**ADMUREC Form 1 - Guidelines and Application Form for Ethics Clearance for Research with Human Participants:**

**For Expedited or Full Review**

|  |
| --- |
| **Application Instructions:**   * Submit the following as SEPARATE PDF FILES together with the application form: * Research protocol: title, investigators and affiliations, research objectives, significance, brief literature review/conceptual framework, full methods (description of sample, setting, recruitment, inclusion criteria; instruments and procedures), ethical considerations pertinent to the study, research budget * Participant recruitment materials/letters/scripts/templates * Informed Consent Forms (ICF) and Assent Forms (if applicable) * Funding/Grant/Sponsor letter or contract and/or Memorandum of Agreement among collaborating institutions (if applicable) * Letters from relevant collaborating offices or data collection areas indicating that the proponent can conduct the study in the setting pending ethics clearance, e.g. schools, companies, barangays; note that certain settings may have inherent risks and reviewers may request additional information * Instruments, questionnaires, interview or FGD scripts and protocols * 1-2 page CV of Principal and Co-Investigator(s) * 2 copies of AdMUREC Form 2: Application Submission Checklist * Submit the soft copy of the application form and the soft copies of all the attachments in separate PDF files to the University Research Ethics Office (UREO). * Obtain the official and dated acknowledgment (Ethics Clearance Application Submission Checklist) from the UREO that your application and attachments are complete and had been received by the office. * For assistance, contact the UREO (Tel. No.: +63 2 426-6001 ext. 4030, mobile No.: 0945 2136758, or Email: univresearchethics@ateneo.edu)   --------------------------------------------------------------------------------------------------------------  **Guidance Notes – please read p. i-ii prior to completing the application form. Do not include p. i-ii when submitting the form.**  The AdMU Research Ethics Committee (AdMUREC) conducts expedited and full reviews of research with human participants. Check the Guidance Note on Exclusions and Exemptions to determine whether your research is exempt from ethics review. If possibly exempt, complete the Form for Validation of Exemption and submit to the UREO to validate exempt status.  An expedited review is conducted by at least two (2) members of the UREC designated by the UREC Chair, rather than deliberated in a convened UREC meeting with the prescribed quorum. In an expedited process, the assigned reviewers exercise all the authorities of the UREC except that the reviewers may not disapprove the research. A research activity may be disapproved only after full review in a UREC meeting.  **Criteria for expedited review**  The research protocol may be eligible for expedited review IF:  1) the research activities present no more than minimal risk to human participants, AND  2) the research involves one or more of the activities listed in the categories of research below.  If your project does not fall under any of these categories and/or it presents greater than minimal risk to participants, it will be subject to full review in a convened UREC meeting.  Minimal risk is defined as the probability and magnitude of physical and psychological harm that is normally encountered in daily life, or in the performance of routine medical, dental, or psychological examination of healthy persons. If the risk level of your study is greater than this, then it may be “greater than minimal risk”.  **Category 1:** Clinical studies of drugs and medical devices only when condition (a) or (b) is met:   1. Research on drugs for which the national drug registration authority (i.e. Food and Drug Administration or FDA) has approved the drug for distribution or (ii) the filing and submission of applications as indicated in FDA Circular 2014-009 is not required. (However, research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product should undergo full review.) 2. Research on medical devices which have been cleared/approved for marketing by the FDA and the Bureau of Health Devices and Technology (BHDT) and the medical device is being used in accordance with its cleared/approved labeling. (However, FDA requires researchers to comply with ISO 14155:2011 for medical device investigations.)   **Category 2:** Collection of blood samples by finger stick, heel stick, ear stick or venipuncture in amounts and frequencies in accord with the age, weight, health of the participant (e.g. from healthy, non-pregnant adults who weigh at least 110 pounds: the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week)    **Category 3:** Prospective collection of biological specimens for research purposes by non-invasive means. Examples include: Hair and nail clippings; Deciduous teeth or permanent teeth if routine extraction; Excreta and external secretions (including sweat); Uncannulated saliva; Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings  **Category 4:** Collection of data through non-invasive procedures routinely employed in clinical practice, not involving general anesthesia or sedation, and excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must have been cleared/approved for marketing and use. Examples include:   * Physical sensors that are applied either to the surface of the body or at a distance, and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy; * Weighing or testing sensory acuity; * Magnetic resonance imaging; * Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; * Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.   (Studies intended to evaluate the safety and effectiveness of medical devices are not generally eligible for expedited review, including studies of cleared medical devices for new indications. Refer to FDA and ISO 14155:2011 for additional guidance.)  **Category 5:** Research involving materials (existing data, documents, records, or specimens) that are collected for non-research purposes (such as medical treatment or diagnosis). (However, if these sources are publicly available or if the information is recorded in such a manner that participants cannot be identified, the study may be exempt for review; refer to Guidance Note on Exclusions and Exemptions.)  **Category 6:** Collection of data from voice, video, digital, and/or image recordings  **Category 7:** Researches on individual or group characteristics or behavior (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (However, refer to Guidance Note on Exclusions and Exemptions for possible exemptions of such studies from review.) |

