Independent
Ethics Committee
(Clinical Research) India

Standard Operating Procedures

(SOP -05/01)

For

Management of Protocol Submissions

Independent Ethics Committee (Clinical Research) India

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is designed to describe how the Secretariat of the Independent Ethics Committee (IEC) manages protocol submissions to the IEC

2. Scope

Protocol submissions include:

- Submission for Initial Review of the Protocol
- Resubmission of Protocols with Corrections
- Protocol Amendment
- Continuing Review of Approved Protocols
- 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 Independent Ethics Committee office for review and approval under any of the 5 sections mentioned below.

5.2 Initial Review Application

5.3 Resubmission of Protocols with Corrections

5.4 Protocol Amendment

5.5 Continuing Review of Approved Protocols

5.6 Protocol Termination

5.2 Initial Review Application

5.2.1 Check for submission items

- The Secretariat will check the following items

  1. A completely filled Independent Ethics Committee Project Submission Application Form for Initial Review *AF/01/01-SOP05/01*.

  2. A checklist for contents of a submitted package *AF/02/01-SOP05/01*

(All the forms are available at Independent Ethics Committee office or can be downloaded from Independent Ethics Committee Website www.iecindia.org)

5.2.2 Verify contents of Submitted Package

The Secretariat will:

- Use the checklist for contents of a submitted package, *AF/02/01-SOP05/01* to verify the applicable documents to ensure that all required forms and documents are contained within the submitted package are received at the IEC office.
- 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/ Associate Member Secretary
  - Summary of protocol
  - Protocol, to include
    1. Title of the Protocol

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2. Name and contact details of Principal Investigator
3. Name and contact details of Sponsor
4. IND Number (if applicable)
5. Abstract (summary/synopsis)
6. Type of Protocol (screening, survey, clinical trial and phase)
7. Objectives
8. Anticipated Outcome
9. Inclusion/Exclusion Criteria
10. Withdrawal or discontinuation Criteria
11. Schedule and Duration of Treatment
12. Modes of Treatment Studied
13. Methodology
14. Activity plan / Timeline
15. Efficacy or Evaluation Criteria (Response/Outcome)
16. Safety Parameters Criteria (Toxicity)
17. Analysis (methods)

- Amendments to protocol (if any)
- Informed consent document in English
- Informed consent document in Regional languages
- Back translations of Informed consent documents
- Back translation certificate
- Amendments to the Informed consent document (if any)
- Case Record Form
- Site profile
- No Objection Certificate from Dean/ Medical Superintendent/ Director of the trial site
- Subject recruitment procedures: advertisement, notices
- Patient instruction card, identity card, diary etc.
- Investigator Brochure
- Regulatory permissions (as applicable)
  1. DCGI approval
  2. Investigator's Undertaking to DCGI
  3. FDA marketing/manufacturing license for herbal drugs
  4. Health Ministry Screening Committee (HMSC) approval
  5. Bhabha Atomic Research Centre (BARC) approval
  6. Genetic Engineering Advisory Committee (GEAC) approval
  7. Director General of Foreign Trade (DGFT) approval
- Principal Investigator's Curriculum Vitae
- Investigator's agreement with Sponsor
- Ethics Committee clearance of other centers
- No. of centers & Sample size for each center
- Insurance policy
- Additional documents

- Check the total number of copies received for all documents. The total number of copies to be submitted will be equivalent to the total number of

Independent Ethics Committee members prevalent at that tenure plus additional copy for Independent Ethics Committee records. For the given tenure the research proposal applicant must submit 12 copies

5.2.3 Complete the submission process

The Secretariat will

- Reconfirm the completeness of information in *AF/01/01-SOP05/01* & *AF/ 02/01-SOP05/01*.
- If the package is incomplete confirm the items missing in the package and fill up the related parts and the missing documents in the Document Receipt Form *AF/03/01-SOP05/01*

The Administrative Officer will

- Stamp the receiving date on the first page of all documents and initial his/her name on the receiving documents.
- Make a photocopy of the completed document receipt form *AF/ 03/01-SOP05/01* and return the original copy of the *AF/03/01-SOP05/01* to the applicants for their records.
- Attach the filled documents, Annex1 -*AF/01/01-SOP05/01*, *AF/02/01-SOP05/01* and *AF/03/01- SOP05/01* with a staple to the Research Protocol packages.
- Keep the copies of the submitted documents with original signatures in the protocol "Submission" file.
- The project file is numbered as IEC/year(00)/Number(00) for e.g. IEC/07/01 will indicate project of year 2007 with number 01.

5.2.4 Despatch and Store the received packages

The Administrative Officer will

- Bind the packages together appropriately.
- Prepare 11 sets of all protocol and protocol related documents to be couriered to each Independent Ethics Committee member along with copy of *AF/01/01-SOP05/01*, *AF/02/01-SOP05/01* and Project Assessment Form for Initial Review *AF/01/01-SOP06/01*. (The original form is kept for Independent Ethics Committee office records in the file).
- Store the original protocol packages in the project submission cupboard in the Independent Ethics Committee office.

