6.1 Purpose

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

6.2 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

6.3 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 IEC authorities and ensure that the communication reaches the concerned recipient.

6.4 Detailed Instructions

6.4.1 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 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 date specified, for consideration in the next meeting of the IEC.

- *Submission of SAE (On-Site):*

As per the timelines stated in concerned SOP 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 7days in advance of the meeting to be considered in the next meeting agenda.

6.4.2 Initial Review Application

The Secretariat will check the hard and soft copies to ensure the availability and full compliance of the following items:

1. 15 sets of hard copies of the proposal (One original and 14 sets of Photostat copies) and a labelled CD/DVD. (Soft copy can be uploaded to the server with security, if so, instructed).
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 docket/package

    - Project submission application form for initial review
    - Covering letter to Member Secretary/ Chairperson duly signed by PI
    - 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's Brochure (as applicable for Drug/Device trials)
- Applicable Regulatory permissions/approvals (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 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 1 year) 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
- Agreement to comply with national and international ethical guidelines, GCP protocols and relevant regulations
- Details of Funding agency / Sponsor and fund allocation
- Clinical Trial Agreement between the sponsors, investigators and the head of the institution(s) if applicable

- Insurance policy (if applicable) with 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.
- Ethics Committee clearance of other centres (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

  - 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 by the Secretariat).

- **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 IEC/ Number (00)/ year (00)
- *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 01A and 01B-SOP*

06A/V1 after the last day of submission is over, ensuring at least 7 days for review before the next meeting *(if applicable).*

- Store the appropriately labelled 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 -01A& AX-1B/SOP 06/V1*

6.4.3 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) with list of comments and clarifications/ changes made at appropriate pages.
- 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.
- The Secretariat will present the docket to the Member Secretary
- The Member Secretary (MS) will determine
  a. Whether all steps as for Initial review are followed.
  b. if the resubmitted protocol is based on query response, then it will be handled as decided in the meeting.

6.4.4 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.

6.4.5 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. 5000/-	Rs. 2000 /-	Rs. 2000 /-
2.	Continuing review (per review)	Rs. 3000/-	Rs. 1000 /-	-
3.	Protocol Amendment (per amendment review) (if applicable)	Rs. 1000 /-	Rs. 500 /-	-
4.	Providing one photocopy of submitted study documents lost by the investigator (amount for 10 pages document, over 10 pages, Rs. 5 per page)	Rs. 2000 /-	Rs. 500 /-	Rs. 500 /-

6.5 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

6.6 Annexures

Annexure 1-A *AX 01-A/SOP 06/V1*- Project submission application form for initial review for regulatory clinical trials (Pharma 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 Regulatory Clinical Trials (Pharma 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 Proposal:	

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

Coordinator				
Coordinator				
(For 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)				

Sponsor Information:

1. Indian a) Government Central ☐ State ☐

b) Private ☐

2. International Government ☐ Private ☐ UN agencies ☐ Others ☐

3. Industry National ☐ Multinational ☐

Contact Address of Sponsor:

.....

.....

.....

.....

.....

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

.....

.....

.....

.....

.....

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 centre ☐ Multi-centric ☐ (Attach list of centres)

If multicentre, how many centres :

India _____and Globally :_____(attach list of countries)

3. **Clinical Trials:**

Drugs/Vaccines/Device/Herbal Remedies:

i. What intervention does the study involve?

Drugs ☐Devices ☐Vaccines ☐

AYUSH - Classical ☐ Non-Classical ☐ Proprietary/Patented ☐

Any other ☐ If others, specify_____ Not Applicable: ☐

ii. Where is it approved and marketed?

In India ☐ UK & Europe ☐ USA ☐

Other countries ☐, specify_____ Not Applicable ☐

iii. Is it an Investigational New Drug (IND)? Yes ☐ No ☐

If yes, IND No:

a) Investigator's Brochure submitted? Yes ☐ No ☐

b) In vitro Study Data? Yes ☐ No ☐

c) Preclinical Studies Done? Yes ☐ No ☐

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 LI attached. ☐

iv. Does it involve a change in use, dosage, route of Administration of an already marketed drug? Yes ☐ No ☐ NA ☐

If yes, whether DCGI permission is obtained? Yes ☐ No ☐

If yes, date of permission:_____

If No, whether DCGI permission is applied for? Yes ☐ No ☐

v. Are you aware if this study/similar study are being done elsewhere?

