|  |  |
| --- | --- |
| Date of Submission |  |

****

**SAFETY MONITORING AND RECERTIFICATION REPORT**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***To be completed electronically by the principal investigator/researcher in accordance with the Standard Operating Procedures for Safety Monitoring and Recertification of the REC and submitted to the REC.*** | | | | | | | | | | | | |
| Faculty: | | | Department: | | | | | | | | | |
| Title of the study: | | | | | | | | | | | | |
| Name of principal investigator  (researcher): | | | | Name and qualification of supervisor(s): | | | | | | | | |
| Name of qualification: | | | | Staff / Student Number: | | | | | | | | |
| Ethical approval number: | | | | Research site: | | | | | | | | |
| Select nature of application | | | | | | | | | | | | |
| **Safety Monitoring Report** |  | | | **Recertification** | | | | |  | | | |
| **Section A – *To be completed by the principal investigator/researcher*** | | | | | | | | | | | | |
| 1. Has sufficient progress been made with respect to anticipated timeframes in the research protocol? (If not, please specify and explain why in an attached report) | | | | | | Yes | | | | No | | N/A |
| 2. Have there been any deviations (intentional/unintentional) from the approved research protocol (If yes, please detail in an attached report) | | | | | |  | | | |  | |  |
| 3. Have any adverse events occurred since commencing the research?  If yes to the above, has an adverse event reporting form been submitted to the REC? | | | | | |  | | | |  | |  |
| 4. Have there been any unforeseen events or circumstances which have/may jeopardies’ participant safety or result in contravention of the approved research protocol.  (If yes, please detail in an attached report) | | | | | |  | | | |  | |  |
| 5. Are you aware of any complaints (formal/informal) from participants or staff or stake holders regarding the conduction of the research? If yes please detail in an attached report) | | | | | |  | | | |  | |  |
| 6. Are you aware of any incidents whereby participants have been managed/treated in a manner other than that stated in the approved research protocol?  (If yes, please detail in an attached report) | | | | | |  | | | |  | |  |
| 7. Has appropriate informed consent been obtained from all participants in keeping with the method stated in the research protocol and is documentary evidence thereof available for on request?  (If no, please detail in an attached report) | | | | | |  | | | |  | |  |
| 8. Has it been necessary to exclude any participants who were previously recruited for the study?  (If yes, please detail in an attached report) | | | | | |  | | | |  | |  |
| 9. Have any participants requested to be withdrawn from the study prematurely? If yes, please details the reasons for such withdrawal in an attached report) | | | | | |  | | | |  | |  |
| 10. Have any participants suddenly left the study? (If yes please detail in an attached report) | | | | | |  | | | |  | |  |
| 11. Are the infrastructure, equipment and manpower at the research site/sites suitable and/or appropriate for the successful conduction of the research in keeping with the approved protocol?  (If no, please detail in an attached report) | | | | | |  | | | |  | |  |
| 12. Are the experimental interventions being applied or administered in keeping with those described in the research protocol? (If no, please detail in an attached report) | | | | | |  | | | |  | |  |
| 13. Is experimental medication being stored, labelled, dispensed, coded and administered according to the approved protocol? (If no, please detail in an attached report) | | | | | |  | | | |  | |  |
| 14. Is all critical documentation (see attached list) available for inspection at the research site(s)?  (If no, please detail in an attached report) | | | | | |  | | | |  | |  |
| 15. Is all critical documentation (see attached list) including confidential data, results and reports safely stored at the research site(s)? (If no, please detail in an attached report) | | | | | |  | | | |  | |  |
| 16. Are you aware of any reason which warrants temporary/permanent suspension of the research activity?  (If yes, please detail in an attached report) | | | | | |  | | | |  | |  |
| 17. Are you aware of any reason that may warrant re-evaluation/ suspension of the ethical clearance by the REC?  (If yes, please detail in an attached report) | | | | | |  | | | |  | |  |
| **Signature:** | | | | | | | | | | **Date:** | | |
| Researcher/Principal investigator: | | | | | | | | | |  | | |
| Promoter/Supervisor: | | | | | | | | | |  | | |
| Head of Department: | | | | | | | | | |  | | |
| Deputy Dean of Faculty**/Research Professor:** | | | | | | | | | |  | | |
| **Section B – *To be completed by the designated Chairperson of the REC*** | | | | | | | | | | | | |
| The findings of the REC with respect to the above mentioned research are detailed as follows: | | | | | | | | | | | | |
|  | | | | | Yes | | | No | | | N/A | |
| 1. The respective study is approved to continue – there are no evident grounds for concern or further investigation. | | | | |  | | |  | | |  | |
| 2. The respective study is approved to continue –however some evidence exists of potential minor transgressions and/or irregularity warranting re-assessment and reporting within 1 month but not requiring a site inspection. | | | | |  | | |  | | |  | |
| 3. The respective study is approved to continue –however a site inspection by the REC is warranted is recommended. | | | | |  | | |  | | |  | |
| 4. The respective study warrants temporary withdrawal of ethical approval - pending a site inspection by the REC - evidence of potential significant transgressions and/or irregularity exists. | | | | |  | | |  | | |  | |
| 5. The respective study warrants immediate withdrawal of ethical approval and suspension and an independent trial audit – significant evidence of transgression and/or irregularity exists. | | | | |  | | |  | | |  | |
| *If yes for points 2-5 is selected – a detailed report by the Chairperson is to be completed below:* | | | | | | | | | | | | |
| Any additional comments to be detailed: | | | | | | | | | | | | |
|  | | **Signature:** | | | | | **Date:** | | | | | |
| Chairperson of REC | |  | | | | |  | | | | | |

**List of documents that must be available at the site:**

The following documents should be available for inspection at the relevant research site:

* Copy of final approved research protocol (and revisions thereof if applicable)
* Copy of ethics clearance certificate by REC
* Copy of regulatory authority approval letters (Department of Health, Site management etc.)
* Copy of all participant information letters and informed consent forms
* Copy of all other recruitment documentation i.e. advertisements posters etc.
* Signed agreements with other involved parties (sponsors, suppliers, diagnostic services etc.)
* CVs of researchers (investigators)
* Subject screening log
* Subject enrolment log
* Blinding and or randomisation schedules
* Investigational equipment service and calibration documents
* Experimental medication stock control documents, dispensing log, labelling protocol
* Dispensing protocol/schedule
* Copy of dispensing license or pharmacist registration documents