APPROVED
19 October 2023
Fr. Roberto E. N. Rivera, S.J.
University President

IREC

Ateneo de Naga University

Institutional Research Ethics Committee Standard Operating Procedures Manual

2023

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OVERVIEW

Background of Ateneo de Naga University (ADNU) IREC

The University, in its aim to excel in research, constituted the Institutional Research Ethics Committee (IREC) to ensure that any research is grounded on ethical principles. Hence, research projects proposed by administrators, faculty, staff, and students in the university undergo a thorough review. Research activities must ensure the safeguarding of the welfare of humans, animals, and the environment by abiding by the principles and guidelines of the Ateneo de Naga University Code of Ethics for Research (2016).

A review of the soundness of the proposed research design and methodology of research proposals should include a review of its ethical procedures to compel the researchers to

- be aware of the responsibility to respect and protect the rights of participants in the study;
- clarify the responsibilities of both researchers and human participants;
- promote the responsible care and use of animals in research;
- be mindful of the protection of the environment; and
- follow relevant government regulations in the conduct of research.

At the start of the IREC operation in 2021, specifically after it finished conducting the initial round of research ethics review orientation to administrators, faculty, staff, and students, it was clear to the IREC that it would accept and process ethics reviews of research proposals of students from the Graduate School, College of Law, as well as faculty and staff applying for grants from the University Research Council (URC). The IREC would also review proposals if external funding agencies allow an in-house research ethics committee to evaluate the ethical considerations of submissions by faculty and staff members of the University.

Mission and Vision of ADNU

Mission

As a university, the Ateneo de Naga seeks the integral formation of men and women who will contribute to the total development of the family and human society.

As a Filipino university, the Ateneo de Naga fosters a love of country and a deep commitment to the culture of human life and care for creation. It commits itself to contribute and benefit from global society for the transformation of the Filipino nation. Its special task is the development of Bicol and the preservation and enhancement of its culture.

As a Catholic university, the Ateneo de Naga is committed to the service of the faith that promotes justice. It seeks to form men and women committed to the person and teaching of Jesus Christ in loyal and dedicated service to the Church and community, particularly the poor.

As a Jesuit university, the Ateneo de Naga draws its inspiration and educational principles from St. Ignatius of Loyola. It thereby seeks to imbue its members with the desire to strive for excellence in every sphere and activity of life. Through teaching, research, community service, and deep personal interaction it aims to form "men and
women for others" who will find God in all things, always seek his greater glory and respond generously and courageously to Christ's call to serve first God's Kingdom – Primum Regnum Dei.

Vision

Ateneo de Naga University, a premier university in the country, provides excellent instruction and formation, conducts vigorous research, and engages in community service that is ultimately transformative to society, especially in Bicol. It is possible through its competent, creative & committed faculty, staff, and administrators, integrated systems, and excellent facilities.

It prides itself in its scholarship support and responsive student services.

It attracts highly qualified students and produces graduates who are responsible citizens formed in the Catholic faith and inspired by Ignatian spirituality. They are globally competent but locally responsive and environmentally sensitive.

Nurtured by Ignatian spirituality, it is a community that is passionate about seeking truth in divergent cultures, cultivating intellectual life, respecting creation, building human community, and promoting justice.

The university engages in and maintains partnerships, linkages, and networks with institutions and individuals to further its mission.

Institutional Policies, History, and Mandate of IREC

The ADNU IREC was initially institutionalized as the Institutional Research Ethics Board (IREB) on September 8, 2016, which specified the Board's role and functions. IREB was then guided by the policy of the University Code of Ethics for Research and Guidelines on Authorship Credit and Authorship Order issued on February 15, 2016. The first constituted IREB was created on January 17, 2017. It was composed of five members including one non-affiliated member.

The IREB was eventually renamed into the Institutional Research Ethics Committee (IREC) on July 7, 2017, and was reconstituted with seven members.

The IREC improved the IREB's guidelines for research ethics review, and it is these improved guidelines that the current IREC is using as its overarching policy framework. Currently, the IREC is guided by the Ateneo de Naga University Guidelines for the Ethics Review of Research (ADNUGERR 2020), approved by the University President on January 29, 2020, and the Ateneo de Naga University Code of Ethics for Research revised in 2020. The IREC also adheres to national and international ethics research guidelines and regulations, such as the National Ethical Guidelines for Health and Health-Related Research 2017 and the National Ethical Guidelines for Research Involving Human Participants 2022 published by the Philippine Health Research Ethics Board, the International Ethical Guidelines for Health-related Research Involving Humans (2016), and the Association of Internet Researchers' Internet Research Ethical Guidelines 3.0 (2019).

In the school year 2020-2021, the IREC began accepting proposals from the Graduate School, College of Law, and the University Research Council.

The Structure of IREC

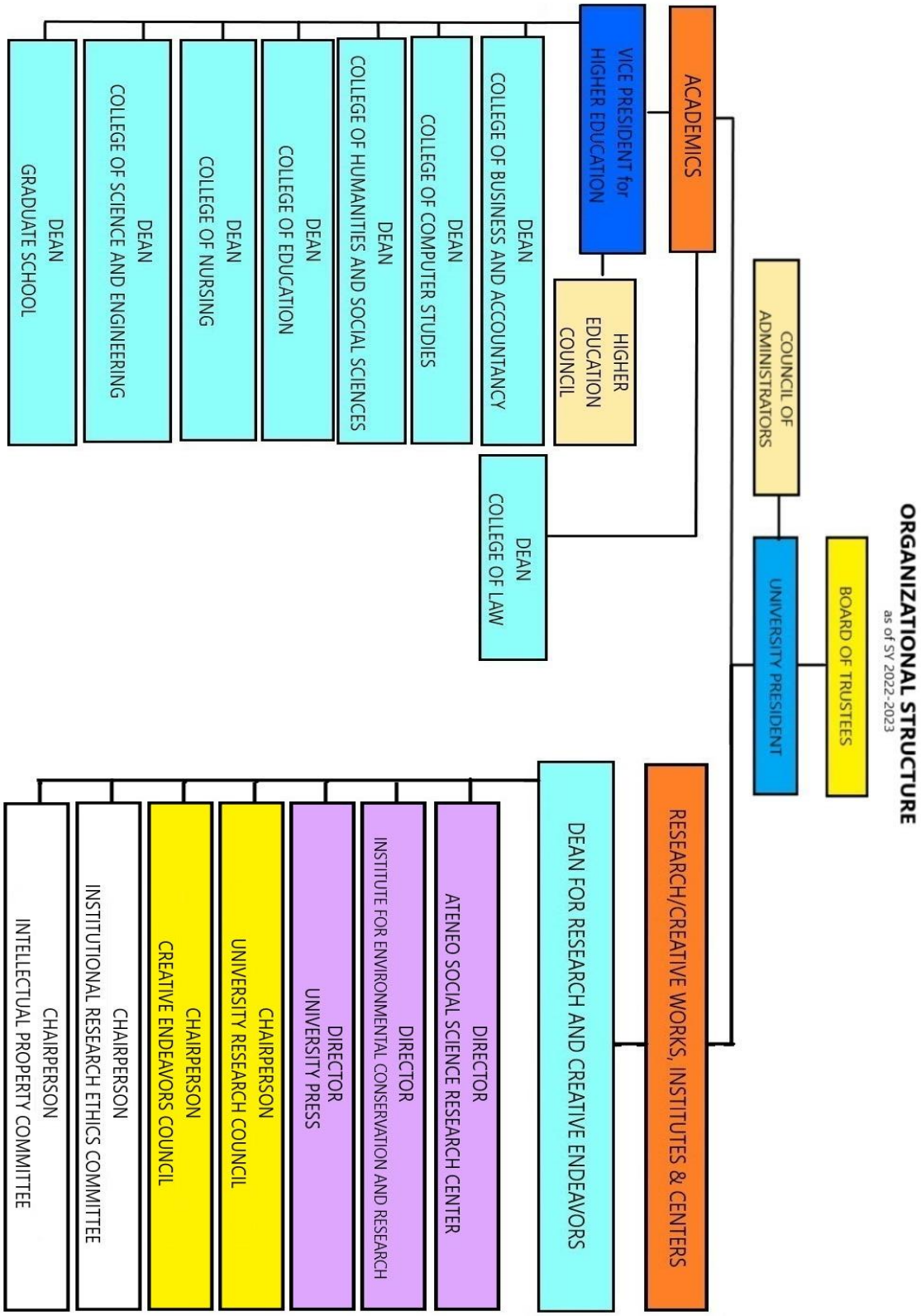
Organizational Structure

IREC is constituted as an independent unit with members, policies, and budget. This Committee directly reports to the Dean of the Office for Research and Creative Endeavors (RaCE). The Office for RaCE conceptualizes and implements policies and practices related to research and creative production at Ateneo de Naga University. It likewise liaises and cultivates relationships with industry, government, and private organizations that support research and creative endeavors.

The other offices, councils, and committees that report directly to the Dean of the Office for RaCE include the Ateneo Social Science Research Center (ASSRC), the Institute for Environmental Conservation and Research (INECAR), Intellectual Property Committee (IPC), University Creative Endeavors Council (UCEC), University Press (UPress), the University Research Council (URC), and the Creative Endeavors Council (CEC).

IREC coordinates with the Deans of the Graduate School and the College of Law which are under the Vice President for Higher Education, on the proposals submitted by their students. IREC also coordinates with the URC Chair on the proposals submitted by the faculty and staff.

Figure 1. Organizational Structure where IREC Belongs



Functions of IREC

The following are the functions of IREC as stated in ADNUGERR 2020:

1. Classify and review submitted research proposals of administrators, faculty, staff, and Graduate School and College of Law student researchers.
2. Draft and regularly update institutional policies and guidelines concerning research ethics review and standard operating procedures, including, but not limited to, the following:
    a. The IREC structure, composition, and compensation
    b. Meeting procedures
    c. Management of initial submissions and resubmissions
    d. Review procedures
    e. Management of post-approval submissions
    f. Documentation of IREC actions
    g. Site visits
    h. Management of queries or complaints
    i. Writing and revising policies
3. Accept requests from appointed person/s from each department or unit in the University (e.g., Chairperson, Dean, Heads of research-related units in the University) to review research proposals identified as more than low risk.
4. Ensure that research conducted at the University complies with existing ethical standards and requirements.
5. Promote awareness of research ethics among members of the University community.
6. Continuously improve and monitor the operational structures for research ethics approval in the University.
7. Review research proposals from external agencies for a fee once accredited.
8. Approve ethically acceptable research undertakings, as well as propose modifications, reject or stop those deemed otherwise.
9. Keep a systematic and organized record of all proposals reviewed, including actions that were taken and other pertinent information.
10. Attend ethics training and certification programs.
11. Participate in the development of best practices for addressing ethical issues in the conduct of research across the region.

12. Secure accreditation from the Philippine Health Research Ethics Board.
13. Maintain confidentiality of the documents and deliberations of IREC meetings.
14. Help settle disputes related to publication authorship, credit, order, and affiliation, as represented by the Chair.

The ADNU IREC SOP Manual

This manual contains the following sections:

SOP 01 – Selection and Appointment of IREC Members
SOP 02 – Appointment of Independent Member
SOP 03 – Appointment of Independent Consultant/s
SOP 04 – Management of Initial Submissions
SOP 05 – Management of Resubmissions
SOP 06 – Exemption from Review
SOP 07 – Expedited Review
SOP 08 – Full Review
SOP 09 – Review of Progress Reports
SOP 10 – Review of Amendments
SOP 11 – Review of Protocol Deviations and/or Violations
SOP 12 – Review of Safety Reports
SOP 13 – Submission of the Final Report
SOP 14 – Review of Early Termination Reports
SOP 15 – Site Visits
SOP 16 – Management of an Application for Continuing Review
SOP 17 – Management of Appeals
SOP 18 – Preparing for a Meeting with the Meeting Agenda
SOP 19 – Conduct of Meeting
SOP 20 – Documentation of IREC Actions
SOP 21 – Management of Active Files
SOP 22 – Archiving of Files
SOP 23 – Management of Queries/Complaints
SOP 24 – Writing and Revising SOPs

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02 Date of Approval: September 1, 2022 Date of Effectivity: September 8, 2022	**SOP No. 01** **Selection and Appointment of IREC Members**

1. Policy Statement

ADNUGERR 2020 Section III, titled the Structure and Composition of IREC, states that the University President approves the composition of the IREC for a specified term, subject to renewal. Members are selected according to their capacities; based on their interest, background, ethical, and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the work of the Ateneo IREC. Since IREC serves as an independent body, members must not hold any key position in the university (e.g., Head of academic or research-related units). The IREC shall be composed of at least seven members with diverse expertise. The appointed members of IREC are expected to serve for at least two (2) academic years in their duties as IREC members.

2. Objective of the Activity

The selection and appointment of IREC Members ensure that the constituted IREC is an independent unit that reports to the Dean of the Office for Research and Creative Endeavors (RaCE) and whose members do not hold key positions in the university. It is also set up to ensure the continuity of policy structures and maximize the application of the training received by the members.

3. Scope

SOP 01 applies specifically to the selection and appointment of IREC members. SOP 01 begins with the receipt of notification of the expiration of the current Member's appointment and ends with the Filing of all communications and documents related to the recommendation and appointment in the IREC digital folder.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Receipt of Notification of Expiration of Current Member's Appointment from HRMO	IREC Chair
Step 2: Search for Prospective Recommended Member	IREC Chair and Members
Step 3: Request for CV, Confidentiality Agreement, and Disclosure of Conflict of Interest from Selected Recommended Member	IREC AA
Step 4: Submission of Written Recommendation to the Dean for RaCE	IREC Chair
Step 5: Receipt of Endorsement from the Dean for RaCE	IREC Chair
Step 6: Submission of Endorsed Recommendation to the Fr. President	IREC Chair
Step 7: Notification of the Fr. President's Approval of the Recommendation to HRMO and the New Member	IREC Chair
Step 8: Filing of All Communications and Documents Related to the Recommendation and Appointment	IREC AA

5. Description of Procedures

Step 1 – **Receipt of Notification of expiration of current Member's appointment from HRMO:** The IREC Chair receives a written notification on the expiration of the contractual appointment of the IREC member/s from HRMO.

Step 2 **– Search for Prospective Recommended Member:** The IREC Chair conducts informal consultation with the academic community on possible recommended individuals. The Dean of RaCE and the other current IREC members are also consulted. Once a name has been selected, the IREC Chair approaches the prospective recommended member for his/her informal acceptance.

Step 3 – **Request for CV, Confidentiality Agreement, and Disclosure of Conflict of Interest from Selected Recommended Member:** The IREC AA requests for a curriculum vitae (See IREC Form 20) of possible recommended

member, confidentiality agreement (See IREC Form 22), and disclosure of conflict-of-interest (see IREC Form 21A).

Step 4 – **Submission of Written Recommendation to the Dean for RaCE:** The IREC Chair submits a written recommendation to the Dean of RaCE, with the attached CV, for her/his endorsement.

Step 5 – **Receipt of Endorsement from the Dean for RaCE:** The IREC Chair receives the letter of recommendation signed by the Dean of RaCE.

Step 6 – **Submission of Endorsed Recommendation to the Fr. President:** The IREC Chair submits the endorsed letter of recommendation to the President for his approval.

Step 7 – **Notification of the Fr. President's Approval of the Recommendation to HRMO and the New Member:** The IREC Chair sends a written notification to HRMO regarding the Fr. President's approval of the recommendation for the processing of the appointment papers. The IREC Chair also informs the new member about the Fr. President's approval of his/her appointment as a new member of the IREC.

Step 8 – **Filing of All Communications Related to the Recommendation and Appointment:** The IREC AA files all communications related to the recommendation and appointment including the CV and the declaration of conflict of interest in the IREC digital folder on "IREC Members."

6. Glossary

AA - Administrative Assistant

ADNUGERR – Ateneo de Naga University Guidelines for Ethics Review of Research

Conflict of Interest – a situation in which the aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect official/primary duties

CV - Curriculum vitae

HRMO – Human Resource Management Office

IREC – Institutional Research Ethics Committee

RaCE – Office for Research and Creative Endeavors

7. Forms

IREC Form 20: Curriculum Vitae (IREC Chair, Members, and Consultants)

IREC Form 21A: Disclosure of Conflict of Interest Agreement (For Members and Consultants before the Start of the Term)

IREC Form 22: Confidentiality Agreement Template (For Members, Observers, or Guests of the Institutional Research Ethics Committee)

8. History

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft
2	2022 September 1	IREC 2022	Policy statement, scope, workflow, description of procedure, glossary, forms, references, styling

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Ateneo de Naga University - Institutional Research Ethics Committee. (2022). *IREC Memo 2022-01*.

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02 Date of Approval: September 1, 2022 Date of Effectivity: September 8, 2022	**SOP No. 02** **Appointment of Independent Member**

1. Policy Statement

Section III of ADNUGERR 2020, titled the Structure and Composition of IREC states that at least one person who is not an employee of Ateneo de Naga University may be invited to be an independent member. The appointed members of IREC are expected to serve for at least two (2) academic years in their duties as IREC members.

2. Objective of the Activity

The appointment of an independent member ensures that the constituted IREC is an independent unit that reports to the Dean of the Office for Research and Creative Endeavors (RaCE) and whose members consist of at least one who is not an employee of the University.

3. Scope

SOP 02 applies specifically to the appointment of an independent member. SOP 02 begins with the notification of the expiration of the term of office of the independent member and ends with the filing of pertinent documents relating to the appointment of the new independent member in IREC files.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Receipt of Notification of Expiration of Current Independent Member's Appointment from HRMO	IREC Chair
Step 2: Search for Prospective Recommended Member	IREC Chair and Members
Step 3: Request for CV, Confidentiality Agreement, and Disclosure of Conflict of Interest from the Recommended Member	IREC AA

Step 4: Submission of Written Recommendation to the Dean for RaCE	IREC Chair
Step 5: Receipt of Endorsement from Dean for RaCE	IREC Chair
Step 6: Submission of Endorsed Recommendation to the Fr. President	IREC Chair
Step 7: Notification of the Fr. President's Approval of the Recommendation to HRMO and the New Independent Member	IREC Chair
Step 8: Filing of All Communications and Documents Related to the Recommendation and Appointment	IREC AA

5. Description of Procedures

Step 1 **– Receipt of Notification of Expiration of Current Independent Member's Appointment:** The IREC Chair receives a written notification on the expiration of the contractual appointment of the independent member from HRMO.

Step 2 – **Search for Prospective Recommended Member:** The IREC Chair conducts informal consultation with the academic community on possible recommended member. The Dean of RaCE and the other current IREC members are also consulted. Once a name has been selected, the IREC Chair approaches the prospective recommended member for his/her informal acceptance.

Step 3 – **Request for CV, Confidentiality Agreement, and Disclosure of Conflict of Interest from the Recommended Member:** The IREC AA requests a CV of the recommended member, confidentiality agreement, and a disclosure of conflict of interest.

Step 4 – **Submission of Written Recommendation to the Dean for RaCE:** The IREC Chair submits a written recommendation to the Dean of RaCE, with the attached CV, for her endorsement.

Step 5 – **Receipt of Endorsement from Dean for RaCE:** The IREC Chair receives the letter of recommendation signed by the Dean of RaCE.

Step 6 – **Submission of Endorsed Recommendation to the Fr. President:** The IREC Chair submits the endorsed letter of recommendation to the President for his approval.

Step 7 – **Notification of the Fr. President's Approval of the Recommendation to HRMO and the New Independent Member:** The IREC Chair sends a written notification to HRMO regarding the Fr. President's approval of the recommendation for the processing of the appointment papers. The IREC Chair also informs the new member about the Fr. President's approval and his/her appointment as a new independent member of IREC.

Step 8 – **Filing of All Communications and Documents Related to the Recommendation and Appointment:** The IREC AA files all communications and documents related to the recommendation and appointment of the new independent member in the IREC digital folder on "IREC Members."

6. Glossary

AA - Administrative Assistant

ADNUGERR – Ateneo de Naga University Guidelines for Ethics Review of Research

Confidentiality – is the duty to not freely disclose private/research information entrusted to an individual or organization

Conflict of Interest – a situation in which aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect official/primary duties

CV - Curriculum Vitae

Expertise – a proficiency, skill, or know-how possessed by experts in a certain academic or professional field

HRMO – Human Resource Management Office

Independent Member – is not an employee of ADNU but a regular voting member of IREC. S/he has expertise in a particular field

IREC – Institutional Research Ethics Committee

RaCE – Office for Research and Creative Endeavors

7. Forms

IREC Form 20: Curriculum Vitae (IREC Chair, Members, and Consultants)

IREC Form 21A: Disclosure of Conflict of Interest Agreement (For Members and Consultants before the Start of the Term)

IREC Form 22: Confidentiality Agreement (For Members, Observers, or Guests of the Institutional Research Ethics Committee)

8. History of SOP

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft
2	2022 September 1	IREC 2022	Policy statement, scope, workflow, description of procedures, glossary, forms, references, styling

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Ateneo de Naga University - Institutional Research Ethics Committee. (2022). *IREC Memo 2022-01*.

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02 Date of Approval: September 1, 2022 Date of Effectivity: September 8, 2022	**SOP No. 03** **Appointment of Independent Consultant/s**

1. Policy Statement

Section VII, B-4b and G-4 of ADNUGERR 2020, titled the "Research Ethics Review Procedure" provides the appointment of Independent Consultant/s if the research project poses a more-than-low risk, and additional ethical expertise is requested by the Dean of the College of Law/Graduate School or the URC Chair. The appointment of an independent Consultant is also sought during appeals of IREC decisions, if necessary, to determine the merits of the appeal.

2. Objective of the Activity

The appointment of an independent consultant conforms with the institutional practice and complements the pool of expertise in IREC.

3. Scope

SOP 03 applies specifically to the selection and appointment of independent consultant/s. SOP 03 begins with the receipt of a request for an independent consultant from the concerned college or unit and ends with the filing of all communications and documents related to the selection and appointment of the independent consultant in the IREC digital folder "Independent Consultants."

