

**Checklist for Principal Investigator**

SN	Particulars		
1	Covering letter	Yes	No
3	Title Page		
	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/V7.1)**

**Study Assessment Form for New Projects**

Protocol Number:

Date (D/M/Y):

Name of Principal Investigator:

Reviewer's name:

**Mark and comment on whatever items applicable to the study.**

1	Objectives of the Study <input type="checkbox"/> Clear <input type="checkbox"/> Unclear	
2	Background and Rationale <input type="checkbox"/> Sufficient <input type="checkbox"/> insufficient	Comment:
3	Methodology <input type="checkbox"/> Clear <input type="checkbox"/> Unclear	Comment
4	Need for diagrammatic representation <input type="checkbox"/> Yes <input type="checkbox"/> No	
6	Study Design and Sample size <input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate	Comment:
7	Inclusion Criteria <input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate	Comment:
8	Exclusion Criteria <input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate	Comment:
9	Statement for protection of rights and interests of Vulnerable Participants Clear <input type="checkbox"/> Unclear <input type="checkbox"/>	Comment:
10	Voluntary, Non-Coercive Recruitment of Participants <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
11	Are Qualifications and experience of the Principal Investigator appropriate? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
13	Facilities and infrastructure of Participating Sites <input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate	Comment:
14	Involvement of Local Researchers and Institution in the Protocol Design, Analysis and dissemination of Results <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
16	Risk-benefit analysis Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
17	Vulnerability assessment Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
18	Benefit to Local Communities <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable	Comment:
19	Are blood/tissue samples sent abroad? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
20	Following documents are submitted or not? CTRI Registration Yes <input type="checkbox"/> No <input type="checkbox"/> Clinical trial agreement Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:

	Insurance policy Yes <input type="checkbox"/> <input type="checkbox"/> No DCGI submission/approval letter Yes <input type="checkbox"/> <input type="checkbox"/> No	
<b>Participant Information Sheet and Informed Consent Documents</b>		
<b>S N</b>	<b>Points</b>	<b>Comments</b>
1	Are procedures for obtaining Informed Consent appropriate? <input type="checkbox"/> Yes <input type="checkbox"/> No	
2	Contents of the Informed Consent Documents Translation and backatranlation certificates <input type="checkbox"/> Clear <input type="checkbox"/> Unclear	
3	Language of the Informed Consent Document: Kannada, Hindi, English and Marathi <input type="checkbox"/> Clear <input type="checkbox"/> Unclear	
4	Risks/ inconveniences mentioned clearly <input type="checkbox"/> Yes <input type="checkbox"/> No	
5	Mention about tests to be performed if any <input type="checkbox"/> Yes <input type="checkbox"/> No	
6	Period of storage of biological samples <input type="checkbox"/> Yes <input type="checkbox"/> No	
7	Are possible benefits mentioned <input type="checkbox"/> Yes <input type="checkbox"/> No	
8	Patient dairy and information sheet (PIS) <input type="checkbox"/> Yes <input type="checkbox"/> No	
9	Privacy & Confidentiality <input type="checkbox"/> Yes <input type="checkbox"/> No	
11	Provision for Medical / Psychosocial Support <input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate	
12	Provision for Treatment of Study Related Injuries <input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate	
13	Provision for Compensation <input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate	

**Reviewer Signature with date:**

**ANNEXURE: 03**

**(AF/IEC/03/06/V7.1)**

**Annual Report Template**

Protocol No:

Protocol Title:

Principal Investigator:

Name of the Co-Investigator:

Duration of the study:

Presented to EC – 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 drop outs/ withdrawn:

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:

Signature of the Principal Investigator with date

**ANNEXURE: 04**

**AF/IEC/04/06/V7.1**

**Study Report Form for Protocol Termination**

Protocol No.:

Principal Investigator:

Protocol Title:

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/V7.1**

**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:

## Clinical Trial Agreement Checklist

Sl. No	Description	Yes	No
1.	<b>Protocol Number and Title</b>		
2.	<b>Effective date</b>		
3	<b>Parties Involved</b> - (Sponsor / CRO , Principal Investigator, Institution and or SMO )		
	<b>Bipartite</b>		
	<b>Tripartite</b>		
	<b>Quadra parted</b>		
4	<b>Agreed terms</b> - Definition, Conduct of the study, Responsibility of the company, Principal investigator, Institution		
5	<b>Study drug and Materials</b>		
6.	<b>Study and Protocol</b>		
7.	<b>The Study Scheduled</b>		
8	<b>Monitoring and audit by the company</b>		
9	<b>Inspection by the regulatory authorities</b>		
10.	<b>Payment Details</b> - 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.	<b>Obligations of the institution and Principal Investigator</b> - EC Approval, Performance of the study, Key personnel, sponsor Visit, Supplies		
12	<b>Study Records , reports and Data</b> - Study records , Case report form, Annual reports, Final Reports , <b>(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)</b> , Reporting of SAE( Sponsor, EC,DCGI and head of institution ) , 14th day PI analysis Report ( Sponsor, EC,DCGI and head of institution ).		
13	<b>Confidentiality</b>		
14	<b>Publications</b>		
15	<b>Ownership of materials, data, inventions and discoveries.</b>		
16	<b>Representations, warranties and covenant.</b> - Of the PI, Of the Sponsor, No other Representations or warranties, Of the Institutions		



17	<b>Governing Law -</b> 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	<b>Indemnification -</b> Sponsor Indemnification, Institution Indemnification, Notification, Claims, Representation, subject injury.		
19	<b>Insurance -</b> Sponsor insurance , Institution Insurance		
20	<b>Compliance, Transparency, Anti - bribery, Anti- corruption and Conflict of Interest.</b>		
21	<b>Term and Termination</b>		
22	<b>Miscellaneous</b>		
23	<b>Agreed by the parties -</b> Sponsor/ CRO, PI, Institution, SMO( if involved)		
24	<b>Witness</b>		