1. Rationale

Research has long been an integral part of the University of the Philippines Manila (UPM) even before it became an autonomous unit of the University of the Philippines System in 1983. However, organized and structured research in UP Manila started with the creation of the Committee on Research Implementation and Development (CRID) in 1979 at the College of Medicine (UPCM) to manage a specific research grant from the China Medical Board (UPCMB). In recognition of its continuing role in the area of research in the UP College of Medicine and the Philippine General Hospital (UP-PGH), CRID was upgraded in 2003 from a committee to an office, called the Research Implementation and Development Office (RIDO). It housed both the Technical and Ethical Review Boards of the UPCM and PGH.

In 1996, the Board of Regents (BOR) created various units to effectively perform the mandate of UP Manila as a center for excellence in health sciences education, research, and training. Among these is the National Institutes of Health (NIH) with its own Board of Advisers. The mission of the NIH is to be a major resource center for health research and capacity building. Subsequently, research institutes were established under the NIH. The UPM-NIH has its own Institutional Review Board composed of the Ethics and Technical Review Boards.
In 2006, the Expanded Hospital Research Office (EHRO) was created at the Philippine General Hospital to coordinate the conduct of research in the hospital. EHRO established its Ethics Review Board to facilitate the review of the significant number of research protocols submitted by fellows and residents, as well as nursing staff and research staff of PGH.

All the three Ethics Review Boards of the RIDO, NIH, and EHRO are registered with the Philippine Health Research Ethics Board (PHREB) and have been surveyed and given recognition by the Forum for Ethics Review Committees in Asia and the Pacific (FERCAP). In addition, both the RIDO[1] and NIH[2] Ethics Review Boards are also registered with the Office of Human Research Protection (OHRP) of the United States Department of Health and Human Services.

In this setting, Chancellor Ramon L. Arcadio issued Administrative Order No. RLA-10-141 on September 27, 2010; creating the University of the Philippines Manila Research Ethics Board (UPMREB) that will unify and integrate all existing review committees under a single research ethics board for UP Manila. The establishment of the UPMREB will streamline and harmonize the process of ethics review in the University, an essential step in research. This strategic move will provide a strongly supportive and enabling environment for research. In addition, it will maximize the utilization of its human and institutional resources, and ensure that all types of

[1] IRB No. 00002648
[2] IRB No. 00002908

protocols are reviewed in accordance with international and national requirements.

This document constitutes the formal statement of the UPMREB applicable to faculty, personnel, and students within the oversight of UPM research system. This is designed to provide an ethical framework and guidance to the conduct of this oversight, and anticipates the variety of situations that can occur in the conduct of research.

2. The UPM Research System

2.1. The UPM Manila Research System is under the oversight of the UP Manila Chancellor (See **Appendix 1: UPM Organizational Structure**)

2.2. The University commits to the establishment and maintenance of an effective ethics review system with the following objectives:

2.2.1. Establish and maintain the UPM Research Ethics Board (UPMREB), determine its composition, and appoint members to the various review panels

2.2.2. Ensure adequate resources to enable the UPMREB and its members to discharge their duties and responsibilities in an effective and timely manner, while providing for annual review of resources

2.2.3. Ensure independence in review and decision

2.2.4. Manage conflicts of interest particularly those involving clinical trials and ensure recording of how an institution resolved or managed the conflict of interest

2.2.5. Accept legal responsibility for the decisions of the UPMREB

2.2.6. Monitor approved protocol for all researches that are done within its jurisdictional premises

2.2.7. Promote responsible publication and dissemination of research findings

2.2.8. Ensure support for training in human subject protection for investigators, Good Clinical Practice (GCP), research methods involving human experimentation, confidentiality, data storage and records keeping, as well as regulation and governance for researchers and staff

2.2.9. Perform and document quality assurance activities to ensure compliance with international and national accreditation bodies

2.2.10. Provide guidelines for the preparation of Memorandum of Agreement (MOA), Memorandum of Understanding (MOU), Clinical Trials Agreement (CTA), Material Transfer Agreement (MTA), and other agreements for multi institutional and multi-center studies, regarding ownership of data, storage of data, registries, databases, as well as human samples

