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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Secretariat of the Institutional Ethics Committee (IHEC) manages protocol and other document submission.

2. Scope

The scope of this SOP includes:

- 1) Submission of Research Project and related documents for Initial Review of the Protocol
- 2) Resubmission of Protocols or Research Projects with corrections
- 3) Submission of Protocol Amendment
- 4) Submissions of written communications related to
 - Review of Approved Protocols periodically
 - Protocol completion/Termination
 - Protocol deviations/violation
 - SAE initial/ follow up/ final reports
 - Submission of Protocol deviations, Protocol violations

3. Responsibility

It is the responsibility of the IHEC Secretariat to receive, record and distribute the received protocols and any other documents for review, act on the instructions given by the appropriate member of the IHEC and ensure that the communication reaches the concerned recipient.

4. Detailed Instructions

4.1 Receive study protocols/ documents

The Principal Investigator (PI) will submit a research proposal to the IHEC office for review and decision under any of the following sections within the specified time period:

5. Sponsored new proposals for Initial Review/ Re-submission of Protocols with Corrections/ Amended Protocols and related documents.
6. Projects should be submitted at least 30 days before for consideration in the ensuing meeting of the IHEC. If to be submitted after 30 days, special permission from the Ethics Committee chairman obtained.



7. *Submission of SAE (On-Site):* As per the timelines stated in IHEC/SOP-13/V1 for initial and detailed reporting of SAE.
- 7.2. All other documents for consideration at the full board meeting (except those related to participant safety, which may be submitted any time) must be submitted at least 72 hours in advance of the meeting to be considered in the next meeting agenda

4.2 Initial Review Application

- *Check for submission items:* The Secretariat will check the hard (and soft copies if required) of the following items:
 - a) 14 sets of the proposal (One .original and 13 set of Xerox copies) and a labeled CD/pen drive containing the soft copy *if required*.
 - b) A completely filled IHEC project submission application form for initial review *ANX 1-A/IHEC/SOP- 07/ V1* or *ANX 1-B/IHEC/SOP-07/V1*
 - c) The marked checklist (*ANX-02/IHEC/SOP-06/V1*)
 - d) Duty Delegation Log of the Study team (*ANX 03/IHEC/SOP- 07/V1*)
 - e) Document Receipt Form (*ANX 04/IHEC/SOP- 07/V1*)
 - f) Conflict of interest document signed by the PI (*ANX 05/IHEC/SOP- 07/V1*)

Verify contents of Submitted Documents:

The Secretariat will:

- Use the checklist (*ANX 02/IHEC/SOP- 06/V1 submitted by the PI*) to confirm whether all the ticked documents are there in the application
- The Secretariat will then ensure that the application is complete in terms of required documents (if any essential document is not available an explanation must be sought in writing for the IHEC to review). All the following documents must be in the docket
- Project submission application form for initial review
- Covering letter to Member Secretary/ Chairperson
- Protocol



- Amendments to protocol (if any)
- Informed consent document (ICD) in English (as per sample format in Guidelines for Investigators) OR Waiver of Consent form as per IHEC/SOP 15/V1
- ICD in Regional languages (if applicable)
- Back translations of ICDs (if applicable)
- Translation and Back translation certificates (if applicable)
- Amendments to the ICD (if any)
- Case Record Form
- Recruitment procedures: advertisement, notices, letters to doctors (if applicable)
- Patient instruction card, identity card, diary etc. (if applicable)
- Investigator Brochure (if applicable)
- Regulatory permissions (DCGI approval, FDA marketing/manufacturing license for herbal drugs, Health Ministry Screening Committee (HMSC) approval, Bhabha Atomic Research Centre (BARC) approval) (as applicable)
- Investigator's Undertaking to DCG

- Administrative sanction from the head of the Institution or Memorandum of Understanding in case of studies involving collaboration with other institutions. (if applicable)
- A copy of Administration sanction from the Head of the Institution or Memorandum of Understanding for sending the samples to laboratories outside the Institution. (if applicable)
- Brief Curriculum Vitae of all the study team members
- GCP training certificate (within 5 years) of principal investigator, co-investigator/s and study coordinator/s. (if applicable)
- Research Methodology training certificate (within 5 years) of principal investigator, co-investigator/s and study coordinator/s (if applicable)
- List of ongoing research studies undertaken by principal investigator
- Investigator's Brochure (as applicable for Drug/Device trials)
- Agreement to comply with national and international ethical guidelines and GCP protocols

