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|  | **(Annexure 4)**  **Logo of the Institute**  **Application/ Notification form for Amendments**    ***(Name of the Institution)***  **EC Ref. No*.(****for office use):* |

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| Title of study:  Principal Investigator (Name, Designation and Affiliation) |

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| 1. | Date of EC approval: Click here to enter a date. Date of start of study: Click here to enter a date. |
| 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 re-consent 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:  Click here to enter a date. | |

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| Title of study:  Principal Investigator (Name, Designation and Affiliation) |

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