2.2.11. Provide guidelines for management and retention of human samples and research data, as well as their secure and safe disposal

2.2.12. Provide the policies on the ownership of and access to databases, registries, and archives that are consistent with confidentiality requirements, laws, privacy rules, and other guidelines including funding agreements

2.2.13. Provide guidelines/policies on ownership of data, database and registry ownership, as well as agreements covering ownership of data whenever researchers or staff leave or transfer to other institutions

2.3. The office directly responsible for research policy implementation in the university is the Office of the Vice-Chancellor for Research (OVCR)

2.3.1. The Vice Chancellor for Research[3], by virtue of the Board of Regent's resolution on its 1139th meeting dated February 17, 2000 serves concurrently as the Executive Director of the National Institutes of Health.

2.3.2. Functions of the OVCR:

- To supervise and coordinate the existing and future research-related units and offices, in addition to the NIH, e.g., Office of Research Services
- To monitor and coordinate the research activities of the University
- To guide the deliberation of research personnel recruitment, promotion, request for leave, secondment, and similar matters, including the preparation of necessary papers
- To prepare reports on research matters requested by the University and other institutions

2.3.3. To perform other functions that may be assigned by the UP Manila Chancellor

2.3.4. The UPMREB is under the supervision of the OVCR through the Office of the Director for Research Management and Translation.

2.4. The office directly responsible for registration of all research implemented within the university is the Research Grants Administration Office (RGAO).

2.4.1. The RGAO is under the Office of the UP Manila Chancellor and is supervised by the Office of the Vice-Chancellor for Research through the Director for Research Management and Translation. RGAO is headed by a Coordinator appointed by the UP Manila Chancellor.

2.4.2. Functions of the RGAO

- To assist investigators in preparing the necessary documents required in applying for grants/funds
- To assist investigators in complying with the requirements of UP Manila, and the sponsor organizations/institutions
- To serve as the central office that will facilitate and administer research grants, receive funds from sponsor organizations/institutions, request for release of funds to investigators, conduct internal audit, and ensure the proper conduct and subsequent termination of completed research projects
- To serve as the liaison and coordinating office between UP Manila and national

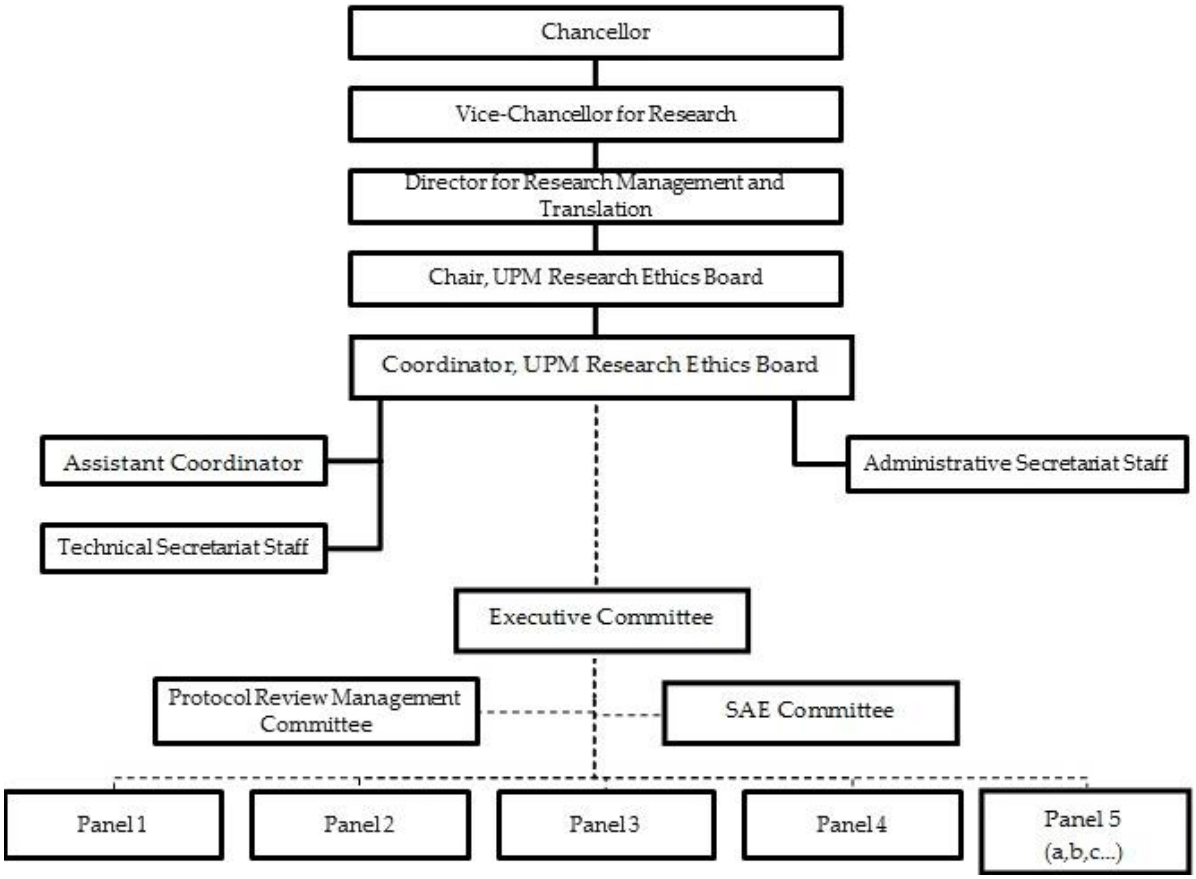
[3] In 2000, the position of the Assistant for Research was created. This was subsequently changed to Vice Chancellor for Research together with the Assistant for Academic Affairs, for Planning and Development and for Administration when the titles of Vice Chancellors were restored in 2001. The four Vice Chancellors report directly to the Chancellor and exercise supervisory functions over the offices/units under them (BOR 1144th Meeting, August 31, 2000).

