



NEGROS ORIENTAL STATE UNIVERSITY

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# **RESEARCH ETHICS**

# **MANUAL 2025**



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**Kagawasan Avenue, Dumaguete City, Negros Oriental, Philippines 6200**

Phone: (63) (35) 522-5050

Email: [president.office@norsu.edu.ph](mailto:president.office@norsu.edu.ph)

[www.norsu.edu.ph](http://www.norsu.edu.ph)

## RESEARCH ETHICS MANUAL

Negros Oriental State University  
Research Ethics Committee  
Research, Innovation, Development, and Extension (RIDE)  
Dumaguete City  
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### PREPARED BY:

Geraldine S. Quiñones  
Edwin F. Romano, Jr.  
Johann Heinrich P. Malongo  
Gilbert Nicanor A. Atillo



## ABOUT THIS MANUAL

The Negros Oriental State University (NORSU) Research Ethics Manual 2025 serves as the official guide in the ethical conduct of research, extension, innovation, technology development, and scholarly activities undertaken by the University. This Manual provides the guiding principles, ethical standards, policies, and procedures that shall govern all research-related activities involving faculty members, students, researchers, non-teaching personnel, external collaborators, and research participants.

This Manual was developed to promote integrity, accountability, transparency, professionalism, and social responsibility in research. It establishes institutional mechanisms that ensure the protection of human participants, the welfare of animals used in research, the responsible handling of data and information, and adherence to national and international ethical standards.

The provisions of this Manual are aligned with recognized ethical frameworks and legal standards, including the Declaration of Helsinki, Belmont Report, Nuremberg Code, Philippine Health Research Ethics Board (PHREB) Guidelines, Data Privacy Act of 2012, Animal Welfare Act, and other applicable government regulations and institutional policies.

This Manual also outlines the roles and responsibilities of researchers, research advisers, the Research Ethics Committee (REC), funding agencies, and the University in ensuring that research activities are conducted responsibly and ethically.

Furthermore, this Manual aims to:

1. Promote ethical awareness and responsible conduct of research within the University;
2. Protect the rights, dignity, safety, and welfare of research participants;
3. Ensure fairness, integrity, and transparency in all stages of the research process;
4. Provide guidance for ethical review, monitoring, and approval of research proposals;
5. Encourage quality research that contributes to national development, innovation, and community welfare; and
6. Strengthen the culture of research excellence and accountability in Negros Oriental State University.

This Manual shall serve as a living document subject to periodic review and revision to ensure its responsiveness to emerging ethical issues, technological advancements, societal changes, and evolving national and international standards in research ethics.

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# INTRODUCTION

The **Negros Oriental State University (NORSU) Research Ethics Manual** establishes the fundamental principles and standards governing the conduct of research, extension, technology development, innovation, and instructional materials production within the University. It serves as the foundational framework for implementing policies and regulations across all research, innovation, extension, and academic undertakings of the University, ensuring the ethical conduct of research.

This Manual guides faculty members, researchers, non-teaching personnel, and students in upholding ethical standards in research. It defines the expected standards of professional behavior in scholarly activities and promotes responsible judgment, accountability, and integrity in all research endeavors.

The NORSU Research Ethics Manual aligns with internationally recognized ethical standards, including the Declaration of Helsinki, the Nuremberg Code, the Belmont Report, and the Animal Welfare Act, Republic Act No. 10532, and the also known as the Philippine National Health Research System Act of 2013 and the Data Privacy Act of 2012 (Republic Act No. 10173). It complements existing University policies, including the Intellectual Property Manual, Research Manual, University Code, Extension Manual, and policies on responsible publication, authorship, and research dissemination.

This Manual is a living document and shall be subject to periodic review and revision to ensure its continued relevance in response to evolving societal values, legal standards, and scientific advancements.

## I. Guiding Principles

As a research university, NORSU is committed to generating knowledge that advances quality of life, promotes social transformation, and strengthens the integration of research and teaching. All research activities shall adhere to the following principles:

1. **Quality**  
Research shall meet national and international standards of excellence. Projects must demonstrate scientific rigor and generate outcomes that contribute meaningfully to community development, innovation, and nation-building.
  2. **Honesty**  
Researchers shall truthfully represent research objectives, methodologies, findings, funding sources, and potential outputs (e.g., patents, utility model commercialization, publication, policy). Misrepresentation, fabrication, falsification, and deception are strictly prohibited. Researchers are accountable for proper documentation and transparent reporting.
  3. **Objectivity**  
Research shall be conducted free from bias in design, implementation, analysis, and interpretation. Peer review, grant acquisition, and commissioned research shall be guid-
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ed by expertise, merit, and alignment with the University research agenda.

**4. Integrity**

Researchers shall uphold professional commitments and honor agreements. Fraud, plagiarism, data manipulation, and duplicate publication are prohibited and subject to disciplinary action in accordance with institutional policies and existing laws.

**5. Carefulness and Safety**

Researchers shall maintain accurate records and exercise diligence in all research stages. The safety and welfare of research team members and participants shall take precedence over research objectives.

**6. Openness**

Researchers are encouraged to engage in collaborative and interdisciplinary research, promote scholarly dialogue, and share findings responsibly while maintaining collegial respect.

**7. Respect for Intellectual Property**

The University shall respect and protect patents, copyrights, and other intellectual property rights. Proper acknowledgment of contributions is mandatory. Unauthorized use of unpublished data or materials is prohibited. Equitable royalty-sharing agreements with traditional knowledge holders shall be formalized through written agreements.

**8. Human Subject Protection and Animal Welfare**

All research involving humans or animals shall comply with recognized ethical standards.

Researchers shall:

- Obtain voluntary informed consent;
- Minimize risks and maximize benefits;
- Protect dignity, privacy, and confidentiality;
- Provide special protections for vulnerable populations;
- Ensure fair distribution of research burdens and benefits.
- Animal research shall be scientifically justified and designed to minimize pain and distress. Alternative methods shall be used whenever possible.

**9. Responsible Publication**

Research dissemination shall advance knowledge and not serve purely personal or career interests. Duplicate publication and unethical authorship practices are prohibited.

**10. Social Responsibility**

Research shall promote societal benefit without harming the environment, biodiversity, or communities.

**11. Authorship**

Authorship shall be based on substantial intellectual contributions to the conception or design of the study; data collection, analysis, or interpretation; drafting or critically revising the manuscript; and approval of the final version for publication. The percentage contribution of each author shall be determined through mutual agreement prior to manuscript submission and shall be accurately documented in the authorship.

**II. Elements of Research Ethics****Social Value**

1. The involvement of people in research is only justified when the study aims to make a real difference whether by addressing a pressing social or health issue, deepening our understanding of it, or helping to improve the well-being of individuals, families, and communities.
2. It's important to clearly describe the significance of the study. This includes an accurate, up-to-date picture of the social or health issue being addressed, and how your research might help move us closer to a solution.
3. The way a study is designed—its methods and how data is gathered should be carefully planned to ensure it effectively supports the study's goals and provides meaningful results.
4. Sharing your findings is key to making a positive impact. A clear plan for how the results will be communicated helps ensure the study benefits those who need it most.
5. The Ethics Committee will review the dissemination plan to ensure it is appropriate, practical, and that the information reaches the right people in the right way.

**Informed Consent**

6. Informed consent is a decision of a competent potential participant to be involved in research after receiving and understanding relevant information, without having been subjected to coercion, undue influence, or inducement.
  7. Obtaining informed consent is an ongoing process that starts from the first interaction with a potential participant and continues throughout the entire study. It involves clearly explaining the study, answering questions as they come up, repeating and clarifying information when needed, and making sure participants fully understand each part of the research. By doing this and gaining their agreement, researchers show respect for the participants' dignity and right to make their own informed choices.
  8. For all research involving humans, the researcher shall obtain the voluntary informed consent of the prospective research participant. In the case of an individual who is incapable of giving or who has diminished capacity to give informed consent, the researcher must exert effort to obtain his or her assent and the consent of a legally authorized representative (LAR), in accordance with applicable laws.
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9. In obtaining informed consent, sponsors and researchers shall have the duty to avoid deception, undue influence, or intimidation.
10. Informing the potential participant shall not be simply a ritual recitation of the contents of a written document. Rather, the researcher shall convey the information, whether orally, in writing, or other modes of communication, in a language and manner that suit the individual's capacity and level of understanding.
11. The researcher shall ensure that the prospective participant has adequately understood the information. The researcher shall give each one the full opportunity to ask questions, and should answer them honestly, promptly, and completely.

### *Essential information for participants*

12. The researcher shall provide the following information to the potential research participant, whether orally or in writing, in a language that suits the participant's level of understanding:
  - 12.1. That the individual is invited to participate in the research which is being undertaken by the researcher. The reasons for considering the individual suitable for the study, and that participation is voluntary;
  - 12.3. That the individual is free to refuse to participate in the research without penalty or loss of benefits to which he or she is entitled;
  - 12.4. The purpose of the research and the procedures to be carried out by the researcher
  - 12.5. The expected duration of the individual's participation and the possibility of early termination of the study, or of the individual's participation in it;
  - 12.6. Any foreseeable risks, pain or discomfort, or inconvenience to the individual as research respondents
  - 12.7. The direct benefits, if any, expected to manifest to individuals from participating in the research;
  - 12.8. Whether money or other forms of material goods will be provided in return for the individual's participation and, if so, the kind and amount;
  - 12.9. The expected benefits of the research to the community or to society at large, or contribution to scientific knowledge;
  - 12.10. Whether, when, and how, any intervention proven by the by the research to be safe and beneficial will be made available to the individuals after they have completed their participation in the research, and whether they will be expected to pay for them;
  - 12.11. The provisions to ensure respect for the privacy of research participants and the confidentiality of records in which they are identified, including documentation through taking of pictures and recording of the interview and that these might be displayed in publications and conferences or fora;
  - 12.12. Legal or other limits to the researcher's ability to safeguard confidentiality, and the possible consequences of breaches of confidentiality;
  - 12.13. The participants are free to withdraw from the research at any time without having to give any reason, and without penalty or loss of benefits to which he or she is entitled;
  - 12.14. The sponsors or funders of the research, the institutional affiliation of the researchers, and the nature and sources of funding for the research;
  - 12.15. The possible research uses, direct or secondary,
  - 12.16. The extent of the researcher's responsibility to ensure needed services to the research

- participant;
- 12.17. That a PHREB-accredited REC has approved or cleared the research protocol; and
- 12.18. The contact information of persons designated to respond to the following:
  - 12.22.1. Queries on the details of the protocol;
  - 12.22.2. Issues relating to the human rights of participants;
  - 12.22.3. Related concerns and grievances; and
  - 12.22.4. Management of research-related injuries.

### ***Documentation of consent***

- 13. As a general rule, documentation of informed consent includes an actual signature or thumb-mark of the prospective participant on the informed consent form.
- 14. When the use of an informed consent form is not feasible or unacceptable to the prospective participant, a description of the process, attested by a witness, may be an alternative that needs prior approval of the REC.

### ***Waiver of the informed consent***

- 15. Waiver of individual informed consent is to be regarded as exceptional, and must be approved by an REC.
- 16. The informed consent process may be waived in specific research contexts, such as:
  - 16.1. Archival research involving publicly available documents;
  - 16.2. Research that uses the method of naturalistic observation provided that all of following requirements are complied with:
    - 16.2.1. Thorough justification for the use of naturalistic observation;
    - 16.2.2. Plan for how the data collected will be used;
    - 16.2.3. Assurance that risks to participants are unlikely; and
    - 16.2.4. Mechanism to ensure confidentiality and anonymity of observed individuals and their data (e.g., observations are recorded in such a way that the individuals involved are not identifiable).
- 17. Some or all of the elements in the informed consent may be waived or altered (with prior approval of the REC) if all these conditions are met:
  - 17.1. The research presents no more than minimal risk;
  - 17.2. The waiver or alteration will not adversely affect the rights and welfare of the participants;
  - 17.3. The research cannot be practicably carried out without the waiver or alteration; and
  - 17.4. The participants will be provided with additional pertinent information after their participation (whenever appropriate).

### ***Renewing consent***

- 18. The informed consent of each research participant shall be renewed under the following conditions:
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- 18.1. If there are any significant changes in the circumstances or procedures of the research;  
or
- 18.2. If new information becomes available that could affect the willingness of research participants to continue to participate; or
- 18.3. In long-term studies at pre-determined intervals even if there are no changes in the design or objectives of the research.

### ***Vulnerability of Research Participants***

19. Vulnerable participants shall require special protection because of certain characteristics or situations that render them as such. Vulnerable participants are those who are relatively or absolutely incapable of deciding for themselves whether or not to participate in a study for reasons such as physical and mental disabilities, poverty, asymmetric power relations, and marginalization, among others and who are at greater risk for some harms.
20. Vulnerable groups shall not be included in research unless such research:
  - 20.1. Is necessary to promote the welfare of the population represented; and
  - 20.1. Cannot be performed on non-vulnerable persons or groups.
21. Researchers, sponsors, or RECs shall not arbitrarily exclude women of reproductive age from biomedical research. The potential for becoming pregnant during a study shall not, in itself, be used as a reason for precluding or limiting women's participation in research.
22. Competent advice and assistance shall be provided to participants who, by virtue of social, economic, political or medical disadvantages, are liable to give consent under duress or without the benefit of adequate information. Caution shall be exercised in obtaining informed consent for a research project if the research participant is in a dependent relationship with the researcher (e.g., as a research participant) to ensure that the consent is not given under duress or undue influence.

### **Risks, Benefits, and Safety**

23. Research is justified if there is a reasonable likelihood that the population from which the participants are derived stand to benefit from the research.
24. All research involving human participants shall be preceded by a careful assessment of predictable risks, burdens, and foreseeable benefits to the research participant or to others.
25. Every precaution shall be taken to minimize the negative impact of the study on the research participant's wellbeing.
26. Research shall be conducted only if there is an acceptable positive benefit-risk ratio.
27. The researcher/funder/sponsor shall endeavor to ensure the reasonable availability and accessibility of favorable research outcomes to the community.
28. When there is ethical and scientific justification to conduct research with individuals capable

of giving informed consent, the risk from research interventions that do not hold out the prospect of direct benefit for the individual participant shall be no more likely and no greater than the risk attached to routine medical or psychological examination of such persons. Slight or minor increases above such risk may be permitted when there is an overriding scientific or medical rationale for such increases and when the REC has approved them.

