ANNEXURE: 02 **(AF/IEC/02/06/V-8.3)**

Study Assessment Form for Reviewer

Protocol Number: Date (D/M/Y):

Name of Principal Investigator:

Protocol version and date:

Primary Reviewer's name with Designation:

Sl. No	Particulars	Appropriate	Not Appropriate	N/A	Comments
1.	**Scientific related issues**				
	Rationale				
	Objectives				
	Study design				
	Study population				
	Inclusion Criteria				
	Exclusion Criteria				
	Withdrawal criteria				
	Procedures used in research				
	The use of placebo				
	The use of medical device				
	Method of Research Assessment - Assessment of efficacy - Assessment of safety				
	Monitoring Complications and solutions				
	Blood or specimens [Frequency & Amount]				
	Duration and number of follow up				
	Static used in analysis				
2.	**Ethical issues**				
	Involvement of Vulnerability				
	- Identification of Vulnerability - Justification for the use of Vulnerable population - Protection of Vulnerable groups				
	Risk to the health of participants				
	- Identify the risk: physical,				

	psychological, economic, legal risk or risk due to invasion of privacy and confidentiality				
	Sufficient measures to prevent or minimize the risks				
	Risk to the health of the embryo or the unborn child or spouse				
	Risk to the research community				
	Direct benefits to participants -During and after the study				
	Benefits to Society				
	Favorable benefits/risk ratio				
3.	**Informed consent issues**				
	a. Person who obtained informed consent b. Time when informed consent was conducted c. Place where informed consent was obtained				
	Objective of the research				
	Voluntary				
	Right to withdraw from the study				
	Alternatives in case of non-participation				
	Rationale of the study				
	Study procedure and participant's responsibilities				
	Risks or discomforts to the participants				
	Benefits to the participants or others				
	Medical care during the study				
	Payment/reimbursement/compensation				
	Privacy and confidentiality				
	Name, contact address, and telephone number of the investigator				
	Contact address and telephone number of				

	the ethics committee				
	Certificate of informed consent form/Assent form				
	Language used in the informed consent form				
4.	**Qualification of Investigator**				
	Expertise of investigator(s)				
	Training of the investigator(s) (GCP for clinical trials or Human Participant Protection)				
	Conflict of interest of the investigator(s)				

For medical device protocols:

Non-significant risk ☐

Significant risk ☐

- Registered with USFDA/MDD approval with supporting document of registration ☐
- Not yet registered with USFDA/MDD or no evidence or information for risk determination ☐

Risk assessment of the protocol:

- Research not involving more than minimal risk ☐
- Research involving greater than minimal risk but presenting the prospect of direct benefit to the participants ☐
- Research involving greater than minimal risk and no prospect of direct benefit to individual participant, but likely to yield generalizable knowledge about the participant's disorder or condition ☐

Duration of progress report:

06-Months ☐ **12** Months ☐

Opinion of the Reviewer:

Approve ☐

Minor modification(s) ☐

Major modification (s) ☐

Disapprove, ☐

please provide reason(s): _____

Reviewer Name signature and date