**(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)