**ADMUREC Form 4 - Validation of Exemption from Ethics Review**

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| **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, methods (description of sample, recruitment, inclusion criteria; instruments and procedures), ethical considerations pertinent to the study * Participant recruitment materials * Informed Consent Forms (ICF) and Assent Forms (if applicable) * Funding/Grant/Sponsor letter or contract (if applicable); letters from relevant collaborating offices (see Guidance Notes in application form) * Instruments or questionnaires * Additional materials relevant to justifying the exemption category (esp. for Cat. 4,5,6) * 1-2 page curriculum vita of Principal 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 and the hard copy of the application form (only) to the University Research Ethics Office (UREO). The hard copy must have the required signatures. * 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 or Email: univresearchethics@ateneo.edu)   --------------------------------------------------------------------------------------------------------------  **Guidance Notes – please read p. i-iii prior to completing the application form. It is also advised that you read through the application form to preclude having to abort the process mid-way because your protocol is not eligible for exemption after all.**  **Do not print or include p. i-iii when submitting the form.**  The following types of research may be exempt from institutional ethics review if it meets the following criteria. The University Reseach Ethics Office (UREO) determines whether a particular research study is exempt. If exempt, the investigator will be so notified by UREO.  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 expedited or full review (refer to AdMUREC Guidelines and Application for Ethics Clearance).  **Criteria for exemption from institutional ethics review**  The research protocol may be eligible for exemption from institutional 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.  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 (def. from the U.S. Federal Policy for the Protection of Human Subjects, retrieved from: http://www.hhs.gov/ohrp/archive/irb/irb\_chapter3.htm). If the risk level of your study is greater than this, then it may be “greater than minimal risk”.  The categories listed here apply regardless of age of participants, unless noted. Standard requirements for informed consent (or its waiver, alteration, or exception) apply.  **Exempt Research Categories**  **Category 1:** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (Both the procedures involve normal education practices and the objectives of the research involve normal educational practices.)  **Category 2:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, UNLESS:   1. information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and 2. any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.   In addition:  Application of this exemption category to research with children is limited to the use of educational tests or to observations of public behavior where the investigator does not participate in the activities being observed. It cannot be applied to projects involving surveys or interviews with children.  **Category 3:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior that is not exempt under Category 2 of this section, IF:   1. the human participants are elected or appointed public officials or candidates for public office; or 2. the law requires without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.   **Category 4:** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available; or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.  **Category 5:** Research and demonstration projects that are conducted by or subject to the approval of national or local government department or agency heads, and which are designed to study, evaluate, or otherwise examine:   1. public benefit or service programs; 2. procedures for obtaining benefits or services under those programs; 3. possible changes in or alternatives to those programs or procedures; 4. possible changes in methods or levels of payment for benefits or services under those programs**.**   In addition:   * The project is supported and authorized by a national or local government agency * The program under study delivers a public benefit or service (e.g. financial or medical benefit; or social, supportive, or nutritional services) * The research or demonstration project is conducted pursuant to specific statutory authority * There is no statutory requirement that the project be reviewed by a research ethics board or committee * The project does not involve significant physical invasions or intrusions upon the privacy of participants * The funding agency concurs with the exemption from institutional ethics review   **Category 6:** Taste and food quality evaluation and consumer acceptance studies if:   1. wholesome foods without additives are consumed; or 2. a food is consumed that contains a food ingredient at or below the level for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the relevant regulatory agencies of the Department of Agriculture and the Department of Health |

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| **ADMUREC Form 4 - Validation of Exemption from Ethics Review**  **Project Title:** |

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| Principal Investigator: | Ateneo ID (e.g., 10011): |
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| University Status: (Faculty, Staff, Student, etc): | If student:  Undergraduate  Graduate |
| Telephone Number: |  |
| Email Address:  School and Department: |  |
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| Mailing Address: |  |

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| Faculty Advisor, if PI is a student: | Ateneo ID (e.g., 13250): |
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| Email Address: | Telephone Number: |
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| School and Department: |  |
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| Mailing Address: |  |

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| 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): | Telephone Number: |
|  |  |
| Email Address: |  |
| School / Department / Center:  Mailing Address: | Role in this study: |

