**Appendix F**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ADVERSE EVENT REPORTING FORM | | | | | | | |
| *To be completed electronically by the principal investigator in accordance with the Standard Operating Procedures for reporting adverse events of the DUT-IREC for all adverse events (AE), serious adverse events (SAE), adverse drug reactions (ADR) and serious adverse drug reactions (SADR) and forwarded to the DUT-IREC.* | | | | | | | |
| Title of the study: | | | | | | | |
| Institution: | | | | | | | |
| Name and qualification of 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 (include patient/participant reference number): | | | | | | | |
| Relationship of event to research process: | | | | | | | |
| Description of the outcome: | | | | | | | |
| Description of intervention thus far: | | | | | | | |
| ***TO BE COMPLETED BY THE CHAIRPERSON OF THE DUT-IREC.*** | | | | | | | |
| Date received: | | | | | Review required: | | |
| Emergency: | Standard | |
| Comments: | | | | | | | |
| Recommendations/interventions imposed by the DUT-IREC: | | | | | | | |
|  | | | | **Signature:** | | | **Date:** |
| Researcher | | | |  | | |  |
| Supervisor | | | |  | | |  |
| Head of Department | | | |  | | |  |
| Executive Dean of Faculty/ Chairperson of FRC | | | |  | | |  |
| Chairperson of DUT-IREC | | | |  | | |  |