### **Privacy and Confidentiality of Information**

29. Researchers shall adhere to the principles of transparency, legitimate purpose, and proportionality in the collection, retention, and processing of personal information (Data Privacy Act of 2012).
  30. Researchers must respect participants' right to privacy. Unless required by law, the confidentiality of information shall at all times be observed. Records that link individuals to specific information shall not be released. This requirement shall be included in the informed consent form.
  31. Researchers shall refrain from identifying individuals or groups when release of information about them can expose them to possible harm or social stigma unless required by law.
  32. Where there is some likelihood or opportunity for the researcher to observe the occurrence of illegal or harmful behaviors (e.g., child abuse, substance use, self-harm, or suicide ideation), the researcher shall:
    - 32.1. Explicitly indicate the limits of confidentiality in the informed consent process, such as when the researcher is ethically and legally obligated to disclose the identity of the respondent to forestall imminent harm to self or others;
    - 32.2. Emphasize the right of the respondent to withdraw from the study or withdraw his or her data, and to refuse to answer any question; and
    - 32.3. Prepare a concrete and realistic protocol for reporting and referral in the event that imminent harm and/or a criminal act is disclosed or discovered in the process of data collection.
  33. Researchers shall recognize that collecting data using group methods (e.g., FGDs) has implications for the privacy and confidentiality of individuals. As it might not be possible for researchers to ensure the confidentiality of information or the anonymity of research participants, the researcher shall ensure that the nature of the study and the questions would cause minimal harm should confidentiality or anonymity be breached.
  34. The researcher shall describe his or her data protection plan in the protocol, including the steps to be taken so that all who have access to the data and the identities of the respondents can safeguard privacy and confidentiality. For example, the researcher shall provide adequate and clear instructions to research assistants, transcribers of audio recordings, or translators of transcriptions.
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## Justice

35. In research involving human participants the principle of justice refers primarily to distributive justice, which requires the equitable distribution of both the burdens and the benefits of participation in research. That is, it should not be the case that one group in society bears the costs of research while another group reaps its benefits. Research should not worsen existing health and social inequities.
  - 35.1. There shall be fair selection in the choice of population, sampling, and assignments.
  - 35.2. There shall be provision of appropriate care to research participants regardless of their economic status, gender, race, or creed.
  - 35.3. There shall be just compensation for harms brought about by participation in the research.
  - 35.4. Research participants shall be reimbursed for lost earnings, travel costs, and other expenses incurred when taking part in a study. Where there is no prospect of direct benefit, participants may be given a reasonable and appropriate incentive for inconvenience. The payments shall not be so large as to induce prospective participants to consent to participate in the research against their better judgment (undue inducement).
36. Individuals and communities shall have access to benefits related to participation in the study.

## Transparency

37. Ethical research shall be characterized by transparency. It is imperative for all parties to be transparent about matters relating to their involvement. Transparency is not diametrically opposed to privacy. On the contrary, transparency is an element of ethical research that promotes confidence in the research enterprise, even when privacy and anonymity need to be preserved about sensitive matters. The need for transparency also entails disclosure of research results.
38. Researchers must be transparent about aspects of a study that may have an impact on the rights, health, and safety of participants, or in respect to information that may have a bearing on the decision of participants to give or withhold their informed consent.
39. Disclosure of research results to research participants shall occur only when all of the following apply:
  - 39.1. The findings are scientifically valid and confirmed;
  - 39.2. The findings have significant implications for the participant's well-being; and
  - 39.3. The course of action to ameliorate these concerns is readily available when research results are disclosed to its participants.
40. Transparency imposes responsibilities on researchers to disclose information about their affiliations, financial interests, or other loyalties that may affect their objectivity and the integrity of their research output.
41. At the same time, transparency imposes responsibilities on research participants to be truthful in declaring their health conditions, and to be candid in expressing their concerns about their involvement in research.

### III. ENSURING QUALITY RESEARCH

#### The Research Protocol

The protocol is the definitive document of the research or study. It provides guidance for those who will conduct the research, reference for evaluators and reviewers, template for validation, substantiation for intellectual property claims, and legacy of the proponent. As such, it should be rigorously conceptualized, carefully crafted, and elegantly formulated.

1. The research protocol shall be sufficiently detailed to serve as documentation of the study. Further, it shall:
  - 1.1. Justify the need for the study, that is, why the study shall be conducted given the current state of knowledge;
  - 1.2. Establish the appropriateness of the proposed methods for investigating the research problem;
  - 1.3. Provide evidence for the feasibility of doing the study as proposed, that is, that the study can be completed successfully in the specified time and with the available resources
  - 1.4. Describe the recruitment process (where, who, how); and
  - 1.5. Describe the dissemination plan for research results and outcomes.
2. The purpose of the study, the design, the population, the methods of data collection, and the planned analyses shall be clearly described.
3. All procedures, whether invasive or not, shall be satisfactorily described in detail.
4. The research protocol shall adequately address the elements of research ethics as part of the Ethical Considerations section.
5. The protocol shall provide information on how the safety and welfare of research participants shall be protected.

#### Qualifications of Researchers

The researcher is the individual who is ultimately responsible and accountable for the research. The ethical discomfort in the use of human participants in research is alleviated by the assurance that the researcher is qualified. Such qualifications need to be vetted by the researcher, the REC, and the sponsors.

1. Persons engaged in research involving human participants shall have moral fortitude, scientific competence, social awareness, cultural sensitivity, intellectual humility, vigilance, and preparedness in safety issues.
2. The researcher shall have the training, ability, and resources to conduct the proposed study.
3. The researcher shall be knowledgeable of the literature on the research topic

### IV. GUIDELINES FOR RESEARCH ETHICS COMMITTEES

RECs are essential components of a human protection system in research. As such, institutions or entities shall have policies regarding research, and ensure that RECs are established and given adequate support according to standards. RECs should be able to provide independent and quality review and monitoring of all health-related research involving human participants. Institutional RECs shall have a manual of SOPs to make REC operations transparent, accountable, competent, timely, and consistent (WHO, 2011).

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## Composition

1. The Negros Oriental State University (NORSU) Research Ethics Committee (REC) shall be recommended by the Vice President for Research, Development, and Extension (VP RDE) and endorsed to the University President for approval, in accordance with NORSU's research policies and relevant national and international ethical standards. Within the institutional organizational structure, the REC shall be positioned under the administrative oversight of the Vice President for Research Development and Extension, as clearly indicated in the organizational chart. Notwithstanding this oversight, the REC shall maintain full independence in rendering ethical review decisions.
2. When appointing members, the institution shall consider the following:
  - 2.1. Membership shall be multidisciplinary and multi-sectoral, with adequate age and gender representation.
  - 2.2. Members shall have relevant scientific expertise, such as medical (in case of RECs reviewing clinical trials), social, or behavioral science; or qualifications relevant to the areas of research the REC is most likely to review. Members with expertise in ethics, law, environment, public health shall also be considered to reflect social and cultural diversity in research.
  - 2.3. The REC shall include an individual (non-medical, non-scientist) who will represent the interests and concerns of the community, as well as serve as the voice of patients, persons living with challenging health conditions, and their families.
    - 2.3.1. The primary role of the non-medical, non-scientist member shall be to share his or her insights about the communities from which participants will be drawn and about the informed consent process and form.
  - 2.4. At least one member shall be independent of the institution or research site (non-affiliated member) to ensure the independence of the REC.
  - 2.5. The number of REC members shall be adequate to ensure that the review can be done efficiently and effectively following international and national standards.
3. In addition to the REC members, the institution shall support the REC with adequate resources including staff, adequate and equipped office and facilities, and financial resources to enable it to carry out its responsibilities.

## Appointment

4. The officers and members of the REC shall be officially appointed by NORSU President.
5. The appointing official shall indicate their functions, terms of office, scope of work, conditions of appointment, and deloading scheme for REC Chair
6. The appointment document shall mention the responsibilities of members with special roles (e.g., officers, non-medical/non-scientist member, non-affiliated member).
7. Procedures for renewal of appointment, resignation, replacement; grounds for disqualification; and procedures with regard to COI due to financial gains shall be included in the SOP manual.

8. Prior to serving as a regular member, each member of the REC shall sign both confidentiality agreement, as well as a disclosure agreement that states that he or she has no COI (e.g., financial interests in a pharmaceutical company or connection with the funding agency) as a reviewer.
9. The appointing official should consider “a fixed rotation system for members that allows for continuity, the development and maintenance of expertise within the committee, and the regular input of fresh ideas and approaches” (WHO, 2000).
10. The senior decision-makers of the entity creating the REC or of any organization that sponsors or conducts research reviewed by the REC (such as director of the institution or his or her agent) shall not serve as members of the REC or as its Chair (WHO, 2011).

### **External or independent consultants**

11. The REC shall establish a list of external or independent consultants who can provide specific expertise regarding ethical, scientific, psychological or social aspects of research for review. They are not considered REC members; therefore, they shall not take part in REC decision making (no voting privilege).
12. In deliberations on research involving special participant groups or concerns (e.g., HIV, AIDS, the physically challenged), best efforts shall be exerted to include participation of advocates.
13. External or independent consultants shall be qualified individuals with the needed expertise and training. They shall also be appointed by the institutional authority, stating the terms of their appointment.

### **Functions and responsibilities**

14. The REC shall act in the full interest of potential research participants and affected communities, taking into account the interests, needs of the researchers, and having due regard for the requirements of relevant regulatory agencies and applicable laws (WHO, 2000 and 2011).
  15. The REC’s functions shall be as follows:
    - 15.1. Review the scientific merit and ethical acceptability of the research involving human participants;
    - 15.2. Undertake the same review process for foreign research protocols even if they have been ethically cleared by a foreign institution, applying ethical standards that are no less stringent than they would be if the research were to be carried out in the country of the sponsoring agency;
    - 15.3. Ensure that the proposed research is responsive to the priorities and National Research Agenda and that it meets the requisite ethical standards;
    - 15.4. Issue the ethical approval required for the implementation of any research it has reviewed and approved;
    - 15.5. Promote research integrity by identifying and resolving conflicts of interest;
    - 15.6. Establish appropriate mechanisms in all stages of the research to:
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- 15.6.1. Ensure the safety, protect the rights, and promote the welfare and well-being of research participants;
- 15.6.2. Provide counsel to research participants, including proponents and researcher;
- 15.6.3. Ensure prompt reporting of changes in the protocol and unanticipated problems;
- 15.6.4. Ensure the proper documentation of and adherence to the confidentiality rule and policy on informed consent; and
- 15.6.5. Monitor the progress of ongoing research until its completion.
- 15.7. Report to the institutional or national authorities any matter that affects the conduct and ethics of research which in its view may affect the rights and safety of research participants;
- 15.8. Keep a systematic and organized record of all proposals reviewed, including actions taken and other pertinent information;
- 15.9. Submit an annual report to the PHREB (within the first quarter of the year ending on March 31), which shall contain the following:
  - 15.9.1. The composition of the REC, including a short curriculum vita (name of the person, educational attainment, most recent ethics training/seminars attended), and term of office of each member;
  - 15.9.2. Members of the REC secretariat, office and email addresses, and contact numbers;
  - 15.9.3. Number of meetings (regular and special) held during the year, including the date and venue;
  - 15.9.4. Number of research reviewed by the REC during the year, classified by the types of research, REC decision or action (approval, minor or major modifications, disapproval), and other information required by PHREB

### **Meetings and deliberations**

16. The REC shall regularly meet as a committee every 2nd Wednesday of the month and twice every after URID R of the University. There shall be a provision for holding special meetings to consider urgent matters as decided by the Chair
17. For RECs with five to nine members, quorum requires at least five members present, otherwise, quorum shall follow the 50%+1 rule. Quorum also requires the presence of at least one non-medical or nonscientist and one non-affiliated member(s) to make decisions about the proposed research (WHO, 2011). In the absence of these required members, there is no quorum.

### **Conflict of Interest**

The conduct of research in NORSU follows the environment of transparency. In the event where the researcher or the research participants has a predetermined financial, personal and institutional interest, it must be disclosed straightforwardly and be resolved with justice and impartiality immediately.

18. Deliberations of the REC shall be characterized by transparency and collegiality. A member who is involved in whatever capacity in the study or project under consideration shall inform

the committee of this potential COI, and his or her further participation in the deliberations shall be determined accordingly. Those with COI shall not be present during the deliberations and decision making. A member who is the principal investigator or researcher may remain during the REC meeting to answer questions for clarification with regards to his or her research, but shall leave the room during the REC deliberation and decision making.

19. The REC shall make clear in its SOP how the committee arrives at a final decision. There shall be a special effort to consider the opinion of the non-scientist (especially with regards to the informed consent process and form) and/or the non-affiliated member. Strong objections shall be addressed and reasonably resolved.

### **Training and continuing education of REC members**

20. Members of the REC shall undergo initial and continuing training on the ethics of social science, health-related research and community extension researches.
  - 20.1. Initial training shall be required of new members. In case, there is no basic ethics training available at the time there are newly appointed members, the REC Chair shall ensure that proper orientation of new members is done on basic ethical principles, international and national ethical guidelines, and REC SOP, before they serve in the REC.
  - 20.2. Members shall be encouraged and given support to attend regular continuing educational activities on research ethics, such as advanced training on ethical issues and concerns. Additionally, the REC shall include similar activities at least once a year. These may be linked with those of RECs within the province or region.

### **Review fees**

21. Review fees are designated to support the operational needs of the Research Ethics Committee (REC), including its training programs and the continuing education of its members. The NORSU REC shall collect a fee of Php 500 for undergraduate theses and Php 1,000 for graduate-level research. All collected fees shall be remitted to the University's official account.

## **V. THE RESEARCH ETHICS REVIEW PROCESS**

The ethical review of research proposals involving human participants is conducted by an REC based on an evaluation of the research activities described in the protocol and protocol-related documents. These are submitted to the REC for approval before study implementation. Since quality of the ethical review is an important concern, the REC shall have a manual of SOPs which shall clearly describe all areas of its work. For the initial and continuing review of protocols, the REC shall indicate a reasonable time frame in their SOPs for completing the review process and provide the proponent a written, signed and dated feedback on its review, preferably within two to four weeks after receipt of the submitted documents. The review must be efficient, transparent, and timely. The ethical review protocols involving several sites may be done as a joint review of a group of PHREB accredited RECs, provided that the review is conducted in accordance with SOPs approved by PHREB.

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## Required documents for REC review of an initial protocol submission

1. The researcher shall be required to submit to the REC the following documents before REC reviews his or her research proposal:
  - 1.1. Application for review addressed to the REC which may be a formal letter or part of an application form as described in the REC's SOP;
  - 1.2. Clearance from technical/ethical review(s) from other committees (if applicable);
  - 1.3. Research protocol which must include the title, project description, research questions, objectives, data collection, research instruments, data analysis, Participant Information Assessment, Permissions, Risk Assessments. The section on Ethical Considerations shall state what relevant international and national guidelines will be used as reference in the study and include ethical issues like anticipated risks (how these will be minimized) and potential benefits; protection of confidentiality of data and privacy of the research participants; vulnerability of research participants; management of adverse events, and how informed consent will be obtained.
  - 1.4. Informed consent and assent documents
  - 1.5. Study tools / Instruments and questionnaires
  - 1.6. Curriculum vitae (CV) of researcher and co-researchers
  - 1.7. Statement of on presence or absence of COI of the researcher;
  - 1.8. Information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest;
  - 1.9. Contracts / Clearances and Permissions, MOA if the study is collaborative in nature; Material Transfer Agreement (MTA), Intellectual Property approval
  - 1.10. Study/protocol budget; and

## Initial review procedure

2. After receipt of the application form and protocol package, the REC office shall check the submitted documents for completeness. The submitted protocol shall be officially recorded in a log book or an electronic database noting the date of submission, protocol title, researcher or principal investigator, funding agency or sponsors, and other relevant fields.
3. The REC Chair, or his or her representative, shall determine the proposal's exemption from review or the kind of review required – full or expedited review.
  - 3.1. Exempt from Review is the term used to denote that a protocol does not need to undergo either full or expedited review after a preliminary assessment by a designated member of the REC. "Exempt from Review" is a decision made by the REC.
    - 3.1.1. Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols) shall be exempted from ethical review.
    - 3.1.2. Provided that the following do not involve more than minimal risks or harms, these protocols may be considered by the REC for exemption from review:
      - 3.1.2.1. Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;
      - 3.1.2.2. Research that only includes interaction involving survey procedures,

interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:

3.1.2.2.1. 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

3.1.2.2.2. 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.

