**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 sex  Orphan  PLWHA  Illiterate  Any 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 records  Statement that consent is voluntary  Right to withdraw  If 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**