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 **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)**

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 c) Total number of participants withdrawn from the study (if any):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