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Receipt of Request for Independent Consultant from the Concerned College/Unit	IREC Chair
Step 2: Communication with the Recommended Independent Consultant and Seeking Acceptance	IREC Chair
Step 3: Submission of Written Recommendation to the Dean for RaCE	IREC Chair

Step 4: Receipt of Approval from the Dean for RaCE	IREC Chair
Step 5: Notification to the Independent Consultant	IREC Chair
Step 6: Filing of All Communications and Documents Related to the Selection and Approval of the Independent Consultant	IREC AA

5. Description of Procedures

Step 1 – **Receipt of Request for Independent Consultant from the Concerned College/Unit:** The IREC Chair receives the request for an independent consultant from the concerned college or unit. S/He evaluates the qualifications of the independent consultant based on the CV, Disclosure of Conflict of Interest Agreement, and Confidentiality Agreement attached to the request.

Step 2 – **Communication with the Recommended Independent Consultant and seeking Acceptance:** The IREC Chair communicates with the potential candidate, and seeks his/her acceptance.

Step 3 – **Submission of Written Recommendation to the Dean for RaCE:** The IREC Chair submits a written recommendation to the Dean of RaCE, with the attached CV, for her endorsement.

Step 4 – **Receipt of Approval from the Dean for RaCE:** The IREC Chair receives the approval from the Dean of RaCE.

Step 5 – **Notification to the Independent Consultant:** The IREC Chair sends a written notification to the independent consultant that includes his/her functions.

Step 6 – **Filing of All Communications and Documents Related to the Selection and Approval of the Independent Consultant:** The IREC AA files all communications and documents related to the recommendation and approval of the independent consultant in the IREC digital folder “Independent Consultants.”

6. Glossary

AA - Administrative Assistant

ADNUGERR – Ateneo de Naga University Guidelines for Ethics Review of Research

Confidentiality – is the duty not to disclose private/research information entrusted to an individual or organization.

Conflict of Interest – a situation in which aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect official/primary duties.

CV - Curriculum Vitae

Expertise – a proficiency, skill, or know-how possessed by experts in a certain academic or professional field.

IREC – Institutional Research Ethics Committee

RaCE – Office for Research and Creative Endeavors

URC - University Research Council

7. Forms

IREC Form 20: Curriculum Vitae (IREC Chair, Members, and Consultants)

IREC Form 21A: Disclosure of Conflict of Interest Agreement (For Members and Consultants before the Start of the Term)

IREC Form 22: Confidentiality Agreement (For Members, Observers, or Guests of the Institutional Research Ethics Committee)

IREC Form 27: Request for Independent Consultant Template

8. History of SOP

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft
2	2022 September 1	IREC 2022	Policy statement, objective of the activity, scope, workflow, description of procedures, glossary, forms, references, styling

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

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Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02 Date of Approval: October 6, 2022 Date of Effectivity: October 13, 2022	**SOP No. 04** **Management of Initial Submissions**

1. Policy Statement

ADNUGERR 2020 states that research projects proposed by administrators, faculty, staff, and students in the university undergo a thorough ethics review. A review of ethical considerations in research is indispensable because it compels the researchers to be aware of the responsibility to respect and protect the rights of participants in the study, clarify the responsibilities of both researchers and human participants, and follow relevant government regulations in the conduct of research.

2. Objective of the Activity

The provisions on "management of initial submissions" ensure that study documents are complete, properly recorded, and evaluated to determine appropriate action or type of review.

3. Scope

SOP 04 ensures that IREC shall accept for initial review documents submitted by the administrators, faculty, staff, and students of the institution. SOP 04 begins with the receipt of study documents for initial review and ends with the updating of entries in the IREC database.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Receipt of Study Documents for Initial Review, Determination of Completeness of Submission, and Assignment of IREC Code	IREC AA
Step 2: Entry Into the IREC Database and Endorsement to the IREC Chair	IREC AA
Step 3: Determination of Type of Review/Action	IREC Chair
Step 4: Preparation of a Digital Document Folder	IREC AA

5. Description of Procedures

Step 1 - **Receipt of Study Documents for Initial Review, Determination of Completeness of Submission, and Assignment of IREC Code:** The IREC AA receives documents digitally through the official email irec@gbox.adnu.edu.ph, where both the IREC AA and the IREC Chair have access. The IREC AA checks the completeness of the study documents based on the checklist (IREC Form 06). If incomplete, the IREC AA informs the proponent of the missing documents. Once the documents are completed, an IREC Code is assigned following the format of "IREC-YEAR-Number of Receipt of the document for the year," e.g., the first document submitted in the year 2022 has an IREC code of "IREC-2022-01". This code is the ID number of the document and cannot be assigned to any other document. When referring to the document in communications or presentations, the code is lengthened to include the proponent and topic as follows, IREC-2022-01-DelaCruz-CS IP, to become more informative.

Step 2 - **Entry into the IREC Database and Endorsement to the IREC Chair:** The IREC AA inputs the necessary information into the IREC database (in an excel file) for official documentation, and records the receipt of particular documents on a specific date and time. The database includes information on (1) Date of Receipt, (2) IREC Code, (3) Name of the Proponent, (4) Course/Unit of the Proponent, (5) Title of the Study, (6) Research Adviser/Point Person, (7) Type of Review, (8) Name of the Reviewers, (9) Action done, (10) Date Conveyed, and (11) Documents Submitted. Once the documents have been verified to be complete by the AA, s/he then endorses the study documents to the IREC Chair.

Step 3 - **Determination of Type of Review/Action:** The IREC Chair conducts a preliminary review of the study document to determine whether it is exempted from review (SOP 06), Expedited (SOP 07), or Full Review (SOP 08), and the appropriate succeeding procedure shall be observed.

Step 4 - **Preparation of a Digital Document Folder:** The IREC AA files the study documents in a digital document folder and labels them accordingly (SOP 21 Managing Active Files).

6. Glossary

AA - Administrative Assistant

ADNUGERR – Ateneo de Naga University Guidelines for Ethics Review of Research

IREC Code - a unique number assigned to a study document indicating the year and series it was received

Database – an excel file containing a chronological record of incoming study documents that includes the (1) Date of Receipt, (2) IREC Code, (3) Name of

the Proponent, (4) Course/Unit of the Proponent, (5) Title of the Study, (6) Research Adviser/Point Person, (7) Type of Review, (8) Name of the Reviewers, (9) Action done, (10) Date Conveyed, and (11) Documents Submitted

Exemption from Review – a decision made by IREC through its Chair or a designated member of the committee regarding a submitted study proposal based on criteria in the ADNU Approved Guidelines for ERR (2020)

Expedited Review – is the ethical evaluation of a research proposal and other study documents, or a resubmission and after-approval submissions conducted by only two (2) members of the committee

Full Review – is the ethical evaluation of a research proposal and other study documents, or a resubmission and after-approval submissions. Full review is conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria

Initial Submission – a set of documents consisting of the full proposal and other study documents that need to be submitted so that review can be conducted

Initial Review – ethical and technical review conducted on the initially-submitted study documents. It may be expedited or full

IREC – Institutional Research Ethics Committee

Study Documents - refer to the proposal, guide questions/questionnaire, informed consent form, required IREC forms, and other attachments necessary to evaluate the ethical procedure of research

7. Forms:

IREC Form 06: Application for Ethics Review of a New Protocol

IREC Form 26: Protocol Index

IREC Database

8. History of SOP

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft
2	2022 October 6	IREC 2022	Policy statement, workflow, description of procedures, glossary, forms, references, styling

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Ateneo de Naga University - Institutional Research Ethics Committee. (2022). *IREC Memo 2022-01*.

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

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IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02 Date of Approval: October 6, 2022 Date of Effectivity: October 13, 2022	**SOP No. 05** **Management of Resubmissions**

1. Policy Statement

ADNUGERR 2020 Section VII, titled "Research Ethics Review Procedure" states that resubmissions occur when IREC decides that a proposal is for Modifications with Major/Minor Ethical Considerations.

2. Objective of the Activity

The provisions of "management of resubmissions" ensures that the researcher addressed the required modifications before the issuance of ethical clearance.

3. Scope

SOP 05 pertains to the resubmission of revised or modified study documents that have been previously reviewed by the IREC. The procedure begins with the receipt of the revised study documents and ends with its filing and updating of the IREC database.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Receipt of Study Documents and Determination of Completeness of Submission	IREC AA
Step 2: Entry Into the Database, Retrieval of the initial decision, and Endorsement to the IREC Chair	IREC AA
Step 3: Validation of Endorsement	IREC Chair
Step 4: Submission of the Study Documents to the Reviewers	IREC AA
Step 5: Review of Resubmission	Reviewers/IREC Chair and Members

Step 6: Communication of Decision	IREC Chair
Step 7: Filing of Documents and Updating of entries	IREC AA

5. Description of Procedures

Step 1 - **Receipt of Study Documents and Determination of Completeness of Submission:** The IREC AA receives and acknowledges the submitted documents through email. S/he checks the completeness of the documents using the accomplished Resubmission Form (Form 10) by the research proponent. If the documents are incomplete based on the latest IREC decision, the AA informs the proponent.

Step 2 - **Entry into the Database, Retrieval of Initial Decision, and Endorsement to the IREC Chair**: Once all documents are found complete, the IREC AA updates the database, retrieves all previous documents from the file, and endorses these along with the resubmitted documents to the Chair including the assignment of reviewers.

Step 3 - **Validation of Endorsement:** The IREC Chair validates the endorsement of the AA and instructs him/her to proceed with the submission of study documents to the reviewers.

Step 4 - **Submission of the Study Documents to the Reviewers:** The AA submits documents for review by the Primary Reviewer and Co-Reviewer.

Step 5 - **Review of the Resubmission:** The resubmission shall go through the expedited review unless the reviewers recommend a full review. The reviewers shall refer to the resubmission form (Form 10) to note the compliance of the proponent to the recommendations made by the IREC and to evaluate whether these were satisfactorily addressed in the resubmitted study document. The Primary Reviewer and Co-Reviewer are given at most two (2) days for the review using the Protocol Reviewer Worksheet (Form 08) and the Consent Checklist (Form 09), if applicable. The results of the expedited review are reported in the next IREC regular meeting. When both reviewers have the same recommendation, the reviews will be endorsed to the Chair for the drafting of the decision. When the reviewers have expressed different or contradictory opinions, the Chair submits the points of disagreement for the majority vote.

Step 6 - **Communication of Decision:** The IREC Chair drafts the letter of the decision based on the review and observes SOP 21 Communicating IREC Decisions.

Step 7 - **Filing of Documents and Updating of entries:** The IREC AA gathers all pertinent documents related to the resubmission (digitally-printed emails, revised protocol, assessment forms, excerpts of minutes, and approval

letter) and files them in the digital document folder. S/he also updates the IREC database accordingly.

6. Glossary

AA - Administrative Assistant

ADNUGERR – Ateneo de Naga University Guidelines for Ethics Review of Research

Coding - a unique number assigned to a study document indicating the year and series it was received

Database – an excel file containing a chronological record of incoming study documents that includes the (1) Date of Receipt, (2) IREC Code, (3) Name of the Proponent, (4) Course/Unit of the Proponent, (5) Title of the Study, (6) Research Adviser/Point Person, (7) Type of Review, (8) Name of the Reviewers, (9) Action done, (10) Date Conveyed, and (11) Documents Submitted

Expedited Review – is the ethical evaluation of a research proposal and other study documents, a resubmission, and after-approval submissions, conducted by two members of the committee.

Full Review – is the ethical evaluation of a research proposal, other study documents, or a resubmission and after-approval submissions conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria

Initial Review – the ethical assessment of the first complete set of study documents submitted to the IREC so that review can be conducted

IREC - Institutional Research Ethics Committee

Resubmission – the revised study proposal that is re-forwarded to the IREC following the recommendations from the initial review

Other Study Documents – refer to documents supporting the proposal, such as the guide questions/questionnaire, informed consent form, required IREC forms, and other attachments necessary to evaluate the ethical procedure of research

7. Forms:

IREC Form 08: Protocol Reviewer Worksheet

IREC Form 09: Consent Checklist

IREC Form 10: Resubmission Form

IREC Form 26: Protocol Index

IREC Database

8. History of SOP

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft
2	2022 October 6	IREC 2022	Policy statement, scope, workflow, description of procedures, glossary, forms, references, styling

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Ateneo de Naga University - Institutional Research Ethics Committee. (2022). *IREC Memo 2022-01*.

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 03 Date of Approval: September 22, 2022 Date of Effectivity: September 29, 2022	**SOP No. 06** **Exemption from Review**

1. Policy Statement

ADNUGERR 2020 Section VII, titled, “Research Ethics Review Procedure" with some provisions revised based on the National Ethical Guidelines for Research Involving Human Participants 2022 (NEGRIHP 2022) as reflected in the IREC Memo 2022-01 provides that a proposal may be exempted from ethics review if it falls on any of the following categories: (a) Research that neither involve human participants nor identifiable human tissue, biological samples, and data; (b) Research that involves human participants provided that it does not involve more than minimal risks or harms, such as research on institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests, and research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording); (c) Research that obtained permission and/or abided by the research requirements or protocols of the institutions where the studies will take place; (d) Research that involves the use of publicly available data or information.

The URC Chair or the Dean of the Graduate School or College of Law shall recommend the “Exempt from Review" and be decided upon by IREC.

2. Objective of the Activity

The provisions on “exemption from review” ensure that the types of research that are only allowed to be exempted from the review are appropriately granted. SOP 06 aims to demonstrate due diligence and high standards in the system of protection of human participants.

3. Scope

SOP 06 applies specifically to the exemption from the review process of research conducted by the IREC, starting from the receipt of study documents and endorsement from the concerned head of the unit where the researcher belongs. SOP 06 ends with the filing of all communications and study documents in the digital IREC folder.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Receipt of Study Documents and Endorsement from the Concerned Head of the Unit, Assignment of IREC Code, and Encoding of the study documents in the IREC Database.	IREC AA
Step 2: Evaluation of the Study Documents Based on the Criteria Listed by IREC	IREC AA
Step 3: Endorsement of the Study Documents to IREC Chair for His/Her Approval	IREC AA
Step 4: Validation of the Endorsement, Conferral with a Member, and Issuance of a Certificate of Exemption from Review	IREC Chair & a Member
Step 5: Filing of All Communications and Documents Related to the study documents	IREC AA

5. Description of Procedures

Step 1 – **Receipt of Study Documents and Endorsement from the Concerned Head of the Unit, Assignment of IREC Code, and Encoding of the study documents in the IREC Database:** The IREC AA receives and checks the study documents as well as the endorsement from the concerned Head of the Unit. S/He then assigns an IREC Code to the study documents and encodes them in the IREC database.

Step 2 – **Evaluation of the Study Documents Based on the Criteria that IREC Listed:** The IREC AA evaluates the study documents based on the criteria listed under the policy statement. For research that involves human participants, the AA shall further inspect the sections on methodology and ethical considerations of the proposal if the researcher commits on the following concerns:

a. There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to 'their financial standing, employability, or reputation, and
b. The investigator records the information obtained in such a manner that the identity of the human participant cannot readily be ascertained directly or through identifiers linked to the participant.

Step 3 – **Endorsement of the Study Documents to the IREC Chair for His/Her Approval:** If all parameters are met, the IREC AA endorses the study documents to IREC Chair for his/her approval.

Step 4 - **Validation of the Endorsement, Conferral with a Member, and Issuance of a Certificate Exemption from Review:** The IREC Chair validates the endorsement of the IREC AA. S/he confers with at least one IREC Member before issuing a certificate of exemption from review. In case of disapproval, the proposal will undergo expedited review (see SOP 7 Expedited Review) or full review (see SOP 8 Full Review).

In evaluating the compliance with Letter (b) of the policy statement, the Chair and the Co-Reviewer shall ensure that the proposal (i.e., the methodology and the ethical considerations) and IREC form 1 manifest the observance of the following criteria: (1) There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to 'their financial standing, employability, or reputation; and (2) The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.

Step 5 – **Filing of All Communications and Study Documents:** The IREC AA files all communications and study documents in the digital IREC folder "Decisions."

6. Glossary

AA - Administrative Assistant

ADNUGERR – Ateneo de Naga University Guidelines for Ethics Review of Research

Database – an excel file containing a chronological record of incoming study documents that includes the (1) Date of Receipt, (2) IREC Code, (3) Name of the Proponent, (4) Course/Unit of the Proponent, (5) Title of the Study, (6) Research Adviser/Point Person, (7) Type of Review, (8) Name of the Reviewers, (9) Action done, (10) Date Conveyed, and (11) Documents Submitted

Discomforts – may include minor side effects of medication, discomforts related to measuring blood pressure, or anxiety induced by an interview (ADNUGERR, p.1).

Interview procedures – include all research activities that involve asking and responding, elaboration, and discussion of participants related to a specific study. It may include key informant interviews, survey interviews, group interviews, or focus group discussions.

IREC – Institutional Research Ethics Committee

Low-risk – discomfort or minimal disruption to human participants.

NEGHHR - National Ethical Guidelines for Health and Health-related Research

Negligible risk – no foreseeable risk of harm or discomfort, and any foreseeable risk is no more than an inconvenience to participants, which may include filling in a form, participating in a de-identified survey, or giving up time to participate in research activity

Studies that do not involve more than minimal risks – negligible-or low-risk research (ADNU, 2020)

Study Documents - refer to the proposal, guide questions/questionnaire, informed consent form, required IREC forms, and other attachments necessary to evaluate the ethical procedure of research

URC - University Research Council

7. Forms

IREC Form 12: Request for Exempt from Review Template

IREC Form 17: Certificate of Exemption from Review Template

IREC Form 26: Protocol Index

IREC Database

8. History of SOP

Version Number	Date	Authors	Change/s
1	2022 May 2	IREC 2022	First draft
2	2022 August 18	IREC 2022	Refined criteria, added definitions
3	2022 September 22	IREC 2022	policy statement, observed consistency with SOP format

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Ateneo de Naga University - Institutional Research Ethics Committee. (2022). *IREC Memo 2022-01*.

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

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IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02 Date of Approval: September 22, 2022 Date of Effectivity: September 29, 2022	**SOP No. 07** **Expedited Review**

1. Policy Statement

ADNUGERR 2020 Section VII, titled “Research Ethics Review Procedure" with some provisions revised based on the NEGRIHP 2022 as reflected in the IREC Memo 2022-01, states that the following projects classified as low risks shall be submitted for expedited review. These include (1) surveys of non-sensitive nature that collect no information that can make apparent, reasonably or directly, an individual’s identity (IRR of Republic Act No. 10173) such as anonymous surveys of opinions, attitudes, practices, and preferences; (2) research involving minor changes in previously approved research projects; and (3) research, which is a local portion of a multi-center or multi-national research project, that has already received a full review from another research ethics committee or institutional review board.

2. Objective of the Activity

The provisions on “expedited review” ensure that the types of research to be subjected for expedited review are appropriate and that the correct review process shall be observed. SOP 07 also aims to demonstrate due diligence and high standards in the system of protection of human participants.

3. Scope

SOP 07 applies specifically to the expedited review process of research conducted by IREC, starting from the submission of study documents to IREC. SOP 07 ends with the filing of the decision.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Receipt of the Study Documents, Assignment of IREC Code, and Encoding of the study documents in the IREC Database	IREC AA
Step 2: Endorsement to the IREC Chair for Expedited Review	IREC AA

Step 3: Confirmation of Endorsement and Assignment of Primary Reviewer and Co-Reviewer	IREC Chair
Step 4: Communication of Assignment and Distribution of study documents to the Primary Reviewer and Co-Reviewer, and Request for Disclosure of Conflict of Interest	IREC AA
Step 5: Submission of Reviews	IREC Members (Primary Reviewer and Co-Reviewer)
Step 6: Collation of Reviews and Endorsement to the IREC Chair	IREC AA
Step 7: Affirmation of Reviews or Communication of Disapproval and Setting a Meeting for Other Members' Comments	IREC Chair
Step 8: Call for a Meeting (In Case of Disagreement)	IREC AA
Step 9: Arrival at the Final Decision	IREC Chair & Members
Step 10: Sending Out of Decision	IREC Chair
Step 11: Filing of All Communications and Documents Related to the study documents	IREC AA

5. Description of Procedures

Step 1 – **Receipt of the Study Documents, Assignment of IREC Code, and Encoding of the study documents in the IREC Database:** The IREC AA receives and checks the completeness of the documents, including the endorsement from the concerned Head of the unit. S/He then assigns an IREC Code to the study documents and encodes them in the IREC database. S/he informs the researcher of any missing documents and defers endorsement to the IREC Chair until all the documents are submitted.

Step 2 – **Endorsement to the IREC Chair for Expedited Review:** If all parameters are met, the IREC AA endorses the study documents to the IREC Chair.

Step 3 – **Confirmation of Endorsement and Assignment of Primary Reviewer and Co-Reviewer:** The IREC Chair confirms the classification of the expedited review and assigns a Primary Reviewer and a Co-Reviewer following

the sequencing established at the start of the school year. The pairing of reviewers should consider the distribution of gender, age, and an equitable rotation of review assignments.

Step 4 – **Communication of Assignment and Distribution of Study Documents to the Primary Reviewer and Co-Reviewer, and Request for Disclosure of Conflict of Interest:** The IREC AA sends out communication of the assignment along with the study documents to the Primary Reviewer and Co-Reviewer.

If the assigned reviewer discloses that they have a conflict of interest, they must fill out the Disclosure of Conflict of Interest (For Members and Consultants before the Review) (IREC Form 21B). The IREC Chair will assign a different reviewer in their place.

If the Chairperson has a Conflict of Interest, the Primary Reviewer or Co-reviewer will preside in the deliberations.

