# ANNEX 2

**AF/02-015/01**

**Format for Review of Research Report**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **I. Protocol No:** | | | | | | |
| **Protocol Title:** | | | | | | |
| **Principal Investigator:** | | | | | | |
| **II. Elements of Review** | | | | | | |
| **Sl**  **No.** | **Protocol parameters** | **Reviewer’s observation *(Please mark ‘X’ in relevant cages)*** | | | | |
| **Same as approved by IRB** | **Minor diversion from that IRB by approved** | | **Major diversion from that approved by IRB** | **Remarks** |
| 1 | Protocol Title |  |  | |  |  |
| 2 | Type of study |  |  | |  |  |
| 3 | Principal investigator(s) |  |  | |  |  |
| 4 | Co-investigator(s) |  |  | |  |  |
| 5 | Objectives |  |  | |  |  |
| 6 | Sample size |  |  | |  |  |
| 7 | Sampling method |  |  | |  |  |
| 8 | Inclusion criteria |  |  | |  |  |
| 9 | Exclusion criteria |  |  | |  |  |
| 10 | Recruitment of subjects |  |  | |  |  |
| 11 | Discontinuation & withdrawal criteria |  |  | |  |  |
| 12 | Voluntary, non-coercive recruitment of subjects |  |  | |  |  |
| 13 | Involvement of vulnerable subjects |  |  | |  |  |
| 14 | Informed consent procedures |  |  | |  |  |
| 15 | Data collection tools |  |  | |  |  |
| 16 | Data analysis |  |  | |  |  |
| 17 | Privacy & Confidentiality |  |  | |  |  |
| 18 | Risk-Benefit assessment / management |  |  | |  |  |
| Any other comments: | | | | | | |
| **IV. Reviewer’s Recommendation on Closure of Research project** | | | | | | |
| I certify that I have made the foregoing observations on the basis of my objective assessment of the protocol and the final report and I confirm that I have complied with the IRB policies and guidelines in reviewing this report.  I, therefore, recommend that the report should be;  Closed as the PI has adhered with the approved protocol and the report is technically sound.    Closed; however, the PI should be reprimand for minor violation(s) (specify violations/comments).................................................................................................................  Either resubmitted with revision or justifications should be provided for the major violations (specify the violations/comments).............................................................................................    **Signature of Reviewer:**…………………………………………….  **Name of Reviewer:** ………………………………………………… | | | | | | |
| **III. IRB Endorsement** | | | | | | |
| The recommendation of the reviewer of research report is endorsed/approved by: | | | | | | |
| 1. By Board Members 2. Unanimous decision 3. By Voting :   i. For: ………………………..........  ii. Against: …………………..........  iii. Total voting members: ………… | | | | B. By Chairperson   1. Approved: 2. Not approved:   Signature: ………………………  Office seal: | | |