3.1.2.3. Protocols that involve the use of publicly available data or information. The decision to exempt from review may be delegated by the REC to an office or group of individuals for efficiency and in the interest of time. There must be assurance, however, that the delegated individuals or office have been properly oriented and trained to make such decisions with due diligence. Subsequently, these decisions shall be documented and submitted to the institutional REC for review. The REC, in its annual report submitted to the PHREB,

The REC, in its annual report submitted to the PHREB, shall include a list of all proposals or protocols that were exempted from review.

3.2. The Chair or the designated officer of the REC shall assign the reviewers for full or expedited review. The proposal shall be distributed to these designated reviewers accordingly.

3.3. Full Review shall be required for protocols that entail more than minimal risk to participants or those that involve vulnerability issues. In a full review, the proposal is assigned for primary review to all REC members or to at least two reviewers (a scientific and a non-scientific/non-medical member) prior to the REC meeting. The reviewers shall present their findings during the REC meeting for discussion and final action.

3.4. Expedited Review can be done by the REC for proposals that do not need a full review such as the following:

3.4.1. chart review

3.4.2. survey of non-sensitive nature

3.4.3. use of anonymous or anonymized laboratory/pathology samples or stored tissues or data

Expedited review refers to the number of REC members doing the initial review rather than the length of time it requires.

3.5. Submissions after the approval (e.g., protocol or informed consent amendments, progress or final reports, monitoring reports) shall be subject to either full or expedited review.

## **Protocol review**

4. Research protocols are evaluated relative to the elements of research ethics and other considerations as follows:

4.1. Social value: scientific validity, relevance to community and national needs, suitability

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- of the dissemination plan and recipients;
- 4.2. Informed consent: voluntariness (absence of coercion and undue influence), comprehensibility of information (use of native and non-technical language), and capacity to decide (of legal age and sound mind);
- 4.3. Risks, benefits, and safety: assessment of risks, favorable risk benefit ratio, and access to favorable research outcomes;
- 4.4. Privacy and confidentiality of information: respect for right to privacy, and mechanisms to protect confidentiality;
- 4.5. Justice: Fairness of selection process, appropriate care, compensation and reimbursement, and access to benefits;
- 4.6. Transparency: Management of COI, sharing of relevant information to participants, honesty in participation, and disclosure of research results;
- 4.7. Qualification of researcher: appropriate education, training, and experience;
- 4.8. Adequacy of facilities: supportive of protocol procedures and well-being of participants; and
- 4.9. Community involvement: respect for local traditions and culture, community empowerment, acknowledgement of participation

### **Action on proposals**

- 5. The action of the REC shall be one of the following:
  - 5.1. Approval, in which case, the REC shall inform the researcher, in writing, of the REC's requirements for approved research that must be complied with during the conduct of the research, with definite timelines such as:
    - 5.1.1. Progress Report, at least once a year or as requested by the REC;
    - 5.1.2. Final Report;
    - 5.1.3. Amendments;
    - 5.1.4. Termination of the research before its anticipated completion date, and the reason for it; and
    - 5.1.5. Protocol deviations and violations.
  - 5.2. Modifications (Minor or Major) Required, in which case, the REC shall clearly communicate to the researcher, in writing, a clear description of required modifications to the protocol and protocol-related documents.
  - 5.3. Disapproval, in which case, the REC shall clearly state the reason(s) for disapproval.
  - 5.4. Deferred, if clarifications are necessary, before a decision of the REC can be made.
  - 5.5. Ethical clearance is usually for a period of one year which may be renewed if an application for continuing review is submitted before the expiration of the earlier ethics clearance.

### **Appeal for reconsideration**

- 6. In case of an unfavorable decision, the researcher may make oral or written representation to the REC for reconsideration.

## **Withdrawal of prior approval**

7. Prior approval may be withdrawn for the following reasons:
  - 7.1. Noncompliance with reportorial requirements;
  - 7.2. Protocol violation(s);
  - 7.3. Valid serious complaints from participants;
  - 7.4. Scientific misconduct

## **Review of post approval submissions**

8. As part of its function, the REC shall monitor the conduct of a research that it has approved. The process includes review of amendments, revisions, protocol deviations, and their approval before implementation. The process also includes review and approval/acceptance of reports (progress, termination, end of study, and final reports). The reviews may be expedited or full.

## **Site monitoring visit**

9. The REC or designated representative may also do an onsite visit of studies that it has approved. This may be done where there is significant number of serious adverse events, new study sites, non-compliance or suspicious conduct, failure to submit required reports, among others.
  - 9.10. REC shall inform the researchers of the visit at a date agreeable both
  - 9.11. The REC shall review the informed consent to see if an updated version is being used, examine study files, observe the informed consent process if possible, inspect the study site, and interview participants.
  - 9.12. After the site visit, a report is given to the principal researcher and to the REC.

## **Completion of the research**

10. Upon completion of the report, the researcher shall inform the REC in writing that the study has been completed and shall furnish the REC copy of the final report. This shall be duly reported during the subsequent REC meeting.

## **Documentation and Archiving/ Data Management**

Researchers must treat all data as confidential and in no way be utilized for personal advancement by anybody in the research teams or organization. It must be safeguarded and stored in appropriate period of time to allow other researchers to validate their data. It can be utilized only for other research initiatives for the advancement of knowledge and not for personal gains

11. All documentation and communication of the REC shall be dated, filed, and archived. Agenda and minutes of REC meetings shall have templates to facilitate their preparation and filing.
    - 11.1. Protocol study files shall be separated into: 1) Protocols awaiting approval; 2) Ongoing approved studies; and 3) Completed or archived study files.
    - 11.2. The study files shall include protocol and current version, informed consent documents, amendments, all communications regarding application, decision, follow-up,
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safety reports, continuing progress reports

11.2.1. Completed study files include all of the above and the final report. They are usually archived for a minimum of three years.

11.2.2. Active and completed studies shall be identified and filed in a secure place.

11.2.3. The REC shall maintain a file of the following:

- REC SOPs;
- International, national and local guidelines;
- Annual REC reports;
- Curriculum vitae of REC members including initial and continuing training in ethics review, GCP, among others, which shall be updated, signed and dated;
- Log books and electronic database to facilitate checking and follow-up of approved protocols;
- Log book for inquiries and complaints (dated especially from study participants with their contact numbers);
- Flow charts of REC procedures which shall be clearly visible to guests; and
- Templates of various forms to be used in ethics review available electronically or in print.

## VI. RESPONSIBILITIES

### Responsibilities of the Research Adviser

All research conducted in NORSU by graduate and undergraduate students including faculty members shall be under the supervision and guidance of a senior research or faculty adviser.

The senior research or faculty adviser shall:

1. Guide the student or faculty in the development of a scientifically and ethically sound research protocol;
2. Assist the student or faculty in the addressing ethical and scientific concerns raised by reviewing bodies;
3. Serve as a model in intellectual humility and refer the student to other persons with expertise in social, legal, and other considerations affecting the research;
4. Supervise the student or faculty in the proper collection and recording of data including the duty to maintain the confidentiality of information and the privacy of human participants for all the phases of the research processes including the disposal or archival of data;
5. Review interim and final reports for accuracy and consistency;
6. Share responsibility and accountability with the student/ faculty for the ethical conduct of the research; and
7. Ensure that the research to be undertaken by undergraduate students involves only minimal risk

### Responsibilities of NORSU

NORSU shall:

1. Provide a supportive environment for ethical research;
  - 1.1. Ensure the ethical conduct and monitoring of research being undertaken in the insti-

tution given the institutions available resources by taking reasonable steps, to comply with CHED Memorandum Order No. 52 Series of 2016 (p.20) which requires higher education institutions to adhere to the National Ethical Guidelines for Health Research. In the absence of an REC, the institution shall refer researchers to other authoritative bodies with expertise in ethics review.

- 1.2. Establish an independent and competent REC and provide adequate administrative support for it, including fair compensation to REC members for protocol review and attendance in meetings.
2. Maintain an efficient recording system of research studies being done and their status and researchers involved in the study;
3. Establish SOPs regarding the review of research studies to be done in the institution including fees to be charged;
4. Establish safety monitoring and management systems (for researchers and participants);
5. Put in place systems, subject to the available resources of the institution, to enable researchers to maintain the privacy and confidentiality of information pertaining to human participants including secure processes for the sharing of data by the research community, as well as the disposal and/or archiving of data;
6. Provide opportunities for dissemination of results in collaboration with other stakeholders;
7. Update itself and systematically disseminate information to its community of researchers and administrative staff, regarding national and international policies and regulations and comply with them; and
8. Ensure that a system for the education and protection of human participants is in place in the institution.

## **Roles and Responsibilities of the Investigator or Researcher**

For the purposes of this set of guidelines, the term “researcher” refers to an individual or group of individuals who conceptualizes, initiates, and conducts a study. On the other hand, Eligibility requirements for conducting research on human participants vary depending on the role of the researcher. Research personnel shall be appropriately qualified by training and experience to perform their research responsibilities. Investigators or researchers shall be responsible for the protocol and the conduct of study. These responsibilities are particularized as follows:

1. Preparing the research protocol and ensuring its ethical acceptability by submission to the REC for review.
  2. Obtaining ethical approval of the protocol, and for cooperation with the REC in the conduct of the clinical trial.
  3. Bearing ultimate accountability for all activities associated with the protocol, including compliance with adopted international guidelines, national and local laws, institutional policies, and ethical principles.
  4. Consulting or collaborating with colleagues in the scientific or academic community to which he or she belongs and seeking advice from authoritative bodies possessing expertise in ethical, legal, social and other issues that the researcher may encounter throughout the research process; from the crafting of the proposal up to the disposal or archiving of data.
  5. Performing or delegating to qualified co-investigators or research staff all the necessary tasks to carry out their studies; while remaining ultimately responsible for proper conduct of the study and fulfillment of all associated obligations.
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6. Providing members of the research team with sufficient oversight, training, and information to facilitate appropriate safety procedures and protocol adherence.
  7. Ensuring that adequate resources (facilities, equipment, supplies, and personnel) exist to:
    - 7.1. Conduct the research (e.g., through internal or external funding for staff, facilities and equipment);
    - 7.2. Protect subjects; and
    - 7.3. Ensure the integrity of the research.
  8. Evaluating the resources available at each site where the research will be conducted, in multicenter/sited studies.
  9. Applying for ethical review and approval before the conduct of a research/clinical trial.
  10. Obtaining informed consent from each prospective research participant (or the participant's legally authorized representative) before the participant begins to participate in the research (including any related eligibility testing not conducted solely for clinical purposes), unless the appropriate REC has approved a waiver of consent, or waiver of documentation
  11. Having adequate time to enlist the necessary number of participants to the research.
  12. Providing a copy of the signed informed consent form to the research participant, and retaining a copy in both the research record
  13. Informing the REC if a researcher or investigator can no longer fulfill his or her duties for any reason including, but not limited to, traveling for a prolonged period of time or illness
  14. Cooperating, at all times, with the REC in fulfilling its responsibilities, and shall provide all information required by the REC as part of the review process such as all key personnel who contribute to the scientific development or execution of a study in a substantive, measurable way.
  15. Bearing accountability for the content of all submissions (e.g., initial review, continuing review, adverse event reporting, reportable negative events, progress reports) to the REC and other review units and for ensuring that those documents are submitted in a timely manner, as required by the REC and other review units (e.g., audit teams).
  16. Conducting the research as specified in the REC-approved protocol and complying with all REC decisions pertinent to the REC-approved protocol.
  17. Reporting promptly to the REC any additional risks that are identified during the course of the research project.
  18. Monitoring the effective period of the ethical approval of the protocol and submitting a continuing review application in a timely manner to the REC, for renewal of approval.
  19. Reporting promptly to the REC any of the following:
    - 19.1. Unanticipated problems involving risks to participants or others, such as an adverse event or exposure of member(s) of the research team to harm;
    - 19.2. Noncompliance with applicable laws or regulations or REC requirements, whether by the researcher or investigator, research staff, or others, even if the noncompliance was unintentional or was discovered in the course of quality assurance or quality improvement activities; and
    - 19.3. Disapprovals, suspensions, or terminations of the project by any University or non-University review units or agencies.
  20. Cooperating with:
    - 20.21. Internal evaluations, inspections, and audits performed by authorized internal oversight authorities, including the RECs.
    - 20.22. External reviews (e.g., by industry sponsors or government agencies such as the FDA).
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- 20.23. Any external investigation, inspection, or other external review and its outcome must be reported to the REC responsible for the research in question
- 20.24. Researchers should consult with their administrators, the RECs, and as appropriate, the legal counsel for assistance and representation.
- 21. The researcher or investigator shall disclose all financial and nonfinancial COI.

### **Responsibilities of Foreign Researchers**

A foreign researcher is

- (1) a non-Filipino doing research in the Philippines,
- (2) Filipino conducting research in the Philippines on behalf of a foreign research institution or in compliance of requirements of a foreign institution.

#### **Requirements**

- 1. Familiarity with the General Guidelines in the National Ethical Guidelines for Health and Health-Related Research 2017 (page 10) and the national governance structure for human protection in research.
  - 2. Submission of required documents to the concerned institutional REC which, in general, include the following:
    - 2.1. Letter requesting for ethics review;
    - 2.2. Accomplished application for ethical review;
    - 2.3. Latest version of the research protocol;
    - 2.4. Informed consent form;
    - 2.5. Data collection forms;
    - 2.6. Letter of endorsement from the foreign institution where researcher is affiliated (if applicable);
    - 2.7. Technical review approval;
    - 2.8. Ethical review clearance from the concerned foreign institutional REC; and
    - 2.9. Curriculum vitae of researcher.
  - 3. Ethical approval of the protocol shall be based on:
    - 3.1. Relevance of the study to Philippine research priorities;
    - 3.2. Acceptability of justification for choosing the Philippines as research-site;
    - 3.3. Identification of a qualified and appropriate local researcher and/or adviser;
    - 3.4. Scientific soundness;
    - 3.5. Ethical soundness;
    - 3.6. Familiarity of the researcher with the culture of the community research site;
    - 3.7. Appropriate expertise of the researcher; and
    - 3.8. Appropriate reporting and dissemination plan.
  - 4. Ethical clearance is usually for a period of one year, which may be renewed if an application for continuing review is submitted before the expiration of the earlier ethics clearance.
  - 5. Ensuring compliance with international, foreign, and local laws and regulations shall be the responsibility of the entire research team. For this purpose, however, the local research collaborators shall be accountable to local authorities, in cases of violations of local laws and regulations.
  - 6. Transfer of biological materials overseas shall be covered by a Material Transfer Agreement (MTA) through an institution-to-institution arrangement, and shall comply with all applica-
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ble international, foreign and local laws and regulations. Examples of said norms include the Convention on Biological Diversity, CITES, the Wildlife Resources Conservation and Protection Act (RA 9147), the issuances of the DENR and DA on scientific studies on wildlife, the bioprospecting regulations, IPRA (RA 8371), and the Technology Transfer Act of 2009 (RA 10055).

