ANNEXURE: 01 **(AF/IEC/01/06/V7.3)**

Checklist for Principal Investigator

Sl.No	Particulars		
1	Covering letter	Yes	No
3	Title Page	Written	Not Written
	Project Title:	Written	Not Written
	Name of the Principal Investigator:	Written	Not Written
	Name of the Co- Investigator/	Written	Not Written
	Enclosures with page nos.	Written	Not Written
4	Face Sheet		
	1) Project Title	Written	Not Written
	2) Principal Investigator / coordinator	Written	Not Written
	- Name, - Affiliation, - Official address - Telephone no's - E-mail address		
	3) Name, address of the Institution / Orgn. Responsible for conduct / coordination of project.	Written	Not Written
	4) Name & address of the Funding / Sponsoring Institution/CRO	Written	Not Written
6	To be answered / responded by the PI / Co-ordinator	Complete	Incomplete
	a) Does the protocol fall under exempt category? (If yes, give reasons on separate sheet)	Given	Not given
	b) Is request made for obtaining waiver from informed consent? (If yes, give reasons on separate sheet)	Given	Not given
	c)) Does the protocol involve Human participants (If yes, will it include)	Yes	No
	i) drawing of blood, body fluids, tissues etc.	Yes	No
	ii) 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)	Yes	No
	iii) Exposure to ionizing radiation	Yes	No
	iv) Use of genetically engineered products (if yes, give	Yes	No

	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.	Yes	No
	Signature of Principal Investigator responsible for conduct of study with mention of date & place	Complete	Incomplete
7	Undertaking by Investigators & Collaborators Signature, Date	Complete	Incomplete
8	Investigator Brochure	Yes	No
9	Case report form	Yes	No
10	Clinical trial agreement	Yes	No
11	Insurance	Yes	No
12	Brief Bio-data of Investigators	Complete	Incomplete
13	Participant Information Sheet:	Complete	Incomplete
14	Informed Consent Document	Complete	Incomplete
15	Participant Record Sheet	Complete	Incomplete
16	Summary of Study Protocol	Complete	Incomplete
17	Detailed Protocol	Complete	Incomplete
18	Data Collection tools	Attached	Not attached
19	GCP Training Certificate of Principal Investigator/Co-Investigators	Attached	Not attached

ANNEXURE: 02 **(AF/IEC/02/06/V7.3)**

Study Assessment Form for New Protocol

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

Name of Principal Investigator:

Reviewer's name with Designation:

Mark and comment on whatever items applicable to the study.

Sl.No	Particulars	Comments
1.	Objectives of the Study ☐ Clear ☐ Unclear	
2.	Background and Rationale ☐ Sufficient ☐ insufficient	
3.	Methodology ☐ Clear ☐ Unclear	
4.	Study Design and Sample size ☐ Appropriate ☐Inappropriate	
5.	Inclusion Criteria ☐ Appropriate ☐Inappropriate	
6.	Exclusion Criteria ☐ Appropriate ☐Inappropriate	
7.	Statement for protection of rights and interests of Vulnerable Participants ☐ Clear ☐Unclear	
8.	Voluntary, Non-Coercive Recruitment of Participants ☐ Yes ☐ No	
9.	Are Qualifications and experience of the Principal Investigator appropriate? ☐ Yes ☐ No	
10.	Facilities and infrastructure of Participating Sites ☐ Appropriate ☐ Inappropriate	
11.	Involvement of Local Researchers and Institution in the Protocol Design, Analysis and dissemination of Results ☐ Yes ☐ No	
12.	Risk-benefit analysis ☐ Yes ☐ No	
13.	Vulnerability assessment ☐ Yes ☐ No	
14.	Benefit to Local Communities ☐ Yes ☐ No ☐ Not applicable	
15.	Are blood/tissue samples sent abroad? ☐ Yes ☐ No	

16.	CTRI No/Document ☐ Yes ☐ No	
17.	Final Clinical Trial Aggrement ☐ Yes ☐ No	
18.	Insurance Policy(Study Specifc) ☐ Yes ☐ No	
19.	DCGI submission letter/Approval Letter ☐Yes ☐ No	
Participant Information Sheet and Informed Consent Documents		
Sl. No	**Points**	**Comments**
1.	Are procedures for obtaining Informed Consent appropriate? ☐ Yes ☐No	
2.	Contents of the Informed Consent Documents Translation and backatranlation certificates ☐ Clear ☐Unclear	
3.	Language of the Informed Consent Document: Kannada, Hindi, English and Marathi ☐ Clear ☐Unclear	
4.	Risks/ inconveniences mentioned clearly ☐ Yes ☐ No	
5.	Period of storage of biological samples ☐ Yes ☐ No	
6.	Are possible benefits mentioned ☐ Yes ☐ No	
7.	Patient dairy and information sheet (PIS) ☐ Yes ☐ No	
8.	Privacy & Confidentiality ☐ Yes ☐ No	
9.	Provision for Medical / Psychosocial Support/Trial related injuries ☐ Appropriate ☐Inappropriate	
10.	Provision for Compensation per subjects in ICFs-TA(INR)/ ☐ Appropriate ☐Inappropriate	