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5.3 Resubmission of Protocols with corrections

5.3.1 Verify the contents

- For resubmitted protocol the Principal Investigator will submit 3/12 copies, depending on IEC decision on *AF/02/01-SOP06/01,* of the Protocol and related documents as informed to him/her by the Secretariat.
- The Secretariat will verify the completeness of the checklist form (*AF/ 02/01-SOP05/01*) and reconfirm that all the copies contain 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 Independent Ethics Committee office during initial review are not resubmitted again.

5.4 Protocol Amendments

- The Principal Investigator will submit 12 copies of Protocol amendment/protocol related documents (as per SOP 09/01).
- The Secretariat will verify the completeness of the checklist for contents of a submitted package, (*AF/ 02/01-SOP05/01*)
- The Secretariat will perform the steps 5.2.2 & 5.2.3
- Check all the copies contain the modification highlighted with respect to the earlier protocol submitted mentioning the justification for the modification.

5.5 Annual Continuing Reviews of Approved Protocols

- The Principal Investigator will submit 12 copies of Annual Study Report and related documents (as per SOP 10/01)
- The Secretariat will verify the completeness of the Continuing Review Application Form (*AF/01/01-SOP10/01*), Progress report/Request letter for extension of approval of the project. The Administrative Officer will sign and date the documents.
- The Secretariat will perform the step 5.2.3

5.6 Protocol Completion

- The Principal Investigator will submit 3 copies of Study Completion Report and related documents (as per SOP 11/01)

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- The Secretariat will verify the completeness of the Study Completion Report Form *AF/02/01-SOP11/01* filled by the Principal Investigator (This form is available on the IEC website www.iecindia.org) and Project Completion Report.
- The Secretariat will perform the steps 5.2.2, 5.2.3

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 24 March 2008)

7. Annexure

ANNEX 1	AF/01/01-SOP05/01	Project Submission Application Form for Initial Review
ANNEX 2	AF/02/01-SOP05/01	Checklist of Documents
ANNEX 3	AF/03/01-SOP05/01	Document Receipt Form

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Annex 1
AF/01/01-SOP05/01

Project Submission Application Form for Initial Review

Serial No of IEC

Proposal Title:

	Name, Designation & Qualifications	**Contact Address Tel & Fax Nos. Email ID**	**Signature**
PI			
Co-PI / Collaborators 1.			
2.			
3.			
Please attach detailed Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years). If additional collaborators attach details on a separate page.			

Sponsor Information :						
1. Indian	a) Government ☐	Central ☐	State ☐			
	b) Private ☐					
2. International	Government ☐	Private ☐	UN agencies ☐			
3. Industry	National ☐	Multinational ☐				
Contact Address of Sponsor:						
Total Budget :						

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Type of Study : Epidemiological Basic Sciences Animal studies Behavioral Clinical: Single center Multicentric Name and Address of the Centers :_____ (Attach the details on a separate sheet)		
2. Status of Review: New Revised		
3. Clinical Trials: **Drug /Vaccines/Device/Herbal Remedies :** **i.** Does the study involve use of : Drug Devices Vaccines Indian Systems of Medicine/ Alternate System of Medicine Any other NA		
ii. Is it approved and marketed In India UK & Europe USA Other countries, specify		
iii. Does it involve a change in use, dosage, route of administration?	Yes	No
If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained?	Yes	No
If yes, Date of permission :		
iv. Is it an Investigational New Drug?	Yes	No
If yes, IND No:		
a). Investigator's Brochure submitted	Yes	No
b). *In vitro* studies data	Yes	No
c). Preclinical Studies done	Yes	No
d). Clinical Study is : Phase I Phase II Phase III Phase IV		
e). Are you aware if this study/similar study is being done else where ?	Yes	No
If Yes, attach details		
4. Brief description 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 (Attach sheet with maximum 500 words):		
5. Subject selection: i. Number of Subjects :		
ii. Duration of study :		

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iii.	Will subjects from both sexes be recruited	Yes	No
iv.	Inclusion / exclusion criteria given	Yes	No
v.	Type of subjects Volunteers Patients		
vi.	Vulnerable subjects Yes ☐ No ☐ (Tick the appropriate boxes) pregnant women children elderly fetus illiterate handicapped terminally ill seriously ill mentally challenged economically & socially backward any other		
vii.	Special group subjects Yes No (Tick the appropriate boxes) captives institutionalized employees students nurses/dependent armed any other staff forces		
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
i.	Use of fetal tissue or abortus		
ii.	Use of organs or body fluids	Yes	No
iii.	Use of recombinant/gene therapy	Yes	No
	If yes, has Department of Biotechnology (DBT) approval for DNA products been obtained?	Yes	No
Iv.	Use of pre-existing/stored/left over samples	Yes	No
v.	Collection for banking/future research	Yes	No
vi.	Use of ionising radiation/radioisotopes	Yes	No
	If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes	No
Vii.	Use of Infectious/biohazardous specimens	Yes	No
Viii.	Proper disposal of material	Yes	No
Ix.	Will any sample collected from the patients be sent abroad ? **If Yes, justify with details of collaborators**	Yes	No
a)	Is the proposal being submitted for clearance from	Yes	No

