# Continuing Review / Annual report format

## SRI BALAJI MEDICAL COLLEGE HOSPITAL AND RESEARCH INSTITUTE

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

Title of study: .....

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.....

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

.....

.....

1. Date of EC Approval: dd mm yy  Validity of approval: dd mm yy
2. Date of Start of study: dd mm yy  Proposed date of Completion: dd mm yy

   Period of Continuing Report: dd mm yy  ---- to ------  dd mm yy
3. Does the study involve recruitment of participants? Yes ☐ No ☐

   (a) If yes, Total number expected..... Number Screened: ..... Number Enrolled: .....

   Number Completed:..... Number on followup:.....

   (b) Enrolment status – ongoing / completed/ stopped

   (c) Report of DSMB[16] Yes ☐ No ☐ NA ☐

   (d) Any other remark.....

   .....

   (e) Have any participants withdrawn from this study since the last approval? Yes ☐ No ☐ NA ☐

   If yes, total number withdrawn and reasons: .....

   .....

   .....
4. Is the study likely to extend beyond the stated period ?[17] Yes ☐ No ☐

   If yes, please provide reasons for the extension. .....

   .....

   .....
5. Have there been any amendments in the research protocol/Informed Consent Document (ICD) during the past approval period?

   If No, skip to item no. 6 Yes ☐ No ☐

   (a) If yes, date of approval for protocol and ICD : dd mm yy

   (b) In case of amendments in the research protocol/ICD, was re-consent sought from participants? Yes ☐ No ☐

   If yes, when / how: .....

   .....

   .....

[16] *In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.*

[17] *Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC*

6. Is any new information available that changes the benefit - risk analysis of human participants involved in this study? Yes ☐ No ☐

If yes, discuss in detail: .....

.....

.....

7. Have any ethical concerns occurred during this period? Yes ☐ No ☐

If yes, give details:.....

.....

8. (a) Have any adverse events been noted since the last review? Yes ☐ No ☐

Describe in brief: .....

.....

.....

(b) Have any SAE's occurred since last review? Yes ☐ No ☐

If yes, number of SAE's :..... Type of SAE's: .....

.....

.....

(c) Is the SAE related to the study? Yes ☐ No ☐

Have you reported the SAE to EC? If no, state reasons Yes ☐ No ☐

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9. Has there been any protocol deviations/violations that occurred during this period?

If yes, number of deviations .....

Have you reported the deviations to EC? If no, state reasons Yes ☐ No ☐

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10. In case of multicenteric trials, have reports of off-site SAEs been submitted to the EC ? Yes ☐ No ☐ NA ☐

11. Are there any publications or presentations during this period? If yes give details Yes ☐ No ☐

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Any other comments:.....

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

# 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*