients who are not part of the research.

- the researcher should provide a distress protocol for studies that could trigger emotional trauma or psychological distress.
- anticipated harms should be minimised by preventing occurrence (i.e., mitigate risk of harms by having a plan to manage, eliminate, or limit setbacks) as far as possible. If the harm should occur, appropriate remedial interventions should be implemented.

The NHREC recommended that a Standard Operating Procedure (SOP) on risk assessment be developed by the FPDREC to enable a more consistent determination of risk. All reviewers and researchers should have access to the SOP's and assessment guidelines and apply these to all studies under review.

FPDREC Review Approach

When reviewing a study FPDREC reviewers must consider the probability of harm occurring as well as the type of harm that can occur. The nature of anticipated harms will vary in accordance with the type of research under consideration and may include physical, psychological, legal, social (including stigma) and financial harms. The possibility of harm to the researcher, study, or project personnel, e.g., safety concerns, must also be assessed. Importantly, the researcher should include a statement in the protocol that indicates a process of self-assessment of risk to self in conducting the study.

Although studies that are identified as "negligible or minimal risk" could be granted exemption from ethics review, all studies submitted to the FPDREC shall be considered and reviewed by the full Committee. When satisfied that a study requires minimal changes required by the researcher before being granted approval, the Committee may task the EXCO of the Committee to finally approve the study after amendments have been submitted.

A copy of the FPDREC SOP on Risk Determination is attached for ease of reference.

COMPLIANCE WITH APPLICABLE LAWS, PRINCIPLES AND GUIDELINES

The FPDREC, in granting its approval is in compliance with, and must be satisfied that the protocol conforms to the spirit of the following guidelines:

- The World Medical Association (WMA) Declaration of Helsinki, Ethical Principles for
Medical Research Involving Human Participants, as amended in 2024;
- South African Constitution, Act No.108 of 1996;
- National Health Act, Act 61 of 2003 and Regulations published in terms of the Act;
- National Environmental Management: Biodiversity Act, Act 10 of 2004;
- Protection, Promotion, Development and Management of Indigenous Knowledge Act, Act 6 of 2019;
- Protected Disclosures Act, Act 26 of 2000;
- Protection of Personal Information Act, Act 4 of 2013;
- Department of Health: South African Ethics in Health Research Guidelines: Principles, Processes and Structures, Third Edition, 2024;
- Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa, 2006;
- Operating Guidelines: Ministerial Consent for Non-therapeutic Health Research with Minors, 2015;
- The Health Professions Council of South Africa (HPCSA): Guidelines for Good Practice in the Health Care Professions General Ethical Guidelines for Biotechnology Research in South Africa, Booklet 14;
- International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines E6(R2) 2016;
- The Belmont Report;
- The Guidelines on Research published by the SA Medical Research Council;
- International Ethical Guidelines for Health-related Research involving Humans, CIOMS & WHO, 2016;
- The WMA Singapore Statement on Research Integrity HYPERLINK:

  http://www.singaporestatement.org/;
- The Global Code of Conduct for Research in Resource-poor Settings (2019): http://www.globalcodeofconduct.org; ● The SAN Code of Research Ethics (2017):

  https://www.globalcodeofconduct.org/affiliated-codes/;
- The WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Bio-banks, as amended 2016;

- The Hong Kong Principles for assessing researchers to enhance research integrity (2019): https://www.wcrif.org/guidance/hong-kong-principles;
- The Rooibos Benefit Sharing Agreement (2019):

  https://www.cambridge.org/core/journals/cambridge-quarterly-of-healthcare-ethics/ar ticle/rooibos-benefit-sharing-agreementbreaking-new-ground-with-respect-hones ty-fairness-and-care/BBCDC539CECC36F1BA946AE7A5F27445;
- Guidelines for Human Specimen Storage, Tracking, Sharing, and Disposal within the NIH Intramural Research Program:

  https://oir.nih.gov/system/files/media/file/2021-11/guidelines-biospecimen.pdf.

STEPS FOR REVIEWING PROPOSALS

Scientific review

Research proposals by FPD students will be submitted to the FPD Internal Scientific Committee to review them for scientific soundness before the proposals are submitted for ethics review by the Committee. The scientific reviews are conducted according to a set review form. The Scientific Committee has to approve any changes requested or recommended by it before an application is submitted to the Committee for ethics review.

