**HEALTH SCIENCES RESEARCH ETHICS COMMITTEE**

**APPLICATION: CONTRACT/CLINICAL RESEARCH NEW PROTOCOL**

**INSTRUCTIONS**

|  |
| --- |
| * Please note that outdated application forms will not be accepted. Reference the [**HSREC webpage**](http://health.ufs.ac.za/content.aspx?uid=13) for all current documentation.
 |

1. **GENERAL INFORMATION**

|  |  |
| --- | --- |
| **Protocol Title:** |  |
| Is this a sub-study linked to an existing main study? | [ ] Yes  | [ ] No  |
| *If Yes, please provide the ethics reference number:* |  |

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| --- | --- | --- |
| **Has this protocol been submitted to another human research ethics committee? (tick** ✓**)** | [ ] Yes  | [ ] No  |
| *If yes, please complete:* | **Name of Institution** | **Outcome** |
|  |  |
|  |  |

1. **INVESTIGATOR(S) PROFILE**

|  |
| --- |
| **2.1 PRINCIPAL INVESTIGATOR**  |
| **Title, Initials, Surname:** |  |
| **Department/Institution:** |  |
| **Phone:** |  |
| **E-mail address:** |  |
| **Department/Office Internal Mail Address for Correspondence:** |  |
| **Professional Registration:** (tick ✓) | [ ] Yes  | [ ] No  | **Registration #:** |  |

|  |
| --- |
| **2.2 UFS PRINCIPAL INVESTIGATOR (if different to 2.1 above)** [ ] N/A  |
| **Title, Initials, Surname:** |  |
| **Department/Institution:** |  |
| **Phone:** |  |
| **E-mail address:** |  |
| **Department/Office Internal Mail Address for Correspondence:** |  |
| **Professional Registration:** (tick ✓) | [ ] Yes  | [ ] No  | **Registration #:** |  |
|  |  |
| **2.3 COLLABORATING INVESTIGATORS** [ ] N/A ***Note:*** *Staff and students involved in the research must be listed as co-investigators* |
| **Title, Initials, Surname:** | **Department/Institution** | **E-mail** |
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| **2.4 IS THIS PROTOCOL FOR DEGREE PURPOSES? (tick** ✓**)** |
| [ ] Yes  | [ ] No  |
| *If yes, please specify* Name of degree*:* |  |
| **2.4.1 SUPERVISOR(S):** [ ] N/A  |
| **Title, Initials, Surname:** | **Department** | **E-mail** |
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1. **FUNDING AND GRANT INFORMATION (Required)**

***Note****: It is mandatory to include a summary budget in your application*

|  |  |
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| **3.1 What is the total budget for this study?** |  |
|  |  |
| **3.2 Funding source** | **(tick ✓ at least one)**  |
| UFS (e.g. departmental funding / student research )  | [ ]  |
| National grant funded research (e.g. NRF, MRC, CSIR, etc) | [ ]  |
| International grant funded research (e.g. Wellcome Trust) | [ ]  |
| Federally funded / Foundation sponsored / Private Institutions (**BELOW R1m**)  | [ ]  |
| Federally funded / Foundation sponsored / Private Institutions (**ABOVE R1m**) | [ ]  |
| Pharmaceutical / Industry Driven company sponsors an investigator to conduct a new research project | [ ]  |
| Pharmaceutical / Industry Driven Additional ClinicalSite / Extension study  | [ ]  |
| No funding/sponsor 🡪 skip to 3.6 | [ ]  |

|  |  |
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| **3.3 Into what entity will the funding be paid?** |  |

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| 3.4 Sponsor details  |
| *For invoicing purposes, please provide:* |
| Sponsor Name |  |
| Company Registration Number |  |
| VAT registration number |  |
| Postal address |  |
| Physical address |  |
| Fax number |  |
| Contact person/monitor |  |
| Contact number |  |
| Email Address |  |
| Purchase order number (if applicable) |  |

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| --- |
| * 1. **Are there any restrictions or conditions attached to publication and/or presentation of the study results?** **(tick** ✓**)** *(Note that any such restrictions or conditions contained in funding contracts must be made available to the Committee along with the proposal)*
 |
| [ ]  Yes  | [ ]  No  |
| *If yes, please explain:* |  |

