**ADMUREC Form 12 - Guidelines and Application Form for Student**

**Ethics Clearance for Research with Human Participants**

|  |
| --- |
| **Application Instructions:**   * Read the Ethics Review Guidelines and Procedures for Student-Initiated Research (Undegraduate Theses and Final Projects) * Submit the following together with the application form: * Research proposal that includes the ethical considerations pertinent to the study * Participant recruitment materials * Informed Consent Forms (ICF) and Assent Forms (if applicable) * Permission letters sent or received from relevant collaborating offices or data collection areas * Instruments, questionnaires, interview or FGD scripts and protocols * Obtain the approval and signature of faculty adviser / instructor * Submit the application form and the attachments to the designated Department Research Ethics Committee (DREC) representative who will review your proposal (assignment of reviewer is done through department protocols and may be through the adviser) * For assistance, contact your DREC head or representative or the University Research Ethics Office (Tel. No.: +63 2 426-6001 ext. 4030 or Email: univresearchethics@ateneo.edu) |

|  |
| --- |
| **ADMUREC Form 12 - Application Form for Student**  **Ethics Clearance for Research with Human Participants** |

|  |  |  |  |
| --- | --- | --- | --- |
| Project Title: |  |  |  |
| Name/s of Investigator/s: | Ateneo ID Numbers: | Email Addresses: | Contact Numbers: |
|  |  |  |  |
| School and Department: | | | |
| SY & Semester first enrolled in thesis / final project course:  SY & Semester this research / project needs to be completed to graduate: | | | |
| **Guidance Note:** Graduate student theses/dissertations/capstone projects are reviewed by the AdMU Research Ethics Committee (UREC); consult adviser and UREO for forms and procedures. If the research is to be conducted and completed for a one-semester graduate class (i.e. required by faculty; not thesis/diss/capstone proj), the review may be conducted by department-level ethics reviewers using this form. | | | |

|  |  |
| --- | --- |
| Faculty Adviser: | Ateneo ID (e.g., 13250): |
|  |  |
| Email Address: | Contact Number: |

|  |
| --- |
| **A: General Purpose & Procedures:**  1. Describe the objectives of the study:    2. Describe the procedures that participants will undergo:    3. How long will participants be involved in this research study? (i.e. the number of sessions; the duration of each session)    4. Where will this research study take place? Include all that apply.    **Guidance Note:** Research in sites such as schools, hospitals, offices, etc. must be approved by an individual in a decision-making position at the site. Documented approval (i.e., a letter of agreement) is required. |
| **B. Participants:**  5. **Choose all categories of participants** who will be involved in this research study.  Healthy adults  Children-individuals under the age of 18  Prisoners  Women who are or may be pregnant, or of childbearing potential 🡪 Tick one:  The research poses no known or suspected risks to the pregnant woman or the fetus if pregnant women are coincidentally enrolled or:  Precautions regarding possible risks to pregnancy and/or lactation and/or the fetus are addressed in the research protocol and included in the consent form  Patients (persons receiving medical treatment)  Individuals with a mental or decisional impairment  Institutionalized individuals (e.g., residing in government facilities, or in homes or centers)  Indigenous groups  Indigent persons (i.e. low socioeconomic status)  Senior citizens  Ateneo de Manila students  LS  HS  GS  Others, pls specify:  Other pertinent characteristic/s not specified above:  6. How many participants will be recruited for the study?  🡪 Briefly justify the number of participants:  7. Are there specific inclusion criteria for participating in the study? (i.e., should possess particular characteristics)  Yes 🡪 Specify:  No  8. Are there specific exclusion criteria for participating in the study? (i.e., should not possess particular characteristics)  Yes 🡪 Specify:  No  9. Could some or all participants be vulnerable to coercion or undue influence due to special circumstances (e.g., employees of researcher’s family-owned or managed company; persons in subordinate positions to researchers or researchers’ families)?  Yes 🡪 Describe the measures taken to preserve voluntary consent of these individuals:  No |
| **C. Recruitment:**  10. Indicate the types of recruitment that will be done for this research and submit copies of the materials and/or verbal scripts. Choose all that apply:  Ads posted or aired in physical or digital media outlets (e.g. news, tv, radio)  Flyers/posters/brochures - Where will the items be displayed/distributed?  Web and social media sites - List the sites:  Letters/Emails/Telephone calls to potential participants  🡪 Explain how potential participants’ contact information are to be obtained:  Letters/Emails to professionals or administrators (e.g. education / health / NGO centers) for recruitment purposes  🡪 Identify the position of administrator who will receive these letters:  Face-to-face approach  Students / Subject Pool 🡪 Indicate the class:  **Guidance Note:** If you are not a member of the subject pool's department, submit the permission and approval letter.  Other 🡪 Explain:  11. Before potential participants sign a consent form, are there any screening questions that will be asked to determine whether an individual is appropriate for the study?  Yes 🡪 Answer Question 12  No 🡪 Skip to Question 13  12. During screening questions, will identifiable information (e.g. name, ID no., contact info) about these individuals be recorded?  Yes 🡪 What is the identifiable information and howwill it be treated if the individual is not continuing to participate in the study?  No  **Guidance Note:** Please submit the procedure, script, and measure/tool for the screening questions.  13. Will investigators access education/medical/assessment records and/or school/hospital/clinic databases for recruitment and selection purposes?  Yes 🡪 Answer Question 14  No 🡪 Skip to Question 15    14. Has permission to access information been granted by the institution holding these records?  Yes 🡪 attach permission letter  No  15. Will professionals or administrators themselves provide identifiable information (e.g., name, telephone number, address) to investigators for recruitment purposes?  Yes 🡪 Provide evidence of the authorization release or consent form from prospective participants, for review  No |
| **D. Informed Consent Process:**  16. Describe the process of obtaining informed consent/assent. If participants do not speak the language of the researchers, are illiterate, or have other special circumstances, describe the procedures in obtaining consent.    17. What type of consent will be obtained? Choose all that apply and submit the informed consent/assent form(s) or scripts (if verbal consent).  Signed consent - participant will sign consent form  **Guidance Note:** If participants are to sign a consent form, they should receive a copy of their signed form.  Implied consent - participant will not sign consent form (e.g., email, on-line survey, mailed survey)  🡪 Justify:  Verbal consent - participant gives consent verbally (e.g., in-person interview, telephone interview)  🡪 Justify:  Passive/Opt-out consent - participant only required to act if they do not want to participate  🡪 Justify:  Complete waiver of informed consent  🡪 Justify:  Other 🡪 Describe:    **Guidance Note:** Refer to Informed Consent Template for guidance on content required in informed consent forms.  18. If multiple groups of participants will be recruited (i.e., children, adults), specify whether and how informed consent procedures will be different for each group of participants: |

