Title: Management of Protocol Submissions

SOP Code: SOP 05/V4 dated 22nd August 2013

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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 (IEC) manages protocol submissions to the IEC.

2. Scope

Protocol submissions include:

- Submission of Research Project for Initial Review of the Protocol and related documents
- Resubmission of Protocols or Research Projects with corrections
- Submission of Protocol Amendment
- Submissions of written communications related to Continuing Review of Approved Protocols
- Submission of written communications for Protocol Termination

3. Responsibility

It is the responsibility of the IEC secretariat to receive the submission packages, record, distribute for review and get the submission packages approved by the IEC, as well as to deliver the review results to the protocol applicants.

4. 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

5. Detailed instructions

5.1 Receive submitted packages

The Principal Investigator can submit research proposal to the Institutional Ethics Committee office for review and approval under any of the 5 sections mentioned below.

- Initial Review Application
- Resubmission of Protocols with corrections
- Protocol Amendment
- Continuing Review of Approved Protocols
- Protocol Termination

5.2 Initial Review Application

5.2.1 Check for submission items

- The Secretariat will check the hard copies and soft copies of following items
  1. A completely filled IEC Project Submission Application Form for Initial Review *AX 1-A/SOP 05/V4 / AX 1-B/SOP 05/V4*
  2. A checklist for contents of a submitted package *AX 02/SOP 05/V4*
  3. Delegation of Responsibilities of Study team *AX 03/SOP 05/V4*
  4. Document Receipt Form *AX 04/SOP 05/V4*
  5. Four sets of the proposal (One original and 3 sets of Xerox copies)

5.2.2 Verify contents of Submitted Package

The Secretariat will:

- Use the checklist for contents of a submitted package, *AX 02/SOP 05/V4* to verify that items listed and ticked in the checklist are present in the packet
- Check if all relevant and applicable forms and documents are in the submitted package being submitted to the IEC office. The correctness of the IEC application form will be assessed at the time of submission by the secretariat. Verify the completeness of the contents of the protocol submitted package to include the following documents:
  - ✓ Project submission application form for initial review
  - ✓ Letter to Member Secretary/ Chairperson
  - ✓ Protocol, to include
    a) Title of the Protocol
    b) Name and contact details of Principal Investigator
    c) Name and contact details of Sponsor
    d) IND Number (if applicable)
    e) Abstract (summary/synopsis)
    f) Study Methodology - Type of Protocol (screening, survey, phase of clinical trial), Objectives, Inclusion/Exclusion Criteria, Withdrawal or discontinuation Criteria, Schedule and Duration of Treatment, Modes of Treatment Studied, Procedures, Activity plan / Timeline, Efficacy or Evaluation Criteria (Response/Outcome), Safety Parameters Criteria (Toxicity), Analysis (methods)
  - ✓ Amendments to protocol (if any)
  - ✓ Informed consent document in English (as per sample format in Annex *AX 06/SOP 05/V4*)
  - ✓ Informed consent document in Regional languages

- ✓ Back translations of Informed consent documents
- ✓ Translation and Back translation certificate
- ✓ Informed Consent Document (ICD) or Amendments to the Informed consent document (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
- ✓ Regulatory permissions (as applicable)
  - ➢ DCGI approval
  - ➢ Investigator's Undertaking to DCGI
  - ➢ FDA marketing/manufacturing license for herbal drugs
  - ➢ Health Ministry Screening Committee (HMSC) approval
  - ➢ Bhabha Atomic Research Centre (BARC) approval
  - ➢ Genetic Engineering Advisory Committee (GEAC) approval
  - ➢ Administrative sanction from the head of the Institution in case of studies involving collaboration with other institutions.
  - ➢ A copy of Administration sanction from the head of the Institution for sending the samples to laboratories outside KEM Hospital.
- ✓ Brief Curriculum Vitae of all the study team members
- ✓ GCP training certificate (within 5 years) of Principle investigator and study co-ordinator.
- ✓ Investigator's agreement with Sponsor
- ✓ Memorandum Of Understanding (MOU)for collaborative studies
- ✓ Insurance policy
- ✓ Ethics Committee clearance of other centers (if applicable)
- ✓ Institutional Stem cell committee approval
- ✓ Any additional document(s), as required by IEC (Cheque/ Demand Draft drawn in the name of "Diamond Jubilee Society Trust, Seth GS Medical College and KEM Hospital" towards payment of IEC processing fees, as decided upon by the IEC from time to time)

5.2.3 Complete the submission process

The Administrative Officer/ any one designated by IEC will

- Stamp the receiving date on the first page/last page of the covering letter and initial his/her name on the receiving documents.

- Make a photocopy of the completed document receipt form *AX 04/SOP 05/V4* and return the original copy of the *AX 04/SOP 05/V4* 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 01/07 will indicate pharmaceutical sponsored study with number 01 of the year 2007.

5.2.4 Dispatch and Store the received packages

The Administrative Officer will

- Prepare **4** sets of a protocol package containing completed application form *AX 1-A/SOP 05/V4 / AX 1-B/SOP 05/V4*, protocol related documents along with checklist *AX 02/SOP 05/V4* and send three sets to the IEC members along with a copy of Project Assessment Form for Initial Review *AX 02/SOP 06/V4.*
- Store the appropriately labeled original protocol packages in the cupboard in the Institutional Ethics Committee office.

5.3 Resubmission of Protocols with corrections

- For resubmitted protocol, the Principal Investigator will submit a soft copy and one hard copy of the Protocol and related documents.
- The Secretariat will verify the completeness of the documents and reconfirm that the copy contains the modification highlighted with respect to the earlier protocol submitted mentioning the justification for the modification. The protocol related documents incorporating the change in the protocol are also submitted and verified by the Secretariat.)
- The Secretariat will perform the steps 5.2.2 & 5.2.3 as mentioned in initial review application. The protocol related documents which do not require to be changed and are already submitted for the Institutional Ethics Committee office during initial review are not required to be submitted again.

