



STANDARD OPERATING PROCEDURES

ANNEX 2

LIST OF IR-EC FORMS

| | TITLE |
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| Form 1.1 | Standard Operating Procedures (SOPs) Template |
| Form 2.1 | Proposed SOP |
| Form 4.1 | Letter of Appointment of IR-EC Member |
| Form 4.2 | Curriculum Vitae |
| Form 4.3 | Confidentiality and Conflict of Interest Declaration |
| Form 5.1 | Appointment Letter of Independent Consultants |
| Form 6.1 | Training Record of IR-EC Member |
| Form 8.1 | Application Form for Protocol Review |
| Form 8.2 | Conflict of Interest Statement (COI) |
| Form 8.3 | Certificate of Exemption from Ethics Review |
| Form 10.1 | Protocol Assessment Form |
| Form 10.2 | Informed Consent Assessment Form |
| Form 10.3 | Notice of Research Protocol Approval |
| Form 12.1 | Protocol Resubmission Form |
| Form 15.1 | Serious Adverse Event (SAE) Report |
| Form 15.2 | Unexpected Event/Unanticipated Risk Report |
| Form 16.1 | Protocol Amendment Review Form |
| Form 17.1 | Progress Report |
| Form 18.1 | Protocol Deviation and Violation Report Form |
| Form 19.1 | Continuing Review Form |
| Form 20.1 | Request/Query Record |
| Form 21.1 | Site Visit Form |
| Form 22.1 | Study Termination Form |
| Form 23.1 | Final Report Form |
| Form 25.1 | Minutes of the Meeting Form |
| Form 26.1 | Notice of the Meeting Form |
| Form 27.1 | Decision Letter of IR-EC |
| Form 31.1 | Confidentiality Agreement Form (for Non IR-EC Members) |
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