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**PROGRESS REPORT**

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

**PLEASE READ THE INFORMATION CONTAINED IN THIS BLOCK (pp 1 – 2) PRIOR TO COMPLETING THE PROGRESS REPORT. THIS INFORMATION BLOCK MUST BE REMOVED PRIOR TO SUBMISSION OF THE PROGRESS REPORT. DEVIATION FROM THE INSTRUCTIONS MIGHT RESULT IN A DELAY IN THE REVIEW AND APPROVAL OF YOUR PROGRESS REPORT.**

**WHAT IS A PROGRESS REPORT?**

A progress report shall be completed for any approved and ***currently active*** project in which humans are the subjects of research (hereafter called a *study*). REC-H is mandated to monitor research projects, this monitoring process being initially actioned by means of the mandatory submission of progress reports at least once per annum. REC-H has the authority to immediately suspend or terminate studies that do not comply with annual reporting requirements, or for which no progress report is forthcoming. The progress report is expected to address the overall progress of the study and the progress since the last progress report/study approval as well as any events/comments/issues arising from the study and required to be reported to REC-H.

**WHO NEEDS TO COMPLETE THIS REPORT?**

It is the responsibility of the Primary Responsible Person (PRP) and Primary Investigator (PI) (collectively called the researchers) to submit a progress report together with all relevant supporting documentation for approval in parallel to their Faculty Postgraduate Studies Committee (FPGSC) and to REC-H. This report is required to be completed for the current year for all studies approved/extended/currently active in the period October of the previous year up to and including September of the current year.

**WHEN SHOULD THIS REPORT BE SUBMITTED?**

The digitally signed progress report shall be submitted in digital format to both the FPGSC and REC-H in parallel by no later than 15 November.

**WHAT MATERIAL IS REQUIRED FOR REFERENCE WHILE COMPLETING THIS REPORT:**

1. Approved version of the application form together with all supporting documentation.
2. Copies of any approvals for study amendments/extensions/renewals (if applicable).
3. Copies of any reports for study violations/deviations (if applicable).
4. Copies of any approvals for adverse events (if applicable).
5. Copies of previous progress reports (if applicable).
6. Access to participant consent forms as well as any data that has already been collected.

**HOW TO COMPLETE THIS REPORT:**

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 report. Handwritten reports will not be accepted. Use the “Save as” option to save the progress report with a filename containing your name(e.g.,“**J Smith** REC-H Progress Report 20YY”, where YY is the current year).
2. Append any additional documentation e.g., unreported violations/deviations, amendment requests, extension request, unreported adverse events, revised documentation in response to adverse events, etc. Ensure that appendices are correctly labelled and **CORRECTLY ORDERED** as given in the progress report template and the provided table of documentation (pp 3). Complete the supporting table (pp 3). Incorrect ordering of or missing appendices may result in a delay of the review and approval of the progress report.
3. **REMOVE THE INSTRUCTION BLOCK AND DEFINITION OF TERMS** (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 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. The signed copy of the original approval letter together with the original approved application must be submitted with the progress report. Submit the signed report via email with the subject heading **RECH ANNUAL REPORT (*your human ethics reference code*)** ***AT THE SAME TIME*** to both the FPGSC representative in the relevant Faculty and 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 progress report.

**DEFINITION OF TERMS USED IN THE PROGRESS REPORT**

1 a) “**Sub-study**” means any research projects being conducted as sub-projects of this study.

1 b) “**PRP**” means primary responsible person. This individual must be a fulltime member of permanent staff or currently active research associate, usually the supervisor of the student in the case of the study being for the purposes of acquiring a qualification

1 c) “**PI**” means primary investigator and is the person undertaking the study

2 “**Recruitment**” refers to the collection of those methods/techniques used by researchers to identify and approach individuals to volunteer to contribute to the data collection for a study (these individuals being referred to as “**volunteers**”). A reasonable period of time should elapse between recruitment of volunteers and enrolment of “**participants**” (those individuals who have indicated a willingness to participate and who have been subsequently selected for participation). “**Enrolment**” refers to the collection of those methods/techniques used by researchers to identify, screen and select participants from those who have volunteered to participate in the study.

3 f) “**Inclusion criteria**” refers to that set of characteristics that all participants must exhibit so as to be included in the data collection procedure. “**Exclusion criteria**” refers to that set of characteristics that excludes volunteers (i.e. those individuals who have been recruited and have indicated a willingness to participate) from contributing to the data collection procedure.

5 “**Violation**” is that occurrence/process that fails to comply with the data collection procedures for which approval was granted. “**Exception**” is that occurrence that is inconsistent with an anticipated outcome. “**Deviation**” is that process that falls outside the approved set of processes.

6 “**Amendment**” is a minor change or addition with the aim of improving the data collection procedure. “**Extension**” is the extension of the period for data collection activities.

7 a) “**Adverse event**” is an undesirable experience on the part of a participant / researcher / non-participant.

8 f) “**Risk**” refers to any possible negative effect of any data collection activity on the welfare of a participant over and above what would be expected from such a participant as a result of routine daily tasks.