Protocols will not be considered for ethics review in the event that they have not passed the scientific review process.

Preliminary and Ethics Review

After the proposal has been approved by the FPD Internal Scientific Committee it will be submitted to the FPDREC EXCO for preliminary review to consider all aspects of the protocol. The EXCO must be satisfied that the research conforms to the following criteria: collaborative partnership, social value, scientific validity, fair selection of study population, favourable risk-benefit ratio, informed consent, respect for recruited participants and study communities, and research translation. There must be justice and beneficence for the participants in all research projects.

Once the EXCO is satisfied that the proposal complies with the above aspects, it is referred to Committee members for review. After members have reviewed the proposal and related documents, they summarise their comments on the proposal and documents using the Assessment Form/Checklist.

Members then document their decision on the appropriate page of the Assessment Form/Checklist. If the decision is ‘disapprove’ they must provide the reasons for the disapproval. If the decision is “modify” the items for revision must be clearly indicated in the Assessment Form/Checklist.

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.

The members’ views are considered at the meeting concerned and a decision is reached by the Committee as set out below.

The Chairperson may also allocate one protocol for comprehensive review to at least two members of the Committee with requisite experience. These members will present their findings to the Committee. All members will be required to familiarise themselves with the synopsis and the consent forms for all protocols as well as members’ comments on the protocol. Notwithstanding the above, all Committee members will participate on an equal basis in a democratic and open deliberation process regarding the science of the protocol, the risks and benefits, the value of the research, fairness in participant selection, the informed consent documentation, and any other ethical issues.

Any member of the Committee may request the Chairperson to invite the investigators and/or funders to attend meetings to elaborate on, or explain certain aspects of the proposal. Such requests must be made before the meeting concerned.

Proposals requiring minor amendments may be approved outside the meeting by the EXCO and noted/ratified at the next meeting. Proposals requiring major amendments will need to be re-submitted to the full Committee. Rejected submissions may be re-submitted for fresh review by the full Committee.

No recruitment, screening or enrolment on a study may take place before the Committee issues its written approval in the form of an approval letter and certificate. This includes written approval for amendments and renewals.

The Committee will not grant retrospective ethics approval for completed research.

Unless joint review or reciprocal recognition of review decisions is conducted in terms of the NHREC Guidelines, the Committee will not review research submitted to another research ethics committee for review. Ethics review of research conducted in South Africa with international collaborators should also be done in terms of the NHREC Guidelines.

VOTING

When a vote is required to arrive at a decision, a simple majority vote of members present suffices. However, any dissenting opinion must be adequately recorded and kept. All members, including co-opted members, are entitled to vote. Each member has one vote. The Chairperson votes only when there is a tie.

Members who have not reviewed the research application cannot vote on that application.

POSSIBLE DECISIONS

After reviewing and considering the application, the Committee may make any of the following decisions:

- Approved: The proposed research is approved in its current form, with no changes required or with minor alterations. The date of approval is considered the date that all conditions were determined to be met and the research study nay commence.
- Require modifications: The concept of the proposed research is accepted and has no major ethical concerns, but a number of clarifications or methodological changes are required. The research applicant must re-submit the revised research application. The review can be finalised by an expedited review process, i.e., without having to serve before the full Committee again. The study may not commence until approval has been granted.
- Request further information or clarification: The proposed research has some methodological and/or ethical concerns and requires clarification and/or further information before the Committee can consider further. The research applicant must submit clarification and/or information as requested. The research application, together with the clarification will be reconsidered at a convened (full) Committee meeting.
- Disapproved, with reasons: The concept of the proposed research is not accepted and has major methodological and/or ethical concerns requiring considerable revision. The research applicant must re-submit the revised research application. The revised research application will be reconsidered at a convened (full) Committee meeting.
- Rejected: The proposed research may not be resubmitted. Decisions are recorded in writing and will include reasons for rejection.

TIMELY DECISIONS

To ensure complete and correctly accomplished applications the FPDREC must communicate to applicant(s) its action or decisions as soon as possible, but preferably within one (1) week, after the meeting where the application was decided on.

If the decision is negative or if revisions are required, the reasons for the decision must be clearly stated.

CONFLICT OF INTEREST

Members who have an interest in any of the studies under review must declare such interest at the meeting concerned. Each member must be given the opportunity at each meeting to declare verbally any conflict of interest.

