1. **Purpose:**
   The purpose of this standard operating procedure is to describe how protocol amendments are managed and reviewed by the IEC

2. **Scope:**
   This SOP applies to previously approved study protocols but later being amended and submitted for approval by the IEC. Amendments made to protocols may not be implemented until reviewed and approved by the IEC. Amended Documents for notifications with minor/Administrative changes should acknowledged by Member Secretary and Chairman of IEC.

3. **Responsibility:**
   It is the responsibility of the IEC Secretariat to manage protocol amendments. Investigators may amend the contents of protocols from time to time. Amendments may be submitted for either "expedited" review by the Chairperson / Secretariat /members / reviewers or full IEC review.

4. **Flow Chart:**

Sl.No.	Activity	Responsibility
1.	Receive the Amendment Package ↓	IEC Secretariat
2.	Check for completeness ↓	IEC Secretariat
3.	Provide it to the affiliated members ↓	IEC Secretariat
4.	Send it to external experts and Chairperson after incorporation of suggestions ↓	IEC Secretariat
5.	Determine whether Expedited or Full Review ↓	IEC Secretariat / Chairperson
6.	Amendment Review Process ↓	IEC Secretariat/EC Members /Chairperson
7.	Inform the Principal Investigator ↓	IEC Secretariat
8.	Store Documents	IEC Secretariat

5. Detailed instructions:

5.1 Manage the Amendment Documents/ Package: ***The Principal Investigator will submit Amended Protocol of an existing and previously approved protocol should be made in the covering letter to the chairperson/Member-Secretary. The request should:***

- State/describe the list of amendments [including summary of changes]
- Provide the reason/justification for the amendment
- If Minor administrative changes are reviewed by the secretariat and approved by Member-Secretary.

- Upon receipt of the amendment document form the PI, the Secretariat of the IEC should follow the receiving procedure in SOP/06/V-8.0 (Management of Protocol Submission) and SOP/23/V-8.0 (Maintaining Confidentiality of IEC Documents).
- After review of the materials, the Member Secretary in consultation with Chairperson will determine whether the protocol requires expedited or full review.
- The amended version of the protocol and related documents should be provided to the affiliated members.
- Keep "Sent" and "Received" acknowledgement on hard copy (Signature for received) related to the notification of the Chairperson/Member Secretary in the protocol file under the Correspondence section-Follow IEC SOP/23/V-8.0 in preparing and distributing the documents.

5.2 Full Review by the IEC:

- Refer to SOP/08/V-8.0 for Initial Review.

5.3 Protocol Amendment Review Process:

5.3.1 Review amended protocols:

- Use the process outlined in the Study Assessment Form (see SOP/06/V-8.0) to review amended protocols and protocol-related documents.
- Note recommendations for changes to the protocol and/or informed consent requested by IEC Members in the minutes as "with modifications made by IEC' and will be communicated to the investigator.

5.3.2 The Chairperson and the IEC members can give the following decisions:

- Approve the protocol amendment as is with no modification in the Participant Information Sheet and Informed Consent Document.
- Require a modification to the proposed amendment or informed consent documents, stating the reason and action required to sustain the study with a follow-up full IEC review
- Suspend the study, until further information is obtained
- Not suspend the study as currently approved, but request further information regarding the amendment and the effects of the amendments on the approved study
- Not approve the amendment request, stating the reason – but allow the study to continue

as previously approved

- If the IEC approves the protocol amendment, the Secretariat staff communicates this decision to the investigator.
- If the IEC does not approve the protocol amendment, the Chairperson notifies the investigator in writing of the decision and the reason for not approving the amendment.
- Keep the minutes of the meeting relevant to the discussion and the decision reached by the IEC as the official records of the amendment review process.

5.4 Notify the Principal Investigator:

"Decision letter" with recommendation excerpts from minutes.

5.5 Store documents: Place the original completed documents, the "clean" version of the protocol and related documents in the protocol file with the other documents pertaining to the amendment.

6. Glossary:

Amendment protocol: A package of the amended parts and related documents of Package, the protocol, previously approved by the IEC. In the course of the study, the Principal Investigator may decide to make changes in the protocol.

Clinical Research department: An institute or an office where the study takes place and where the principal investigator and/or his/her staff may be reached.

7. Annexure:

Check list for amended study protocol

8. References:

- ✓ International Conference on Harmonization of technical requirements for pharmaceuticals for human use(ICH)-2016
- ✓ Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006
- ✓ WMA Declaration of Helsinki-Ethical principal for medical Research involving human subjects-2013
- ✓ Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
- ✓ New Drugs and Clinical Trial Rules, 2019

ANNEXURE: 01 **AF/IEC/01/12/V-8.0**

Submission of Amended study proposal Template

Protocol title:

Amended Version:

<table>
<tr><td>1.</td><td>Date of EC approval: Click here to enter a date. Date of start of study: Click here to enter a date.</td></tr>
<tr><td>2.</td><td>Details of amendment(s)
<table>
<tr><td>S.No</td><td>Existing Provision</td><td>Proposed Amendment</td><td>Reason</td><td>Location in the protocol/ICD</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
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</table></td></tr>
<tr><td>3.</td><td>Impact on benefit-risk analysis
Yes ☐ No ☐ If yes, describe in brief:</td></tr>
<tr><td>4.</td><td>Is any re-consent necessary?
Yes ☐ No ☐
If yes, have necessary changes been made in the informed consent?
Yes ☐ No ☐</td></tr>
<tr><td>5.</td><td>Type of review requested for amendment:
Expedited review (No alteration in risk to participants)
☐
Full review by EC (There is an increased alteration in the risk to participants)
☐</td></tr>
<tr><td>6.</td><td>Version number of amended Protocol/Investigator’s brochure/ICD:</td></tr>
<tr><td colspan="2">Signature of PI:</td></tr>
</table>

ANNEXURE: 02 **(AF/IEC/02/12/V-8.0)**

Study Assessment Form for Amended Document

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

Name of Principal Investigator:

Reviewer's name with Designation:

Mark and comment on whatever items applicable to the study.

Sl. No	Particulars	Comments
	Details of Amended Protocol (If Applicable)	
1.	Summary of Changes ☐ Clear ☐Unclear	
2.	Inclusion Criteria ☐ Appropriate ☐Inappropriate	
3.	Exclusion Criteria ☐ Appropriate ☐Inappropriate	
4.	Vulnerability assessment (If Applicable) ☐ Yes ☐ No	
5.	Are blood/tissue samples will be sent to Abroad? ☐ Yes ☐ No	
6.	DCGI submission letter/Approval Letter ☐Yes ☐ No	
Participant Information Sheet and Informed Consent Documents (If Applicable)		
Sl. No	**Points**	Comments
1.	Contents of the Informed Consent Documents Translation and back translation certificates ☐ Clear ☐Unclear	
2.	Language of the Informed Consent Document: Kannada, Hindi, English and Marathi ☐ Clear ☐Unclear	
3.	Risks/ inconveniences mentioned clearly ☐ Yes ☐ No	
4.	Period of storage of biological samples ☐ Yes ☐ No	
5.	Privacy & Confidentiality ☐ Yes ☐ No	
6.	Provision for Compensation per subjects in ICFs-TA(INR) ☐ Appropriate ☐Inappropriate	

List of additional documents required (if applicable)

Reviewer Signature