**BASIS FOR EXEMPTION**

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| **A. Category of Exemption:**  1. Does the funding agency and/or sponsor and/or institutional authority of this project require review and approval by an institutional ethics review?  Yes 🡪 study is not exempt; stop & submit AdMUREC Application for Ethics Clearance  No  2. **Exempt Categories:** Choose one or more that apply to your research. Your research must fit in at least one category to be considered for exemption. (See page ii-iii for specifics)  Category 1  Category 2  Category 3  Category 4  Category 5  Category 6  None of these categories 🡪 study is not exempt; stop & submit AdMUREC Application for Ethics Clearance |
| **B. Participants:**  3. **Choose all categories of participants** who will be involved in this research study.  Healthy adults  Children-individuals under the age of 18  🡪 but see Exemption Cat. 2; if investigator interacts with children via surveys (not standard educational tests) or interviews, this study is not exempt. Stop & submit AdMUREC Application for Ethics Clearance  Adult persons elected to public office; Specify person/s or office:  Ateneo de Manila students  LS  HS  GS  Others, pls specify:  4. Will any of the following categories of participants be involved in this research study:  - prisoners  - 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)  - pregnant women, fetuses, neonates, fetal material in vitro fertilization  - HIV-positive individuals  - indigenous groups  - indigent persons  - senior citizens  No participants in the above categories will be part of this research  Yes, the study includes participants in the above categories 🡪 study is not exempt; stop & submit AdMUREC Application for Ethics Clearance  5. Could some or all participants in #3 be vulnerable to coercion or undue influence due to special circumstances? e.g., enrolled in a class or employed by research personnel in this study  Yes 🡪 Describe the measures taken to avoid participant coercion & undue influence:  No |
| **C. Recruitment:**  6. Indicate the types of recruitment that will be done for this research and attach copies of the materials and verbal scripts. Choose all that apply:  Newspaper/magazine ads  Radio/TV ads  Letters/Emails/Telephone calls to potential participants  🡪 Explain how potential participants’ contact information are to be obtained:  Letters/Emails to healthcare professionals for recruitment purposes  🡪 Which healthcare groups will receive these letters?  Flyers/posters/brochures - Where will the items be displayed/distributed?  Web sites - List the sites the recruitment materials will be posted  Face-to-face or verbal 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:  7. Who will approach and/or respond to potential participants?    8. 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 9  No 🡪 Skip to Question 10  9. During screening questions, will identifiable information about these individuals be recorded?  Yes 🡪 study is not exempt; stop & submit AdMUREC Application for Ethics Clearance  No  **Guidance Note:** Please attach the procedure, script, and measure/tool for the screening questions.  10. Will investigators access non-anonymous education/medical/assessment records and/or school/hospital/clinic databases from institutions and/or authorized personnel, for recruitment and selection purposes?  Yes 🡪 study is not exempt; stop & submit AdMUREC Application for Ethics Clearance  No |
| **D. Payment for Participation:**  11. 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 12  Raffle Explain:  Other (e.g., merchandise) Explain:  Compensation will **NOT** be offered Skip to Question 13  12. If participation is compensated in the form of class credit or other benefit, an equivalent alternative must be available in place of participating in the research. Describe the alternative available for earning the credit or benefit. The description should include the procedures for the alternative as well as how undue influence will be prevented. |
| **E. Data Collection Methods / Sources of Data:**  13. Identify which of the following data collection methods or data sources will be used in this study. **Attach a copy of all instruments/measures, interview and focus group topics/questions to the application.**  standard educational practices  standard educational / achievement / cognitive tests  standard personality / psychological tests  other surveys or questionnaires (e.g. self-reported/paper-pencil; online; telephone)  interviews or focus groups  observations of public behaviors  photographs / audio / video recordings – Description, justification and privacy protection:  existing or secondary datasets/databases/records – Describe (org that collects or administers; access):  existing biological specimens - Describe (org that collects or administers; access):  Other 🡪 Explain:    14. Will any participant interaction in this study be conducted on the Internet or via email (e.g., online surveys via SurveyMonkey, PsychData, or Google), observations of chatrooms or blogs, online interviews (e.g. Skype)?  Yes 🡪 Describe the nature of the computer/online use, justification, and privacy protection:  No    15. Will a commercial server or online Cloud services (e.g., Dropbox, Google Drive) be used to collect data or for data storage?  Yes 🡪 Description, justification, and privacy protection:  No |
