**(Annexure 5)**

## Application/Notification form for Amendments

### ……………………....……………………………………………………………………………………

***(Name of the Institution)***  MPHREC Ref. No. ***(For office use):***

Title of study:

……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………….

Principal Investigator (Name, Designation and Affiliation): ……………………………………………………………………………………………………………………………………………………………………………………………………………………

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Date of MPHREC approval: | | |  | |
| MPHREC Number: | | |  | |
| Date of start of study: | | |  | |
| S.No | Existing Provision | Proposed Amendment | Reason | Location in the protocol/ICD [[1]](#footnote-1) |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| 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: | |  | | |

1. Location implies page number in the ICD/protocol where the amendment is proposed. [↑](#footnote-ref-1)