Step 5 – **Submission of Reviews:** The Primary Reviewer and Co-Reviewer are given at most five (5) days for the review. They review the submitted documents using the Protocol Reviewer Worksheet (IREC Form 08) and the Consent Checklist (IREC Form 09), when applicable. The reviewers submit the forms to the IREC AA, who will collate the reviews. The results of the expedited review are reported in the next IREC regular meeting. When both reviewers have the same recommendation, the reviews will be endorsed to the Chair for the drafting of the decision. When the reviewers have expressed different or contradictory opinions, the Chair will submit the contentious points to the other members for discussion, and a majority vote will be sought.

Step 6 – **Collation of Reviews and Endorsement to the IREC Chair:** The IREC AA collates the reviews of the Primary Reviewer and Co-Reviewer, and endorses them to the IREC Chair.

Step 7 – **Affirmation of Reviews or Communication of Disapproval and Setting a Meeting for Other Members' Comments:** The IREC Chair evaluates and may question/give/add comments on the review submitted. S/he then affirms or disapproves the reviews and sets a meeting to allow other IREC Members to provide their comments.

Step 8 - **Call for a Meeting (In Case of Disagreement):** The IREC AA sends out a call for a meeting to all IREC Members to discuss disagreement regarding the review of the study documents.

In case a member discloses that they have a conflict of interest, they must fill out the Disclosure of Conflict of Interest (For Members and Consultants before the Review) (IREC Form 21B). They must inhibit temporarily from the meeting during the discussion of the study documents.

Step 9 - **Arrival at the Final Decision:** The IREC Members discuss, comment, and arrive at a decision to resolve the disagreement regarding the review.

Step 10 - **Drafting of Decision and Communication to the Researcher:** The IREC Chair sends out the decision by email to the research proponent with copies furnished to the concerned official (e.g., URC Chair/GS/COL Dean) and the IREC Members.

Step 11 – **Filing of All Communications and Documents Related to the study documents:** The IREC AA files all communications and study documents in the digital IREC folder titled “Decisions.”

6. Glossary

AA - Administrative Assistant

ADNUGERR – Ateneo de Naga University Guidelines for Ethics Review of Research

COL - College of Law

Database – an excel file containing a chronological record of incoming study documents that includes the (1) Date of Receipt, (2) IREC Code, (3) Name of the Proponent, (4) Course/Unit of the Proponent, (5) Title of the Study, (6) Research Adviser/Point Person, (7) Type of Review, (8) Name of the Reviewers, (9) Action done, (10) Date Conveyed, and (11) Documents Submitted

GS - Graduate School

IREC – Institutional Research Ethics Committee

IRR - Implementing Rules and Regulations

NEGHHR - National Ethical Guidelines for Health and Health-related Research

Study Documents - refer to the proposal, guide questions/questionnaire, informed consent form, required IREC forms, and other attachments necessary to evaluate the ethical procedure of research

URC - University Research Council

7. Forms

IREC Form 01: Ethical Procedures in Conducting Research Involving Humans

IREC Form 06: Application for Ethics Review of a New Protocol

IREC Form 07: Curriculum Vitae-Researcher

IREC Form 08: Protocol Reviewer Worksheet

IREC Form 09: Consent Checklist

IREC Form 21B: Disclosure of Conflict of Interest (For Members and Consultants before the Review)

IREC Form 26: Protocol Index

IREC Database

8. History of SOP

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft
2	2022 September 22	IREC 2022	Policy statement, objective of the activity, scope, workflow, description of procedures, glossary, forms, references, styling

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Ateneo de Naga University - Institutional Research Ethics Committee. (2022). *IREC Memo 2022-01*.

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02 Date of Approval: September 22, 2022 Date of Effectivity: September 29, 2022	**SOP No. 08** **Full Review**

1. Policy Statement

ADNUGERR 2020 Section VII titled, "Research Ethics Review Procedure," states that full reviews are conducted on research projects which pose a more-than-low risk to research participants or subjects. These include (a) research involving vulnerable groups, such as the elderly, youth-at-risk, or special children; (b) research involving sensitive topics, such as substance use, sexual behaviors, or criminal or politically sensitive behaviors; (c) research with groups which necessitate permission to acquire access to them, such as research with indigenous communities; (d) research which will require withholding its nature or other pertinent information or which will be conducted without the participants' full and informed consent at the time data is to be collected; (e) research that will require access to personal and confidential information of identifiable individuals, such as genetic or biological information, medical records, or psychological assessment records; (g) research that will cause physical and/or psychological harm or pain, or will cause humiliation, stress or anxiety; (h) research that will involve intrusive interventions, such as hypnotherapy, drug administration, or vigorous exercise, which may cause participants to reveal information about themselves they otherwise would not normally want to be revealed in their everyday lives; and (i) research involving deceased persons, body parts, or other human elements.

2. Objective of the Activity

The provisions on "full review" ensure that the types of research to be subjected for full review are appropriate and that the correct review process shall be observed. SOP 08 also aims to demonstrate due diligence and high standards in the system of protection of human participants.

3. Scope

SOP 08 applies specifically to the full review process of research conducted by the IREC, starting from the submission of study documents to IREC and ending with the filing of the decision.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Receipt of the Study Documents and Encoding in the IREC Database and Assignment of IREC Code	IREC AA
Step 2: Endorsement to the IREC Chair for a Full Review	IREC AA
Step 3: Confirmation of Endorsement of a Full Review and Assignment of Primary Reviewer and Co-Reviewer, and Request for Disclosure of Conflict of Interest	IREC Chair
Step 4: Communication of Assignment and Distribution of Study Documents to the Primary Reviewer and Co-Reviewer	IREC AA
Step 5: Submission of Reviews	Primary Reviewer & Co-Reviewer
Step 6: Collation of Review and Call for a Full Review Meeting	IREC AA & IREC Chair
Step 7: Agreements Arrived at the Full Review	Full Committee
Step 8: Sending Out of Decision	IREC Chair
Step 9: Filing of All Communications and Study Documents	IREC AA

5. Description of Procedures

Step 1 – **Receipt of the Study Documents and Encoding in the IREC Database and Assignment of IREC Code:** The IREC AA receives and checks the completeness of the study documents, including the endorsement from the concerned Head of the Unit. S/He then assigns an IREC Code to the study documents and encodes them in the IREC database. S/he informs the researcher of any missing documents and defers endorsement to the IREC Chair until all the documents are submitted.

Step 2 – **Endorsement to the IREC Chair for a Full Review:** If all parameters are met, the IREC AA endorses the study documents to the IREC Chair.

Step 3 – **Confirmation of Endorsement of a Full Review and Assignment of Primary Reviewer and Co-Reviewer:** The IREC Chair confirms the classification of the full review and assigns a Primary Reviewer and a Co-Reviewer following the sequencing established at the start of the school year. The pairing of reviewers should consider the distribution of gender, age, and an equitable rotation of review assignments.

Step 4 – **Communication of Assignment and Distribution of Study Documents to the Primary Reviewer and Co-Reviewer, and Request for Disclosure of Conflict of Interest:** The IREC AA sends out communication of the assignment along with the study documents to the Primary Reviewer and Co-Reviewer.

If the assigned reviewer discloses that they have a conflict of interest, they must fill out the Disclosure of Conflict of Interest (For Members and Consultants before the Review) (IREC Form 21B). The IREC Chair will assign a different reviewer in their place.

If the Chairperson has a Conflict of Interest, the Primary Reviewer or Co-reviewer will preside in the deliberations.

Step 5 – **Submission of Reviews:** The Primary Reviewer and Co-Reviewer are given at most five (5) days for the review. They review the submitted documents using the Protocol Reviewer Worksheet (IREC Form 08) and the Consent Checklist (IREC Form 09), when applicable. The reviewers submit the forms to the IREC AA, who will collate the reviews.

Step 6 – **Collation of Review and Call for a Full Review Meeting:** The IREC AA collates the reviews of the Primary Review and Co-Reviewer and endorses them to the IREC Chair. Once validated, the IREC Chair instructs the AA to call a full review meeting.

In case a member discloses that they have a conflict of interest, they must fill out the Disclosure of Conflict of Interest (For Members and Consultants before the Review) (IREC Form 21B). They must inhibit temporarily from the meeting during the discussion of the study documents.

Step 7 – **Agreements Arrived at the Full Review:** The IREC Members discuss, comment, and arrive at an agreement regarding the full review of the research proposal. The IREC AA collates the agreements and forwards these to the IREC Chair for the drafting of the decision.

Step 8 – **Sending out of Decision:** The IREC Chair sends out the decision letter by email to the research proponent with copies furnished to the concerned official (e.g., URC Chair/GS/COL Dean) and the IREC Members.

Step 9 – **Filing of All Communications and Documents Related to the study documents:** The IREC AA files all communications and study documents in the digital IREC folder titled “Decisions.”

6. Glossary

AA - Administrative Assistant

ADNUGERR – Ateneo de Naga University Guidelines for Ethics Review of Research

COL - College of Law

Database – an excel file containing a chronological record of incoming study documents that includes the (1) Date of Receipt, (2) IREC Code, (3) Name of the Proponent, (4) Course/Unit of the Proponent, (5) Title of the Study, (6) Research Adviser/Point Person, (7) Type of Review, (8) Name of the Reviewers, (9) Action done, (10) Date Conveyed, and (11) Documents Submitted

Decision – the result of the deliberations of the IREC in the review of a study document or other submissions

GS - Graduate School

IREC – Institutional Research Ethics Committee

More than Low Risk - a term used when the probability and magnitude of harm or discomfort anticipated in the research are greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests

Study Documents - refer to the proposal, guide questions/questionnaire, informed consent form, required IREC forms, and other attachments necessary to evaluate the ethical procedure of research

URC - University Research Council

Vulnerable Groups – participants or potential participants of a research study who may not have the full capacity to protect their interests and may be relatively or absolutely incapable of deciding for themselves whether or not to participate in the research. They may also be at a higher risk of being harmed or taken advantage of.

7. Forms

IREC Form 01: Ethical Procedures in Conducting Research Involving Humans

IREC Form 06: Application for Ethics Review of a New Protocol

IREC Form 07: Curriculum Vitae-Researcher

IREC Form 08: Protocol Reviewer Worksheet

IREC Form 09: Consent Checklist

IREC Form 21B: Disclosure of Conflict of Interest (For Members and Consultants before the Review)

IREC Form 26: Protocol Index

IREC Database

8. History of SOP

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft
2	2022 September 22	IREC 2022	Policy statement, objective of the study, scope, workflow, description of procedures, glossary, forms, references, styling

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Ateneo de Naga University - Institutional Research Ethics Committee. (2022). *IREC Memo 2022-01*.

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02 Date of Approval: February 3, 2023 Date of Effectivity: February 10, 2023	**SOP No. 09** **Review of Progress Report**

1. Policy Statement

The ADNUGERR 2020 states that IREC must ensure that research conducted in the University complies with existing ethical standards and requirements. Thus, IREC adopts the NEGRIHP (2022), which states that IREC shall monitor the conduct of research that it has approved. All researchers shall submit a progress report for review to IREC two months before the expiration of the ethical clearance or as decided by the IREC.

2. Objective of the Activity

The provisions of the "review of progress report" aims to ensure that the conduct of the study is in compliance with the approved protocol and that the safety and welfare of study participants are promoted.

3. Scope

SOP 09 applies to the management and review of progress reports submitted by the proponent while the study is ongoing. SOP 09 begins with receipt and entry into the IREC database and ends with the filing of the progress report and the committee decision in the protocol file.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Notice of Submission of Progress Report	IREC AA
Step 2: Receipt and Entry into Database of the Progress Report (SOP 21 on Management of Active Files)	IREC AA
Step 3: Retrieval of Pertinent Study Document and Endorsement to the Chair	IREC AA

Step 4: Validation of the Endorsement and Determination of Type of Review: Expedited Review (SOP 07) or Full Review (SOP 08)	IREC Chair
Step 5: Submission of Study Documents to the Primary Reviewer and Co-Reviewer	IREC AA
Step 6: Review of Progress Report	Primary Reviewer & Co-Reviewer
Step 7: Communication of Committee Decision (SOP on Documentation of IREC Actions (SOP 20))	IREC Chair
Step 8: Filing of Progress Report and Committee Decision and Update of the Database (SOP on Management of Active Files (SOP 21))	IREC AA

5. Description of Procedures

Step 1 - **Notice of Submission of Progress Report:** IREC AA notifies the researcher to submit the progress report.

Step 2 - **Receipt and Entry into Database of the Progress Report:** IREC AA receives the progress report and enters the date and pertinent information in the IREC database (See SOP 21: Management of Active Files).

Step 3 - **Retrieval of Pertinent Study Document and Endorsement to the Chair:** IREC AA retrieves the corresponding study documents and endorses these to the Chair.

Step 4 - **Validation of Endorsement and Determination of Type of Review:** The IREC Chair validates the endorsement of the AA and instructs him/her to proceed with the submission of study documents to the reviewers.

Step 5 - **Submission of the Study Documents to the Reviewers:** The AA submits documents for review by the Primary Reviewer and Co-Reviewer.

Step 6 - **Review of Progress Report:** The progress report shall go through the same type of review as its initial submission, and the corresponding procedure shall be observed, i.e., SOP 7 for expedited review and SOP 8 for the full review. The reviewers shall refer to the previous decisions issued to note the compliance of the proponent to the recommendations made by the IREC and to evaluate whether these were satisfactorily addressed in the progress report. The results of the expedited review are reported in the next IREC regular meeting.

If the progress report presents a protocol deviation or violation, it should be reviewed alongside the application for continuing review and the protocol deviation or violation report.

Step 7 - **Communication of Committee Decision:** IREC Chair prepares a draft of the committee decision based on the minutes of the meeting. IREC Chair signs the decision letter as follows: (a) approval, (b) approval with an extension of ethical clearance, (c) request for additional information, or (d) specific action/s.

Step 8 – **Filing of Progress Report and Committee Decision and Update of the Database:** IREC AA files the progress report and the committee decision in the appropriate digital folder. S/he proceeds to update the pertinent IREC database.

6. Glossary

AA - Administrative Assistant

ADNUGERR – Ateneo de Naga University Guidelines for Ethics Review of Research

Database – an excel file containing a chronological record of incoming study documents that includes the (1) Date of Receipt, (2) IREC Code, (3) Name of the Proponent, (4) Course/Unit of the Proponent, (5) Title of the Study, (6) Research Adviser/Point Person, (7) Type of Review, (8) Name of the Reviewers, (9) Action done, (10) Date Conveyed, and (11) Documents Submitted

Expedited Review – is the ethical evaluation of a research proposal and other study documents, a resubmission, and after-approval submissions, conducted by only two members of the committee.

Full Review – is the ethical evaluation of a research proposal, other study documents, or a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria

IREC - Institutional Research Ethics Committee

Primary Reviewer – a member of the Institutional Research Ethics Committee assigned to do an in-depth evaluation of the study documents using technical and ethical criteria established by the committee

Progress Report – description of how the implementation of the study is moving forward through submission of a brief progress report. The frequency of submission (e.g., quarterly, semi-annually, or annually) is determined by the IREC based on the level of risk.

Other Study Documents – refer to the documents supporting the research proposal, such as guide questions/questionnaire, informed consent form, required IREC forms, and other attachments necessary to evaluate the ethical procedure of research

7. Forms

IREC Form 13: Application for Ethics Review of Progress Reports

IREC Form 26: Protocol Index

IREC Database

8. History

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft
2	2023 February 3	IREC 2022	Policy statement, workflow, description of procedures, glossary, forms, references, styling

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Ateneo de Naga University - Institutional Research Ethics Committee. (2022). *IREC Memo 2022-01*.

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02 Date of Approval: February 3, 2023 Date of Effectivity: February 10, 2023	**SOP No. 10** **Review of Amendments**

1. Policy Statement

An amendment is a written description of a proposed change(s) (i.e., protocol, informed consent documents, and other protocol-related documents) that is approved by REC but yet to be implemented (NEGRIHP, 2022). Section VII of ADNUGERR 2020 titled “Research Ethics Review Procedure " further states that amendment/s to the approved protocol shall need another review and approval by IREC. The researcher should state the changes or amendments and the reasons. These changes should be endorsed by the Research Adviser and the Head of the Unit where the researcher belongs (e.g., Dean of GS/COL or URC Chairperson).

2. Objective of the Activity

The provisions of “review of amendments” aims to ensure that any amendments do not impact the safety and welfare of study participants.

3. Scope

SOP 10 applies to the management and review of protocol amendments submitted by the proponent whose study is going to be implemented. SOP 10 begins with the receipt and entry of submission of the application for review of amendments (IREC Form 14) to the database and ends with the filing of the amendments report and the committee decision in the protocol file.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Receipt and Entry into Database (SOP 21 on Management of Active Files)	IREC AA
Step 2: Retrieval of Pertinent Study Documents and Endorsement to the IREC Chair	IREC AA
Step 3: Validation of Endorsement and Determination of Type of Review	IREC Chair

Step 4: Submission of Study Documents to Primary Reviewer and Co-Reviewer	IREC AA
Step 5: Review of Amendments	Assigned IREC Members & IREC Chair/Full Committee
Step 6: Communication of Committee Decision	IREC Chair
Step 7: Filing of Amendment Documents and Committee Decision and Update of the Database. (SOP 21 on Management of Active Files)	IREC AA

5. Description of Procedures

Step 1 - **Receipt and Entry into Database:** IREC AA receives the Application for Review of Amendments (IREC Form 14), enters the pertinent information into the database (See SOP 21: Management of Active files), and checks the completeness of the submission including the endorsement from the concerned Head of the Unit.

Step 2 - **Retrieval of Pertinent Protocol File and Endorsement to the Chair:** IREC AA retrieves the corresponding study documents and endorses them to the IREC Chair.

Step 3 - **Validation of Endorsement and Determination of Type of Review:** The IREC Chair validates the endorsement of the IREC AA on the completeness of the study documents and determines the type of review, whether Expedited Review (SOP 07) or Full Review (SOP 08).

Step 4 - **Submission of Study Documents to the Primary Reviewer and Co-Reviewer:** The IREC AA submits the study documents to the Primary Reviewer and Co-Reviewer.

Step 5 - **Review of Amendments:** The amendment shall go through the type of review as determined by the Chair, and the corresponding procedure shall be observed, i.e., SOP 7 for expedited review and SOP 8 for the full review. The reviewers shall refer to the application for review of the amendment form (IREC Form 14) in its evaluation. The results of the expedited review are reported in the next IREC regular meeting.

Step 6 - **Communication of Committee Decision:** IREC Chair communicates the committee action (see SOP 20: Documentation of IREC Actions). For amendments, committee action may be any of the following: (1) approved, (2) additional justification/information required, (3) re-consent required, or (4) disapproved.

Step 7 – **Filing of Amendment Documents and Committee Decision and Update of the Database:** IREC AA files the Amendment and the committee decision in the appropriate digital folder. S/he proceeds to update the IREC database.

6. Glossary

AA - Administrative Assistant

ADNUGERR – Ateneo de Naga University Guidelines for Ethics Review of Research

Amendment – Any change or revision in the protocol made after its approval that is yet to be implemented. IREC's approval is required before its implementation.

Database – an excel file containing a chronological record of incoming study documents that includes the (1) Date of Receipt, (2) IREC Code, (3) Name of the Proponent, (4) Course/Unit of the Proponent, (5) Title of the Study, (6) Research Adviser/Point Person, (7) Type of Review, (8) Name of the Reviewers, (9) Action done, (10) Date Conveyed, and (11) Documents Submitted

Expedited Review – is the ethical evaluation of a research proposal, other study documents, or a resubmission and after-approval submissions, conducted by only two members of the committee.

Full Review – is the ethical evaluation of a research proposal, other study documents, or a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria

IREC - Institutional Research Ethics Committee

Other Study Documents – refer to documents supporting the research proposal, such as guide questions/questionnaire, informed consent form, required IREC forms, and other attachments necessary to evaluate the ethical procedure of research

7. Forms

IREC Form 14: Application for Ethics Review of Amendments

IREC Form 26: Protocol Index

IREC Database

8. History

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft
2	2023 February 3	IREC 2022	Policy statement, objective of the activity, scope, workflow,

			description of procedures, glossary, forms, references, styling

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Ateneo de Naga University - Institutional Research Ethics Committee. (2022). *IREC Memo 2022-01*.

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02 Date of Approval: February 3, 2023 Date of Effectivity: February 10, 2023	**SOP No. 11** **Review of Protocol Deviations and/or Violations**

1. Policy Statement

The ADNUGERR 2020 states that IREC must ensure that research conducted in the University complies with existing ethical standards and requirements. Thus, IREC adopts the definitions put forth by the Council for International Organizations of Medical Sciences [CIOMS] (2016) and the National Ethics Committee (2022). Protocol deviations, whether major or minor, and violations may occur from the original IREC-approved study protocol affecting study participants' rights or interests or impacting the study's scientific validity (CIOMS, 2016). The source or cause of the deviation may come from the participant, researcher, or others (National Ethics Committee, 2022). Thus, deviations and violations, whether unintentional or deliberate, must be reported to IREC immediately for review. The researcher should not proceed with the research project until IREC evaluates that the participants are not put at risk of harm. Deviation/violation of protocol that may affect the research's scientific validity or study participants' rights or interests is subject to continuing review by IREC.

2. Objective of the Activity

The provisions of "review of protocol deviations" aims to ensure that the safety and welfare of human participants in the study are safeguarded and that the credibility and integrity of data are maintained.

3. Scope

SOP 11 applies to the review of reports of protocol deviations or violations in the conduct of approved ongoing studies. SOP 11 begins with the receipt and documentation of reports of protocol deviations and violations in the IREC database and ends with the filing of all related documents and updating the database.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Receipt of Protocol Deviation/Violation Report (SOP 21 on Management of Active Files)	IREC AA
Step 2: Retrieval of Pertinent Study Documents and Endorsement to the Chair	IREC AA
Step 3: Determination of Type of Review	IREC Chair
Step 4: Review of Protocol Deviation/Violation (SOP 07 on Expedited Review or SOP 08 on Full Review)	Primary Reviewer & Co-Reviewer & IREC Chair/Full Committee
Step 5: Filing of documents and Update the Database (SOP 21 on Management of Active Files)	IREC AA

5. Description of Procedures

Step 1 - **Receipt Protocol Deviation or Violation Report**: The IREC AA receives the report on protocol deviation or violation as an attachment to the application for continuing ethics review, checks the completeness of submission, and records this into the database.