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| --- |
| * 1. **Will additional costs be incurred by the institution where research is being conducted?**
 |
| [ ]  Yes  | [ ]  No  |
| *If yes, please specify:* |  |

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| --- |
| * 1. **Will participants receive any remuneration?** [ ]  N/A
 |
| [ ]  Yes  | [ ]  No  |
| *If yes, please specify:**(e.g. monetary)* |  |
| *If yes, explain what the remuneration is for:* |  |

1. **PROTOCOL PROFILE**

|  |  |
| --- | --- |
| **4.1 Anticipated start and end date of data collection** |  |
| **4.2 Category of research**Please select an appropriate category for your protocol. If the protocol falls in more than one category please designate a primary and secondary category by entering a ‘1’ and a ‘2’. |
| Medical intervention/ clinical trial (e.g. medicines, traditional or complementary medicines, nutriceuticals, devices or innovations) | [ ]  |
| Behavioural/ psychosocial interventions (e.g. comparison of counselling programmes) | [ ]  |
| Epidemiology/ observational study (e.g. survey, prevalence, case control, cohort studies) | [ ]  |
| Quality improvement | [ ]  |
| Testing new technologies | [ ]  |
| Medical record review, audit | [ ]  |
| Establishment of a specimen repository, medical data base/ registry | [ ]  |
| Clinical laboratory studies | [ ]  |
| Clinical laboratory studies (DNA related) | [ ]  |
| Qualitative research (e.g. focus groups, in-depth interviewing, ethnography) | [ ]  |
| Pilot study | [ ]  |
| Other. Please describe: |  |

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| --- | --- | --- |
| **4.3 Does the study involve innovative therapy?***Innovative therapy is a newly introduced or modified therapy with unproven effect or side effect, and is being delivered in the best interest of the patient. While there are clear distinctions in the aims of research and care, innovative therapy is experimental in nature and may involve data collection, similar to that for research. The HSREC needs to determine whether the planned intervention classes as research.* | [ ]  Yes  | [ ]  No  |
| Please describe the innovative therapy: |  |

|  |  |
| --- | --- |
| **4.4 Does the Research involve Human Participants?***Please note: for retrospective data review involving human participants, this section must also be completed.*  | [ ]  Yes [ ]  No  |
| *If* ***No****, continue to Section 5* |
| **4.4.1 Category of participants** | [ ]  Adults | [ ]  Minors (<18 years).  |
| **4.4.1.1 Are any of the following vulnerable populations included in your protocol? Please check [✓]** [ ]  N/A |
| [ ]  | Minors (children and adolescents)  | [ ]  | Persons highly dependent on medical care  |
| [ ]  | Pregnant women, foetuses, neonates | [ ]  | Persons with physical disabilities  |
| [ ]  | Adults with incapacity to provide informed consent  | [ ]  | Prisoners  |
| [ ]  | Persons in dependent relationships  | [ ]  | Other, please specify:  |  |
| * + - 1. **If conducting research with any vulnerable group, what is the justification?** *(Please explain)*
 |
|  |
| * + 1. **What is the age range of participants in the study?**
 |  |
| **4.4.3 Estimated number of participants** *(for multi-center studies, only for the local site)* |  |
|  |  |
| **Research with Minors** [ ]  N/A |
| **4.4.4 Is the research considered ‘non-therapeutic’ i.e. does not hold out the likelihood of direct benefit to the minor participants?** | [ ]  Yes | [ ]  No | [ ]  N/A |
| *For “Non-therapeutic” health research with minors, as part of the statutory requirements, Form A (NHREC Operational Guidelines for Ministerial Consent: v19 Feb 2015) must be completed and must accompany your application.* *Non-therapeutic research is classified as research that includes interventions that do not hold the prospect of direct health-related benefit to the participant but may produce results that contribute to generalisable knowledge.*  |
|  |
| **Procedures** |
| **4.4.5 Please check [✓] the appropriate box below** |
| Record review/checklist | [ ]  |
| Structured interview/questionnaire (must be attached)/checklist (must be attached) | [ ]  |
| Self-administered questionnaire (must be attached) | [ ]  |
| Examination (state below at explanation: nature and frequency of examination) | [ ]  |
| Drug or other substance administration  | [ ]  |
| X-rays (approval from the Radiation Committee required) | [ ]  |
| Isotope administration (state below at explanation: name, dose, and frequency) (approval from the Radiation Committee required) | [ ]  |
| Blood sampling; □Venous; □Arterial (state below at explanation: Volume to be taken and the frequency of sampling) | [ ]  |
| Biopsy | [ ]  |
| Focus groups/In depth interviews/nominal group technique | [ ]  |
| Radiotherapy (approval from the Radiation Committee required) | [ ]  |
| Other procedures, *specify* |  | [ ]  |
| **4.4.6 Is / are procedure(s):** *(Please check [✓] all that apply)* |
| Routine for diagnosis / management? | [ ]  |
| Specific to this research? | [ ]  |
| * + 1. **Who will carry out the procedure(s)?** *(Give names, qualifications, expertise with procedures below)*
 |
|  |
| * + 1. **Risks of the study procedures** *(Please check [*✓*] all that apply)*
 |
| [ ]  | Minimal / No risk | [ ]  | Physical discomfort |
| [ ]  | Pain | [ ]  | Possible complications |
| [ ]  | Side effects from agents used | [ ]  | Breach of confidentiality |
| [ ]  | Possible stigmatisation | [ ]  | Psychological stress |
| [ ]  | Other: *Specify* |  |
| **4.4.9 If you checked any of the above except ‘no risk’ please provide details:** |
|  |

