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| HSRC_logoBW | **RESEARCH ETHICS COMMITTEE APPLICATION FORM**  **Human Sciences Research Council (HSRC), South Africa**  Application to the HSRC Research Ethics Committee for ethics review of new/revised research projects | |
| CLEARANCE NUMBER *[for office use only]* | |  |

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| **SECTION A:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **APPLICANT/PRINCIPAL INVESTIGATOR:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Title: / Mr |  | | | | / Ms | | |  | | | / Mrs | |  | | / Dr | |  | | | | / Prof | | |  | | | / Rev | | |  | / Mx | | |
| Name: |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Designation or position in HSRC: | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| Designation if not in HSRC: | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| Affiliation: *(Institution/Research programme/Unit/Centre)[[1]](#footnote-1)* | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | |
| Postal address: | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Contact phone numbers: Office: | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| Mobile number: | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fax number: | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Email address: | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **CO-PRINCIPAL INVESTIGATOR/S :** *(NB! For international applicants, CO-PI must be based in South Africa)* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Title: / Mr |  | | | | / Ms | | |  | | | / Mrs | |  | | / Dr | |  | | | | / Prof | | |  | | | / Rev | | |  | / Mx | | |
| Name: |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Designation: | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| Affiliation: *(Institution/Research programme/Unit/Centre)[[2]](#footnote-2)* | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | |
| Postal address: | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Contact phone numbers: Office: | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| Mobile number: | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fax number: | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Email address: | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Full title of research project: *(Please DO NOT use abbreviations or acronyms)* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Please furnish name of HSRC research programme/unit/centre or name of institution and particular department/ section/centre/unit. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Where will the research be carried out? *(i.e. name the locations and sites)* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Any non-South African sites? *(Please list if applicable)* | Yes |  | No |  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Has ethics approval been applied for at the non-South Africa sites? | Yes |  | No |  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **FUNDING OF THE RESEARCH:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Nature of funding: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Contract | |  | | | | | Grant | | |  | | | | Self | |  | | | | Other | | | | |  | | | | *(If other, please EXPLAIN below.)* | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name of funder: | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Value of contract in ZAR: | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | |
| Date of contract signature: | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | |
| **PURPOSE OF THE RESEARCH:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Not for degree purposes: Degree/diploma *(Please STATE which.)* | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | |
| If for degree/diploma, name the Institution: | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **AIMS AND OBJECTIVES OF THE RESEARCH** *(All the following sections must be completed.)[[3]](#footnote-3)* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Please explain briefly, in lay terms, the rationale for the research, its primary aims & objectives, the selected methodology, sample size and nature of data analysis (Max 800 words). | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **SECTION B:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **1. NATURE AND REQUIREMENTS OF THE RESEARCH** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Is this an extension/further phase of a protocol previously approved by the HSRC Research Ethics Committee? | | | | | | | | | | | | | | | | | Yes | | | | |  | No | | |  | |  | | | | | |
