

**HEALTH RESEARCH ETHICS COMMITTEE 1 AND 2**

**APPLICATION FORM: MINOR/MAJOR STUDY AMENDMENT**

*(INFORMATION SHOULD BE TYPED)*

*Researchers must ensure that they use the current version of the HREC amendment application form at* [*www.sun.ac.za/rds*](http://www.sun.ac.za/rds) *Applications on outdated HREC amendment application forms will be rejected.*

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| **SECTION A: AMENDMENT REPORTING CATEGORY** *(please check [x] appropriate box)* | | |
| **Minor amendment** *(Do not change the risk benefit profile of the study in any way)*  **Major or substantive amendment** *(Require a change(s) to the study methodology or procedure that may result in an alteration of the risk benefit profile of the study)*  ***Please refer to the*** [**guideline**](#guideline) ***overleaf on page 3 for examples of minor and major/substantive amendments.*** | | |
| **SECTION B: DETAILS OF PRINCIPAL INVESTIGATOR** | | |
| **Title, First name, Surname:** | | |
| **University DIVISION:** | | |
| **University DEPARTMENT:** | | |
| **Address:** | | |
| **Telephone No:** | **Fax No:** | **E-mail:** |
| **SECTION C: PROJECT DETAILS** | | |
| **Title of study:** | | |
| **HREC Ref No:** | | |
| **Date study commenced:** | | |
| **Amendment number and date:** | | |

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| **SECTION D: HOW IS THIS RESEARCH FUNDED?** | | | |
| 1. **Industry** |  | 1. **NIH/US government funded research** |  |
| 1. **Other international grant funded research (e.g. Wellcome Trust)** |  | 1. **National grant funded research (e.g. NRF, MRC, CSIR, etc)** |  |
| 1. **Harry Crossley funded research** |  | 1. **Research funded solely from Stellenbosch University departmental budget** |  |
| 1. **Self funded research** |  | 1. **Non-sponsored student research for degree purposes at Sellenbosch University** |  |
| **SECTION E: TYPE OF AMENDMENT (indicate all that apply in bold)** | | | |
| 1. Amendment to the protocol (i.e. changes in study aims, objectives or design)   **Yes**  **No**  If yes, please submit the revised protocol with a new version number and date, highlighting the changes in bold.  ***Note: If you intend to pursue a new research question, please submit a new application (see section 2 on HREC new application form) where you can indicate that this is a sub-study linked to your existing/main study.*** | | | |
| 1. Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study   **Yes**  **No**  If yes, please submit the revised documents with new version numbers and dates, highlighting new text in bold. | | | |
| 1. Amendment to the research team (e.g. addition of new investigators, research assistants or other relevant research staff)   **Yes**  **No**  If yes, indicate whether any of the additional researchers are ☐ **Postgraduate students** ☐**Undergraduate students** | | | |
| 1. Is this a modified version of an amendment previously notified to the HREC and given an unfavourable opinion?   **Yes**  **No** | | | |
| **SECTION F: SUMMARY OF CHANGES** | | | |
| *Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their relevance to the original study. In the case of a modified amendment, highlight the modifications that have been made.*  *Does the amendment alter the risk-benefit profile of this study? Justify your answer.* | | | |

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| **SECTION G: ANY OTHER RELEVANT INFORMATION** | | |
| *Applicants may indicate any specific ethical issues relating to the amendment, on which the opinion of the HREC is sought.* | | |
| **SECTION H: LIST OF ENCLOSED DOCUMENTS** | | |
| **Document** | **Version** | **Date** |
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| **SECTION I: DECLARATION** | | |
| I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility of it. I consider that it would be reasonable for the proposed amendment to be implemented.  …………………………………………………….. ……………………………………… ………………………………………..  **Signature of Principal Investigator Print name Date** | | |

**INSTRUCTIONS: How to submit an amendment application**

**CLINCIAL TRIALS, human/HEALTH and student research:**

1. **1 hard copy of full application**
   * + **Submit to Elvira Rohland, room 5007, 5th floor, teaching block, Faculty of Medicine and Health Sciences**

**AND**

1. **1 electronic copy of full application**
   * + **Submit in one email to ethics@sun.ac.za**
     + **Submit the protocol and any other documents created in Microsoft word as either word documents or .pdf files**
     + **Submit supporting documents as individual .pdf files**

e.g. one .pdf file for the amendment application form, one .pdf file for the consent form, etc.

* **Submit a scanned .pdf file of each signed document**

**APPLICATION FOR APPROVAL OF A MAJOR STUDY AMENDMENT:**

**GUIDELINE**

Health Research Ethics Committee has the discretion to decide whether or not a proposed amendment is substantial and requires ethical review. Principal investigators and sponsors should seek advice from the HREC if in doubt.

The HREC must be notified of ALL amendments and approval for these must be granted before ANY of the changes are implemented. Amendments may not be implemented without HREC approval unless patient safety is at stake and the issues have been discussed with the HREC Chair or Manager.

1. ***Minor amendments*** *do not change the risk benefit profile of the study in any way.*

*Examples of typical minor amendments:*

1. *Additional investigators or study sites*
2. *Small changes in the Informed Consent*
3. *Change in background information or update of literature review*
4. *Extension of period of study*
5. *Other changes that do not affect study design and will not affect study outcomes or results*
6. *Administrative changes*
7. *Stricter inclusion or exclusion criteria*
8. ***Major or substantive amendments*** *require a change(s) to the study methodology or procedure that* ***may result in an alteration of the risk benefit profile of the study.***

*Examples of typical major or substantive amendments:*

1. *Change in study aims, objectives or design*
2. *Resulting changes to consent documents*
3. *Additional study procedures*
4. *Easing of inclusion or exclusion criteria*