A conflict of interest exists where there is a divergence between the individual interests of a person and their professional responsibilities in such a way that an independent observer might reasonably conclude that the professional actions of that person are unduly influenced by their own interests.

Conflicts of interest in the research area are common, and it is important that they are disclosed and dealt with properly. Conflicts of interest have the potential to compromise judgments and decisions that should be made impartially. Conflicts of interest may arise, for instance, when the reviewer has financial ties to the project. Financial conflicts of interest are foremost in the public mind, but other conflicts of interest also occur in research, including personal, professional and institutional advantages.

The perception that a conflict of interest exists is a serious matter and raises concerns about the integrity of members or the management practices of the Committee.

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.

Only members without conflict of interest with the research under review may participate in the deliberations and vote. However, members who have a conflict of interest with the research under review may attend the meeting concerned with the approval of the Committee to answer questions or to elaborate on the protocol, if indicated, but may not participate in the final deliberations or vote.

EXPEDITED REVIEW

Well-motivated requests to the Chairperson for an expedited review of a protocol is possible where proposals pose no significant risks, need only minor revisions after previous conditional approval or amendments that are urgent. In such a case the EXCO may finalise the review.

A new research application may be considered suitable for minimal risk, and thus qualify for expedited review, if the risk level of the proposed research meets the criteria outlined in the following definition:

- Minimal risk research: the probability and magnitude of harm or discomfort anticipated in the research, is not greater, in and of itself, than that ordinarily encountered in daily life, or during the performance of routine physical or psychological examinations or tests.

Minor amendments are those that do not change the risk benefit profile of the study in any way. Examples of typical minor amendments:

- Additional Investigators or study sites;
- Small changes in the consent process;
- Change in background information or update of literature review;
- Extension of period of study provided the study length does not exceed one year unless well motivated;
- Other changes that do not affect study design and will not affect study outcomes or results;
- Administrative changes;
- Stricter inclusion or exclusion criteria.

Major amendments are those that require changes to the study methodology or procedure that may result in an alteration of the risk benefit profile of the study. Examples include:

- Change in study aims, objectives or design;
- Resulting changes to consent documents;
- Additional study procedures;
- Easing of inclusion or exclusion criteria;
- Extension of period of study to exceed one year with motivation.

If the EXCO reaches a consensus decision, the matter will be finalised and the decision ratified by the full Committee during the next meeting. If a consensus cannot be reached, the proposal must be given a full review by the Committee. The applicant must be informed about the situation.

Administrative changes that will have no impact on the study may be approved by the Chairperson and the Secretariat. The timeframe for the expedited review should occur in no more than ten (10) working days from receipt of the request.

PRINCIPAL INVESTIGATOR (PI) AND CO-PRINCIPAL INVESTIGATOR (CO-PI)

Communication between the FPDREC and the researchers and investigators should be directed through the Principal Investigator (PI). The PI is, inter alia, responsible for the following:

- Complying with the SA and ICH Good Clinical Practice (GCP) guidelines;
- Submitting an application for consideration to the FPDREC;
- The scientific and ethics aspects of the study; and
- Communication with the FPDREC.

Once a study is in progress, all reports of adverse events and management issues dealt with by the investigators or sponsors should be transmitted to the Committee, ideally through the PI or Co-PI, who should be fully informed of these issues.

PIs must inform the Committee of the number of projects in which they are involved, and the percentage time spent on each with every new submission to the FPDREC.

VULNERABILITY AND RISKS

The Committee may impose additional measures to protect the welfare of participants, especially with regard to informed consent. The Committee may make it mandatory to conduct post-research investigations to review whether there was compliance with the additional measures imposed. If compliance was defective, the Committee may suspend or withdraw approval for the research investigation concerned.

While all research involving human subjects should be approved by the FPDREC and subjected to scrutiny, research involving reviews of administrative records which are de-identified may require a lower level of scrutiny, while research involving solely aggregated data and literature reviews needs the lowest scrutiny.

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.

Special attention should be given to evaluating the risks of participants in relation to benefits and to protecting the welfare of certain classes of participants.

