ATENEO DE MANILA UNIVERSITY

UNIVERSITY RESEARCH ETHICS OFFICE

ADMUREC FORM 8 - UNANTICIPATED PROBLEM / UNANTICIPATED ADVERSE EVENT REPORT FORM

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: This report should be submitted to the University Research Ethics Office as promptly as possible, or within 2 weeks of the investigator becoming aware of the problem. Unanticipated problems that are serious adverse events should be reported within one week of the investigator becoming aware of the event.

Complete all the requested information. If the item is not applicable to your protocol, write "NA". Submit the report in electronic format to univresearchethics@ateneo.edu and in hard copy (with signatures) to the University Research Ethics Office. Date and sign this form before submission.

AdMUREC CODE (UREO only):	
STUDY PROTOCOL TITLE	
PRINCIPAL INVESTIGATOR	
EMAIL AND TELEPHONE NUMBER	**SCHOOL / DEPARTMENT / AFFILIATION**
FUNDING SOURCE OR SPONSOR AND DURATION OF GRANT	
FUNDING SOURCE OR SPONSOR CONTACT (NAME AND CONTACT INFORMATION)	
STUDY PROTOCOL APPROVAL DATE/S (INDICATE DATES OF CONTINUING REVIEW AND/OR PROTOCOL AMENDMENT DATES, IF APPLICABLE)	
1. **SUMMARY OF STUDY AIMS**	
2. **STUDY SITE/S**	
3. **ONSET DATE OF UNANTICIPATED PROBLEM**	**DATE THE STUDY TEAM HAD KNOWLEDGE OF THE EVENT**

4. **THE EVENT MEETS THE CRITERIA OF AN UNANTICIPATED PROBLEM BECAUSE:**

4.1 The event is unexpected (choose at least one option below):
- ☐ in terms of nature, severity, or frequency, compared to what was indicated in the previously approved research procedures and informed consent document
- ☐ for the population being studied

4.2 ☐ The event is related or possibly related to participation in the research (i.e. reasonable possibility that the incident may have been caused by the procedures in the research)

4.3 The event (choose at least one option below):
- ☐ places participants or others at greater risk for harm (including physical, psychological, economic, or social harm) than was previously known or recognized
- ☐ has already resulted in harm to the participant/s or others

Note: The event has to meet all 3 criteria (2.1, 2.2, 2.3) to be considered an unanticipated problem. If otherwise, the problem may not need to be reported using this form, but should be reported using the Progress Report or Final Report, whichever is relevant to the protocol.

5. **IS THE UNANTICIPATED PROBLEM AN ADVERSE EVENT [1]?**

5.1 ☐ No

5.2 ☐ Yes ☐ Serious Adverse Event ☐ Not a Serious Adverse Event
6. **DETAILED DESCRIPTION OF THE UNANTICIPATED PROBLEM (CAN PROVIDE RELEVANT SUPPORTING DOCUMENTS)**
7. **DESCRIPTION OF CORRECTIVE OR MITIGATING ACTIONS AND PLAN TO PREVENT THE PROBLEM FROM RECURRING. ATTACH NEW MATERIALS AND INFORMED CONSENT FORM, IF RELEVANT.**
8. **HAVE ANY OF THE CORRECTIVE OR MITIGATING ACTIONS BEEN APPLIED PRIOR TO THIS REPORT?** ☐ Yes: provide reasons for implementing changes prior to UREC notification and approval ☐ No
DECLARATION ☐ I confirm that the unanticipated problem has been fully and accurately described in this report. ☐ I confirm that the study team will await the official response and recommendations of the UREC with respect to the proposed corrective or mitigating actions, except for actions that need to be immediately implemented in order to prevent further harm or risk to participants.
SIGNATURE OF PRINCIPAL INVESTIGATOR:
UNANTICIPATED PROBLEM REPORT SUBMISSION DATE:

RECOMMENDATIONS (for AdMUREC use only)

Comments of Reviewer(s)	Details
RECOMMENDED ACTION (Check only one of the following options): ☐ APPROVE PROPOSED CORRECTIVE/MITIGATING ACTIONS ☐ MAJOR MODIFICATIONS REQUIRED to PROPOSED CORRECTIVE/MITIGATING ACTIONS ☐ MINOR MODIFICATIONS REQUIRED to PROPOSED CORRECTIVE/MITIGATING ACTIONS ☐ DISAPPROVE PROPOSED CORRECTIVE/MITIGATING ACTIONS AND RECOMMEND OTHER ACTION	

REVIEWER(S)		Signature:		Signature:
Date:		Name		Name
UREC/PANEL CHAIR		Signature:		
Date:		Name		

Endnotes

[1] Adverse events include any event meeting the following definition: Any untoward or unfavorable medical occurrence in a human participant, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

Serious adverse events are those temporally associated with the individual's participation in the study that meets any of the following criteria:

- results in death;
- is life-threatening;
- requires inpatient hospitalization or prolongation of existing hospitalization;
- results in persistent or significant disability or incapacity;
- results in a congenital anomaly/birth defect; or
- any adverse event that, based on appropriate medical judgment, may jeopardize the participant's health and may require medical or surgical intervention to prevent any of the aforementioned outcomes