ATENEO DE MANILA UNIVERSITY
UNIVERSITY RESEARCH ETHICS OFFICE

ADMUREC FORM 6 - CONTINUING REVIEW APPLICATION FORM

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: Ethical clearance or approval is granted for a specific period, typically one year, as indicated in your ethics approval letter. A continuing review and approval is necessary if interaction with human participants goes beyond the period of the initial or previous ethics approval. If a continuing ethics approval application is not submitted, the protocol will be rendered inactive and interactions with human participants must stop as per university policies and national ethics regulations. The P.I. is advised to submit this form 45 days prior to the expiry date of the original approval.

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 AND EXPIRATION 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. **TARGET COMPLETION DATE**:	
5. **STATUS OF THE RESEARCH (PLEASE CHECK ALL THAT APPLY AND ELABORATE AS NEEDED IN SPACE BELOW):** ☐ Research has not begun: <reason/s> ☐ Research was initiated but on hold: <reason/s> ☐ Recruiting participants / following up on (enrolled) participants ☐ Data collection has begun and is ongoing ☐ Data analysis only (note: if data analysis is with de-identified data and there are no further interactions with human participants, study protocol may be closed and final report submitted to UREO; no continuing ethics review is necessary) ☐ Other: <explain>	
6. **REPORT ON RESEARCH PARTICIPANTS**	
6.1 TARGET NUMBER OF PARTICIPANTS APPROVED BY UREC	
6.2 NEW PARTICIPANTS ACCRUED SINCE LAST REVIEW/ APPROVAL	
6.3 TOTAL PARTICIPANTS ACCRUED SINCE STUDY BEGAN	
6.4 PARTICIPANTS STILL INVOLVED IN THE STUDY	
6.5 PARTICIPANTS WHO DISCONTINUED OR WITHDRAWN FROM THE STUDY	

6.6 PARTICIPANTS WHO HAVE COMPLETED THE STUDY	

7. **HAVE THERE BEEN ANY CHANGES OR 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, AND OTHER CHANGES THAT MATERIALLY AFFECT THE RISK-BENEFIT RATIO OF THE STUDY OR MAY INCREASE RISKS TO PARTICIPANTS**

7.1 ☐ No, all procedures are in compliance with the UREC-approved protocols and materials.
7.2 ☐ Yes: submit Protocol Amendment Form or indicate date/s when Protocol Amendment Form was submitted to UREO.

8. **HAVE THERE BEEN NEW/ADDITIONAL INVESTIGATIONAL NEW DRUG/DEVICE REGISTRATIONS ASSOCIATED WITH THIS STUDY SINCE THE LAST REVIEW/APPROVAL? (INDICATE REGISTRATION INFORMATION; NOTE THAT THE UREC IS NOT ACCREDITED TO REVIEW CLINICAL TRIALS INVOLVING NEW DRUGS)**

☐ NA 8.1 ☐ None 8.2 ☐ Investigational New Drug (IND) 8.3. ☐ Investigational Device Exemption (IDE)	FDA Registration No. Product Name: Sponsor: Holder:

9. **HAVE ANY INVESTIGATORS DEVELOPED EQUITY OR CONSULTATIVE RELATIONSHIP WITH A PARTY RELATED TO THIS STUDY PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST, SINCE THE LAST REVIEW/APPROVAL?**

9.1 ☐ No
9.2 ☐ Yes (append a statement of disclosure)

10. **PLS REVIEW THE INFORMED CONSENT FORM. FROM YOUR EXPERIENCE IN THE CONDUCT OF THE STUDY, ARE THE ACTUAL RISKS AND PROCEDURES STILL ADEQUATELY REPRESENTED IN THE ICF? HAVE THERE BEEN CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE LAST REVIEW / APPROVAL?**

10.1 ☐ No (complete Protocol Amendment Form and submit revised ICFs)
10.2 ☐ Yes

11. **HAS ANY INFORMATION APPEARED IN THE RESEARCH LITERATURE THAT MIGHT AFFECT THE RISK/BENEFIT ASSESSMENT FOR HUMAN PARTICIPANTS INVOLVED IN THE STUDY (E.G. NEW INFORMATION ABOUT THE RISKS OF METHODS CURRENTLY BEING APPLIED)?**

11.1 ☐ No
11.2 ☐ Yes (Describe briefly and provide copy of literature, if applicable; UREC may recommend or require protocol amendments)

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

12.1 ☐ No problems or adverse events have arisen in the course of the study
12.2 ☐ Yes: Describe the problems and if applicable, submit Form 8 – Unanticipated Problem/Adverse Event Report Form or indicate date/s when Unanticipated Problems/Unanticipated Adverse Events Report/s were submitted to UREO

13. **DESCRIBE PARTICIPANTS' COMPLAINTS, UNFAVORABLE COMMENTS, OR GRIEVANCES DOCUMENTED IN THE COURSE OF THE STUDY. IF THERE HAVE BEEN NO COMPLAINTS OR UNFAVORABLE COMMENTS, INDICATE "N/A"**

14. **SUMMARY OF BENEFITS OF THE STUDY SO FAR (DIRECT OR INDIRECT)**

15. **ARE IDENTIFIABLE DATA[2] BEING USED, COLLECTED, AND STORED FOR THIS STUDY?**

☐ Yes – check one of the following:
  ☐ treatment of identifiable data is compliant with UREC-approved protocol
  ☐ treatment of identifiable data requires UREC approval: submit Protocol Amendment Form
☐ No – data is anonymous

DECLARATION

☐ I confirm that the study and its principal investigators and research personnel continue to abide by the ethics standards and guidelines of the Ateneo de Manila University.
☐ I confirm that, if necessary, I will submit the relevant, requisite forms and reports (e.g. Protocol Amendment Form, Continuing Ethics Review Application, Unanticipated Problems Report, etc.) to

the University Research Ethics Office to update on the status of the project.
SIGNATURE OF PRINCIPAL INVESTIGATOR:
CONTINUING REVIEW APPLICATION SUBMISSION DATE:

RECOMMENDATIONS (for AdMUREC use only)

Comments of Primary Reviewer(s) (i.e. compliance with the terms of the approved protocol; overall assessment of risks against benefits in the conduct of study)				
RECOMMENDED ACTION ☐ UPHOLD ETHICS APPROVAL UNTIL <dd/mm/yyyy>_____ ☐ REQUEST INFORMATION ☐ RECOMMEND FURTHER ACTION			Details	
PRIMARY REVIEWER(S)		Signature:		Signature:
Date:		Name		Name
UREC/PANEL CHAIR		Signature:		
Date:		Name		

Endnotes

[i] 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-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

[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