

# FOUNDATION FOR PROFESSIONAL DEVELOPMENT (FPDREC) PROTOCOL SUBMISSION GUIDELINES

## Introduction

The FPDREC meets in general every second Tuesday of the month. The closing date for submission of protocols and studies by researchers is fifteen (15) working days before the meeting date. Protocol applications for approval must be submitted in English electronically to the FPDREC Secretariat and must contain all the information set out in this document. Investigators are also referred to the FPDREC Standard Operating Procedures (SOP) for detailed guidelines on the review process followed by the Committee.

The FPDREC Secretariat will screen all applications for completeness and that the correct documentation accompanies the application. Applications with incomplete or incorrect documents will be returned no later than one week after receipt of the application by the Secretariat.

Complete and correct submissions are sent to the FPDREC Scientific Sub-committee which will screen the protocol for scientific soundness before the study is submitted to the FPDREC for review.

## Review

Research proposals need to be scientifically sound in order to be ethical. Peer review is the normative scientific practice for guaranteeing quality in research design. In judging research proposals, the FPDREC would comment on the methodological, technical and ethical soundness of the proposal.

When reviewing a proposal for a research study the FPDREC would consider the following issues:

- 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.

**Documentation to be submitted.**

The following documentation and information should be submitted with the application to review a protocol:

- 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. The process of obtaining informed consent and assessing understanding of the consent information should be included in the protocol.
- Researchers' names, current Curricula Vitae, affiliations, addresses and contact numbers.
- Detail of organisation(s) or institution(s) involved in the study and of any sponsors or funders.
- A summary, synopsis, or diagrammatic representation (flowchart) of the protocol.
- Other pertinent information such a conflict of interests.
- Participant recruitment procedures, education material (e.g., advertisements) and any other written information to be provided to participants.
- Description of the process for obtaining informed consent together with the Information Leaflet.

- Written Informed Consent Form or Assent Form (if applicable) in English and in the language of the potential participant as well as the written version of the Verbal Informed Consent Form (if applicable).
- A list of site details, including the site address and names of the PI, sub-investigators, study coordinators and all other research team members.
- Description and/or amounts of compensation including reimbursements, gifts, or services to be provided to participants as well as a description of any financial costs to participants (if applicable).
- 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.
- Statement agreeing to comply with ethical principles set out in the FPDREC SOP's.
- 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.
- Letter(s) of permission from relevant bodies (if applicable)
- A copy of the study budget (if applicable)
- Detail of funder(s) of study

### **Summary Sheet**

This Summary Sheet must be completed and accompany every submission.

FULL STUDY TITLE


STUDY DURATION

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FULL NAME/S OF PRINCIPAL INVESTIGATOR/S

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ACADEMIC AND PROFESSIONAL QUALIFICATIONS OF INVESTIGTOR/S


CONTACT PARTICULARS OF PRINCIPAL INVESTIGATOR/S

Current addresses	
e-mail addresses	
Telephone numbers	

ABSTRACT OF THE PROPOSAL (word count of 500)

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RESEARCH OBJECTIVES (as stated in the full proposal)

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RESEARCH DESIGN (as stated in the full proposal)

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HOW SHOULD THIS STUDY BE CHARACTERISED? (Please tick all appropriate boxes)

Personal, social, and other relevant information collected direct from participants.	Yes	No
Participants to undergo physical examination <sup>a</sup>	Yes	No
Participants to undergo psychometric testing <sup>b</sup>	Yes	No
Identifiable information to be collected about people from available records (e.g., medical records, staff records etc.).	Yes	No
Other (please specify)	Yes	No

<sup>a</sup> Depending on the nature of the examination, medical or related procedures, the application might need to be submitted to a medical ethics committee.

<sup>b</sup> Please add details on copyright issues related to standardized psychometric tests.

WHAT IS THE AGE RANGE OF THE INTENDED PARTICIPANTS IN THIS STUDY?