| *(If YES, please PROVIDE approval number and date):* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Note**: The overarching ethics guidance for the HSRC REC is the Department of Health (2015) *Ethics in Health Research: Principles, Processes & Structures* 2nd edition. See <http://www.nhrec.org.za/index.php/grids-preview?download=10:doh-2015-ethics> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |  |
| 1.1 How should this research be characterised? *(Please TICK ALL appropriate boxes.)* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes | No |
| * + 1. Personal and social information to be collected directly from participants | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |  |
| 1.1.2 Participants to undergo psychometric testing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |  |
| 1.1.3 Participants to undergo learner achievement tests | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |  |
| 1.1.4 Identifiable information to be collected about people from available records | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |  |
| 1.1.5 Anonymous information to be collected from available records | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |  |
| 1.1.6 Literature, documents or archival material to be collected on individuals/groups | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |  |
| 1.1.7 Research involves human physical/biological examination or specimens | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |  |
| 1.1.8 Informants to be giving information on identifiable third parties | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |  |
| 1.1.9 Study of documents in the public domain | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |  |
| 1.1.10 Study of sensitive archival documents not in the public domain | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |  |
| 1.1.11 Other | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |  |
| 1.2 Participant Information Sheet[[4]](#footnote-4) attached *(For written and verbal consent.)* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |  |
| 1.3 Participant Informed Consent Form[[5]](#footnote-5) attached | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |  |
| * Written consent form | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |  |
| * Verbal consent | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |  |
| * Informed consent is not necessary? *If so, then STATE why not* : | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |  |
| 1.4 Any questionnaire, interview schedule, observation or focus group schedule or framework for ethnographic study to be used in the research must be attached.  Is it attached?[[6]](#footnote-6) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes | No |
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| **2. PARTICIPANTS IN THE STUDY** | | | | | |
| 2.1 ENSURING FAIR SELECTION OF PARTICIPANTS | | | | | |
| 2.1.1 State where potential participants will be recruited. State geographic location (e.g. Gauteng etc.) and type of place (e.g. school, clinic etc.) | | | | | |
| 2.1.2 Describe any activities and/or consultations (*if any*) with the target population of this study that have preceded or will precede data collection. | | | | | |
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| 2.1.3.1 Participants will be asked to volunteer? | Yes |  | No |  |  |
| 2.1.3.2 Participants will be selected? | Yes |  | No |  |  |
| 2.1.4 Describe in detail the recruitment and selection processes, including who will do the recruitment *(e.g. the researcher should ideally not recruit if they are also the participant’s service provider, to avoid perceptions of recruitment bias)*: | | | | | |
|  | | | | | |
| 2.1.5 What factors may increase the vulnerability of participants or increase their susceptibility to harm? *(e.g., researcher is a service provider to participants; participants are subordinate to the person doing the recruiting; participants are legally or socially marginalised’ members of hierarchical systems, prisoners, persons with mental incapacity etc).* | | | | | |
|  | | | | | |
| 2.1.6 Is the researcher a service provider to participants? | Yes |  | No |  |  |
| 2.1.7 Describe measures to offset the vulnerability of participants and reduce their risk of harm *(e.g. patient advocates, special consent measures).* | | | | | |
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| 2.1.8 Will incentives[[7]](#footnote-7) be offered to facilitate recruitment? (*If YES, describe in detail.*) | | | | | | | | | | | | | | | Yes | | |  | | | No | |  | |  |
|  | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2.1.9 Will participants be reimbursed[[8]](#footnote-8) for costs associated with participation? | | | | | | | | | | | | | | | Yes | | |  | | | No | |  | |  |
