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**APPLICATION FOR MAJOR AMENDMENT TO APPROVED STUDY**

**NELSON MANDELA UNIVERSITY RESEARCH ETHICS COMMITTEE (HUMAN)**

**PLEASE READ THE INFORMATION CONTAINED IN THIS BLOCK (pp 1 – 2) PRIOR TO COMPLETING THE APPLICATION FOR A MAJOR AMENDMENT TO AN APPROVED STUDY. THIS INFORMATION BLOCK MUST BE REMOVED PRIOR TO SUBMISSION OF THE APPLICATION. DEVIATION FROM THE INSTRUCTIONS MIGHT RESULT IN A DELAY IN THE REVIEW AND APPROVAL OF YOUR APPLICATION.**

**EXAMPLES OF MAJOR AMENDMENTS INCLUDE BUT ARE NOT LIMITED TO:**

* Increasing the inclusion criteria;
* Reducing the exclusion criteria;
* Emergence of new and/or serious and/or significant risks to either participants and/or researchers;
* Requirement for new and/or additional study documentation to be distributed to or viewed by participants that include information and/or data collection items significantly different to that in materials previously approved by REC-H; and
* Any other change that does not qualify as a minor amendment (the scope of minor amendments is available on the REC-H website).

**WHO NEEDS TO COMPLETE THIS APPLICATION?**

It is the responsibility of the Primary Responsible Person (PRP) and Primary Investigator (PI) (collectively called the researchers) to submit an application for a major amendment to an approved study prior to the implementation of such an amendment. Retrospective application and approval of study amendments are not permitted under any circumstances, except where it is essential to prevent and/or exclude immediate hazards and/or risks to currently enrolled participants (in case of the latter situation, please make use of form RECH-009, report on study deviations/violations/exceptions available on the REC-H website and not this procedure). The application for a major amendment to the study must be supported by a current progress report (RECH-004), which may be an updated version of the most recently submitted progress report. The application will be subject to an expedited review where after approval/non-approval (with reasons, if applicable) of the application is issued to the researchers in writing. Upon receiving written approval for the amendment, the researchers may implement the amendment to the study (in particular data collection activities). Unless there are extenuating circumstances, continuous applications for amendments to a particular study will not be viewed in a favourable light. This application is NOT for requesting approval for a deviation from (for this request please make use of form RECH-009) or extension/renewal of a previously approved protocol (for this please make use of form RECH-005).

**WHEN SHOULD THIS APPLICATION BE SUBMITTED?**

The digitally signed application for a major amendment together with supporting progress report (RECH-004) shall be submitted in digital format to REC-H a reasonable time period prior to the planned implementation of such an amendment.

**HOW TO COMPLETE THIS APPLICATION FORM:**

1. Complete Sections 1 to 8 (as from pp 3) in typescript (tab between fields, select from pull-downs, information may be pasted from existing Word® documents), and save the completed form. Handwritten forms will not be accepted. Use the “Save as” option to save the application with a filename containing your name(e.g.“**J Smith** REC-H Amendment 20YY.doc”, where YY is the current year). For clarification of definition of terms, refer to the progress report (RECH-004) and/or application form template (RECH-001).
2. Append the progress report.
3. **REMOVE THE INSTRUCTION BLOCK** (pp 1 – 2).
4. **Electronic copy (signed) for submission**: Print the document, get each page initialled on the lower right hand corner and get Section 9 signed by the relevant parties. Scan in the signed hardcopy and all supporting documentation. Alternatively print the report as a PDF document, correctly appending all supporting documentation to it in a single PDF document, and sign the document digitally. Submit the signed form via email with the subject heading **RECH MAJOR AMENDMENT APPLICATION (*your human ethics reference code*)** to REC-H ([Imtiaz.Khan@mandela.ac.za](mailto:Imtiaz.Khan@mandela.ac.za)). Any deviation from the instructions may result in a delay in processing your application.

**END OF INFORMATION BLOCK**

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| **FOR OFFICIAL USE ONLY**  **This serves as notification of major amendment approval** | |
| 🞏 Approved 🞏 Partially approved (refer to copy of Section 6 returned to PI and PRP) | |
| 🞏 Not approved | Refer to comments section below |
| NAME (CHAIR:REC-H) SIGNATURE Date | |
| **COMMENTS to PRP/PI from the REC-H** | |
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| 1. **PROTOCOL INFORMATION** | | | | | |
| **Reference code**\***:**  *\* Refer to letter(s) of approval* | **H** | **…………** | **…………** | **…………** | **…………** |
| **HUMAN** | **YEAR** | **FACULTY** | **DEPARTMENT** | **NUMBER** |
| **Current Ethics Approval is granted until**\***:**  *\* Refer to current letter of approval* | | Click or tap to enter a date. | | | |
| **Approved title of study:** **Type title here** | | | | | |
| **RESEARCHERS** | | | | | |
| 1. PRP identification and affiliation details:   **Type PRP staff number here Type PRP name here Type PRP Email address here**  Faculty **Select Faculty** **Specify here, if “other”** Department (or equivalent): **Type department name here** | | | | | |
| 1. PI (may be same as PRP) identification and affiliation details:   **Type PI staff number/student number here Type PI name here Type PI Email address here**  Faculty **Select Faculty** **Specify here, if “other”** Department (or equivalent): **Type department name here** | | | | | |