Step 2 - **Retrieval of Pertinent Study Documents and Endorsement to the Chair**: IREC AA retrieves the pertinent study documents and endorses them to the IREC Chair.

Step 3 - **Determination of Type of Review:** The IREC Chair validates the endorsement of the IREC AA on the completeness of the study documents, determines the type of review, and communicates to the Primary Reviewer and Co-Reviewer.

Step 4 - **Review of Protocol Deviation/Violation:** The Primary Reviewer and Co-Reviewer are given, at most, three (3) days to review the deviation/violation report. The review of the protocol deviation/violation report is a necessary step to decide on the application for continuing ethics review. Study documents will undergo the same process as the initial review (see SOP 7: Expedited Review and SOP 8: Full Review). The review of the protocol deviation/violation report is the basis for the Committee's action on the application for continuing review, which may be: (1) Uphold original approval/ethical clearance, (2) additional justification/information required, (3) need for corrective action, and (4) cancellation of ethical clearance.

Step 5 – **Filing of Documents and Update the Database:** IREC AA files the protocol deviation or violation and related reports in the appropriate digital folder. S/he proceeds to update the pertinent IREC database.

6. Glossary

AA - Administrative Assistant

Additional justification/information required - is a temporary decision given by IREC when the details of the deviation/violation are inadequate, or there is a need for an explanation of why and how the deviation/violation happened (National Ethics Committee, 2022)

ADNUGERR - Ateneo de Naga University Guidelines for Ethics Review of Research

Cancellation of ethical clearance - is the decision made by IREC when it stops the continuation of a previously approved protocol. This is decided upon when it finds grave protocol violations or other misconduct on the part of the researcher/s. With the cancellation of the ethical clearance, IREC will report the serious or continuing non-compliance with ethical standards in the conduct of previously approved research projects to the appropriate university authority, i.e., in the case of GS/COL student, the GS/COL Dean who will constitute the Ad Hoc Disciplinary Committee as provided on p. 37 of the ADNU GS Student Handbook; and in the case of administrator, faculty, or staff member, the URC Chairperson and the HRMO Director who will recommend the constitution of the Grievance Committee. When IREC has been accredited, a serious violation of external researchers shall be reported to the sponsor and institutional or governmental authorities (CIOMS, 2016).

Clarificatory meeting - a meeting or consultation of IREC with the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the Committee.

Corrective action required - refers to IREC's decision requiring the researcher to implement corrective action (e.g., new informed consent form, additional information/letter of apology to the study participants, additional procedure, e.g., debriefing of study participants, etc.) so that the deviation/violation will not be repeated (National Ethics Committee, 2022). Ethical clearance is suspended until corrective action has been satisfied.

Database – an excel file containing a chronological record of incoming study documents that includes the (1) Date of Receipt, (2) IREC Code, (3) Name of the Proponent, (4) Course/Unit of the Proponent, (5) Title of the Study, (6) Research Adviser/Point Person, (7) Type of Review, (8) Name of the Reviewers, (9) Action done, (10) Date Conveyed, and (11) Documents Submitted

Digital Folder – is an organized electronic compilation of all documents related to the research proposal.

Deviation from the approved research plan or protocol - is a form of noncompliance with the conditions of IREC clearance and may cause the IREC to revisit the approval (NEGRIHP, 2022).

Expedited Review- is the ethical evaluation of a research proposal and other study documents, a resubmission, and after-approval submissions, conducted by two members of the committee

Full Review - is the ethical evaluation of a research proposal, other study documents, or a resubmission and after-approval submissions, conducted by IREC en banc, in the presence of a quorum, using established technical and ethical criteria

IREC - Institutional Research Ethics Committee

Minor protocol deviation - refers to non-systematic protocol noncompliance with minor consequences to the participant's/subject's rights, safety or welfare, or the integrity of study data. It includes deviations that are administrative in nature (Department of Health – Health Policy Development and Planning Bureau [DOH-HPDPB], 2021)

Major protocol deviation - refers to persistent protocol noncompliance with potentially serious consequences that could critically affect data analysis or put study participants' safety at risk (DOH-HPDPB, 2021)

Other Study Documents – refer to documents supporting the research proposal, such as guide questions/questionnaire, informed consent form, required IREC forms, and other attachments necessary to evaluate the ethical procedure of research protocol or deviation from the approved protocol that does not increase risk or decrease benefit to participants or does not significantly affect their rights, safety or welfare or the integrity of data. Examples are missed visits, non-submission of a food diary on time

Protocol Violation - non-compliance with the approved protocol that increases risk or decreases benefit to participants or significantly affects their rights, safety or welfare, or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria

Uphold original approval/ethical clearance - is the decision communicated to the researcher when the protocol deviations/violations are minor, and there is no negative impact on the risk-benefit ratio and integrity of data. No further action is required. (DOH-HPDPB, 2021; National Ethics Committee, 2022).

7. Forms

IREC Form 15: Protocol Violation/Deviation Report

IREC Form 26: Protocol Index

IREC Database

8. History of SOP

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft
2	2023 February 3	IREC 2022	Policy statement, scope, workflow, description of procedures, glossary, references, styling

9. References

Ateneo de Naga University (2013). Ateneo de Naga University Staff Manual.

Ateneo de Naga University (2018). Ateneo de Naga University Graduate School Student Handbook.

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

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Council for International Organizations of Medical Sciences (CIOMS). (2016). International ethical guidelines for health-related research involving humans (4th Ed.). https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

Philippine Council for Health Research and Development-National Ethics. Committee. (2022, March). National Ethics Committee standard operating procedures. https://nec.pchrd.dost.gov.ph/index.php/download/category/2-standard-operating-procedures?download=15:nec-sop-4th-edition-18-march-2022

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 01 Date of Approval: January 12, 2023 Date of Effectivity: January 19, 2023	**SOP No. 12** **Review of Safety Reports**

1. Policy Statement

The ADNUGERR 2020 states that IREC must ensure that research conducted in the University complies with existing ethical standards and requirements. Thus, IREC adopts the guidelines on safety reports put forth in the 2022 National Ethical Guidelines for Research Involving Human Participants. This policy applies to clinical studies, e.g., comparing different therapy techniques and administration of drugs, among others. IREC is required to monitor safety reports for these particular studies. IREC provides the report forms for serious adverse events (SAE) or suspected unexpected serious adverse reactions (SUSAR) that may be used by the researchers. The form includes the determination of the expectedness of an SAE/SUSAR and its relationship to the drug, health product, or device used in research. If the study is trial-related, IREC determines what action to take, including the appropriate medical/clinical management of the participants.

2. Objective of the Study

The provisions of "review of safety reports" aim to ensure that the conduct of the studies complies with the approved protocol, the measures for the safety and welfare of study participants are in place, and the integrity and credibility of the data are maintained.

3. Scope

SOP 12 applies to the review of safety reports in the conduct of previously approved studies. SOP 12 begins with the receipt and documentation of the SAE/SUSAR report in the IREC database and ends with filing all related documents and updating the database.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Receipt of the SAE/SUSAR Reports and Input of Received Documents into the IREC Database	IREC AA

Step 2: Retrieval of Study Documents and Endorsement to the IREC Chair	IREC AA
Step 3: Full Review (SOP 08 Full Review)	IREC
Step 4: Communication of Committee Action (SOP 20 on Documentation of IREC Actions)	IREC Chair
Step 5: Filing of Documents in the Appropriate Document Folder and Updating the IREC Database	IREC AA

5. Description of Procedures

Step 1 - Receipt of the SAE/SUSAR Reports and Input of Received Documents into the IREC Database: The IREC AA receives the SAE/SUSAR report and records this in the database as incoming documents.

Step 2 - Retrieval of Study Documents and Endorsement to the IREC Chair: The IREC AA retrieves the corresponding study document as a reference in reviewing safety reports. S/he then endorses these to the IREC Chair for appropriate action.

Step 3 - Full Review: The IREC Chair and Members deliberate on the implication of the SAE/SUSAR Report on the rights, safety, and welfare of the study participants. It determines if the plan for termination includes a termination package with a set of procedures, i.e., to adopt specific provisions for continued access to protective mechanisms and information of the study participants. IREC's decision is either an acceptance of the original decision with no further action, a request for additional information, or a requirement for further action (SOP 08 on Full Review).

Step 4 - Communication of Committee Action (SOP 20 on Documentation of IREC Actions): The IREC Chair sends the decision to the researcher via email. She/he furnishes the adviser or the designated point person and the unit head where the researcher belongs (SOP 20 Documentation of IREC Actions) a copy of the decision.

Step 5 - Filing Documents in the Appropriate Document Folder and Updating the IREC Database: The IREC AA files the decision and related documents and updates the IREC database accordingly (SOP 21 Management of Active Files).

6. Glossary

AA - Administrative Assistant

Database – an excel file containing a chronological record of incoming study documents that includes the (1) Date of Receipt, (2) IREC Code, (3) Name of the Proponent, (4) Course/Unit of the Proponent, (5) Title of the Study, (6) Research Adviser/Point Person, (7) Type of Review, (8) Name of the

Reviewers, (9) Action done, (10) Date Conveyed, and (11) Documents Submitted

Digital Folder – is an organized electronic compilation of all documents related to the research proposal

IREC - Institutional Research Ethics Committee

Serious Adverse Event (SAE) – is an event observed during the implementation of a study where the outcome is any of the following:

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability or permanent damage
- Congenital anomaly/birth defects
- Required intervention/a device to prevent permanent impairment or damage
- Other serious (important medical) events which may or may not be related to the study intervention

Suspected Unexpected Serious Adverse Reactions (SUSAR) - These are some serious adverse reactions experienced by the research participants who took the drugs under study. The reactions, which may or may not be dose-related, are unexpected or unanticipated since these reactions are not consistent with the current information about the medicinal product in question.

Study Documents – refer to the proposal, guide questions/questionnaires, informed consent form, required IREC forms, and other attachments necessary to evaluate the ethical procedure of research

7. Forms

IREC Form 29: SAE/SUSAR Report Form

IREC Form 26: Protocol Index

IREC Database

8. History

Version Number	Date	Authors	Change/s
1	2023 January 12	IREC 2022	First draft

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02 Date of Approval: January 20, 2023 Date of Effectivity: January 27, 2023	**SOP No. 13** **Submission of the Final Report**

1. Policy Statement

ADNUGERR 2020 states that the advancement of human knowledge toward a better appropriation of truth is the highest aim of any conduct of research. To ensure that researchers consistently uphold this goal in every aspect and stage of their research project, IREC requires the researchers to submit to IREC a pdf copy of the final research report one week after it has been approved by the technical review panel/granting unit. The research report should include the approval/acceptance sheet issued by the technical review panel/granting unit.

2. Objective of the Activity

The provisions of the "submission of the final report" aim to ensure that the conduct of the study was in compliance with the approved protocol, that measures to protect the rights and welfare of study participants were in place, and that the integrity of data was protected until the end of the study.

3. Scope

SOP 13 applies to the checking of the final reports submitted by researchers at the end of the study. SOP 13 begins with the receipt and entry of the final report into the database and ends with updating the IREC database.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Receipt of Final Report Form and the Final Research Report and Entry into the Database (SOP 21 on Management of Active Files)	IREC AA
Step 2: Retrieval of Pertinent Study Documents	IREC AA
Step 3: Checking of the Final Report vis-a-vis IREC Recommendations and Endorsement of the Final	IREC AA

Report to the IREC Chair for approval/acceptance or further actions	
Step 4: Confirmation of IREC AA's Endorsement and Communication of the Committee's Acceptance/ Notation	IREC CHAIR
Step 5: Filing the Final Research Report and Updating the Database	IREC AA

5. Description of Procedures

Step 1 - **Receipt of the Final Report Form and the Final Research Report and Entry into the Database** (SOP 21 on Management of Active Files): The IREC AA receives the accomplished Final Report Form and the final dissertation/thesis/research report with the approval/acceptance page signed by the technical review panel/granting unit. S/he then records the date of receipt in the database.

Step 2 - **Retrieval of Pertinent Study Documents**: The IREC AA retrieves the corresponding study documents as references in the review of the final report.

Step 3 **- Checking the Final Report vis-a-vis IREC Recommendations and Endorsement to the IREC Chair:** Once all documents received are found complete, the IREC AA checks the final report vis-a-vis IREC recommendations. When everything is in order, s/he endorses the documents to the IREC Chair for his/her approval. S/he also notes the recommendations that were not complied with.

Step 4 - **Confirmation of IREC AA's Endorsement and Communication of Committee's Acceptance/Notation:** The IREC Chair confirms the IREC AA's endorsement by checking/noting noncompliance. S/he then communicates to the researcher, adviser, and the Graduate School the acceptance or notation about the noncompliance of the recommendations.

Step 5 - **Filing the Final Research Report and Updating the Protocol Database:** The IREC AA files the Final Research Report and study documents in the appropriate folder and updates the IREC database.

6. Glossary

AA - Administrative Assistant

ADNUGERR - Ateneo de Naga University Guidelines for Ethics Review of Research

Database – an excel file containing a chronological record of incoming study documents that includes the (1) Date of Receipt, (2) IREC Code, (3) Name of the Proponent, (4) Course/Unit of the Proponent, (5) Title of the Study, (6) Research Adviser/Point Person, (7) Type of Review, (8) Name of the

Reviewers, (9) Action done, (10) Date Conveyed, and (11) Documents Submitted

Final Report - the accomplished Final Report Form and the final research report.

Final Research Report– is either the final approved thesis/dissertation of the student researcher or the final technical report in the case of research under the URC

IREC - Institutional Research Ethics Committee

Study Documents – refer to the proposal, guide questions/questionnaire, informed consent form, required IREC forms, and other attachments necessary to evaluate the ethical procedure of research

7. Forms

IREC Form 11: Final Report Form

IREC Form 26: Protocol Index

IREC Database

8. History

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft
2	2023 January 20	IREC 2022	Policy statement, scope, workflow, description procedures, glossary, forms, references, styling

9. References

Ateneo de Naga University (2020). Guidelines for Ethics Review of Research. https://www.adnu.edu.ph/irec/

Philippine Health Ethics Review Board (PHREB) (2020). 2020 PHREB standard operating procedures. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). National Ethical Guidelines for Research Involving Human Participants 2022. Philippine

Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02 Date of Approval: January 20, 2023 Date of Effectivity: January 27, 2023	**SOP No. 14** **Review of Early Termination Reports**

1. Policy Statement

ADNUGERR 2020 states that IREC must ensure that research conducted in the University complies with existing ethical standards and requirements. Thus, IREC adopts the provisions under the National Ethical Guidelines for Research Involving Human Participants (2022) on researches which are terminated earlier than expected. When a decision for early termination of the research has been made by the researcher, the well-being and safety of study participants that have already been recruited shall be a primary consideration, and the plan for termination shall reflect this concern. Early termination reports shall undergo full review.

2. Objective of the Activity

The provisions of "review of early termination reports" aim to ensure that the decision to terminate research takes into consideration the safety and welfare of study participants that have already been recruited. The procedures for termination should exercise fairness for all concerned.

3. Scope

SOP 14 applies to the review of early termination reports. SOP 14 begins with the receipt and entry to the database of the early termination reports and ends with the communication of committee action to the researcher/investigator and updating of the IREC database.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Receipt of the Early Termination Report and Entry into the Database (SOP 21 Management of Active Files)	IREC AA
Step 2: Retrieval of Study Documents and Endorsement to the IREC Chair	IREC AA

Step 3: Assignment of Primary and Co-Reviewers	IREC Chair
Step 4: Full review (SOP 08 on Full Review)	IREC
Step 5: Communication of Committee Action (SOP 20 Documentation of IREC Actions)	IREC Chair
Step 6: Update the IREC Database (SOP 21 Management of Active Files)	IREC AA

5. Description of Procedures

Step 1 - **Receipt of the Early Termination Report and Entry into the Database**: The IREC AA receives the Early Termination Report (IREC Form 16) and enters the appropriate information into the database (SOP 21 Management of Active Files).

Step 2 - **Retrieval of Study Documents and Endorsement to the IREC Chair**: The IREC AA retrieves the study documents and summarizes the documents that have been submitted. S/he then endorses the documents to the IREC Chair for appropriate action.

Step 3 - **Assignment of Primary and Co-Reviewers**: The IREC Chair assigns the Primary Reviewer and Co-Reviewers.

Step 4 - **Full review**: The IREC Chair and Members deliberate. The review shall deliberate on the implication of the early termination on the rights, safety, and welfare of the study participants. It should determine if the plan for termination includes a termination package with a set of procedures. The procedures may include adapting specific provisions for continued access to protective mechanisms and information by the study participants. IREC considers either an Acceptance of the decision with no further action, a Request for additional information, or a Requirement for further action (SOP 08 on Full Review).

Step 5 - **Communication of Committee Action**: The IREC Chair, through email, communicates the decision to the Researcher. The Adviser or the Designated Point Person and the Head of the Unit where the Researcher belongs (SOP 20 Documentation of IREC Actions) are copy-furnished of this decision.

Step 6 - **Update of the IREC Database:** The IREC AA files the decision and related documents and updates the IREC database accordingly (SOP 21 Management of Active Files).

6. Glossary

AA - Administrative Assistant

ADNUGERR - Ateneo de Naga University Guidelines for Ethics Review of Research

Database – an excel file containing a chronological record of incoming study documents that includes the (1) Date of Receipt, (2) IREC Code, (3) Name of the Proponent, (4) Course/Unit of the Proponent, (5) Title of the Study, (6) Research Adviser/Point Person, (7) Type of Review, (8) Name of the Reviewers, (9) Action done, (10) Date Conveyed, and (11) Documents Submitted

Designated Point Person – refers to the official faculty assigned to the research proponent/s who has an approved grant from the University Research Council

Early Termination - refers to the decision of the researcher, principal investigator, institution, or sponsor to end the implementation of a study before its completion

Full Review – is the ethical evaluation of a research proposal and other study documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria

IREC - Institutional Research Ethics Committee

Research Adviser – the official faculty assigned to guide the student researcher in the whole process of conducting her/his thesis/dissertation

Study Documents – refer to the proposal, guide questions/questionnaire, informed consent form, required IREC forms, and other attachments necessary to evaluate the ethical procedure of research

Termination package - refers to the entitlements of study participants in the event of discontinuance of the study, which can come in the form of access to the study intervention, treatment, or information, for purposes of adherence to the principle of fairness for all concerned

7. Forms

IREC Form 16: Early Termination Report Form

IREC Form 26: Protocol Index

IREC Database

8. History

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft
2	2023 January 20	IREC 2022	Policy statement, objective of the activity, workflow, description of

			procedures, glossary, forms, references, styling

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02 Date of Approval: September 22, 2022 Date of Effectivity: September 29, 2022	**SOP No. 15** **Site Visits**

1. Policy Statement

The ADNUGERR 2020 under Section VII titled “Research Ethics Review Procedure” states that IREC will conduct site visits as part of continuing review. If necessary, IREC members or a designated representative may do an onsite visit or audit of ongoing and completed studies. These site visits may be done where there is a significant number of serious adverse events related to or affecting the study, non-compliance to the ethics procedures, suspicious conduct, or failure to submit required reports, among others.

2. Objective of the Activity

The provisions of "site visits" monitor compliance with approved protocols and the consent process. SOP 15 ensures that research proponents provide continuing protection and promotion of participants' dignity, rights, and well-being.

3. Scope

SOP 15 includes the steps for conducting visits to study sites for reasons decided by IREC. SOP 15 begins with the selection of the site to be visited and ends with the filing of Site Visit Reports in the document folder and updating the IREC database.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Decision to Conduct Site Visit	IREC
Step 2: Notification and Seeking the Consent of the Researcher	IREC AA

Step 3: Retrieval of Study Documents	IREC AA
Step 4: Creation of Site Visit Team	IREC Chair
Step 5: Conduct a Site Visit	Site-Visit Team (IREC Members)
Step 6: Draft of a Report and Its Presentation	Site Visit Team Head
Step 7: Transmittal of Final Report and Recommendations to the Researcher/Investigator	IREC Chair
Step 8: Filing of Site-Visit Reports and Updating of IREC Database	IREC AA

5. Description of Procedures

Step 1 - **Decision to conduct Site Visit**: IREC decides to conduct a site visit based on the presence of any of the following criteria: consistent non-submission or failure to submit after-approval requirements, reports of major protocol noncompliance, a significant number of serious adverse events, or reports of complaints from study participants.

Step 2 - **Notification and Seeking the Consent of the Researcher**: IREC shall email the researcher to express its intent to visit the research site. This shall include a date and time for the visitation. The researcher agrees to the scheduled date.

Step 3 - **Retrieval of Study Documents**: The IREC AA retrieves the study document for reference during the site visit. The file includes the initially submitted ICF, research tools, and other related documents.

Step 4 - **Creation of Site Visit Team**: The Chair assigns three members of the Committee to conduct the site visit. A head of the team shall also be named.

Step 5 - **Conduct of Site Visit**: The team makes use of the site visit monitoring form (Form 05) to assess the compliance with approved protocols, consent process, and continuing protection and promotion of the participant's dignity, rights, and well-being or to ascertain the veracity of the report on serious adverse events or complaints of study participants. The Team reviews the informed consent to see if an updated version is being used, examines the study files, observes the informed consent process if possible, inspects the study site, and interviews participants.

Step 6 - **Draft of a Report and Its Presentation**: The Team Head shall finalize the report based on the agreed observations and recommendations provided

by all the team members. The findings and recommendations shall be presented to the IREC Chair and other members for approval/acceptance. The final recommendation shall be a consensus of the IREC Chair and Members.