7. Safeguards shall be in place to ensure protection of sensitive and personal information that will be transmitted outside the country.
8. Compliance with local regulations shall be ensured by the foreign researcher.

### **Responsibilities of the Funding Agency and Sponsor**

Sponsor is defined as an individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial (ICH-GCP, 1997). This definition describes the role of the sponsor in initiating the research, including protocol development. This definition also differentiates the sponsor from an agency that is mainly responsible for financing or funding of the research. The latter is what this guideline refers to as the “Funding Agency”.

1. The funding agency shall:
  - 1.1. Ensure competent technical and ethical review of all research projects receiving its support;
  - 1.2. Ensure regular and timely release of funds to support research;
  - 1.3. Monitor the proper implementation of the protocol;
  - 1.4. Promote research integrity;
  - 1.5. Provide remedial support in case of incident problems;
  - 1.6. Ensure satisfactory completion of the project within a reasonable time; and
  - 1.7. Provide opportunities for dissemination of results.

## **VII. GUIDANCE FOR RESEARCH PARTICIPANTS**

Research participants are the primary subjects of a study. The research may involve recording and analysis of their personal information, health status, reactions, feelings, attitudes, knowledge, and opinions. The credibility of the study results is largely dependent on the correctness of this information. Participants normally get to understand the research objectives and procedures through the informed consent process.

1. A research is conducted in accordance with a document called the Protocol. It is the principal reference for the implementation of the research.
2. The protocol is also the source of information to be given to potential participants for their consideration when they are recruited in to the research.

### **Dealing with Human Subjects**

When research participants are subjected to testing, or blood and body fluids are withdrawn from them, the researcher must exercise utmost care. Only competent professionals are allowed to administer the test and withdraw blood or body fluids. Researchers must uphold at all times the welfare, safety and dignity of the human subject. Human subject testing are permitted only when the researchers can fully articulate the benefits of the experiments to human society. Researchers has to

fully explain to the participants the danger as well as the pain incurred in withdrawing blood. Sample of blood to be withdrawn has to reflect thoroughly to prevent over collection of blood samples.

### *Infor med consent*

3. Every research involving humans shall have a document which is intended for participants to sign as evidence of their consent to participate in the study. This document is called the Informed Consent Form. Informed consent is a process by which a participant confirms his or her willingness to participate in a study, after having been informed of all aspects of the study that are relevant to the participant's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.
  4. The informed consent process requires communicating relevant information about the study to the participant before he or she decides to participate.
  5. Willingness to participate is emphasized, such that joining a particular study shall not be obligatory, hence, prospective participants:
    - 5.1. May consult family members or friends if they have issues about participation;
    - 5.2. Should not be ashamed to turn down participation; and
    - 5.3. May refuse to participate or withdraw from the study, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.
  6. The informed consent form shall contain the following information:
    - 6.1. Who sponsors or funds the study?
    - 6.2. Is there prior research about the subject of the study? In which countries was the study conducted or will be conducted?
    - 6.3. Who are the researchers and what are their responsibilities?
    - 6.4. What are the responsibilities of the participants?
    - 6.5. What procedures will participants undertake?
    - 6.6. Will there be a probability for random assignment of participants into groups which will undergo different procedures?
    - 6.7. What are the reasonably foreseeable risks or inconveniences to the participants?
    - 6.8. How long will the participation take?
    - 6.9. Are there anticipated expenses to the participant for participating in the study?
    - 6.10. Will there be payment or any form of c compensation to the participant for participating in the study
    - 6.11. Who will be accountable in case participants are harmed?
    - 6.12. Will there be post-study benefits? For example:
      - ☐ Treatment
      - ☐ Membership in support groups
      - ☐ Information regarding the results of the study
    - 6.13. 6.13. Was the study given approval by a PHREB-accredited REC?
  7. Research participants must have the capacity to understand information regarding study participation.
    - 7.1. In what language was the informed consent document written?
    - 7.2. Can participants easily understand the information about the study?
  8. The following can give informed consent:
    - 8.1. The participant, if he or she is:
      - ☐ Of legal age (18 years or above);
-

- ☐ Of sound mind;
  - ☐ Capable of understanding the nature of his or her participation; and
  - ☐ Capable of reading and signing the informed consent form.
- 8.2. Representatives of the participant, if the participant does not have the capacity to give informed consent, such as:
- ☐ Parent (if minor);
  - ☐ Spouse; or
  - ☐ Legally authorized representative
9. Participants may request additional information from the following if there are issues regarding the contents of the informed consent form:
- ☐ Doctor (if the study is a clinical trial);
  - ☐ Researcher or Investigator; and/or
- The REC who gave ethical clearance for the study (the contact number of the REC shall be written in the informed consent form)

## VIII. COMMUNITY PARTICIPATION

The research participants are asked for informed consent and made to understand that joining the research as participant is voluntary and they are free to withdraw anytime if they find undue distress in the research process. Seeking of IP clearance from NICP is necessary prior to the conduct of research for research project involving members of IP community.

Likewise, research participants are informed on the duration of the interview as well as the objectives of the research. The participants are not remunerated but can be given transportation and food allowance as necessary. Keeping the confidentiality on the identity and safety of the research participants will be ascertained by the researchers at all times. Informed consent is in written form and in the language which can be understood by the participants themselves.

Community participation is not only an ethical consideration but it also has practical value. It aims to involve the communities themselves in the formulation of research questions, and to link the research to their own development. Such a participatory process with the community is a continuum that includes community consultation in protocol development, appropriate information disclosure and informed consent, protection of confidentiality, right of dissent, and community involvement in the actual conduct of research, and in the sharing of benefits (Wendler & Emanuel, 2000). Community participation provides a proactive character in the research, and establishes a symbiotic relationship in knowledge production.

1. Researchers shall actively engage with communities in decision-making about the design and conduct of research (including the informed consent process), while being sensitive to and respecting the communities' cultural, traditional, and religious practices (WHO, 2011).
2. Community consultation shall be seriously taken into consideration when:
  - 2.1. The study involves established community practices;
  - 2.2. The results of the study may impact on the health and welfare of the community constituents; or
  - 2.3. The study outcome may bring economic benefit to the community.
3. Involvement of a community representative in the study team may be required when:

- 3.1. There is risk that the study procedures may be disrespectful of community traditions and practices; or
- 3.2. The community itself requests for representation in the ownership and outputs of the study.
4. The REC may invite a representative from the community during deliberations.

## **IX. OTHER CONSIDERATIONS**

### *National Research Agenda*

1. In general, all research shall support and contribute to the achievement of the current Philippine Development Plan as formulated by the National Economic Development Authority (NEDA).
2. Health research shall adhere to the National Unified Health Research Agenda (NUHRA) and Regional Unified Health Research Agenda (RUHRA) must be firmly grounded through a process of priority-setting.
3. Government funding agencies shall seriously consider conformity of the proposal with their respective research priorities.

### *Externally-funded collaborative research*

4. Sponsors and researchers involved in externally-funded collaborative research, have the ethical obligation to ensure that the research project shall contribute effectively to capacity building. Protection of the environment and biosafety
5. The conduct of biomedical or behavioral research shall be in a manner that minimizes possible harm to the environment.
6. Research involving the use of biological and hazardous materials including those that involved genetic modification and manipulation of microorganisms and of animal and plant tissue cells must be reviewed and approved by the National Committee of Biosafety of the Philippines (NCBP) before implementation.

### *Welfare of animals*

#### **Dealing with Animal Subjects**

Researchers in NORSU are allowed to use animals as subjects for experiments only if alternative subject is not available at the time of study. When subjecting animals to experiments the researchers must guarantee that minimal number of animals are used in the whole period of the experiment.

Also proper handling of animals must be uphold at all times in order to minimize pain, suffering and distress of animals during and after the experiment. Gratuitous permit must be secured from proper agencies prior to fieldwork. Additional permits are necessary especially when dealing with wildlife in the protected areas and animals listed in IUCN.

7. The use of animals for research shall adhere with Animal Welfare Act of 1998 (RA 8485), amendments on its certain sections (RA 10631), and its Implementing Rules and Regulations
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through the Department of Agriculture AO No. 40 series of 1998 and the Code of Practice for the Care and Use of Laboratory Animals in the Philippines, 2nd edition, 2002 developed by the Philippine Association for Laboratory Animal Science (PALAS)

## **X. ETHICAL GUIDELINES FOR HERBAL RESEARCH**

- 1.1 Conduct a comprehensive review of existing scientific literature before initiating the study.
- 1.2 Establish a clear scientific rationale and objectives.
- 1.3 Employ scientifically sound and validated research methodologies.
- 1.4 Ensure that herbal identification, preparation, extraction, formulation, and analysis follow accepted scientific standards.

### **Good manufacturing Practices**

- 1.5 Conduct appropriate quality control and authentication of plant materials.
- 1.6 Follow Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP), where applicable.
- 1.7 Maintain proper documentation of harvesting, processing, storage, extraction, and formulation.
- 1.8 Ensure reproducibility of herbal preparations.

## **2. Protection of Indigenous Knowledge and Cultural Heritage**

- 2.1 Prior Informed Consent (PIC) shall be obtained from the appropriate Indigenous Cultural Communities/Indigenous Peoples (ICCs/IPs) or traditional knowledge holders.
- 2.2 Community customs, traditions, and cultural practices shall be respected.
- 2.3 Traditional knowledge shall not be misappropriated or commercially exploited without appropriate authorization.
- 2.4 Fair and equitable benefit-sharing mechanisms shall be established whenever applicable.

## **3. Biodiversity Conservation**

### **Researchers shall:**

- 3.1 Harvest plant materials responsibly and sustainably.
- 3.2 Avoid unnecessary destruction of natural habitats.
- 3.3 Comply with national laws governing biodiversity conservation and wildlife protection.
- 3.4 Give preference to cultivated sources whenever feasible to reduce pressure on wild populations.
- 3.5 Avoid collecting endangered, threatened, or protected plant species without the required permits.

## **4. Commercialization and Benefit Sharing**

- 4.1 Commercial development arising from herbal medicine research recognizes the legitimate rights of contributors and traditional knowledge holders.
- 4.2 Benefit-sharing arrangements are fair, transparent, and mutually agreed upon.

- 4.3 Intellectual property rights are managed ethically and in accordance with applicable laws and institutional policies.
5. In research that aims to validate the therapeutic or diagnostic value of a traditional herbal preparation,
  - 5.1. There shall be proof of a long history of use of the herbal plant or remedy to be tested. An exhaustive literature search about the therapeutic or diagnostic value of the herbal plants must serve as the background, or justification to the research proposal. Any documents supporting its putative actions and traditional use in the community must be incorporated in the research proposal. Proof of its use may be both in the written, oral, or video form. Evidence regarding usage of the herbal preparation shall be validated with the National Commission on Indigenous Peoples (NCIP), the National Museum, or by an expert opinion, should the need arise.
  - 5.2. The original herbal preparations and manner of use by people in the community shall be similar to the intended form and use in the proposed research. For example, if the herbal plant is applied as a poultice for a condition to be studied, then it shall be given in the same form to the research participants.
  - 5.3. The geographic area, maturity of collection of the plant, and the method of its preparation must be clearly described
6. Research in herbal remedies shall include standardization of the preparation and identification of markers to ensure that the ingredients being studied and assessed are the same. This method must be followed all throughout the conduct of research.
7. When the traditional herbal preparation is modified in some way— either shape or form—including dose, dosage form, mode of administration, herbal medicinal ingredients, methods of preparation and medical indications, it is classified as a herbal product.
8. Herbal product research shall undergo Phases I and II studies prior to Phase III. Phase III studies shall require the same information in Phase I/II clinical trials and an environmental impact statement.
9. Once an active principle is identified from the herbal preparation, and there are intentions to synthesize it for research and eventual commercial purposes, any studies thereafter, need to be reviewed, based on the ICH-GCP and Good Manufacturing Practice (GMP) Guidelines.

#### *Participation of traditional healers*

8. Cultural settings and expectations must be considered in the review of the proposal, and this may require inviting a traditional healer, or a known scholar of herbal medicines in the REC. The traditional healer is the community's steward of indigenous knowledge.
9. No indigenous materials used in the research may be transported outside the country unless the source (represented by the community leader, government agency, or institution) of the material and the recipient sign a material transfer agreement (MTA).
10. Researchers shall comply with the MTA if plant products or herbal preparations will be tested outside the country.

#### *Benefit sharing*

11. When possible, the community from where the herbal preparation/product originates shall be consulted during the course of the research, and the results and benefits of the research shall be shared with this community (WHO, 2005).
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12. A memorandum of agreement regarding benefit sharing and patenting conditions, especially for indigenous plant products, shall be set as early as the planning stage of the research.

#### *Commercialization of herbal preparations*

13. Researchers shall include provisions for conditions when the herbal preparation or product may likely be commercialized. They shall be guided by existing laws and regulations of the Intellectual Property Office of the Philippines (IPOP HL).

#### *Safeguarding indigenous knowledge*

14. It is recommended that the rich knowledge about indigenous herbal plants in a community must be documented, appropriately recorded, and archived for posterity.

### **XI. ETHICAL GUIDELINES FOR RESEARCH IN COMPLEMENTARY AND ALTERNATIVE MEDICINE**

#### *Background information*

1. There should be adequate documentation of the use of the therapy in the community in, at least, one generation.

#### *Involvement of an external resource person in the review*

2. The REC shall include an expert or practitioner in the specific traditional medicine modality being considered in the research protocol.
3. The REC shall also include a member of the community where the specific traditional medicine is being or will be used.

#### *Use of randomized controlled trial design*

4. In contrast to conventional medicine, CAM modalities focus on beneficial effects (e.g., quality of life) rather than efficacy. In this context, study designs other than randomized controlled trials may be acceptable.
5. Assignment of treatments may use geographic separation of groups to avoid contamination of data.

#### *Blinding*

6. Blinding could be difficult to achieve in the application of certain CAM modalities, in which case, the research protocol shall provide mechanisms for blinding the clinical outcome evaluator.

#### *Safety*

7. The study shall ensure that there is evidence of safety and that the experimental arm will not worsen the patient's condition by the delay in administering conventional medicine.
8. The protocol must identify and describe the rescue medication, which shall be available to the research participants who may require such an intervention.

## **XII. ETHICAL GUIDELINES FOR RESEARCH USING ONLINE AND DIGITAL TOOLS**

Online and digital tools provide a relatively new platform for health-related research. They present several opportunities, but also raise ethical issues, especially in the informed consent process.

Ambiguity in the determination of risk arises from the minimal interaction between the researcher and the participant. In Internet research, there is little means of gauging participant characteristics (e.g., age), and how participants are responding to the study. In addition, there are issues that are associated with data and personal privacy, and access that are inherent in most Internet activities

While ethical guidelines and standards have yet to be established for Internet based research, researchers shall be mindful of these issues, and consider current best practices to safeguard the rights of participants and protect them from harm.

