Title: Management of Protocol Submission

SOP Code: SOP/06/V1.5

Effective date: 07/11/2017

Table of Content

1. Purpose

This standard operating procedure is designed to describe how the Secretariat of the Institutional Ethics Committee (IEC) manages protocol submissions to the IEC.

2. Scope

Protocol submissions include :

- Submission for Initial Review
- Resubmission of Protocols with Corrections
- Protocol Amendment
- Continuing Review of Approved Protocols
- Serious Adverse Event reports
- Protocol Termination
- Protocol completion reports

3. Responsibility

It is the responsibility of the IEC secretariat to receive, record, distribute for review and get the project proposals approved by the IEC, as well as to deliver the review results by the way of discussion with / Minutes to the Principal Investigators

4. Flow chart

No.	Activity	Responsibility
1	Receive Submitted project proposals ↓	IEC Secretariat
2	Check for submission items: • Initial Review Application • Resubmission of Protocols with Corrections • Protocol Amendment • Continuing Review of Approved Protocols • Serious Adverse Event reports • Protocol Termination • Protocol completion reports ↓	IEC Secretariat
3	Complete the submission process ↓	IEC Secretariat
4	Store the received documents	IEC Secretariat

5. Detailed instructions

5.1 Receive submitted documents

5.1.1 Initial Review Application

 Go to 5.2.

5.1.2 Resubmission of Protocols with Corrections

 Go to 5.2.1.2

5.1.3 Protocol Amendment

- Go to 5.2.1.3

5.1.4 Continuing Review of Approved Protocols including AE/SAE

- Go to 5.2.1.4

5.1.5 Protocol Termination

- Go to 5.2.1.5.

5.2 Check for submission items

5.2.1 Check the submitted documents

Receive the documents from the Scientists/ Principal Investigator after confirming that they are complete with respect to information, forms, approval letters, enclosures, page nos. on each page etc.

5.2.1.1 Initial Review

- Check for contents of a submitted project proposal as per Checklist, form AF/EC/01/06/V1.5 (see ANNEX 1),
- Review Report form AF/EC/02/06/V1.5 (see ANNEX 2),
- Go to step 5.2.2

5.2.1.2 Resubmission of Protocols with corrections

- Check for contents of a re-submitted project proposal as per Checklist, form AF/EC/01/06/V1.5 (see ANNEX 1),
- Review Report form AF/EC/02/06/V1.5 (see ANNEX 2),
- Go to step 5.2.2

5.2.1.3 Protocol Amendments

- Check for contents of a submitted project proposal as per Checklist, form AF/EC/01/06/V1.5 (see ANNEX 1),
- Go to step 5.2.2

5.2.1.4 Annual Continuing Reviews of Approved Protocols

- Check the Annual Report with the template AF/EC/03/06/V1.5 (see ANNEX 3) for all the points covered.
- Take out the relevant file and check for the information given in report is same as mentioned in the file.
- If any point/information is missing, provide Template (soft copy) to the Principal Investigator and request them to give information as per the template only.
- Go to step 5.4

5.2.1.5 Protocol Termination/ Completion

- Check for contents of a submitted package, as per the format of final review AF/EC/04/06/V1.5 (see ANNEX 4),
- Go to step 5.4

5.2.2 Fill in the forms:

- Tick mark the points on the Checklist AF/EC/01/06/V1.5 (see ANNEX 1).

5.2.3. Verify contents of submitted project proposal

Title Page should be complete in following respects

- Project Title:
- Name of the Principal Investigator:
- Name of the Co- Investigator/ Collaborator:
- Enclosures with page nos.

Face Sheet should be complete as per the Checklist (ANNEX 1 AF/EC/01/06/V1.5)

Participant Information Sheet: refer (ANNEX 5 AF/EC/05/08/V1.7)
To see that all the question are included in the Participant Information Sheet as per the given format
Informed Consent Document refer (ANNEX 6 AF/EC/06/08/V1.7)
Summary of Study Protocol and Detailed Protocol should include the following points refer (ANNEX 3 AF/EC/03/08/V1.7)

5.3 Complete the submission process

- Check for completeness of the submitted documents
- Notify the applicants if the package is incomplete.
- State clearly the items missing in the package.
- Fill up the related parts and the missing documents.
- If the documents found to be complete, put 'Received' stamp on the Covering letter and the first page of the documents
- Initial the receiver's name on the receiving documents. Put date, time and inward number for receiving the documents.
- Attach the filled checklist (ANNEX 1 AF/EC/01/06/V1.5) with the copy of the Study Assessment form (ANNEX 2 AF/EC/02/06/V1.5) to the Research Protocol documents.