Step 7 - **Transmittal of the Final Report and Recommendations to the Researcher/ Investigator:** The IREC Chair emails the findings and recommendations of the Committee to the Researcher with a copy furnished to the Head of the unit where the researcher belongs and the Research Adviser when applicable (SOP 20 Documentation of IREC Actions).

Step 8 - **Filing of Site-Visit Reports and Updating of Protocol Database**: The IREC AA files the Site Visit Report and recommendations in the appropriate folder and updates the IREC database accordingly (SOP 21 Management of Active Files).

6. Glossary

AA - Administrative Assistant

ADNUGERR - Ateneo de Naga University Guidelines for Ethics Review of Research

After-approval reports – are reports, e.g., progress reports, protocol deviation/violation reports, amendment, early termination reports, final reports, and applications for continuing review, required by the IREC for submission by the researcher/investigator after the study has been approved for implementation

Database – an excel file containing a chronological record of incoming study documents that includes the (1) Date of Receipt, (2) IREC Code, (3) Name of the Proponent, (4) Course/Unit of the Proponent, (5) Title of the Study, (6) Research Adviser/Point Person, (7) Type of Review, (8) Name of the Reviewers, (9) Action done, (10) Date Conveyed, and (11) Documents Submitted

Decision - the result of the deliberations of IREC in the review of study documents or other submissions

IREC - Institutional Research Ethics Committee

Protocol Violation - non-compliance with the approved protocol that may result in increased risk or decreased benefit to participants that significantly affects their rights, safety, welfare, or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria

Site Visit - is an action of IREC based on the established criteria in which an assigned team goes to the research site or office for specific monitoring purposes

Study Documents – refer to the proposal, guide questions/questionnaire, informed consent form, required IREC forms, and other attachments necessary to evaluate the ethical procedure of research

7. Forms

IREC Form 05: Site Visit Monitoring Form

IREC Form 26: Protocol Index

IREC Database

8. History of SOP

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft
2	2022 September 22	IREC 2022	Policy statement, workflow, description of procedures, glossary, forms, references, styling

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02 Date of Approval: February 17, 2023 Date of Effectivity: February 24, 2023	**SOP No. 16** **Management of an Application for Continuing Review**

1. Policy Statement

The ADNUGERR 2020 Section VII, titled “Research Ethics Review Procedure,” states that research proponents can apply for continuing review of approved research projects. Continuing review is issued for approved research projects where the research procedures were modified. The review will be conducted once a year until the end of the project. Still, it may increase upon IREC’s recommendation depending on the appraisal of the degree of risk to the subjects posed by the research procedures.

2. Objective of the Activity

The provisions of "management of an application for continuing review” aim to ensure that the conduct of the study complies with the approved protocol, that the measures for the safety and welfare of study participants are in place, and the integrity of data is protected until the study is completed.

3. Scope

SOP 16 applies to the application for continuing reviews for studies that are not yet completed. This SOP begins with the receipt of an application for continuing review and ends with the entry to the database.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Receipt of the Application for Continuing Review and Entry into the Database (SOP 21 Management of Active Files)	IREC AA
Step 2: Retrieval of Pertinent Study Documents and Endorsement to the Chair	IREC AA
Step 3: Validation of Endorsement and Determination of Type of Review	IREC Chair

Step 4: Review of Application for Continuing Review (SOP 07 on Expedited Review or SOP 08 on Full Review)	Primary Reviewer & Co-Reviewer & IREC Chair/Full Committee
Step 5: Communication of Committee Action (SOP 20 on Documentation of IREC Actions)	IREC Chair
Step 6: Filing Documents in the Appropriate Document Folder	IREC AA

5. Description of Procedures

Step 1 - **Receipt of the Application for Continuing Review and Entry into Database**: The IREC AA receives the application for Continuing Review (IREC Form 4) and enters the information in the IREC database.

Step 2 - **Retrieval of Pertinent Study Documents and Endorsement to the Chair**: IREC AA retrieves the corresponding study documents and endorses these to the Chair.

Step 3 - **Validation of Endorsement and Determination of Type of Review**: The IREC Chair validates the endorsement of the IREC AA on the completeness of the study documents, determines the type of review, and communicates to the Primary Reviewer and Co-Reviewer.

Step 4 - **Review of Application for Continuing Review (SOP 07 on Expedited Review or SOP 08 on Full Review):** Uncompleted research projects where the procedures had been modified shall undergo a new review. Using IREC Form 04 (Application for Continuing Ethics Review) and IREC Form 15 (Protocol Deviation or Violation Report) or IREC Form (Application for Ethics Review of Amendments), the Primary Reviewer and Co-Reviewer are given at most three (3) days for the review. Study documents that underwent Full Review in their initial submission shall undergo Full Review in their application for Continuing Review. Similarly, study documents that underwent Expedited review shall undergo Expedited review in their application for continuing review (see SOP 7: Expedited Review and SOP 8: Full Review).

Step 5 - **Communication of Committee Action:** The IREC Chair drafts the decision and has this reviewed by the two IREC reviewers. The IREC Chair, through email, communicates the decision to the research proponent/s with a copy furnished to the Research Adviser (for student researchers) or designated point person (for administrators, faculty/staff). The Committee's action may be any of the following: (1) Uphold original approval/ethical clearance, (2) Require additional justification/information and/or corrective action, and (4) Cancel ethical clearance.

Step 6 – **Filing Documents in the Appropriate Document Folder:** The IREC AA files the application for Continuing review, the recommendations of the reviewers, and the decision letter in the appropriate document folder.

6. Glossary

AA - Administrative Assistant

ADNUGERR - Ateneo de Naga University Guidelines for Ethics Review of Research

Continuing Review - is the decision of the IREC to extend the ethical clearance of a study based on an assessment that the research is proceeding according to the approved study documents and there is a reasonable expectation of its completion

Database – an excel file containing a chronological record of incoming study documents that includes the (1) Date of Receipt, (2) IREC Code, (3) Name of the Proponent, (4) Course/Unit of the Proponent, (5) Title of the Study, (6) Research Adviser/Point Person, (7) Type of Review, (8) Name of the Reviewers, (9) Action done, (10) Date Conveyed, and (11) Documents Submitted

Expedited Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission, and after-approval submissions, conducted by only 2-3 members of the committee without the involvement of the whole committee

Full Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission, and after-approval submissions, conducted by the IREC en banc, in the presence of a quorum, using established technical and ethical criteria

IREC - Institutional Research Ethics Committee

Study Documents – refer to the proposal, guide questions/questionnaire, informed consent form, required IREC forms, and other attachments necessary to evaluate the ethical procedure of research

7. Forms

IREC Form 04: Continuing Ethics Review Form

IREC Form 13: Application for Ethics Review of Progress Reports

IREC Form 26: Protocol Index

IREC Database

8. History

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft
2	2023 February 17	IREC 2022	Policy statement, scope, workflow, description of procedures, glossary, forms, references, styling

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02 Date of Approval: January 14, 2023 Date of Effectivity: January 21, 2023	**SOP No. 17** **Management of Appeals**

1. Policy Statement

The ADNUGERR 2020 Section VII, titled "Research Ethics Review Procedure" states that a researcher may appeal the decision of the IREC whenever there is information related to the ethics issue at hand that the IREC should know and could use as a basis for revising its decision on any of the following: (a) there were procedural irregularities that occurred during the deliberation; and (b) there is demonstrable evidence of prejudice, bias, or inadequate review.

2. Objective of the Activity

The provisions of "management of appeals" ensure fairness, transparency, and comprehensiveness of ethics review that takes into consideration the perspective of the researcher.

3. Scope

SOP 17 on "management of appeals" covers procedures that begin with the receipt of the appeal and end with communicating the committee's action to the researcher and updating the database.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Receipt of an Appeal	IREC AA
Step 2: Retrieval of Study Document and Endorsement to the IREC Chair	IREC AA
Step 3: Full review (SOP 08 on Full Review)	IREC
Step 4: Communication of Committee Action (SOP 20 Documentation of IREC Actions)	IREC Chair
Step 5: Filing of Documents and Updating the IREC Database	IREC AA

5. Description of Procedures

Step 1 - **Receipt of an Appeal:** The IREC AA receives the letter of appeal through a letter/ an email from the appellant and enters the pertinent information into the database. S/he then reviews if the appeal contains the following pertinent information: (a) The title of the research proposal; (b) The name of the adviser, if appropriate; (c) The decision to be appealed; and (d) An explanation of the points for reconsiderations.

Step 2 - **Retrieval of Study Document and Endorsement to the IREC Chair**: The IREC AA retrieves the study document for reference in the review. The file includes the initially submitted protocol, ICF, research tools, and other related documents. S/he then endorses these files to the IREC Chair for appropriate action.

Step 3 - **Full review**: The IREC Chair and Members deliberate on the implication of the early termination on the rights, safety, and welfare of the study participants. They should determine whether (a) there were procedural irregularities that occurred during the deliberation, which raise a concern whether the same decision would have been arrived at if the irregularities had not happened; (b) there is demonstrable evidence of prejudice, bias, or inadequate review; and (c) if the plan for termination includes a termination package with a set of procedures. The procedures may include adapting specific provisions for continued access to protective mechanisms and information by the study participants. IREC considers either an Acceptance of the decision with no further action, a Request for additional information, or a Requirement for further action (SOP 08 on Full Review).

Step 4 - **Communication of Committee Action:** The IREC Chair drafts the decision letter and distributes copies for review by the IREC Members. The IREC Chair communicates the decision to the research proponent through email with a copy furnished to the Research Adviser/Designated Point Person and the academic unit head where the research proponent belongs.

Step 5 - **Filing of Documents and Update of IREC Database:** The IREC AA files all the documents into the appropriate folder and updates the IREC database accordingly.

6. Glossary

AA - Administrative Assistant

ADNUGERR - Ateneo de Naga University Guidelines for Ethics Review of Research

Appeal – a request of a researcher/ investigator for a reconsideration of the IREC recommendation.

Database – an excel file containing a chronological record of incoming study documents that includes the (1) Date of Receipt, (2) IREC Code, (3) Name of

the Proponent, (4) Course/Unit of the Proponent, (5) Title of the Study, (6) Research Adviser/Point Person, (7) Type of Review, (8) Name of the Reviewers, (9) Action done, (10) Date Conveyed, and (11) Documents Submitted

ICF - Informed Consent Form

IREC - Institutional Research Ethics Committee

Study Documents – refer to the proposal, guide questions/questionnaire, informed consent form, required IREC forms, and other attachments necessary to evaluate the ethical procedure of research

7. Forms

IREC Form 26: Protocol Index

IREC Database

8. History

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft
2	2023 January 14	IREC 2022	Policy statement, workflow, description of procedures, glossary, forms, references, styling

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02 Date of Approval: January 14, 2023 Date of Effectivity: January 21, 2023	**SOP No. 18** **Preparing for a Meeting with the Meeting Agenda**

1. Policy Statement

The Revised ADNUGERR states that IREC shall maintain the confidentiality of the documents and deliberations of IREC meetings.

2. Objective of the Activity

The provisions of "preparing for a meeting" aim to contribute to the smooth, orderly, and efficient conduct of meetings.

3. Scope

SOP 18 covers all activities before the conduct of an IREC meeting and determines what items are to be included in the agenda of regular and special meetings. SOP 18 begins with the preparation of the draft meeting agenda and ends with the notification of IREC Members and confirmation of attendance.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Setting of Regular Meeting Schedule and Provision for Special Meetings	IREC
Step 2: Preparation of the Agenda and Draft of the Meeting Agenda	IREC AA
Step 3: Approval of Meeting Agenda and Notice to Members	IREC Chair
Step 4: Filing of Final Meeting Agenda (SOP 21 on Management of Active Files)	IREC AA
Step 5: Preparation of Documents and Logistical Requirements for the Meeting	IREC AA
Step 6: Notification of IREC Members and Confirmation of Attendance	IREC AA and Members

5. Description of Procedures

Step 1 - **Setting of Regular Meeting Schedule and Provision for Special Meetings**: Since the IREC Members are full-time faculty, IREC has to set the regular meeting schedule at the start of the semester. The regular meeting schedule should be at least once a month. The IREC also meets as soon as new proposals are submitted. If the submission of a proposal does not coincide with a regular meeting schedule, a special meeting is called. All meetings should not be more than two times per week.

Step 2 - **Preparation of the Agenda and Draft of the Meeting Agenda:** The Chair prepares the agenda if the concern is about submitted study documents, and the agenda of the meeting will solely focus on it. However, if there are no submitted study documents, the agenda includes the following: (1) Declaration of Quorum and Provisional Agenda, (2) Declaration of Conflict of Interest, (3) Review and Approval of the Minutes of the Previous Meeting, (4) Update of Business Arising from Previous Minutes, (5) New Business. Other than the former, the agenda shall be agreed upon by IREC Chair and Members. The IREC AA, in consultation with the IREC Chair, prepares a draft agenda one (1) week before the scheduled meeting using the Notice of Meeting with Provisional Agenda Template (IREC Form 23).

Step 3 - **Approval of Meeting Agenda and Notice to Members**: The IREC Chair approves the provisional agenda in consultation with the IREC Members and sends notice of the meeting to the members through email within three days before the meeting. The provisional agenda is included in the Notice of Meeting (see IREC Form 23 - Notice of Meeting with Provisional Agenda Template).

Step 4 - **Filing of the Final Meeting Agenda**: The IREC AA files the final (approved) meeting agenda in a special folder that contains all meeting agendas in chronological order. (See SOP 21 Management of Active Files).

Step 5 - **Preparation of Documents and Logistical Requirements for the Meeting**: The IREC AA ensures that documents, e.g., study documents, attendance sheet, minutes of the previous meeting for approval, and logistical requirements (e.g., GMeet links) were sent; internet connectivity is available; laptop and other pertinent materials are prepared for the meeting.

Step 6 - **Notification of IREC Members and Confirmation of Attendance**: The IREC AA, in consultation with the IREC Chair, prepares a Notice of Meeting with Provisional Agenda (IREC Form 23). The IREC AA sends notice of the meeting, including required attachments to members of the committee at least three (3) days before the schedule and follows up on confirmation of attendance to ensure a quorum. In case a quorum cannot be met, the IREC AA informs the Chair, and a new schedule is set.

6. Glossary

AA - Administrative Assistant

ADNUGERR - Ateneo de Naga University Guidelines for Ethics Review of Research

Agenda- the list of topics or items to be taken up in a meeting arranged sequentially. It is an outline of the meeting procedure.

Conflict of Interest - a situation in which aims or concerns of two (primary and secondary) different roles or duties are not compatible such that decisions may adversely affect the official/primary duty

Final Meeting Agenda - is the order of business that includes the list of topics or items approved for discussion in a meeting by the IREC Members in a regular or special meeting

IREC - Institutional Research Ethics Committee

Provisional Meeting Agenda – this is the order of business that includes the list of topics or items approved for discussion in a meeting by the IREC Chair. The deliberation of submitted study documents is always given priority.

Quorum – the minimum number (i.e., majority of the members or 50%+1) and type of members of the IREC that are required to be present in any meeting for the proceedings to be considered valid. International and national guidelines require the presence of at least five (5) regular members, including the non-affiliated and the non-scientist members

Regular Meeting - a periodically scheduled assembly of IREC, which should be once a month

Special Meeting - an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like the selection of an officer, approval of a revised or new SOP, or a report of a critical research problem that requires immediate action

Study Documents – refer to the proposal, guide questions/questionnaire, informed consent form, required IREC forms, and other attachments necessary to evaluate the ethical procedure of research

7. Forms

IREC Form 23: Notice of Meeting with Provisional Agenda Template

8. History

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft

2	2023 January 14	IREC 2022	Policy statement, objective of the activity, scope, workflow, description of procedures, glossary, forms, references, styling

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02 Date of Approval: January 14, 2023 Date of Effectivity: January 21, 2023	**SOP No. 19** **Conduct of Meeting**

1. Policy Statement

The ADNUGERR 2020 under Section IV, titled "General Functions of the IREC" states the following on "preparing for a meeting": Draft institutional policies on matters including, but not limited to, meeting procedures.

2. Objective/s of the Activity

The provisions of "conducts of meeting" provide an opportunity for IREC to arrive at collegial decisions regarding study documents and IREC operations and to be informed of pertinent administrative matters.

3. Scope

SOP 19 describes how the IREC conducts all its meetings. It covers IREC actions and activities from the time the meeting is called to order, and a quorum is declared to the time the meeting is adjourned. SOP 19 begins with the declaration of quorum and ends with the collection, storage, and disposal/deletion of meeting materials.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Declaration of Quorum (Formal Start)	IREC Chair
Step 2: Declaration of Conflict of Interest (COI)	IREC Members (who have COI)
Step 3: Approval of Minutes of the Previous Meeting	IREC
Step 4: Discussion of "Business Arising from the Minutes"	IREC

Step 5: Report of Results of Expedited Review (SOP 05 on Expedited Review	IREC Chair
Step 6: Review of Study Documents (SOP 08 on Full Review)	IREC
Step 7: Discussion of Operations-Related Matters	IREC
Step 8: Adjournment	IREC Chair
Step 9: Collection, Storage, and Disposal of Meeting Materials	IREC AA

5. Description of Procedures

Step 1 - **Declaration of Quorum**: The IREC Chair, based on the physical/digital attendance of IREC Members, declares the quorum and official start of the meeting.

Step 2 - **Declaration of Conflict of Interest:** IREC members declare a conflict of interest if there is any.

Step 3 - **Approval of Minutes of Previous Meeting**: The IREC Chair requests the approval of the minutes of the previous meeting whose minutes were distributed before the meeting. An IREC Member will approve the minutes, and another IREC Member will second the motion.

Step 4 - **Discussion of "Business Arising from the Minutes"**: The IREC Chair will update the IREC Members on the business arising from the previous minutes or may assign a Member to do it.

Step 5 - **Report of Results of Expedited Review**: The IREC Chair will request the assigned IREC Member to report on the results of the expedited review, if any, for the information of the other IREC members and documentation of the review results.

Step 6 - **Review of Study Documents**: The IREC Chair will present the collated comments from the members about the submitted study documents for a full review. The IREC Members will consent or react to the presented comments. For issues where no consensus was arrived at, the IREC Chair will open the options for voting. The IREC Chair will present the summary of comments and recommendations that will be written in the decision.

Step 7 - **Discussion of Operations-Related Matters**: This matter will only be placed on the agenda when there is no study document submitted.

Step 8 - **Adjournment**: The meeting is adjourned after all items on the agenda have been discussed and/or resolved. A member must move for the adjournment of the meeting, and another will second the motion for it to be declared adjourned. If the meeting has to be adjourned due to time constraints, a new meeting schedule shall be set to discuss and resolve the remaining items on the agenda.

Step 9 - **Collection, Storage, and Disposal of Meeting Materials:** The IREC AA collects physical meeting materials to be disposed of for on-site meetings/reminds the IREC Members to delete the meeting materials from their emails and desktop/laptop computers. Physical materials are only disposed of/shredded upon approval of the IREC Chair. Other physical materials or study documents that are necessary for the next meeting need to be stored properly in a secured cabinet. Digital materials are secured in the digital folders in the IREC AA's computer.

6. Glossary

AA - Administrative Assistant

ADNUGERR - Ateneo de Naga University Guidelines for Ethics Review of Research

Adjournment – Formal closure of the meeting. Motion for adjournment and record of the time are documented

Agenda - the list of topics or items to be taken up in a meeting arranged sequentially. It is an outline of the meeting procedure and starts with a "Call to Order."

Business Arising from the Minutes – are matters generated from the discussions in the previous meeting that need continuing attention and require reporting

Clarificatory Interview/meeting – is a face-to-face consultation between the IREC and the researcher to obtain explanations or clarity regarding some research issues identified by the REC to make these issues less confusing or more comprehensible

Collegial Decision – a course of action arrived at after a group deliberation where members were considered of equal authority such that the course of action is considered a group action and is not ascribed to any particular member.

Conflict of Interest - a situation in which aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect the official/primary duties.

Consensus – the process of deciding without voting but by generating the overall sentiment of a group such that deliberations continue until no more objection is registered

IREC - Institutional Research Ethics Committee

IREC Operations - the overall activities of IREC that reflect the performance of its functions and responsibilities

Meeting Minutes – the official narration and record of the proceedings of the assembly of IREC Members, based on the agenda

Operations-related Matters – are items included in the agenda that are not directly related to any study document under review

Quorum– the minimum number (i.e., majority of the members) of IREC Members required to be present in any meeting for the proceedings to be considered valid. International and national guidelines require the presence of at least five (5) regular members, including the non-affiliated and the non-scientist members

Study Documents – refer to the proposal, guide questions/questionnaire, informed consent form, required IREC forms, and other attachments necessary to evaluate the ethical procedure of research

Voting – the act of formally manifesting a choice in a meeting

7. Forms

IREC Form 24: IREC Attendance Sheet

8. History of SOP

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft
2	2023 January 14	IREC 2022	Policy statement, objective of the activity, scope, workflow, description of procedures, glossary, forms, references, styling

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02	**SOP No. 20** **Documentation of IREC Actions**
Date of Approval: January 14, 2023	
Date of Effectivity: January 21, 2023	

1. Policy Statement

ADNUGERR 2020 states that it is the function of IREC to keep a systematic and organized filing system of all proposals reviewed, including actions taken and other pertinent information. It includes digital recording/documentation of all IREC actions of decisions arrived during meetings (e.g., full review and operations-related matters) and outside of the meetings (e.g., exemption from review and expedited review) and transmittal of decisions to the concerned individuals and units as well as for future references.

2. Objective of the Activity

The provisions of “documentation of IREC action” ensure that all procedures and decisions of IREC are documented to ensure that all stakeholders are appropriately, accurately, and promptly informed. It aims to establish accountability and an efficient and effective tracking system.

