Title: Management of Submission of Research Study Protocol and Study Related Documents

SOP Code: SOP 06/V1

Effective Date: aa/bb/cccc

[The IEC members (author/s, reviewer/s) and Chairperson will sign and date the SOP on this first page]

Prepared by:

Dr. Padmaja Marathe, FERCI Member	(Signature with Date)

Reviewed by:

Dr. U. M. Thatte, FERCI Secretary	(Signature with Date)
Dr. S. K. Kamat, FERCI Treasurer	(Signature with Date)

Approved by:

Dr. Vasantha Muthuswamy, FERCI President	(Signature with Date)
Dr. Nandini Kumar, FERCI Vice President	(Signature with Date)

Table of Contents:

1. Purpose

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

2. Scope

The scope of this SOP includes:

- Submission of Research Project and related documents for Initial Review of the Protocol
- Resubmission of Protocols or Research Projects with corrections
- Submission of Protocol Amendment
- Submissions of written communications related to
    - Continuing Review of Approved Protocols
    - 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 IEC 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 IEC 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 IEC office for review and decision under any of the following 5 sections within the specified time period:

- *New Proposals for Initial Review/ Re-submission of Protocols with Corrections/ Amended Protocols and related documents:*

  Projects should be submitted on the 20th of the month for consideration in the next monthly meeting of the IEC. (This date can be as per individual IEC's policy).

  Submission of SAE (On-Site): As per the timelines stated in SOP 9/V1 for initial and detailed reporting of SAE.

- 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 of the following items:

1. Two sets of the proposal (One original and 1 set of Xerox copies) and a labelled CD/pen drive containing the soft copy*(The number of hard copies can be decided by each IEC as per their policy)*
2. A completely filled IEC Project Submission Application Form for Initial Review *AX 1-A/SOP 06/ V1* and *AX 1-B/SOP 06/V1*
3. The marked checklist (*AX 02/SOP 06/V1)*
4. Duty Delegation Log of the Study team (*AX 03/SOP 06/V1)*
5. Document Receipt Form (*AX 04/SOP 06/V1)*

- *Verify contents of Submitted Documents:* The Secretariat will:
  - Use the checklist (*AX 02/SOP 06/V1)* 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 IEC 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 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 DCGI
- Administrative sanction from the head of the Institution or Memorandum of Understannding 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 Understannding 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 IEC

- **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 *AX 04/SOP 06/V1* and return the original copy of the *AX 04/SOP 06/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 EC/PHARMA Number (00)/ year (00) for pharmaceutical sponsored studies and EC/GOVT Number (00)/ year (00) for Government/ Government-agency sponsored studies, EC/Number (00)/year (00) for thesis and EC/OA Number (00) for non-sponsored / OA-Other Academic studies e.g. EC/PHARMA 03/15 will indicate pharmaceutical sponsored study with number 01 of the year 2015. (This numbering process should be as per IEC 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 of a protocol package containing completed application form *AX 1-A/SOP 06/V1* and *AX 1-B/SOP 06/V1*, protocol related documents along with

checklist *AX 02/SOP 06/V1* and send 1 set to the IEC members along with a copy of Project Assessment Form for Initial Review *AX 02/SOP 07A/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 IEC office.
- If the IEC members prefer to receive and review soft copies, these are sent in a CD/pen drive along with a copy of Project Assessment Form for Initial Review *AX 02/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 soft copy and one hard copy of the amended Protocol and related documents (as per SOP 09/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 protocol related documents which do not require to be changed and are already submitted for the IEC office during initial review are not required to be submitted again. *(IEC can decide as per policy)*
- The Secretariat will present the docket to the Member Secretary
- The Member Secretary (MS) will decide

a. if it is a resubmitted protocol it will follow all steps as per Section 4.5 of SOP 7A/V1 (Initial review)

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)

4.4 Annual Continuing Reviews of Approved Protocols, Amended Protocols and related documents, Study completion/ termination, SAE report, Protocol deviations

The IEC will receive one soft copy and one hard copy of the Continuing Review Report, Amended Protocols and related documents, Study completion/ termination, SAE report, protocol deviations in the prescribed format as given in the applicable SOPs.

4.5 Processing Fees for IEC review

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

Sr. No.	**Category of review**	**Pharma industry sponsored Research**	**Govt sponsored/ NGO Research**	**Academic or Investigator initiated Research**
1.	New study protocol	Rs. XXXX /-	Rs. XX /-	Rs. XX /-
2.	Continuing review (per review)	Rs. XXXX /-	Rs. XX /-	-
3.	Protocol Amendment (per amendment review) (if applicable)	Rs. XXXX /-	Rs. XX /-	-
4.	Providing one photocopy of submitted study documents lost by the	Rs. XXXX /-	Rs. XX /-	Rs. XX /-

	investigator (amount for 10 pages document, over 10 pages, Re. 1 per page)			

5. Reference to other applicable SOPs

SOP 7A/V1: Full-Board Review of Research Study Protocols

SOP 09/V1: Review of Amended Protocol, Protocol-related Documents and Resubmitted protocol

SOP15/V1: Request for Waiver of Written Informed Consent and Waiver of Consent

6. Annexures

Annexure 1-A *AX 01-A/SOP 06/V1*- Project submission application form for initial review for drug trials and other regulatory studies (Industry and Government sponsored studies).

