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