|  |
| --- |
| **ADMUREC Form 1 - Ethics Clearance Application for Research with**  **Human Participants: For Expedited or Full Review**  **Project Title:** |

|  |  |
| --- | --- |
| Principal Investigator: | Ateneo ID (e.g., 10011): |
|  |  |
| University Status: (Faculty, Staff, Graduate Student, etc.): | |
| School / Department / Center: |  |
| Email Address: | |
| Telephone Number:  Mailing Address:  **Guidance Note:** Undergraduate student research is reviewed by department-level ethics reviewers; consult adviser or Department Chair for forms and procedures. | |

|  |  |
| --- | --- |
| Faculty Adviser, if PI is a student: |  |
|  |  |
| Email Address: | Telephone Number: |
|  |  |
| School and Department: |  |
|  |  |
| Mailing Address: |  |

|  |  |
| --- | --- |
| Is there anyone you wish to include in correspondence related to this study (e.g., a study coordinator, etc.)? | |
|  |  |
| Name: | Ateneo ID (e.g., 12450): |
|  |  |
| University Status: (Faculty, Staff, Student, etc): | Role in this study: |
| School / Department / Center: |  |
| Email Address: |  |
| Telephone Number:  Mailing Address: |  |

|  |
| --- |
| **A. Funding:**  1. Is this research study funded?  Yes   No 🡪 Skip to Question 6  Pending 🡪 Answer Questions 2-5  Internal 🡪 Answer Questions 2-4  External 🡪 Answer Questions 2-4  2. Provide the name and mailing address of the internal and external sources of funding. Provide a copy of your grant proposal/contract with the application. If a copy of the grant proposal is not included, explain.  3. Is the funding entity providing the drug /device to be tested free of charge?  Yes  No  N/A  4. Will the funding entity pay for direct costs of treating injuries   Yes  No  N/A  and/or other adverse events attributable to participation in the study?  5. If the funding is not awarded, will the research still be conducted?  Yes  No  N/A |
| **B. Conflict of Interest:**  6. Do any of the investigators, key personnel, and/or their spouses or dependent children have a conflict of interest (COI), associated with this research (e.g. have significant financial or other interest related to the research, such as holding a position in the setting where the study will be conducted)?  Yes 🡪 Explain the conflict of interest:  No  7. Does AdMU have an ownership or royalty interest in any intellectual property related to this study?  Yes 🡪 List the IP related matter here:        No  8. Will the project entail the use of AdMU time and/or equipment?  Yes 🡪 List down units/load (eg. faculty/staff time) and/or equipment:  No |
| **C. For Graduate Students:** This form is for graduate theses, dissertations or capstone / culminating projects.  9. Provide the following information:  Faculty Adviser’s Name:  SY & Semester first enrolled in thesis/dissertation/capstone course:  SY & Semester this research/project needs to be completed to graduate:  **If you defended your research proposal to a technical or defense panel, list the names of your panelists below (if not, write NA):**    **Guidance Note:** 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 is to be conducted by department-level ethics reviewers. Consult instructor or Department Chair for forms and procedures. |
| **D. Review Level:**  10. What is the level of review you expect this research to have?  Expedited 🡪 Answer Question 11  Full 🡪 Skip to Question 12  11. Expedited Review Categories: Choose one or more that apply to your research. Your research must fit in at least one category to be considered for an expedited review. (See page ii for specifics)  Category 1  Category 2  Category 3  Category 4  Category 5  Category 6  Category 7 |