Annexure 1-B *AX 01-B/SOP 06/V1*- Project submission application form for initial review for academic (non-regulatory) studies.

Annexure 2 *AX 02/SOP 06/V1*-Checklist of protocol submission

Annexure 3 *AX 03/SOP 06/V1*- Duty Delegation Log of Study team

Annexure 4 *AX 04/SOP 06/V1*- Document Receipt Form

Annexure 1-A: AX 1-A/SOP 06/V1

Project Submission Application Form for Initial 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

IEC 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

Is the study funded? ☐ Or non-funded (investigator initiated) ☐

1.**Sponsor Information** :

1. Indian a) Government ☐ Central ☐ State ☐

b) Private ☐

2. International ☐ Government ☐ Private ☐ UN agencies ☐

3. Industry ☐ National ☐ Multinational ☐

Contact Address of Sponsor:

_____

If sponsor is not from India, contact address in India:

_____

_____

2.Total Budget : Rs._____

Research Fund will be deposited in:

_____

Allocation of budget heads:

_____

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

Type of Study : Epidemiological ☐ Basic Sciences ☐ Animal studies ☐

Any Other ☐

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? If yes, whether DCGI permission is obtained? If yes, date of permission :---------- If No, whether DCGI permission is applied for?			

v. Are you aware if this study/similar study is being done elsewhere? If Yes, Specify details ----------	Yes	No	
vi. Whether DCGI's permission for testing IND obtained? If yes, date of permission :----------	Yes	No	NA
vii. Whether DCGI's permission for testing IND is applied for?			
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	

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	☐
dependent staff	☐	institutionalized	☐	students	☐

employees HIV ☐ Any other ☐ To specify_____			
6. **Privacy and confidentiality** i. Study involves - Direct Identifiers ☐ Indirect Identifiers/coded ☐ Completely anonymised/ delinked ☐			
ii. Confidential handling of data by staff	Yes	No	
7. **Use of biological/ hazardous materials** i. Use of fetal tissue abortus	Yes	No	NA
ii. Use of organs or body fluids			
iii. Use of recombinant/gene therapy If yes, has Department of Biotechnology (DBT) approval for DNA products been obtained?			
iv. Use of pre-existing/stored/left over samples			
v. Collection for banking/future research			
vi. Use of ionizing radiation/radioisotopes			

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

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

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 ☐ NA ☐

i. 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 inju ☐

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)	Yes	No	NA
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? If Yes, Minimal or no risk ☐ More than minimum risk ☐ High risk ☐	Yes	No	NA
iv. Is there a benefit (a) To the research participants? Direct ☐ Indirect ☐ (b) Benefit to society ☐			
14. **Data Monitoring** i. Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No	NA
iii. Is there a plan for interim analysis of data?	Yes	No	NA
vi. Are there plans for storage and maintenance of all trial database? If Yes, for how long? ----------	Yes	No	
15. Is there compensation for participation If Yes, Monetary ☐ In kind ☐ Specify amount and type: ----------	Yes	No	NA

16. Is there provision for compensation for study related injury? If Yes, by Sponsor ☐ by Investigator ☐ by insurance company ☐ by any other ☐	Yes	No	NA
17. Do you have any **conflict of interest** in the present study? (financial/non financial) If Yes, specify :---------- ----------	Yes	No	
18. Number of protocols handled by the PI at present including current Status of ongoing studies approved by IEC 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)	(To be enclosed along with the form)		
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 _____ Registration number: _____ If not registered, state the reason_____	Yes	No	NA

Statement of Compliance:

We hereby declare that the information given above is true and that we will comply with the guidelines mentioned in the Schedule Y [Drugs and Cosmetic Act 1940; amendment 20th January 2005, 30th January 2013, 8th February 2013 and any other recent notification/s from CDSCO (updated as applicable)], Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research (2006), Indian GCP Guidelines (2001) and the International Conference on Harmonisation - Good Clinical Practices (ICH-GCP) Guidelines (1996) while 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: AX 1-B/SOP 06/V1

Project Submission Application Form for Initial 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

IEC 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 ☐ Other Academic ☐

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

If sponsored,

Total Budget : Rs._____

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)