5.4 Processing the submitted documents

- The Principal Investigator will be informed to make multiple copies as required. If the project is to be put forth to the meeting, it will be assigned number and the file of the project with that number will be made. The entry will be made in the 'Project Register' and in excel for writing further information. If the project is found to be incomplete, the Principal Investigator will be asked to make the corrections in the proposal.

5.5 Create a Protocol Specific File (for Initial Review)

- Create the 'Project' file.
- Record the name of the Principal Investigator, title and assign number to the project.
- Keep the copy of the submitted documents with original signatures in the respective file.

5.6 Store the received documents

- Bind the documents together appropriately.
- Store the dated and initial original protocol documents on the IEC submission shelf for review in chronological order.

6. References

6.1 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
6.2 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
6.3 Associated SOPs: SOP/08/V1.7
6.3 Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006
6.4 Additional recent reference

7. ANNEX

ANNEX 1	(AF/EC/01/06/V1.5)	Checklist
ANNEX 2	(AF/EC/02/06/V1.5)	Study Assessment Form
ANNEX 3	(AF/EC/03/06/V1.5)	Annual Report Template
ANNEX 4	(AF/EC/04/06/V1.5)	Study Report form for protocol completion
ANNEX 5	(AF/EC/05/06/V1.5)	Study Report form for protocol termination
ANNEX 6	(AF/EC/06/06/V1.5)	Document History

ANNEX 1 **(AF/EC/01/06/V1.5)**

Checklist for Principal Investigator

SN	Particulars		
1	Covering letter	Yes	No
2	Copy of the latest Minutes	Yes	No
3	Title Page		
	Project Title:	Written	Not Written
	Name of the Principal Investigator:	Written	Not Written
	Name of the Co- Investigator/ Collaborator:	Written	Not Written
	Enclosures with page nos.	Written	Not Written
4	Face Sheet		
	1) Project Title	Written	Not Written
	2) Principal Investigator / Co-ordinator	Written	Not Written
	- Name, - affiliation, - official postal address, - telephone nos., - e-mail address		
	3) Name,address of the Institution / Orgn. responsible for conduct / coordination of project.	Written	Not Written
	3a) Name & address of the Officer responsible for institutional supervision	Written	Not Written
	4) Name & address of the Funding / Sponsoring Institution/CRO	Written	Not Written
	4(a) Name & address of the Officer-in-Charge of the Funding/Sponsoring institution/CRO	Written	Not Written
5	Monitor of the Project: - Name - Address	Written	Not Written
6	Comments/Recommendations of the SAC/ SRC/ ICSCRT/ Technical Experts (Attach Minutes/Letter) If attached, mention page no.	Attached	Not attached
7	Comments / Recommendations of the Statistician: If attached, mention page no.	Attached	Not attached
8	To be answered / responded by the PI / Co-ordinator	Complete	Incomplete

	a) Does the protocol fall under exempt category? (If yes, give reasons on separate sheet)	Given	Not given
	b) Is request made for obtaining waiver from informed consent? (If yes, give reasons on separate sheet)	Given	Not given
	c) Is request made for expedited review? *(If yes, give reasons on separate sheet)*	Yes	No
	d)) Does the protocol involve Human participants (If yes, will it include)	Yes	No
	i) drawing of blood, body fluids, tissues etc.	Yes	No
	ii) Administration of an investigational substance / implantation of a device (if yes, provide name of the drug / substance / device etc. and its manufacture's name and address) (Also, clearance from the DCGI, if relevant)	Yes	No
	iii) exposure to ionizing radiation	Yes	No
	iv) Use of genetically engineered products (if yes, give details of the product, and appropriate clearances from the DBT, GEAC, DCGI, etc.)	Yes	No
	e) Does the protocol involve inclusion of vulnerable participants (if yes, special precautions proposed to safeguard their rights and interests shall be documented on separate sheet) Page No.	Yes	No
	f) Does the protocol involves sending samples abroad		
	Signature of Principal Investigator/coordinator responsible for conduct of study with mention of date & place	Complete	Incomplete
	Signature of HOD / Chairperson of the Department with mention of date and place	Complete	Incomplete
	Signature of Head of the Institution/ Authorized person with mention of date and place	Complete	Incomplete
9	Undertaking by Investigators & Collaborators Signature, Date	Complete	Incomplete
10	Brief Bio-data of Investigators signed and dated	Complete	Incomplete
11	Role of various Investigators	Complete	Incomplete
12	Participant Information Sheet:	Complete	Incomplete
13	Informed Consent Document	Complete	Incomplete
14	Participant Record Sheet	Complete	Incomplete
15	Summary of Study Protocol	Complete	Incomplete
16	Detailed Protocol	Complete	Incomplete
17	Data Collection tools/ questionnaire	Attached	Not attached
18	GCP Training Certificate of Principal Investigator/Co-Investigators/Collaborators	Attached	Not attached