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| **Recruitment** |
| **4.4.10 Please describe where and how recruitment will take place and who will be recruited?** |
|  |
| **4.4.11 Who will be responsible for recruiting participants in this study?*****Note:*** *if the clinician involved in standard of care, will be involved in this study and the recruitment of participants, please explain how the potential for therapeutic misconception will be minimized or avoided.* |
|  |
|  |
| **Genetic studies and the storing of genetic material** |
| **4.4.12 Will genetic material be collected as part of the study?** | [ ]  Yes[x]  No |
| If **No**, continue to question 4.4.15 |
| *If yes, has a separate consent form been included in your application?* | [ ]  Yes[ ]  No |
| **4.4.13 Will genetic material be stored for future use or future testing as part of the study?** | [ ]  Yes[ ]  No |
| *If yes, has a separate consent form been included in your application?*  | [ ]  Yes[ ]  No |
| *Provide the location of the storage facility:* |
|  |
| *Type of specimen to be retained:* |
|  |
| *Where will investigations be performed:* |
|  |

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| **4.4.14 Do you anticipate exporting samples/data to other site(s), locally or internationally** | [ ]  Yes[ ]  No |
| *If yes, please provide a justification:* |
|  |
| *Has a draft Material Transfer Agreement (MTA) been included in your application?* | [ ]  Yes[ ]  No |

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| **Language**  |
| **4.4.15 Will non-English speaking/non-English fluent participants be enrolled in the study? (tick** ✓**)** |
| [ ]  Yes | [ ]  No | [ ]  N/A |
| If Yes, please **tick ✓** what measures will be used to promote participants’ and families’ understanding: |
| 4.4.15.1 Written translation of consent/ assent forms and information documents into Afrikaans | [ ]  |
| 4.4.15.2 Written translation of consent/ assent forms and information documents into Sesotho | [ ]  |
| 4.4.15.3 Written translation of consent/ assent forms and information documents into other languages | [ ]  |
| 4.4.15.4 Use of trained translator(s)/ interpreter(s) | [ ]  |
| If Yes to 4.4.15.4 above, please explain the criteria for selecting above mentioned: |
|  |
| *Please specify below and describe how the investigators intend to explain the study to potential participants and ensure their understanding:* |
|  |