- Details of Funding agency / Sponsor and fund allocation
- Clinical Trial Agreement between the sponsors, investigators and the head of the institution(s)
- Insurance policy (it is preferable to have the policy and not only the insurance certificate) for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage of risk
- Indemnity policy clearly indicating the conditions of coverage, date of commencement and date of expiry of coverage of risk
- Memorandum Of Understanding (MOU)for collaborative studies (if applicable)
- Ethics Committee clearance of other centers (if applicable)
- Institutional Stem cell Research Committee approval (if applicable)
- Documentation of clinical trial registration (if available)
- Processing fee payment receipt (*See Guidelines for investigators*)
- Any additional document(s), as required by IHEC
- **Complete the submission process:** The Secretariat will:
 - Complete the checklist of submission
 - Stamp the receiving date on the first page/last page of the covering letter and initial it.
 - Make a photocopy of the completed document receipt form *ANX 04/IHEC/SOP-07/V1* and return the original copy of the *ANX04/IHEC/SOP-07/V1* to the applicants for their records.
 - Keep the copies of the submitted documents with original signatures in the protocol “Submission” file.
 - Number the project file as MSMP/IHEC/PHARMA Number (00)/ year (00) for pharmaceutical sponsored studies and MSMP/IHEC/GOVT Number (00)/ year (00) for Government/ Government-agency sponsored studies, MSMP/IHEC/Number (00)/year (00) for thesis and IHEC/IHEC/OA Number (00) for non-sponsored / OA-Other Academic studies e.g. MSMP/IHEC/PHARMA 03/15 will indicate pharmaceutical sponsored study with number 01 of the year 2015. (This numbering process should be as per IHEC Policy – although it is generally recommended that numbering should be such that identification and location of a project is easy.)



- **Dispatch and Store the received Documents:** The Secretariat will
 - Prepare 2 sets (original for stocking at of a protocol package containing completed application form *ANX 1-A/IHEC/SOP-07/V1* and *ANX-1-IHEC/SOP-07/V1*, protocol related documents along with checklist *ANX-02/IHEC/SOP-07/V1* and send 1 set to the IHEC members along with a copy of Project Assessment Form for Review *ANX-02/IHEC/SOP-08A/V1* after the last day of submission is over, ensuring at least 15 days for review before the next meeting (*if applicable*).
 - Store the appropriately labeled original protocol documents in the designated storage area in the IHEC office.
 - If the IHEC members who prefer to receive and review soft copies, these are sent in an email along with a copy of project assessment form for initial review *ANX 02/IHEC/SOP-7A/V1* after the last day of submission is over, ensuring at least 15 days for review before the next meeting.

4.3 Resubmission of Protocols with corrections and Amendments of protocol/ related documents

- For resubmitted protocol, the PI will submit one hard copy of the amended Protocol and related documents (as per IHEC/SOP-10/V1).
- The Secretariat will verify the completeness of the documents and confirm that the copy contains the modifications highlighted with respect to the earlier protocol submitted mentioning the justification for the amendment.
- The Secretariat will present the resubmitted document to the Member Secretary
- The Member Secretary (MS) will decide
 - a. if it is a resubmitted protocol, all steps as per Section 4.5 of IHEC/SOP -7A/V1 (Initial review) will be followed
 - b. if it is an resubmitted protocol based on query response, the Member Secretary will handle it as decided in the meeting (e.g. Carry out review by one or more member(s) selected by the Chairperson. The selected members are normally those who reviewed and recommended the previous version of that protocol or keep on full board agenda)

Annual Review of Approved Protocols, Amended Protocols and related

documents, Study completion/ termination, SAE report, Protocol deviations

The IHEC will receive one soft copy and one hard copy of the Annual Review Report, Amended

Sr. No.	Category of review	Rs.
1.	New study protocol (Drug Trials)	50,000 /-
2.	New study protocol – External studies (Patient Registries)	25,000 /-
3.	New study protocol – Internal studies	5,000/-
4.	PG Thesis	1000/-
5.	Amendment (Drug Trials) and extension of phases	30,000/-
6.	Amendment (Patient Registries)	5,000/-
7	Archival Fees	10,000/-

Protocols and related documents, Study completion/ termination, SAE report, protocol deviations in the prescribed format as given in the respective SOPs.

