To be completed electronically by the principal investigator in accordance with the Standard Operating Procedures for reporting adverse events of the UZREC for all adverse events (AE), serious adverse events (SAE), adverse drug reactions (ADR), and serious adverse drug reactions (SADR) and forwarded to UZREC.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Title of the study: | | | | | | | |
| Department & Faculty: | | | | | | | |
| Name and qualification of the principal investigator  (researcher): | | | | | Name and qualification of supervisor(s): | | |
| Name of qualification: | | | | | Student Number: | | |
| Ethical approval number: | | | | | Research site: | | |
| AE | SAE | ADR | SADR | | Date of event: | | |
| Brief description of the event: *Context, extent, where, when, how & who was affected (including participant reference number):* | | | | | | | |
| Relationship of the event to the research process: | | | | | | | |
| Description of the outcome: | | | | | | | |
| Description of intervention thus far: | | | | | | | |
| ***TO BE COMPLETED BY THE CHAIRPERSON OF THE UZREC.*** | | | | | | | |
| Date received: | | | | | Review required: | | |
| Emergency: | Standard | |
| Recommendations/ interventions imposed by the UZREC: | | | | | | | |
|  | | | | **Signature:** | | | **Date:** |
| Researcher | | | |  | | |  |
| Supervisor | | | |  | | |  |
| Head of Department | | | |  | | |  |
| Chairperson of FREC | | | |  | | |  |
| Chairperson of UZREC | | | |  | | |  |