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| --- |
| **Confidentiality** |
| **4.4.16 What measures will be taken to protect confidentiality? (tick** ✓**)** |
| Paper-based records will be kept in a secure location and only accessible to personnel involved in the study | [ ]  |
| Computer-based records will only be available to personnel involved in the study through the use of access privileges and passwords | [ ]  |
| Personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information | [ ]  |
| Personal identifiers will be removed from research-related information | [ ]  |
| Encryption | [ ]  |
| Audio and/ or video recordings will be transcribed and then destroyed to eliminate identification of participants | [ ]  |
| Use of pseudonyms | [ ]  |
| Participants in focus groups will be advised that confidentiality cannot be assured | [ ]  |
| Other. *Please specify:* |  |

|  |  |
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| **4.4.17 Which authority will be approached for institutional approval?** |  |

**Note:**

* If the research is to be conducted at a site requiring administrative approval/consent (e.g., a hospital, clinic, or school), it is the responsibility of the researchers to determine what other means of approval are required, and to obtain approval prior to starting the project.
* **If interviewing UFS staff and/or students:** Please obtain permission from UFS Authorities by completing the Approval from UFS Authorities form (HSREC 17) available on the [HSREC webpage.](http://health.ufs.ac.za/content.aspx?uid=13)

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| **4.4.18 Location(s) of the study**: (Please supply name of the research unit / site and/orhospital/institutionand particular department as applicable) |
|  |

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| --- | --- |
| **4.4.19 Will biohazardous material be involved in the project***“Biohazardous material” refers to recombinant DNA molecules, viruses, fungi, parasites, bacteria and all other potentially biohazardous material or products that are dangerous to the research participant, the researcher and/or the environment.* | [ ]  Yes[ ]  No  |

|  |  |
| --- | --- |
| **5.1 Is this protocol an intervention trial?** (tick ✓): *If* ***No****, continue to Section 6* | [ ]  Yes[ ]  No |
| This section must be completed **only** if the research involves a clinical trial of drugs/ medicines, herbal, complementary indigenous therapies; or a substance testing a clinical outcome, therapeutic devices; an innovative therapy or intervention; off-label use or a departure from standard treatment or care. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.’ |

1. **INTERVENTION TRIALS**

|  |  |
| --- | --- |
| **5.2 Drug/product name:** [ ]  N/A |  |
| *Manufacturer name:* |  |
| *Country of manufacture:* |  |
| **5.2.1 Washout period, if applicable:** |  |

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| --- | --- | --- | --- |
| **5.3 Is the product registered with the Medicines Control Council (MCC)?** (tick ✓) | [ ]  Yes | [ ]  No | [ ]  N/A |
| *If Yes, please provide the registration number* |  |
| *If No, is the MCC’s approval letter for use of an unregistered medicine attached?****Note:*** *HSREC approval must be obtained prior to study commencement.* | [ ]  Yes | [ ]  No |
| [ ]  Application submitted  |
| \*If registered, will the product be studied for an **indication** different to that approved in the SA package insert? | [ ]  Yes | [ ]  No |
| \*If registered, will the product be studied using a **dose** different to that approved in the SA package insert? | [ ]  Yes | [ ]  No |
| \*If registered, will the product be studied using a **formulation** different to that approved in the SA package insert? | [ ]  Yes | [ ]  No |
| \*If registered, will the product be studied using **a route of administration** different to that approved in the SA package insert? | [ ]  Yes | [ ]  No |

***\*Note:*** *If yes to any of the above, MCC approval is required*.

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| **5.4 Does the study involve an FDA-monitored product (drug, device or biological)?** (tick ✓) | [ ]  Yes | [ ]  No |

|  |  |  |
| --- | --- | --- |
| **5.5 Does this trial comply with the Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa, 2nd Edition, 2006?** (tick ✓) | [ ]  Yes | [ ]  No |
| *If no, please justify* |  |

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| **5.6 Care after research**  |
| **Please provide information about the provision of appropriate care or benefits after the study has been completed.** ***Note:*** *In accordance with Helsinki 2013, this must include provision of the investigational product once the study has been completed, for participants that benefit, or a justification as to why investigational product will not be provided.* |
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| --- | --- | --- |
| **5.7 Is the Principal** **Investigator covered by professional liability insurance? (tick ✓)** | [ ]  Yes | [ ]  No |
| If yes, please provide insurance company and number |  |

