# ANNEX 6

**AF/06-008/06 Conflict of Interests Declaration and Undertaking Form**

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|  | Protocol Title:  Protocol Version Number: Dated: |
|  | Have you ever been involved in or convicted of a crime, disciplined by a public or private medical organization, or by a licensing authority?  ⬜ No ⬜ Yes, explain ………………………………………................................. |
|  | Do you or your family members/relatives have any financial relationship with the sponsor other than payment for the conduct of the study?  ⬜ No ⬜ Yes, If Yes describe the relationship ………………………………………………….. |
|  | Do you or your family members/relatives have any other personal considerations that may compromise, or have the appearance of compromising a researcher's professional judgment in conducting or reporting research?  ⬜ No ⬜ Yes, If Yes describe it ………………………………………………………………………………. |
|  | Do you meet the ICMJE authorship criteria for the work[[1]](#footnote-1)?  ⬜ Yes ⬜ No, If “No” explain …………..……………………………………………………………………. |
|  | 1. I declare that all the information provided above is correct. 2. I do hereby confirm that I undertake to abide by responsibilities of investigators or sponsor-investigator (if the investigator is also the sponsor) having understood each responsibilities as spelled in the ICH Good Clinical Practice E6 (R2), WMA Declaration of Helsinki– Ethical Principles for Medical Research Involving Human Subjects, CIOMS International Ethical Guidelines for Health-related Research Involving Humans, National Ethical Guidelines for Health-related Research Involving Humans, and the applicable regulatory requirement(s) in Bhutan. 3. I shall abide by all the conditions that would be reflected in the REBH Approval Letter, if this protocol is approved by REBH. 4. In particular, I understand that in the event that I do not adhere to any one of these responsibilities, I shall be held liable as per Laws of the Land.   (Affix Legal Stamp)    **Investigator’s Name & signature:** ……………………………………………… Date: …………  **Witness’s Name & signature:** …………………………………………………… Date: ………… |

1. The ICMJE recommends that authorship be based on the following 4 criteria:

   Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

   Drafting the work or revising it critically for important intellectual content; AND

   Final approval of the version to be published [or submission to REBH]; AND

   Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. [↑](#footnote-ref-1)