Application/Notification form for Amendments

SRI BALAJI MEDICAL COLLEGE, HOSPITAL AND RESEARCH INSTITUTE

EC Ref. No. *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval: dd mm yy Date of start of study dd mm yy

2. Details of amendment(s)

S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD [18]

3. Impact on benefit-risk analysis Yes ☐ No ☐

If yes, describe in brief: .....

.....

4. Is any reconsent necessary? Yes ☐ No ☐

If yes, have necessary changes been made in the informed consent? Yes ☐ No ☐

5. 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) ☐

6. Version number of amended Protocol/Investigator's brochure/ICD: .....

Signature of PI: ..... dd mm yy

[18] *Location implies page number in the ICD/protocol where the amendment is proposed.*

Format for Curriculum Vitae for Investigators

SRI BALAJI MEDICAL COLLEGE, HOSPITAL AND RESEARCH INSTITUTE

EC Ref. No. *(For office use):*

Name:
Present affiliation *(Job title, department, and organisation)*:
Address (Full work address):
Telephone number: Email address:
Qualifications:
Professional registration *(Name of body, registration number and date of registration):*
Previous and other affiliations *(Include previous affiliations in the last 5 years and other current affiliations):*
Projects undertaken in the last 5 years:

Relevant research training/experience in the area [25] :
Relevant publications *(Give references to all relevant publications in the last five years):*

Signature	Date:

[25] *Details of any relevant training in the design or conduct of research, for example in the Ethics Training, Human participants' protection courses, Clinical Trials Regulations, Good Clinical Practice, consent, research ethics training or other training appropriate to non-clinical research. Give the date of the training*