ANNEXURE 03

Confidentiality Agreement Form for Independent Consultants

I, Dr./Mr./Ms./Master ……..……..(Name and Designation) as a non-member of IHEC understand that the copy given to me by the IHEC is confidential. I shall use the information only for the indicated purpose as described to the IHEC and will not duplicate, give or distribute these documents to any person(s) without permission from the IHEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as confidential.

Signature Date:

ANNEXURE 04

Institutional Human Ethics Committee Protocol Form

1. General Information:

i. Principal Investigator:
ii. Title:
iii. Date of Submission:
iv. Duration:

2. Abstract: It must be written in non-technical language for the lay reader and address, as appropriate, the following points:

- A brief description of the background and/or scientific context of the study.
- The hypotheses being tested.
- A brief description of the experimental design, how the study will be conducted, and human subject involvement and duration.
- Anticipated results.

3. Purpose, Methods and Procedures: Describe in detail the purpose, research methods and procedures of the study.

4. Details of Drug and/or Therapy: Describe in detail the safety of proposed intervention and any drug or vaccine to be tested, including results of relevant animal and human research conducted. A description of plans for withdrawal of drugs or any therapies in the course of research. For research involving more than minimal risk, an account of plans to provide medical therapy for such risk or injury or toxicity due to over dosage should be included.

5. Subject Selection: Indicate how many subjects will be included in the study, how they will be recruited, from where recruited, and when. When vulnerable populations are involved, describe why they are necessary. Provide criteria for the exclusion or inclusion of potential subjects, and justification for the exclusion of any groups on the basis of age, sex, ethnicity, or social or economic factors.

6. Risks: Describe any potential physical, psychological, social or legal risks to subjects. Assess the likelihood and seriousness of those risks. If the methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used.

7. Benefits: Describe the anticipated benefits of the research to the individual subjects, to the particular group or class from which the subject population is drawn. If there is no

direct benefit to the subject, state so. Describe what, if any, societal/scientific benefits can be expected from the study.

8. Risk-Benefit Ratio: Assess the relative weights of the study's risks and benefits.

9. Compensation or Costs to Subjects: If the investigation involves the possibility of added expense to the subject or to a third party, such as an insurer (e.g., longer hospitalization, extra laboratory tests, travel) indicate how this is justified. If there is compensation for unpleasant or risky procedures, provide details of that compensation.

For research carrying more than minimal risk, provide information regarding what, if any, medical treatment or compensation will be available to the subject if s/he is injured as a result of participating this study.

10. Disclosure of Personal and Financial Interest in the Research Study and/or Sponsor: The investigator must disclose any personal and financial interests in the research as well as the extent of personal and financial interest in the sponsor.

11. Obtaining Informed Consent: Describe the setting in which the consent process will take place. Include a complete list of individuals (include title) who will obtain written informed consent. Any person designated to obtain consent must be fully knowledgeable of all details of the protocol and be able to answer any questions from subjects, such as risks or alternative treatments and therapies. If the investigator is requesting a waiver from obtaining informed consent, or any of the required elements of informed consent, justification must be provided.

12. Research Personnel: Include a complete list of all key research personnel involved in the conduct of this study.

13. Statistical Analysis:

14. Storage and Maintenance of Data:

15. Maintenance of Confidentiality: Address procedures for maintaining privacy and confidentiality during the recruitment and study period, as well as after the study has been completed.

16. Sources of Funding:

17. Other Ethical Issues/ Conflict of interest

ANNEXURE: 05

Amendment Reporting Form

IHEC Study No:	Approval date:
Title:	
Principal Investigator :	
Has the amended portion been highlighted?	
Does this amendment entail any changes in Informed consent forms (ICFs)	Yes/No
If yes, whether amended ICFs are submitted pl. specify Version No. & Date.	
Please mention version no. and date of amended Protocol / Investigators brochure / Addendum.	
No. of active study participants	

Signature of the Principal Investigator & Date:

ANNEXURE 06

Checklist of documents to be resubmitted with the Resubmitted Study Protocol

Study Protocol No:				
Study Title:				
Sr. No.	**List of items**	**Yes**	**No**	**NA**
1.	Cover Letter			
2.	Brief Description of Study Protocol			
3.	Inform Consent Form			
4.	Copy of questionnaire			
5.	Consent of Hospital/ Doctors			
6.	Regulatory Authority Clearance Certificate			
7.	Permission letter(s) from heads of departments other than that of the PI, if study involves data collection / uses diagnostic and/or imaging services from departments of BITS, Pilani.			
8.	CV of all Investigators and other coordinators involve in CT.			
9.	Investigator's brochure (IB)			
10.	Copy of advertisements / recruitment documents (if any)			
11.	Copy of clinical trial protocol			
12.	Fee for review- if applicable			
13.	Material Transfer Agreement (MTA)			
14.	Clinical Trial Agreement (CTA)			
15.	Insurance coverage certificate (for participants)			
16.	Insurance certificate (for team members)			
17.	CTRI Number			
18.	Other (specify):			

Undertaking: I hereby declare that contents of the soft and hard copies of this document submitted to the IHEC are the same.

