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**NOTICE OF STUDY CLOSURE/DISCONTINUATION FOR APPROVED STUDY**

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

 **PLEASE READ THE INFORMATION CONTAINED IN THIS BLOCK (pp 1) PRIOR TO COMPLETING THE NOTICE OF STUDY CLOSURE/DISCONTINUATION OF AN APPROVED STUDY. THIS INFORMATION BLOCK MUST BE REMOVED PRIOR TO SUBMISSION OF THE NOTICE. DEVIATION FROM THE INSTRUCTIONS MIGHT RESULT IN A DELAY IN THE REVIEW AND APPROVAL OF YOUR REQUEST.**

**WHO NEEDS TO COMPLETE THIS NOTICE?**

It is the responsibility of the Primary Responsible Person (PRP) and Primary Investigator (PI) (collectively called the researchers) to submit the notice for a study closure/discontinuation for an approved study.

**WHEN SHOULD THIS NOTICE BE SUBMITTED?**

The digitally signed notice for closure/discontinuation of an approved study shall be submitted in digital format to REC-H a reasonable time period after the closure/discontinuation of the study, and no later than 4 weeks after such closure/discontinuation.

**HOW TO COMPLETE THIS NOTICE:**

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 Closure 20YY”, 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. **REMOVE THE INSTRUCTION BLOCK** (pp 1).
3. The closure/discontinuation form of a study must be supported by an updated progress report RECH-004). However, if a progress report has been submitted and approved within three months of the date of the closure report, the letter of approval for the progress report may be submitted instead.
4. **Electronic copy (signed) for submission**: Print the documents, each page must be initialled on the lower right hand corner as well as fully signed by the relevant parties where requested. 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 CLOSURE/DISCONTINUATION NOTICE (*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 notice.

**END OF INFORMATION BLOCK**

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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. The date to be stated is 1 calendar year after the date on which the approval letter was issued.*  | Click or tap to enter a date.***Signed copy of original approval letter must be******attached as addendum to this report.***  |
| **Approved title of study:** **Type title here** |
| **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.  |
| [ ]  Recruitment commenced on Click or tap to enter a date. and closed on Click or tap to enter a date.  |
|  | [ ]  Enrolment commenced on Click or tap to enter a date. |
|  | [ ]  Enrolment commenced on Click or tap to enter a date. and closed on Click or tap to enter a date. |
|  |  | [ ]  Data collection related activities are complete, no further engagement with participants[ ]  Data collection discontinued |

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| 1. REASON(S) FOR CLOSING/DISCONTINUING THE STUDY
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| [ ]  Research completed | [ ]  No time for PI to conduct research |
| [ ]  Terminated due to adverse event(s) | [ ]  Insufficient funding |
| [ ]  PI left institution/affiliated sites/cancelled studies | [ ]  Loss of interest |
| [ ]  Slow data accrual | [ ]  Research never commenced |
| [ ]  Other, please specify: **Type response here** |

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| 1. SUBMISSION OF REPORTS
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| [ ]  Final report has been submitted to overseeing body e.g. NRF, DoH, DoE etc. (**Type name of overseeing body here or select “Not applicable”**) on Click or tap to enter a date. |
| [ ]  For any other reports submitted as part of research obligations (excluding those required by REC-H), please specify (e.g., treatise, dissertation, or thesis):**Type response here or select “Not applicable”** |

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| 1. DISSEMINATION OF FINDINGS
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| Please describe the manner in which research findings have been disseminated to participants, communities and/or stakeholders: **Type response here or select “Not applicable”** |

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| 1. DATA STORAGE AND PROTECTION
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| Please indicate how and for how long the data will be stored: **Type response here or select “Not applicable”** |
| Please indicate how the data will be protected: **Type response here or select “Not applicable”** |

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| 1. RESEARCH OUTPUT
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| Please list and/or attach any research outputs (articles, conference outputs, etc.) emanating from this study: **Type response here or select “Not applicable”** |

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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 notice to close/discontinue the study, including any attachments, 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 |
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