**Appendix E**



|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 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 IREC for all adverse events (AE), serious adverse events (SAE), adverse drug reactions (ADR) and serious adverse drug reactions (SADR) and forwarded to the 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 IREC.*** | | | | | | | |
| Date received: | | | | | Review required: | | |
| Emergency: | Standard | |
| Comments: | | | | | | | |
| Recommendations/interventions imposed by the IREC: | | | | | | | |
|  | | | | **Signature:** | | | **Date:** |
| Researcher | | | |  | | |  |
| Supervisor | | | |  | | |  |
| Head of Department | | | |  | | |  |
| Chairperson of IREC | | | |  | | |  |
| Executive Dean of Faculty/ Chairperson of FRC | | | |  | | |  |