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

SOP Code: KIMS/SOP-07/V2
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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:

- 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
  - 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:

- *Sponsored new proposals for Initial Review/ Re-submission of Protocols with Corrections/ Amended Protocols and related documents.*
- 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.
- *Submission of SAE (On-Site):* As per the timelines stated in KIMS/SOP-13/V2 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 if required) of the following items:

1. 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.*
2. A completely filled IHEC project submission application form for initial review *ANX 1-A/KIMS/SOP- 07/ V2* or *ANX 1-B/KIMS/SOP-07/V2*
3. The marked checklist (*ANX-02/KIMS/SOP-06/V2)*
4. Duty Delegation Log of the Study team (*ANX 03/KIMS/SOP- 07/V2)*
5. Document Receipt Form (*ANX 04/KIMS/SOP- 07/V2)*
6. Conflict of interest document signed by the PI (*ANX 05/KIMS/SOP- 07/V2)*

Verify contents of Submitted Documents: The Secretariat will:

- Use the checklist (*ANX 02/KIMS/SOP- 06/V2 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 KIMS/SOP 15/V2
- 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 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/KIMS/SOP-07/V2* and return the original copy of the *ANX04/KIMS/SOP-07/V2* 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 KIMS/IHEC/PHARMA Number (00)/ year (00) for pharmaceutical sponsored studies and KIMS/IHEC/GOVT Number (00)/ year (00) for Government/ Government-agency sponsored studies, KIMS/IHEC/Number (00)/year (00) for thesis and KIMS/IHEC/OA Number (00) for non-sponsored / OA-Other Academic studies e.g. KIMS/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/KIMS/SOP-07/V2* and *ANX-1-B/KIMS/SOP-07/V2*, protocol related documents along with checklist *ANX-02/KIMS/SOP-07/V2* and send 1 set to the IHEC members along with a copy of Project Assessment Form for Review *ANX-02/KIMS/SOP-08A/V2* 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 a CD/pen drive along with a copy of project assessment form for initial review *ANX 02/KIMS/SOP-7A/V2* 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 KIMS/SOP-10/V2).

- 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 KIMS/SOP -7A/V2 (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)

4.4 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 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:

Sr. No.	Category of review	Rs.
1.	New study protocol (Drug Trials)	50,000 /-
2.	New study protocol (Patient Registries)	15,000 /-
3.	Investigator Initiated Trials	3,000
4.	PG Thesis	0/-
5.	Amendment (Drug Trials) and extension of phases	10,000/-
6.	Amendment (Patient Registries)	5,000/-
7	Archival Fees	10,000/-

Reference to other applicable SOPs

SOP 8A/V2: Full-Board Review of Research Study Protocol
SOP 10/V2: Review of Amended Protocol, Protocol-related Documents and Resubmitted Protocol
SOP16/V2: 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/KIMS/SOP-07/V2*- 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/KIMS/SOP-07/V2*- Project submission application form for initial review for academic (non-regulatory) studies.

Annexure 2 *ANX-02/KIMS/SOP-07/V2*-Checklist of protocol submission

Annexure 3 *ANX-03/KIMS/SOP-07/V2*- Duty Delegation Log of Study team

Annexure 4 *ANX-04/KIMS/SOP-07/V2*- Document Receipt Form

Annexure 5 *ANX-05/KIMS/SOP-07/V2*- Confidentiality of interest for the PI

Annexure 1-A: ANX-1-A/KIMS/SOP-07/V2

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

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 ☐

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 ☐

(*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?	☐	☐	☐

		Yes	No	NA
v.	Are you aware if this study/similar study is being done elsewhere?			
	If yes, Specify details……	☐	☐	☐

		Yes	No	NA
vi.	Whether DCGI's permission for testing IND obtained?			
	If yes specify details ……	☐	☐	☐

		Yes	No	NA
vii.	Whether DCGI's permission for testing IND is applied for?			
	If yes specify details ……	☐	☐	☐

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	☐
		Indirect Indentifiers / coded	☐
		Completely anomymised / delinked	☐

7. Use of biological/ hazardous materials

		Yes	No	NA
i.	Use of fetal tissue abortus	☐	☐	☐
ii.	Use of organs or body fluids	☐	☐	☐
iii.	Use of recombinant/gene therapy			
	If yes, has Department of Biotechnology (DBT) approval or DNA products been obtained?	☐	☐	☐
iii.	Use of pre-existing/stored/left over samples	☐	☐	☐
iv.	Collection for banking/future research	☐	☐	☐
v.	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 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 **Schedule Y** of **Drugs and Cosmetics Act** and guidelines of **CDSCO, 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//KIMS/SOP-- 06/V2

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/KIMS/SOP-07/V2

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/ 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) 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/KIMS/SOP – 06/V2)			
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/KIMS/SOP- 07/V2

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)

(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 documentation drug dispensing storage & accountability										
O	Person to whom research participants should contact in case of adverse events										
P	Report all serious adverse event										
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	Resolving queries										
V	Overall coordination and supervision										

Annexure 4: ANX-04/KIMS/SOP-7-07/V2

Document Receipt Form for initial review

<table>
<tr><td>Protocol Number:</td><td>Received number:</td><td>Submitted date:</td></tr>
<tr><td>Protocol Title:</td><td colspan="2"></td></tr>
<tr><td>Principal investigator :</td><td colspan="2"></td></tr>
<tr><td>Department</td><td colspan="2"></td></tr>
<tr><td>Communication with the IHEC:</td><td colspan="2">E-mail address
Phone
FANX</td></tr>
<tr><td colspan="3">For office use only</td></tr>
<tr><td>Documents submitted</td><td colspan="2">☐ Complete ☐ Incomplete, will submit on……..…</td></tr>
<tr><td>Documents to be submitted later:</td><td>☐final signed clinical trial agreement
☐ Informed consent form (in vernacular language)
☐ study budget
☐ DCGI
☐ CTRI
☐ GCP Training certificate
Other sites EC approvals</td><td>To verify and tick whether documents received
☐ final signed clinical trial agreement
☐ informed consent form (in vernacular language)
☐ study budget
☐ DCGI
☐ CTRI</td></tr>
<tr><td>Received by (Name and Signature)</td><td colspan="2"></td></tr>
<tr><td>Date on which documents received:</td><td colspan="2"></td></tr>
</table>

Annexure 5 ANX-05/KIMS/SOP-07/V2- 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, KIMS and his/her arrangements with the granting agency. It is important from an ethical standpoint that the Institutional Human Ethics Committee, KIMS, 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 <u>other than</u> 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, KIMS, 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, KIMS, 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