5.4 Protocol Amendments

- The Principal Investigator will submit a hard copy and soft copy of the Protocol and related documents (as per SOP 09/V4)
- The Secretariat will verify the completeness of the checklist for contents of a submitted package
- The Secretariat will check that the copy contains a list of modifications and the modifications are highlighted with respect to the earlier protocol submitted mentioning the justification for the modification.
- The Chairperson will decide whether to

- Take a decision regarding allowing or disallowing amendments without review by a selected group of IEC members or review by IEC members at an IEC meeting for minor administrative amendments
- Carry out review by a 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, if it is not submitted for the first time. In this case, the decision on approval /disapproval will be taken by the Chairperson and / or Member secretary after receiving the comments of the designated members and will be informed to all the IEC members in the forthcoming meeting.
- Consider for discussion at the full board meeting

5.5 Annual Continuing Reviews of Approved Protocols

- The Principal Investigator will submit one copy (soft and hard) of Annual Study Report and related documents (as per SOP 10/V4).
- The Secretariat will verify the completeness of the Continuing Review Application Form *AX 01/SOP 10/V4*, Progress report/Request letter for extension of approval of the project. The Administrative Officer will sign and date the documents.

5.6 Protocol Completion

- The Principal Investigator will submit one copy (hard and soft) of Study Completion Report and related documents (as per SOP 11/V4)
- The Secretariat will verify the completeness of the Study Completion Report Form *AX 02/SOP 11/V4* filled by the Principal Investigator

6. Reference

[1] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- *http://www.ich.org/LOB/media/MEDIA482.pdf* (last accessed 31st August 2013)

7. Annexure

Annexure 1-A	*AX 01-A/SOP 05/V4*	Project submission application form for initial review for Industry and Government sponsored studies.
Annexure 1-B	*AX 01-B/SOP 05/V4*	Project submission application form for initial review for all academic (non sponsored) studies.
Annexure 2	*AX 02/SOP 05/V4*	Checklist of protocol submission
Annexure 3	*AX 03/SOP 05/V4*	Delegation of Responsibilities of Study team
Annexure 4	*AX 04/SOP 05/V4*	Document Receipt Form
Annexure 5	*AX 5/SOP 05/V4*	Guidelines for Investigators
Annexure 6	*AX 06/SOP 05/V4*	Sample format of an Informed Consent Document
Annexure 7	*AX 07/SOP 05/V4*	Format for submission of an Informed Consent Document for Genetic Studies

Annexure 1-A

AX 1-A/SOP 05/V4

Project submission application form for initial review

for 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 & Qualifications**	**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

Non-sponsored (Investigator Initiated) **study** ☐ **Sponsored study** ☐

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 from out of India, contact address in India:

_____

_____

2.Total Budget : Rs._____

Research Fund will be deposited in: DJST ☐ DDF ☐ Research Society ☐ Other ☐

If other, please

specify_____

Please give details of allocation of budget in an attachment. Attached

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

Any Other ☐

Please specify_____

Clinical: Single center ____ Multicentric ____ (Attach a list of centers)

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

3. Clinical Trials:

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

i. Does the study involve use of :

Medicine ☐ Devices ☐ Vaccines ☐

Indian Systems of Medicine/ ☐ Any other ☐ NA ☐

If other, specify_____

ii. Is it approved and marketed

In India ☐ UK & Europe ☐ USA ☐ NA ☐

Other countries, specify _____

(Tick the appropriate box/option)			
iii. Does it involve a change in use, dosage, route of Administration?	Yes	No	NA
If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained?	Yes	No	NA
If yes, Date of permission :----------			
If No, whether DCGI's /Any other Regulatory Authority's Permission applied for?	Yes	No	NA
iv. Is it an Investigational New Drug (IND)?	Yes	No	NA

If yes, IND No:			
a) Investigator's Brochure submitted	Yes	No	NA
b) *In vitro* studies data	Yes	No	NA
c) Preclinical Studies done	Yes	No	NA
d) Clinical Study is : Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐			
e) To submit package insert in case test drug is already marketed in India Attached ☐			
e) Are you aware if this study/similar study is being done else where ? **If Yes**, Specify details ---------- ----------	Yes	No	
f) Whether DCGI's permission for testing IND obtained? If yes, Date of permission :----------	Yes	No	NA
g) whether DCGI's permission for testing IND applied for?	Yes	No	NA
h) For Ayurvedic or herbal formulation, a copy of the marketing/manufacturing license issued by the FDA to the company to be 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 **selection:** 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 (in the world):			
ii. Duration of study : No. of visits :			
iii. Will research participants from both sexes be	Yes	No	NA

recruited			
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 employees ☐ students ☐ 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	Yes	No	NA
i. Use of fetal tissue or abortus			
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 **If yes,** has Bhaba Atomic Research Centre (BARC)	Yes	No	NA

approval for radioactive isotopes been obtained?	Yes	No	NA
Vii. Use of Infectious/biohazardous 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 KEM ☐

Outside KEM ☐

If outside KEM, Address: _____

If Yes, specify with details of collaborators

9. Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration? (required 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 ☐

11. Consent : *Written ☐ Oral ☐ Audio-visual ☐ NA ☐

i. Consent form : (tick the included elements)

Understandable 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 ☐

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

iii. 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	Yes	No	NA

(DSMB)?			
ii. Is there a plan for reporting of adverse events? **If Yes,** reporting is done to : Sponsor ☐ IEC ☐ DSMB ☐	Yes	No	
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 compensation for 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 or IEC 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)		

(Information about GCP training of PI and co investigator)			
20. GCP training certificates of principal investigator and coordinators (mandatory only for drug and device trials not for observational studies**)**	(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), 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.

We also ensure that Principal Investigator / Institution will pay for treatment and / or compensation if study related injury occurred due to protocol violation by PI / study team.

Signature of Principal Investigator with date: _____

Signature/s with date of Co-investigators: 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 05/V4

Project submission application form for initial review

for all academic (non-sponsored) 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/KVPY ☐ Other Academic ☐

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

If sponsored,

Total Budget : Rs._____

From where is the study being funded

a) Research fund is being utilized from DJST ☐ Research Society ☐ Others ☐

If any other, please give details _____

1.Type of Study : Prospective ☐ Retrospective ☐ Cross-sectional ☐

Is the study observational/ Interventional? _____

If interventional, does the study involve any deviation from routine/standard practices?

_____
_

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

New Technique (surgical/PT/OT, etc) ☐ Diagnostic Kit/ Investigations ☐

If other, pleasespecify_____

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

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

Yes ☐ No ☐

If yes, please attach copy of DCGI permission.

If no, please attach copy of package insert/product insert.

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 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 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) approval.	Yes ☐	No ☐
5. Will any advertising be done for recruitment of Subjects? (Posters, flyers, brochures, etc.) If yes, kindly attach a copy for IEC review.	Yes ☐	No ☐
6. Is there compensation for participation (traveling 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 HOD
…….

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 05/V4

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	NA
1	*Project submission application form duly filled		__	_____	__
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		-	_____	
9	Translation and Back translation certificates		_	_____	
10	*Case Record Form		__	_____	__
11	*Research participants recruitment procedures: advertisement, notices (If applicable)		__	_____	__
12	*Patient instruction card, identity card, diary etc.				
13	*Research participants Questionnaire/s (If applicable)		__	_____	__
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, 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)				
	b) Administrative sanction from the Head of the Institution for the samples to be sent to outside KEM Hospital (one copy)				
23	*Signed and dated brief current curriculum vitae of the study team members (principal investigator, co-investigator, study co-ordinator) (one copy only)		__	_____	__
24	*Ethics Committee clearance of other centers (Total No _____)		__	_____	__
25	*Log of delegation of responsibility of the study team members - Sample Format Enclosed)		__	_____	__

26	*Document Receipt Form (one copy only)		__	_____	__
27	*Current Status of Ongoing Studies approved by IEC and IEC conducted by principal investigator (information may be submitted separately)		__	_____	__
28	Documentation of CTRI registration/ any other WHO platform registry (whenever applicable)				
29	*GCP training certificates of principal investigator and study co-ordinator for interventional clinical trial sponsored by pharmaceuticals companies (one copy only)				
30	Any other Documents submitted				

To be filled in by the IEC – Checklist for EC form:

1. Contact Address of Sponsor ☐
2. Total Budget ☐
3. Information on Clinical Trials ☐
4. Information on Protocol of the proposal ☐
5. Research participants selection ☐
6. Privacy and confidentiality ☐
7. Use of biological/ hazardous materials ☐
8. Consent ☐
9. Risks & Benefits ☐
10. Data Monitoring ☐
11. Compensation for participation ☐
12. Compensation for injury ☐
13. Statement on conflict of interest ☐

Annexure 3

AX 03/SOP 05/V4

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 1	Role 2	Role 3	Role 4	Role 5	Role 6	Role 7	Role 8	Role 9	Role 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 05/V4

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 (Local 3rd Vernacular language) ☐ study budget ☐ DCGI ☐ CTRI ☐GCP Training certificate ☐ Other sites EC permission ☐ Others…… _____ _____	Check what documents are received later on. ☐ final signed clinical trial agreement ☐ informed consent form (Local 3rd Vernacular language) ☐ study budget ☐ DCGI ☐ CTRI ☐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.

Current Contact Details:

Institutional Ethics Committee (IEC),
New UG/PG Hostel, 20th Storey hostel building, ground floor, KEM Hospital Campus, near main boy's hostel, Parel, Mumbai 400 012.

Telephone no. (GSMC and KEMH): 91 22 410 7000 Ext. 7515, 24107515, 24122188
Email: ethicscommittee@kem.edu

Annexure 5

AX 05/SOP 05/V4

Guidelines for Investigators

1. All the studies qualifying as 'clinical research' need to be submitted for the Institutional Ethics Committees review.
2. An Investigator planning to conduct a research study involving human participants; **funded by Government agencies and Pharmaceutical companies** at Seth G.S. Medical College & K.E.M. Hospital, should seek permission of the **Institutional Ethics Committee(IEC)** before commencing a study.

   Research studies which are undertaken as **dissertation projects** (postgraduate students :MD, MS, MCh, DM, DNB, PhD, MSc, MPTh, MOTh, Nursing), **research projects of undergraduate students** (Indian Council for Medical research studentship) and **investigator initiated** research studies which are **self funded** and those funded by Research Society of KEM Hospital, Diamond jubilee Society trust will need an approval by the **Institutional Ethics Committee (IEC)**.
3. Location and Office Address (current):

   Institutional Ethics Committee (IEC),

   New UG/PG Hostel, 20 Storey hostel building, ground floor, KEM Hospital Campus, near main boy's hostel, Parel, Mumbai 400 012. Telephone no. (GSMC and KEMH): 91 22 410 7000 Ext. 7515, 24107515, 24122188, Email: ethicscommittee@kem.edu

   The IEC office hours for submission of documents, enquiries and telephonic communication with the IEC staff are as follows:

   Monday to Friday - 1.30 p.m. to 4.00 p.m.
   Saturday - 10.30 a.m. to 12.00 noon
   The office will remain closed on Sundays and all public holidays.
4. There will be no meetings held in the month of May and November (during college vacations). In case a meeting is to be held during vacation due to unavoidable reasons, the decision will be taken by the Member Secretary in consultation with Chairperson.

5. The clinical trial (Any investigation in human research participants intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy [ICH-GCP]) must be registered with the Clinical Trial Registry of India (CTRI) or any other WHO platform registry and a copy of the documentation of registration must be provided at the time of submission of a new study proposal for review.
6. The principal investigator(PI) and the study co-ordinator should be GCP trained before initiating the study and copies of the GCP training certificates (at least one) within the preceding five years should be provided to the IEC at the time of submission of a new study proposal / prior to initiation as applicable.
7. The IEC is currently following the version 4 dated 22nd August 2013 of the Standard Operating Procedures (SOPs), which are individual activity based and are 24 in number. The SOPs are available with the General Manager in the office of the IEC. An investigator may submit a request in writing for a hard copy/ an electronic version of the SOPs of the IEC.
8. The following steps need to be followed by investigators while communicating with the IEC:

I <u>Prior to approval of a research study</u>

a) **Submission of a New Study Proposal**

The Project Submission Application Form ***AX 1-A/SOP 05/V4 / AX 1-B/SOP 05/V4*** **with** Checklist of Protocol Submission ***AX 02/SOP 05/V4*** to be submitted is available at the IEC office. **Four** sets of project proposal (one original set and three sets of photocopies and soft copy of whole proposal [on CD]) should be submitted. For some general and administrative documents (specified in the Check List for Protocol Submission ***AX 02/SOP 05/V4***) only one copy can be submitted. Project proposals submitted to the office of the IEC **<u>on or before 20th of every month will</u>** <u>usually be taken up for discussion at the next month's IEC meeting</u>. Each set shall contain the documents mentioned in ***AX 02/SOP 05/V4*** on A 4 size paper arranged in a plastic file in the same order. Please use the following form and checklist available in the IEC office for submission of new study.

- Project Submission Application Form for Initial Review ***AX 1-A/SOP 05/V4 / AX 1-B/SOP 05/V4***
- Checklist for protocol submission ***AX 02/SOP 05/V4***
- Appendix I *(enclosed)* states *r*egulatory permissions **t**o be sought wherever applicable.

b) The investigator should ensure that there is an 'Ethics Section' in the protocol which is in compliance with the ICMR 2006 Guidelines. The section should include the

following aspects which may be stated in the Ethics Section or elsewhere in the protocol:

- A statement saying that the study will be conducted in adherence to relevant national/international laws.
- Policy regarding autonomy (voluntariness, right to withdraw).
- Confidentiality
- Recruitment policy ensuring equitable enrollment.
- Protection of vulnerable participants.
- Process of obtaining informed consent.
- Policy regarding treatment of study related injury, compensation for study related injury and compensation for participation.
- Policy regarding dissemination of data, presentation of data, publication.

c) An investigator is required to fill in all the details in the form ***AX 1-A/SOP 05/V4 / AX 1-B/SOP 05/V4*** **very** clearly in legible handwriting. **Incompletely filled forms / forms without signatures will not be accepted.**

d) The study proposals will be circulated after 20th of every month to the IEC members for review and discussed at the IEC meeting to be held in the following month.

e) For all projects sponsored by pharmaceuticals, the processing fees will be Rs. 50,000/ project (effective from 1st September 2013), for the Government sponsored projects, the processing fees will be Rs. 5,000 /project (effective from 1st September 2013) and for all academic (non- sponsored) projects the processing fees will be Rs. 500/-project (in hard cash) (effective from 10th October 2010). The processing fees shall be collected only once at the time of submission of the project. The sponsored projects fees will be accepted by cheque / demand draft drawn in the name of 'Diamond Jubilee Society Trust, Seth G. S. Medical College'. The funds of the IEC are maintained in the Diamond Jubilee Society Trust (DJST) account, PAN no. AABTS5336G.

Duplicate copy of any document (for e. g. Permission letter, certificate, query letter) will be charged Rs. 200/- & the entire protocol will be charged Rs. 250/- for academic studies.

f) An investigator may be invited (telephonically/ through written communication) to the IEC meeting to discuss issues related to the study proposal.

g) An investigator may call up the IEC office to know the date of next scheduled meeting of the IEC.

h) For clinical study planned on an "alternative system of medicine" (Ayurveda, Homeopathy, Siddha, Unani), a Co-Investigator/ Collaborator from that system should be included in the study team. The co-investigator appointed should be independent and he/she should not have a conflict of interest with the study, investigator or sponsor. This is in accordance with the ICMR 2006 guidelines.

i) An investigator may refer to the SOP on 'Exemption from the Ethics Review for Research Projects' - SOP no. 22 and 'Request for Waiver of Written Informed Consent' - SOP no. 23 whenever necessary.

j) An investigator is required to refer to the format of an Informed Consent Document for genetic study whenever applicable *AX 07/SOP 05/V4*

k) An investigator is expected to submit reply to the letter of recommendations/ queries sent by the IEC within 180 days of date of receipt of the letter. In the absence of any response, the project will be declared closed for the IEC office records.

II <u>Once approval for a study is granted</u>

a) An approval will be granted for the entire duration of the study.

b) It is the responsibility of the principle investigator that for studies which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval)

C) Submission of Study Related Documents for IEC review

Study related documents (protocol amendments, SAE reports, status reports, study completion reports, protocol deviations/ violations) will be accepted during the office hours specified above. Only one set of the above stated study related documents need to be submitted for the IEC review.

Agenda for the IEC meeting is prepared 3 days in advance before the date of meeting and is sent to the IEC members at least 2 days in advance. Hence the study related documents like answers to the IEC queries and amended study related documents (Protocol, ICD, CRF and IB) received within seven days and other types of documents within 3 days preceding the date of meeting will not be considered for the meeting. It will be deferred to the next month's meeting for discussion (**<u>Exception</u> -** any matter which in the opinion of the IEC secretariat has direct bearing on the safety of the research participants such as SAE report, major protocol violation).

d) Submission of Amended Protocol and Protocol Related Documents

All amendments to the approved research proposal (only one set) should be submitted to the committee for its review no later than 7 seven days prior to the date of forthcoming meeting.

No changes in the protocol, case record form and /or Informed Consent Document shall be initiated without prior written approval from the committee, except when necessary to eliminate immediate hazards to the research participants, or when the change(s) involve only logistical or administrative aspects of the trial (e.g. change of monitor(s), telephone number(s).

