

**Annexure 01/SOP/9/V2.1**

**Notification form for Amendments**

SMVMCH-EC Ref. No. (for office use) :

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Date of EC Approval: Date of Start of study:
2. Details of amendment(s)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| S. No | Existing Provision | Proposed Amendment | Reason | Location in the protocol / ICD (*Location implies page number in the ICD/protocol where the amendment is proposed.)* |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1. Impact on benefit-risk analysis Yes No

If yes, describe in brief: ………………………………………………………………………………………………………………………………………....…....………

1. Is any re-consent necessary? Yes No

If yes, have necessary changes been made in the informed consent? Yes No

1. 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)

1. Version number of amended Protocol/Investigator’s brochure/ICD: ………………………

Signature of PI with date: