

**HEALTH RESEARCH ETHICS COMMITTEE 1 & 2**

**ANNUAL PROGRESS/FINAL REPORT FOR CLINICAL TRIALS:**

**LOCAL SITE SUMMARY**

*(INFORMATION SHOULD BE TYPED)*

**This summary must be accompanied by your submission of the copy of the MCC progress report(s) for the same reporting period.**

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| **SECTION A: REPORT TYPE** *(please check [x] appropriate box)* | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Final report** (to be submitted after study/site closure)  **Annual progress report** (request for extension/annual renewal of ethics approval) | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Reporting Period: From** dd/mm/yyyy **to** dd/mm/yyyy | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **SECTION B: DETAILS OF PRINCIPAL INVESTIGATOR** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Title, First name, Surname:** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **University DIVISION/CRO:** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **University DEPARTMENT:** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Telephone number:** | | | | | | | | | | | | | **E-mail:** | | | | | | | | | | | | | | |
| **SECTION C: PROJECT DETAILS** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Title of study:** | | | | | | | | | | | | | | | | **HREC Ref No:** | | | | | | | | | | | |
| **Approval date:** | | | | | | | **Start date:** | | | | | | | | | **Expected date of completion:** | | | | | | | | | | | |
| **SECTION D: FUNDING – HOW IS THE PROJECT FUNDED?** *(please check [x] appropriate box)* | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Industry** | | | | | | | | | | |  | | 1. **NIH/US government funded research** | | | | | | | | | | | | | |  |
| 1. **Other international grant funded research (e.g. Wellcome Trust)** | | | | | | | | | | |  | | 1. **National grant funded research (e.g. NRF, MRC, CSIR, etc)** | | | | | | | | | | | | | |  |
| 1. **Harry Crossley funded research** | | | | | | | | | | |  | | 1. **Research funded solely from SU departmental budget** | | | | | | | | | | | | | |  |
| 1. **Self funded research** | | | | | | | | | | |  | | 1. **Non-sponsored student research for degree purposes at Stellenbosch University** | | | | | | | | | | | | | |  |
| **SECTION E: PARTICIPANTS** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | **Local Site** | | | | | **South Africa** | | | | | | **Global** | | | |
| **Expected number of participants (total)** | | | | | | | | | | | | |  | | | | |  | | | | | |  | | | |
| **Number of participants screened to date** | | | | | | | | | | | | |  | | | | |  | | | | | |  | | | |
| **Number of participants enrolled in this reporting period** | | | | | | | | | | | | |  | | | | |  | | | | | |  | | | |
| **Total number of participants enrolled to date** | | | | | | | | | | | | |  | | | | |  | | | | | |  | | | |
| **Number of participants completed** | | | | | | | | | | | | |  | | | | |  | | | | | |  | | | |
| **Number of participants withdrawn before completion** | | | | | | | | | | | | |  | | | | |  | | | | | |  | | | |
| **Reasons for withdrawal** | | | | | | | | | | | | |  | | | | |  | | | | | |  | | | |
| **SECTION F: SUMMARY OF PROGRESS TO DATE** (Refer to the number of participants recruited, participant retention,  withdrawals, unanticipated problems, adverse events, positive outcomes, etc.) | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Participant recruitment**  **(Detail the number of participants recruited)** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Participant retention**  **(Summary of any withdrawal of participants from the research since the last REC review)** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Unanticipated problems**  **(Summary of unanticipated problems, in some cases such a summary could be a simple brief statement that there have been no unanticipated problems)** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Adverse events** (this does not include SAEs)  **(Summary of available information regarding adverse events, in some cases such a summary could be a simple brief statement that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document and any investigator brochure)** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Positive outcomes** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Publications/Dissemination of results**  **(List of publications from this research and/or summary of other media for dissemination of results)** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **SECTION G: SERIOUS ADVERSE EVENTS** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | **Local Site** | **South Africa** | | | **Global** | | |  | | | | | | | | **Local site** | | **South Africa** | | | **Global** | | |
| **Number of SAE’s for reporting period** | | | | |  |  | | |  | | | **Total number of SAE’s since start of trial** | | | | | | | |  | |  | | |  | | |
| **Summary of LOCAL SITE SAE’s for reporting period** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Ref. No./**  **Participant No.** | **Date** | **Event** | | | | | | | | | | **Causality**  (Related/ unrelated/  unknown) | | | **Outcome**  (Resolved/ unresolved/ death) | | | | **Previously reported to HREC** (Yes/No) | | | | | | | | |
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| **SECTION H: PROTOCOL NON-COMPLIANCE *(Please attach details)*** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | **Local Site** | | | | **South Africa** | | | **Global** | | | |  | | | | | | | **Local Site** | | **South Africa** | | | **Global** | |
| **Number of protocol deviations for reporting period** | | |  | | | |  | | |  | | | | **Total protocol deviations** | | | | | | |  | |  | | |  | |
| **Summary of LOCAL SITE DEVIATIONS for reporting period** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Ref. No. (If applicable)** | | | | **Date** | | | | **Incident** | | | | | | | | | **Explanation** | | | | | | | | | | |
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| **SECTION I: ATTACHMENTS**  **Kindly indicate if you have attached any of the following documentation. Include documents only if relevant to your progress report application.** | | |
| **Current informed consent documents** | |  |
| **Relevant multi-centre trial reports e.g. DSMB reports** | |  |
| **Published articles or abstracts** | |  |
| **Literature (a summary of any recent literature that may be relevant to the research)** | |  |
| **SECTION J: HREC REVIEW FEE** | | |
| **I have completed a payment instruction form** | **Yes**  **No** | |
| **I have attached proof of payment** | **Yes**  **No** | |
| **SECTION K: DECLARATION** | | |
| I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility of it  …………………………………………………….. ……………………………………… ………………………………………..  **Signature of Principal Investigator Print name Date** | | |
| I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility of it.  …………………………………………………….. ……………………………………… ………………………………………..  **Signature of Study Coordinator Print name Date** | | |