A covering letter should be submitted mentioning reason/s for amendments and summary of changes and the amended text must be highlighted in the revised Protocol and Protocol Related Documents.

e) Submission of Report of Protocol Deviations/ Violations in the study protocol

Please use 1- Deviation / Non-Compliance / Violation Record *AX 01/SOP 12/V4* for submitting report of Protocol Deviations/ Non-Compliance / Violations.

f) Submission of Report of Serious Adverse Events (SAEs)

The Principal Investigator should submit within 24 hours on site SAE report or the unexpected adverse event report as per the format specified in *AX 01/SOP 14/V4* (Appendix XI of Schedule Y) and *AX 02/SOP 14/V4 to* the IEC or by email. The report of SAE of death after due analysis shall be forwarded by the Investigator to chairman of the IEC and Chairman of the Expert Committee constituted by the Licensing Authority under Appendix XII with a copy of the report to the Licensing Authority and the head of the institution where the trial is been conducted within 10 calendar days of SAE of death. The report of the SAE other than death after due analysis shall be forwarded by the Investigator to Licensing Authority, chairman of the IEC and the head of the institution where the trial is been conducted within 10 calendar days of occurrence of SAE.

The SAE report should be accompanied by detailed narrative of the SAE and CIOMS form.

It should be submitted as per checklist detailed by Licensing Authority in (Annexure A) and given in ***AX*** *01/SOP 14/V4.*

The sponsor or his representative shall pay the compensation in case of clinical trial related injury or death within 30 days of the receipt of such an order from Licensing Authority.

g) Any new information that may adversely affect the safety of the research participants or conduct of the trial should be informed to the IEC.

h) If an investigator wishes to appeal against the decision about rejection of a research proposal by the IEC, please contact the IEC and submit your appeal in writing, addressed to the IEC Chairperson with justification relevant to the issues/ objections raised by the committee within twelve (12) weeks of the receipt of the committee's decision. In absence of appeal, the project will be declared closed for the IEC office records.

i) Submission of continuing review report in case of studies which continues for more than a year.

- For studies which will continue for more than a year, a continuing review report as per the format *AX 02/SOP 10/V4* will need to be submitted for review
- If the Principal Investigator fails to submit the continuing review report within one month of the due date (i.e. 11^{th} months from the date of approval, unless specified otherwise), the IEC secretariat will send a reminder as per the format *AX 01/SOP 10/V4* within 7 working days of this due date. If there is no response within 15 days after the date of reminder, the IEC secretariat will put up the matter for discussion at the forthcoming full board meeting for appropriate action which may consist of but not limited to

  a) A letter of reprimanding the Investigator

  b) Not reviewing future projects from the PI for a specified period of time

  c) A letter asking the Investigator to put recruitment of new participants on hold

III Once a study is over

Submission of Study Completion Report

For studies which are completed within the IEC approval period, a study completion report as per the format given in *AX 01/SOP 11/V4* should be submitted to the IEC, by the investigator. The study completion report is expected for review within 1 month of completion of the study at the site. A brief study report containing data analysis from all centres should be submitted once available from the sponsor.

IV In case a study is not initiated or terminated, the same should be communicated to the IEC stating reasons for the same. The format for submission of report of premature termination of the study is as per *AX 01/SOP 13/V4* should be used

1. The IEC archives all the study related documents for a period of 5 years after the study is completed / terminated/ reported as not initiated at our site. In case, an investigator needs a copy of any document submitted to the IEC, a written request can be made for retrieval of the same using the form1- Document Request Form *AX 01/SOP 19/V4*

Sponsor responsibilities

Any report of serious adverse event or death occurring in clinical trial after due analysis shall be forwarded by the sponsor to the chairman of the IEC and the head of the institution where the trial is been conducted within ten calendar days of occurrence of the SAE or death. The report of the SAE other than death after due analysis shall be forwarded to chairman of the IEC and the head of the institution.

In case of injury or death occurring trial subject the sponsor (whether a pharmaceutical company or an institution) or his representative, whosever had obtained permission from the Licensing Authority for conduct of the clinical trial shall make payments for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the manner as prescribed in SOP 5 Annexure 6.

Appendix I: Regulatory permissions

- **DCG(I) approval**

  Studies which plan to use a new drug (as defined in 122-E of the Drugs and Cosmetics Act, 1945) require DCG (I) permission. For such studies, a copy of the permission letter issued by the DCG (I) to the pharmaceutical company/investigator also needs to be submitted to the IEC. If the DCG (I) permission is awaited, a letter of provisional 'approval will be issued by the IEC and the final IEC approval will be given after a copy of DCG(I) permission is submitted to the IEC. No study should be initiated until the final letter of permission is issued by the IEC.

- FDA marketing/manufacturing license for Ayurvedic/ herbal formulations/ nutraceutics
- Health Ministry Screening Committee (HMSC) approval in case a study involves collaboration with any foreign laboratory/clinic/institution
- Bhabha Atomic Research Centre (BARC) approval in case a study involves use of radioisotopes/ ionizing radiations