and international research agencies, particularly with regard to financial matters
- To register all protocols submitted to UPM for ethics review
- To assess institutional fees/review fees from investigators/sponsors

2.4.3. All research proposals from UP Manila colleges and units are required to be registered with RGAO, thus all initial submission of documents should be done through RGAO. In addition, RGAO may accept proposals from non- UP Manila units and other agencies that may need ethical evaluation by the UPMREB.

3. The UPM Research Ethics Board

3.1. Organizational Structure



3.2. Functions

3.2.1. To develop, recommend, and implement guidelines on the ethical review of research protocols[4]

[4] Research policies are endorsed by the University Research Executive Committee (UREC), which is comprised of all College/Unit Research Coordinators including the Heads/Chairs of all offices under the VCR and submitted to the Chancellor for approval through the Chancellor's Advisory Committee

3.2.2. To ensure satisfactory review of submitted research protocols by following standard operating procedures
3.2.3. To issue ethical clearance to approved research protocols
3.2.4. To issue certificate of exemption for protocols not fulfilling the human research definition in the NEGHHR 2017
3.2.5. To ensure the protection of the rights and the wellbeing and safety of human participants in research
3.2.6. To ensure the protection of the integrity of the scientific data
3.2.7. To address and act on concerns of research participants and other stakeholders

3.3. UPMREB Review Panels are independent review panels constituted in accordance with **UPMREB SOP I** requirements for structure and composition and operate under one set of harmonized standard operating procedures aligned with the national framework for ethical oversight of research involving human participants.

4. UPMREB GENERAL POLICIES AND GUIDELINES

4.1. Scope of policy

4.1.1. The UPMREB implements a university policy of oversight of institutional research. Institutional research includes any research conducted by regular faculty members, students, clinical faculty members, residents and fellows of PGH and other UP Manila researchers. All institutional research protocols must undergo ethics review as stipulated in this manual.

4.2. Adherence to international and national guidelines

4.2.1. UPMREB complies with the requirements of the following international and national guidelines. These guidelines have been developed to protect the human participants in research and to ensure the integrity of the scientific data.