Vulnerable groups are defined as:

- Minors (persons under the age of 18);
- Women in general and pregnant women in particular;
- Adults with factual incapacity to provide informed consent e.g. persons with intellectual or mental impairment;
- Persons in dependent relationships, including sex workers;
- Persons highly dependent on medical care;
- Persons with physical disabilities such as visual, auditory or mobility impairments;
- Inmates (called offenders when convicted);
- Persons participating in research as groups (referred to as collectivities);
- Elderly persons;
- Indigent persons;

Persons in dependent relationships include persons in junior or subordinate positions in hierarchically structured groups and may include relationships between elderly persons and their caregivers; persons with chronic conditions or disabilities and their caregivers; persons with life-threatening illnesses; patients and health care professionals; wards of state and guardians; students and teachers (including university teachers); employees and employers, including farm workers, members of the uniformed services and hospital staff and their respective employers.

‘Collectivity’ is a term used to distinguish some distinct groups from informal communities, commercial or social groups. Collectivities are persons who participate in research in groups distinguished by:

- common beliefs, values, social structures, and other features that identify them as a separate group;
- customary collective decision-making according to tradition and beliefs;
- the custom that leaders express a collective view;
- members of the collectivity being aware of common activities and common interests;

Research involves a collectivity when:

- property or information private to the group as a whole is studied or used;
- permission of people occupying positions of authority, whether formal or informal, is required;
- participation of members acknowledged as representatives is involved.

In addition, the Committee has the duty to ensure that adequate protection is provided for elderly or aged participants, pregnant women, minorities, students, employees and proposed participants whose first language is not English.

NON-THERAPEUTIC RESEARCH ON MINORS

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.

In principle, minors may not choose independently whether to participate in research because of their status of legal incapacity. However, parents or guardians do not choose for the minors who have factual capacity to choose. The parent or guardian rather gives permission for the minor to choose and to assent to participation in the research. Where a minor is very young (less than 7 years old) or is factually incapable of exercising a choice, then the parent or guardian chooses whether the minor should participate.

The NHREC Guidelines state that in special circumstances, e.g., for reasons of sensitivity, like sexual activities, substance, or other forms of abuse, etc., it may be desirable and ethically justifiable for children and adolescents (especially adolescents 16 years and older) to choose independently without parental assistance, whether to participate in research or not. The Guidelines emphasise that generally, only minimal risk research is suitable for independent consent. Reasons supporting the desirability of independent consent may include being able to recruit enough minors who otherwise would be unwilling to participate if they must tell their parents about the nature of the research to obtain parental permission.

Therapeutic research on a minor may be conducted only if it is in the best interests of the child, and if the assent of the child (if he or she is capable of understanding) as well as the consent of his or her parent or guardian, has been obtained.

The consent process for a minor’s participation in research requires, therefore, the following:

- Permission in writing from parents or legal guardian for the minor to be approached and invited to participate (in accordance with section 10 of the Children’s Act 38 of 2005);
- Assent from the minor in writing (i.e., agreement to participate) if they choose to participate.

Non-therapeutic research may only be conducted on a minor with the consent of the following persons: the Minister, the parent or guardian of the child, and the child if he or she is capable of understanding. The Minister may not give consent if the research or experimentation poses a significant risk to the health of the child.

In terms of Section 71(3) (a) (ii) of the National Health Act (NHA) the consent to 'non-therapeutic' health research with minors by the Minister of Health is required, but only after considering whether the following four criteria are met:

- in such a manner and on such conditions as may be prescribed;
- with the consent of the Minister;
- with the consent of the parent or guardian of the minor; and
- if the minor is capable of understanding what the meaning of the consent of participating in the research means.

The Minister may delegate authority, in terms of section 92(a) of the Act, to any person in the employ of the state, a council, board or committee established in terms of the Act to give this consent on behalf of the Minister.

To provide guidance to health Research Ethics Committees (REC's) and researchers regarding this delegated authority, Operational Guidelines entitled "Ministerial Consent for Non-Therapeutic Health Research with Minors", have been published by the National Department of Health in 2015. **A copy of the Operating Guidelines is attached to this SOP for ease of reference for researchers.**

Regulations for research with human participants, published on 19 September 2014 (R 719) contain Form A that sets out the four criteria mentioned above to be met for the additional review of 'non-therapeutic' health research with minors. Proper use of Form A should provide adequate evidence that these reviews are performed appropriately.