|  |
| --- |
| **E. Payment for Participation:**  19. Indicate the type and amount of payment for participation that will be offered. **Choose all that apply.**  Money Amount:  Gift Certificate Amount:  Extra/Class Credit (e.g., 5 points, 1% of final grade) Explain:       🡪 Answer Question 20  Raffle Explain:  Other (e.g., merchandise) Explain:  Compensation will **NOT** be offered Skip to Question 21  20. If participation is compensated in the form of class credit, an alternative, equal in time and effort, must be offered in place of participating in the research. Describe the alternative available for earning the class credit. |
| **F. Data Collection Methods / Sources of Data:**  21. Identify all of the data collection methods or data sources that will be used in this study. Submit a copy of all instruments/measures, interview and focus group topics/questions.  educational / achievement / cognitive tests  psychological tests  surveys or questionnaires (e.g. self-reported/paper-pencil; online; telephone)  individual interviews  focus group discussions  participant diaries/journals  participant posts or entries in Internet blogs and/or social media  behavior observations  photograph / audio / video recordings  existing or secondary datasets/databases/records  existing biological specimens  collected biological specimens - blood, urine & other human-derived samples  biomedical devices- e.g., EEG, EKG, MRI  physical testing measures – e.g., height, weight, Body Mass Index, blood pressure  Other 🡪 Explain:  22. Will participants be assigned to or compared by groups (eg experimental or quasi-experimental design)?  Yes 🡪 Answer Question 23  No 🡪 Skip to Question 24  23. Will a control or comparison group(s) be used?  Yes 🡪 Describe what condition or stimuli the control group will undergo:  No |
| **G. Discomforts and Risks**  24. List all of the potential discomforts and risks (physical, psychological, legal, social, or economic) and describe the a) likelihood and b) magnitude of the discomforts/risks.      25. Describe all the steps taken to minimize risks to participants throughout the study:    26. Will medical, psychological, or other reparative measures be provided for participants who may require it as a result of their participation in the study?  Yes 🡪 Describe & identify the source of medical or psychological care - include institution & contact information:  No 🡪 Explain why medical, psychological, or other reparative measures will not be available: |
| **H. Benefits**  27. What are the potential direct benefits of the study to the participants?  **Guidance Note**: Payment or token is not considered a benefit as these are intended to compensate for time and other costs of participation.    28. What are the potential indirect benefits of the study (i.e., to society)?      29. Explain how the benefits outweigh the risks of the study. |
| **I. Confidentiality and Privacy**  30. Describe the provisions made to maintain confidentiality of the data. Select all that apply:  Use of identification codes (i.e., code numbers, pseudonyms)  **Guidance Note**: documents linking the ID codes with participants’ identities should be confidential  Password protected computer files  Locked file cabinets  Locked offices  Other 🡪 Explain:  31. Describe how participants' privacy will be maintained in the process of data collection.    32. Could the information being collected for this study have adverse consequences for participants or be damaging to their financial standing, employability, or reputation if accidentally disclosed?  Yes 🡪 Indicate the information being collected:  No  33. What will happen to the research data when the study has been completed? Choose only one:  Destroyed immediately  Stored  Explain and justify length of time of storage:  Explain and justify whether identifiers will be removed or remain attached to data:  Who will have access to the stored data:    34. Is it possible investigators will discover a condition previously unknown to the participant (e.g., disease) as a result of study procedures?  Yes 🡪 Explain how and when such a discovery would be handled:        No  35. Is it possible investigators will discover that a participant is engaging in illegal activities (e.g., drug use, child abuse/neglect, underage drinking) or has risk of harming self or others (e.g. suicidal ideation) in the process of the study?  Yes 🡪 Answer Question 36-37  No  36. What is the protocol in the event of discovery of illegal activities or high risk behaviors? Note that the faculty adviser should be directly involved in the protocol for such events:  37. Will the discovery of illegal activities or high risk behaviors entail disclosure of identifying information to other parties?  Yes 🡪 Who will the information be disclosed to:  **Guidance Note**: Indicate the limits of confidentiality (i.e. conditions when information may be released) in informed consent form  No |
| **J. Drugs, Medical Devices, and Other Substances**  38. Does this research study involve drugs or biologics?  Yes 🡪 What are these and what is known about them so far (safety, risks, etc)?  No  39. Does this research study involve a medical device?  Yes 🡪 Note that the device must be approved for use and registered with the appropriate national agencies.  No |

