

APPLICATION FOR SUBMITTING PROTOCOL AMENDMENTS TO IHEC

(Please do not delete the headings and subheadings in this form)

- 1. Title of Research:**
- 2. Unique Protocol ID, if any:**
- 3. IHEC approval details:** (provide month, year, and, if applicable the study account number)
- 4. Name and Designation of Principal Investigator and Address for communication** (including telephone and fax numbers and email id):
- 5. Details of protocol amendments** (Please list all protocol amendments and provide page number(s) in revised protocol (if applicable))
- 6. Justify the need for protocol amendments** (if data has been acquired with approved protocol, provide preliminary data generated thus far)
- 7. Will any of these amendments significantly alter the balance of risks and benefits to study participants? (please describe)**
- 8. Will any of the amendments significantly alter the design of the study? (please describe)**
- 9. Will any of the amendments require the informed Consent form or information sheet provided to participants to be modified? If *yes*, please supply the revised informed consent document.**
- 10. Signature of Principal Investigator** (after ensuring that all co-investigators have approved this submission)

NB: Please submit one hard copy of this form along with the amended protocol (or part thereof) and informed consent form and information sheet (if applicable) to the IITM IHEC Secretariat by -----
----- . Soft copy of the same needs to be sent to iec@iitm.ac.in.