ANNEX 2 **(AF/EC/02/06/V1.5)**

Study Assessment Form for New Projects

Protocol Number: Date (D/M/Y):

Protocol Title:

Name of Principal Investigator:

Reviewer's name:

Mark and comment on whatever items applicable to the study.

1	Objectives of the Study ☐ Clear ☐ Unclear	What should be improved?
2	Background and Rationale ☐ Sufficient ☐ insufficient	Comment:
3	Methodology ☐ Clear ☐ Unclear	What should be improved?
4	Need for diagrammatic representation ☐ Yes ☐ No	Comment :
5	If diagrammatic representation given: ☐ Clear ☐ Unclear	What should be improved?
6	Study Design and Sample size ☐ Appropriate ☐ Inappropriate	Comment:
7	Inclusion Criteria ☐ Appropriate ☐ Inappropriate	Comment:
8	Exclusion Criteria ☐ Appropriate ☐ Inappropriate	Comment:
9	Statement for protection of rights and interests of Vulnerable Participants ☐ Clear ☐ Unclear	Comment:
10	Voluntary, Non-Coercive Recruitment of Participants ☐ Yes ☐ No	Comment:

11	Are Qualification and experience of the Participating Investigators appropriate? ☐ Yes ☐ No	Comment:
12	Disclosure or Declaration of Potential Conflicts of Interest ☐ Yes ☐ No	Comment:
13	Facilities and infrastructure of Participating Sites ☐ Appropriate ☐ Inappropriate	Comment:
14	Involvement of Local Researchers and Institution in the Protocol Design, Analysis and dissemination of Results ☐ Yes ☐ No	Comment:
15	Contribution to Development of Local Capacity for Research and Treatment ☐ Yes ☐ No	Comment:
16	Community consultation where needed ☐ Yes ☐ No	Comment:
17	Benefit to Local Communities ☐ Yes ☐ No ☐ Not applicable	Comment:
18	Are blood/tissue samples sent abroad? ☐ Yes ☐ No	Comment:
19	MOU's with collaborating organisation ☐ Yes ☐ No	Comment:
	Participation Information Sheet and Informed Consent Documents	
S N	**Points**	**Comments**
1	Are procedures for obtaining Informed Consent appropriate? ☐ Yes ☐ No	
2	Contents of the Informed Consent Document ☐ Clear ☐ Unclear	
3	Language of the Informed Consent Document ☐ Clear ☐ Unclear	

4	Risks/ inconveniences mentioned clearly ☐ Yes ☐ No	
5	Risk benefit analysis ☐ Yes ☐ No	
6	Mention about tests to be performed if any ☐ Yes ☐ No	
7	Period of storage of biological samples ☐ Yes ☐ No	
8	Are possible benefits mentioned ☐ Yes ☐ No	
9	Contact Persons for Participants ☐ Yes ☐ No	
10	Privacy & Confidentiality ☐ Yes ☐ No	
11	Inducement for Participation ☐ Unlikely ☐ Likely	
12	Provision for Medical / Psychosocial Support ☐ Appropriate ☐ Inappropriate	
13	Provision for Treatment of Study Related Injuries ☐ Appropriate ☐ Inappropriate	
14	Provision for Compensation ☐ Appropriate ☐ Inappropriate	

Signature with date :

ANNEX 3 **(AF/EC/03/06/V1.5)**

Continuing Review Template

Project No: Principal Investigator:

Name of the project:

Name of the Co-Investigator:

Collaborators:

Duration of the study:

Presented to EC – date: Approval date:

Study initiation - date

Amendments if any:

Approval given for the Amendment:

Financial Status

Budget

Objectives:

Sample size:

Number of study participants enrolled: Number of drop outs/ withdrawn:

Summary of the work done (preferably in 1-2 paragraphs):

Number on study/follow-up:

Risk benefit ratio: Number of AE/SAE:

Change in risk benefit ratio:

Completion/Termination of the study – date

Any protocol deviation and violations:

Need of Extension with justification

Publication:

Signature of the Principal Investigator with date

ANNEX 4 **AF/EC/04/06/V1.5**

Study Report Form for Protocol Completion

Protocol No.: Principal Investigator:

Protocol Title :

Date of EC Approval

Phone number: E-mail address :

Sponsor's /Funding Agencies Name

Address: Phone : E-mail :

Study site(s): No. of Participants as each site:

Study Design and Sample Size:

Objectives:

Methodology:

Duration of the study: Total Number of study participants:

No. of Study Arms (If any): Number of participants in each of the Study Arms:

Study dose(s):

Provision for follow-up of patients :

Risk benefit ratio: Number of AE/SAE:

Change in risk benefit ratio:

Whether the study samples are being retained for future use:

Results:
(Use extra blank paper, if more space is required.)

Outcome and Implications of the Study:

Publications (If any) :

Presentations (If any) :

Signature of P.I.: Date:

ANNEX 5 **AF/EC/05/06/V1.5**

Study Report Form for Protocol Termination

Protocol No.: Principal Investigator:

Protocol Title :

Date of EC Approval

Phone number: E-mail address :

Sponsor's /Funding Agencies Name

Address: Phone : E-mail :

Study site(s): No. of Participants as each site:

Study Design and Sample Size:

Objectives:

Methodology:

Duration of the study: Total Number of study participants:

No. of Study Arms (If any): Number of participants in each of the Study Arms:

Study dose(s):

Reasons for termination (if any):

Provision for follow-up of patients :

Risk benefit ratio: Number of AE/SAE:

Change in risk benefit ratio:

Whether the study samples are being retained for future use:

Results:
(Use extra blank paper, if more space is required.)

Outcome and Implications of the Study:

Publications (If any) :

Presentations (If any) :

Signature of P.I.: Date:

ANNEX 6 **AF/EC/06/06/V1.5**

Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1	20th March 2013	First approved copy
Dr. Ragini Kulkarni	Version 1.1	03rd June 2013	Minor Changes in 1) Project Review Report form and 2) Study Report Form for Protocol Termination/ Completion - Inclusion of a) Date of EC Approval b) No. of Participants at each site c) Number of Participants in each of the Study Arms d) Reasons for Termination e) Whether the study samples are retained for future use f) Presentations (If any) Deletion of a) Number of Participants who received the test intervention/drug
Dr. Ragini Kulkarni	Version 1.2	24th September 2014	Changes in – Document checklist Continuing review report form Study report form for protocol termination/completion Inclusion of Study Assessment Form
Dr. Ragini Kulkarni	Version 1.3	15th April 2015	Changes in – Document checklist, addition of the point no.18 - GCP Training Certificate of Principal Investigator/ Co-Investigators/Collaborators – Attached/Not Attached
Dr. Ragini Kulkarni	Version 1.4	1st September 2016	Pg.11 - added 'Signature with date' under Study Assessment form for New Projects
Dr. Ragini Kulkarni	Version 1.5	3rd October 2017	Pg.3 Added Serious Adverse Event reports and Protocol completion reports under point 2 and in flow chart point no.2 added in point 5.1.4 AE/SAE Pg.4, point 5.1.5 deleted the word Completion Pg.4, point 5.2.1 deleted the word 'received' and inserted the world 'submitted' Pg.4 5.2.1.3 deleted the sentence 'Review Report form AF/EC/02/06/V1.4 (see ANNEX 2)' Pg.4 5.2.1.4 and 5.2.1.5 deleted 5.2.2 and written as 5.4 Pg.6 point 5.4 deleted the sentence 'After review of the project by the Secretariat, invite the Internal IEC

			members for review of project proposal and hand over the proposals for checking along with Checklist and Review Report form to internal reviewers. If the internal IEC members find the project to be technically sound and complete in all respect to be placed before the Full Board/ERC', Under Annex 1 – Checklist point 8 added point f) Does the protocol involves sending samples abroad Under point 10 added 'signed and dated' Annex 2 added point 19 MOU's with collaborating organisation Annex 3 deleted Annual Report and written as Continuing Review <u>Inserted in Annex 3 – added the points</u> Budget, need of extension with justification, Risk benefit ratio and Change in risk benefit ratio: <u>Inserted in Annex 4 – – added the points</u> Risk benefit ratio and Change in risk benefit ratio: Deleted word termination from Annexure title Pg.15Annex 5 added new annexure for 'Study Report form for protocol Termination'