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| --- | --- |
| **5.8 Is this a multi-center study?** | [ ]  Yes[ ]  No |
| *If yes,* list the other sites involved in this study below as well as the Research Ethics Committees (RECs) who will be performing initial/continuing review: |
| **SITE(S)** | **REC(S)** | **REC Secretariat(s) email address** |
|  |  |  |
|  |  |  |
| ***If this is a multi-center study, the UFS Investigator* *undertakes that he or she is fully conversant with the content of the protocol, understands fully the ethical implications of the protocol, and takes full responsibility for the implementation of the protocol meeting ethical standards.*** |
| Signature of Principal Investigator |  | Date |  |
| Print name |  |

|  |  |
| --- | --- |
| **5.9 Justification for the trial: Has a literature search been done and included?** | [ ]  Yes[ ]  No |
| *If* ***No****, please submit a systematic literature review or meta-analysis as justification of the trial together with statistical evaluations* |

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| **5.10 Study phase:** |
| [ ]   | Phase 1 | [ ]  | Phase 1 and 2 |
| [ ]   | Phase 2 | [ ]  | Phase 2 and 3 |
| [ ]   | Phase 3 | [ ]  | Phase 4 |
| [ ]   | Other, please specify:  |  |

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| **5.11 Intervention type:** |
| [ ]   | Unregistered drug | [ ]   | Registered drug, new indication |
| [ ]   | Registered drug | [ ]   | Gene transfer |
| [ ]   | Device | [ ]   | Procedural |
| [ ]   | Vaccine | [ ]   | Care change |
| [ ]   | Behavioural | [ ]   | Training |
| [ ]   | Stem cell | [ ]   | Treatment |
| [ ]   | Other, please specify: |  |

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| **5.12 Purpose:** |
| [ ]   | Treatment | [ ]   | Education/counselling/training |
| [ ]   | Non-therapeutic (e.g. phase 1) | [ ]   | Diagnostic |
| [ ]   | Prevention | [ ]   | Other, specify |  |

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| **5.13 Allocation:** |
| [ ]  | Randomised | [ ]  | Non-Randomised |

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| **5.14 Masking:** |
| [ ]  | Open | [ ]  | Single-blind |
| [ ]  | Double-blind |

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| **5.15 Assignment:** |
| [ ]  | Single group | [ ]  | Cross-over |
| [ ]  | Parallel | [ ]  | Factorial |
| [ ]  | Expanded access | [ ]  | Other; *specify* |  |

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| **5.15.1** **Describe the control group below:** |
|  |
| *Is the justification for the control group attached?* | [ ]  Yes[ ]  No |
|  |
| **5.16 Endpoints:** |
| [ ]  | Safety | [ ]  | Safety/Efficacy |
| [ ]  | Efficacy | [ ]  | Bioequivalence |
| [ ]  | Pharmacokinetic | [ ]  | Other; *specify*: |  |
| [ ]  | Pharmacodynamics |

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| **5.17 Good Clinical Practice (GCP)** |
| *Give the date and name of GCP course attended for all investigators, and include GCP certificates as part of application.* |
| **Name of investigator** | **GCP course attended** | **Date** |
|  |  |  |
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1. **STATEMENT OF CONFLICT OF INTEREST**

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| --- |
| The Principal Investigatoris expected to declare any existing or potential conflict of interest that may affect the scientific integrity and ethical conduct of this research. For purposes of this section, ‘immediate family’ means the Principal Investigator‘sspouse or domestic partner and dependent children. **Please tick** ✓ **all that apply.** |
| **6.1 No conflict of interest declared:** |
| I, nor any member of my immediate family, **do not** have any interest related to this research (e.g. financial interest in the sponsor of the research or intervention being tested.) | [ ]  |
| I, nor any member of my immediate family, **do not** have a proprietary interest in the product being tested in this research (e.g. patent, trademark, copyright, licensing agreement). | [ ]  |
| I, nor any member of my immediate family, **do not** have any relationships related to this research (e.g. board membership, consultative, executive, employment) or any entity with an ownership interest in the research other than the relationship of sponsor-investigator. | [ ]  |

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| **6.2 Conflict of interest declared:** [ ] N/A |
| As Principal Investigator of this research **I am aware** **of a potential conflict of interest**. Please describe and provide a plan to manage the conflict of interest in the space below: | [ ]  |
|  |

