



**APPLICATION TO THE BVDUDC&H-
PUNE/INSTITUTIONAL ETHICS COMMITTEE
FOR APPROVAL OF A RESEARCH PROJECT (STUDY
COMPLETION/FINAL REPORT FORMAT)**



EC No.....(For office use only)

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Date of EC approval:

2. Date of start of study:

Date of study completion:

3. Provide details of:

a) Total number of study participants approved by the EC for recruitment:

b) Total number of study participants recruited:

c) Total number of participants withdrawn from the study (if any):

Provide the reasons for withdrawal of participants:

4. Describe the main ethical issues encountered in the study (if any):

5. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period:

Deviations:

Violation:

Amendments:

6. Is there a plan for post study follow-up? Yes / No
If yes, describe in brief:

7. Describe results (summary) with Conclusion (very briefly):

8. Number of (Serious Adverse Events) SAEs that occurred in the study. Write Nil if no SAE.

9. Have all SAEs been intimated to the EC? Yes / No. Write not applicable if no SAE.

10. Is medical management or compensation for SAEs provided to the participants? Yes / No
If yes, provide details. Write not applicable if no SAE.

Name and Signature of PI

Name and Signature of Guide

Name and Signature of HOD
with seal of Department