3. Scope

SOP 20 includes the documentation of IREC actions related to the decisions arrived at during meetings and outside of the meetings and the communications of IREC decisions sent to the concerned individuals and units. This SOP begins with the entry of preliminary information on the minutes of the meeting and ends with the filing of all approved documents.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Recording and Classifying of Incoming Communications	IREC AA

Step 2: Filing into an Existing Digital Folder or Create a New Folder	IREC AA
Step 3: Taking Notes/Audio-Recording of the Minutes of the Meeting	IREC AA
Step 4: Preparation of the Draft Minutes	IREC AA
Step 5: Notation of the Draft Minutes, Finalization of Recommendations of the Committee or Finalization of Recommendations of Reviewers, and Transfer of Information from Minutes of Meeting or Reports to IREC Letter on Communicating Decision, and Acting on Incoming Communications	IREC AA
Step 6: Review of Minutes and Approval of the IREC Decision Document	IREC Chair and Members
Step 7: Transmittal of IREC Decision to Researcher	IREC Chair
Step 8: Approval of the Minutes in the Next IREC Meeting	IREC Chair and Members
Step 9: Filing of All Approved Documents (SOP 21 on Management of Active Files)	IREC AA

5. Description of Procedures

Step 1 - **Recording and Classifying of Incoming Communications**: All communications, such as letters, official memoranda, or emails, are received by the IREC AA. The IREC AA shall have access to the official email address of IREC (irec@gbox.adnu.edu.ph). All digital communications are printed into PDF copies and submitted to the Chair for her instruction: (a) filing; (b) submission to the Primary and Co-Reviewers; or (c) inclusion in the agenda of the next IREC meeting.

Step 2 - **Filing into an Existing Digital Folder or Creating a New Folder:** The IREC AA files the study-related communications in one digital folder, which contains the individual study documents. Each file is issued an IREC Code, which is the year_sequential number that starts from 01. Each folder contains the file name: year_series number for the year_surname of proponent_first name initial. Non-study-related documents are filed in another digital file termed an administrative file. Administrative files contain matters on external communication on accreditation, training, and the like; personnel matters like termination of contractual appointments and the like; and other administrative and related matters.

Step 3 - **Taking Notes/Audio-Recording of Minutes:** The IREC AA encodes the preliminary information, such as the date of the meeting, time expected to start, provisional attendance, and agenda of the meeting a day before the scheduled meeting. During the meeting, he/she sets up the audio recorder in a position where the voices of the attendees can be heard. He/She takes down important notes on the matters being discussed.

Step 4 - **Preparation of the Draft Minutes:** The IREC AA prepares the draft minutes, and it should follow the agenda as listed. Each main agendum should include the issue being discussed, comments, and recommendations of members. The draft minutes should be ready for editing by the IREC Chair a week after the scheduled meeting.

Step 5 - **Notation of the Draft Minutes, Finalization of Recommendations of the Committee or Finalization of Recommendations of Reviewers, and Transfer of Information from Minutes of Meeting or Reports to IREC Letter on Communicating Decision and Acting on Incoming Communications**: After editing the draft minutes, the IREC Chair places her signature and submits the noted minutes to the IREC AA in PDF. The draft minutes are expected to have the following information:

- Date and venue of the meeting
- Members' attendance (members present and absent)
- Presence of Independent consultants, primary investigators, guests, and observer's attendance (if any)
- Time when the meeting was called to order
- Declaration of Quorum
- Name of Presiding officer
- Conflict of Interest (COI) declaration
- Items discussed, issues raised, and resolutions
- IREC decisions and recommendations
- Name and signature of the person who prepared the minutes
- Name and signature of the Chair and date of notation

For finalization of the Committee's Recommendations see SOP 06 on Full Review or for finalization of Reviewers' Recommendations, see SOP 05 Expedited Review.

Step 6 - **Review of Minutes and Approval of the IREC Decision Document:** The IREC Members raised their comments and corrections in the next regular IREC meeting. One member shall approve and will be seconded by another.

The draft decision is distributed by the IREC Chair to the IREC Members for their review and approval.

Step 7 - **Transmittal of IREC Decision to Researcher**

Step 8 - **Storage of the Approved Minutes**: The approved minutes shall be digitized and kept in a separate digital folder named minutes of IREC meetings. Inside the digital folder, there will be subfolders with the indicated years. The file name of each approved minutes of the meeting should indicate the year_date of the meeting_IREC minutes_reg/spl (which stands for a regular or special meeting). All IREC files shall have another copy in Google Drive and the external hard drive aside from the office files.

6. Glossary

AA - Administrative Assistant

ADNUGERR - Ateneo de Naga University Guidelines for Ethics Review of Research

Conflict of Interest – a situation in which aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect the official/primary duties

Draft Meeting Minutes – Proceedings of the meeting prepared by the IREC Staff under the supervision of the IREC Chair

Final Meeting Minutes – Proceedings of the meeting that have been approved by the IREC members

IREC - Institutional Research Ethics Committee

Meeting Agenda- the list of topics or items to be taken up in a meeting arranged in a sequential manner

Provisional Meeting Minutes – Proceedings of the meeting that have been noted or approved by the Presiding officer

Real-time Recording – the process of documenting the minutes of the meeting as the meeting proceeds simultaneously

7. Forms

IREC Form 25: Minutes of the Meeting Template

8. History of SOP

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft

2	2023 January 12	IREC 2022	Policy statement, objective of the activity, scope, workflow, description of procedures, glossary, forms, references, styling

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02	**SOP No. 21** **Management of Active Files**
Date of Approval: January 20, 2023	
Date of Effectivity: January 27, 2023	

1. Policy Statement

The ADNUGERR 2020 states that IREC must keep a systematic and organized record of all proposals and study documents, including actions taken and other pertinent information. It must maintain the confidentiality of documents and IREC meetings as a way to respect and protect the rights of the researchers.

Active files are digitized and kept on the office desktop with copies kept in Google Drive and an external hard drive. These files are arranged in an orderly manner that allows easy identification and retrieval.

Access to the IREC confidential files shall be regulated and limited to IREC Chair, members, and staff. Other persons with a legitimate interest in these files (e.g., institutional authorities, regulatory agencies, sponsors) shall be allowed to access specific files with proper justification. Researchers/Investigators shall be allowed access only to their study documents upon request.

This is to protect the intellectual property rights of research proponents and to protect IREC Chair and members from unnecessary scrutiny and pressure from non-authorized individuals.

2. Objective/s of the Activity

The provisions of "management of active files" ensure accessibility, easy retrieval of current files, and protection of those that require confidentiality. It helps protect the intellectual property rights of researchers and enhances the credibility and integrity of the IREC.

3. Scope

SOP 21 covers procedures related to study documents accepted for review, undergoing review, or having been approved by the IREC. The SOP on the management of active files begins with the digitization, classification, and coding of active files and ends with the periodic updating of the files. It also consists of procedures for accessing confidential files, including document handling and distribution. The SOP on accessing confidential files begins with the receipt of the request to access and ends with the return of the documents to the IREC database.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Digitization, Classification, and Coding of Active Files	IREC AA
Step 2.: Preparation of the Study Documents	IREC AA
Step 3: Periodic Updating of the IREC Database	IREC AA

5. Description of Procedure

Step 1 - **Digitization, Classification, and Coding of Active Files**: The IREC AA, under the supervision of the IREC Chair, classifies active files as follows:

- Initial Submission
- Resubmission
- Progress Report
- Amendment
- Protocol Deviation
- Protocol Violation
- Early Termination
- Continuing Review
- Final Report/ Close-Out Report

The IREC AA assigns a code to the Initial Submission and indicates the same for the rest of the submissions related to the initial submission. The code consists of the year and the serial number that indicates the sequence order of receipt. For example, a study document received in 2019 as the 10th submission in that year will be coded as 2019-010.

All communications received are classified as either of the following:

A. Operations - contains SOPs, Plans, Meetings (Tasking, Minutes, Audio Recording, and PDF copy/link of the discussed materials),

Communication from other units, Forms, Training Materials, References, Membership, and Reports

B. Decisions - contains the IREC database in an Excel file and the main folder titled "Study Files." Inside the main "Study file" folder are folders containing the decisions of (1) awaiting approval, (2) ongoing approved studies, and (3) completed studies. Each research proponent's folder is subsequently divided into the first submission and corresponding submissions. Each folder contains a PDF-printed copy of communications from the researcher, study documents, relevant forms, and the IREC decision. The ethical clearance is placed in the last submission. The folders of the proponents are sequentially arranged by IREC Code.

C. Exemption from Review - contains the Graduate School, College of Law, and URC Folder that contains requests for exemptions, Certificates of exemption from review, and a list of researchers given exemption from review for each school year.

Step 2 - **Preparation of the Study Documents**: The IREC AA files all digitized documents on a study in a digital folder that is labeled with: IREC Code- Study Title - Proponent's Family Name – Unit/Sponsor. A word file is created to indicate the protocol index and the contents of the folder.

Step 3 - **Periodic Updating of the IREC Database**: The IREC AA ensures that the documents are filed chronologically by placing a sequential number on the folder's name. These documents inside the digital folder include the following:

- Document (Original and Revised) versions
- Informed consent (Original and Revised) versions
- Reports: Progress, Protocol Deviation/Violation, Final, Amendment, Early Termination, Site Visit Reports
- Assessment Forms for each of the submitted and reviewed reports should be signed and dated
- Excerpts of Minutes of Meetings when the protocol and reports were included in the agenda
- Decision and Approval Letters
- Communications

The IREC AA updates the protocol index each time a new document is added to the file. The study document is periodically checked for orderliness and completeness.

6. Glossary

AA - Administrative Assistant

ADNUGERR - Ateneo de Naga University Guidelines for Ethics Review of Research

Amendments - a change in or revision of the protocol made after it has been approved

Assessment Form – evaluation tool accomplished by the reviewers when appraising the protocol or the informed consent form

Continuing Review - is the decision of the REC to extend ethical clearance of a study beyond the initial period of effectivity based on an appreciation that the research is proceeding according to the approved protocol and there is a reasonable expectation of its completion

Early Termination - is ending the implementation of a study before its completion. This is a decision made by the sponsor or regulatory authority (i.e., a government office) and/or recommended by the ADNU Data Privacy Office, researcher/investigator in consideration of participants' safety, funding issues, protocol violations, and data integrity issues

Final Reports – this is a summary of the outputs and outcomes of the study upon its completion. The IREC requires the accomplishment of the Final Report form within a reasonable period after the end of the study

Initial Submission - a set of documents consisting of the full proposal and other study-related documents that are received by the IREC so that an ethical review can be done

IREC - Institutional Research Ethics Committee

Protocol Deviation – non-compliance with the approved protocol that does not increase risk nor decrease benefit to participants and does not significantly affect their rights, safety or welfare, or the integrity of data. Example: missed visit, non-submission of a food diary on time

Protocol Index - is a chronological record of the documents in the protocol file. The protocol index is in table form, indicating the date of filing, the nature of the document filed, the name and signature of the person who filed, and an extra column to record any movement of the document. The index is placed inside the researcher's protocol file/folder for easy reference and checking

Progress Reports - A systematized description of how the implementation of the study is moving forward. This is done by accomplishing the Application for Ethics Review of Progress Reports (IREC Form 13). The frequency of submission (e.g., quarterly, semi-annually, or annually) is determined by the IREC based on the level of risk

Protocol Violation - non-compliance with the approved protocol that may result in increased risk or decreased benefit to participants or significantly affect their

rights, safety or welfare, or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria

Resubmission - the revised study proposal that is forwarded to the IREC in response to the recommendations given during the initial review

Serious Adverse Event (SAE) – is an event observed during the implementation of a study where the outcome is any of the following:

- Death
- Life-threatening situation
- Hospitalization (initial or prolonged)
- Disability or permanent damage
- Congenital anomaly/ birth defect
- Required intervention to prevent permanent impairment or damage (devices)
- Other serious (important medical) events, whether or not it is related to the study intervention

Study Documents – refer to the proposal, guide questions/questionnaire, informed consent form, required IREC forms, and other attachments necessary to evaluate the ethical procedure of research

7. Forms:

IREC Form 26: Protocol Index

IREC Database

8. History of SOP

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft
2	2023 January 20	IREC 2022	Policy statement, objective of the activity, scope, workflow, description of procedures, glossary, forms, styling

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02	**SOP No. 22** **Archiving of Files**
Date of Approval: January 20, 2023	
Date of Effectivity: January 27, 2023	

1. Policy Statement

The ADNUGERR 2020 states that IREC must keep a systematic and organized record of all proposals and study documents. It must maintain the confidentiality of documents and IREC meetings as a way to respect and protect the rights of the researchers. Thus, IREC adopts the provisions under the National Guidelines Ethical Guidelines for Research Involving Human Participants (2022) on archiving of files. IREC shall archive files to ensure that data are not lost or corrupted, that only IREC can access the documents, and the documents are organized and easy to access.

Files for archiving include those (a) with approved/accepted Final Reports, (b) with approved Early Termination reports, and (c) whose proponent/researcher/investigator has not submitted a revision based on IREC recommendations.

Studies of researchers who have not resubmitted their proposals within one (1) year after receiving the Notification Letter of IREC Decision shall be considered inactive.

After five years, files of studies that have been terminated or completed or declared inactive shall be kept in separate storage.

2. Objective/s of the Activity

The provisions of “archiving of files” ensure efficient retrieval of information from the files for reference and compliance with national and international guidelines. It helps protect the intellectual property rights of researchers.

3. Scope

SOP 22 includes procedures related to the storage and retrieval of study documents that are classified as inactive, terminated, or completed. The SOP on storage and retrieval of files begins with the acceptance of final reports, early

termination reports, and identification of a study as inactive and ends with the inclusion of the files in the archives and updating of the IREC database. It contains procedures for accessing archived confidential files, including document handling and distribution. The SOP on accessing files begins with the receipt of the request to access and ends with the return of the documents to storage.

4. Workflow

ACTIVITY	RESPONSIBILITY
Archiving of Files	
Step 1: Acceptance of Final Reports or Early Termination Reports (SOP 13 Review of Final Reports, SOP 14 Review of Early Termination Reports), and Identification of an Inactive File.	IREC AA
Step 2: Transfer the Document Folder to the Archives and Updating the IREC Database	IREC AA
Retrieval/Accessing of Files	
Step 1: Acceptance of request to retrieve or access files	IREC AA
Step 2: Approval of request	IREC Chair
Step 3: Retrieval of files from the storage	IREC AA
Step 4: Return the documents to the storage	IREC AA

5. Description of Procedures

Step 1 - **Acceptance of Final or Early Termination Reports and Identification of an Inactive File:** The Committee members approve or accept the final report or early termination report during a meeting (SOP 13 Review of Final Reports; SOP 14 Review of an Early Termination Report). In the identification of an Inactive File, the IREC AA informs the IREC Chair of the failure of a concerned researcher/ proponent/ investigator to respond to the recommendations of the IREC in the last three months, during which time the researcher/proponent/investigator has been appropriately reminded of the

requirement. This is included in the agenda of the next meeting, where the study document is declared inactive.

Step 2 - **Updating of the Corresponding Active File**: The IREC AA files the Final or Early Termination Report in the corresponding document folder, including the excerpts of the minutes that approved the report or declared the study document inactive.

Step 3 - **Transfer of the Document Folder in the Archives and Update of the IREC Database:** The IREC AA checks whether the documents listed in the protocol file index are complete and removes extraneous documents. Accordingly, the IREC AA transfers the folder to the archive section and updates the IREC database.

6. Glossary

AA - Administrative Assistant

Active Study – is an ongoing study, implementation of which is within the period covered by ethics clearance

ADNUGERR - Ateneo de Naga University Guidelines for Ethics Review of Research

Archiving - is the systematic keeping of protocol files in storage after the studies have been completed with final reports accepted, or terminated or declared inactive

Confidentiality of Documents – pertains to the recognition and awareness that certain documents that have been entrusted or submitted to the IREC must not be freely shared or disclosed

Controlled document – pertains to the document that has been entrusted or submitted to the IREC that must not be freely shared or disclosed such that it is appropriately tagged and its distribution carefully tracked, monitored, and appropriately recorded

Database – an excel file containing a chronological record of incoming study documents that includes the (1) Date of Receipt, (2) IREC Code, (3) Name of the Proponent, (4) Course/Unit of the Proponent, (5) Title of the Study, (6) Research Adviser/Point Person, (7) Type of Review, (8) Name of the Reviewers, (9) Action done, (10) Date Conveyed, and (11) Documents Submitted

Early Termination - ending the implementation of a study before its completion

Final Report – is a summary of the outputs and outcomes of the study upon its completion. The IREC requires the accomplishment of the Final Report form within a reasonable period after the end of the study

Inactive Study – a study whose proponent has not communicated with the IREC concerning issues on the approval or implementation of the study – within a period required by the IREC

IREC - Institutional Research Ethics Committee

Study Documents – refer to the proposal, guide questions/questionnaire, informed consent form, required IREC forms, and other attachments necessary to evaluate the ethical procedure of research

7. Forms

IREC Form 26: Protocol Index

IREC Database

8. History of SOP

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft
2	2023 January 20	IREC 2022	Policy statement, objective of the activity, scope, workflow, description of procedures, glossary, forms, references, styling

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02	**SOP No. 23** **Management of Queries and Complaints**
Date of Approval: January 20, 2023	
Date of Effectivity: January 27, 2023	

1. Policy Statement

The addendum to the ADNUGERR 2020 states that queries and complaints from clients or research participants shall be attended to promptly and appropriately while exercising due diligence. The nature of queries shall determine whether they can be answered by the IREC AA or referred to the primary reviewers of the research project. All complaints shall be referred to the IREC Chair, who shall determine the level of risk involved. Complaints of minimal risk shall be referred to the primary reviewers for resolution. Complaints of more than minimal risk shall be taken up in a special meeting within 48 hours for deliberation by the committee en banc, with the primary reviewers leading the discussion.

2. Objective/s of the Activity

The provisions of management of queries and complaints aim to promote public trust and confidence in the institution, especially in the IREC, and to ensure that the rights and well-being of participants are attended to.

3. Scope

SOP 23 is limited to queries and complaints of researchers, research participants, their families, or other stakeholders in studies that have been issued ethics clearance by the IREC. SOP 23 begins with the receipt, logging, and acknowledgment of queries and complaints and ends with the logging of the response and inclusion in the agenda of the IREC meeting.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Receipt, Logging, and Acknowledgement of Queries and Complaints (SOP 20 on Documentation of IREC Actions)	IREC AA
Step 2: Referral of Query or Complaint to the IREC Chair	IREC AA
Step 3: Formulation of Response 3.1. Study-Related Queries 3.2. Minimal-Risk Complaints 3.3. More than Minimal Risk Complaints: En-Banc Committee	 IREC Chair/Assigned IREC Members Assigned IREC Members IREC Chair & Members
Step 4: Communication of Response (SOP 20 on Documentation of IREC Actions)	IREC Chair
Step 5: Logging of the Response and Inclusion in the Agenda of the IREC Meeting (SOP 20 on Documentation of IREC Actions)	IREC AA

5. Description of Procedures

Step 1 - **Receipt, Logging, and Acknowledgement of Queries and Complaints:** The IREC AA receives the letter of query and/or complaint and logs the same in the database. The database contains the following information: date, time, name of the concerned party, specific study, and nature of query or complaint.

Step 2 - **Referral of Query or Complaint to Competent Authority**:

2.1. The IREC AA refers queries related to specific protocols approved by the IREC to the assigned IREC Members

2.2. On the other hand, the IREC AA refers all complaints to the IREC Chair, who determines the level of risk affected by the issue.

2.2.1. Minimal risk complaints are referred to the assigned IREC Members of the concerned protocol.

2.2.2. Complaints that involve more than minimal risk are referred to the Committee through a special meeting that shall be called within 48 hours. The AA notifies the concerned primary reviewers that they will lead the discussion. Pertinent materials are provided to them as references.

Step 3 - **Formulation of Response**:

3.1. For queries, the IREC Chair responds through a letter/email.

3.2. For minimal risk complaints, the assigned IREC Member writes the letter of response

3.3. For more than minimal risk, the committee may choose any of the following options:

3.3.1. Constitute a team who will visit the research site and gather more information, verification, and clarification regarding the source and cause/s of the complaint.

3.3.2. Designate IREC Members who will meet the complainants and the researcher (preferably separately) to clarify the issues and obtain suggestions for resolution.

3.3.3. Formulate recommendation if satisfied with the adequacy of information:

- request for explanation/justification from the researcher
- accept the request/demand of the participant
- suspension of further recruitment
- an amendment of protocol and re-consent of participants
- others

Step 4 - **Communication of Response**: IREC Chair communicates the IREC response to the complainant

Step 5 – **Logging of the Response and Inclusion in the Agenda of the IREC Meeting**: The IREC AA logs the response in the database and prepares the provisional agenda of the IREC meeting (See SOP 22 on Managing IREC Incoming/Outgoing Communications and SOP 18 on Preparing the Meeting Agenda)

6. Glossary

AA - Administrative Assistant

ADNUGERR - Ateneo de Naga University Guidelines for Ethics Review of Research

Complaint – the act of expressing discontent or unease about certain events or arrangements in connection with a study.

Competent Authority – designated officer or member of the IREC with authority to respond to queries and complaints regarding studies approved by the IREC

Database – an excel file containing a chronological record of incoming study documents that includes the (1) Date of Receipt, (2) IREC Code, (3) Name of the Proponent, (4) Course/Unit of the Proponent, (5) Title of the Study, (6) Research Adviser/Point Person, (7) Type of Review, (8) Name of the Reviewers, (9) Action done, (10) Date Conveyed, and (11) Documents Submitted

IREC - Institutional Research Ethics Committee

Primary Reviewers – are members of the Institutional Research Ethics Committee (usually a scientist and a non-scientist) assigned to do an in-depth evaluation of the study documents using the ethical criteria established by the committee

Query – the act of asking for information or clarification about a study

Regular Meeting – a periodically scheduled assembly of the IREC.

