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**PROGRESS REPORT**

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

**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.**

**WHAT IS A PROGRESS REPORT?**

A progress report shall be completed for any approved and ***currently active*** project in which animals are the subjects of research (hereafter called a *study*). REC-A 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-A 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-A.

**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 by REC-A. This report is required to be completed for the current year for all studies approved/renewed/extended in the period January of the current year up to and including December of the current year.

**WHEN SHOULD THIS REPORT BE SUBMITTED?**

The digitally signed progress report shall be submitted in digital format to REC-A no later than 15 January 2020.

**WHAT REFERENCE DOCUMENTS YOU MAY NEED TO USE WHEN COMPLETING THIS REPORT:**

1. Copy of the original Ethics application submitted and approved.
2. Copy(ies) of the original and most recent approval letter(s).
3. Copies of any approvals for study amendments/extensions/renewals (if applicable).
4. Copies of any reports for study violations/deviations (if applicable).
5. Copies of any approvals for adverse events (if applicable).
6. Copies of previous progress reports (if applicable).

**HOW TO COMPLETE THIS REPORT:**

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 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-A Progress Report 20YY.doc”, where YY is the current year).
2. Append any additional documentation e.g. Unreported violations/deviations, Amendment\extension\renewal requests, Unreported adverse events, Revised documentation in response to Adverse events, etc. as Appendices correctly labelled and **CORRECTLY ORDERED** as given in the progress report template and the provided table of Supporting Documentation. Complete the Supporting Documentation table where applicable. 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)**: Print the document, get each page **initialled by both the PI and PRP** 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 sign the document digitally. Submit the signed document to Imtiaz.khan@mandela.ac.za for review by RECA.

**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

3 a) Severity category refers to the impact on animal wellbeing, “**None”** - Observational Studies; **“Mild”** – Captured, held in captivity and/or Released; **“Moderate”** - Captured for data logging and/or blood sampling or other procedure; **“Servere”** - Captured and euthanised.

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\renewal**” is the extension of the period for data collection activities.

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

8 f) “**Risk**” refers to any possible negative effect of any data collection activity on the welfare of an animal over and above what would be expected 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 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 [DELETE ALL ABOVE BEFORE SUBMISSION]**

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| **FOR OFFICIAL USE ONLY****This serves as notification of progress report approval, including any supporting documentation** |
| 🞏 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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| **Supporting Documentation**  |
|  |  |
| **Document** | **Page reference** |
| Appendix 1: Study Closure\Discontinuation report  |  |
| Appendix 2: Unreported violations/deviations since last progress report/study approval  |  |
| Appendix 3: Amendment Request  |  |
| Appendix 4: Extension\Renewal Request  |  |
| Appendix 5: Unreported adverse events since last progress report/study approval  |  |
| Appendix 6: Revised study documentation in response to adverse event(s) |  |
| Appendix 7: *Other documentation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*  |  |
| Appendix 8:  *Other documentation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |  |
| Appendix 9:  *Other documentation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |  |