1. Researchers utilizing online and digital tools shall be guided by the following questions to ensure that respondents' right to privacy and confidentiality is upheld:
    - ☐ How will participants be recruited?
    - ☐ How can the requirements for informed consent be fulfilled?
    - ☐ Are the individuals identifiable or anonymous? (note that "online identity", even if a pseudonym, may already be attached to an individual's real identity)
    - ☐ Is the online behavior "public" or do respondents have reasonable expectations of privacy?
    - ☐ Did individuals know or expect that records were being kept (versus ephemeral or impermanent data)?
  2. If individuals have reasonable expectations of privacy and impermanence of their online activities, then researchers may need to take specific measures to inform the respondents and obtain their consent to use their data for research, with the attendant protections to their rights to privacy.
  3. Soliciting the participation of minors shall be done with extreme care given that the researcher is unable to verify the age of the respondent, and shall include strategies for checking and ensuring parental consent. Internet research involving minors should be limited to minimal risk research.
  4. Research in the Internet shall be limited to those that entail minimal risk. Moreover, data collection via the Internet shall be justified (versus other means).
  5. Additional safeguards for maintaining privacy and confidentiality of information shall be used (e.g., pseudonyms, modified quotes to prevent immediate retrieval through search engines, encryption, separation of data files for identifiers and responses).
  6. The study team shall include a member who is familiar with technical issues concerning Internet security, including additional safeguards.
  7. Use password-protected devices and encrypted storage whenever feasible.
  8. Regularly back up research data using secure systems.
  9. Protect research records from unauthorized access, alteration, loss, or cyberattacks.
  10. Follow NORSU policies on data retention and secure disposal.
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### XIII. ETHICAL GUIDELINES FOR RESEARCH INVOLVING INDIGENOUS PEOPLES

#### *Oversight considerations*

1. In deliberations on research involving special populations by an REC, the following considerations shall be included:
  - 1.1. Social and cultural needs of the IPs/ICCs;
  - 1.2. Clarification of the various roles of different stakeholders such as the sponsors, researchers, and volunteer workers and identification of potential conflicts of interest;
  - 1.3. Compliance with existing national and local regulations and international guidelines relevant to the protection of rights of IP populations and establishment of a monitoring mechanism to ensure that the guidelines are complied with such as the:
    - ☐ Indigenous Peoples' Rights Act (IPRA) of 1997 (RA 8371)
    - ☐ United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP);
    - ☐ Convention on Biological Diversity (CBD)
  - 1.4. Access to a member, advocate, or representative of IPs/ICCs who has a good understanding of the nature of indigenous knowledge and its means of expression;
  - 1.5. Recognition of the right to self-determination of the IP; and
  - 1.6. Recognition of the members of IPs/ICCs as partners with equal rights in the research process.

#### *Informed consent*

2. Research involving IPs/ICCs must comply with standard elements of free and prior informed consent (FPIC), such as capacity to consent, disclosure, comprehension of information disclosed, voluntariness, and signification of consent, both oral and written, including a memorandum of agreement with the community, as needed; with special consideration for IP values and concepts.
3. Obtaining informed consent involves two interrelated processes: (a) obtaining the FPIC of the community for the study to proceed, and (b) individual consent to participate. The first is required by IPs/ICCs for the second to proceed.
4. Whereas balance must be sought between community approval and individual informed consent, the former cannot override the latter. If a member of the community feels compelled to consent because the community has already approved the study, then such autonomy may be regarded as compromised. However, if community approval was arrived at after several community meetings, discussions, consensus taking, where members freely participated, the community approval may be regarded as the representation of the members' decision. In this case, the group's decision strengthens individual decision rather than violates individual autonomy.
5. Community consultations are required for approval to conduct the study prior to approaching individual members for consent. Community consultations will provide the opportunity to the researcher to learn culturally appropriate ways of soliciting individual consent, and at the same time, to explain the rationale for individual consent. This may require iteration of the informed consent process to truly reflect community consultation, which the research budget should allow.
6. Securing free and prior informed consent shall be in adherence to the processes specified under the IPRA and if possible, with the presence of NCIP members.
7. Other documents may be required in addition to the standard informed consent form (e.g., IPRA documentary requirements such as a memorandum of agreement with the community).

**XIV. ETHICAL GUIDELINES FOR RESEARCH INVOLVING MINORS OR CHILDREN**

“Minors” are persons under 18 years of age and the term may be used interchangeably with the term “children.” Republic Act No. 6809 places the age of majority at 18 years of age at which time the person is emancipated from parental authority, and is considered “qualified and responsible for all acts of civil life”, and can enter into contracts on their own, or sign the ICF. Pediatric practice, on the other hand, includes patients who are more than 18 years though under 19 years old.

The practice means that pediatric research may include patients who can already sign the ICF on their own, without requiring parental consent. Assent is the manifestation of the agreement of a minor to participate in a research or clinical trial. The assent may be in the oral or written form. Minors are considered as belonging to a vulnerable population.

1. Research involving minors is justified when:
  - 1.1. The research cannot be carried equally well in adults; Examples include research on pediatric cancer, systemic lupus erythematosus, adolescent depression, childhood abuse, Down’s syndrome, among others such that research among adults who had these illnesses in their childhood will not elicit accurate results.
  - 1.2. The purpose of the research is to obtain knowledge relevant to the health needs of children.

*Requirement for permission from a legally authorized representative*

2. A parent or legally authorized representative (LAR) of each child shall provide the necessary consent for participation of the minor. In default of parents or judicially declared guardians, this order of authority shall be followed:
  - 2.1. Grandparents;
  - 2.2. Oldest sibling over 21 years of age, unless unfit or disqualified;
  - 2.3. Actual custodian over 21 years of age, unless unfit or disqualified.
3. Where the parents are both of minor age or themselves incapacitated to enter contracts, or give consent to their child’s participation in research, the guidelines on medical treatment of such a child may be followed whereby a third party may give the consent (i.e., the child’s grandparents, physician, or the hospital administrator, as in emergency cases).

*Requirement for assent*

4. Aside from the informed consent being required from LARs, assent from minors must also be obtained. Thus, the protocol must include the procedure for obtaining the minor’s assent. The minor’s assent to participate in the study shall be obtained without coercion.
  5. At any age, any sign of dissent shall be observed, and children who dissent must not be recruited to the study.
  6. The manner and form by which a minor provides his or her assent shall be as follows:
    - 6.1. If the minor is under 7 years-old, no formal assent, whether verbal or written, is needed as long as there is no manifestation of dissent.
    - 6.2. If the minor is 7 to under 12 years-old a verbal assent is acceptable. Documentation of the verbal assent is required. Documentation may be in the form of a written description of the process and witnessed.
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- 6.3. If the minor is 12 to under 15 years-old, he or she shall sign a simplified Assent Form that is different from the Informed Consent Form which the parents or guardian's sign. The Assent Form shall have been reviewed and approved by the REC. The decision to have an Assent Form for participants below 12 years-old rests on the REC.: Informed Assent Template)
- 6.4. If the minor is 15 to under 18 years-old, he or she can sign on the same informed consent document signed by the parents.
7. A minor's refusal to participate or continue in the research shall be respected.
8. Information on the study to which the child's participation is sought, and terms such as "research," "study design," "procedures," "adverse effect," "voluntary" shall be explained in a manner and language the child understands for purposes of assent and dissent. Determining the age of the child
9. The age of the child shall be determined by documentary evidence as follows:
  - 9.1. Child's birth certificate;
  - 9.2. Child's baptismal certificate;
  - 9.3. Any other pertinent documents such as, but not limited to, the child's school records, dental records, or travel papers;
  - 9.4. In the absence of all of the above, competent testimonial evidence may be used.
10. In case of doubt as to the age of the child, after all measures are exhausted to determine it, the age shall be resolved in the best interest of the child.
11. Assent presupposes that the child is mentally and physically capable of understanding what study participation entails. However, a competency examination of a child, *motu proprio* or by request of a party, shall be conducted when there exists substantial doubt regarding the ability of the child to understand the nature and consequences of giving assent.

## **XV. ETHICAL GUIDELINES FOR RESEARCH INVOLVING OLDER PERSONS**

The Philippines needs to prepare for the burgeoning population of older persons. The population of those who are 60 years and above has grown at a very rapid rate, increasing from 2.4 million in 1980 to 5.4 million in 2007, comprising 6.2 percent of the population. The older population is projected to increase rapidly in the future. By the year 2025, 10 percent of our population will be composed of senior citizens, at which time the country will be considered an aging society by UN definition (assuming that the medium-term assumptions of the Philippine population projections will hold true). However, there is inadequate representation of older persons in most research including, but not limited to, biomedical, clinical, socio psychological, and epidemiological. It is therefore appropriate to recommend the inclusion of older persons—60 years and older, frail, ambulatory, home-bound, and institutionalized—in research. There is a need to differentiate between legal competency and the capacity to make research-related decisions. Ethical challenges in research on older persons include the following:

1. Variability of health status and functional capacity among the young old (60 to 69 years), middle old (70 to 79 years), and the oldest old (80 years and above). This implies that researchers will need to design protocols to take into consideration such variability and to disaggregate data during the stage of data analysis. In drug trials, the presence of multiple chronic diseases and polypharmacy (intake of five or more drugs) need to be considered as potential sources of drug-disease, drug-drug, and drug-research participant interactions, leading to adverse drug events.

2. Physical and sensorial disabilities such as blindness, deafness, and mobility problems may inappropriately exclude such persons from needed participation in research.
3. Neurological and psychiatric illnesses that affect mood, movement, and cognition are accompanied by challenges in obtaining informed consent
4. Research participants' expectations regarding participation in research among persons with chronic, debilitating, and incurable diseases may be unrealistic, such that the research activities may be regarded as bringing cure, rather than alleviation or stabilization of disease or disability.
5. An increasing number of older persons living in long-term care institutions, or home-bound, may be inadvertently excluded from participating in research, leading to recruitment bias.
6. Socio-economic demographic characteristics may render the older persons more vulnerable, and may affect their participation in research.

#### *Inclusion of older persons in research*

7. Older persons with different health and functional status, including those who are terminally ill, regardless of venue of care, who will potentially benefit from the knowledge generated shall be represented in research. Informed consent
8. Researchers must be careful to clarify the purpose of the study to address participants' desires for therapeutic outcome, social contact, or practical help.
9. Researchers need to determine the best way by which consent will be obtained and continuing participation be ensured from a person who has difficulty with written or oral communication, mobility, cognition, and emotion.
10. Researchers must be on the look-out for cognitive, psychiatric, and functional problems common among older persons that may affect their capacity to give informed consent. But these shall not necessarily exclude them from participation in the research.
11. In the absence of capacity or competency to provide informed consent, a legally authorized representatives (LAR) may provide consent on behalf of the research participant, using the substituted judgment or best interest standard. Persons with movement disorders, such as Parkinson's disease or stroke, may give their consent through a thumb mark rather than a signature.
12. The protocol shall include safeguards that are proportionate to impairment and experimental risk and benefit. Conduct of the research

#### *Design of research*

13. Involve LARs and primary caregivers in all phases of the research. This may entail regular, weekly communication between the study staff and the primary caregiver
14. The research participant has the right to withdraw from the research, at any time, during the conduct of the research. The LAR and researcher must be sensitive to signs of dissent from the research participant, especially those with communication problems. Dissent must be respected.
15. The researcher shall ensure that the study compensation will directly benefit the research participants.

#### *Dissemination of research output*

16. The researcher must ensure that the research participants (with special attention to those who are institutionalized, homebound, or those who have communication and mobility problems) are informed of the results of the study.
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17. Reports of study results that are communicated to older persons must be in the form that is easily understandable to the participant.

## **XVI. ETHICAL GUIDELINES FOR RESEARCH INVOLVING MILITARY PERSONNEL**

Military organizations have their own culture and tradition that is rooted on discipline, obedience, and value for training. In this context, research may be expected to accord substantial consideration for the nature of the hierarchical or superior-subordinate relationship in the military, based on the “obey first before you complain” principle. Thus, soldiers are rendered vulnerable in the context of health research.

1. Involvement of soldiers in a research framed within the above military tradition must be justified by any of the following reasons:
  - 1.1. The study pertains to a special concern of military personnel;
  - 1.2. The study will provide direct benefit to military personnel; or
  - 1.3. The risk entailed is minimal. Recruitment and enrollment
2. Officers shall not influence the decision of their subordinates.
3. Officers and senior non-commissioned officers shall not be present at the time of recruitment of the subordinates.
4. Officers and senior non-commissioned officers shall be recruited separate from the subordinates. Informed consent
5. Special protection must be accorded to military personnel to ensure that the informed consent process is truly voluntary, free from undue influence or a coercive presence or intimidation from superior officers.
6. Researcher-officers shall not to be in military uniforms when obtaining informed consent.

## **XVII. ETHICAL GUIDELINES FOR RESEARCH INVOLVING PEOPLE WITH DISABILITIES**

Any research involving human participants is ethically bound to be done in a manner that respects the human rights of the concerned individuals. With respect to persons with disabilities (PWDs), the UN Convention on the Rights of Persons with Disability has made it clear that these human rights include the respect for the inherent dignity, individual autonomy, and independence of persons. In ethical review of research involving PWDs, other core principles in Article 3 of the UN Convention, such as equality, full and effective participation and inclusion in society, respect for difference, and accessibility must be addressed.

Under the Magna Carta for Disabled Persons (RA 7277), disabled persons are those persons suffering from restriction or different abilities, as a result of a mental, physical, or sensory impairment, to perform an activity in the manner or within the range considered normal for a human being. Impairment may be any loss, diminution or aberration of psychological, physiological, or anatomical structure or function. Any research protocol would therefore have to address and accommodate the nature and type of disabilities of the intended research participants.

The general principles in research involving persons with disabilities, as enumerated, are not any different from those involving persons without disabilities. However, it is the depth of sensitivity to the PWD situation, and the representation of this population in the collection of data that spells the

difference. PWDs are classified as vulnerable participants, and the informed consent process shall ensure freedom from manipulation and coercion; with special consideration to this population's special needs.

1. The well-being of the PWDs participating in research, involved in or affected by the research process shall be promoted at all times.
2. The dignity, autonomy, equality, and diversity of all the persons involved in the research process shall be respected.
3. The researcher shall respect the PWDs freedom to choose to participate or not, and protect their privacy and the confidentiality of their personal information.
4. Respecting autonomy means that PWDs who participate in a research have the right to make their own decisions regarding participation in the research process. Participation of PWDs in research
5. If research involving humans is to be truly representative, PWDs should be equally eligible to participate as research participants, and the protocol shall describe the necessary steps to facilitate such participation.
6. The diverse nature of research means that the various ways of including PWDs need to be assessed in order to decide which one is appropriate for a particular study.
7. The researcher shall consult with PWDs or their representative groups regarding the research topic, research questions, and research design. Disability awareness and sensitivity training
8. Researchers and the research staff shall have disability awareness training (or equivalent qualifications) in preparation for the implementation of any research conducted with this population. Facilitating participation in research of PWDs
9. The researcher shall endeavor to address the needs of research participants with visual, hearing, speech, cognitive, or other physical impairments in order to facilitate participation in research as follows:
  - 9.1. Use of large print materials or audio tape for people with vision impairments;
  - 9.2. Provision of easy-to-read materials or interpreters for people with cognitive impairments;
  - 9.3. Facilitation of interviews through lip-reading, written materials, or sign language interpretation for people who have hearing impairments; and
  - 9.4. Use of physically accessible venues during interviews or focus group discussions (FGDs).

