ATENEO DE MANILA UNIVERSITY
UNIVERSITY RESEARCH ETHICS OFFICE

ADMUREC FORM 11 - FINAL REPORT FORM

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: The final report should be submitted to the University Research Ethics Office within 30 days of completion of the study. Completion indicates that there are no further interactions with and data collection from human participants in the study, and that the data is being handled and/or stored in accordance with the UREC-approved protocol. The final report, if deemed satisfactory by the UREC, signifies that the protocol is to be rendered inactive and archived.

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. **START DATE**:	
4. **COMPLETION DATE**:	
5. **REPORT ON RESEARCH PARTICIPANTS**	
5.1 TARGET NUMBER OF PARTICIPANTS APPROVED BY UREC	
5.2 PARTICIPANTS WHO DISCONTINUED OR WITHDREW FROM THE STUDY	
5.3 PARTICIPANTS WHO COMPLETED THE STUDY	
6. **WERE THERE ANY DEVIATIONS TO YOUR UREC-APPROVED STUDY PROTOCOL? CHANGES OR DEVIATIONS MAY BE IN STUDY POPULATION/SITES, SELECTION CRITERIA, RECRUITMENT OR DATA COLLECTION METHODS, NEW INSTRUMENTS, NEW DATA COLLECTED, NEW PERSONNEL, STORAGE OF IDENTIFIABLE DATA, AND OTHER CHANGES THAT MATERIALLY AFFECT THE RISK-BENEFIT RATIO OF THE STUDY OR MAY INCREASE RISKS TO PARTICIPANTS** 6.1 ☐ No, all procedures were in compliance with the UREC-approved protocols and materials. 6.2 ☐ Yes: date/s when Protocol Amendment Form/s submitted to UREO (if Protocol Amendment not submitted to UREO – indicate reason/s for not submitting and describe the protocol deviations):	

7. **WERE THERE PROBLEMS (ANTICIPATED OR UNANTICIPATED), ADVERSE EVENTS, AND/OR SERIOUS ADVERSE EVENTS[1] DOCUMENTED IN THE COURSE OF THE STUDY? DESCRIBE IF THERE WERE, AND THE CORRESPONDING RESPONSES AND MITIGATING ACTIONS OF THE PIS.**

7.1 ☐ No problems or adverse events arose in the course of the study
7.2 ☐ Yes: Indicate date/s when Form 8 - Unanticipated Problems/ Adverse Events report/s were submitted to UREO, if applicable. If not previously reported to UREO, indicate reason for not reporting:

8. **DESCRIBE PARTICIPANTS' COMPLAINTS, UNFAVORABLE COMMENTS, OR GRIEVANCES DOCUMENTED IN THE COURSE OF THE STUDY. IF THERE WERE NO COMPLAINTS OR UNFAVORABLE COMMENTS, INDICATE "NA"**

9. **SUMMARY OF BENEFITS OF THE STUDY (DIRECT OR INDIRECT)**

10. **ARE IDENTIFIABLE DATA[2] STILL BEING USED AND STORED FOR THIS STUDY?**

☐ Yes – treatment of identifiable data is compliant with UREC-approved protocol

Briefly describe what information is being stored, in what format, and the the measures you are taking to protect the confidentiality of records

☐ No – data has been deidentified / anonymized (relinking with identifiers not possible) or was collected anonymously

11. **DID YOUR PROTOCOL AND CONSENT FORM INDICATE THAT YOU WILL PROVIDE FEEDBACK TO YOUR PARTICIPANTS IN THIS STUDY? IF YES, ATTACH A COPY OF THE FEEDBACK PROVIDED TO PARTICIPANTS AND HOW IT WAS DELIVERED. IF FEEDBACK HAS NOT BEEN PROVIDED, INDICATE REASONS.**

12. **HAVE YOU PUBLISHED YOUR RESEARCH FINDINGS OR PRESENTED THEM IN A CONFERENCE OR OTHER FORUM? PLEASE PROVIDE PUBLICATION AND/OR DISSEMINATION PLANS AND DETAILS.**

13. **SUMMARY OR ABSTRACT OF RESULTS (CAN BE PRELIMINARY) WITH RESPECT TO THE STUDY AIMS**

DECLARATION

☐ I confirm that no further interactions and data collection involving human participants wll be undertaken in relation to this protocol.
☐ I continue to accept ethical and legal responsibility associated with this research protocol.
☐ I confirm that the University Research Ethics Office (UREO) should now render this project inactive and archive its records.

SIGNATURE OF PRINCIPAL INVESTIGATOR:

FINAL REPORT SUBMISSION DATE:

RECOMMENDATIONS (for AdMUREC use only)

Comments of Reviewer(s) (i.e. compliance with the terms of the approved protocol; overall assessment of risks against benefits in the conduct of study)	Details
RECOMMENDED ACTION ☐ SATISFACTORY [PROTOCOL CAN BE ARCHIVED] ☐ REQUEST INFORMATION	

☐ RECOMMEND FURTHER ACTION				
REVIEWER(S)		Signature:		Signature:
Date:		Name		Name
UREC/PANEL CHAIR		Signature:		
Date:		Name		

Endnotes

[1] Problems and adverse events may be anticipated (reported in the initial application for ethics clearance) or unanticipated. It is mandatory to report unanticipated problems and adverse events to UREO. Unanticipated problems are defined as any incident, experience, or outcome that meets all of the following criteria: a) it is unexpected, in terms of nature, severity, or frequency, given the research procedures that are described in the UREC-approved protocol and informed consent document, and the characteristics of the subject population being studied; b) related or possibly related to participation in the research; and c) suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.

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-threatenting;
- 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

[2] Identifiers include: name, residence, email address, telephone/cellphone number, birthdate, social security numbers, gov-issued ID numbers, financial accounts/records, biometric data, IP / device serial numbers, full face photo and/or video