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| 1. STATUS OF DATA COLLECTION PROCEDURE(S) | | |
| Recruitment has NOT yet commenced.  If YES, please provide reasons for not having yet commenced with recruitment of participants.  **Type response here or select “Not applicable”** | | |
| Recruitment commenced on Click or tap to enter a date. and is currently continuing | | |
| Recruitment commenced on Click or tap to enter a date. and closed on Click or tap to enter a date.  (select relevant status below) | | |
|  | Enrolment commenced on Click or tap to enter a date.and is currently continuing | |
|  | Enrolment commenced on Click or tap to enter a date. and closed on Click or tap to enter a date.  (select relevant status below) | |
|  |  | Data collection related activities are ongoing  Data collection related activities are complete, follow-up activities only |

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| 1. PREVIOUS AMENDMENTS/EXTENSIONS/RENEWALS |
| No amendments/extensions/renewals have been made since original approval of study |
| All amendments/extensions/renewals to the original study have already been requested and approved by REC-H (provide a brief summary of all previous amendments/extensions/renewals previously approved below)  **Type response here or select “Not applicable”** |

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| 1. PROPOSED CHANGES WILL AFFECT (indicate all that are applicable) |
| Study aims/objectives and/or design |
| Study data collection instruments (e.g. interview schedules, questionnaires) |
| Recruitment method(s) and/or materials (e.g. advertisements) |
| Eligibility requirements (i.e. increasing inclusion criteria and/or decreasing exclusion criteria) for fair selection of participants |
| Enrolment method(s) |
| Data collection and/or data analysis method(s) |
| Consent form and/or written/oral information |
| Risk to participants (i.e. there will be new/increased risk/discomfort/inconvenience to participants) |
| Risk to researcher(s) (i.e. there will be new/increased risk to researchers) |
| Other, please specify **Provide description of major amendment(s)** |

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| 1. FOLLOW-UP ACTION(S) FOR ALREADY ENROLLED PARTICIPANTS (indicate all that are applicable) |
| Inform currently enrolled participants as soon as amendment is approved |
| Re-consent currently enrolled participants with revised consent/assent forms and/or oral/written information |
| No action required |
| Eligibility requirements (i.e. increasing inclusion criteria and/or decreasing exclusion criteria) for fair selection of participants |
| Other, please specify **Provide description of follow-up action(s)** |

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| 1. LIST OF PROPOSED AMENDMENTS | | |
| *Please itemise below each individual amendment that requires review and approval (remove any unused rows\* from row 2 onwards or add additional rows\*\* to the table if there are more than 5 amendments*). *A copy of the itemised list will be returned to the PI and PRP as notification of the extent of amendment approval.*  *\* To remove rows, highlight the rows/cells in rows to be removed, click mouse right button, select DELETE CELLS/ROWS and follow the prompts. \*\* To add a row, in the last cell of the table, click mouse right button, select INSERT then INSERT ROWS BELOW. Add the required details.* | | |
| **Amendment Reference** | **Approval Status**  **FOR OFFICIAL USE ONLY** | **Comments**  **FOR OFFICIAL USE ONLY** |
| 1. **Brief descriptor of amendment**  attached as Appendix A. | 🞏 Approved 🞏 Not approved |  |
| 2. **Brief descriptor of amendment**  attached as Appendix B. | 🞏 Approved 🞏 Not approved |  |
| 3. **Brief descriptor of amendment**  attached as Appendix C. | 🞏 Approved 🞏 Not approved |  |
| 4. **Brief descriptor of amendment**  attached as Appendix D. | 🞏 Approved 🞏 Not approved |  |
| 5. **Brief descriptor of amendment**  attached as Appendix E. | 🞏 Approved 🞏 Not approved |  |

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| 1. DETAILED DESCRIPTION OF PROPOSED AMENDMENTS |
| For ***each*** of the listed amendments above, attach as clearly labelled Appendices to this application:  Amendment *n* Appendix A: A detailed description/explanation of the amendment;  Amendment *n* Appendix B: Detailed rationale/justification for the amendment; and  Amendment *n* Appendix C: Copies of any and all relevant revised documentation (if applicable) for the amendment, in particular   * 1. One copy of each amended document clearly highlighting the changes from the currently approved document (highlighting of changes can be implemented by means of tracked changes, striking through “old text” and showing the “new text” in bold, underlined or italics, or similar); and   2. One clean copy of each amended document. |

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| 1. ADDITIONAL COMMENTS |
| I would like the REC-H to take note of the following additional information: **Type response here or select “Not applicable”** |

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| 1. DECLARATION |
| I declare that the details contained in the application for major amendments to the study and attached progress report are complete and accurate. |
| **21 May 2020**  SIGNATURE: **Type name here** (Primary Responsible Person) Date |
| **21 May 2020**  SIGNATURE: **Type name here** (Principal Investigator/Researcher) Date |