#### *Dissemination of research findings*

10. The researcher shall ensure that research participants and disability groups are included in the dissemination of the research findings.

### **XVIII. ETHICAL GUIDELINES FOR RESEARCH INVOLVING POPULATIONS IN DISASTER SITUATIONS**

Disasters may have lingering physical, social, and psychological consequences, including chronic poverty, deprivation of basic needs, violation of basic rights, vulnerabilities, and a pervasive sense of hopelessness and disempowerment. These guidelines refer to research conducted among populations that have experienced extreme forms of stress due to natural calamities (e.g., floods, earthquake, fire, etc.), armed conflict, or other forms of violence.

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Research involving populations in the aftermath of emergencies and disasters must be guided by principles in consonance with the practice of humanitarian assistance and work with vulnerable groups, in general. Of relevance are universal humanitarian imperatives of alleviating human suffering, preserving human dignity, as well as protecting and respecting human rights, regardless of race, creed, nationality or political belief.

Research in post-disaster areas shall promote the following norms:

- Allowing for stability in the aftermath of the disaster, such that basic physical and safety needs are met
- Sensitivity to heightened vulnerabilities of the participants:
- Heightened psychological and physical risks against potential benefits (refer to the diagram below for the period of highest vulnerability),
- Vulnerability to undue influence (especially if research is linked to service),
- Diminished capacity to make decisions about participation due to stress. Prioritizing welfare of participants or community versus scientific goals (i.e., utilitarianism and social justice)
- Prioritizing welfare of participants or community versus scientific goals (i.e., utilitarianism and social justice)

Proper assessment of benefits and risks requires that the following questions are addressed first by the researcher, and later by the REC during the ethical review: Are there known potential harms and risks to individuals and the participant population, overall, by their involvement in the proposed research? How can the risks be mitigated, and how much will it cost?

These guidelines address several issues related to risks, benefits (i.e., contribution to the healing of the affected community), COI, recruitment and informed consent, and gender and cultural sensitivity. The potential for harm resulting from the research process itself and its sociopolitical implications, implies an equal potential for exploitation of participants.

The ideal situation would be that government or academic institutions in the community have RECs that can undertake the ethical review of the proposed studies. In their absence, however, concerned agencies (e.g., Event Response Short-term Recovery Long-term Recovery High Low Vulnerability The “Bermuda Triangle” of Disaster Research: the greatest respondent vulnerability, and the least social “order” to accomplish research Time Since Disaster Abramson, David. 2007 National Center for Disaster Preparedness Social Systems and Order (Regarding Social Welfare and Research) DOH, DSWD, CHED, or the DOST) may refer such studies for review to the NEC.

#### *Ethics committee review*

1. Research in emergencies and disasters shall give special attention to the unique needs and special concerns of victims and their specific cultural, religious, racial, and ethnic affiliations, so that pursuit of answers to the study questions may also bring about services and opportunities that are appropriate and acceptable to these individuals.
2. During the deliberations of the review committee on research involving populations in emergencies and disasters, a community representative or an accepted and established advocate for similarly situated populations must be present.
3. The ethical review process shall address the following considerations related to the care of the study population:

- 3.1. Is the research necessary? Justified in a post-disaster context?
  - 3.2. Where does the research fall along the disaster-time continuum?
  - 3.3. How ephemeral (time-bound) are the data?
  - 3.4. What is the nature of exposure to the disaster?
  - 3.5. Who are the research participants? How vulnerable? How will they be selected?
  - 3.6. What are the risks and benefits to participants?
  - 3.7. Can one obtain local support or endorsement (e.g., barangay or municipal endorsement)?
  - 3.8. How should the informed consent process be conducted?
  - 3.9. How will referrals for help be handled?
  - 3.10. Are the research design, tools, methods, valid, and appropriate to the research questions?
  - 3.11. Roles and responsibilities
4. The different roles of the researchers, health providers and volunteer workers shall be clarified and the actual and potential conflicts of interest identified.
  5. The researchers shall have the responsibility to identify the specific vulnerabilities of the research population relevant to the study and the mechanisms that are being put in place to address them.
  6. Researchers must demonstrate familiarity with the community's situation and their cultural beliefs and practices.
    - 6.1. The research team may include a local community counterpart (e.g., barangay or municipal officials).
    - 6.2. The research team must describe a preliminary community mapping or scoping exercise to ensure familiarity with the situation of the community, as well as identify local resources that will support the faithful implementation of the project.
    - 6.3. The research team must demonstrate ability to anticipate potential negative events (e.g., post-disaster trauma) and facilitate appropriate interventions.

#### *Justification for the study*

7. Research in disaster areas shall be justified if it can demonstrate that the objectives of the study cannot, otherwise, be achieved if done in a more stable setting
8. The research proposal must explain how its objectives relate to the priorities of the interests of the community.

#### *Research design and methodology*

9. Collecting personal data on traumatic experiences shall not be allowed, unless clearly justified in the protocol. It must be understood, however, that in many instances, people themselves want to talk about these as a form of therapy.
  10. Group methods shall be used with much caution because confidentiality and anonymity cannot be guaranteed (in all types of research among this population); and in security sensitive situations, this takes greater importance. For example, when recruiting Focus Group Discussion (FGD) participants, people with history of conflict shall not be placed in the same FGD group. Potential research participants must be informed that they can be identified and that their views could not be kept confidential.
  11. The protocol shall include provisions for proper intervention, or referral mechanisms, to ad-
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dress the health needs and security of research participants and the study team; and exit strategies, including closure activities and associated costs, throughout the proposed duration of the project.

12. In research involving people in emergencies or disasters, the involvement of participants is of prime importance. The study design shall provide the highest possible degree of participation and involvement of research participants
13. Procedures shall be established for a course of action in the event that a criminal act is disclosed or discovered through data collection, such as interviews.

#### *Recruitment and the informed consent process*

14. The researchers shall consult the community and secure its permission before approaching individuals for their informed consent. Further, there shall be close coordination with the local government in the conduct of the research.
15. The research team shall identify factors that serve as a barrier to the freedom of individual members of the participant population to give consent, and provide effective mechanisms to address them.
16. The withholding or non-disclosure of pertinent information must be justified in the context of protecting the research participants from specific harm or risks, and must be done according to the Guidelines for Health-Related Social Research (page 108), and with the approval of the REC. Risks and benefits
17. Direct benefits to the participants and to the community shall be a primary consideration in the conduct of the research. The research activity shall contribute to or enhance the development of intervention programs and shall not impede the healing or recovery of the community.
18. Possible repeat traumatization and potential risks (e.g., stigmatization and reprisals) for the study population shall be anticipated and planned for in the proposal.
19. The security risks for studies on population in an armed conflict situation shall be clearly identified and included in the ethical considerations section, specifically in the risk- benefit assessment, recruitment and informed consent process, and contents of the informed consent form
20. Data security shall be accorded top priority.
  - 20.1. The protocol shall anticipate potential misuse of seemingly “innocent” demographic or family data (e.g., number of males, females in the family) that may put individuals at risk (e.g., forced recruitment of male members by any of the combatant groups). Protection of sensitive information that can escalate violence shall be guaranteed to prevent potential misuse (e.g., information on delivery of supplies could lead to an ambush).

#### *Conduct of the research*

21. Researchers shall provide professional help (or at least a referral) during the conduct of the research to take care of the psychosocial needs of the community.

## **XIX. ETHICAL GUIDELINES FOR INTERNATIONAL COLLABORATIVE RESEARCH**

### **Collaboration in Research**

Researchers collaborate in research project that are within their range of competencies so that they can share their expertise to meet the objectives of the research project. The researchers involve

in the research project take responsibility on the integrity of the research design, data analysis and results of the study. They must demand the same standards with other research collaborators. Research collaborations in NORSU are accepted provided that the researchers has the expertise on the research subject

International collaborative research may be of different forms where each form presents unique issues. The different forms are as follows:

Type1: An International Study Group working on a global phenomenon or disease problem. The Study Group is composed of country representatives, each of whom contributes local data toward better understanding of a global phenomenon. The International Study may have a common international funder, several local funders, or mixed funding providing financial support. Here, the Filipino member generates local data and includes these to the global data pool.

Type2: A multi-country research group (an international collaboration) working on a specific disease that is endemic in the Philippines. Different aspects of the disease are addressed jointly, or separately by different research groups based in different countries. In this arrangement, patient clinical data and biological samples are sourced in the Philippines and shared with foreign collaborators identified in different countries.

Type3: Clinical drug trials is the most common international collaborative research. In the usual setup, a foreign pharmaceutical company sponsors the clinical trial of an investigational new drug, such that the same protocol is implemented in different countries by different investigators. Reporting of clinical data follows the standards of the ICH-GCP Guidelines.

Some major ethical issues when developing countries are involved have constantly been raised like:

- The standard of care that shall be used in research in developing countries;
- The “reasonable availability” of interventions that are proven to be beneficial during the conduct of research;
- The quality of the informed consent. The persistence of these issues has been partly due to the different interpretations of existing ethical guidelines, as well as the varied perspectives and thinking of sponsors, funders, and collaborators from developed and developing economies.

One other major issue is that of inequitable funding—only 10 percent of global research funding goes to diseases that make up 90 percent of the global burden. We can address the inequity by identifying the national priorities that are going to be the basis for setting the research agenda.

Whereas, scientific advances are the usual yardstick used to measure success in international collaboration, priorities such as areas of work, the sustainability of the studied interventions outside the research setting, and the investment in local research capacity should be equally regarded as indicators of success.

Relevant and meaningful health research in developing countries must focus on promoting health equity and developing local capacity in bioethics. Involvement of patients in international research collaboration raises hope, thus implying greater disappointment and frustration in research failure.

In 2008 and 2010, the KFPE (Commission for Research Partnerships with Developing Coun-

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tries) adopted a framework for ethical research that includes eight principles and 31 benchmarks that systematically specify practical measures to determine the extent to which the research satisfies the principles. These were just recently updated to include the following:

- Set agenda together
- Create transparency
- Promote mutual learning
- Share data and networks
- Pool profit and merits
- Secure outcomes
- Be accountable
- Clarify responsibilities
- Enhance capacities
- Disseminate results
- Apply results

The above practical measures are adopted in addressing ethical issues in international collaborations, most especially in Types 1 and 2 arrangements.

### *Setting the agenda together*

1. Filipino researchers shall take into account local capacities and needs in developing the agenda in Type 1 collaboration.
2. Filipino researchers shall be deeply involved in setting the research agenda especially in Type 2 arrangements.

### *Being mutually accountable*

3. Collegial decision-making and respect for one another's opinions shall be promoted, such that group decisions are respected and finger pointing is avoided. An openness to constructive criticism shall be an important indicator of maturity in the collaborative interaction.
4. Technical review shall be the responsibility of an international panel, but ethical review must be done at the local level. In the case of Type 2 arrangements, the involvement of Filipino patients requires ethical review by a Filipino REC. Creating transparency
5. The partnership shall develop comprehensive SOPs that shall guide processes and indicative activities, to promote transparency in all transactions and decisions.
6. The informed consent obtained from patients must indicate the specific research protocol, the name of the proponent, source of funding, procedures involved, and the site of research data collection. Clarifying responsibilities
7. A set of terms of reference shall be developed and agreed upon by the collaborators, in order to clearly delineate responsibilities and accountabilities of experts, clinicians, funders/sponsors/research managers, and the like. lead researchers,
8. Each study shall have separate terms of reference with regard to funding support on the basis of scientific merit and ethical soundness.
9. Deficiencies in the performance of agreed upon responsibilities shall be addressed in such a manner that attainment of objectives is still ensured.
10. Responsibilities shall be set proportionately based on capacities in relation to the overall research agenda.
11. In case of conflict, there shall be initial attempts for resolution internally at the level of the collaboration group, before it is allowed to escalate beyond the group (e.g., involvement of disciplinary and legal authorities).

### *Promoting mutual learning*

12. Research is a continuing search for knowledge. Each member of the research team is benefited by his or her participation in the form of new knowledge and insights from both good and bad

decisions, or right and wrong techniques. There shall be periodic meetings to assess developments and consolidate learnings derived from the different research experiences.

#### *Enhancing capacities*

13. The collaboration shall include workshops and seminars toward enhancing technical and research skills.

#### *Sharing data and networks*

14. Data sharing as a strategy for ensuring data integrity and promoting geometric growth of knowledge shall be part of the basic agreements in research collaboration. This is not to say that authorship rights must be set aside, but only to emphasize that a very important advantage of research collaboration is the presence of many minds.
15. Transfer of materials and data shall be covered by a memorandum of agreement and shall comply with existing Philippine laws and regulations (e.g., Intellectual Property Code [RA 8293], Data Privacy Act [RA 10173]).
16. Sensitive and personal information that will be transmitted outside the country shall be covered by the Data Privacy Act of 2012.
17. Despite an agreement on transfer of patient data and biological samples in Type 2 collaboration, ownership of data and biological samples remains with the Filipino collaborators, and further use of remaining samples shall be subject to Philippine approval.

#### *Dissemination of results*

18. International collaboration shall disseminate results that impact on the improvement of the health of the patients in the collaborating countries. The social value of research is best appreciated when results are disseminated.

#### *Pooling profit and recognition*

19. Basic agreements among the collaborators shall be forged in the beginning of the collaboration that shall describe how profits and recognitions shall be enjoyed and shared. Applying results
20. All collaborators shall endeavor to translate research results into better outcomes in the care of Filipinos suffering from the disease or condition under study.

#### *Securing outcomes*

21. Sustainability of good outcomes shall be part of the strategic plan from day 1 of the collaboration. Without sustainability, the impact will be small and narrow.

#### *Further use of clinical data and biological materials*

22. At the end of the collaborative project, further use of clinical data and biological materials shall require approval of the source-country researchers. The request for approval shall include an offer for further collaboration.

## **XX. ETHICAL GUIDELINES FOR AUTHORSHIP AND PUBLICATION AND DISSEMINATION**

In the fulfilment of the researchers' responsibility to the larger community, the research findings are disseminated in full, unbiased, non-selective and in sensible manner to the community of interest. The research activities are reported accurately to ascertain reliability of the research results.

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The research reports cited in other studies must not be represented as their own work.

Only researchers with substantial contribution like conceptualizing, design, analysis and writing of reports must be granted authorship. Workers doing data gathering in the field, collection of specimens, conducting the survey, doing statistical works and encoding are remunerated and properly acknowledged in the final report. Authors must be consulted before the final submission of paper to journals as a matter of ethical principle in responsible publication.

Authorship implies ownership of an idea or product, and confers privileges and responsibilities to the author. Guidelines emphasize the proper assignment of credit to, and the corresponding accountability of those identified as authors of a scientific or creative work.