| **F. Risks**  16. Is this research likely to involve any foreseeable risk (physical, psychological, social, legal or economic) to participants, above the level normally experienced in everyday life (i.e. greater than minimal risk)?  No  Yes 🡪 study is not exempt; stop & submit AdMUREC Application for Ethics Clearance  17. Does this research involve any of the following:  - sensitive topics that may make participants feel uncomfortable or distressed (e.g. sexual behavior, illegal activities, risky activities, racial biases, etc.)  - substance use (i.e. drugs, alcohol)  - invasive procedures (e.g. blood sampling)  - physical stress or discomfort  - psychological/mental/emotional stress or discomfort  - deception or withholding of information about the study from the participants  - access to the data by individuals or organizations other than the investigators listed in this application  - social, legal, economic ramifications to participants if their data were disclosed  This research does not involve any of the above topics or issues  Yes, the research involves one or more of the above topics or issues 🡪 study is not exempt; stop & submit AdMUREC Application for Ethics Clearance  18. Is it possible investigators will unexpectedly discover a condition previously unknown to the participant (e.g., disease, wrongpaternity), or a high risk or sensitive condition (e.g. suicide ideation), or illegal behavior (e.g. abuse) as a result of study procedures?  Yes 🡪 Explain how and when such a discovery would be handled  No |
| **G. Benefits**  19. What are the potential benefits to the individual participants? If there are none, state “no benefits”.  **Note**: Payment or compensation for participation is not considered a benefit.    20. What are the potential benefits to society? If none, state “no benefits”. |
| **H. Confidentiality and Privacy**  21. Will the collected data be anonymous (i.e. information about the identity of the respondent is not obtained) or identifiable (i.e., where it is possible to link the data with the identity of the respondent)?  Anonymous  Identifiable, directly or through identifiers linked to participants, and not involving public officials 🡪 study is not exempt; stop & submit AdMUREC Application for Ethics Clearance  22. Who will have access to the data?      23. What will happen to the research records when the research has been completed? Choose only one:  Stored indefinitely without identifiers  Stored for length of time required by national regulations/funding source & then destroyed 🡪 Specify number of years:  Destroyed after a number of years 🡪 Specify the number of years:  Destroyed when notified by sponsor  Other 🡪 Explain: |
| **I. Informed Consent:**  19. When and where will participants be approached to obtain informed consent/assent [include the timing of obtaining consent in theresponse]? If participants do not speak the language of the P.I., illiterate, or have other special circumstances, describe the procedure in obtaining consent. **Attach a copy of the informed consent/assent form(s).**    24. Who will be responsible for obtaining informed consent/assent from participants?    25. Do the people listed in Question 20 above speak the same language as the participants?  Yes  No 🡪 Explain how consent will be obtained.  26. What type of consent will be obtained? Choose all that apply.  Signed consent - participant will sign consent form  Implied consent - participant will not sign consent form (e.g., mail survey, email, on-line 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 Guidance Note-Informed Consent Template for guidance on content required in informed consent forms.  27. If multiple groups of participants are being utilized (i.e., teachers, parents, children, people over 18), who will and will not sign the assent/consent form? Specify for each group of participants.    28. If signed consent, participants are to receive a copy of the informed consent form with the approval box/statement on it. Their signed consent should not be linked to their data/responses. Describe how participants will receive a copy of the informed consent form and how this will be disassociated with their data. |

