|  |  |  |
| --- | --- | --- |
| **Form A3 - Review Checklist**  **To be completed by the Supervisor, HoD, and Ethics Rep, before the review; and to be completed by the Chair of the Review Panel after the review** | | |
| Section for completion by **Review Panel Chairperson:** | | |
| **Panel chair’s Title Initial Surname** | Click or tap here to enter text. | |
| **Panel chair’s Email address** | Click or tap here to enter text. | |
| **Date of the review** | Click or tap here to enter text. | |
| **All subject experts: Title Initial Surnames** | | **Email addresses** |
| Click or tap here to enter text. | | Click or tap here to enter text. |
| Click or tap here to enter text. | | Click or tap here to enter text. |
| Click or tap here to enter text. | | Click or tap here to enter text. |
| Click or tap here to enter text. | | Click or tap here to enter text. |
| **Details of CPR representative: Title Initial Surname** | | Click or tap here to enter text. |

|  |
| --- |
| **PhD Student Surname & UT number: Click or tap here to enter text.** |

|  |  |  |  |
| --- | --- | --- | --- |
| **SELECT ONE: OVERALL RECOMMENDATION FROM THE REVIEW PANEL (x)** | | | |
|  | **Acceptable to the panel without any changes.** | | |
|  | **Acceptable to the panel provided that changes are applied and approved by recommended supervisor(s). The supervisors have to submit a written report to the CPR.** | | |
|  | **Changes to be applied and the protocol to be resubmitted to the panel. Modified protocol to be submitted to the Review Panel and then to the Tygerberg Doctoral Office (**[**tyg-phd@sun.ac.za**](mailto:tyg-phd@sun.ac.za)**) for submitting to the CPR.** | | |
|  | **Protocol unacceptable.** | | |
| Please take cognisance of the fact that it remains the duty of the supervisors and candidates to follow up and make any changes to the protocol as required before final approval. | | | |
| Shape  Description automatically generated with low confidence | |  | Click or tap to enter a date. |
| Signature: Chair of Review Panel | |  | Date |
|  | |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Section for completion by most relevant Research Ethics Committee representative:** | | | |
| **Title Initial Surname of Ethics representative:** | Click or tap here to enter text. | **Member of which REC?** Choose an item. | |
| **Do you endorse the preferred ethics route as indicated by the supervisor, below?** | | | Choose an item. |
| If no, please state why and briefly indicate suggested route.  Click or tap here to enter text. | | | |