1. **DECLARATIONS AND SIGNATURES**

**Note: This application will not be processed unless all the required declarations and signatures are completed.**

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| **7.1 Principal investigator**  |
| My signature confirms that:1. Information in this application is true and accurate.
2. I will begin the research only after written HSREC approval is obtained.
3. I accept full responsibility for the conduct of this research and the protection of participants’ rights and welfare.
4. I will conduct the research according to all ethical, regulatory and legal requirements stipulated in the HSREC’s Standard Operating Procedures.
5. I will provide progress reports to the HSREC as requested, including a final closing report at the end of the research.
6. I will notify the HSREC in writing if any change to the research is proposed and await approval before proceeding with the proposed change except when urgently necessary to protect participants’ safety.
7. I will notify the HSREC in writing immediately if any adverse event or unanticipated problem occurs during the research.
8. I will allow an audit of my research if requested by the HSREC.
9. I have the time, training, experience and resources to oversee this research.
10. I will endeavour to publish and disseminate the findings of the study.
 |
| Signature of Principal Investigator |  | Date |  |
| Print name |  |

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| --- |
| **7.2 Student Main Supervisor (if research is for a qualification)** [ ] N/A |
| My signature confirms that:1. The student researcher has adequate training and resources to complete the research in the allocated timeframe.
2. The research has scholarly merit.
3. The level of risk inherent in the study is commensurate with the student researcher’s experience and the extent of oversight that I will provide.
4. I have time, training, experience and resources to oversee this research.
5. I will meet the student on a regular basis to monitor progress and address any problems that may arise during the study.
6. I will ensure that the research undergoes continuing review as required by the HSREC, including annual progress reports, protocol amendments and a final closing report at the end of the research.
7. If applicable, I will ensure that I report unanticipated problems or serious adverse events to the HSREC.
8. I will arrange for an alternative faculty supervisor to take responsibility for this research during periods of absence such as sabbatical or annual leave.
 |
| Signature of Supervisor |  | Date |  |
| Print name: |  |

***Note:*** *The main supervisor and student researcher are jointly responsible for the ethical conduct of this research from inception to dissemination of findings.*

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| **7.3 Co-supervisors** [ ]  N/A |
| My/our signature(s) confirm that:1. Information in this application is true and accurate.
2. I/we will begin the research only after HSREC approval is obtained.
3. I/we accept full responsibility for the conduct of this research and the protection of participants’ rights and welfare.
4. I/we will conduct the research according to all ethical, regulatory and legal requirements as stipulated in the HSREC’s Standard Operating Procedures.
 |
| Name  |  | Signature |  | Date |  |
| Name  |  | Signature |  | Date |  |
| Name  |  | Signature |  | Date |  |

|  |
| --- |
| **7.4 Collaborating Investigators** [ ]  N/A |
| My/our signature(s) confirm that:1. Information in this application is true and accurate.
2. I/we will begin the research only after HSREC approval is obtained.
3. I/we accept full responsibility for the conduct of this research and the protection of participants’ rights and welfare.
4. I/we will conduct the research according to all ethical, regulatory and legal requirements as stipulated in the HSREC’s Standard Operating Procedures.
 |
| Name  |  | Signature |  | Date |  |
| Name  |  | Signature |  | Date |  |
| Name  |  | Signature |  | Date |  |
| Name  |  | Signature |  | Date |  |