4.5 Processing Fees for IHEC review

The fees for reviewing various categories of research study proposals in Indian Rupees (INR); non-refundable are as given in the following table:

Reference to other applicable SOPs

SOP 8A/V1: Full-Board Review of Research Study Protocol

SOP 10/V1: Review of Amended Protocol, Protocol-related Documents and Resubmitted Protocol

SOP16/V1: Request for Waiver of Written Informed Consent and Waiver of Consent

Note: The processing fees will be waived off if the proposed study is not a funded/sponsored one and no payment is received towards recruitment of patients. The application for waiver of fees should be duly reviewed and forwarded with recommendations by the Head of Clinical Research Division.



6. Annexures

Annexure 1-A *ANX-01-A/IHEC/SOP-07/V1*- Project submission application form for initial review for drug trials and other regulatory studies (Industry and Government sponsored studies).

Annexure 1-B *ANX-01-B/IHEC/SOP-07/V1*- Project submission application form for initial review for academic (non-regulatory) studies.

Annexure 2 *ANX-02/IHEC/SOP-07/V1*-Checklist of protocol submission

Annexure 3 *ANX-03/IHEC/SOP-07/V1*- Duty Delegation Log of Study team

Annexure 4 *ANX-04/IHEC/SOP-07/V1*- Document Receipt Form

Annexure 5 *ANX-05/IHEC/SOP-07/V1*- Confidentiality of interest for the PI



Annexure 1-A: ANX-1-A/IHEC/SOP-07/V1

***Project Submission Application Form for Review for Drug Trials and Other Regulatory Studies
 (Industry and Government sponsored studies)***

- Please fill in the details in legible hand writing
- Tick ✓ in the box for the appropriate answer
- Tick/ Write NA if question is not applicable

IHEC Protocol No. _____

Title of the protocol

	Name	Designation	Department & Institution	Signature
Principal Investigator				
Co- Investigator				
Co-Investigator				
Co-Investigator				
Co-Investigator				
Co-Investigator				
Coordinator				
Coordinator				

(If additional collaborators attach details and letter of Consent by the collaborator(s) on a separate page.)

Please attach brief curriculum vitae of the study team members
 (principal investigator, co-investigator, study coordinator)

Attached



Please give details of allocation of budget in a separate attachment if needed. Attached

Type of study : Epidemiological Basic Sciences Animal Studies

Please specify _____

Clinical: Single center _____ Multi-centric _____ (Attach list of centers)

If multicentric, how many centres : India _____ and Globally : _____ (attach list of countries)

3. Clinical Trials:

Medicines/Vaccines/Device/Herbal Remedies: (Tick the appropriate boxes)

i. What does the study involve use of?

Medicine Devices Vaccines

Indian Systems of Medicine Any other NA

If others, specify _____

ii. Where is it approved and marketed?

In India UK & Europe USA NA

Other countries, specify _____

iii. Is it an Investigational New Drug (IND)?

If yes, IND No: _____

a) Investigator's Brochure submitted

b) In vitro studies data

c) Preclinical studies done

d) Clinical Study is in : Phase I Phase II Phase III Phase IV

e) To submit package insert in case test drug is already marketed in India



Attached

(Tick the appropriate box/option)

	Yes	No	NA
iv. Does it involve a change in use, dosage, route of Administration of an already marketed drug?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes, whether DCGI permission is obtained?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes, date of permission :-----	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If No, whether DCGI permission is applied for?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<hr/>			
v. Are you aware if this study/similar study is being done elsewhere?	Yes	No	NA
If yes, Specify details.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<hr/>			
vi. Whether DCGI's permission for testing IND obtained?	Yes	No	NA
If yes specify details	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<hr/>			
vii. Whether DCGI's permission for testing IND is applied for?	Yes	No	NA
If yes specify details	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<hr/>			
viii. For ayurvedic or herbal formulations, is a copy of the marketing / manufacturing license issued by the FDA to the company submitted?			