8 h) “**Conflict of interest**” refers to a compromised situation as regards ethical conduct of research as a result of conflicting duties, responsibilities or interests (personal, professional or otherwise) on the part of the PI and/or PRP and/or participant recruiter and/or gatekeeper and/or sponsor of the study.

8 i) “**Benefit**” refers to any possible positive effect of any data collection activity on the welfare of a participant over and above what would be expected from such a participant as a result of routine daily tasks.

8 j) “**Societal and/or ethical value**” refers to any possible benefit as a result of the study/data collection procedure that would be either temporarily or permanently transferred to the community from which participants are drawn.

**END OF INFORMATION BLOCK**

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| **Supporting Documentation** | |
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| **Document** | **Page reference** |
| Appendix 1: Study Closure\Discontinuation report (Form RECH-008), if applicable |  |
| Appendix 2: Unreported violations/deviations since last progress report/study approval (letter or other document), if applicable |  |
| Appendix 3: Amendment Request (Form RECH-006), if applicable |  |
| Appendix 4: Extension Request (Form RECH-005), if applicable |  |
| Appendix 5: Unreported adverse events since last progress report/study approval (Form RECH-007), if applicable |  |
| Appendix 6: Revised study documentation in response to adverse event(s), if applicable |  |
| Appendix 7: Summary of findings, other monitoring and audit activities, if applicable |  |
| Appendix 8: Original ethics approval letter |  |
| Appendix 9: Original approved application and any amendments (if applicable) |  |
| Appendix 10:  *Other documentation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |  |
| Appendix 11:  *Other documentation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |  |

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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** | | | | | |
| 1. Are there any sub-studies linked to this study? **Select an item**   If YES, please provide the REC-H reference codes for each sub-study (**Note**: A separate Progress Report (Form RECH-004) is required to be submitted for each sub-study): **Type response here or select “Not applicable”** | | | | | |
| **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 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, possible further engagement with participants  Data collection-related activities are complete, no further engagement with participants (Study Closure\Discontinuation Report (Form RECH-008) to be submitted as Appendix 1)  Final reports approved (e.g., article submitted, thesis/treatise/dissertation passed) (Study Closure\Discontinuation Report (Form RECH-008) to be submitted as *Appendix 1*)  Study discontinued (Study Closure\Discontinuation Report (Form RECH-008) to be submitted as *Appendix 1*) |

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| 1. SUMMARY OF PARTICIPATION BY HUMAN SUBJECTS | |
| 1. With reference to the approved application form, state the minimum and maximum number of participants involved. In the cases of a mixed methodology being used, for each data collection phase/method/technique/participant grouping, list the phase/method/technique/ participant grouping and indicate the required number of participants for the relevant phase/method/technique/ participant grouping in the appropriate places below.  Min: **Type minimum number here** Max: **Type maximum number here** | |
| **RECRUITMENT** (*for each data collection phase/method/technique/participant grouping, list the phase/method/ technique/participant grouping and indicate the required number of participants for the relevant phase/method/ technique/participant grouping in the appropriate places below*) | |
| 1. Total number of individuals invited to participate to date: | **Type number here** |
| 1. Total number of individuals invited to join the study, but declined to participate: | **Type number here** |
| 1. Total number of individuals invited to join the study and agreed to participate: | **Type number here** |
| **ENROLMENT** (*for each data collection phase/method/technique/participant grouping, list the phase/method/ technique/participant grouping and indicate the required number of participants for the relevant phase/method/ technique/participant grouping in the appropriate places below*) | |
| 1. Number of participants excluded from participation (i.e. after application of inclusion and/or exclusion criteria): | **Type number here** |
| 1. Number of participants enrolled with consent to date: | **Type number here** |
| 1. Additional number of participants needed to complete the study: | **Type number here** |
| **PARTICIPATION** (*for each data collection phase/method/technique/participant grouping, list the phase/method/ technique/participant grouping and indicate the required number of participants for the relevant phase/method/ technique/participant grouping in the appropriate places below*) | |
| 1. Number of participants currently active on the study (if data collection is complete, this will be 0): | **Type number here** |
| 1. Number of participants successfully completed study (without events leading to withdrawal): | **Type number here** |
| 1. Number of participants withdrawn (either at participant’s request or by PI/PRP): | **Type number here**  Reasons for withdrawal of participants:  **Type reasons (and number of affected participants) here** |

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| 1. PROGRESS OF STUDY |
| Please provide a brief summary (max. 1½ pages) of the research to date including overall progress and the progress since the last progress report as well as any matters that require to be reported to REC-H: |
| **Type summary here** |

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| 1. STUDY VIOLATIONS, EXCEPTIONS AND DEVIATIONS (select all that apply) | |
| No occurrences of violations and/or exceptions and/or deviations since original approval of study | |
| If a previous request for an extension was successful, all occurrences of violations and/or exceptions and/or deviations, since the last progress report have been reported to REC-H (select relevant status below) | |
|  | Acknowledgement/approval of violations and/or exceptions and/or deviations is awaited |
|  | Acknowledgement/approval of violations and/or exceptions and/or deviations is concluded |
| Unreported violations and/or exceptions and/or deviations that have occurred since the last progress report attached as *Appendix 2*) | |

