# ANNEX 2

**AF/02-015/01**

**Format for Review of Research Report**

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| **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 Chairperson1. Approved:
2. Not approved:

Signature: ………………………Office seal: |