4. Protocol of the proposal

Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale *(Submit as attachment)*



5. Research participants

Sample Size :

- i. Number of research participants at this centre : Number
 of research participants at other sites in India :

Total number of research participants at all sites (globally):

- ii. Duration of study :
 No. of visits :

- iii. Will research participants from both genders
 be recruited **Yes** **No** **NA**

- iv. Inclusion / exclusion criteria given **Yes** **No** **NA**

- v. Type of research participants:
 Volunteers Patients NA

- vi. Vulnerable research participants **Yes** **No** **NA**

Pregnant women elderly mentally challenged

Fetus illiterate handicapped

Children captives terminally ill

Elderly seriously ill

economically or socially backward students

dependent staff institutionalized

HIV Any other

6. Privacy and confidentiality

- i. Study involves-
- | | |
|----------------------------------|--------------------------|
| Direct Identifies | <input type="checkbox"/> |
| Indirect Identifiers / coded | <input type="checkbox"/> |
| Completely anomymised / delinked | <input type="checkbox"/> |
-

7. Use of biological/ hazardous materials

- | | Yes | No | NA |
|---|--------------------------|--------------------------|--------------------------|
| i. Use of fetal tissue abortus | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| ii. Use of organs or body fluids | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| iii. Use of recombinant/gene therapy | | | |
| If yes, has Department of Biotechnology (DBT) approval or DNA products been obtained? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| iii. Use of pre-existing/stored/left over samples | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| iv. Collection for banking/future research | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| v. Use of ionizing radiation/radioisotopes | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

If yes, has Bhabha Atomic Research Centre (BARC) approval for radioactive isotopes been obtained?

- | | | | |
|---|------------|-----------|-----------|
| vii. Use of Infectious/ bio hazardous specimens | Yes | No | NA |
|---|------------|-----------|-----------|
-

- | | | | |
|-----------------------------------|------------|-----------|-----------|
| viii. Proper disposal of material | Yes | No | NA |
|-----------------------------------|------------|-----------|-----------|
-

- 8. Will any sample collected from the patients be sent abroad? Yes No NA**
- | | | | |
|--|--------------------------|--------------------------|--------------------------|
| | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|--|--------------------------|--------------------------|--------------------------|

If yes,

- a) Sample will be sent abroad because (Tick appropriate box):

Facility not available in India

Facility in India inaccessible

Facility available but not being accessed

If so, reasons.....



Lab. Address: _____

If no,

b) test on samples be carried out:

In institution

Outside institution

If outside institution, Address: _____

If Yes, specify with details of collaborators Yes No NA

9. Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) / ICMR for international collaboration ? (as applicable in case of studies involving collaborations with foreign Laboratory / Clinic Institution)

Yes No NA

10. In case of studies involving collaborations with other Indian or foreign Laboratory/ Clinic/Institution has administrative sanction from the Dean obtained/ applied for?

Yes No NA

Memorandum of Understanding: Yes No NA

If applicable)

Material Transfer Agreement: Yes No NA

If applicable)

11. Consent *Written Oral Audio-visual

1. Consent form : (tick the included elements)

Simple language Alternatives to participation

Statement that study involves research Confidentiality of records

Sponsor of study Contact information

Purpose and procedures Statement that consent is voluntary

Risks & Discomforts Right to withdraw

Benefits Compensation for study related injury



Compensation for participation

Benefits, if any, on future commercialization NA

Consent for future use of biological material NA

If written consent will not be obtained, give reasons: _____

Whether applied for waiver of Consent: _____

ii. Who will obtain consent?

PI/Co/PI Nurse/Counselor

Research staff Any other, specify

12. Will any advertising be done for recruitment of research participants? (posters, flyers, brochure, websites – please attach a copy)

13. Risks & Benefits:

i. Is the risk reasonable compared to the anticipated benefits to research participants / community / country? Yes No NA

ii. Is there physical / social psychological risk / discomfort? Yes No NA

If yes,

- minimal or no risk
- More than minimum risk
- High risk



iii. Is there a benefit

(a) To the research participants? Direct Indirect

(b) Benefit to society

14. Data and monitoring

- i. Is there a data & safety monitoring committee / Board (DSMB)? Yes No NA
- ii. Is there a plan for interim analysis of data Yes No NA
- iii. Are there plans for storage and maintenance of all trial database? If yes, for how long? Yes No NA

15. Is there compensation for participation Yes No NA

If yes, Monetary In kind

Specify amount and type:.....