|  |
| --- |
| **Section for completion by the main, internal Supervisor:** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Doctoral Candidate Surname** | Click or tap here to enter text. | | **Student Number** | | Click or tap here to enter text. |
| **PhD Programme (as per yearbook)** | Click or tap here to enter text. | **Intended completion date** (please aim for 2 years after ethics approval) | | Click or tap here to enter text. | |
| **Proposed Title of Study**  (proofread with care) | Click or tap here to enter text. | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Intended format of dissertation** | **Conventional** |  | **Publication** |  | **Hybrid** |  |
| **Will already published scientific articles be incorporated into the dissertation?**  If so, please note that this is limited to one article published during the last three years prior to registration. In addition, the following requirements apply: (a) First authorship of the article; and (b) a central research question related to the published work. If applicable, please include the article with the application. | | | | | **YES** |  |
| **NO** |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Attended a supervision course? ↓ | | | | |
| **Supervisor: Title Initial Surname** | | Click or tap here to enter text. | | **No  Yes** |
| **Supervisor:  Academic environment** | | Click or tap here to enter text. | |
| **All co-supervisors:** | **Title Initial Surnames** | | **Email addresses** |  |
| Click or tap here to enter text. | | Click or tap here to enter text. | **No  Yes** |
| Click or tap here to enter text. | | Click or tap here to enter text. | **No  Yes** |
| Click or tap here to enter text. | | Click or tap here to enter text. | **No  Yes** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **All PhD candidates in the FMHS are expected to apply for ethical clearance of their protocol within about 9 months of starting their doctoral studies.**  **To which ethics committee will the proposal be submitted? (X)** | | [**Research Ethics Committee: Animal Care and Use  (REC: ACU)**](http://www.sun.ac.za/english/research-innovation/Research-Development/integrity-ethics/animal-ethics) | |  |
| [**Research Ethics Committee: Biosafety and Environmental Ethics (REC: BEE)**](http://www.sun.ac.za/english/research-innovation/Research-Development/integrity-ethics/biosafety-environmental-ethics) | |  |
| **Health Research Ethics Committee (HREC)** | |  |
| [**REC: Social, Behavioural and Education Research (REC: SBE**](http://www.sun.ac.za/english/research-innovation/Research-Development/integrity-ethics/human-research-(humanities)-ethics)***)*** | |  |
| **Please indicate,  is this study (X)** |  | **(a) Completely new** | | |
|  | **(b) Encompassed by an already-approved parent project** | | |
|  | **(c) An additional, but related, research question or sub-question,   objectives, or methods within an approved parent project** | | |
| **Supervisor Signature: Shape  Description automatically generated with low confidence** | | | **Date** Click or tap to enter a date. | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Section for completion by Head of Division,** or where the Head of Division is also a supervisor, then by the executive **Head of Department** | | | | | |
| Do you approve of the proposed panel members, and specifically, the domain expert/s? | |  | **Yes** |  | **No** |
| (Approval comments on points 1.1-1.8):  Click or tap here to enter text. | | | | | |
| **Head: Title Initial Surname (Environment)**  Click or tap here to enter text. | **HoD Signature**  **Shape  Description automatically generated with low confidence** | | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Section for completion by supervisor before, and  by the review chair after, the review:** | | **Supervisor** | | | **Review Chair** | | |
| **1. GENERAL** | | **N/A** | **YES** | **NO** | **N/A** | **YES** | **NO** |
| 1.1 | Has the main supervisor and have all co-supervisors read the full research proposal in detail, and approved its quality for formal review? |  |  |  |  |  |  |
| 1.2 | Do the proposed supervisor (s) and co- supervisor(s) themselves have first-hand knowledge of and experience concerning the research topic and techniques? Are they able to offer directive guidance? |  |  |  |  |  |  |
| 1.3 | Have the proposed supervisor(s) previously guided doctoral candidates successfully? |  |  |  |  |  |  |
| 1.4 | Are there any possible areas of conflict of interest between the supervisor, co- supervisor(s) and the candidate? |  |  |  |  |  |  |
| 1.5 | Does the candidate have the necessary background and knowledge of research administration and research methodology, and the ability to do high-level research? (ie has the candidate published articles; presented research results at a conference; participated as a co-worker in research studies?) |  |  |  |  |  |  |
| 1.6 | Does this protocol form part of a larger study? |  |  |  |  |  |  |
| 1.7 | Has any part of this protocol been submitted for ethics review previously? If so, please provide ethics number  Click or tap here to enter text. |  |  |  |  |  |  |
| 1.8 | Is the budget adequate/reasonable; finances available for successful completion of the study? |  |  |  |  |  |  |
| 1.9 | Reference list/bibliography: all data; and references in text consistent with type of reference system? |  |  |  |  |  |  |
| 1.10 | All components of a protocol included: rationale/reason, aim and/or objectives and/ or hypothesis, test sample, data collection, analysis of data, ethical aspects, general logistics? |  |  |  |  |  |  |
| 1.11 | Scientific language; correct use of language: No major typing and spelling errors? Formal language editing undertaken? |  |  |  |  |  |  |
| 1.12 | Does the protocol meet the requirements of the Faculty policy with regard to plagiarism? |  |  |  |  |  |  |
| 1.13 | Has it been checked for plagiarism (ie by means of computer software such as Turnitin)? |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | | **Supervisor** | | | **Review Chair** | | |
| **2. INTRODUCTION, AIMS, LITERATURE REVIEW** | | **N/A** | **YES** | **NO** | **N/A** | **YES** | **NO** |
| 2.1 | Is the literature review adequate? |  |  |  |  |  |  |
| 2.2 | Does the protocol specify the aim of the investigation, with clear objectives and/or hypotheses appropriate to the relevant study/research methodology? Are study aim and objectives achievable in the given time frame? |  |  |  |  |  |  |
| 2.3 | Is there appropriate justification for this study protocol?  Is there adequate preliminary data to justify the study? Is it clear why it is important to conduct this study? |  |  |  |  |  |  |
| 2.4 | Will the proposed study provide an original contribution to the particular subject/discipline? |  |  |  |  |  |  |
| 2.5 | Is the project feasible, ie has the candidate undertaken a feasibility study or a pilot study with provisional and projected results and/or has the candidate made sound progress with this/has the candidate undertaken a literature study to contextualise the research problem? |  |  |  |  |  |  |
| **3. SCIENTIFIC DESIGN** | | **N/A** | **YES** | **NO** | **N/A** | **YES** | **NO** |
| 3.1 | Is the proposed methodology acceptable for doctoral studies? |  |  |  |  |  |  |
| 3.2 | Is the scientific design adequate to answer the study question(s) and is it adequately described and justified? |  |  |  |  |  |  |
| 3.3 | Are the depth and scope of the proposed studies acceptable as a doctoral study? |  |  |  |  |  |  |
| 3.4 | Does the protocol specify the intended materials and technique; taking of samples (size, method clearly defined); provisional instruments, ie questionnaires, checklists, as appropriate? |  |  |  |  |  |  |
| **4. DATA AND STATISTICAL ANALYSIS** | | **N/A** | **YES** | **NO** | **N/A** | **YES** | **NO** |
| 4.1 | Does the protocol indicate the involvement of a statistician from as early as the preparation of the protocol? |  |  |  |  |  |  |
| 4.2 | Are the plans for data and statistical analysis defined and justified? |  |  |  |  |  |  |
| 4.3 | Has the sample size and selection been adequately justified? |  |  |  |  |  |  |
| **5. AT THE END OF THE STUDY** | | **N/A** | **YES** | **NO** | **N/A** | **YES** | **NO** |
| 5.1 | Is it specified how communities and participants will be informed of significant findings, if applicable? |  |  |  |  |  |  |
| 5.2 | Is it specified how findings will be disseminated more broadly ie through publishing, presenting at conferences etc? |  |  |  |  |  |  |