| 2.1.10 If reimbursement will be offered, describe the nature of costs to be reimbursed. | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 2.1.11 If reimbursement will be offered, DESCRIBE the amount/method/value of the reimbursement[[9]](#footnote-9) | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 2.1.12.1 What is the age range of the **adult** participants in the study? *(See also informed consent.)* | | | | | | | | | | | | | From | | |  | | | | to | |  | | Years | |
| 2.1.12.2 What is the age range of the **child** (minor) participants in the study? | | | | | | | | | | | | | From | | |  | | | | to | |  | | Years | |
| 2.1.13 Demographic profile of participants *(Check/tick ALL appropriate boxes below.)* | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2.1.13.1 Female | | |  | Male | | |  | | Trans |  |  | | | | | | | | | | | | | | |
| 2.1.13.2 Population group/s: | | | | | | | | | | | | | | | | | | | | | | | | | |
| African |  | Coloured | | |  | Indian/Asian | | | |  | White |  | |  | | |  | |  | | | | | | |
| 2.1.13.3 Language group/s (DESCRIBE which languages & whether translators or interpreters are to be used): | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2.1.14 Intended number of participants: | | | | | | | |  | | and controls[[10]](#footnote-10): | |  | | | | | | | | | | | | | |

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| 2.1.15 Have steps been taken to ensure that gender[[11]](#footnote-11) has been carefully considered in this project? *(Read the footnote)* | | | Yes |  | No |  |  |
| *(If YES, please EXPLAIN steps taken. If NO, please motivate or describe steps to ensure that gender will be taken into account.)* | | | | | | | |
| 2.2 DETAILING RESEARCH INTERVENTIONS AND PROCEDURE *(Tick which research procedure(s) will be used)*: | | | | | | | |
| 2.2.1 Reviews: | | | | | | | |
|  |  | Literature | | | | | |
|  |  | Documentary | | | | | |
|  |  | Personal records  *(If ‘personal records’ is marked, what records, if any, will be used, and how will records be accessed and selected?)* | | | | | |
|  | | | | | | | |
| 2.2.2 Personal information: | | | | | | | |
|  |  | Interviews | | | | | |
|  |  | Survey | | | | | |
|  |  | Participant observation | | | | | |
|  |  | Other *(Describe, e.g. clinical assessment, treatment records)* | | | | | |
|  | | | | | | | |
|  |  | Focus Groups | | | | | |
|  |  | Photographs | | | | | |
|  |  | Audio recording | | | | | |
|  |  | Video recording/film | | | | | |
| *(NB: Justify using visual images and audio recordings, mentioning 1) how such data are to be systematically analysed and 2) whether these are to be treated as raw data only, or whether recorded static images or audio and/or video clips will also be reported/presented in the public domain):* | | | | | | | |
| 2.2.3 Social and related: | | | | | | | |
|  |  | Interview form/schedule *(must be attached)* | | | | | |
|  |  | Questionnaire *(must be attached)* | | | | | |
|  |  | Observation schedule/framework *(must be attached)* | | | | | |
|  | | | | | | | |
| 2.2.4 Biomedical and related *(Examination: State below nature and frequency of examination.)* | | | | | | | |
|  |  | Blood sampling | | | | | |
|  |  | Venous | | | | | |
|  |  | Arterial *(State below amount to be taken and the frequency of blood sampling.)* | | | | | |
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|  |  | Safe storage required? | | | | | |
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| For the following biomedical or related procedures (other than examination and blood sampling), please discuss your proposal with the HSRC REC chair to determine suitability of this committee for your application. | | | | | | | |
|  |  | Biopsy/Gene identification *(Not for HSRC ethics committee.)* | | | | | |
|  |  | Substance administration *(State below name[s] of substance[s] and dose[s] and frequency of administration (not for HSRC research ethics committee.)* | | | | | |
|  | | | | | | | |
|  |  | X-rays *(Not for HSRC research ethics committee.)* | | | | | |
|  |  | Isotope administration *(State below name[s] of isotope[s] and frequency) (not for HSRC research ethics committee.)* | | | | | |
|  | | | | | | | |
|  |  | Other procedures *(Provide details, and indicate clearly whether medical-related.)* | | | | | |
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| 2.3 SPECIFYING AND MINIMIZING POTENTIAL RISKS OF HARM FROM RESEARCH INTERVENTION(S) AND PROCEDURE(S) *(e.g., emotional/psychological harms can include distress, embarrassment, trauma reactivation etc; social harms can include stigma; victimization or adverse publicity; assault due to disclosure of participation or HIV status, etc., legal risks can include discrimination; physical harms can include pain & discomfort, side effects from agents used).* | | | | | | | |