16. Is there provision for compensation for study related injury? Yes No NA

If yes, by Sponsor by investigator
 by insurance by any other company

17. Do you have any conflict of interest in the present study ? (financial / non financial) Yes No NA

If yes, Specify :.....

18. Number of protocols handled by the PI at present including current status of ongoing studies approved by IHEC and carried out by the Principal investigator:

(Information to be given: whether study is initiated , no. of approved research participants, no. of research participants enrolled, no. of active research participants, no. of research participants who have completed the study and total duration of the study. Describe briefly in a separate sheet, if required)



19. Current Brief Curriculum Vitae (signed and dated copy) of the study team members principal investigator, co-investigator and study coordinator (Information required age, designation and department, educational qualification, previous research experience in last five years)
20. GCP training certificates of principal investigator and coordinators
(To be enclosed along with the form)
21. Is the trial registered with clinical trial registry? (mandatory only for drug trials)
 Clinical Trial Registry of India (CTRI) / any other WHO Platform Registry

Yes No NA

Registraton number: _____

If not registered, state the reason _____

Statement of Compliance:

We hereby declare that the information given above is true and that we will comply with the guidelines mentioned in the **New Drugs Clinical Trials Rules 2019** and guidelines of **ICMR, IGCP** and other relevant national and international guidelines for conducting the research study

Signature of Principal Investigator with date: _____

Signature/s of Co-investigators with date: 1. _____

2. _____ 3. _____ 4. _____ 5. _____

Signature of coordinator: 1. _____ 2. _____

Forwarded by Heads of Department(s)

Signature/s with date of Heads of Department(s):

_____, _____, _____, _____

_____, _____, _____, _____

Stamp/Seal of the Department(s)



Annexure 1-B: ANX 1-B//IHEC/SOP-- 06/V1

Project Submission Application Form for Review for Academic (non-regulatory) Studies

Please fill in the details in legible hand writing

Tick ✓ in the box for the appropriate answer/ Write NA if question is not applicable

IHEC Protocol no. _____

Title of the project

	Name	Designation	Department and Institution
Principal Investigator			
Co-Investigator			
Co-Investigator			
Co-Investigator			
Co-Investigator			

If additional collaborators attach details and letter of consent by the collaborator (s) on a separate page.

Non-sponsored study

Sponsored study



If Non-Sponsored Study:

Type of study: Thesis /dissertation ICMR

Duration of study _____ Approx. Completion date (MM/YY)

If sponsored,

From where is the study being funded _____

Research fund is being utilized from in-house funding authority _____

Any other if any other, please give details _____

Allocation of budget heads (Please attach separate sheet if needed)

Type of study : Prospective Retrospective Cross-sectional

Is the study Observational/ Interventional? _____

If interventional, does the study involve testing of a new drug or any deviation from routine/standard of care practices?

2. Does the study involve use of : Drug / Vaccine Device Alternative Medicine

New Technique (surgical PT/OT/Pshychotherapy etc)

Diagnostic Kit / investigations

If other, please specify _____

i) Is the test drug / device marketed in India Yes No

Please attach copy of package insert / product insert

ii) Does the test drug involve a change in use, dosage, route of administration?



Yes No

If yes, please attach copy of DCGI permission

3. Subject selection:

- i) Number of subjects at this centre if multicentric, total number of subjects
ii) Vulnerable subjects Yes No (If yes tick the appropriate boxes)

Pregnant women illiterate seriously / terminally ill
Children neonate mentally challenged
Elderly handicapped economically / socially backward
Institutional employees / students Any other
If other, please specify _____

4. Does the study involve use of

- i) Fetal tissue or abortus Yes No
ii) Organs or body fluids Yes No
iii) Gene therapy Yes No

If yes, please submit a copy of Genetic Engineering Advisory Committee (GEAC) permission

- iv) Ionizing radiation / radioisotopes Yes No

If yes, please submit a copy of Bhabha Atomic Research Centre (BARC) permission

- v) Infectious / bio-hazardous specimens Yes No
vi) Will pre-existing / stored / left over samples be used Yes No
vii) Will samples be collected for banking / future research Yes No
viii) Will any sample collected from patient be sent abroad Yes No

If yes, please submit a copy of Director General or Foreign Trade (DGFT) permission

- ix) Is there any collaboration with any foreign lab, clinic or hospital?
Yes No
- x) If yes, please submit a copy of Health Ministry screening committee (HMSC) /ICMR approval (as applicable for foreign collaborations).



