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**APPLICATION FOR CHANGE OF RESEARCHERS TO APPROVED STUDY**

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

 **PLEASE READ THE INFORMATION CONTAINED IN THIS BLOCK (pp 1) PRIOR TO COMPLETING THE APPLICATION FOR THE CHANGE OF RESEARCHERS 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.**

**WHO NEEDS TO COMPLETE THIS APPLICATION?**

It is the responsibility of the replacement (if applicable) Primary Responsible Person (PRP) and replacement (if applicable) Primary Investigator (PI) (collectively called the researchers) to submit an application for the change of researchers to an approved study prior to the implementation of such a change. Retrospective application and approval of such changes 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 and/or the currently approved PRP and/or PI. The application for change of researchers for a 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 requested change, the researchers may implement the change to the study. Unless there are extenuating circumstances, continuous applications for changes of researchers for a particular study will not be viewed in a favourable light. This application is NOT for requesting approval for any deviation from (for this request please make use of form RECH-009), extension/renewal of (for this please make use of form RECH-005) or amendment to the protocol of a previously approved protocol (for this please make use of form RECH-006).

**WHEN SHOULD THIS APPLICATION BE SUBMITTED?**

The digitally signed application for a change in study researchers 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 a change.

**HOW TO COMPLETE THIS APPLICATION FORM:**

1. Complete Sections 1 to 9 (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 Researcher Change 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).
4. **Electronic copy (signed) for submission**: Print the document, get each page initialled on the lower right hand corner and get Section 10 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 STUDY RESEARCHER CHANGE APPLICATION (*your human ethics reference code*)** to REC-H (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 change in study researcher approval** |
| 🞏 Approved  |
| 🞏 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**
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| **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** |
| **CURRENTLY APPROVED RESEARCHERS*****Please note -*** ***The Protection of Personal Information Act, 2013 (POPI Act) has been promulgated and implemented on 1 July 2020. All personal identifiable information provided by you shall be treated in accordance with this statute and only used for research ethics application and/or reporting processes, as indicated in the University’s Privacy Policy. By providing your information, you are giving your consent for the use of all of your personal identifiable information, provided to the University, for the aforesaid purposes.*** |
| 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
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| [ ]  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 STUDY RESEARCHER CHANGES (indicate all that are applicable)
 |
| [ ]  Change in PI and/or PRP |
| [ ]  New collaborators/researchers are being added to the study |
| [ ]  Current collaborators/researchers are being removed from the study |
| [ ]  Other, please specify **Provide description of study researcher change(s)** |

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| 1. FOLLOW-UP ACTION(S) FOR ALREADY ENROLLED PARTICIPANTS (indicate all that are applicable)
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| [ ]  Inform currently enrolled participants as soon as the change in researcher(s) is approved |
| [ ]  Re-consent currently enrolled participants with revised consent/assent forms and/or oral/written information, should the change entail revised documentation to reflect the change in study researcher(s) |
| [ ]  No action required |
| [ ]  Other, please specify **Provide description of follow-up action(s)** |

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| 1. STUDY RESEARCHERS BEING REMOVED FROM THE STUDY
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| *Please list below each individual researcher that is being removed from involvement in the study (add additional pages as an Appendix to this application if required).*  |
| **Researcher Name** **(Title, First Name, Surname)** | **Role in currently approved study**  |
| **Type researcher name here** | **Choose an item.** |
| **Type researcher name here** | **Choose an item.** |
| **Type researcher name here** | **Choose an item.** |
| **Type researcher name here** | **Choose an item.** |
| **Type researcher name here** | **Choose an item.** |

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| 1. STUDY RESEARCHERS BEING ADDED TO THE STUDY
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| *Please provide details below for each individual researcher that is being added to the study (add additional pages as an Appendix to this application if required).*  |
| **Researcher Name** **(Title, First Name, Surname): Staff number (if applicable)** | **Faculty and Department (if applicable)** | **Email address** | **Role of new researcher in currently approved study**  |
| **Type researcher name here** | **Select Faculty, Type department name here** | **Type Email address here** | **Choose an item.** |
| **Type researcher name here** | **Select Faculty, Type department name here** | **Type Email address here** | **Choose an item.** |
| **Type researcher name here** | **Select Faculty, Type department name here** | **Type Email address here** | **Choose an item.** |
| **Type researcher name here** | **Select Faculty, Type department name here** | **Type Email address here** | **Choose an item.** |
| **Type researcher name here** | **Select Faculty, Type department name here** | **Type Email address here** | **Choose an item.** |

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| 1. IMPACT OF PROPOSED CHANGE OF RESEARCHERS TO EXISTING DOCUMENTATION
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| For the proposed changes in study researchers, attach as clearly labelled Appendices to this application:1. A detailed explanation of the need for a change in study researcher(s);
2. For a change in PI and/or PRP, revised conflict of interest and declaration statements; and
3. Copies of any and all relevant revised documentation (if applicable) for the change in study researcher(s), 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
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| 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
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| I declare that the details contained in the application for change in researcher(s) to the study and attached progress report are complete and accurate.  |
|   **05 August 2022**SIGNATURE: **Type name here** (Primary Responsible Person) Date |
|   **05 August 2022**SIGNATURE: **Type name here** (Principal Investigator/Researcher) Date |