|  |
| --- |
| **E. Research Personnel:**  **Guidance Note:** The Principal Investigator is responsible for ensuring that all individuals conducting procedures described in this application are trained adequately in research ethics prior to interacting with human participants.  12. Provide the names of the individual(s) assisting in this study who: (1) are responsible for the design/conduct of the study, (2) have access to the human participants (i.e., will seek consent from the participants, collect the data), or (3) have access to identifying and confidential information. If additional space is needed, attach a separate sheet with the information.  **Name**  **Email Ateneo ID**  **Role in Study Research Experience** |

|  |
| --- |
| 13. Is this a multi-center study outside of AdMU (i.e. involving other institutions or centers)?  Yes 🡪 Answer Question 14  No 🡪 Skip to Question 16  14. Is any AdMU investigator on this application the lead investigator/project director of this multi-center study?  Yes 🡪 Answer Question 16  No  15. Provide the name and location of all other centers. |
| **F: General Purpose & Procedures:**  16. Describe the objectives of the study:    17. Describe the procedures that participants will undergo:    18. How long will participants be involved in this research study? (i.e. the number of sessions; the duration of each session)    19. 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. |
| **G. Participants:**  20. **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)  Fetuses, neonates, fetal material in vitro fertilization  HIV-positive individuals  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:  21. How many participants will be recruited for the study?  🡪 Briefly justify the number of participants:  22. Are there specific inclusion criteria for participating in the study? (i.e., should possess particular characteristics)  Yes 🡪 Specify:  No  23. Are there specific exclusion criteria for participating in the study? (i.e., should not possess particular characteristics)  Yes 🡪 Specify:  No  24. Will participants be currently enrolled in a course/class of any personnel listed on this application?  Yes 🡪 Describe the measures taken to preserve voluntary consent and avoid coercion/undue influence to participate:  No  25. Will participants be employees of any personnel listed on this application?  Yes 🡪 Describe the measures taken to preserve voluntary consent and avoid coercion/undue influence to participate:  No  26. Could some or all participants be vulnerable to coercion or undue influence due to special circumstances aside from indicated in #24 and #25?  Yes 🡪 Describe the measures taken to preserve voluntary consent of these individuals:  No |
| **H. Recruitment:**  27. 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 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:  28. Who will approach and/or respond to potential participants?    29. 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 30  No 🡪 Skip to Question 31  30. During screening questions, will identifiable information (e.g. name, ID no., contact info – see #56) 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 attach the procedure, script, and measure/tool for the screening questions.  31. Will investigators access education/medical/assessment records and/or school/hospital/clinic databases for recruitment and selection purposes?  Yes 🡪 Answer Question 32  No 🡪 Skip to Question 33    32. Has permission to access information been granted by the institution holding these records?  Yes 🡪 attach permission letter  No  33. 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 |
| **I. Informed Consent Process [refer to IC template for additional guidance]:**  34. Describe the process of obtaining informed consent/assent. If participants do not speak the language of the P.I., are illiterate, or have other special circumstances, describe the procedures in obtaining consent.    35. Who will be responsible for obtaining informed consent/assent from participants?    36. Do the people listed in Question 35 speak the same language as the participants?  Yes  No 🡪 Explain how consent will be obtained:  37. What type of consent will be obtained? Select and submit the informed consent/assent form(s) or scripts (if verbal consent).  Active Signed consent - participant will sign a consent form  Active consent - participant will not sign a consent form but provides consent via an intentional action (e.g., clicking a link signifying consent in an online survey)  🡪 Justify:  Active Verbal consent - participant gives active consent verbally (e.g., in-person, online, or telephone interview)  🡪 Justify:  Waiver of informed consent (e.g. naturalistic observation of public behs; use only when all of the ff conditions are met: waiver will not adversely affect the rights and welfare of participants, study is minimal risk, study cannot be practicably done without the waiver, participants obtain pertinent relevant info after participation)  🡪 Justify:  Other 🡪 Describe:    **Guidance Note:** Refer to Informed Consent Template for guidance on content required in informed consent forms.  38. 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:    39. Informed consent must be documented and participants should have a record of their consent and the information about the research. Describe how participants’ consent is documented and how they will receive a record of their consent and study information. If the principal risk to participants in the study is the potential harm resulting from breach of confidentiality, and the informed consent is the only record that contains personal or identifiable information of the participant (e.g. full name, signature), describe how this personal information is to be protected.    40. Does this study involve giving false or misleading information to participants or withholding information from them?  Yes 🡪 Justify the use of deception:  No |