The NHREC Guidelines provide that RECs with delegated authority to grant Ministerial Consent must draw to the attention of researchers the following requirements:

- That researchers must consider carefully whether their planned research involving minors holds out the prospect of direct benefit to participants ('therapeutic research'); or whether it holds out no prospect of direct benefit to participants but holds out the prospect of generalisable knowledge ('non-therapeutic research');
- That 'non-therapeutic' research must meet the four criteria mentioned above to be eligible for Ministerial Consent;
- That the ethics application for 'non-therapeutic' health research with minors must include Form A completed appropriately;
- That where the REC judges that the research involves 'non-therapeutic' health research with minors, this view will be communicated to the researcher with a request to complete Form A accordingly;

- That the content supplied in Form A should draw on relevant sections of the protocol or ethics application, for example, the sections that deal with the scientific justification for enrolling minors; how knowledge will be advanced by enrolling minors; the benefits to society in terms of knowledge gained by enrolling minors; and the potential risks to enrolled minors and risk minimisation;
- That the outcome (whether consent for non-therapeutic health research with minors is granted) will be communicated by the REC, as part of the overall feedback about the application;
- That 'therapeutic' health research with minors does not require this additional review but is reviewed in the usual way to ensure norms and standards are met.

The FPDREC would only grant approval, with Ministerial Consent, after review of the application leads to the decision to grant ethics approval, and the careful review of Form A satisfies the Committee that the four criteria have been met.

Specific records of applications, and the outcomes, will be kept by the Committee and reported on. A traceable link to each application will be maintained.

Research involving children should respect their evolving capacity to give consent. Minors who turn 18 years old during the course of a study should be approached at the time of their birthday to re-consent in their own right.

Researchers should also familiarise themselves with the legal obligations to report child abuse and neglect.

PARTICIPANT INFORMATION AND INFORMED CONSENT

Requirements

Complete participant information and informed consent documents must be submitted for each protocol. If applicable, consent and assent documentation for participants who are minors (children under the age of eighteen (18) years, but older than seven (7) years) should be submitted.

It is recommended that the Information Sheet and Informed Consent template developed by the FPDREC be use as a guide to complete the participant information sheet and informed consent document. A copy of the template is attached for ease of reference.

The NHREC Guidelines (pages 28 and 29) stipulate as follows where vulnerable participants are concerned:

Vulnerability may be caused by limited decision-making capacity, or limited access to social goods, such as health care, education, or social support. Individuals or groups may experience vulnerability to different degrees and at different times, depending on prevailing circumstances. Vulnerability is assigned to minors (persons <18 years) by the law to protect them from their lack of experience and knowledge. It is expected that life changing decisions are made with the knowledge and assistance of their parents or guardians.

Persons may be factually incapable or less capable of understanding information and processing it to reach a decision about whether to participate in research. For example, this may occur because of brain damage or the effect of the aging process.

It is important to note the difference between legal incapacity and factual incapacity. No person may claim that, because a minor is factually capable, their legal incapacity should be waived. Legal incapacity prevails notwithstanding the existence of factual capacity.

On the other hand, no adult may be assumed to be incapable unless incapacity is established factually. Consequently, mental incapacity must be established by a factual assessment of the individual’s abilities to understand and to communicate that understanding.

Historically, vulnerable groups and individuals in the research context have included children, the elderly, students, women, inmates, individuals with mental health problems, and those with diminished capacity for decision-making or self-determination. Vulnerable individuals or groups require careful consideration to ensure that, where appropriate, additional precautions are put into place so that adequate protection of their rights and welfare interests occurs.

In South Africa, researchers must be particularly aware of the vulnerability of prospective participants in terms of access to health services and education levels. Research details must be provided in a clear, simple, and culturally appropriate manner. If a participant lacks capacity to exercise an informed choice to participate, an appropriate person to make the choice for them must be identified by the investigator. A participant is free at any time to withdraw consent to further involvement in the research, without having to face any unfair negative consequence or disadvantage.

The following essential elements must be understood and appreciated before a participant is capable of giving informed consent:

- That consent is being given freely to participate in research;
- The purpose of the research is clearly understood;
- The expected duration of the participant’s involvement in the research is given;
- A description of the procedures to which the participant will be subjected, including any experimental procedures that are innovative and have not been used in medical practice is provided.

The informed consent document should be written in clear and understandable language and prospective participants should be helped to arrive at an informed decision by, for instance, the use of appropriate language, selection of a non-threatening environment for interaction, and the availability of peer counselling.

Participants may find information about the following points useful:

- The investigators' qualifications;
- Explanation of participants' responsibilities;
- Description of foreseeable risks or discomforts;
- Description of benefits to the participants or to others, both during and after the research;
- Disclosure of alternative procedures or courses of treatment;
- Description of the extent to which confidentiality will be maintained;
- Statement that sponsors of the study may be able to inspect research records;
- Statement that the research has been approved by an accredited research ethics committee;
- Contact details of research ethics committee representatives;
- Explanation regarding compensation for research-related injuries;
- Explanation regarding the consequences of injury, including medical treatments;
- Explanation of who to contact in the event of research-related injury;
- Statement that participants' data may be added to a big database of journals/funders/researchers/sponsors. Participants may decline consent to data sharing;
- Statement that data, including audio recordings, will be retained for at least five (5) years before being destroyed;
- Statement on benefit sharing.

Investigators must further assure potential participants that participation is voluntary, and that refusal to participate, or a decision to discontinue participation, will not involve any form of penalty.

The following disclosures are important and should be explained:

- The approximate number of participants;
- The nature of experimental and control groups and circumstances that might lead to the termination of participation;

- Unforeseeable risks obviously cannot be anticipated, but the nature and extent of risks – including financial risks – attendant on participation;
- Participants’ right to be informed of relevant new findings, and of the consequences of their withdrawal from research;
- Whether the investigator might terminate participation.

Educational materials should be developed where possible. The above points may be regarded as essential elements of informed consent, and all should be incorporated in an informed consent form or document. Informed consent is a vital requirement in ethical conduct of research and is valid only when it is obtained without deceit or misrepresentation. The informed consent requirements are not intended to pre-empt the laws of the country, which may require that additional information be provided to participants.

In particular the Committee requires the following information on the informed consent process with each new application:

- A description of the process for obtaining informed consent, including the process for ascertaining understanding and appreciation of the information provided. The adequacy, completeness, and understandability of written and oral information to be given to the research participants, and when appropriate, the legally acceptable representatives of proposed participants. Clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent for such individuals;
- Assurances that research participants will receive information that becomes available during the course of the research relevant to their participation;
- The provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project;
- In all instances verbal and/or written informed consent, and assent in the case of minor participants, should be obtained;
- Verbal consent, where the participant is illiterate, should be obtained in the presence of and countersigned by a literate, independent witness confirming that all the relevant information was provided to the research participant in an understandable manner. The participant must put her/his thumbprint on the document as evidence that s/he consents to the study;
- For minor participants under the age of 18 years, consent from the parent or legal guardian must be sought.
- In addition to the consent of the parent or legal guardian, assent must also be obtained from the minor participant if the minor is capable of understanding.

Maturity, psychological state of mind and age should be taken into account. Special care should be taken to create an informed consent document that will be understandable to minors. Where a minor is not competent to consent, assent from the minor may be obtained. However, in all such cases, the protocol must provide sufficient information outlining the steps that will be taken to obtain the child's assent and how it will be documented.

- Following approval of original English versions, all translations with authenticity certificates (or other method used to confirm accuracy) must be submitted to the Committee for information and filing;
- Information regarding the insurance for the study should be included if applicable.

PROTOCOL AMENDMENTS AND RE-SUBMISSIONS

Major deficiencies will usually result in a refusal to approve the protocol or amendment. A new submission will have to be made.

Minor deficiencies in the submission of a protocol or an amendment will result in conditional approval with a request for changes or additional information.

An amendment to a protocol could be any of the following:

- a change that is administrative in nature;
- has an impact on the safety or integrity of the participants;
- alters scientific value of the research or interpretation of the results;
- affects validity of data, the design of the study or planned statistical analyses; or
- significantly alters other aspects of the research.

The nature and examples of minor and major amendments are discussed above. Protocol amendments received will be tabled as part of the agenda at the next Committee meeting for review by the full Committee unless the amendments are of such a nature that the EXCO can review them.

Administrative amendments may be approved by the Committee Secretariat in consultation with the Chairperson.

The following documentation relating to amendments should be submitted to the Committee timeously as determined by the ongoing processes linked to ethics reviews and amended from time to time as recommended by the Secretariat to streamline applications and minimise delays:

- Cover letter explaining the nature of and reason for the amendment;

- Application form that includes a justification for each amendment;
- Revised protocol with tracked changes;
- Revised informed consent document with tracked changes;
- Any other relevant material that was revised with the amendment.

