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 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 and a hard copy of the form (with signatures) to the University Research Ethics Office. Date and sign this form before submission.

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| **AdMUREC CODE (UREO only):** |
| **Study Protocol Title** |
|  |
| **Study Protocol Approval Date/s** |
|  |
| **Principal Investigator** |
|  |
| **Email and Telephone Number** | |
|  | |
| **School / Department / Affiliation** | |
|  | |
| **Study Site/s** | |
|  | |
| **Funding Source or Sponsor** | |
|  | |
| **Funding Source or Sponsor Contact (name and contact information)** | |
|  | |
| **Number of Amendments to Report:** | |
| **In a separate document, enumerate, describe, and 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.** | |
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| **Type of Review (check one)** |
| □EXPEDITED REVIEW, FOR AMENDMENTS THAT:   * Do not involve changes in study populations * Do not involve the collection of (new/additional) private information that may place participants at risk if identities are revealed * Do not change approved use of anonymized or archived samples * Involve study protocols previously classified under expedited review * 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 |
| **Signature of Principal Investigator**: |
| **Amendment Submission Date:** | |

RECOMMENDATIONS (for AdMUREC use only)

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| Comments of Primary Reviewer(s) | | |  | |
| RECOMMENDED ACTION ON PROPOSED AMENDMENTS:   * APPROVE * REQUEST INFORMATION * MINOR MODIFICATIONS * MAJOR MODIFICATIONS * RECOMMEND FURTHER ACTION * DISAPPROVE | | | | |
| PRIMARY REVIEWER(S) |  | Signature: |  | Signature: |
| Date: |  | Name |  | Name |
| UREC/PANEL CHAIR |  | Signature: |  | |
| Date: |  | Name |  | |