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Not applicable Reason:
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IF THE PROPOSED PARTICIPANTS ARE 18 YEARS AND OLDER, IS THE INFORMATION LEAFLET AN INFORMED CONSENT FORM FOR PARTICIPANTS ATTACHED?

Yes	No	Not applicable
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IF THE PROPOSED PARTICIPANTS ARE YOUNGER THAN 18 YEARS, ARE INFORMED CONSENT AND ASSENT FORMS ATTACHED? (In order for minors –younger than 18 years of age- to participate in a research study, parental or guardian permission must be obtained. For minors an Assent Form is required.)

Yes	No	Not applicable
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DO THE INTENDED RESEARCH PARTICIPANTS FALL UNDER THE CATEGORY 'VULNERABLE PARTICIPANTS' AS DESCRIBED IN THE FPDREC SOP'S?

Yes	Please provide details and outline steps to protect such vulnerable groups:
No	

DOES THE PROPOSED STUDY INVOLVE COLLABORATIVE, MULTI-INSTITUTIONAL OR MULTI-COUNTRY RESEARCH? (Please refer to the FPDREC SOPs in this regard)

Research in 1 country only	Please state country:
Research in more than 1 country	Please state countries:
Research to be conducted in 1 institution <sup>c</sup>	Details:
Research is multi-institutional <sup>c</sup>	Please give details:

c. In certain cases, consent is required from the institutions where the research will be undertaken (such as a hospital, clinic, facility, or school) and the relevant National, Provincial and Local health or educational authorities.

DESCRIPTION OF THE PROCESS FOR OBTAINING INFORMED CONSENT (IF APPLICABLE)?

Not applicable. Reason:

DESCRIPTION OF THE RISKS POSED BY THE PROPOSED STUDY WHICH RESEARCH PARTICIPANTS MAY/WILL SUFFER AS WELL AS THE LEVEL OF RISK (IF APPLICABLE) (Please consider any discomfort, pain/physical or psychological problems/side-effects, persecution, stigmatization, or negative labeling. Departments should guide their research on the dimensions of harm and the possibilities of debriefing, counseling and harm reduction.)

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DESCRIPTION OF STEPS TO BE UNDERTAKEN IN CASE OF ADVERSE EVENTS OR WHEN INJURY OR HARM IS EXPERIENCED BY THE PARTICIPANTS ATTRIBUTED TO THEIR PARTICIPATION IN THE STUDY (IF APPLICABLE)

DESCRIPTION AND/OR AMOUNTS OF COMPENSATION INCLUDING REIMBURSEMENTS, GIFTS OR SERVICES TO BE PROVIDED TO PARTICIPANTS (IF APPLICABLE) (Will the participants incur financial costs by participating in the study? Will incentives be given to the participants for participation in the study)?

DESCRIPTION FOR ARRANGEMENT FOR INDEMNITY FOR PARTICIPANTS? (IF APPLICABLE)



PRINCIPAL INVESTIGATOR STATEMENT AGREEING TO COMPLY WITH ETHICAL PRINCIPLES SET OUT IN THE FPDREC SOP's

I ..... (Full name of principal investigator) declare that I have read the FPDREC SOP's and that the contents of this document are a true and accurate reflection of the methodological and ethical implications of my proposed study. I shall carry out the study in strict accordance with the approved proposal and the ethics policy of the FPDREC, and maintain security procedures for the protection of privacy. I shall record the way in which the ethical guidelines as suggested in the proposal have been implemented in my research. I undertake to notify the FPDREC in writing immediately if any changes to the study is proposed, and also if any adverse event occurs or when injury or harm is experienced by the participants attributable to their participation in the study. I will also notify the FPDREC if for whatever reason the study has not commenced or has been stopped. I have taken note of the detail regarding integrity in research as set out in the FPDREC SOP's and have read and understood the Policy for Copyright Infringement and Plagiarism of FPD.

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Signature

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Date