|  |  | Emotional/psychological | | | | | |
|  |  | Social *(e.g. stigma, discrimination, adverse publicity)* | | | | | |
|  |  | Legal | | | | | |
|  |  | Physical | | | | | |
| * List each intervention or procedure in the research, and describe potential harms | | | | | | | |
|  | | | | | | | |
| * Describe the measures to be taken to minimise potential harms | | | | | | | |
|  | | | | | | | |
| * Is the researcher professionally and legally qualified to carry out specific assessment and intervention or other procedures? If not, describe who will carry out the procedure? *(Attach current CV)* | | | | | | | |
|  | | | | | | | |
| * + Does the researcher have a recent research ethics training (within three years)? Describe the nature of the training e.g. online; name of course, etc. (*Attach copies of certificates*) | | | | | | | |
| 2.4 SPECIFYING AND MAXIMISING THE EXPECTED BENEFITS OF RESEARCH INTERVENTION(S) OR PROCEDURE(S) | | | | | | | |
| * Explain the risk of harm and the likelihood of benefit to participants. (See DoH 2015 for guidance): * Describe steps to be taken to maximise benefit to participants: * Describe how feedback on study results will be made avaiable to participants: | | | | | | | |
|  | | | | | | | |
| 2.5 MINORS AND WRITTEN INFORMED CONSENT (PERSONS UNDER THE AGE OF 18 YEARS) | | | | | | | |
| See DoH (2015 chapter 3.2.2) and National Health Act, Section 71   |  | | --- | | http://www.info.gov.za/view/DownloadFileAction?id=68039 | | | | | | | | |
|  | | | | | | | |
| 2.5.1 Explain why the research must involve minors, including how the research problem is relevant to minors. | | | | | | | |
|  | | | | | | | |
| 2.5.2 Information and consent documents for Parent/Guardian attached | | | Yes |  | No |  |  |
| 2.5.3 Information and assent documents for Minor attached | | | Yes |  | No |  |  |
| 2.5.4 Consent to be obtained from parents or guardians? | | | Yes |  | No |  |  |
| *(If YES, describe the circumstances and indicate how this study plans to implement this, include obtaining assent from minors, referring to theDoH 2015 guideline for assistance).* | | | | | | | |
|  | | | | | | | |
| 2.5.5 Consent to be obtained from parental substitutes? | | | Yes |  | No |  |  |
| *(If YES, describe the circumstances and indicate how this study plans to implement this. Refer to the DoH 2015 guideline for assistance).* | | | | | | | |
|  | | | | | | | |
| 2.5.6 Is it anticipated that independent consent by older minors is justifiable  *(i.e. without involvement of parent or guardian)?* | | | Yes |  | No |  |  |
| *(If YES, describe the circumstances and indicate how this study plans to implement this. Refer to the DoH 2015 guideline for assistance).* | | | | | | | |
|  | | | | | | | |
| 2.6 WITHHOLDING OF INFORMATION OR DECEPTION | | | | | | | |
| * Are there any aspects of the research about which participants will not be informed, or about which they will be deceived? | | | Yes |  | No |  |  |
| *(If YES, please justify (e.g., why is this methodologically unavoidable?)* | | | | | | | |
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| * Describe whether participants will be debriefed and how: | | | | | | | | |
|  | | | | | | | | |
| 2.7 DEMONSTRATING ONGOING RESPECT FOR ENROLLED PARTICIPANTS | | | | | | | | |
| * How will *ongoing consent to participate* be affirmed? | | | | | | | | |
| * How will *confidentiality* be maintained to ensure that participants/patients/controls are not identifiable to persons not involved in the research?[[12]](#footnote-12) | | | | | | | | |
|  | | | | | | | | |
| * Are there any anticipated limits to confidentiality that participants and guardians should consent to *(e.g. adolescent disclosures that trigger mandatory reporting requirements? Focus group discussions?)[[13]](#footnote-13)* | | | | | | | | |
|  | | | | | | | | |
| * How will the limits of confidentiality be managed?[[14]](#footnote-14) | | | | | | | | |
|  | | | | | | | | |
| * How will the findings be reported to the research participants, and in what time-frame? | | | | | | | | |
|  | | | | | | | | |
| * Where relevant, will participants be “unblinded”[[15]](#footnote-15)? | Yes |  | No |  | | Not applicable | |  |
|  | | | | | | | | |
| * Where relevant, how will ongoing risks to enrolled participants be monitored? | | | | | | | | |
| * Explain where paper-based information will be stored and who will have access to it while the documents are being worked on and also after that period[[16]](#footnote-16). | | | | | | | | |
| 2.8 RESEARCH PERIOD | | | | | | | | |
| * When will the research commence? | | | | | | | | |
| * The research will have a duration of months from: |  | | (date) to | |  | | (date) | |

