Annexure: 01 (AF/IEC/01/06/V-8.3)

Checklist for Principal Investigator

Name of the Principal Investigator	
Protocol Version and date	
Name of the Department/Affiliation	

Sl.No	Particulars			
1.	Covering letter	Yes	No	NA
2.	Protocol Title page:			
	Name of the Principal Investigator:			
	Name of the Co- Investigator/			
	Enclosures with page nos./Index			
3.	**Face Sheet**			
	1) Protocol/Project Title			
	2) Principal Investigator / Site coordinator			
	Name, Affiliation, Official address and E-mail address			
	3) Name, address of the Institution / Orgn. Responsible for conduct / coordination of project.			
	4) Name & address of the Funding / Sponsoring Institution/CRO/Sponsors			
4.	**To be answered / responded by the PI / coordinator**			
	a) Is request made for obtaining waiver from informed consent? (If yes, give reasons on separate sheet)			
5.	**Drawing of blood, body fluids, tissues etc.**			
	i) Administration of an investigational substance / implantation of a device (if yes, provide name of the drug / substance / device etc. and its manufacture's name and address) (Also, clearance from the DCGI, if relevant)			
	ii) Exposure to ionizing radiation			
	iii) Use of genetically engineered products (if yes, give details of the product, and appropriate clearances from the DBT, GEAC, DCGI, etc.)			
	d) Does the protocol involve inclusion of vulnerable participants (if yes, special			

	precautions proposed to safeguard their rights and interests shall be documented on a separate sheet) Page No.			
6.	**Proposal Related**			
	Conflict of interest to be provided- if involved in the IEC membership or any other			
	Signature of Principal Investigator responsible for conduct of study with mention of date & place			
	Undertaking by Investigators & Collaborators Signature, Date			
	Investigator Brochure version and date			
	Clinical trial agreement			
	Site or Study-specific Insurance			
	Brief Bio-data of Investigators/Co-investigator [Includes ongoing trial details] - signed and dated			
	Informed Consent Document/ Participant Record Sheet version and date			
	Summary of Study Protocol & Detailed Protocol version and date			
	Assent for minors (12-18 Years) English and translated version and date			
	Data Collection tools and Case report form			
	List of participating centers if the Multicentric trial			
	Sample size overall and site sample size			
	Study participant Accrual methods			
7.	**GCP Training Certificate of Study Team (Investigator)-Recent**			
8.	**Permission from the Governing Authorities**			
	CTRI			
	DCGI			
	NAC-SCRT			
	ICSCR			
	BARC			
	Tribal			
Signature of the PI				