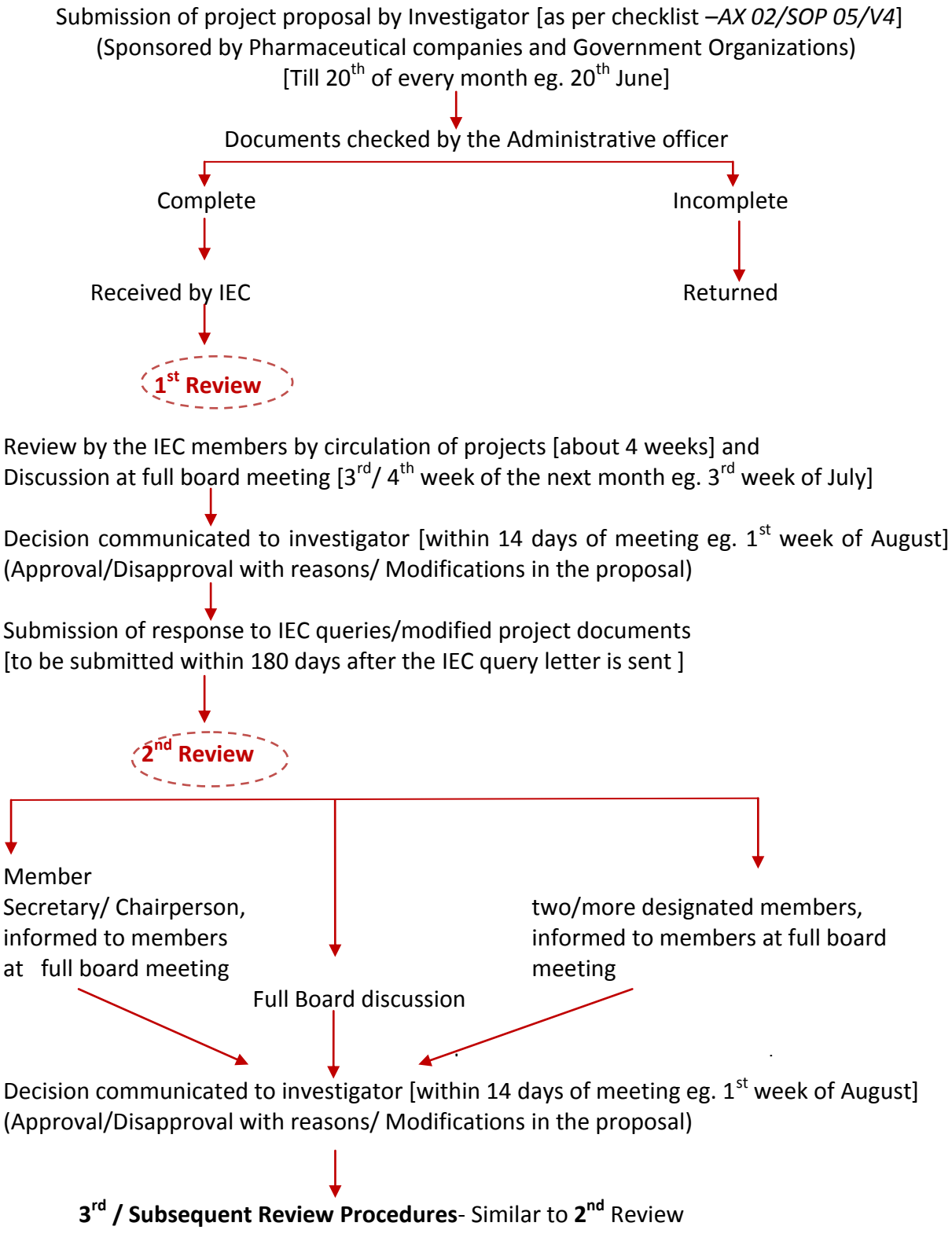
- Genetic Engineering Advisory Committee (GEAC) approval in case a study involves use of gene therapy
- **Administrative sanction** from the head of the Institution should be sought by investigators for studies involving collaboration with other Indian or foreign Laboratory/ Clinic/Institution.
- **Administration sanction** from the head of the Institution for sending the samples to laboratories outside KEM Hospital.
- It is mandatory as per the directive by the DCGI (w.e.f.15th June 2009, which is applicable for clinical trials initiated after 15th June 2009) to register clinical trial at ICMR clinical trial registry at www.ctri.in before enrolling first patient in the study. (Registration is mandatory for interventional clinical trials)

Appendix II: List of forms required for submission of study related documents

The following forms are available in the IEC office and should be used for submission of study protocol and other study related documents as per revised SOPs of the IEC:

- Project Submission Application Form for Initial Review ***AX 1-A/SOP 05/V4 / AX 1-B/SOP 05/V4***
- Checklist of Protocol submission ***AX 02/SOP 05/V4***
- Serious Adverse Event Report Assessment Form for SAE at our site *AX 01/SOP 14/V4*
- Deviation / Non-Compliance / Violation Record *AX 01/SOP 12/V4*
- Continuing Review Report Form *AX 01/SOP 10/V4*
- Study Completion Report *AX 01/SOP 11/V4*
- Premature Termination Report *AX 01/SOP 13/V4*
- Document Request Form *AX 01/SOP 19/V4*

Submission of Projects for IEC Review



Annexure 6

AX 06/SOP 05/V4

Sample Format of an Informed consent document in English (This template should be customized according to the requirement of individual research project)

I Project title:

To test the efficacy and tolerability of XXXXXXXX (an antihypertensive test drug) as compared to XXXXX (a standard antihypertensive drug)

II Introduction:

You are invited to participate in a research study. It is important that you read this description of the study and understand your role in it including the nature and risks of participation.

Please give your consent to participate in this clinical study only if you have completely understood the nature and course of this study and if you are aware of your rights as a participant.

III Purpose of the study:

It is well known that people who suffer from high blood pressure are at high risk for cardiovascular disease, including heart attacks, strokes and even death. Anti-hypertensive medications are commonly prescribed to such patients to prevent the occurrence of cardiovascular events. XXXX is a new drug, which has been found to decrease the blood pressure in initial studies. The study plans to study the efficacy and safety of this drug in patients having high blood pressure.

IV Expected duration of the study and number of research participants:

You will be one of approximately XXX people who will participate in this study. You will be in the study for about XXX days. (If multicentric study – mention that the study is also being carried out at xxx other centers).

V Study procedures to be followed:

If you agree to participate in this study you will a)be asked about previous medical problems, your current health and your medications; b)have a brief physical examination (to give details);c) need to undergo baseline investigation such as XXXXXX(to give details)

The study staff will review the results of these evaluations & test. If you are eligible to participate you will be randomly assigned (like the flip of a coin) to a study group to receive one of the two study treatments.

The study would require a total of XX visits. At each visit XX ml (mention1-2 tsp/tbsp as applicable) of your blood will be withdrawn after fasting for XX hours. The blood samples that are drawn, will be used to check your blood sugar levels, kidney and liver function etc. (mention whatever is applicable).

