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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)

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| S.No | Existing Provision | Proposed Amendment | Reason | Location in the protocol/ICD*18* |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |

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| 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.