|  |
| --- |
| **J. Payment for Participation:**  41. 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 42  Raffle Explain:  Other (e.g., merchandise) Explain:  Compensation will **NOT** be offered Skip to Question 43  41.a When and how will compensation be given to the participants?  42. 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. |
| **K. Data Collection Methods / Sources of Data:**  43. 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  modality (face-to-face, online, etc):      ; if online, specify the platform/app:  individual interviews  modality (face-to-face, online, etc):      ; if online, specify the platform/app:  focus group discussions  modality (face-to-face, online, etc); if online, specify the platform/app:  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:  44. Will participants be assigned to or compared by groups (eg experimental or quasi-experimental design)?  Yes 🡪 Answer Questions 45-47  No 🡪 Skip to Question 48  45. Will a control or comparison group(s) be used?  Yes 🡪 Choose one of the following:  Placebo control  Treatment-as-usual or standard treatment control  Waitlist control  Other control method 🡪 Explain:  No  46. Is the research a blind (masked) study; i.e. generally to avoid bias, participants are kept unaware of the treatment or stimulus that they are assigned to and the hypothesized outcomes  Yes 🡪 Answer Question 47  No 🡪 Skip to Question 48  47. Is emergency unblinding permitted (i.e. providing information to participant and/or relevant persons about the treatment a participant is undergoing for safety or precautionary reasons)?  Yes  No 🡪 Explain why emergency unblinding is NOT permitted: |
| **L. Discomforts and Risks**  48. 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.      49. Does this research involve possibly greater than minimal risk to the participants (i.e. risks greater than they normatively face in daily life)?  Yes  No  50. Describe all the steps taken to minimize risks to participants throughout the study:    51. 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:  52. Does the research protocol have a plan for routine monitoring of procedures or analysis of the data to periodically assess the safety of this research study?  Yes 🡪 Describe plan for monitoring:  No  **Note**: For studies involving greater than minimal risk, a reparation and monitoring plan will need to be developed for review and approval at the convened UREC. |
| **M. Benefits**  53. 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.    54. What are the potential indirect benefits of the study (i.e., to society)?      55. Explain how the benefits outweigh the risks of the study. |
| **N. Confidentiality and Privacy**  56. Aside from the research data, indicate the identifiable information that you will collect or have access to in this study. Select all that apply:  Name (first and last name)  Home/residence address  Email address  Birthdate  Telephone/Cellphone number  Social security numbers (e.g. SSS, GSIS)  Govt-issued ID numbers (e.g. passport, driver’s license, professional license)  Financial accounts/records (e.g. TIN, bank accounts, tax forms)  Biometric data (e.g. fingerprints)  IP / Device serial numbers  Full face photo and/or video  Other unique identifier:  **Justify why you will collect or access this information:**        57. Describe the measures you will take to maintain the confidentiality of the identifiable information (#56) and your research data. Select all that apply:  Use of identification codes (i.e., code numbers, pseudonyms)  Password protected computer files  Password protected web- or cloud-based storage or servers:        Locked file cabinets  Locked offices  Other 🡪 Explain:  57a. Describe how participants' privacy will be maintained in the process of data collection.    58. Could the research data being collected for this study have adverse consequences for participants or be damaging to their financial standing, employability, or reputation if accidentally disclosed (e.g. health information)?  Yes 🡪 Indicate the information being collected:  No  59. Who will have access to the identifiable information (#56) and research data in all the stages of research (i.e. collection, analysis, storage, disposal)? Identify all personnel:      60. Will identifying information (#56) be disclosed or shared to a funder/sponsor or to collaborators at another institution?  Yes 🡪 List the identifiers that will be disclosed and explain why this is necessary:  No  61. Will identification codes (i.e. code numbers, pseudonyms) be used in encoding and reporting data?  Yes 🡪 Answer Question 62  No 🡪 Skip to Question 66  62. Will there be a list or document linking the codes and participants' identities?  Yes 🡪 Answer Questions 63 - 65  No 🡪 Skip to Question 66  63. How will the document linking the codes to participants' identities be stored and secured?    64. Who will have access to the document linking the codes to participants' identities?    65. Will the document linking the code to participants' identity be destroyed?  Yes 🡪 When will the document be destroyed?  No 🡪 Justify:  66. What will happen to the research data when the study has been completed? Choose only one:  Destroyed immediately  Stored for specific length of time with identifiers (#56) removed 🡪 Specify number of years:  Stored for specific length of time with identifiers attached🡪 Specify number of years:  🡪 List the identifiers that will be attached to the data:  🡪 Explain why the data must be stored with identifiers:  Stored indefinitely with identifiers removed  Stored indefinitely with identifiers (#56) attached  🡪 List the identifiers that will be attached to the data:  🡪 Explain why the data must be stored with identifiers:  Other 🡪 Explain:    67. 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  68. 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 69-70  No  69. What is the investigator’s protocol in the event of discovery of illegal activities or high risk behaviors?  70. 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 limits of confidentiality (i.e. conditions when information may be released) in informed consent form  No |
| **O. Drugs, Medical Devices, and Other Substances**  71. Does this research study involve drugs or biologics?  Yes 🡪 What are these and what is known about them so far (safety, risks, etc)?  No  72. Does this research study involve a medical device?  Yes 🡪 Go to Question 73  No 🡪 Skip to Question 74    73. Is the device registered with the Food and Drug Administration (FDA) and/or the Bureau of Health Devices and Technology (BHDT) ?  Yes 🡪 What is the registration number of this device  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. |