**CHECKLIST**

*To be completed by Applicant and checked by HSREC Administration*

|  |
| --- |
| **CHECKLIST - COMPULSORY DOCUMENTS ATTACHED *(mandatory)*** |
| Have you attached the following documents? Please answer in the applicant column. | **Applicant** | **Office use only** |
| *Please check [✓] the appropriate box below:* | *Please check [✓] the appropriate box below:* |
| 1. **Application form**
 | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| 1. **Cover Letter**
 | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| *2.1.**All documents submitted are clearly listed with version numbers and dates on the cover letter.* | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| 1. **Study protocol**
 | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| *3.1 Page numbers, version numbers and dates on protocol* | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| 1. **Investigator’s Brochure and other related material**
 | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |
| 1. **Protocol summary in layman’s terms (not exceeding 1 page) and emailed to** **ethicsfhs@ufs.ac.za** **in Word format**
 | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| *5.1 Simple, clear language has been used (Maximum Grade 8 reading level) and all medical and technical terms have been explained.* | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| 1. **Questionnaires**
 | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |
| 1. **Other measuring tools/instruments**
 | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |
| 1. **Recruitment material/ Advertisement(s)**
 | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |
| 1. **Material Transfer Agreement**
 | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |
| 1. **Budget**
 | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| 1. **Letter requesting permission from the Head of Dept./Head of the School of Medicine/Nursing/Allied Health Professions**
 | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |
| *11.1 Permission received and included in application* | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| 1. **Approval requested from School Research Committee, if applicable**
 | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |
| *12.1 Permission received and included in application* | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| 1. **Completed permission from UFS authorities form (HSREC 17) if research is to be done amongst students and/or employees of the UFS**
 | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |
| *13.1 HSREC 17 signed and included in application* | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| 1. **Letter requesting permission from the institution where study will be conducted, if applicable**
 | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |
| *14.1 Permission received and included in application* | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| 1. **Approval requested from Radiation Committee, if applicable**
 | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |
| *15.1 Permission received and included in application* | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| 1. **Informed Consent and Information Document for adults in the language common to the research area**
 | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |
| 1. **Assent form for minors**
 | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |
| 1. **Evaluation Committee approval: Masters (excluding M.Med.) and Doctoral degrees**
 | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |
| 1. **Insurance Certificate**
 | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |
| 1. **Letter requesting permission from the relevant provincial department**
 | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |
| * 1. *Permission received and included in application*
 | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| 1. **Letter requesting permission from the Head Master of a school**
 | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |
| * 1. *Permission received and included in application*
 | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| 1. **Investigator CV’s attached?**
 | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| *22.1 Principal Investigator:*  |
| * *CV attached?*
* *Declaration signed?*
* *Conflict of interest signed?*
 | [ ]  Yes to all [ ]  N/A | [ ]  Yes to all [ ]  N/A |
| *22.2 Supervisor(s) [only for student research]:*  |
| * *CV attached?*
* *Declaration signed?*
 | [ ]  Yes to all [ ]  No to any[ ]  N/A | [ ]  Yes to all [ ]  No to any[ ]  N/A |
| * 1. *Sub/Co-Investigators:*
 |
| * + *CV attached?*
	+ *Declaration signed?*
 | [ ]  Yes to all [ ]  No to any[ ]  N/A | [ ]  Yes to all [ ]  No to any[ ]  N/A |
| 1. **Approval letter from biostatistician included in application**
 | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |
| 1. **Attended a Good Clinical Practice (GCP) Course? Include Certificate**
 | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |
| 1. **Professional Registration**
 | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |
| 1. **NHREC Registration form**
 | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |
| 1. **MCC application letter**
 | [ ]  Yes [ ]  No[ ]  N/A  | [ ]  Yes [ ]  No[ ]  N/A |
| * 1. *MCC approval received and included in application*
 | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |

**HOW TO SUBMIT AN ETHICS APPLICATION: NEW PROTOCOL**

**TWO HARD COPIES:**

1. Arrange documentation in the order provided in the preceding list.
2. **Two** complete sets, including application forms, cover letters, letters of approval, etc., must be submitted.
3. Make use of index cards, sticky notes, etc., to separate various documents.
4. Please bind or file your applications (in two separate documents/files).

**Please contact HSREC Administration for questions and guidance:**

|  |
| --- |
| **HSREC ADMINISTRATION CONTACT DETAILS:** |
| The Chair: Health Sciences Research Ethics CommitteeDr SM Le GrangeFor Attention: Mrs M MaraisBlock D, Room 104,Francois Retief BuildingPo Box 339 (G40)Nelson Mandela DriveFaculty of Health SciencesUniversity of the Free StateBloemfontein9300 | Mrs M Marais*Head: Administration*Mrs J du Plessis*Administration* | 051-401 7795051-401 7794 |
| Fax number | 051-4444359 |
| Email | ethicsfhs@ufs.ac.za |
| Office hours | 07h45 – 16h30 |