



ATENEUM DE MANILA UNIVERSITY  
UNIVERSITY RESEARCH ETHICS OFFICE

ADMUREC FORM 5 - RESEARCH PROTOCOL AMENDMENT FORM

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: A research protocol amendment is a written description of a change(s) to or formal clarification of a protocol and/or informed consent documents. Approval should be obtained from the AdMUREC (or any of its subpanels, i.e. ASHS-REC, DREC) prior to the implementation of an amendment.

Amendments that should be submitted for approval are generally those that have implications for the considerations of risks and benefits of the study to its human participants.

Complete all requested information. Multiple amendments can be submitted in one form. Submit the form plus relevant attachments in electronic format as separate PDF files to [univresearchethics@ateneo.edu](mailto:univresearchethics@ateneo.edu) or the appropriate panel/subpanel. Date and sign this form before submission.

<b>REC CODE:</b>
<b>STUDY PROTOCOL TITLE</b>
<b>STUDY PROTOCOL ETHICS APPROVAL DATE/S</b>
<b>PRINCIPAL INVESTIGATOR</b>
<b>EMAIL AND TELEPHONE NUMBER</b>
<b>SCHOOL / DEPARTMENT / AFFILIATION</b>
<b>STUDY SITE/S</b>
<b>FUNDING SOURCE OR SPONSOR</b>
<b>FUNDING SOURCE OR SPONSOR CONTACT (NAME AND CONTACT INFORMATION)</b>
<b>NUMBER OF AMENDMENTS TO REPORT:</b>
<b>IN A SEPARATE DOCUMENT: (1) ENUMERATE, (2) DESCRIBE, AND (3) JUSTIFY THE PROTOCOL AMENDMENTS WITH REFERENCE TO HOW THESE HAVE CHANGED OR DIFFER FROM THE APPROVED PROTOCOL, E.G. AS A TABLE COMPARING THE PREVIOUS AND AMENDED ASPECTS. ATTACH RELEVANT SUPPORTING DOCUMENTS SUCH AS NEW INSTRUMENTS, NEW ICF, ETC.</b>
<b>TYPE OF REVIEW (CHECK ONE – SUBJECT TO REC REVIEW)</b>

EXPEDITED REVIEW, for amendments that:

- Do not involve substantial changes in study populations
- Do not involve the collection of (new/additional) private information that may place participants at substantial risk if identities are revealed
- Do not substantially change approved use of anonymized or archived samples
- Involve study protocols previously classified under expedited or regular review at the UREC or DREC/ASHS-REC level
- Are administrative in nature (such as changes in major study personnel)
- Do not materially affect the risk-benefit ratio of the approved protocol or increase risks to study participants

FULL BOARD REVIEW, for any amendments not cited under EXPEDITED REVIEW and proposed for submissions to the UREC LS or ASMPH panels

**SIGNATURE OF PRINCIPAL INVESTIGATOR:**

**AMENDMENT SUBMISSION DATE:**