5. Will any advertising be done for recruitment of subjects? (Posters , flyers, brochures, etc)
 If yes, please attach a copy for IHEC review. Yes No

6. Is there compensation for participation (travelling allowance)? Yes No
 If yes, monetary In kind
 Specify amount / type

7. Are there any arrangements for compensation / treatment of trial related injury?
Yes No
 If yes, by sponsor by investigator
 By insurance company by others
 Please submit a copy of the insurance policy if it is available

8. Do you have any conflict of interest in the present study?
 (financial / non-financial / any other)
 If yes, specify

9. Is any other department involved in participant recruitment / investigation, or
 collaborators?
Yes No
 If yes, specify _____

Name and signature of concerned Head of Department.....

We hereby declare the information given above is true. A copy of the study report will be
 submitted at the end of the study.

Signature of Principal Investigator: _____

Signatures of Co- investigators: 1. _____
 2. _____
 3. _____
 4. _____

Forwarded by Heads of Department(s) _____



Stamp/Seal of the Department(s)

Please fill the form in legible handwriting or type the information.

Write 'Not Applicable' (NA) wherever necessary. Incompletely filled form will not be accepted.

Annexure 2: ANX 02/IHEC/SOP-07/V1

Check List for Protocol Submission

Check List of Documents for Protocol Submission to the Institutional Ethics Committee to be filled in by the study team

Protocol submission for initial review

*(Tick accordingly; compulsory documents have to be submitted by ticking in the box marked as 'Yes') * mandatory for review.*

Sl. No.	Document	Yes	No	NA
1	Project submission application form duly filled			
	a) Covering letter			
	b) Project proposal – 14 hard copies			
	c) Project proposal – soft copy sent by email / CD-ROM			
	d) CV of all investigators (including guide)			
	e) Fee for review			
2	Approval of departmental review Board (DRB) for thesis/dissertations proposals)			
3	Letter to Member Secretary / Chairperson			
4	*Summary of protocol (in not more than 500 words)			



5	*Protocol			
6	*Informed consent document in English			
7	*Informed consent documents in Regional languages (Total No:.....)			
8	Back translation of Informed consent documents (if available)			
9	Translation and Back translation certificates (if available)			
10	*Case Record Form			

11	*Research participants recruitment procedures: advertisement, notices (If applicable)			
12	*Patient instruction card, identity card, diary etc.			
13	a) *Research Participants Questionnaire/s if applicable			
	b) Research participants confidentially statement			
14	*Investigator Brochure			
15	*Insurance certificate and policy			
16	*Investigator's undertaking to DCG(I)			
17	DCG(I) approval [if DCGI approval is awaited, the same is mentioned in the covering letter to the IHEC]			
18	*Clinical trial agreement for drug trial / memorandum of understanding / copy of clinical trial protocol material transfer agreement (MTA), as applicable, for collaborator & Govt. sponsored trials (draft if final not ready)			
19	FDA marketing/manufacturing license for herbal formulations/ nutraceuticals			
20	Bhabha Atomic Research Centre (BARC) approval in case study involves use of radioisotopes/ ionizing radiations			



21	Genetic Engineering Advisory Committee (GEAC) approval in case study involves use of gene therapy			
22	a) Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions / foreign agencies (one copy) Or memorandum of understanding (as applicable)			
	b) Administration sanction from the head of the institution for the samples to be sent to outside institution (one copy) Or c) Material Transfer Agreement (as applicable)			

23	*Budget sheet for the proposed study(Format for budget sheet stated below)@			
24	*Signed and dated brief current curriculum vitae of the study team members (principal investigator, co-investigator, study co-ordinator) (one copy only)			
25	*Ethics committee clearance of other centres (Total No.....)			
26	*Log of delegation of responsibility of the study members – Sample format enclosed) (ANX03/IHEC/SOP – 06/V1)			
27	*Document Receipt Form (One copy)			
29	*Current status of ongoing studies approved by IHEC and IHEC conducted by principal investigator (information may be submitted separately)			
29	Documentation of clinical trial registration (in clinical trial registry of India) / any other WHO platform registry (whenever is applicable)			
30	*GCP training certificates of principal investigator, co-investigators study coordinators for interventional clinical trial sponsored by pharmaceuticals companies of training taken in last 5 years (one copy only)			
31	Any other documents submitted			