The Committee on Publication Ethics (COPE) Council (2014) stipulated that whereas various disciplines and institutions have norms and practices, those who want to be identified as author should, at the very least, provide assurance that they have actually done the work as presented and that they have not violated any other author's copyright.

1. The guidelines issued by the International Committee of Medical Journal Editors (ICMJE) that define authorship as fulfillment of all four of the following criteria:
  - 1.1. Substantial contribution to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work;
  - 1.2. Drafting the work or revising it critically for important intellectual content;
  - 1.3. Final approval of the version to be published; and
  - 1.4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. In applying the above criteria, all individuals who have participated in criterion 1.1 should be given the opportunity to be part (or to decline to be part) of criteria 1.2, 1.3, and 1.4.
2. The following activities shall not be regarded as sufficient grounds for attributing authorship:
  - 2.1. Acquisition of grant money;
  - 2.2. General supervision;
  - 2.3. Collection of data;
  - 2.4. Involvement in the technical writing and editing.
3. Authors shall obtain the informed consent of research participants as a condition for the publication of photographs or identifiable information.
4. In submitting research proposal to REC for funding by the University, the authors shall accomplish the Authorship Agreement Form
  - 4.1. The specific contribution of each author to the research;
  - 4.2. An acknowledgment of the contributions made by people other than the authors; and
  - 4.3. A statement that the authors complied with ethical review requirements.
5. The basis for listing of authors shall be transparent, and may follow any of, but not limited to, the following norms depending on prior agreements:
  - 5.1. Alphabetical listing;
  - 5.2. Listing based on level of contribution;
  - 5.3. or First author is the one who did most of the work, the last author is the most senior in the group.

6. The student shall be listed as principal author of a publication that substantially derives from the student's dissertation or thesis
7. In collaborative groups, the important consideration shall be the identification of the responsible individual for the integrity of the work and the corresponding author.

## **XXI. GUIDE TO THE RESPONSIBLE CONDUCT OF RESEARCH IN NORSU**

### **I. Research Teams /Organization**

A research team or organization is a group of researchers whose activities are geared towards the attainment of the research project objectives. The member researchers possess the apt qualities, competence and technical or professional expertise to undertake the research project.

1. Project Leader
  - 1.1. Responsibilities of the Project Leader

The project leader has the responsibility in the selection, hiring and firing of research staff. Likewise it also the duty of the project leader to allocate research tasks to members as well as the remuneration fit to their expertise and qualities. He/she will ascertain that the researchers are properly remunerated of their contribution in the research project. These tasks and remuneration are well articulated in the terms of reference and must be understood by the researchers themselves before the research proceeds.
  - 1.2. Mentoring and Supervision

The project leader is responsible for mentoring the research members. He/she must provide direction related to the research project to all members and supervise the activities to ensure that the research will be completed on time. It is also the responsibility of the project leader to ensure that the research methodology is conducted professionally so that the research output meet the expected standard of the research project.
  - 1.3. Protecting the Integrity of the University

In the event that the integrity of the University is at stake or it may pose potential damage on the reputation as well as name of the University arising from the implementation of the research project, the project leader must inform REXIL immediately. The case will be elevated to University Research Ethics Council.
  - 1.4. Training of Research members

It is the responsibility of the project leader to send research members to training in order to fill the unmet needs of the researcher. In this way the researcher can collaborate fully to the research team.

### **II. Funding Management and Accounting**

Since NORSU is under the supervision of COA, hence researchers are obliged to conform to COA rules in the procurement, release, use and liquidation of funds for research especially researches funded by the University. Any irregularities in the management of funds observe by members of the research team will be reported immediately to the right personnel in the University.

1. Management of Funds

Research funds both from external and internal funding are deposited in the Business office of the University. Withdrawal procedures are subject to terms set by NORSU Business office. Request of funds are all in accordance to the funding agreement set in the research project line item budget.
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2. **Accounting and Liquidation**  
The project leader will see to it that proper liquidation of funds are in agreement set by COA rules. It is also his/her duty to ensure prompt liquidation to expedite the release of funds thus avoiding delay of project implementation. The accounting office regularly reconciles with the project leader of the fund reports and account balance in order to generate accurate report and henceforth apprise the funding agency.
3. Researchers must make known to the University the research funds and other material support they sourced outside the University. The funder must be properly acknowledged in the final report of the research project.

### **III. Collaborative Research**

Researchers collaborate and get involved in research project that are within their range of competencies so that they can share their expertise to meet the objectives of the research project. The researchers involve in the research project take responsibility on the integrity of the research design, data analysis and results of the study. They must demand the same standards with other research collaborators. Collaborations can be within or between local, national or international and likewise it can be in the academe, industry, government agencies, non-government organizations or people's organizations.

1. Research organizations involve in collaborative research should:
  - 1.1. Establish agreements for each collaboration (MOA/MOU is required)  
Research partners should establish written agreements in the implementation of the research project and must be adhered by all parties until the conduct of research is completed. The guiding principles found in this Research Ethics Manual should be observed especially in terms of honesty, integrity, quality and openness.
  - 1.2. All documents requiring NORSU support should be accomplished in writing. It should cover but not limited to intellectual property, copy right agreements, confidentiality, responsibility for clearances/ permit issues, ethics on sharing of commercialization revenues, and other legal matters. Protocols are established in data and other research materials management, dissemination of research results and journal publications.
  - 1.3. The project leader must ensure that each research members has understood the agreements in the MOA governing the research collaborations
2. Researchers involve in collaborative research should:
  - 2.1. Observe bilateral and multi-institutional agreements especially involving dissemination of research results and management and retention of data and other research materials
  - 2.2. Know and comply with the standards in conducting the research project and report any concerns and irregularities to the right person as soon as any party becomes aware of such irregularity
  - 2.3. Declare immediately any actual or foreseen conflict of interest involving any aspect in the conduct of research project
  - 2.4. Explicate any plans to use the research data, model, framework and concepts for competition, publication or IEC materials purposes.

### **IV. Conflict of Interest**

The University provides mechanism in identifying, managing and resolving conflict of interest

at any facet of the research project. The conflict of interest should be resolved at the lowest level and the resolutions should be properly documented. Relevant parties should conform to the resolution in order to eliminate the conflict of interest at once.

1. All aspects of the research project should be disclosed to all members of the research parties to identify actual and apparent conflict of interest.
2. In cases where the research project has the potential for commercialization, this concern must be addressed through MOA especially if it involves traditional knowledge holders who are not cognizant on publication, patent and commercialization.
3. Premature disclosure of privileged communication or information in whatever form to non-member parties that may harm the University or collaborating parties should never be tolerated and has to be dealt with properly by all parties.

## **V. Dealing with Research Participants and Community**

Researchers must have the responsibility of the research participants or otherwise known as research respondents or research subjects. Subjects here are derived from Nuremberg and Helsinki code and Belmont Report

1. Researchers must ensure to the research participants that joining the research is voluntary. Participants must not feel that they are forced to join through deceptive information, experienced unnecessary distress especially captive participants in the classrooms, group meetings, prison cells, churches, functions or any similar activities.
  2. The research including its end goal are explained to the participants in a form and language that are understood by the participants so that participants can discharge an informed consent.
  3. Participants must be aware that prior to joining the research they were asked for informed consent and they are allowed to withdraw anytime.
  4. Researchers who have the intention to give inducements to participants must not be announced prior to participating the research.
  5. Researchers must not put the participants in a place where they might be at risk physically or psychologically as a result of their participation in the research study.
  6. Research participants must be cognizant of their roles and risk in joining the research project. They must be informed on the duration of their involvement, the purpose of the project, personal or collective consequences in joining as participants of the research and other elements that will influence their being part of the study. The consent must be documented in writing.
  7. Researchers must guarantee at least minimum identity of the research participants. Likewise researchers must assure participants that their identifying informations are only available to members of the research teams.
  8. The research code affirms the following for community based research project
  9. The community and the research teams share control of the research objectives through active participation in the research concept, design and implementation of the research project
  10. The research outcomes must promote social benefit and change.
  11. The autonomy of the community must be recognized and the decision to join the research must be respected. The community must be treated as research partners and regular consultation with the stakeholders in the community will demonstrate the partnership.
  12. The researchers must be aware that all data collected belongs to the community and has to be returned once the research project is completed. The community must also agree on the publication and other manner of dissemination of the research results.
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13. The University Ethics Committee resolves any uncertainties arising from the participation of the community in the research project.

## VI. Dealing with Human Subjects

When research activity involves human subjects for testing or experiment, NORSU is guided by the principle of doing no harm to human subject. Researchers observe the protection of rights and dignity of human, freedom from health risk and preservation of self. NORSU adheres to the Nuremberg Code of 1949 and anchors its code of ethics when dealing with human subjects on this code.

1. Human subjects are utilized in research experiments only if there is no other alternative and that human society can benefit from the results of the experiment.
  - 1.1. Participation of human subjects in the experiment must be absolutely voluntary.
    - 1.1.1. Informed consent of the research participants must be acquired by researchers in the form of written document.
    - 1.1.2. Researchers must inform participants their manner of participation or how the data is gathered in the research experiment that might influence their willingness to participate in the research project.
    - 1.1.3. Participants are also oriented on who will utilize the result of the study.
    - 1.1.4. Informed consent shall be discussed when another procedure is required to obtain a data for the study.
    - 1.1.5. Minors, students, vulnerable groups (women, elderly, pregnant) must not be compelled to participate in the research study.
  - 1.2. Preceding informed consent, the participants must be made aware on the effects of their participation in the research activity; the different research process that they will be involved, health risks and benefits; access or feedback to the result of the experiment; personal and social consequences in the dissemination of the research result and possible consequences on the disclosure of information arising from the data gathered in the conduct of the research activity.
  - 1.3. Human subjects are allowed to withdraw even after signing the informed consent document.
  - 1.4. Individual circumstances of human subjects must be determined and documented before, during and after the experiment. These are but not limited to age, sexual orientation, disability, existing illness and other biomedical circumstance.
  - 1.5. Researchers in NORSU advocate the respect for human privacy. Human participants in the research activity has the right to remain unnamed or codes can be utilized for this purpose.
    - 1.5.1. However adults can waive their right to privacy but minors are not allowed to waive their right to privacy even if their guardians think otherwise. Minors will remain anonymous at all times in the whole duration of the research process.
    - 1.5.2. If human subjects wanted to remain unidentified then identifying data like names, geographical location, communities, residence area should be removed from the research report during dissemination or publication of research result.
  - 1.6. The responsible conduct of research ensures the safety of human subjects in all aspects of the research.
    - 1.6.1. Researchers must not inflict unnecessary pain whether physical or mental to the human subjects. Participants must be protected from injury or death.

- 1.6.2. Researchers will only allow a licensed professional or competent individual or expert experimenter to administer to human subjects.
- 1.6.3. The researchers has the right to terminate the research experiment if the human subjects are on the verge of injury, death or disability. Researchers must never engage in experiment involving human subjects with high probability of injury disability and death
- 1.7. Researchers must maintain a professional relationship with the human subjects during the whole duration of the study.
- 1.8. Appropriateness and timing must be determined with due diligence. Prior to the transfer of funds from the research organization to human subjects to defray their food and transportation expenses or token fee
- 1.9. Data gathered from the research activity must be presented in the right context.
- 1.10. It is the duty of the University Ethics Committee to resolve any uncertainties, atypical problem arising from the research study involving human subjects immediately. Resolution must be properly documented since these are deem useful in the review and revision of this Research Code of Ethics.

## **VII. Ensuring Safety and Protecting the Environment**

Researchers must ensure safety of research workers, participants and the community during the conduct of the research.

1. Research workers must be properly trained to handle equipment and use the facilities in the research laboratory.
  2. Researchers must undergo training before doing fieldwork to ensure that non target species and the environment are not destroyed during the conduct of the research.
  3. Research workers must undergo training on handling hazardous materials or products and disposal of such. They must be mindful on the dangers that these materials pose to themselves and other people and the possible impact of these materials to the environment.
  4. Researchers must adhere to the Laboratory Safety Rules prepared by the owner of the laboratory for the safe conduct of the research experiment at all times. They must be cognizant and follow strictly warning signs in the laboratory like radioactive signs, live microorganisms, and high voltage signs, wearing of mask warning signs, observance of sterility, hazardous materials, waste segregation, no eating and other relevant warning signs.
  5. Researchers have the responsibility to inspect the safeness of the laboratory and compliance of the laboratory to safety standards thru certification from the certifying body before they deploy their research workers in that laboratory.
  6. Researchers must ensure that research workers are equipped with safety tools and gears when they are working in laboratory where hazardous materials and waste are apparent.
  7. Research workers are trained to eliminate or handle accidents in the laboratory. Safety officer of the University can assist the research workers in dealing with accidents in the laboratory.
  8. Researchers must disclose all toxic materials used and produced in the laboratory in the course of doing the experiment. The disclosure includes handling, storing and disposal of the toxic waste. It must be examined by the environmental officer who is a member of the University Research Ethics Review Committee.
  9. In cases of emergency safety of the laboratory has to be secured before the personnel vacates the premises.
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10. When accidents happened an incident report must be submitted to the safety officer of the University for Documentation.
11. An accredited and certified hazardous and toxic waste collecting agency is available on call for the disposal of waste generated in the laboratory.
12. In dealing with wildlife, the University adheres to the protocols issued by Department of Environment and Natural Resources Wildlife Bureau

## VIII. Completion and Dissemination of Research

Completion of research in NORSU means accomplishment of the following

- Acceptance of the final research report by the funding agency or organization
- Liquidation of funds provided by the funding agency or organization
- Dissemination of research reports in appropriate form, language, audience and venue.

The University provides support to the faculty researchers for the completion of the research project. Non completion of the funded research project is not acceptable in NORSU unless it is impossible and no longer relevant to complete it. If there are forces natural or man-made which is beyond the control of the researchers or the University then the non-completion of research is acceptable.

No research project in NORSU is considered complete unless it has undergone dissemination to appropriate takers, venues, language and form. NORSU commits itself in sharing knowledge and technology to the community, industry, people's organization, government agencies and non-government organizations.

1. The University provides all the necessary assistance to the researchers for the dissemination of research reports.
2. The dissemination of research reports must be clear. The form and language must be in harmony with the target audience.
3. Dissemination of reports maybe part or whole depending on the judgment of researchers and the Research Ethics Review Committee of NORSU.
4. The University provides a standard format for the presentation of research report. This format must be adhered by the researchers in the dissemination of research report unless the funding agency or organization stipulates their standard.
5. Research reports must be disseminated within the period where the result is still current, significant and high utilitarian value.
6. Dissemination can be and not limited in the following form:
  - Publication in peer reviewed academic and professional journals recognized as high indexed journals
  - Presentation to research conferences
  - Delivering through lectures in public gathering
  - Conducting workshops
  - Mounting exhibits
  - Presentation of research result in radio, television and other multi media outlets.
  - Production of IEC materials
7. In internal presentation, the University provides the appropriate venue and mechanisms. RDE provides audience who can benefit much to the research results.
8. Publication Office as well as ITSO of the University must provide necessary security to the

research result, technology or innovations in order to protect the IP of the authors and innovators.

