(Annexure: 01)

Check list for Investigator

Institutional Ethics Committee of KAHER

Sl.No	Particulars			
1.	Covering letter	Yes	No	NA
2.	Title Page			
	Protocol Title:			
	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			
	a. Name b. Affiliation, c. Official address d. 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) Does the protocol fall under exempt category? (If yes, give reasons on separate sheet)			
	b) Is request made for obtaining waiver from informed consent? (If yes, give reasons on separate sheet)			
	c)) Does the protocol involve Human participants (If yes, will it include)			
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 separate sheet) Page No.			
6.	Proposal Related			
	Signature of Principal Investigator responsible for conduct of study with mention of date & place			
	Undertaking by Investigators & Collaborators Signature, Date			
	Investigator Brochure			
	Clinical trial agreement			
	Site or Study specific Insurance			
	Brief Bio-data of Investigators			
	Informed Consent Document/ Participant Record Sheet			
	Summary of Study Protocol & Detailed Protocol			
	Assent for minors(12-18 Years) English and translated			
	Data Collection tools and Case report form			
7.	GCP Training Certificate of Study Team (Investigator)-in last 03 Years			
8.	Permission from the Governing Authorities			
	CTRI			
	DCGI			
	NAC-SCRT			
	ICSCR			
	BARC			
	Tribal			
Signature of the PI				