ADVERTISEMENTS

The content of any advertisements or public notices which will be used to recruit participants to a study must be submitted to the Committee for review and approval and should comply with the following guidelines:

- The advertisement should be in line with the NHREC Guidelines template for advertisements;
- The advertisement may be published in any medium, printed or electronic, including the internet and television, provided all the rules pertaining to advertisements as laid down in this document are adhered to;
- There are no limitations on the size or number of times a notice may be published;
- Purpose of the research and a summary of eligibility criteria;
- Straightforward and truthful description of the benefits to the subject, if any;
- Direct mailing of advertisements is permissible;
- Bulk distribution is not permissible;
- Advertisements may be made available for issue individually to existing patients at the rooms of health care professionals and also at local information centres;
- That the study protects participants' rights to privacy.

ONGOING MONITORING AND REVIEW

The FPDREC evaluates ongoing research that it has previously approved.

Six monthly status reports should be submitted to the Committee by the Principal Investigator (PI) in writing. Status reports must be completed per site and must be signed and dated by the Principal Investigator. The status report should include the following information:

- The number of participants entered per site;

- Any changes in the research design including methodology. Any envisaged change in the study design or methodology that has potential or actual ethical repercussions must first be approved by the FPDREC;
- 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;
- The number of withdrawals and the reason for the withdrawals per site;.
- Any relevant new information;
- All relevant line listings;
- Community engagement outcomes;
- Reports of any adverse event, 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 the occurrence of the event;
- 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.

Failure to submit status or progress reports or applications for renewal will lead to deregistration of the study.

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. All terminations of approved research projects will be documented and recorded.

In conducting continuing review, all members will receive and review a protocol summary and a status report on the progress of the research at the sites approved by the Committee.

At the end of the study a final close-out report must be submitted for each site.

The Committee generally does not evaluate high risk studies, but should high-risk studies be submitted for review, the Committee will conduct active monitoring in addition to the ongoing passive monitoring.

Refer to the attached SOP 'ACTIVE MONITORING OF HIGH-RISK STUDIES'

REVIEW FEES

A standard review fee may be charged for external research protocols or research which is externally funded. The fee is payable upon submission of the proposal for review. The fee structure is set by FPD in consultation with the Committee from time to time. Monies thus collected may be spent on the operation of the FPDREC.

RECORDING AND ARCHIVING OF DECISIONS

The FPDREC will maintain a record of all research protocols received and reviewed. The Committee will retain on file a copy of each research protocol and application submitted for approval. The file will include information sheets, consent forms and relevant correspondence, all in the form in which they were approved. A list will be kept of the Committee members who were present during discussion of the application and when the final decision of the Committee was reached. The Committee will retain one set of all submitted documents related to applications for a period of at least 5 (five) years, following the completion of a study. This will include electronic and hard copies of the documentation.

COMPLAINTS AND SUSPENSION OR DISCONTINUATION OF RESEARCH

The FPDREC takes ethics and ethical standards very seriously. Any complaint of misconduct in research must be made to the Chairperson of the FPDREC for an initial assessment of the nature and severity of the complaint. All complaints will be investigated as directed by the FPDREC Chairperson and complaining parties will receive a response from the Committee.

The contact details of the Committee Chairperson and Secretariat are available to all research participants, community stakeholders and researchers in the event that they wish to forward a complaint. These contact details may be accessed on the FPD website: https://www.foundation.co.za

Where the Committee is satisfied that circumstances have arisen that a research project is not being conducted in accordance with the approved protocol and that the welfare or rights of participants are being compromised, the Committee may withdraw approval after following the process as provided for in the SOP.

The Committee will inform the researcher and/or sponsor of its action and will recommend discontinuation or suspension. In such instances, the researcher must discontinue the research and comply with any special conditions required by the Committee. Principal Investigators should document the Committee's withdrawal of the study approval and report this to the relevant regulatory authorities / sponsors / collaborators.

If the matter remains unresolved at FPDREC level, it will be escalated via the FPD complaints process. If the matter cannot be resolved at FPD level, it could be escalated to the NHREC, but internal remedies should be exhausted before the matter is brought to the NHREC.

MULTI-CENTRE AND INTERNATIONAL COLLABORATIVE RESEARCH

If research is conducted at more than one site in South Africa, with the PI and Co-PIs from different institutions resulting in the involvement of another registered RECs, either that REC or FPDREC may be the designated Committee of Record for that study. The FPDREC and the other REC must be in agreement upfront. This will be determined on a case-by-case basis.