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| **3. PRESERVATION AND DISSEMINATION OF RESEARCH DATA** | | | | | | | | |
| 3.1 Will the electronic files be stored in the HSRC’s e-repository[[17]](#footnote-17)? | Yes | |  | No | |  |  | |
| *(If NO, explain why and where it will be stored.)* | | | | | | | | |
|  | | | | | | | | |
| 3.2 Please confirm that the data from the study will be made accessible[[18]](#footnote-18), with due regard for the confidentiality of individual and institutional identifiers and that appropriate information on data sharing has been provided in the participants’ Information Sheets and Consent Forms. | | | | | | | | |
|  | Yes |  | | | No |  | |  |
| 3.3 Is the Data Preservation and Sharing Plan[[19]](#footnote-19) attached? *(Not for external applicants)* | Yes |  | | | No |  | |  |

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| **4. GENERAL** | | | | | | | | |
| 4.1 Has permission of relevant authorities/gatekeepers been obtained? | | | | | | | | |
| Yes |  | No |  | | Not applicable | | |  |
| *(If YES, state name/s of authority/ies and attach copies of approval letters.)* | | | | | | | | |
|  | | | | | | | | |
| 4.2 If this study is planned for an area/population under the jurisdiction of a Traditional Leader as designated in Section 14(6) of the HSRC Act 17 of 2008, has the leader been informed that the study is planned? | | | | | | | | |
| Yes |  | No |  | | Not applicable | | |  |
| 4.3 Does this research involve indigenous knowledge? | | | | Yes | |  | No |  |
| *(If YES, please confirm that this research will comply with Section 14 (3 a and b) of the HSRC Act 17 of 2008 and that appropriate protocols for the transfer and protection of indigenous knowledge are in place)* | | | | | | | | |
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| **5. COSTS** | | | | | |
| There will be financial costs to: | | | | | |
| * Participant | Yes |  | No |  | *(If YES, how will participants be reimbursed)?* |
|  | | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| * Host institution | Yes |  | No |  | | Other |  | *(Explain any box marked.)* | | | | |
|  | | | | | | | | | | | | |
| * Is the research proposal/protocol attached? | | | | | | | | Yes |  | No |  |  |
| * Any other information, e.g. relationship between this application and other approved or pending applications, which may be of value to the Research Ethics Committee should be provided here: | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| Date: | | | | | Applicant’s Signature: | | | | | | | |
| **IF STUDENT RESEARCH, SUPERVISOR MUST CO-SIGN THE APPLICATION** | | | | | | | | | | | | |
| Name: | | | | | Programme/Institution/Department: | | | | | | | |
| Date: | | | | | Signature: | | | | | | | |
| **SIGNATURE: Executive Director/Director/Head/Research Coordinator of Department or Division in which study is conducted, or Line Manager of External Applicant**  *(If the Applicant is also the Executive Director/Director/Head/Research Coordinator of the department/institute in which the study is conducted then an appropriate alternate person must sign on their behalf.)* | | | | | | | | | | | | |
| Name: | | | | |  | | | | | | | |
| Date: | | | | | Signature: | | | | | | | |

1. If not employed by the HSRC, please indicate clearly where correspondence should be sent. [↑](#footnote-ref-1)
2. If not employed by the HSRC, please indicate clearly where correspondence should be sent. [↑](#footnote-ref-2)
3. This requirement holds even if a detailed research proposal detailing the background to the research, the design of the investigation and the methodology, is submitted with the application. **This form must be self-sufficient**. [↑](#footnote-ref-3)
4. Whether written or verbal consent is to be obtained, the HSRC requires a **Participant Information Sheet** written in language understandable to the participant (or guardian) detailing what the participant will be told. This should include the following:(1) investigator introduction; (2) participation is voluntary, and refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled; (3) the participant may discontinue participation at any time without penalty or loss of benefits; (4) a brief description of the research, its duration, procedures and what the participant may expect and/or be expected to do; (5) any foreseeable risks, discomforts, side-effects or benefits; and obligation on researcher to report statutory offences and (6) disclosure of alternatives available to the participant; (7) Investigator’s contact details and the HSRC REC email address ([researchethics@hsrc.ac.za](mailto:researchethics@hsrc.ac.za)) and the 24-hour toll-free ethics complaints telephone number; (8) an explanation regarding access to services to be provided (e.g. counselling) in the event of a negative participant experience. (9) **Focus group consent forms must include an explicit statement that while confidentiality amongst participants will be encouraged, it cannot be guaranteed, so that participants must be advised not to make personally sensitive disclosures.** The Participant Information Sheet may be incorporated into the consent form, or the consent form may be submitted separately. (10) the research data will be archived and used and, if appropriate, shared for secondary research purposes with due regard for the confidentiality of the participant. [↑](#footnote-ref-4)
