

**BASIC AND SOCIAL SCIENCES RESEARCH ETHICS COMMITTEE (BaSSREC)**

**ANNUAL MONITORING REPORT / AMENDMENT REPORT**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Please complete the form according to the following guidelines:   * *All researchers* need to complete Sections A and E. * Section B is only completed if the research project is *quantitative* in nature. * Section C is only completed if the research project is *qualitative* in nature. * Section D is only completed if the researchers are making use of *previously collected biological samples or data.* | | | | | | | | | | | | | | | | | | |
| **SECTION A: GENERAL INFORMATION AND PROGRESS** | | | | | | | | | | | | | | | | | | |
| 1. **Project Head/Principle Investigator/Study leader Details** | | | | | | | | | | | | | | | | | | |
| **Surname** |  | | | | | | **Initials** | |  | | | | **Title** | | |  | | |
| **Department** |  | | | | | | | | | | | | | | | | | |
| **E-mail** |  | | | | | | | | | | | | | | | | | |
| **Telephone** | **Work** |  | | | | | **Cell** | |  | | | | | **Fax** | |  | | |
| 1. **Student Details** | | | | | | | | | | | | | | | | | | |
| **Surname** |  | | | | | | **Initials** | |  | | | | **Title** | | |  | | |
| **Department** |  | | | | | | | | | | | | | | | | | |
| **E-mail** |  | | | | | | | | | | | | | | | | | |
| **Telephone** | **Work** |  | | | | | **Cell** | |  | | | | | **Fax** | |  | | |
| 1. **Details of approved proposal/protocol** | | | | | | | | | | | | | | | | | | |
| **Title** |  | | | | | | | | | | | | | | | | | |
| **Ethics Approval Number** | | | |  | | | | | | | **Risk level** | | | |  | | | |
| **Approval date** |  | | | | | | **Expiry date** | | | |  | | | | | | | |
| **Are there any sub-studies/affiliated studies linked to this project?** | | | | | | **Yes** |  | **If yes, please indicate titles of the sub-study/affiliated study below and mark whether a report has been submitted.** | | | | | | | | | | |
| **No** |  |
| **Titles of sub-studies/affiliated studies** | | | | | | | | **Students/researchers included** | | | | | | | | | **Report in?**  **(Please attach)** | |
| **Yes** | **No** |
|  | | | | | | | |  | | | | | | | | |  |  |
|  | | | | | | | |  | | | | | | | | |  |  |
|  | | | | | | | |  | | | | | | | | |  |  |
| 1. **Funding details (Where do you receive your funding from? Please mark with an X)** | | | | | | | | | | | | | | | | | | |
| **Internal** | | |  | | **National (NRF/MRC)** | | | | |  | | **NIH/US Gov** | | | | | |  |
| **Industry** | | |  | | **International grant** | | | | |  | | **Self** | | | | | |  |
|  | | | | | | | | | | | | | | | | **Yes** | **No** | **NA** |
| **Were you able to fund your project as initially intended?**  **If not, please indicate here in what way it has changed:** | | | | | | | | | | | | | | | |  |  |  |
| 1. **Summary of progress to date** | | | | | | | | | | | | | | | | | | |
| **Shortly describe the overall progress to date of the project (500 words):** | | | | | | | | | | | | | | | | | | |
| **Please describe any ethical issues (both minor and/or major) that may have arisen during the past year (500 words):** | | | | | | | | | | | | | | | | | | |
| **Describe the research monitoring approach you followed:** | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | **Yes** | **No** | **NA** |
| **Has the level of risk to the participants changed during the past year?**  **If yes, please explain here (new level, reason, how HSSREC was notified):** | | | | | | | | | | | | | | | |  |  |  |
| **Has any new conflict of interest occurred during the past year?**  **If yes, please explain here:** | | | | | | | | | | | | | | | |  |  |  |
| **Have the research records produced (both hard and soft copies) been correctly maintained and secured as stated in the application?**  **Please explain your system here:** | | | | | | | | | | | | | | | |  |  |  |
| **If the Human Social Sciences Research Ethics Committee (HSSREC), has provided *provisional approval* for your project, have you fulfilled the conditions of the provisional approval e.g. approval from the Department of Health, goodwill permission from the school principal etc. and provided the HSSREC with these?**  **Please give greater detail regarding the manner in which you *have/have not* adhered to the conditions of provisional approval provided by the ethics committee:** | | | | | | | | | | | | | | | |  |  |  |
| **6. Adverse events/Serious adverse events/Incidents (if applicable)** | | | | | | | | | | | | | | | | **Yes** | **No** | **NA** |
| **Has there been any adverse events/serious adverse events/incidents in the project during the past year?**  **Please give the following for each of the adverse events/serious adverse events/incidents: the date, a narrative overview, how it was managed and how the HSSREC was notified.**  1)  2)  3) | | | | | | | | | | | | | | | |  |  |  |
| **If a data safety monitoring board was part of your planned research have they evaluated the adverse events/serious adverse events/incidents?**  **If yes, please attach a copy of the report.** | | | | | | | | | | | | | | | |  |  |  |
| **7. External monitoring (if applicable)** | | | | | | | | | | | | | | | | **Yes** | **No** | **NA** |
| **Has the study been externally monitored or audited?**  **If yes, please indicate the name of the agency:**  **Please attach a copy of the report.** | | | | | | | | | | | | | | | |  |  |  |