Signature of PI

Name: Date:

ANNEXURE 07

Study Completion Report Form

Proposal No. : Protocol Title: Principal Investigator:	
Phone number, email address	
Sponsor	
Address	
Phone, E mail	
Total no. of study participants recruited	
Study Initiation Date	
Total no. of study participants approved by the IHEC for recruitment	
On site SAEs (Total number and type)	
Whether all SAEs intimated to the IHEC (Yes/No) If no give reason	
No. of participants withdrawn	
Reasons for withdrawal	
Protocol deviations-Violations (Number and nature)	
Any Ethical Issue encountered during the study	
Undertaking: I hereby declare that contents of the soft and hard copies of this document submitted to the IHEC are the same.	
Signature of PI Date:	

ANNEXURE 08

Premature Termination / Suspension / Discontinuation Report

Proposal No.:	
Protocol Title:	
Name of PI:	
Phone :	E-Mail:
Study Site:	
Sponsor:	
IHEC Approval Date:	Date on which Status Report Last Submitted to IHEC:

Starting Date:	Termination Date:
No. of Participants Enrolled:	No. of Participants Completed:
No. of Ongoing Participants:	No. of Drop Outs:
SAE (Total No.):	SAE Event:
Summary of Results:	
Reason for Premature Termination/Suspension/Discontinuation:	

PI Signature:	Date:

ANNEXURE 09

Application form for requesting Waiver of Written Informed Consent/ waiver of consent

1. Proposal Number :
2. Principal Investigator's name:
3. Department:
4. Title of project:
5. Names of co-investigators:
6. Request for waiver of informed consent:

I hereby assure that the rights of the participants will not be violated.

Following are the measures described in the Protocol for protecting confidentiality of data and privacy of research participant

1.
2.
3.

Undertaking: I hereby declare that contents of the soft and hard copies of this document submitted to the IHEC are the same.

Principal Investigator's signature with date:

ANNEXURE 10

Site Monitoring Visit Report

Proposal Number:	Date of the Visit:
Study Title:	
Principal Investigators:	Phone:
Institute:	Site:
Sponsor:	
Total number of participants enrolled:	Total participants ongoing:
No. of participants completed:	No. of drop outs:
Are site facilities appropriate? Yes No	Comment:
Are Informed Consents of recent version used? Yes No	Comment:
Archives of AV consent available Yes No	Comment
Is it approved by the IHEC? Yes No	Comment:
Whether consent has been taken from all patients? Yes No	Comment:
Whether appropriate vernacular consent have been taken? Yes No	Comment:

Are Protocols of recent version used? Yes No	Comment:
Is it approved by the IHEC? Yes No	Comment:
Any adverse events found? Yes No	Comment:
Any SAEs found? Yes No	Comment:
Were the SAEs informed to IHEC within 7 working days & SAE death within 24 H? Yes No	Comment:
Are all Case Record Forms up to date? Yes No	Comment:
Are storage of data and investigating products locked? Yes No	Comment:
How well are participants protected? Good Fair Not good	Comment:
Any outstanding tasks or results of visit? Yes No	Give details:
Is the documentation complete? Yes No	Comment:
Duration of visit: ……. hours	Starting from: Finish:
Name of IHEC/ representatives:	
Completed by: Signature:	Date:

ANNEXURE 11

Form for filing of Complaint / Query

Date Received:	
Received by :	
Request from :	Telephone No of the caller FAX No Letter / Date E-mail / Date Walk-in: Date /Time
Participant's Name:	
Contact Address: Phone:	
Proposal number:	
Title of the Study:	
Date of enrollment in the study:	
What is requested?	
Action taken:	

Outcome:

ANNEXURE 12

Document Request Form

Project No.:	Project Title :
Name of PI:	
Requested by:	
Documents requested:	
Purpose of the request:	
Principal Investigator's Signature:	
Signature of the requesting person:	

Comments by Member-Secretary, IHEC: Signature of Member-Secretary, IHEC with date:

ANNEXURE 13

Format for disposal of study documents log

Proposal No	Title	No of files	EC approval	Study Initiation Date	Study Closure Date	Name& Sign of Authorized Individual