**OTHER INFORMATION ABOUT THE RESEARCH**

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| **J. Funding:** |
| 29. Is this research study funded? |
| Yes   No 🡪 Skip to Question 31  Pending 🡪 Answer Question 30  Internal 🡪 Answer Question 30  External 🡪 Answer Question 30 |
| 30. 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. |
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| **K. Conflict of Interest:** |
| 31. 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 interest related to the research)? |
| Yes 🡪 State the conflict of interest  No |
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| 32. Does AdMU have an ownership or royalty interest in any intellectual property related to this study? |
| Yes 🡪 List the IP related matter here  No |
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| 33. Will the project entail the use of AdMU time and/or equipment? |
| Yes 🡪 List down no. of units/equipment  No |
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| 34. Is there anything you need to disclose that is applicable to this study? |
| Yes 🡪 State the possible conflicts of interest  No |
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| **L. Class / Course-Related Projects:** |
| 35. Is this a class or course-related project? |
| Yes 🡪 Provide the following information:   No   * Instructor’s Name:   Course Title and Number:  Semester course is being offered: |

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| **M. Research Personnel:**  **Guidance Note:**  The Principal Investigator is responsible for ensuring that all individuals conducting procedures described in this application, e.g. (1) are responsible for the design/conduct of the study, (2) will have access to the human participants (i.e., will seek consent from the participants, conduct the study), or (3) will have access to identifying and confidential information, are taught or trained adequately in research ethics prior to involving human participants in the study. |

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| 36. Provide the name of the other individual(s) assisting in this study who (1) will be responsible for the design/conduct of the study, (2) will have access to the human participants (i.e., will seek consent from the participants, conduct the study), or (3) will have access to identifying AND confidential information. If the individual does not have an Ateneo ID, please provide some other form of contact information. If additional space is needed, attach a separate sheet containing the same information.  **Name**  **Email Address** **Ateneo ID** **Mailing Address** **Role in this Study**  **(e.g., 11065)** |
| 37. Identify (1) the procedures/techniques to be performed by each person (including advisors) listed in Question 36 and on the first page of the application and (2) briefly describe their level of research experience. |
| 38. Is this a multi-center study outside of AdMU (i.e. involving several institutions or centers)?  Yes 🡪 Answer Question 13  No |
| 39. Is any AdMU investigator on this application the lead investigator/project director of this multi-center study?  Yes   No |
| 40. Provide the name and location of all other centers. |
| **N: General Purpose & Procedures:**  41. Briefly describe the purpose of the study and procedures that participants will undergo: |
| 42. How long will participants be involved in this research study? Include the number of sessions and the duration of each session. |
| 43. Where will this research study take place? Include all that apply. |
| **Guidance Note:** For sites such as schools, hospitals, offices, etc., the University Research Ethics Committee requires that research conducted at these sites be approved by an individual in a decision-making position at the site. Documented approval (i.e., a letter of agreement) is required. |

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| **V. Assurances**    As the Principal Investigator on this research study, I assure that...   1. This application accurately reflects all procedures involving human participants, and also reflects what is described in the grant proposal to the funding agency previously noted (for research with funding/sponsors). An explanation has been given for any differences. 2. I will obtain approval from the UREC before initiating any changes to the approved study protocol, including changes in procedures, personnel, documents, instruments, etc., except where necessary to eliminate apparent immediate hazards to participants. In the latter instance, the UREC must be notified by the next working day. 3. I am familiar with and will comply with all pertinent institutional and national regulations and policies regarding research ethics with human participants. 4. The information provided in this application reasonably summarizes the nature and extent of the proposed involvement of human participants in my study. 5. I will notify the UREC within 5 working days regarding any significant adverse events that impact my human participants. 6. All individuals listed on this form are competent and have been properly trained in research and ethical behavior towards human participants. 7. Any individual associated with or responsible for the design, the conduct, or the reporting of this research will comply with AdMU rules and regulations.     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Principal Investigator, REQUIRED Date**  I hereby confirm that I have read this application and my signature denotes the accuracy of the information provided. I confirm that I have approved the technical/scientific aspects of the study, and that I will provide the necessary supervision to the student as he or she conducts the study, in my capacity as his or her faculty advisor.    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **PRINTED Name and SIGNATURE of Faculty Advisor Date**  **(REQUIRED IF PI IS A STUDENT)** |
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| I hereby confirm that I have read and noted this application. To the best of my knowledge, the information in the attached application relating to member/s of my department or unit is correct.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **PRINTED Name and SIGNATURE of PI’s Dept/Unit Head Date** |