**SECTION B: QUANTITATIVE STUDIES**

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| **8. Enrolment of participants** | | | | |
| **Total number of participants planned to be included in the project.** | | |  | |
| **Actual number of participants enrolled in the project.** | | |  | |
| **Number of participants that withdrew from the project out of own choice.**  **Please provide reasons here for participants’ withdrawal:** | | |  | |
| **Number of participants withdrawn by primary investigator due to adverse events/serious adverse events/incidents/other reasons.**  **Please provide reasons here for these withdrawals:** | | |  | |
| **Number of participants lost to follow-up (if appropriate).**  **Please explain here why they were lost:** | | |  | |
| **SECTION C: QUALITATIVE ANALYSES** | | | | |
| **9. Methods used** | | | | |
| **How many participants have been enrolled to date?** | | |  | |
|  | **Yes** | | **No** | **NA** |
| **Has data saturation been reached in this project?** |  | |  |  |
| **Please give an overview of the methodology used to determine the indicated data saturation:** | | | | |
| **Number of participants that withdrew from the project out of own choice.**  **Please provide reasons for participants’ withdrawal:** | | |  | |
| **Number of participants withdrawn by the primary investigator due to adverse events/serious adverse events/incidents/other reasons.**  **Please provide reasons for these withdrawals:** | | |  | |
| **Number of participants lost to follow-up (if appropriate).**  **Please explain why they were lost:** | | |  | |
| **SECTION D: USE OF PREVIOUSLY COLLECTED DATA** | | | | |
| **10. Databases** | **Yes** | | **No** | **NA** |
| **Was the database you received anonymised?**  **Describe the process:** |  | |  |  |
| **Was the database you received password protected?** |  | |  |  |
| **SECTION E: PROJECT AMENDMENTS AND STUDY STATUS** | | | | |
| **12. Amendments** | **Yes** | **No** | | **NA** |
| **Has the study been amended or changed during the past year?** |  |  | |  |
| **Amendments** | **Date** | | | |
|  |  | | | |
|  |  | | | |
| **13. Status of study** | **Yes** | **No** | | **NA** |
| **Has the study been completed and does this serve as your final report?** |  |  | |  |
| **Has this project been terminated?**  **If so, please indicate the date, reason for termination and when the HSSREC was notified:** |  |  | |  |
| **Does the project have to continue in the following year?** |  |  | |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **14. Signature** | | | |
| **By signing this document, I certify that the information provided is accurate and complete.** | | | |
| **Signature by the primary investigator** |  | **Date** |  |

Some sections of this document have been adapted from similar HREC documentation of the University of Stellenbosch and the University of the Cape Town.

Content adapted from HSSREC Standard Operating Procedure compiled by Professor Chrizanne van Eeden.