**ENDS.**

**HREC ADDENDUM: HREC Approval for PhD Projects**

**Background**

During the PhD Protocol Review process, an HREC representative is one of the members of the review panel if the study involves human participants in health or health-related research. While some PhD projects consist entirely of new investigations, other PhD projects may include links to existing, ethically approved projects. For this reason, it is important have a clear overview of how ethics approval has or will be obtained for each study/phase/aim of the PhD.

**Preparing the HREC Submission**

* Kindly **complete the table** below by ticking the relevant column for each study/phase/aim of the PhD.
* The PhD submission should be accompanied by a **cover letter** in which the candidate provides any additional information and attaches the documents as set out in (a), (b) and (c) below, as applicable.
* If any study/phase/aim involves a **new application**, the entire PhD proposal should be submitted as a new application, but the table and cover letter should clearly indicate for which study/phases/aims new ethics approval is required.
* If the PhD will involve both a **new application and an amendment** to an existing study, the entire PhD proposal should be submitted as a new application **and** the relevant amendment application made via the existing study.
* Please note that where a PhD project falls **wholly in the HREC exemption category**, the candidate must upload the full protocol and documentation from the PhD Review panel as an exemption application.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| PhD components | Requires a new ethics application (Including a Sub-study to an existing, approved study a) | Requires an amendment to an existing, approved studyb | Falls entirely within an existing, approved studyc | Eligible for Exemption (eg, a systematic, scoping review, uses publicly available data, etc) |
| Study/Chapter/Phase/Aim 1 |  |  |  |  |
| Study/Chapter/Phase/Aim 2 |  |  |  |  |
| Study/Chapter/Phase/Aim 3 |  |  |  |  |
| Study/Chapter/Phase/Aim 4 |  |  |  |  |
| Study/Chapter/Phase/Aim 5 |  |  |  |  |
| Study/Chapter/Phase/Aim 6 |  |  |  |  |
| Study/Chapter/Phase/Aim 7 |  |  |  |  |
| Study/Chapter/Phase/Aim 8 |  |  |  |  |
| Any additional information not covered in the protocol:  Click or tap here to enter text. | | | | |

a Sub-studies use data from an existing study but address a new research question. Such studies require a **new ethics application** rather than an amendment to the existing study. The new application should include

* A cover letter providing (i) The ethics reference number and title of the existing, approved study, (ii) An explanation of the aims, objectives and methods of the existing study and the aims, objectives, and methods of the sub-study.
* A copy of the final approved study protocol (and ICF, if applicable) of the existing overarching study as supporting documents.

b PhD proposals with studies/phases/aims that fall entirely within an existing approved study typically also involve some new investigation/s. In this case the full PhD proposal should be submitted as a new application. The submission should include a cover letter providing

1. The ethics reference number and title of the existing, approved study and
2. An explanation of how the PhD study/phase/aim is accommodated within the existing approved study.

c The amendment submission should include

* A cover letter explaining the relationship of the PhD to the existing study
* Addition of the PhD candidate as an investigator on the existing study if this is not already the case
* The final PhD protocol as a supporting document.