Budget Sheet for the Proposed Study

1	Title of the Project:	
2	Name of Principal Investigator (PI)	
3	Designation and address of the PI	
4	Names of Co-investigators with department/ institution:	
5	Source of funding	
	Government:	Central [], State [], Local []
	In-house	

	Private Foundation:	Indian [], Foreign []
	Non profit agency/trust funded	
	Pharma./ industry sponsored	
	Other:	
	No funding required	
	Address, phone, fANX. E-mail of sponsor with the name of the contact person	
6	Total Budget for the entire project in Rs.	
7	Duration of the Project in months	
8	Proposed date of starting the project	
9	Direct payments to investigators, if any	
10	Any other benefits to the investigators/department/institution	



11	Conflict of Interests, if any	
Name of PI:		Signature & Date

Annexure 3: ANX-03/IHEC/SOP- 07/V1

Delegation of Responsibilities of Study team

Study title: _____

Name	Role	No.
	Principal Investigator	1
	Co-Investigator	2
	Co-Investigator	3
	Co-Investigator	4
	Co-Investigator	5
	Co-Investigator	6
	Study Co-ordinator	7
	Study Co-ordinator	8
	Laboratory Technician	9
		10

* Study coordinator may preferably be a person specifically appointed for coordinating the clinical trial; other than the staff member (assistant / associate professor)



Annexure 4: ANX-04/IHEC/SOP-7-07/V1

Document Receipt Form for initial review

Protocol Number:	Received number:	Submitted date:
Protocol Title:		
Principal investigator :		
Department		
Communication with the IHEC:	E-mail address Phone FANX	
For office use only		
Documents submitted	<input type="checkbox"/> <input type="checkbox"/> Complete <input type="checkbox"/> <input type="checkbox"/> Incomplete, will submit on.....	
Documents to be submitted later:	<input type="checkbox"/> final signed clinical trial agreement <input type="checkbox"/> Informed consent form (in vernacular language) <input type="checkbox"/> study budget <input type="checkbox"/> DCGI <input type="checkbox"/> CTRI <input type="checkbox"/> GCP Training certificate Other sites EC approvals	To verify and tick whether documents received <input type="checkbox"/> final signed clinical trial agreement <input type="checkbox"/> informed consent form (in vernacular language) <input type="checkbox"/> study budget <input type="checkbox"/> DCGI <input type="checkbox"/> CTRI
Received by (Name and Signature)		
Date on which documents received:		

Annexure 5 ANX-05/IHEC/SOP-07/V1- Confidentiality of interest for the PI

Study Title:

There may be occasions when conflicts arise between a researcher's responsibilities related to the Institutional Human Ethics Committee, IHEC and his/her arrangements with the granting agency. It is important from an ethical standpoint that the Institutional Human Ethics Committee, IHEC, is aware of the nature of any such arrangements in order to ensure that there are no conflicts which could be perceived to adversely affect subjects enrolled in research projects. If there is any doubt as to the possibility of there being a conflict of interest, the onus is on the investigator to discuss the situation with the Committee Chair.

As the investigator involved in this study, are you receiving any direct personal remuneration for taking part in this investigation other than to cover administrative and clinical costs?

YES NO

If yes, please append to this page a letter detailing these activities.

It is ethically unacceptable for investigators to receive personal or family financial benefits (either direct or indirect) for participation in approved studies. "Other financial benefits" may include contractual agreements, stock or share holdings or future options with the sponsoring company, computing equipment, travel benefits, etc. The Institutional Human Ethics Committee, IHEC, considers the payment of any fee or cash gifts directly to an individual for soliciting the enrollment of subjects into a clinical trial to be unacceptable and such payments will not be allowed.

All investigators who need further clarifications in this regard are required to contact Dr CC Kartha, Chairman, IHEC, IHEC, at Ph. No. 04713942168

Your signatures below will indicate that you have read the instructions above and will never entertain any personal or family financial benefits that may adversely affect subjects enrolled in research projects

Signed (Investigator): _____

Name: _____

Date: _____

7. Flow chart