Site Visiting Team– members/AA of the IREC (2-4 members) assigned by the IREC Chair to formally go to the research site, meet with the research team and evaluate compliance with the approved protocol and Informed Consent Form and Process, including other related research procedures to ensure the promotion of the rights, dignity, and well-being of participants and protection of the integrity of data

Special Meeting - an assembly of the Committee outside of the regular schedule of meetings for a specific purpose

7. Forms

IREC Form 26: Protocol Index

IREC Database

8. History of SOP

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft
2	2023 January 20	IREC 2022	Policy statement, objective of the activity, scope, workflow, description of

			procedures, glossary, references, styling

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

IREC	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE
Version No: 02	**SOP No. 24** **Writing and Revising SOPs**
Date of Approval: January 20, 2023	
Date of Effectivity: January 27, 2023	

1. Policy Statement

The Policy includes a provision for writing and revising SOPs. The IREC shall review its SOPs annually or when the need arises to determine their continuing relevance and effectiveness to its operations.

2. Objective of the Activity

Writing and revising SOPs ensures continuing quality assurance of IREC functions.

3. Scope

SOP 24 applies to all IREC activities related to writing and revising SOPs. SOP 24 involves the development, revisions, publications, and dissemination of its SOPs to the ADNU community. SOP 24 begins with the proposal and approval for revision or writing of new SOPs and ends with the inclusion of the new or revised SOPs in the SOP Manual and its dissemination.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Proposal for Revision of an SOP or a New SOP	Any IREC Member
Step 2: Deliberation of the Proposed Revision or Constitution of New SOPs	IREC Chair and IREC Members

Step 3: Drafting of the Revision or New SOP and Dissemination to the Members of the Committee	SOP Team
Step 4: Review and Approval of SOP	IREC Members
Step 5. Submission of the SOP to the Dean of RaCE for her/his Approval	IREC Chair
Step 6: Inclusion of the New or Revised SOP in the SOP Manual and its Dissemination	IREC AA

5. Description of Procedures

Step 1 - **Proposal for a Revision of an SOP or a New SOP**: Any member of the committee may propose to amend old SOPs or suggest new SOPs for review. This proposal is presented formally during a regular meeting where members evaluate the merits of the proposal. The Chair then schedules a special meeting where the proponent/s presents the rationale for the proposal.

Step 2 **- Deliberation of the Proposed Revision or Constitution of New SOPs:** If the proposal is adjudged meritorious by the Committee, the Chair assigns all members to evaluate the proposal and, in subsequent meetings, facilitate the discussion/argumentation. Approval to revise or constitute new SOPs shall be decided by a majority vote.

Step 3 - **Drafting of the Revision or New SOP and Dissemination to the Members of the Committee:** The proponent/s shall draft the proposed amendment or the new SOPs and present them to the Chair. The Chair then distributes the drafts to the Committee for comments. In writing the draft, the following template is recommended:

(a) *Title, which is descriptive of contents*

(b) *Policy Statement*

(c) *Objective/s of the activity, which defines the purpose and intended outcome*

(d) *Scope, which defines the extent of coverage of the SOP and its limitations*

(e) *Workflow provides a graphic representation of the essential steps to implement the SOP and the responsible person for each step.*

(f) *Description of Procedures, which elaborate on the steps listed in the workflow*

(g) *Glossary – acronyms and terms which need to be defined*

(h) *Forms, documents to be accomplished by different parties as required by the SOP,*

(i) *Document history, which tabulates the different versions (from draft to final versions) of the document by author, version, date, and description of main changes*

(j) *References, which lists the instruments used to draft the Guideline such as other SOPs, guidelines, or policies*

Step 4 - **Review and Approval of SOP**: The Chair shall present the draft to the Committee for final review and deliberation. If approved, an editor is then assigned to check and prepare the draft for official publication.

Step 5 – **Submission of the SOP to the Dean of RaCE for her/his Approval.**

Step 6 - **Inclusion of the New or Revised SOP in the SOP Manual and its Dissemination**: Amended or newly constituted SOPs shall be included in the Manual in its "new edition" or "revised edition" publication.

6. Glossary

AA - Administrative Assistant

ADNUGERR - Ateneo de Naga University Guidelines for Ethics Review of Research

Coding – a unique number assigned to a particular SOP that reflects its serial position among the SOPs and version number to indicate the number of times it has been revised

Date of Effectivity – the date of the enforcement of the guidelines

IREC - Institutional Research Ethics Committee

Format- general style or layout of the document

Standard Operating Procedures - These are the step-by-step descriptions of the different procedures done to accomplish the objective of an activity. They consist of clear, unambiguous instructions for the conduct of ethical reviews to ensure quality and consistency

7. Forms

8. History of SOP

Version Number	Date	Authors	Change/s
1	2021 November 5	IREC 2021	First draft

2	2023 January 20	IREC 2022	Policy statement, objective of the activity, scope, workflow, description of procedures, glossary, references, styling

9. References

Ateneo de Naga University (2020). *Guidelines for Ethics Review of Research*. https://www.adnu.edu.ph/irec/

Philippine Health Ethics Review Board (PHREB) (2020). *2020 PHREB standard operating procedures*. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook

Philippine Health Research Ethics Board (PHREB) (2022). *National Ethical Guidelines for Research Involving Human Participants 2022.* Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/

APPENDICES

GROUP A

IREC Forms for IREC Members, Consultants, and Observers

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	**CURRICULUM VITAE (for IREC Chair, Members, and Consultants)**	IREC Form No.	20
		Version No.	03
		Date of Effectivity	November 17, 2022

1. **General Information**			
Name		Date of birth:	
Address:		Contact number: Email address:	
Affiliation:	Name of Department:	Name of Institution:	
Position:		Specialty:	
Highest Educational Attainment:	Name of Institution:	Course/Degree:	Year/s attended:
Research Related Trainings including Research Ethics:	Name of Course:	Offered by:	Year:

Name and signature:	Date:

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	**DISCLOSURE OF CONFLICT OF INTEREST AGREEMENT (For Members and Consultants before The Start of Term)**	IREC Form No.	21A
		Version No.	04
		Date of Effectivity	August 31, 2023

In general, *Conflict of Interest* occurs when there is conflict (actual, potential, or perceived) between an individual's duties and his/her personal or private interest. *Conflict of Interest* impairs one's ability to exercise objectivity in the performance of official duties.

The Members (including the Chairperson) of the Institutional Research Ethics Committee and consultants shall sign this agreement to disclose any *Conflict of Interest* that they may have in the review of study documents and other related documents every start of their term of office.

INSTRUCTIONS TO IREC MEMBERS

Before affixing your signature below, please consider the following statements for every review assignment concerning 1) all your past and current official positions and 2) all your immediate family members, especially your spouse and children.

STATEMENTS
· I/My family has affiliation by consanguinity or affinity with the proponent/proponent's organization(s).
· I/My family has owned stocks and shares in the proponent organization(s).
· I/My family has received a salary, an honorarium, compensation, concessions, and gifts from the proponent organization(s).
· I/My family has served as an officer, director, advisor, trustee, consultant, or an active participant in the activities of the proponent organization(s).
· I/My family/my other organizations have had research work experience with the principal investigator(s).
· I/My family/my other organizations have a long-standing issue against the principal investigator(s), the proponent organization(s), or the funding agency.
· I/My family has regular social activities, such as parties, home visits, and civic organization and sports events, with the principal investigator(s).

· I/my family/my other organizations have an interest in or an ownership issue against the proposed topic.

As a member/consultant of the Institutional Research Ethics Committee, I shall disclose any conflict of interest that I may have in connection with the review of specific study documents and related documents.

I shall submit a conflict of interest form before or during any deliberations/review so that I may not participate in the decision regarding the said protocol.

_____ _____

SIGNATURE OVER PRINTED NAME DATE

_____

INSTITUTIONAL AFFILIATION

_____

ADDRESS

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	**DISCLOSURE OF CONFLICT OF INTEREST (For Members and Consultants before the Review)**	IREC Form No.	21B
		Version No.	04
		Date of Effectivity	August 31, 2023

In general, Conflict of Interest occurs when there is conflict (actual, potential, or perceived) between an individual's duties and his/her personal or private interest. Conflict of Interest impairs one's ability to exercise objectivity in the performance of official duties.

The Members (including the Chairperson) of the Institutional Research Ethics Committee and its consultants shall sign this agreement to disclose any *Conflict of Interest* that they may have in the review of study documents and other related documents before review or deliberations.

INSTRUCTIONS TO IREC MEMBERS OR CONSULTANTS

IREC Code: _____

Before affixing your signature below, please consider the following statements for every review assignment concerning 1) all your past and current official positions and 2) all your immediate family members, especially your spouse and children. If you answer "yes" in any of the statements, please declare that you have a conflict of interest.

STATEMENTS	YES	NO
· I/My family has affiliation by consanguinity or affinity with the proponent/proponent's organization(s).		
· I/My family has owned stocks and shares in the proponent organization(s).		
· I/My family has received a salary, an honorarium, compensation, concessions, and gifts from the proponent organization(s).		
· I/My family has served as an officer, director, advisor, trustee, consultant, or an active participant in the activities of the proponent organization(s).		

· I/My family/my other organizations have had research work experience with the principal investigator(s).		
· I/My family/my other organizations have a long-standing issue against the principal investigator(s), the proponent organization(s), or the funding agency.		
· I/My family has regular social activities, such as parties, home visits, and civic organization and sports events, with the principal investigator(s).		
· I/my family/my other organizations have an interest in or an ownership issue against the proposed topic.		

I, a member/consultant of the Institutional Research Ethics Committee, disclose that I have a conflict of interest with the proponent and thus, inhibit myself from the deliberations and review of the proponent's study and related documents.

I affix my signature below on the indicated date to attest the truthfulness of my declaration.

_____ _____

SIGNATURE OVER PRINTED NAME DATE

_____

INSTITUTIONAL AFFILIATION

_____

ADDRESS

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	**Confidentiality Agreement (For Members, Observers or Guests of the Institutional Research Ethics Committee)**	IREC Form No.	22
		Version No.	02
		Date of Effectivity	November 17, 2022

I sign this document as _____ of the Institutional Research Ethics Committee and voluntarily agree not to disclose or reproduce any confidential information and/or study documents under consideration during the course of my activities with the Committee, or anytime afterward.

Confidentiality covers information or materials prepared by the investigators, and/or sponsors for the ethics committee review either in written or verbal forms. This information includes technical and scientific data and financial and personal information concerning wages, remunerations, salaries, and benefits. I agree to return the related data or document to the office of IREC after the completion of the activity.

In case I have to disclose the confidential information by court order, I will so inform the committee within two days after notification.

Signature _____

Name _____

Institutional Affiliation _____

Address_____

Noted

_____ _____

IREC Chair Date

IREC Form 27 - REQUEST FOR INDEPENDENT CONSULTANT TEMPLATE

(Date)

(NAME OF IREC Chair)
IREC Chairman
Ateneo de Naga University
Ateneo Avenue, Naga City

RE: (Title of research proposal)
IREC code

Subject: Request for Independent Consultant

Dear ***(Title and Family name of IREC Chair)***

This is to acknowledge the receipt of the Institutional Research Ethics Committee's decision on the research proposal.

In response to the decision, we would like to request that an independent consultant be commissioned in order to provide additional expertise /appeal the decision. We have chosen (Name of the independent consultant) as the independent consultant who we believe has the necessary qualifications and can provide his/her expertise on such subject matter.

The following attached forms are the necessary requirements for the appointment of an independent consultant:

1. IREC Form 20: Curriculum Vitae Form
2. IREC Form 21A: Disclosure of Conflict of Interest Agreement (For Members and Consultants before the Start of Term)
3. IREC Form 22: Confidentiality Agreement

Very truly yours,

(Signature)
(Name of the requester)
(Position of the requester)

GROUP B

IREC Letter Templates

IREC Form No. 17: Template for the Certificate of Exempt from Ethics Review

(Date)

To: **(Name of Proponent)**
(Designation)
(Unit & Institution)
(Address)

Cc: **(Name of Dean/URC Chair/Designated Point Person)**
(Designation)
(Unit &Institution)
(Address)

(Name of Research Adviser)
(Designation)
(Unit & Institution)
(Address)

RE: **(Title of project/study)**
IREC code

Subject: Certificate of Exempt from Ethics Review

_____

Dear **(Title and Family name of proponent)**:

This is to acknowledge the submission of the following documents *(include version numbers and dates)*

- _
- _
- _

The ADNU Institutional Research Ethics Committee accepts that the research proposal titled, _____, be **exempted from ethics review** by the ADNU IREC as the said proposal has been positively reviewed and endorsed by the (Dean/Chairperson) of (College/GS/URC).

This means that the study may be implemented without undergoing an expedited or full review. Neither will the proponent/s be required to submit further documents to the committee as long as there is no amendment or alteration in the protocol that will change the nature of the study or the level of risk involved.

Very truly yours,

(Signature)
(Name)
IREC Chair

IREC Form No. 18 DECISION LETTER TEMPLATE

(Date)

To: **(Name of Proponent)**
(Designation)
(Unit & Institution)
(Address)

Cc: **(Name of Dean/URC Chair/Designated Point Person)**
(Designation)
(Unit &Institution)
(Address)

(Name of Research Adviser)
(Designation)
(Unit & Institution)
(Address)

RE: **(Title of project/study)**
IREC code

Subject: Decision on Review

Dear ***(Name of proponent)***:

This is to acknowledge receipt of your request and the following supporting documents dated_____.

- _
- _
- _
- _
- _

The above documents underwent full/expedited review, which generated the following:

(List of findings)

(List of recommendations)

(Specific instructions to the proponent, if any)

Very truly yours,

(Signature)
(Name)
IREC Chair

IREC Form No. 19 ETHICAL CLEARANCE TEMPLATE

(Date)

To: **(Name of Proponent)**
(Designation)
(Unit & Institution)
(Address)

Cc: **(Name of Dean/URC Chair/Designated Point Person)**
(Designation)
(Unit &Institution)
(Address)

(Name of Research Adviser)
(Designation)
(Unit & Institution)
(Address)

RE: **(Title of project/study)**
IREC code

Subject: Ethical Clearance

Dear ***(Name of proponent)***

(Acknowledgment of request (date of letter) and submitted documents with version numbers and dates)

- _
- _

(Information on the type of review and date of the meeting, if full review)

(Validity of ethical clearance)

(Provisions for post-approval submissions)

Very truly yours,

(Signature)
(Name)
IREC Chair

GROUP C

Forms and Letter Templates for Proponents

IREC Form 1:

Research Project Title:_____
Purpose of Project: _____
Proponent 1: _____ gbox Email:_____
Department / Unit: _____ Course: _____
Proponent 2: _____ gbox Email: _____
Department / Unit: _____ Course: _____
Name of Adviser: _____ gbox Email: _____

A. RESEARCH METHODS. Mark, as many research methods as relevant to this research proposal.

- ○ Anonymous questionnaires/surveys
- ○ Coded (potentially identifiable) questionnaires/surveys
- ○ Examination of student work, journals, etc.
- ○ Examination of medical, educational, personnel, or confidential records
- ○ Observation (visible)
- ○ Observation (hidden)
- ○ Face-to-face interviews (structured or unstructured)
- ○ Face-to-face FGD
- ○ Online interviews (with video and audio on)
- ○ Online interviews (with audio only on)
- ○ Telephone interviews
- ○ Online FGD (with video and audio on)
- ○ Online FGD (with audio only on)
- ○ Design of physical experiments (e.g., exercise, reacting to stimulus)
- ○ Administration of substances (e.g., drugs, alcohol, food)
- ○ Physical examination of participants (e.g., blood glucose, blood pressure)
- ○ Collection of human body tissues or fluid samples
- ○ Other [Please specify.]_____

B. RISKS AND BENEFITS

1. Does the project involve the risk of emotional distress or physical harm to the participants? ○ YES ○ NO

If YES, what are the risks?_____

If YES, explain how the risks of physical/emotional harm or distress will be minimized or corrected. _____

_____

2. Is sensitive information likely to be revealed during the study?
   ○ YES ○ NO

If YES, identify (e.g., criminal record, drug use, etc.)

_____

3. What are the expected benefits of the study to the participants and/or the wider community?

   _____

C. PARTICIPANTS

1. Mark as many characteristics of participants/subjects as relevant to this research proposal.

○ Healthy members of the community
○ Tertiary students (18 and above)
○ Employees of a specific company/government agency/organization
○ Members of a specific community/organization or indigenous groups
○ Clients of a service provider
○ School children (minors below 18 years old)
○ Hospital in-patients
○ Clinical clients (e.g., patients)
○ Members of socially disadvantaged groups
○ Persons with disability
○ Cadavers/cadaveric organs
○ Other [Please specify.]_____

2. Mark as many expected ages of participants as relevant to this research proposal.

○ Children (under seven years old)
○ Children (7-12 years old)
○ Adolescents (13-15 years old)
○ Adolescents (16-17 years old)
○ Adults (18 and over)

3. Why did you select these participants from these groups?_____

   _____

D. RECRUITMENT OF PARTICIPANTS

1. How will potential participants be approached initially and informed about the project? (e.g., direct approach, mailed letters, etc.)_____

[Please attach a copy of any letter or advertisement to be used for recruiting participants. Label it APPENDIX A.]

2. Where will potential participants be approached by the researchers?___

3. Where will research activities involving participants be conducted?____

4. How many participants in total are anticipated to be involved in the project? If the number of participants varies at different stages of the research, provide the total number of participants per stage._____

E. CONSENT PROCESS

1. Generally, the consent of participants must be obtained before conducting the study (Please label it APPENDIX B). The Informed Consent Form (ICF) must contain two parts: (1) the information sheet (letter format) and (2) the consent certificate

   Please note that ICFs should be written in a simple language understandable to the recipients using a simple format (without headings).

   I. The information sheet contains the following information *(This section is written in a letter format [without headings] and addressed to the recipient in the second person)*:
      1. Purpose of research
      2. Benefits of the study to the participant and the wider community.
      3. Duration of the participant's involvement in the study
      4. Foreseeable discomforts to the participant
      5. Maintaining the confidentiality of records and data
      6. For at-risk studies, an explanation of how participants can be compensated or treated for long-term effects
      7. A statement that participation in the study is voluntary. Non-participation or withdrawal from the study will not incur any penalty or loss of benefits for the participant.

8. Contact details of the researchers for further information about the study or participant's rights
9. Contact details of the IREC (irec@gbox.adnu.edu.ph) to report any violation of ethical procedures in the conduct of the study

II. A consent certificate contains a statement of a declaration by the research participant on his/her suitability (qualification as a research participant); competence (confirmation of understanding of his/her participation); was allowed to ask questions and receive satisfactory answers, given time to reflect, weigh options, read, discuss with others, decide; there was an absence of force or intimidation; and his/her agreement/confirmation of participation. (*This section is written in the first person from the point of view of the research participant*).

2. Will consent for participation be obtained from participants (adults) or their legal guardians? ○ YES ○ NO

3. How will consent for participation be obtained?

   ○ In writing
   ○ Verbally
   ○ Tacit (e.g., suggested by completion and return of survey)
   ○ Others [Pls. Specify.]
   ○ Consent not being sought

4. Explain why the method chosen is ethical._____
   _____

5. *Note: The following should be prepared if children are research participants:*
   ● Less than seven years old – ICF signed by a parent/legally authorized representative (LAR); the child needs no formal assent
   ● 7-12 years old – ICF signed by a parent/LAR; documented verbal assent from the child
   ● 13-15 years old – ICF signed by a parent/LAR; simplified assent form from the child
   ● 16-17 years old – ICF signed by a parent/LAR and the research participant.

6. Is it anticipated that all participants will have the capacity to consent to their participation in the research? ○ YES ○ NO

   If NO, explain why not (e.g., children, non-literates, etc.) and explain how proxy consent will be obtained from the person with legal authority to consent on the participant's behalf.

7. For participants who can consent, how does the process ensure that informed consent is freely obtained from the participant?_____

8. Are any participants in a dependent or subordinate relationship with the researcher or Ateneo de Naga University (e.g., the researcher's students, recipients of services, or funding by ADNU)?
   ○ YES ○ NO

   If YES, what steps will be taken to ensure that participants are free to participate, refuse, or withdraw from the study at any time?_____

9. If participants withdraw from the study, will they be able to withdraw the data concerning themselves as well? ○ YES ○ NO

10. Does the project involve deception or withholding relevant information from participants?
    ○ YES ○ NO

    If YES,
    a. What is the justification for this deception or withholding of information?
       _____

    b. How will the participants' right to complete information be addressed?
       _____

11. State clearly what you will provide the participants with incentives as a result of their participation. Incentives should not go beyond reimbursements for expenses incurred as a result of the involvement in the research. These may include travel costs, reimbursement for time lost, and snacks/meals commensurate to time and effort spent during the data collection period._____

F. CONFIDENTIALITY AND PRIVACY

1. How will the privacy of individual participants be protected when recording or analyzing data?_____

2. Will information collected from data or interviews be published or reported?

○ YES ○ NO

a. If YES, What form will this take?_____

b. Have the participants consented to this? ○ YES ○ NO

3. Will the data be visually or audio recorded? ○ YES ○ NO

   If YES, justify its use._____

   _____

4. Where will the data be stored, and for how long?_____

   _____

5. Who will have access to the data during and upon completion of the project?_____

6. How will data be de-identified?_____

   _____

DECLARATION BY RESEARCHER/S

I/We, the researcher/s of this project, ensure that I/we will conduct the study following legal and ethical responsibilities.

That I/we make this application on the basis that the Institutional Research Ethics Committee of Ateneo de Naga University will keep all information in this form in strict confidence.