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| 1. AMENDMENTS/EXTENSIONS (select all that apply) |
| No amendments/extensions have been made since original approval of study |
| All amendments/extensions to the original study have already been requested and approved by REC-H |
| New/additional amendments to the study are requested as part of this progress report (Form RECH-006 attached as *Appendix 3*) |
| New/additional extensions of the study are requested as part of this progress report (Form RECH-005 attached as *Appendix 4*) |

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| 1. ADVERSE EVENTS |
| 1. Have there been any serious adverse events and/or unanticipated problems since approval/the last progress report)? **Select an item** If YES, please list the adverse events and/or unanticipated problems and attach a letter outlining the adverse event and/or unanticipated problem as *Appendix 5*. **Type response here or select “Not applicable”**   Attach as *Appendix 6* all documentation revised in response to the stated adverse events and/or unanticipated problems. |
| 1. Have participants received appropriate treatment/follow-up/referral when applicable (e.g. in the case of incidental findings, mandatory reporting obligations, etc.)? **Select an item** If YES, please describe. **Type response here or select “Not applicable”** |

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| 1. SUMMARY OF OTHER MONITORING AND AUDIT ACTIVITIES |
| 1. Was the study subject to monitoring/auditing by an external/internal unit (other than REC-H) since approval/the last progress report? **Select an item** |
| 1. Has any report been published due to monitoring/auditing by an external/internal unit (other than REC-H) since approval/the last progress report? **Select an item** If YES, please identify the unit and attach a summary of the findings as *Appendix 7*. **Type response here or select “Not applicable”** |
| 1. Has the study been subjected to any external/internal unit (other than REC-H), institutional or other inquiry in respect of non-compliance? **Select an item** If YES, please elaborate. **Type response here or select “Not applicable”** |
| 1. Has there been any complaint from participants or any third party regarding research activities in the study? **Select an item** If YES, please elaborate. **Type response here or select “Not applicable”** |
| 1. Has there been any finding of non-compliance concerning any member of the research team? **Select an item** If YES, please elaborate. **Type response here or select “Not applicable”** |
| 1. Please indicate whether the level of risk to participants has **Select an item**   If there has been any change in the risk to participants from that originally envisaged, please elaborate**. Type response here or select “Not applicable”** |
| 1. Please indicate whether the level of risk to researchers has **Select an item**   If there has been any change in the risk to researchers from that originally envisaged, please elaborate. **Type response here or select “Not applicable”** |
| 1. Has there been any change in the conflict of interest status of the study since original approval? **Select an item**   If YES, please elaborate. **Type response here or select “Not applicable”** |
| 1. Please indicate whether the level of benefit to participants has **Select an item**   If there has been any change in the benefit to participants from that originally envisaged, please elaborate**. Type response here or select “Not applicable”** |
| 1. Please indicate whether the level of societal value to the community from which participants are drawn has **Select an item**   If there has been any change in the societal value from that originally envisaged, please elaborate**. Type response here or select “Not applicable”** |

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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 report contents and attached appendices are complete and accurate. |
| **26 October 2022**  SIGNATURE: **Type name here** (Primary Responsible Person) Date |
| **26 October 2022**  SIGNATURE: **Type name here** (Principal Investigator/Researcher) Date |

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| 1. APPENDICES |
| In order to expedite the review of this progress report, please ensure that all the required information, as specified below, is attached (where applicable). You are required to please clearly label each Appendix in the top right hand corner of all supporting documentation and retain the numbering order, transferring page numbers to the Supporting Documentation table on pp 1 of this application (after removal of the information block). Any deviation from this requirement may result in a delay in the review and approval of the progress report, and subsequent renewal of the study (if applicable). |
| **APPENDIX 1: Study Closure\discontinuation (Form RECH-008)** |
| If applicable, attach completed Form RECH-008 as "Appendix 1” |
| **APPENDIX 2: Unexpected violations\exceptions\deviations** |
| If applicable, attach letter/document as "Appendix 2” |
| **APPENDIX 3: Amendments (Form RECH-006)** |
| If applicable, attach completed Form RECH-006 as "Appendix 3” |
| **APPENDIX 4: Extension (Form RECH-005)** |
| If applicable, attach completed Form RECH-005 as "Appendix 4” |
| **APPENDIX 5: Adverse incident report** |
| If applicable, attach completed Form RECH-007 as "Appendix 5” |
| **APPENDIX 6: Revised documentation in response to adverse incidents** |
| If applicable, attach the relevant documentation, as "Appendix 6". Clearly highlight in the amended documentation all modifications made together with a rationale for such modifications. |
| **APPENDIX 7: Summary of findings, other monitoring and audit activities** |
| If applicable, attach the relevant documentation, as "Appendix 7". |
| **APPENDIX 8: Original approval letter** |
| Attach the original ethics approval letter |
| **Appendix 9: Original approved application** |
| Attach the original approved application and any amendments that have been made |
| **APPENDICES 10 – 11: Other** |
| If applicable, attach the required information to your progress report, appropriately and clearly labelled. |