|  |
| --- |
| **Guidance Note: FDA's Definition of a Medical Device as indicated in Republic Act 9711:** “Medical device” means any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material, or other similar or related article intended by the manufacturer to be used alone, or in combination, for human beings for one or more of the specific purpose(s) of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of, or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life: preventing infection; control of conception; disinfection of medical devices; and providing information for medical or diagnostic purposes by means of in-vitro examination of specimens derived from the human body. This device does not achieve its primary intended action in or on the human body by pharmacological, immunological, or, metabolic means but which may be assisted in its intended function by such means. |

|  |
| --- |
| **K. Biological Specimens**  40. Will biological specimens (including blood, urine and other human-derived samples) be used in this study?  Yes 🡪 Describe and justify:  No 🡪 Skip to Question 42  41. What will be done with these samples when the research has been completed? Choose only one:  Destroyed immediately  Stored  Explain and justify length of time of storage:  Explain and justify whether identifiers will be removed or remain attached to data:  Who will have access to the stored data: |
| **L. Other Biomedical Procedures - Diagnostic Radiation Procedures, Physical Activity, Diet Modifications**  42. Will participants be asked to undergo diagnostic radiation procedures while enrolled in this study?  Yes 🡪 Describe and justify:  No  43. Will participants be required to engage in or perform any form of physical activity?  Yes 🡪 Describe the nature and extent of the physical activity:  No  44. Will any type of electrical equipment other than audio headphones be attached to the participants (e.g., EMG, EKG)?  Yes 🡪 Describe and justify:       (submit documentation on the recent safety checks of the equipment)  No  45. Will there be any diet modifications or restrictions?  Yes 🡪 Describe and justify:  No |

|  |
| --- |
| **M. Assurances**  As the Principal Investigators on this research study, we assure that...   1. This application accurately reflects all procedures involving human participants and the nature and extent of their proposed involvement in my study. 2. I am familiar with and will comply with pertinent institutional and national regulations and policies regarding research ethics with human participants. I will inform my faculty adviser if I need support or advice regarding an ethical concern. 3. I will notify my faculty adviser and a DREC representative within one week regarding any significant adverse events that impact my human participants. 4. All research personnel listed on this form possess the requisite competencies and have been adequately trained in research and ethical behavior towards human participants. 5. Any individual associated with or responsible for the design, the conduct, or the reporting of this research will comply with Ateneo de Manila University rules and regulations.       **Printed Names & Signatures of Principal Investigators Date**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  I hereby confirm that I have supervised the completion of this application and my signature denotes the accuracy of the information provided.  I confirm that I will supervise the students as they conduct their study, and monitor that ethical standards and practices are maintained in the study.    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Printed Name & Signature of Faculty Adviser Date** |
|  |