5. The Informed Consent Form must include a clear statement that the participant is consenting to participate in research rather than to research/treatment that will necessarily provide personal benefit. Any direct personal benefit should be mentioned where this is possible. Importantly, include the statement that the participant is free to refuse participation and may withdraw from the research at any time without prejudicing any benefits or treatment required for existing or future psychological/medical conditions. If this is not made clear, the researcher risks the accusation that consent was obtained by undue inducement or subtle coercion (that is, instead of free voluntary consent, the perception may be that consent was forced). [↑](#footnote-ref-5)
6. Note: (if ‘no’, the application cannot be considered. Alternately, ethics approval should be sought in stages/phases as the instruments are developed, e.g. in action research). [↑](#footnote-ref-6)
7. See DoH 2015 3.1.7 for an explanation of incentives or inducements. [↑](#footnote-ref-7)
8. See DoH 2015 3.1.7 for an explanation of reimbursements. [↑](#footnote-ref-8)
9. See DoH 2015 3.1.7 regarding suitable rates [↑](#footnote-ref-9)
10. Where relevant. [↑](#footnote-ref-10)
11. **The incorporation of a ‘gender perspective’ does not simply mean numerical representation of women, men and transgender people in the research.** A gender perspective is underpinned by the broad principle of gender mainstreaming following the United Nations’ Report of the Economic and Social Council for 1997. A/52/3.18 September 1997, at 28: "Mainstreaming a gender perspective is the process of assessing the implications for women and men of any planned action, including legislation, policies or programmes, in all areas and at all levels. It is a strategy for making women's as well as men's concerns and experiences an integral dimension of the design, implementation, monitoring and evaluation of policies and programmes in all political, economic and societal spheres so that women and men benefit equally and inequality is not perpetuated. The ultimate goal is to achieve gender equality." For the purposes of research “gender” will imply the representation of men, women and transgender people as participants and drivers of research. Additionally, depending on the focus of research, this could also include an analysis of gender roles, sexuality, and sex roles from the perspective of social construction. Justification must be provided if pregnant women are to be excluded from enrolment. [↑](#footnote-ref-11)
12. See DoH 2015 3.1.8 for discussion on confidentiality & privacy interests. [↑](#footnote-ref-12)
13. See DoH 2015 3.1.8 for guidance. [↑](#footnote-ref-13)
14. See DoH 2015 3.1.8 for guidance. [↑](#footnote-ref-14)
15. “Unblinding” implies that participants consented to certain information being withheld on enrolment, on condition that the information is provided at the conclusion of the study. [↑](#footnote-ref-15)
16. The HSRC is required by law to keep all questionnaires and related research documents for a minimum of five years. Documents that have been worked on and are ready to be stored are taken off-site by a provider approved by the National Archives and Records Service of South Africa, and kept in a secure environment until permission has been given for them to be destroyed. Access to these documents is restricted to HSRC personnel and all requests are routed through Information Services. [↑](#footnote-ref-16)
17. Research related documents and data must be securely stored for an indefinite period. The HRSC’s e-repository is the Knowledge Tree software application that provides file storage and sharing facility where all final versions of project documents must be saved. [↑](#footnote-ref-17)
18. Data should be shared in compliance with Section 3 of the HSRC Act 17 of 2008 according to the HSRC’s Data Sharing Policy [↑](#footnote-ref-18)
19. The HSRC’s data preservation and sharing policies require that data preservation and sharing be explicitly catered for in a Data Preservation and Sharing Plan. [↑](#footnote-ref-19)