List of additional documents required (if applicable)

Reviewer Signature

ANNEXURE: 03 **(AF/IEC/03/06/V7.3)**

Annual Report Template

Protocol No:

Protocol Title:

Principal Investigator:

Name of the Co-Investigator:

Duration of the study:

PI Presented to IEC Meeting – date:

Approval date:

Study initiation: - date

Amendments if any:

Approval given for the Amendment:

Financial Status:

Objectives:

Sample size:

Number of study participants enrolled:

Number of Drops outs:

Number of screen failures:

Number of ongoing:

Number of Randomized:

Summary of the work done (preferably in 1-2 paragraphs):

Number on study/follow-up:

Number of AE/SAE:

Completion/Termination of the study – date

Any protocol deviation and violations:

Next due for the study Approval:

Signature of the Principal Investigator with date

ANNEXURE: 04 **AF/IEC/04/06/V7.3**

Study Report Form for Protocol Termination

Protocol No.:

Protocol Title:

Principal Investigator:

Date of EC Approval:

Phone number: E-mail address:

Sponsors /Funding Agencies Name:

Address:

Phone: E-mail:

Study site(s): No. of Participants as each site:

Study Design and Sample Size:

Objectives:

Methodology:

Duration of the study:

Total Number of study participants:

No. of Study Arms (If any):

Number of participants in each of the Study Arms:

Study dose(s):

Reasons for termination (if any):

Provision for follow-up of patients:

Whether the study samples are being retained for future use:

Results:

(Use extra blank paper, if more space is required.)

Outcome and Implications of the Study:

Presentations (If any):

Signature of P.I.: Date:

ANNEXURE: 05 **AF/IEC/05/06/V7.3**

Study Report Form for study Completion

Protocol No.: Principal Investigator:

Protocol Title:

Date of IEC Approval

Phone number: E-mail address:

Sponsors /Funding Agencies Name:

Address:

Phone: E-mail:

Study site(s): No. of Participants as each site:

Study Design and Sample Size:

Objectives:

Duration of the study:

Total Number of study participants:

No. of Study Arms (If any): Number of participants in each of the Study Arms:

Study dose(s):

Provision for follow-up of patients:

Whether the study samples are being retained for future use:

Outcome and Implications of the Study:

Presentations (If any):
Signature of P.I.: Date:

ANNEXURE: 06 **AF/IEC/06/06/V7.3**

Clinical Trial Agreement Checklist

Sl. No	Description	Yes	No
1.	**Protocol Number and Title**		
2.	**Effective date**		
3	**Parties Involved** - (Sponsor / CRO , Principal Investigator, Institution and or SMO) **Bipartite**		
	Tripartite		
	Quadra parted		
4	**Agreed terms** - Definition, Conduct of the study, Responsibility of the company, Principal investigator, Institution		
5	**Study drug and Materials**		
6.	**Study and Protocol**		
7.	**The Study Scheduled**		
8	**Monitoring and audit by the company**		
9	**Inspection by the regulatory authorities**		
10.	**Payment Details**- Budget and Payment scheduled, Payment of cost outside budget and payment schedule, Payment terms, payment recipient and address, Reimbursement, Payment for screen failure, payment for study coordinator.		
11.	**Obligations of the institution and Principal Investigator** - EC Approval, Performance of the study, Key personnel, sponsor Visit, Supplies		
12	**Study Records , reports and Data** - Study records , Case report form, Annual reports, Final Reports , **(In case of PI is no longer associated with the institute, Institute head or authorized designee will be responsible for maintenance and retention of study records)** , Reporting of SAE(Sponsor, EC,DCGI and head of institution), 14th day PI analysis Report (Sponsor, EC,DCGI and		

	head of institution).		
13	**Confidentiality**		
14	**Publications**		
15	**Ownership of materials, data, inventions and discoveries.**		
16	**Representations, warranties and covenant**.- Of the PI, Of the Sponsor, No other Representations or warranties, Of the Institutions		
17	**Governing Law -**This agreement and any dispute or claim out of or in connections with it or its subject matter (including non- contractual disputes or claims) shall be governed by and constructed in accordance with the laws of India without regard to the conflict of law principles thereof. The parties irrevocably agree that the courts of India shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this agreement or its subject matter (including non-contractual disputes or claims).		
18	**Indemnification** - Sponsor Indemnification, Institution Indemnification, Notification, Claims, Representation, subject injury.		
19	**Insurance** - Sponsor insurance , Institution Insurance		
20	**Compliance, Transparency, Anti - bribery, Anti- corruption and Conflict of Interest**.		
21	**Term and Termination**		
22	**Miscellaneous**		
23	**Agreed by the parties** - Sponsor/ CRO, PI, Institution, SMO(if involved)		
24	**Witness**		

ANNEXURE: 07 **AF/IEC/07/06/V7.3**

Document History

Author	Version	Date	Description of the Change
IEC members	V7.2	Nov-2017	Revised the Assessment of New Project Proposal form