Yes ☐ No ☐ NA ☐

If Yes, Specify detail

_____

_____

___

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?

Yes ☐ No ☐ NA ☐

viii. For Ayurvedic or herbal formulations, is a copy of the marketing/ manufacturin license issued by the FDA to the company submitted?

Yes ☐ No ☐ NA ☐

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 all 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 ☐ If Yes, pregnant women ☐ elderly ☐ mentally challenged ☐ fetus ☐ illiterate ☐ handicapped ☐ elderly ☐ children ☐ captives ☐ terminally ill ☐ seriously ill ☐ economically or socially backward ☐ dependent staff ☐ institutionalized students ☐ employees ☐ HIV ☐ Any Other 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 ☐ NA ☐
7. **Use of biological/ hazardous materials** i. Use of foetal tissue abortus Yes ☐ No ☐ NA ☐
ii. Use of organs or body fluids Yes ☐ No ☐ NA ☐
iii. Use of recombinant/gene therapy Yes ☐ No ☐ NA ☐ If yes, has Department of Biotechnology (DBT) approval for DNA products been obtained? Yes ☐ No ☐ NA ☐
iv. Use of pre-existing/stored/left over samples Yes ☐ No ☐ NA ☐
v. Collection for banking/future research Yes ☐ No ☐ NA ☐
vi. Use of ionizing radiation/radioisotopes Yes ☐ No ☐ NA ☐ If yes, has Bhabha Atomic Research Centre (BARC) approval for radioactive isotopes been obtained? Yes ☐ No ☐ NA ☐
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 Yes ☐ No ☐

Facility in India inaccessible Yes ☐ No ☐

Facility available but not being accessed Yes ☐ No ☐

If so, reasons……..

Lab. Address:_____

If no,

b) test on samples be carried out:

In institution Yes ☐ No ☐

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/Head of the institution obtained/ applied for?

Yes ☐ No ☐ NA ☐

Memorandum of Understanding: Yes ☐ No ☐ NA ☐

Material Transfer Agreement : Yes ☐ No ☐ NA ☐

11. Consent :

i. Consent form : (tick the included elements)

*Written Oral Audio-visual NA

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/Counsellor Research staff Any other, specify

12. Will any advertising be done for recruitment of research participants? (posters, flyers, brochure, websites (If so, 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?

Yes ☐ No ☐ NA ☐

If Yes, Minimal or no risk ☐ More than minimum risk ☐ High risk ☐

iv.Is there a benefit

(a) To the research participants? Direct ☐ Indirect ☐

Benefit to society Yes ☐ No ☐ NA ☐

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?

iv. Yes ☐ No ☐ NA ☐

vi. Are there plans for storage and maintenance of all trial databases? Yes ☐ No ☐ NA ☐

If Yes, for how long?_____

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? Yes ☐ No ☐ NA ☐ (financial/non financial)

If Yes, specify :_____

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 Yes ☐ No ☐ If yes, Registration 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 relevant guidelines and regulations 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 (2017), Indian GCP Guidelines and the International Council on Harmonisation - Good Clinical Practices (ICH-GCP) Guidelines (R1 – 1996 and R2 -016) 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	Signature
Principal Investigator				
Co-Investigator				
Co-Investigator				
Co-Investigator				
Co-Investigator				

For 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☐er
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 of care practices? ☐
_____
_

2. Does the study involve use of : Drug / Vaccine Device Alternative Medicine New Technique (surgical/PT/OT/Pshychotherapy etc) / 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 handicappe☐
economically/socially backward
institutional employees / students any other
If other, please specify_____

☐

4. Does the study involve use of ☐ i) foetal 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 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 – 5 hard copies				
c.	Project proposal – soft copy sent by e-mail/ CD-ROM/ by uploading				
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 coordinator) (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 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 coordinator/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) with signature	
3	Designation and address of the PI	
4	Names of Co-investigators with department/ institution and signature:	
5	Source of funding	
	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:		**Submitted date:**
Protocol Title:		
Principal Investigator:		
Department		
Communication with the IEC :	E-mail address Phone Fax	
For office use only		
Documents submitted:	Incomplete 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 □ Other sites EC permission □Others……	To verify and tick whether documents received. □ final signed clinical trial agreement □ informed consent form (in vernacular language) □ study budget □ DCGI □ CTRI □GCP Training certificate □Other sites EC permission □ Others…… ? Research methodology
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.

6.7. 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