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| 1. **PROTOCOL INFORMATION (To be completed by the PRP/PI)**
 |
| **Application reference code**\***:***\* Refer to letter(s) of approval* | **A** | **…………** | **…………** | **…………** | **…………** |
|  | **Animal** | **YEAR** | **FACULTY** | **DEPARTMENT** | **NUMBER** |
| **Current Ethics Approval is granted until**\***:***\* Refer to letter(s) of approval* | **DD / MM / 20YY** |
| **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-A reference codes for each sub-study (**Note**: A separate Progress Report 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** |
| 1. STATUS OF DATA COLLECTION PROCEDURE(S)
 |
| **CONTINUING STUDY**[ ] Study commenced on **DD / MM / 20YY** and is currently continuing  |
|  |  | [ ]  Research-related activities are ongoing[ ]  Research-related activities are complete, follow-up activities only [ ]  Research-related activities are complete, data analysis only |
| **OR COMPLETED STUDY**[ ]  Study commenced on **DD / MM / 20YY** and closed on **DD / MM / 20YY**   (tick ✓ relevant status below) |
|  |  | [ ]  Main study is complete but sub-study research-related activities are ongoing[ ]  Study closed successfully (Study Closure\Discontinuation Report to be submitted as *Appendix 1*)[ ]  Study discontinued (Study Closure\Discontinuation Report to be submitted as *Appendix 1*) |
| 1. SUMMARY EXPERIMENTAL DESIGN AND PROCEDURES
 |
| 1. List the animals used in this study (if multiple species list common and scientific name of each)
 |
| Animal[[1]](#footnote-1) numbers used per species and severity category (as defined in the SANS 10386) *add rows if necessary* |
| **Species[[2]](#footnote-2)** | **Animals used** | **Number of animals euthanised due to over-breeding or NOT used** |
|  | **Data on Numbers used available?** | **TOTAL number of animals used** | **Of the total number of animals used, indicate the number of animals, where the impact on animal wellbeing (severity category) was as indicated below** |  |
|  | **Yes** | **No** |  | **None** | **Mild** | **Moderate** | **Severe** |  |
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| 1. If endangered species were used, please list and describe briefly. **Type response here or select “Not applicable”**
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| 1. What environmental impact did the study have, if any? Give detail. **Type response here or select “Not applicable”**
 |
| 1. Give details of the drugs and dosages used in the study (if applicable). **Type response here or select “Not applicable”**
 |
| 1. Briefly describe surgical techniques used (if applicable). **Type response here or select “Not applicable”**
 |
| 1. State method of euthanasia if used and listed above. **Type response here or select “Not applicable”**
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| 1. PROGRESS OF STUDY
 |
| Please provide a brief summary/outline (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-A: |
| **Type summary here** |
| 1. STUDY VIOLATIONS, EXCEPTIONS AND DEVIATIONS (tick ✓all that apply)
 |
| [ ]  No occurrences of violations and/or exceptions and/or deviations since original approval of study |
| [ ]  All occurrences of violations and/or exceptions and/or deviations since the last progress report have been reported to REC-A (tick ✓ 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*  |
| 1. AMENDMENTS/EXTENSIONS/RENEWALS (tick ✓all that apply)
 |
| [ ]  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-A |
| [ ]  New/additional amendments to the study are requested as part of this progress report (attached as *Appendix 3*) |
| [ ]  New/additional extensions/renewals to/of the study are requested as part of this progress report (attached as *Appendix 4*) |
| 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 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 animals received appropriate treatment or been euthanised when applicable (e.g. in the case of incidental findings, mandatory reporting obligations, distress, anxiety, amongst other cases)? **Select an item**If YES, please describe. **Type response here or select “Not applicable”**
 |
| 1. SUMMARY OF OTHER MONITORING AND AUDIT ACTIVITIES
 |
| 1. Was the study subject to monitoring/auditing by an external/internal unit (other than REC-A 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-A) 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-A), 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 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 animals has **Select an item**

If there has been any change in the risk to animals 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. DECLARATION
 |
| I declare that the report contents and attached appendices are complete and accurate.  |
|  **30 June 2021**SIGNATURE: **Type name here** (Primary Responsible Person) Date |
|  **30 June 2021**SIGNATURE: **Type name here** (Principal Investigator/Researcher) Date |
| 1. APPENDICES
 |
| In order to expedite the review of this progress report, please ensure that all the required information, as specified below, is attached. 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 2 of this application. Any deviation from this requirement may result in a delay in the review and approval of the progress report. |
| **APPENDIX 1: Study Closure\discontinuation**  |
| If applicable, attach as "Appendix 1”  |
| **APPENDIX 2: Unexpected violations\exceptions\deviations**  |
| If applicable, attach as "Appendix 2”  |
| **APPENDIX 3: Amendments**  |
| If applicable, attach as "Appendix 3”  |
| **APPENDIX 4: Extension\renewal**  |
| If applicable, attach as "Appendix 4”  |
| **APPENDIX 5: Adverse incident report)** |
| If applicable, attach as "Appendix 5”  |
| **APPENDIX 6: Revised documentation in response to adverse incidents** |
| If applicable, attach the relevant documentation, as "Appendix 9". Clearly highlight in the amended documentation all modifications made together with a rationale for such modifications. |
| **APPENDICES 7 – 9: Other**  |
| If applicable, attach the required information to your progress report, appropriately and clearly labelled. |

1. All animals used should be listed, even invertebrates. Please give number estimates if you do not have exact numbers, i.e. zooplankton, insects that were subsampled for counts. If species currently unknown/unidentified please list the lowest taxonomic level identified, e.g. Chironomidae [↑](#footnote-ref-1)
2. Includes eggs, foetuses and embryos; embryonated eggs; non-human primates, wildlife. [↑](#footnote-ref-2)