**Research and Development Directorate**

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**PROVINCIAL HEALTH RESEARCH AND ETHICS COMMIITTEE (PHREC)**

**APPLICATION FORM FOR ETHICAL CLEARANCE**

**2018**

**SECTION 1: DETAILS OF APPLICANT**

|  |  |
| --- | --- |
| **NAME**: Prof/Dr/Mr/Mrs/Miss/Ms |  |
| **PROFESSIONAL STATUS**  |  |
| **IF STUDENT/FELLOW** (Tick the appropriate code)  | YES/NO |
| **DEGREE APPLICABLE** (Masters/PhD/Post doc/Staff) |  |
| **PRINCIPAL INVESTIGATOR** (Name, Designation, Organisation, Contact details) |  |
| **CO-INVESTIGATORS** (Name, Designation, Organization, Contact details such as Email, telephone, cellphone, fax) |  |
| **INSTITUTION/ORGANIZATION** where applicant registered/employed and full address  |  |
| **ETHICAL APPROVAL**: Does the proposal being granted ethical approval from other institution? | YES/NO |
| If yes, please indicate name of institution and reference No |  |

**Please attach detailed Curriculum Vitae of all Investigators**

**SECTION 2: PROJECT DETAILS**

|  |  |
| --- | --- |
| **1. TITLE OF PROJECT in full** (do not abbreviate) |  |
| **2.TYPE OF STUDY :** Biomedical & Clinical Research=1 Social Science Research=2 Epidemiological Study=3 Policy Management Study=4 Other (specify) =5 |
| **3. STATUS OF REVIEW:** New Revised |
| **4. SPONSOR INFORMATION** :1. South African a) Government Institutional  b) Private Specify details c) International |
| **5.** **TYPE OF STUDY:** National Provincial Specify details |
| **6**. **ETHICAL CLEARANCE:** If the proposal is international or national submitted for clearance from National Department of Health? | Yes/No |
| **7. CONTACT ADDRESS OF SPONSOR (IF ANY):** |
| **8. TOTAL EXPECTED BUDGET** (Rand): |
| **9. DESCRIPTION OF THE PROPOSAL** – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Brief summary of the proposal): |
| **10. RESEARCH PARTICIPANT SELECTION:**1. Number of Subjects :
 |
| 1. Duration of study :
 |
|  iii. Will subjects from both sexes be recruited  |  Yes |  No |
| 1. Inclusion / exclusion criteria given
 |  Yes |  No |
| 1. Type of subjects Non-patients Patients Both
 |
| 1. Specific group of study

Women Children Youth Men Both sexOrphanPLWHAIlliterateAny other (specify)  |
| **11. Privacy and confidentiality** i. Study involves - Direct Identifiers  Indirect Identifiers/coded  Anonymous/delinked |
|  ii. Confidential handling of data by staff  | Yes | No |
| **12. Use of biological/ hazardous materials**   | Yes | No |
|  i. Use of blood | Yes | No |
| ii. Use of body fluids | Yes | No |
| **13. Consent :** Written Oral  i. Consent form : (tick the included elements) Understandable language Purpose and procedures Risks & Discomforts Benefits Compensation for participation Statement that study involves research Confidentiality of recordsStatement that consent is voluntaryRight to withdrawIf written consent is not obtained, give reasons: |
|  ii. Who will obtain consent ? PI/Co-PI Nurse/Counsellor  Research staff Any other (specify) |
| **14. Will any advertising be done for recruitment of Subjects?**  (posters, flyers, brochure, websites – if so kindly attach a copy) | Yes | No |
| **15. Risks & Benefits:** i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?  |  Yes |  No  |
|  ii. Is there physical / social / psychological risk / discomfort? **If Yes,** Minimal or no risk  More than minimum risk High risk | Yes | No |
|  iii.Is there a benefit a) to the subject ?  Direct Indirect  b) Benefit to society  |
| **16. HEALTH RESEARCH ETHICS MONITORING**  i. Has provision been made for ethical evaluation by the Provincial Health Research and Ethics Committee?  | Yes | No |
|  ii. Is there a plan for interim analysis of the process?  | Yes | No |
| iii. Is there a plan for reporting of adverse events? | Yes | No |
| **17. IS THERE COMPENSATION FOR PARTICIPATION?** **If Yes,** Monetary In kind  Specify amount and purpose:  | Yes | No |
| **18. IS THERE COMPENSATION FOR MEDICAL CARE?** **If Yes,** by Sponsor by Investigator by Insurance by any other  company  | Yes | No |
| **19. DO YOU HAVE CONFLICT OF INTEREST?** **(financial/nonfinancial)** **If Yes, specify :** | Yes | No |

|  |
| --- |
| **20. CHECKLIST** **FOR** **ATTACHED** **DOCUMENTS**: Project proposal – 1Copy Curriculum Vitae of Investigators Brief description (abstract) of proposal Participant information sheet Informed Consent form  Copy of questionnaire  Ethical clearance if obtained   |

**Name of Applicant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_**

**Place: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**