**Summary Sheet**

This Summary Sheetmust be completed and accompany every submission.

FULL STUDY TITLE

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STUDY DURATION

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FULL NAME/S OF PRINCIPAL INVESTIGATOR/S

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ACADEMIC AND PROFESSIONAL QUALIFICATIONS OF INVESTIGTOR/S

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CONTACT PARTICULARS OF PRINCIPAL INVESTIGATOR/S

|  |  |
| --- | --- |
| Current addresses |  |
| e-mail addresses |  |
| Telephone numbers |  |

ASTRACT 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)

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| --- | --- | --- |
| Personal, social and other relevant information collected direct from participants | Yes | No |
| Participants to undergo physical examination a | Yes | No |
| Participants to undergo psychometric testing b | 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 |

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

**b *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 applicableReason: |

IF THE PROPOSED PARTICIPANTS ARE 18 YEARS AND OLDER, IS THE INFORMATION LEAFLET AN INFORMED CONSENT FORM FOR PARTICIPANTS ATTACHED?

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| --- | --- | --- |
| Yes | No | Not applicable |

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.)

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| Yes | No | Not applicable |

 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)

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| --- | --- |
| Research in 1 country only | Please state country: |
| Research in more than 1 country | Please state countries: |
| Research to be conducted in 1 institution c | Details: |
| Research is multi-institutional c | 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)?

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| Not applicable. Reason: |

DESCRIPTION OF THE RISKS POSED BY THE PROPOSED STUDY WHICH RESARCH 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 FOF STEPS TO BE UNDERTAKEN IN CASE OF ADVERSE EVENTS OR WHEN INURY OR HARM IS EXPERIENCED BY THE PARTICIPANTS ATTRIBUTED TO THEIR PARTICIPATION IN THE STUDY (IF APPLICABLE)

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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)?

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

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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 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 Date