Regardless of the group to which you have been assigned, you will return to the study centre after XXXX days / weeks / months. It is important that you bring all of your study medications, diary etc. along with you.

At each visit, a) you will be asked about your health, side effects of medications, b) your physical examination will be carried out c) you will be given a new supply of study drug.

VI Risks and discomforts of participating:

The study testing 2 different therapies in high risk people that may prevent heart attacks, strokes or death from cardiovascular causes:

Based on studies in animals and other studies with people, the drug(s) used in this study may cause some side effects. The known risks and side effects associated with the drugs proposed for use here are summarized below.

Side effects of test drug – XXXXX (Give Details)

Side effects of standard drug – XXXXX (Give Details)

Other side effects that you may experience could include injection site reactions, allergic reactions to the medication, itching rash and pain at the injection site (if the drug is to be administered parenterally). While collecting blood from your vein, you will have to undergo the discomfort of brief pain or rarely develop bruising or even a minor infection. In case this occurs appropriate management will be provided

Finally new problems or side effects other than those that have been seen before could occur during this study. You will therefore be asked about side effects at each visit. It is important that you report any of the side effects described in this form or any other ones to the study physician immediately at the numbers listed below.

Because the safety of the study drugs for an unborn fetus or newborn is unknown, if you intend to become pregnant, are pregnant or are breastfeeding you cannot participate in this study. If you are a woman who is able to have children, you will be required to undergo a urine pregnancy test. If you are no pregnant you will be asked to take precautions to prevent pregnancy until the end of the study. The doctors will discuss the contraception options with you. Pregnancy test may be repeated during the study. If you become pregnant despite these precautions you should immediately notify the study team. Pregnancy will be a reason to stop study treatment.

Any new important information that is discovered during the study and which may influence your decision to continue in the study will be provided to you or your legally acceptable representative in a timely manner. You will be told of any new risks or side effects.

VII Possible benefits of the study:

By participating in this study, you may have a possible cure or improvement in your condition. However, there is no guarantee that you will receive direct health benefit from being in this study your participation in this study may provide information that may in the future help other patients suffering from high blood pressure.

VIII What happens when the research trials stops?

Because this is a research trial, the test drug will not be available at the end of this trial for treatment of this disease. Alternate therapy, if appropriate, will be provided once the trial is finished. Occasionally the company sponsoring the research may stop the study early – if this occurs the reason(s) will be explained to you.

IX Compensation for participation:

Participation in this study will be at no cost to you. The medication and clinic visits will be provided free of charge. No compensation will be provided for your participation. Payment for things such as lost wages is not available. (Wherever applicable give details e.g. reasonable travel assistance will be provided for your participation etc.)

X Treatment and Compensation for study related injury:

You will be provided medical IEC at this institute for any physical injury or illness that occurs as a direct result of your participation in this study. This medical IEC will be at no cost to you. The study doctor/sponsor will compensate anyone in case there is temporary/ permanent disability or death as a direct result of participation in this trial In case of death, their dependents are entitled to material compensation.(provision of insurance coverage by the sponsor for study related injury, if available, may be stated here). You will not give up any of your legal rights by signing this form.

Any injury or death of the participant occurring in clinical trial due to following reasons shall be considered as clinical trial related injury or death and the subject or his/her nominee (s) as the case can be are entitled for financial compensation .

a) adverse effect of investigational product (s)
b) violation of the approved protocol, scientific misconduct by the sponsor or the investigator.
c) failure of the investigational product to provide intended therapeutic effect
d) use of placebo
e) Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol.
f) for injury to child in utero because of the parents participation in the trial
g) any clinical trial procedure involved in the study.

[**Paragraph from ICMR 2006 guidelines** –
Obligation of the sponsor to pay: The sponsor whether a pharmaceutical company, government, or an institution, should agree, before the research begins, in the a priori agreement to provide compensation for any physical or psychological injury for which participants are entitled or agree to provide insurance coverage for an unforeseen injury whenever possible.]

[**As per the notification from the office of DCGI (Notification GSR NO 53 (E) Dated 30-01-2013, 122 DAB),** it is mandatory for the sponsors to comply the following requirement :

A. "In event of any injury occurring to the clinical trial subject, such subject shall be provided free medical management as long as required.
In the event of a trial related injury or death, the sponsor or his representative should

provide financial compensation for the injury or death . The financial compensation will be over and above any expenses incurred on the medical management of the subject.

In case of clinical trial related death of the subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and same should be included in Patient Information Sheet / Informed Consent Form"].

B. Date of Birth /Age …….
Address of the subject…….
Qualification…….
Occupation- student/self-employed/service/housewife/other (please tick as appropriate)
Annual income of the subject ……
Name and address of the nominee(s) and his relation to the subject …….
(for the purpose of compensation in case of trial related death)
C. Name of the witness ……..
(copy of the Patient information sheet and duly filled ICF shall be handed over to the participant or his/her **attendant)**

XI Right to withdraw from the study:

Participation in this study is entirely voluntary. You may choose not to take part or you may leave the study at any time. Your decision will not affect your further treatment at this institute. If you decide to leave the study, you may have to undergo some tests and/or procedures, which will be done to protect your safety.

XII Confidentiality:

All study records will be kept confidential at all times. Your identity will not be revealed except as required by law. The results of your treatment (details: laboratory tests, photographs, x-rays etc.) may be published for scientific reasons. Your identity will not be revealed in these publications.

XIII Contact for further information:

Thank you for taking the time to read (or have read to you) the information about this study. Before you sign this document, you should ask questions about anything that you do not understand. The study staff will answer questions before, during & after the study.

If you have questions about this study or how it is being run, drug side effects or a possible research related illness or injury, you can contact the study doctor XXXXXXXX, designation, department XXXXXXXX at telephone number XXXXXX during the office hours, or at XXXXX at outside office hours.