To prevent unnecessary duplication of work, FPDRECs may, at its own discretion, recognise the review and approval of a research protocol granted by another registered South African REC. Reciprocal recognition means that two or more registered RECs decide to recognise each other's review.

Research involving Multi-institutional research with external bodies (e.g. laboratories/institutions/universities) in 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. International studies that will be conducted in South Africa must have a local Principal Investigator. The researchers will seek legal guidance regarding the agreements governing the research grant and submit it with their application.

The Committee will review all applications from the perspective of South African law, under which the Committee operates and is held accountable.

If the country where the research is being conducted has an ethics review system or research ethics committee, that committee must also approve the research. If no ethics review system exists in that country the FPDREC may review the application provided the NHREC has been advised and the host country does not object. The contact details on the informed consent forms must be local numbers. An email address of the South African PI must be included.

There are challenges to approving research in another country, e.g., monitoring, regulatory issues, payment of participants, requirements regarding informed consent for children or parental consent, etc. In international collaborative research the parties are host country institutions, collaborating country institutions, researchers from both, research participants and/or communities. 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. 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).

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

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

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

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

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.

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 deprivation through poverty.

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, 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. A Data Sharing/Transfer Agreement template is available from the Secretariat.

PRIVACY, ANONYMITY AND CONFIDENTIALITY

The NHREC Guidelines state that a research participant has the right to privacy and to confidentiality meaning that access to personal information directly or via third parties without consent of the participant is not permitted. Therefore, a proposal must explain how these constitutionally protected rights will be managed and protected during the research.

Privacy concerns the participant's control over who has access to their personal information and records, including clinical health care records; while confidentiality is about the appropriate measures that will prevent disclosure of information that might identify the participant (inadvertently or not) either during the research or afterwards.

The Protection of Personal Information Act, Act 4 of 2013 (POPI Act) has increased need to ensure computer safety, locked record storage facilities and careful gate keeping about access to raw data including completed informed consent documents. All research studies must comply with the provisions of the POPI Act.

Researchers should take measures to ensure protection of privacy and confidentiality interests throughout the research period, including when disseminating results or findings. Bear in mind, however, that if a participant wishes to be identified, this should not be denied without consideration of possible ethical implications and providing appropriate advice. All research participants, therefore, have the right to privacy to the extent permitted by law. However, in certain cases the law allows for the right to privacy to be overruled, for example, it is obligatory to report child abuse cases to the appropriate authorities in terms of the law.

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.

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.

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 for 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).

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 format in which the individuals could be identified.

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.

Researchers should make appropriate arrangements for the preservation and confidentiality of research records for five years after the submission of the report or results.

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.

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.

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.

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).

Participants' consent should be sought where data identifying them is 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.).

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

DATA SHARING

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.

Data which does not identify participants, and which are in the form of anonymous 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 public.

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.

Research data should be maintained by the researchers for at least five (5) years after the end of the study.

If indicated researchers should submit Data Sharing/ Transfer Agreements where data is transferred or shared with a third party.

Refer to the FPDREC DATA SHARING AGREEMENT TEMPLATE.

REPORTING AND PUBLICATION OF RESEARCH RESULTS

Investigators have an obligation to disseminate research results, whether positive or negative, in a timely and competent manner. It is, however, important that the release of research findings be done in an ethical manner, to ensure that false expectations are not raised in a vulnerable population. 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.

Requests to withhold findings, to change or tone down the content of a report are not acceptable in good ethics practice. However, sponsors or stakeholders should be afforded the opportunity to comment on research findings prior to publication, without any entitlement to veto, change the conclusions, or unreasonably delay publication of results. In collaborative research with pharmaceutical or other companies, the conditions of publication should be spelt out clearly in the protocol. The Committee should be satisfied that there is no interference with the right to publish results. Participants should always receive the results prior to the public release.

If a client/sponsor/funder requires non-publication 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 Committee. If the request not to publish is based on strategic or other reasonable grounds, the Committee may consider non- publication 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.

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

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

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

Aspects regarding authorship should be determined at 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.

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.

PRESS RELEASES

Investigators have an obligation to communicate research results during press releases in an ethically responsible manner.

COMPENSATION AND INSURANCE

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.

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.

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.

Participants have the right to get help and be assisted. Researchers should help participant(s) in cases of adverse consequences 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.

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