**INSTRUCTIONS: How to submit a progress report**

**CLINCIAL TRIALS, human/HEALTH and student research:**

1. **1 hard copy of full application**
   * + **Submit to Elvira Rohland, room 5007, 5th floor, teaching block, Faculty of Medicine and Health Sciences**

**AND**

1. **1 electronic copy of full application**
   * + **Submit in one email to ethics@sun.ac.za**
     + **Submit any documents created in Microsoft word as either word documents or .pdf files**
     + **Submit a scanned .pdf file of each signed document**

**GUIDELINES FOR COMPLETING PROGRESS REPORTS**

*(NB. Please delete this Page before you print out and submit your progress report.)*

1. **Ethics approval is valid for one year only**. A progress report is an application for renewal of ethics approval and must be submitted annually, well before the ethics approval expiry date, so that the progress report can be reviewed and the project re-approved **prior** to the expiry date. No research may continue without this process and re-approval. NB! Six monthly progress reports may occasionally be requested if the HREC deems the project to be of particularly high risk.
2. All clinical trials falling under the jurisdiction of the MCC must submit a progress report to the MCC six monthly and should provide the REC with a copy of this report. However a **site specific** progress report must be submitted annually, for ethics reapproval, using this format.
3. The progress report should contain sufficient information to allow the reviewer to conduct a substantive and meaningful review of the progress of the project, including any challenges or problems encountered.
4. For multi-centre studies the information in the progress report must pertain specifically to SU sites.
5. An updated complete protocol, incorporating all approved amendments should be submitted approximately every three years unless there have been no, or minimal changes to the project. If so, state this in the progress report.
6. Copies of published abstracts and/or papers, may be submitted as attachments, but may **NOT** replace text required in Section F.

1. All investigators whose projects are funded by US government federal funds (NIH, CDC etc) must comply fully with OHRP requirements for continuing review. These can be found at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>