If you have any questions about your rights as a research participant, or complaints regarding the research study, you should call XXXXXXX who is the Member Secretary of Institutional Ethics Committee on the following telephone number on working days. Tel.

no.: 91 22 2410 7000, Ext. 7515, 91 22 24107515, 91 22 24122188 (Monday to Friday-9:00am to 4:00pm; Saturday-9:00am to 1:00pm).

XIV Consent:

[1] I have read or have had read to me the information given in the Informed Consent Document for this study entitled **"XXXXXXX"**

[2] I have received an explanation of the nature, purpose, duration, and foreseeable effects and risks of the trial and what I will be expected to do. My questions have been answered satisfactorily.

[3] I understand that my participation in the trial is voluntary and that I may refuse to participate or may withdraw from the trial at any time, without penalty or loss of benefits to which am otherwise entitled.

[4] I further understand that any information that becomes available during the course of the study that may affect my willingness to take part will be informed to me.

[5] Institutional Ethics Committee authorities may wish to examine my medical records to verify the information collected. By signing this document, I give permission for this review of my records.

[6] I understand that my identity will not be revealed in any report or publication.

[7] I agree to take part in the above study.

_____	_____	_____
Name of research participants	**Signature/ thumb impression of research participants**	**Date**

_____	_____	_____	_____
Name of Legal Representative (LAR)	**Relation to research participants**	**Signature / Thumb Impression of LAR**	**Date**

_____	_____	_____
Name of the Impartial Witness	**Signature of the Impartial Witness**	**Date**

_____	_____	_____
Name of the person Administering consent	**Signature of the person administering consent**	**Date**

Child assent statement for children above age 7 and below 18 (wherever applicable)

I have had the above research project explained to me in language that I can understand and I agree to participate.

_____	_____	_____
Name of child	**Signature of child**	**Date**
_____	_____	_____
Name of person obtaining Consent	**Signature of person obtaining consent**	**Date**

PLEASE NOTE THAT THE INFORMED CONSENT DOCUMENT SHOULD HAVE **PAGE NUMBERS**

Annexure 7

AX 07/SOP 05/V4

Format for Informed Consent Document for Genetic Studies

This document will, in general, follow the format of the informed consent document contained in Annexure 4 of SOP no. 5 *AX 04/SOP 05/V4*. The additional specific components related to genetic studies are elucidated here.

These guidelines are meant to provide assistance in framing informed consent documents for genetic research studies. The examples given may be inserted, where relevant, by the investigator/sponsor.

A. Project Title and Purpose of the Study

Given the more complex nature of genetic research, the sponsor/investigator should make the nature of the research abundantly clear to the research participant. The sponsor/investigator should also generally define genetic/genomic research in the context of the study under consideration in layman's terms. If the investigator so desires, a glossary of genetic terms used may also be provided.

Example:

1. *The purpose of this document is to enable you to understand the nature of the research that we are undertaking. Do take time to review this document IEC fully and do not hesitate to ask the investigator any question or clarification related to the research.*
2. *This study involves the analysis of how genes, blood components or DNA relate to the way that investigational therapies are absorbed, broken down and eliminated from the body, how they affect the body and how DNA relates to human disease."*

B. Study Procedures to be followed

The sponsor/investigator should explain in layman's terms the procedure to obtain any genetic material/tissue from a research participant.

C. Risks and Discomforts

The sponsor/investigator must explain the risks involved in the procedures to obtain any genetic material/tissue. Separate risks relating to genetic information obtained should also be explained.

Example: *"There is a chance that participation in this study could cause psychological distress, social and economic harm either to you individually or to your community."*

D. Possible benefits of the study

The sponsor/investigator ought to mention benefits if any that may accrue to the participants/community. If no such benefits are seen/ guaranteed at this point in time, the same may be explicitly stated. However, if there is a possibility of long-term societal benefits, this should be incorporated. The sponsor should also state his/her policy regarding commercial benefit to participant/community.

E. **What happens when the research trial stops?**

The storage of samples, the duration of such storage, the method of destruction of such samples should be stated. The possibility, if any, of using such samples in the future by the same or different investigators should be mentioned. Also, if the genetic study is being carried out as a sub-study, it ought to be stated that stoppage of the genetic study would not result in automatic cessation of the main study. If the study is stopped before schedule and the data is not anonymised, the option of knowing the results of the study should be made available to the research participant. Moreover, if the results of the study indicate that there might be implications for the participant, as regards future medical conditions; appropriate counseling ought to be provided. For example, the necessity of avoiding certain drugs in the future should be explained.

The genetic studies are often carried out as part of basic research and the data generated in initial studies is inadequate. It may inappropriate to use the preliminary data in management of patient's condition. This aspect needs to be explained (whenever applicable).

Example: *These analyses are done as part of basic research. Basic research analyses are performed under conditions that are different from routine laboratory testing that your doctor may do. Therefore, it would not generally be appropriate for your doctor to use these results as part of your IEC."*

F. Compensation for participation and Treatment and Compensation for study related injury

The provisions of the earlier format contained in Annexure 4 of SOP no. 5 (*AX 04/SOP 05/V4*) are applicable.

G. Right to withdraw from the study

If the genetic study is being carried on as a sub-study, withdrawal from the genetic study should not affect participation in the main study**.** The participant should be given the right

to request for destruction of his/her sample provided the sample has not been anonymised till that time.

H. Confidentiality

The participant should be informed whether the samples are to be unidentified, unlinked or coded as defined in the ICMR Guidelines, 2006. If the investigator does not intend to disclose the results of the study (for example, in the case of a preliminary/pilot study), the samples should be 'anonymous.'

If the investigator intends to disclose the results of the genetic testing, the participant should have the right to decide whether or not he desires such disclosure. Family members are not entitled to know each others' diagnosis and specific consent is needed from a participant before sharing the information with family members.
Example: *The investigator will provide the genetic analyses to your family, the doctor conducting the main study or any doctor involved in your IEC, your insurance company or your employer, only after obtaining your written consent. However, this is subject to the requirement of disclosure of such information to a court of law. It may also be made accessible to members of the IEC and regulators.*"