_____

1.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 ☐ neonates ☐ mentally challenged ☐

elderly ☐ handicapped ☐ economically/socially backward ☐

institutional employees / students ☐ any othe ☐

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 If yes, please submit a copy of Genetic Engineering Advisory Committee (GEAC) permission.	Yes ☐	No ☐
iv) ionizing radiation/radioisotopes If yes, please submit a copy of Bhabha Atomic Research Centre (BARC) Permission.	Yes ☐	No ☐
v) infectious / biohazardous 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? If yes, please submit a copy of Director General of Foreign Trade (DGFT) permission.	Yes ☐	No ☐
ix) Is there any collaboration with any foreign lab., clinic or hospital ? If yes, please submit a copy of Health Ministry Screening Committee (HMSC)/ ICMR approval (as applicable for foreign collaborations).	Yes ☐	No ☐
5. Will any advertising be done for recruitment of Subjects? (Posters, flyers, brochures, etc.) If yes, please attach a copy for IEC review.	Yes ☐	No ☐
6. Is there compensation for participation (travelling allowance)? If Yes, Monetary ☐ In kind ☐ Specify amount / type: _____	Yes ☐	No ☐
7. Are there any arrangements for compensation / treatment of trial related injury? If yes , by sponsor ☐ by investigator ☐ By insurance company ☐ by others ☐ Please submit a copy of the insurance policy if it is available.	Yes ☐	No ☐

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, but not co-investigators 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: AX 02/SOP 06/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') * Compulsory documents for initial review.

Sr. No.	Document	Yes	No	Date by which it will be submitted, if pending	N A
1	*Project submission application form duly filled		__	_____	__
a.	. Covering Letter				
b.	Project proposal – 3 hard copies				
c.	Project proposal – soft copy sent by e-mail / 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)		__	_____	__
13.b	Research participants confidentiality 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 IEC]				
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/ nutraceutics				
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) Administrative sanction from the Head of the Institution for the samples to be sent to outside institution (one copy) Or 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 team members - Sample Format Enclosed) (*AX 03/SOP 06/V1*)		__	_____	__
27	*Document Receipt Form (one copy only)		__	_____	__
28	*Current Status of Ongoing Studies approved by IEC and IEC 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 applicable)				
30	*GCP training certificates of principal investigator, co investigator/s, study co-ordinator/s 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, fax. 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: AX 03/SOP 06/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 *	7
	Laboratory Technician	8
		9
		10

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

(Please place tick marks against assigned duties for each member in the following table)

Code	**TASKS**	**Role Played by Each Study Team Member**									
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
A	All relevant documents pertaining to protect blinding										

B	Research participants selection/ Screening										
C	Obtain informed consent										
D	Evaluate inclusion/ exclusion criteria										
E	Conduct the visit assessments										
F	Physical examination										
G	Complete the source documents										
H	Complete Case Record Form										
I	Final review and sign Case Record Form										
J	Collect laboratory safety test samples										
K	Processing of blood samples										
L	Preparing aliquots & keeping a track of the samples sent										

M	Review & sign of the lab reports										
N	Receive the study drug**, ,** document drug dispensing, storage & accountability										
O	Person to whom research participants should contact in case of adverse event										
P	Report all serious adverse events										
Q	Follow up of Serious Adverse Event										
R	Maintaining study site master file										
S	In-charge of inventory & supplies										
T	Archiving of study documents										
U	Resolution of queries										
V	Overall coordination and supervision										

Annexure 4: AX 04/SOP 06/V1

Document Receipt Form for initial review

Protocol Number:	**Received number:**	**Submitted date:**
Protocol Title:	_____ _____	
Principal Investigator:		
Department		
Communication with the IEC :	E-mail address Phone Fax	
For office use only		
Documents submitted:	☐ Complete ☐ **I**ncomplete, will submit on……..	
Documents to be submitted later :	☐ final signed clinical trial agreement ☐ informed consent form (in vernacular language) ☐ study budget ☐ DCGI ☐ CTRI ☐ GCP Training certificate	To verify and tick whether documents received. ☐ final signed clinical trial agreement ☐ informed consent form (in vernacular language) ☐ study budget ☐ DCGI ☐ CTRI

	☐ Other sites EC permission ☐ Others……	☐GCP Training certificate ☐Other sites EC permission ☐ Others…… _____
Received by (Name and signature) :		
Date on which documents received:		

Note: Please bring this receipt with you when you visit the office of the Institutional Ethics Committee.

7. Flow chart

No.	Activity	Responsibility
1	Receive Submitted Packages	IEC Secretariat
2	Initial Review Application	IEC Secretariat
3	Resubmission of Protocols with Corrections	IEC Secretariat
4	Protocol Amendments	IEC Secretariat
5	Annual Continuing Review of Approved Protocols	IEC Secretariat
6	Protocol Completion	IEC Secretariat