## **IX. Publication**

Publishing of research reports benefits others as well as the faculty researchers in terms of evaluation points, building of academic track record, collaborations with other researchers and the build-up of his/her academic career. Peer reviews before publication is painful and slow yet it is the best way where the research work can be improved.

1. PRISM is the research journal of the University which is CHED accredited where various research disciplines are accepted for publication. This journal is a developmental tool where faculty researchers can hone their skills in academic writing and as a way of publicizing the works of faculty researchers.
2. In submitting research reports for publication the researchers must be guided by the principles of quality, integrity and honesty.
3. As much as possible the research report must be published in full or whole unless the researchers are subjected to limitations such as confidentiality issues, patent applications and sensitivity of the issues found in the research works.
4. Researchers must describe the research findings accurately and truthfully even if it is in contradictory to their beliefs and expectations.
5. When researchers repeat the previous works of other researchers, the research work must be properly cited.
6. Publication office must ensure that faculty researchers have obtained copyright permission when images, pictures, data, diagrams, tables and graphs are used by the faculty researchers.
7. Researchers must acknowledge all those involved in research like funding agency, data gatherer, statisticians, finance officer, secretary and other personnel whose work is not enough to warrant authorship.
8. Papers are published in different journals at the same time will lead to black listing of the authors. Only when the paper is rejected by the editor where the authors can submit to other peer reviewed journals for consideration. Rewriting of the paper is necessary as journals is to each of its own in terms of form and editorial policies.
9. Researchers must be encouraged to improve the work even if the review is negative. The researchers must address the feedback given by the peer review panel.
10. If a misleading statement comes to the attention of the authors, they must inform the editor of the publication the soonest possible time.

## **X. Authorship**

Authorship is a recognition of an individual who made a scholarly contribution to the body of knowledge. This authorship must be distributed to all the members of the research team. All identified authors must express their consent to be included as authors. NORSU adopted the Vancouver Protocol, where an individual has to accomplish all of the following to be included as authors:

- a. Conception and design, analysis and interpretation of data
- b. Drafting the article or revising it for intellectual content
- c. Final approval for the publication

Researchers must comply with IP Code on Copyright. Authorship does not only mean natural

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person who did the actual writing of the write up, but include those who contributed intellectually to the research work. The amount of contribution that individuals contributed in the project is the basis for their places in the list of authors. In most cases the principal author is also the corresponding author or the author who communicates directly to the publisher. The list must be agreed by all the authors. NORSU assists research teams during authorship attribution by considering the following:

- a. Conception and design of the research work or study
- b. Development of equipment or instruments to collect and interpret data
- c. Development of sampling design or sample collection
- d. Use of computer program to compute data, model or simulate
- e. Processing and analysis of data
- f. Development of prototypes
- g. Development of explanation, theory or core idea
- h. Providing insights that leads to the solution of research problem
- i. Drafting significant parts of research report
- j. Critically revised the research draft

People who do not meet the criteria above should not be offered authorship. Research assistants like students and staff of the University but has meet the criteria above must be included as authors. “Honorary authors “or person listed as authors even if he/ she has not contributed to the research output is unethical and hence unacceptable in the University. If the research team deviates to the criteria above then they must seek permission from the REC. If the research project is a student dissertation, thesis or project , then the student becomes the first author. If the student and the mentor comes to an agreement that the student is not the first author, then they must seek clearance from the REC by accomplishing the Authorship Percent Distribution Form

On the other hand the following does not qualify for authorship

- a. Mechanical gathering of data
- b. Sourcing for funding agency
- c. Providing financial, material, laboratory support
- d. Providing technical support like fixing the equipment, repairing and maintenance
- e. Supplying technical data
- f. Text editing and word processing
- g. Administrative supervision being the head of the unit or research center where the research is involved

In cases of disputes on authorship then it must be resolved by the University Ethics Committee as soon as possible. All authors of the research project must be present during the negotiations. The University Ethics Committee will serve as mediators.

## **XI. Management, Storage, Retention of Data**

Data management includes ownership, collection, storage and sharing of data.

1. Data must be stored safely that permits retrospective audit. Retention and retrieval of data are essential in the conduct of responsible research.
2. Laboratory journals and computer files should be saved in secure places.
3. Laboratory samples should be preserved to prevent degradation overtime
4. Laboratory results should be keep in an indexed laboratory book.

5. Precautionary measures must be ensured to protect the data from fire, flood, rain and other catastrophic events.
6. Researchers are expected to share primary data, samples, collections and other supporting materials gathered in the conduct of research.
7. Researchers are expected to share data under the guiding principles of privacy, intellectual property and confidentiality.
8. Random codes can be used to uphold confidentiality of the data collected. It is the responsibility of the research to protect the confidentiality of the data.
9. Data must be retained in a format in accord with the nature of the research. It must be retained within reasonable time. If the funding agency has a regulation regarding data retention then their guidelines will prevail.
10. Researchers who are leaving the University and wish to retain research data that are owned by the University, must request permission clearance from the University Ethics Committee. Permission is refused if the data is used beyond the terms agreed by all authors in the research project.

## **XII. Peer Review**

Peer review is a scholarly exercise to foster collegiality among researchers and uphold the principle of quality research. Peer reviewers must run under the principle of honesty, objectivity and integrity. They must not derive benefit from the paper they are reviewing. They are also responsible of doing their assessment diligently and returning the paper within a reasonable time so that authors can benefit from the peer reviewers' work.

Peer review refers to the thorough, fair, and objective evaluation of components of the research process by experts in the area or discipline pertinent to the review subject, and is an essential component of the conduct of research to validate research initiatives. NORSU is cognizant that peer review is a critical factor in maintaining a culture of quality and cooperation with various academic scholars in the responsible conduct of research. Peer review increase networking possibilities within research communities and it is still the only widely accepted method for research validation (Elsevier, 2009).

1. To advocate the ethical standards and uphold the principle of quality peer review should be conducted on all research results submitted for dissemination to high indexed journals . Peer review is also a standard practice in NORSU particularly in processes of financing settlement for projects funded by NORSU funds and acceptance of publications in the research journal of NORSU (PRISM) and in the publication and dissemination of IEC materials.
    - 1.1. The review process is designed to the level program/project being reviewed.
    - 1.2. All final manuscripts are gauged against the same set of standards, and the process and procedures applied are open and objective. NORSU ensure that authors are fully informed of the review process and its outcomes.
    - 1.3. RDE create and enforce guidelines for the writing of peer reviews to ensure that these are comprehensive and detailed.
    - 1.4. The identity of peer reviewers is withheld from authors.
    - 1.5. NORSU peer reviewers are guided by honesty, mindfulness and openness. They do not derive unfair competitive advantage from the reviewing process and from their knowledge of other researcher's ideas or research plans.
    - 1.6. Material under review is used in any manner by the reviewer outside the review pro-
-

cess.

- 1.7. Peer reviewers, once they have committed to the review process, are obliged to perform their tasks and submit their reviews promptly and without sloppiness.

### **XIII. Breaches in the Code for the Responsible Conduct of Research**

All members of NORSU are responsible to formally report misconduct in research to RDE office immediately after they are made aware of the act. When research misconduct occurs in the NORSU the following actions are done.

- Complainant submits a written report to RDE
- RDE conducts discreet investigations
- RDE sets a formal inquiry
- NORSU REC will conduct thorough investigations and impose sanctions once the reported research misconduct is established
- The NORSU REC recommends actions after thorough deliberations
- RDE will make public statements relative to the case.

It is preferable that first offense will be dealt only at the college level or the person committing the research misconduct will be reprimanded.

NORSU REC identifies the following but not limited to as research misconduct

- Fabrication of results
- Misrepresentation of results
- Plagiarism
- Unauthorized use of another person's works and writings
- Financial fraud or misuse of research funds
- Risking the safety and welfare of research participants, animals and the environment
- Misrepresentation to obtain funding
- Concealment of research misconduct done by others
- Failure to manage conflict of interest
- Willful neglect of NORSU REC
- When the research induces traditional knowledge from traditional knowledge holders
- When the research produces product, utility models and other patentable materials without IP clearance

### **XIV. Amendments / Revision**

This Research Ethics Manual may be reviewed every two years. Any University faculty, employee, students and non-teaching staff may propose changes by writing to RDE office. The changes must be accompanied with specific explanations and reasons or justifications for the proposed change/s. The proposed change/s will be discussed by the RDE office. If the proposed change/s deemed meritorious then the change/s will be implemented.

### **XV. References**

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RA 9299 Republic of the Philippines June 25, 2004  
**NEGROS ORIENTAL STATE UNIVERSITY**  
 NCOP (1967) NCIS (1967) FVSAT (1968) CVP (1981)  
 Kagawasan Avenue Dumaguete City, Negros Oriental, Philippines 6200  
 Phone 522-5050 Fax 225-4751 Email: president.office@norsu.edu.ph Website: www.norsu.edu.ph



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## OFFICE OF THE UNIVERSITY PRESIDENT

*File*

May 27, 2024

### EXECUTIVE ORDER

No. 48-C, s. 2024

**TO : DR. MERIVIC G. CATADA, VICE-PRESIDENT, RIDE**  
**DR. ROSE MARIE T. PINILI, VICE-PRESIDENT, ACADEMIC AFFAIRS**  
**DR. NOEL MARJON E. YASI, VICE-PRESIDENT, ADMIN. AND FINANCE**  
**CAMPUS ADMINISTRATORS**  
**COLLEGE DEANS**

**SUBJECT : BOARD OF REGENTS' (BOR) APPROVAL OF THE RESEARCH ETHICS MANUAL**

1. Pursuant to Republic Act 9299 which authorizes the BOR to "enact rules and regulations not contrary to law as may be necessary to carry out the purposes and functions of the university or college" (IRR: CMO 7, s. 2022, Rule V, Section 17-a), you are hereby informed that BOR Resolution No. 40-C, s. 2024 was issued during the April 12, 2024 special meeting of the BOR to approve the Research Ethics Manual.
2. You are informed further that the approval is subject to compliance with CMO No. 52, s. 2016, RA 11293, RA 7722, and other pertinent government implementing rules and guidelines.
3. Dr. Merivic G. Catada, Vice-President for RIDE, is hereby directed to coordinate all efforts to facilitate the effective implementation of this Governing Board action.
4. For fast dissemination and strict compliance.

**JOEL P. LIMSON, Ph.D.**

University President

**Reference:** BOR Resolution No. 40-C, s. 2024

**Allotment:** The Vice-Presidents  
 The University Board Secretary  
 The Center/Office Directors  
 The Deans/Campus Administrators  
 The Resident Auditor  
 Other Heads of Offices

The HRMO  
 The Chief Accountant  
 The Supply Officer  
 Procurement Service Office  
 Chief Administrative Officer-Administration  
 Chief Administrative Officer-Finance

**To be included in the Perpetual Index under the following subjects:**

Executive Orders  
 Research Ethics Manual

|                          |                         |              |      |          |
|--------------------------|-------------------------|--------------|------|----------|
| Form ID                  | DGAM-OTUP-DE0048-C-001C |              |      | Page   1 |
| Issue Date               | 27 05 2024              | Issue Status | 010  |          |
| Reviewed & Authorized by |                         | Approved by  | OTUP |          |



RA 9299 Republic of the Philippines June 25, 2004  
**NEGROS ORIENTAL STATE UNIVERSITY**  
 NOPS (1907) NOTS (1927) EVSAT (1968) CVPC (1983)  
 Kagawasan Avenue, Dumaguete City, Negros Oriental, Philippines 6200  
 Phone (83) (35) 225-9400 Fax 225-4751 Email: president.office@norsu.edu.ph www.norsu.edu.ph



### BOARD OF REGENTS

**AN EXCERPT FROM THE 1<sup>st</sup> SPECIAL NORSU BOARD OF REGENTS (BOR) MEETING  
 FOR CY 2024 HELD ON THE 12<sup>th</sup> OF APRIL, 2024, 2:00 P.M.  
 AT CHED CENTRAL OFFICE, DILIMAN, QUEZON CITY**

#### "BOR RESOLUTION NO. 40-C, s. of 2024

**RESOLVED, TO APPROVE THE FOLLOWING MANUAL OF NEGROS ORIENTAL STATE  
 UNIVERSITY (NORSU):**

**RESEARCH ETHICS MANUAL (document referred form part and parcel hereto)**

**SUBJECT TO COMPLIANCE WITH RA 10532, DEPARTMENT OF HEALTH ADMINISTRATIVE  
 ORDER NOS. 2016-0012 AND 2017-0013, CHED REGIONAL MEMORANDUM ORDER NO. 02, S. 2019,  
 AND OTHER PERTINENT GOVERNMENT IMPLEMENTING RULES AND GUIDELINES.**

**APPROVED."**

**HON. RONALD L. ADAMAT, PH.D., P. D.**  
 CHED Commissioner and Chair/Presiding Officer

**HON. JOEL P. LIMSON, Ph.D.**  
 University President

**HON. FRANCIS JOSEPH G. ESCUDERO, Senator**  
 Chair, Committee on Higher, Technical and  
 Vocational Education  
 Senate of the Philippines, Member  
 Represented by:

**HON. EDWARD RYAN C. TORREDA**  
 LDRMO N. LGU Bayawan City, Neg. Or.

**HON. MARK O. GO, Congressman**  
 Chair, Committee on Higher and Technical Education  
 House of Representatives of the Philippines, Member  
 Represented by:

**HON. JENNIFER C. BRETANA**  
 Regional Director, NEDA RO 7, Member

**HON. MANUEL T. SAGARBARRIA**  
 Congressman, Second District, Negros Oriental

**HON. PROFETIZA S. LIM**  
 Representative, Private Sector, Member

**HON. JESUS F. ZAMORA, JR.**  
 Regional Director, DOST RO 7, Member

**HON. JOSE EDWIN D. MARTINEZ**  
 Representative, Private Sector, Member

**HON. STEPHEN C. PEDROSA**  
 President, Federation of Student Governments  
 Member

**NO REPRESENTATION**  
 (per BOR Resolution No. 54, s. of 2022)  
 President, Federated Faculty Association  
 Member

**NO REPRESENTATION**  
 (per BOR Resolution No. 110, s. of 2019)  
 President, Federation of NORSU Alumni Association  
 Member

**ATTESTED:**

**PRISCILLA S. CIELO, Ph.D.**  
 Acting University Board Secretary



**Research, Development, and Extension (RDE) Office,**  
**Negros Oriental State University, Kagawasan Ave.,**  
Dumaguete City, Negros Oriental, Philippines 6200



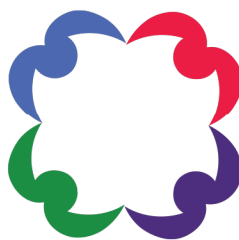
[researchethics@norsu.edu.ph](mailto:researchethics@norsu.edu.ph)



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(035) 225-5050 local 1023



**NEGROS ORIENTAL STATE UNIVERSITY**  
**Research, Development, and Extension (RDE) Office**  
**Research Ethics Office**

**Edited by**  
*Joanna Marie M. Palagtiw*

**Layout and Cover Design**  
*Arvil R. Ducusin & Homilo Gerard P. Abiera*