|  |
| --- |
| **P. Biological Specimens**  74. Will biological specimens (including blood, urine and other human-derived samples) be used in this study?  Yes 🡪 Describe and justify:  No 🡪 Skip to Question 77  75. Will genetic data be derived from these samples?  Yes 🡪 Describe and justify:  No  76. What will be done with these samples when the research has been completed? Choose only one:  Destroyed immediately after data has been used or extracted  Stored for specific length of time with identifiers removed 🡪 Specify number of years:  Stored for specific length of time with identifiers attached🡪 Specify number of years:  🡪 List the identifiers that will be attached to the data:  🡪 Explain why the data must be stored with identifiers:  Stored indefinitely with identifiers removed  Stored indefinitely with identifiers attached  🡪 List the identifiers that will be attached to the data:  🡪 Explain why the data must be stored with identifiers:  Other 🡪 Explain: |
| **Q. Other Biomedical Procedures - Diagnostic Radiation Procedures, Physical Activity, Diet Modifications**  77. Will participants be asked to undergo diagnostic radiation procedures while enrolled in this study?  Yes 🡪 Describe and justify:  No  78. 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  79. 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  80. Will there be any diet modifications or restrictions?  Yes 🡪 Describe and justify:  No |
|  |

|  |
| --- |
| **R. Assurances**  **As the Principal Investigator on this research study, I 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 the UREO if I need support or advice regarding an ethical concern. 3. I will notify the UREC within one week regarding any significant unexpected problems and/or unexpected 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 Name & Signature of Principal Investigator Date**  **I hereby confirm that I have read this application and my signature denotes the accuracy of the information provided. I confirm that I will supervise the studennt as they conduct their study, and monitor that ethical standards and practices are maintained in the study.**    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Printed Name & Signature of Faculty Adviser Date**  **(REQUIRED IF PI IS A STUDENT)** |
|  |

|  |
| --- |
| **I hereby confirm that I have read and noted this application. To the best of my knowledge, the information in the application relating to member/s of my department or unit is accurate.**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Printed Name & Signature of Dept/Unit Head Date**  **(REQUIRED IF PI IS A STUDENT/FACULTY)** |