_____
Signature Over Name of Proponent 1
Date: _____

_____
Signature Over Name of Proponent 2
Date: _____

Endorsed by:

_____
Printed Name and Signature of Thesis/Dissertation Adviser / URC Chair

_____
Printed Name and Signature of Dean of College/Graduate School

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	**APPLICATION FOR ETHICS REVIEW OF A NEW PROTOCOL**	IREC Form No.	06
		Version No.	02
		Date of Effectivity	September 22, 2022

I. General Information			
Title of Study			
IREC Code		Study Site	
Name of Researcher		Contact Information	Mobile No:
Co-researcher (if any)			Email:
Institution ☐ GS ☐ LAW ☐ College, specify _____ ☐ External, specify _____			
Address of Institution (If ADNU, specify department/office only)			
Type of Study	☐ Social / Behavioral Research ☐ Others, please specify _____		
Type of Study Site	☐ Multicenter (International) ☐ Multicenter (National) ☐ Single Site		

Source of Funding	☐ Self-Funded ☐ Institution-Funded ☐ Government-Funded, specify institution ☐ Scholarship/Research Grant, specify Institution		
Duration of the Study	Start date: End date:	No. of study participants	
Has the research been revised based on a technical review? ☐ Yes ☐ No			
Has the research been submitted to another Research Ethics Board? ☐ Yes ☐ No			

2. Checklist of Documents

Basic Requirements	Supplementary Documents
☐ Signed IREC Form 1 (endorsed by the Adviser & the Dean)	☐ Survey Interview Questionnaire (if applicable)
☐ Other IREC Form, specify _____ (endorsed by the Adviser & the Dean)	☐ KII Questionnaire (if applicable)
☐ Cover email/Request for Review (cc: Dean and Research Adviser)	☐ FGD Guide Questions (if applicable)
☐ Full Proposal	☐ Data Collection Forms (if applicable)
☐ Technical Review Approval/Matrix of Action/Recommendation	☐ Observation Form & Protocol (e.g., field notes, diary, etc.), if applicable
☐ Curriculum Vitae of Researcher/s	☐ A special permit, if applicable, please specify _____ ☐ Draft MOA with the community, if applicable
☐ Informed Consent Form (if applicable)	

☐ English Version ☐ Adult participant

☐ Filipino version ☐ Minor participant (15-17 years old)

☐ Bicol version ☐ Guardian

☐ Other, please specify _____

☐ Assent Form (7-14 years old) (if applicable)

☐ English version ☐ Bicol version

☐ Filipino version ☐ Other, please specify _____

Accomplished by

_____

Signature

Date submitted

---------- To be filled by the IREC Secretariat ----------

Completeness of Document **Complete**
Incomplete

Lacking Documents/ Other Remarks	

Received by	*Signature Over Printed Name*	**Date Received**	

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	**CURRICULUM VITAE FORM (for Research Proponents)**	IREC Form No.	07
		Version No.	01
		Date of Effectivity	March 2022

Instruction: Each Research Proponent must accomplish this form.

1. Name of Research Proponent: _____
2. Course (for ADNU applicant): _____
3. Highest Educational Attainment: _____
4. Affiliation – Name of Institution: _____
5. Affiliation – Name of Department: _____
6. Job Position: _____
7. Brief description of job position: _____
8. Address of employment: Barangay: _____

   Municipality/City: _____
9. Are you related by work to the study participants? Yes No
10. If yes in no. 8, describe briefly how you are related by work to the study participants (e.g., the study participants are the clients of my institution/my students/my subordinates/students of the school where I am the head/I supervise).

_____ _____

Signature of Proponent Date

IREC Form 12 – Letter Template for Application for Exempt from Ethics Review

(Date)

_____
Chairperson, IREC
Ateneo de Naga University

Subject: Request for Exempt from Ethics Review

Dear _____**,**

I would like to request an exemption from the ethics review of my research proposal titled, _____because _____
_____.

Please find attached the following required documents for your perusal:

- ☐ Technical-panel approved proposal;
- ☐ Written permission from the agency or office where the data will be obtained, if applicable (*see Notes 1 & 3 below)*;
- ☐ IREC Form 1, if applicable (*see Note 2b below)*;
- ☐ Internet/Web link of the publicly available data, if applicable (*see Note 4 below)*;

Thank you.

Sincerely,

_____
Researcher
Unit: _____
Course (If applicable): _____

Endorsed:

_____
Dean/Chairperson

_____
Academic Unit

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	**RESUBMISSION FORM**	IREC Form No.	10
		Version No.	1
		Date of Effectivity	November 2021

General Information			
Title of Study			
Version number/date			
IREC Code		Study Site	
Name of Researcher		Contact Information	Mobile No:
Co-researcher/s (if any)			Email:
Institution of Researcher			
Address of Institution			

IREC Recommendations	Response of Researcher	Section and page number of revisions

Signature of Researcher/s: _____ Date: _____

_____

Endorsed by:

_____

Name and Signature of the Research Adviser/URC Chair/Designated Point Person

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	**APPLICATION FOR ETHICS REVIEW OF PROGRESS REPORTS**	IREC Form No.	13
		Version No.	2
		Date of Effectivity	February 3, 2023

General Information			
Title of Study			
IREC Code		Approved Protocol Date	
Name of Researcher			
Co-researcher/s (if any)		Study Site	
Contact Information	Mobile No:	Email:	

Progress Report *(Please use additional sheets if necessary)*

1. Start of study _____

2. Original plan of end of study _____

3. Current Status of the Study (What were accomplished so far? / What had been accomplished at this stage in the research?)

4. Is there a protocol deviation in your study? (Protocol deviation is any change made on the implementation of the study after the issuance of ethical clearance.)
   - ☐ Yes (Please submit IREC Form 15 - Protocol Violation/Deviation Report)
   - ☐ No

5. Is there a violation (participants, scientific validity) in your study?
   - ☐ Yes (Please submit IREC Form 15 – Protocol Violation/Deviation Report and IREC Form 04 – Application for Continuing Review)
   - ☐ No

6. Further Steps to be Undertaken

Steps	Date

7. Expected Date of Submission of the Final Thesis/Dissertation/Report to IREC _____

I/We certify that the information provided herein is the actual procedures conducted during the study.

☐ I/we request your approval without an extension of the ethical clearance.

☐ I/we would like to apply for an extension of the ethical clearance.

☐ I/we would like to apply for continuing review. Please see the attached filled out

☐ IREC Form 04 – Application for Continuing Review

☐ IREC Form 15 – Protocol Deviation/Violation Report

Signature of Researcher/s: _____ Date: _____

_____

Endorsed by:

_____

Name and Signature of the Research Adviser/URC Chair/Designated Point Person

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	**APPLICATION FOR ETHICS REVIEW OF AMENDMENTS**	IREC Form No.	14
		Version No.	02
		Date of Effectivity	February 3, 2023

General Information			
Title of Study			
IREC Code		Approved Protocol Date	
Name of Researcher			
Co-researcher/s (if any)		Study Site	
Contact Information:	Mobile No:	Email:	

Amendment Report (*Please use additional sheets if necessary)*		
Original Procedure/ Provision	Proposed Amendment/s	Justification

Signature of Researcher/s: _____ Date: _____

_____

Endorsed by:

_____

Name and Signature of the Research Adviser/URC Chair/Designated Point Person

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	**PROTOCOL DEVIATION / VIOLATION REPORT**	IREC Form No.	15
		Version No.	01
		Date of Effectivity	February 3, 2023

General Information			
Title of Study			
IREC Code		Approved Protocol Date	
Name of Researcher			
Co-researcher/s (if any)		Study Site	
Contact Information	Mobile No:	Email:	

Protocol Deviation/Violation Report *(Please use additional sheets if necessary)*

Original Procedure/ Provision	Protocol Deviation/Violation	Explanation for Deviation/Violation	Impact of Deviation/Violation on Participants and Integrity of Data

I/We certify that the information provided herein is the actual procedures conducted during the study.

Signature of Researcher/s: _____ Date: _____

_____

Endorsed by:

_____

Name and Signature of the Research Adviser/URC Chair/Designated Point Person

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	**APPLICATION FOR CONTINUING REVIEW / EXTENSION OF ETHICAL CLEARANCE**	IREC Form No.	04
		Version No.	02
		Date of Effectivity	February 17, 2023

General Information			
Title of Study			
IREC Code		Approved Protocol Date	
Name of Researcher			
Co-researcher/s (if any)		Study Site	
Contact Information	Mobile No:	Email:	

A. AMENDMENTS, DEVIATIONS, OR VIOLATIONS OF THE APPROVED PROTOCOL

1. What amendments, deviations, or violations to the approved protocol for this research have been made?

   _____

2. What are the reasons for these amendments, deviations, or violations?

   _____

3. Do these amendments, deviations, or violations put the participants at risk of harm and/or compromise the scientific integrity of the research?

   ☐ Yes (Proceed to B)

   ☐ No

B. STEPS TAKEN TO MITIGATE RISK OR HARM TO THE STUDY PARTICIPANTS AND/OR PRESERVE SCIENTIFIC INTEGRITY

1. What steps have you taken to mitigate the risk of harm to the study participants?

   _____

2. How did you preserve the scientific integrity of the research?

_____

DECLARATION BY RESEARCHER/S

I/We certify that the information provided herein is the actual procedures conducted during the study.

Signature of Researcher/s: _____ Date: _____

_____

Endorsed by:

_____

Name and Signature of the Research Adviser/URC Chair/Designated Point Person

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	**EARLY TERMINATION REPORT**	IREC Form No.	16
		Version No.	1
		Date of Effectivity	January 24, 2023

General Information			
Title of Study			
IREC Code		Study Site	
Name of Researcher		Contact Information	Mobile No:
Co-researcher (if any)			Email:
Institution			
Address of Institution			
Ethical clearance effectivity period			
Recommended by:			

Early Termination Report	
1. Start of study	2. Expected end of the study
3. Number of enrolled participants	4. Number of required participants
5. Reason/s for termination	
6. Support mechanisms/Interventions for Enrolled Participants	
7. Post-Termination Actions	

Signature of Researcher: _____ Date: _____

Endorsed:

_____

Name and Signature of the Research Adviser/URC Chair/Designated Point Person

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	FINAL REPORT FORM	REC Form No.	11
		Version No.	02
		Date of Effectivity	January 9, 2023

General Information			
Title of Study			
IREC Code		Approved Protocol Date	
Name of Researcher			
Co-researcher/s (if any)		Study Site	
Contact Information	Mobile No:	Email:	
Final Report			
1. Start of study _____		2. End of study _____	

3. List down IREC recommendations before the issuance of ethical clearance with the corresponding actions taken by the researcher indicating the section/page in the revised thesis/dissertation/final report *(Use additional sheets if necessary)*.

IREC Recommendations	Actions Taken by the Researcher	Section & page in the Final Thesis/ Dissertation/ Research Report

4. Deviations from the approved protocol
5. Issues/problems encountered
6. Actions for dissemination of study results:

Signature of Researcher: _____ Date: _____

Endorsed:

_____

Name and Signature of the Research Adviser/URC Chair/Designated Point Person

GROUP D

Reviewer's Forms

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	**PROTOCOL REVIEWER WORKSHEET**	IREC Form No.	08
		Version No.	02
		Date of Effectivity	November 17, 2022

Title of Study			
IREC Code		Type of Review	
Researcher/s		Course (If applicable)	
Name of Reviewer		Date Received	
Reviewer	☐ Primary Reviewer ☐ Co-Reviewer		

Instructions: Tick "Yes/No/Not Applicable" and write your comments on the cell.

Guide questions for reviewing the proposal/protocol	Reviewer
1. Does the study have social value (e.g., scientific value, relevance to national /community needs)?	☐ Yes ☐ No Comment/s:
2. Is the study background adequate?	☐ Yes ☐ No Comment/s:
3. Are the study objectives (as implied by the research questions) Specific, Measurable, Attainable, Realistic, Time-bound?	☐ Yes ☐ No Comment/s:
4. Do the research questions include deception in purpose (giving false/misleading information)?	☐ Yes ☐ No Comment/s:

5. Are the research questions supported by the Review of Literature?	☐ Yes ☐ No Comment/s:
6. Does the research need to be carried out with human participants?	☐ Yes ☐ No Comment/s:
7. Is the research design appropriate?	☐ Yes ☐ No Comment/s:
7.1. Is the population identified and defined?	☐ Yes ☐ No Comment/s:
7.2. Is the sample size justified?	☐ Yes ☐ No Comment/s:
7.3. Is the selection of study participants described?	☐ Yes ☐ No Comment/s:
7.4. Is the plan for data collection described?	☐ Yes ☐ No Comment/s:
7.5. Is the plan for data analysis described?	☐ Yes ☐ No Comment/s:
7.6. Are the study participants randomly assigned to treatment conditions?	☐ Yes ☐ No ☐ Not applicable Comment/s:

7.7. Are the research facilities adequate?	☐ Yes ☐ No ☐ Not applicable Comment/s:
8. Does the study have a vulnerability issue?	☐ Yes ☐ No Comment/s:
9. Are appropriate mechanisms/interventions in place to address the vulnerability issue/s?	☐ Yes ☐ No Comment/s:
10. Are there risks/ probable harms to the human participants in the study (See IREC Form 0-Research Ethics Risk Checklist)?	☐ Yes ☐ No Comment/s:
11. Are there measures to mitigate the risks?	☐ Yes ☐ No Comment/s:
12. Is the informed consent procedure & form adequate and culturally appropriate (See IREC Form 09 – Consent Checklist)?	☐ Yes ☐ No Comment/s:
13. Is/are the investigator/s adequately trained and do they have sufficient experience to undertake the study?	☐ Yes ☐ No Comment/s:
14. Are there any other concerns in the study?	Comment/s:

Notes.

Vulnerability, in the context of research, is either an intrinsic (e.g., IPs, children, persons with mental illness or retardation) or situational condition (e.g., impoverished, incarcerated, or unemployed individuals) of some individuals that

puts them at greater risk of being used in ethically inappropriate ways in research (National Bioethics Advisory Commission, 2001).

All items, except for items 4, 8, and 10, should have responses of “Yes” to pass the ethical review. If item 10 has a response of “No” but there is a “Yes” for number 11, there is no ethical issue. Contrary to these means an ethical concern.

References:

National Bioethics Advisory Commission. (2001). Ethical and policy issues in research involving human participants. https://bioethicsarchive.georgetown.edu/nbac/human/overvol1.pdf
PHREB (2020). 2020 PHREB SOP Workbook. https://ethics.healthresearch.ph/index.php/2012-04-19-05-10-10/402-2020-phreb-sop-workbook

Recommendation:

☐ **Approved**
☐ **Minor revision/s required**

_____

☐ **Major revision/s required**

_____

☐ **Disapproved**

Reasons for disapproval:

_____

Name and Signature of Reviewer

Review Date

Note: This form is posted for reference only. This is for IREC’s use.

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	**CONSENT CHECKLIST**	IREC Form No.	09
		Version No.	02
		Date of Effectivity	November 17, 2022

Title of Study			
IREC Code		Type of Review	
Proponent		Course/ Institution	
Name of Reviewer		Reviewer	☐ Primary Reviewer ☐ Co-Reviewer

Guide questions for reviewing the informed consent process and form	**Reviewer**
1. Is it necessary to seek the informed consent of the participants?	☐ Yes ☐ No
If NO, please explain.	
2. <u>If YES</u>, are the participants provided with sufficient information regarding:	
2.1. Purpose of the study?	☐ Yes ☐ No
2.2. Expected duration of participation?	☐ Yes ☐ No
2.3. Procedures to be carried out?	☐ Yes ☐ No
2.4. Discomforts and inconveniences?	☐ Yes ☐ No

2.5. Risks (physical/psychological/social harm including possible discrimination)?	☐ Yes ☐ No
2.6. Random assignment to the trial treatments?	☐ Yes ☐ No ☐ Not Applicable
2.7. Benefits to the participants?	☐ Yes ☐ No
2.8. Alternative treatments/ procedures?	☐ Yes ☐ No ☐ Not Applicable
2.9. Compensation and/or medical treatments in case of injury?	☐ Yes ☐ No ☐ Not Applicable
2.10. Refusal to participate or discontinuance at any time will not involve a penalty or loss of benefits to which the subject is entitled?	☐ Yes ☐ No
2.11. The extent of confidentiality in terms of:	
2.11.1. Protection of privacy of the participants?	☐ Yes ☐ No
2.11.2. Publication of information collected from participants?	☐ Yes ☐ No

2.11.3. Storage of information collected from participants?	☐ Yes ☐ No
2.11.4. Access to information collected from participants?	☐ Yes ☐ No
2.12. Who to contact for pertinent questions and/or for assistance in a research-related injury/harm?	☐ Yes ☐ No
3. Is the informed consent written or presented in simple language that participants can understand?	☐ Yes ☐ No
4. Does the protocol include an adequate process for ensuring that consent is voluntary (i.e., with a certificate of consent/provision of a declaration by the consent-giver about his/her suitability, competence, opportunity to ask questions and receive satisfactory answers, given time to reflect, weigh options, read, discuss with others, decide, absence of force or intimidation, and agreement)?	☐ Yes ☐ No
5. Is there an accompanying informed consent to be obtained from the participants' legal guardians?	☐ Yes ☐ No
6. Do you have any other concerns?	

Recommendation:

☐ **Approved**

☐ **Minor revisions required**

_____

Signature over Printed Name of Reviewer

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	SITE VISIT MONITORING FORM	IREC Form No.	05
		Version No.	02
		Date of Effectivity	Nov 17, 2022

Research Project Title: _____
IREC No. _____
Purpose of Project: _____
Proponent 1: _____ Gbox E-mail: _____
Department / Unit: _____ Course: _____
Proponent 2: _____ Gbox E-mail: _____
Department / Unit: _____ Course: _____
Name of Adviser _____ Gbox Email: _____

Date of Site Visit: _____
Monitoring IREC Member: _____

The following were noted during the site visit:

_____ a. adverse events in the conduct of research: _____
_____ b. new study sites: _____
_____ c. non-compliance of protocol: _____
_____ d. suspicious conduct of the study: _____
_____ e. Other: _____

Recommendations:

_____

GROUP E

Operational Templates

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	NOTICE OF MEETING WITH PROVISIONAL AGENDA	IREC Form No.	23
		Version No.	03
		Date of Effectivity	November 17, 2022

Date of Notice:
Date of Meeting:
Venue:
Time:

1. Call to Order
2. Declaration of Quorum
3. Disclosure of Conflict of Interest
4. Approval of the Provisional Agenda
5. Review and Approval of the Minutes of the Previous Meeting
6. Business Arising
7. New Business
8. Full Review of New Proposals (Initial)
   - 8.1. IREC Code - Title
   - 8.2. IREC Code - Title
9. Report on Expedited Review of Proposals
   - 9.1. IREC Code - Title
   - 9.2. IREC Code - Title
10. Updates on Full Review of Proposals (Resubmission)
    - 10.1. IREC Code - Title
    - 10.2. IREC Code - Title
11. Updates on Expedited Review of Proposals (Resubmissions)
    - 11.1. IREC Code - Title
    - 11.2. IREC Code - Title
12. Updates on Approved, Ongoing Research
    - 12.1. IREC Code - Title
    - 12.2. IREC Code - Title
13. Other Matters
14. Adjournment

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	**ATTENDANCE SHEET**	IREC Form No.	24
		Version No.	01
		Date of Effectivity	Sep 2022

Type of Meeting:
Date:
Time:
Venue:

Attendance:
Present

Name	Office

Absent

Name	Office

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	**Meeting Minutes Template**	IREC Form No.	25
		Version No.	01
		Date of Effectivity	Sep 2022

Type of Meeting:
Date:
Time:
Venue:

Attendance:

Those present were:

Also present were:

Those absent were:

1. Call to Order
2. Declaration of Quorum
3. Disclosure of Conflict of Interest
4. Approval of the Provisional Agenda
5. Review and Approval of the Minutes of the Previous Meeting (Date)
6. Business arising from the minutes of the meeting
7. Full Review of Proposals (Initial)

7.1.

IREC Code:	
Title:	
Researcher/s:	
Submission date	
Reviewers:	
Discussion/Comments: Scientific Soundness:	

Ethical Considerations -Social Value -Vulnerability issue -Measures to protect vulnerability population -Risk/benefit ratio -Measures to mitigate risks -Confidentiality and privacy -Informed Consent process, form and content	
Recommendations:	
Decision:	
Decision letter date	

8. Report on Expedited Review of Proposals (Initial)
   8.1.

IREC Code:	
Title:	
Researcher/s:	
Reviewers:	
Submission Date	
Discussion/Comments/Recommendations:	
Decision:	
Decision letter date	

9. Updates on Full Review of Proposals (Resubmissions)
   9.1.

IREC Code:	
Title:	
Researcher/s:	
Submission date	
Reviewers:	
Discussion/Comments/Recommendations:	
Decision:	
Decision letter date	

10. Updates on Expedited Review of Proposals (Resubmissions)
    10.1.

IREC Code:	
Title:	
Researcher/s:	
Submission date	
Reviewers:	
Discussion/Comments/Recommendations:	
Decision:	
Decision letter date	

11. Updates on Approved, Ongoing Research
    11.1.

IREC Code:	
Title:	
Researcher/s:	
Submission date	
Approval letter sent	
Amendment/Report submission date	
Lead Reviewers	
Discussion/Comments/Recommendations:	
Decision:	
Decision letter date	

12. Other Matters

13. Adjournment

Prepared by:

(Name)
IREC AA
Date:

Noted by:

(Name)
IREC Chair
Date:

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	**PROTOCOL INDEX**	IREC Form No.	26
		Version No.	01
		Date of Effectivity	Sep 2022

Date of Filing	Nature of document (e.g., Other study document, proposal, decision, etc.)	Name of Filer	Comments
1.			
2.			
3.			

	ATENEO DE NAGA UNIVERSITY INSTITUTIONAL RESEARCH ETHICS COMMITTEE		
IREC	**LOGBOOK FOR INCOMING/OUTGOING COMMUNICATION**	IREC Form No.	28
		Version No.	01
		Date of Effectivity	Oct 2022

Date	Incoming / Outgoing	Nature of document (Decision letter, Approval letter, Invitation, Notice of Meeting, etc.)	Sender	Recipient	Received by	Delivered by

IREC DATABASE

Date Filed	IREC Code	Proponent	Unit	Course	Research Adviser	Type of Review	Primary Reviewer (2nd Row: Team Member)	Action	Date Conveyed	Proposal Title	Documents Submitted