To be completed electronically by the principal investigator/researcher in accordance with the Standard Operating Procedures for Safety Monitoring and Recertification of the UZREC. Must be Submitted to UZREC.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Title of the study: | | | | | | |
| Name and qualification of principal investigator  (researcher): | | Name and qualification of supervisor(s): | | | | |
| Name of qualification/project: | | Student/Staff Number: | | | | |
|  | |  | | | | |
| Ethical approval number: | | Research site: | | | | |
| **SELECT NATURE OF APPLICATION (*Mark appropriate box with* X):** | | | | | | |
| Safety Monitoring Report |  | Recertification | | |  | |
| **SECTION A – To be completed by the principal investigator/researcher** | | | | | | |
|  | | | | **Yes** | **No** | **N/A** |
| Has sufficient progress been made with respect to anticipated timeframes in the research protocol? (If not, please explain reasons and attached in a report) | | | |  |  |  |
| Have there been any deviations (intentional/unintentional) from the approved research protocol (If yes, please attach a detailed report) | | | |  |  |  |
| Have any adverse events occurred since commencing the research? | | | |  |  |  |
| Has an adverse event reporting form been submitted to the UZREC? | | | |  |  |  |
| Have there been any unforeseen events or circumstances which have/may jeopardize participant safety or result in contravention of the approved research protocol. (If yes, please attach a detailed report) | | | |  |  |  |
| Are you aware of any complaints from participants or staff or stake holders regarding the conduction of the research? If yes, please attach report) | | | |  |  |  |
| 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 attach a detailed report) | | | |  |  |  |
| 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 inspection? (If no, please attach a detailed report) | | | |  |  |  |
| Has it been necessary to exclude any participants who were previously recruited for the study? (If yes, please attach a detailed report) | | | |  |  |  |
| Have any participants requested to be withdrawn from the study prematurely? If yes, please details the reasons for such withdrawal in an attached report) | | | |  |  |  |
| Have any participants absconded from the study? (If yes, please attach a report) | | | |  |  |  |
| 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 attach a detailed report) | | | |  |  |  |
| Are the experimental interventions being administered in keeping with those described in the research protocol? (If no, please attach a detailed report) | | | |  |  |  |
| Is experimental medication being stored, labelled, dispensed, and administered according to the approved protocol? (If no, please attach a detailed report) | | | |  |  |  |
| Is all critical documentation (see attached list) available for inspection at the research site(s)? (If no, please attach a detailed report) | | | |  |  |  |
| Is all critical documentation including confidential data, results and reports safely stored at the research site(s)? (If no, please attach a detailed report) | | | |  |  |  |
| Are you aware of any reason which warrants temporary/permanent suspension of the research activity? (If yes, please attach a detailed report) | | | |  |  |  |
| Are you aware of any reason that may warrant re-evaluation/ suspension of the ethical clearance by the UZREC? (If yes, please attach a detailed report) | | | |  |  |  |
|  | | | | | | |
| **Signature:** | | | | | **Date:** | |
| Researcher/principal investigator: | | | | |  | |
| Supervisor: | | | | |  | |
| Head of Department: | | | | |  | |
|  | | | | | | |
| **SECTION B – *To be completed by the Chairperson of UZREC, or designated member its Safety Monitoring*** ***Committee (SMC).*** | | | | | | |
| UZREC/SMC findings with respect to the above mentioned research are detailed as follows: | | | | | | |
|  | | | | **Yes** | **No** | **N/A** |
| 1. Study is approved to continue. No evidence for concern/further investigation. | | | |  |  |  |
| 2. Study is approved to continue –however some evidence exists of potential minor transgressions and/or irregularity warranting re-assessment and reporting within one (1) month but not requiring a site inspection. | | | |  |  |  |
| 3. Approved to continue –however a site inspection is warranted/ recommended. | | | |  |  |  |
| 4. Study warrants temporary withdrawal of ethical approval - pending a site inspection by the SMC, due to evident transgressions/irregularity. | | | |  |  |  |
| 5. Study warrants immediate withdrawal of ethical approval and suspension and an independent trial audit – due to evident transgressions/irregularity | | | |  |  |  |
|  | | | | | | |
| *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 below:* | | | | | | |
|  | | | | | | |
|  | | | | | | |
|  | | | **Signature:** | **Date:** | | |
| Chairperson of SMC (if necessary) | | |  |  | | |
| Chairperson of UZREC | | |  |  | | |
| Executive Dean of Faculty/ Chairperson of FRC | | |  |  | | |

**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 UZREC

 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 randomization 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