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Health Ministry's Screening Committee (HMSC) for International collaboration?		
b) 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…		
8. Consent : *Written Oral Audio-visual i. Consent form : (tick the included elements) Understandable language Statement that study involves research Sponsor of study Purpose and procedures Risks & Discomforts Benefits Compensation for participation Compensation for study related injury Alternatives to participation Confidentiality of records Contact information Statement that consent is voluntary Right to withdraw Consent for future use of biological material Benefits if any on future commercialization eg. genetic basis for drug development *If written consent is not obtained, give reasons:		
ii. Who will obtain consent? PI/Co-PI ☐ Nurse/Counselor ☐ Research staff ☐ Any other ☐		
9. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so kindly attach a copy)	Yes	No
10. Risks & Benefits: i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?	Yes	No
ii. Is there physical / social / psychological risk / discomfort? **If Yes,** Minimal or no risk More than minimum risk High risk	Yes	No
iii. Is there a benefit a) to the subject? Direct Indirect b) Benefit to society		
11. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No

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ii. Is there a plan for reporting of adverse events ? **If Yes,** reporting is done to : Sponsor ☐ Ethics Committee ☐ DSMB ☐	Yes	No
iii. Is there a plan for interim analysis of data?	Yes	No
vi. Are there plans for storage and maintenance of all trial database? **If Yes,** for how long?	Yes	No
12. Is there compensation for participation **If Yes,** Monetary In kind Specify amount and type:	Yes	No
13. Is there compensation for injury? **If Yes,** by Sponsor ☐ by Investigator by insurance ☐ by any other company	Yes	No
14. Do you have conflict of interest? (financial/nonfinancial) **If Yes, specify :**	Yes	No

Place:

Date: Signature & Designation of PI

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Annex 2
AF/02/01-SOP05/01

Checklist of Documents

Application No :- IEC/ 200-/
Check List of Documents received by Independent Ethics Committee office on - ---------- (for IEC office)
□ Protocol submission for initial review
□ Resubmitted protocol
□ Amended protocol
□ Other documents (Tick accordingly)

Sr. No.	Document	No. of copies to be submit -ted	No. of copies submit -ted	Yes	No	NA
1	Project submission application form					
2	Letter to Member Secretary/ Chairperson /Associate Member Secretary					
3	Summary of protocol					
4	Protocol					
5	Amendments to protocol					
6	Informed consent document in English					
7	Informed consent documents in Regional languages (Total No:-)					
8	Back translations of Informed consent documents					
9	Back translation certificate					
10	Amendments to the informed consent document					
11	Case Record Form					
12	Site profile					
13	No Objection Certificate from Dean/Medical Superintendent/Director of the trial site.					

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Sr. No.	Document	No. of copies to be submit-ted	No. of copies submit-ted	Yes	No	NA
14	Subject recruitment procedures: advertisement, notices					
15	Patient instruction card, identity card, diary etc.					
16	Investigator Brochure					
17	Regulatory permissions					
A	DCG(I) approval					
B	Insurance policy					
C	Investigator's undertaking to DCG(I)					
D	Investigator's agreement with sponsor					
E	FDA marketing/manufacturing license for herbal drugs.					
F	Health Ministry Screening Committee (HMSC)approval					
G	Bhabha Atomic Research Centre (BARC) approval					
H	Genetic Engineering Advisory Committee (GEAC)approval					
I	Director General of Foreign Trade (DGFT) approval					
18	Principal investigators Current Curriculum Vitae					
19	Ethics Committee clearance of other centers(Total No _____)					
20	No of centers :- Sample Size for each center					
*****	Additional Documents.					

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Annex 3
AF/03/01-SOP05/01

Document Receipt Form

		Received number:	FFF / FF - FF
Protocol Number:		**Submitted date:**	
Type of Submission:	F Initial Review F Resubmission for re-review F Protocol Amendments	F Continuing Review of Approved Protocols F Protocol Termination	
Protocol Title:			
Principal Investigator:			
Telephone number:		**Fax :**	
E-mail:		**Preferred Contact**	F Phone F Fax F e-mail
Institute:			
Delivery route:	F Post F E-submission F in Person		
Documents submitted:	F Complete F Incomplete, will submit on……..		
Documents to be submitted later :	information for subjects informed consent form case report forms (CRF) study budget investigator's brochure others……	Check what documents are received later on. information for subjects informed consent form case report forms (CRF) study budget investigator's brochure others……	
Received by:			
Date received:			

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Note: Please bring this receipt with you when contacting the Independent Ethics Committee office :- Independent
Ethics Committee Dept of
Clinical Pharmacology.
Old RMO Bldg., 5th Floor, TN Medical College and BYL Nair Ch. Hospital
Kolkata Central, Kolkata 400008.
Tel & Fax No :- 022- 23012223