- World Medical Association Declaration of Helsinki (WMA-DoH)[5]
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use: ICH Harmonised Tripartite Guideline for Good Clinical Practice E6 (R1)[6]
- Council for International Organization of Medical Sciences International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS-Biomedical)[7]
- Council for International Organization of Medical Sciences International Ethical Guidelines for Epidemiological Studies (CIOMS-Epidemiology)[8]
- National Ethical Guidelines for Health and Health-Related Research 2017[9]

[5] http://www.wma.net/en/30publications/10policies/b3/
[6] http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf
[7] http://www.cioms.ch/publications/layout_guide2002.pdf
[8] International Ethical Guidelines for Epidemiological Studies (CIOMS), (Geneva: WHO, 2009) 128
[9] https://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg

- Department of Science and Technology (DOST) Administrative Order 001 Series of 2007 requiring ethics review of all health researches involving human participants[10]
- Department of Science and Technology (DOST) Administrative Order 001 Series 2008 requiring all Ethics Review Committees (ERB)/Institutional Review Committees (IRB) to register with the Philippine Health Research Ethics Board (PHREB)[11]
- Commission on Higher Education (CHED)Memorandum Order 34 Series 2007 in support of the DOST memorandum requiring all academic institutions engaged in human research to establish ethics review boards/committees[12]

4.3. ***Technical review***

4.3.1. All research protocols must undergo technical review prior to submission to UPMREB.

4.3.2. Technical review evaluates the relevance and scientific merit of research proposals and is the responsibility of the department and of the college or unit endorsing a study protocol.

4.3.3. Protocols carrying technical approvals must be endorsed by the department and the college/unit to UPMREB for ethics review.

4.3.4. For graduate student's research, a member of the student's thesis/dissertation panel may come from the Technical Review Committee of the college/unit where the student is enrolled

4.3.5. Technical reviewers may be guided by **Section II** of the **UPMREB FORM 2 (B) 2012: Registration and Application Form (See UPMREB SOP II).**

4.3.6. Investigators must submit evidence of technical review. Applications for ethical approval without prior technical review will not be processed and will be returned to the investigator.

4.3.7. The UPMREB reserves the right to request for additional technical review from an independent expert consultant.

4.4. ***Ethics review***

4.4.1. All research proposals shall be submitted for ethics review.

4.4.2. All research protocols should include a section on Ethical Considerations that details the ethical issues and corresponding measures to reduce the risks to human participants, laboratory animals, and the environment.

4.4.3. Informed consent (IC) and documentation (e.g. signatures) of IC shall be obtained

[10] http://records.dost.gov.ph/RMS/index.php?option=com_docman&task=cat_view&gid=136&Itemid=2

[11] http://records.dost.gov.ph/RMS/index.php?option=com_docman&task=cat_view&gid=133&Itemid=2

[12] http://202.57.63.198/chedwww/index.php/eng/Information/CHED-Memorandum-Orders/2007-CHED-Memorandum-Orders

from all research participants unless waived by the UPMREB. Only under special circumstances as stipulated in the UPMREB SOPs can the IC and/or IC documentation be waived.

4.5. ***Mandatory registration***

4.5.1. Mandatory registration of research within the university is an expression of the University's rights to:
- Monitor and regulate utilization of its facilities
- Monitor and regulate use of its name
- Protect its intellectual property

4.5.2. Registration of research is a UP Manila requirement and non-compliance is subject to University rules and regulations.

4.5.3. All UPM researches and those seeking UPMREB Clearance should be registered with RGAO using the **UPMREB FORM 2 (B) 2012: Registration and Application Form (See UPMREB SOP II).**

4.6. ***Investigator's qualifications and responsibilities***

4.6.1. Qualification requirements apply to the following:
- *Coordinating investigator* assigned the responsibility for the coordination of investigators at research sites participating in multicenter research
- *Investigator* or the researcher responsible for the conduct of the research at a specific research site. If research is conducted by a team of individuals at a research site, the investigator who is the responsible leader of the team may be called the principal investigator.
- *Sponsor-Investigator*, who is an individual that both initiates and conducts, alone or with others, research, and under whose immediate direction the investigational product or intervention (social, medical, behavioral) is administered to, dispensed to, or used by a subject/participant; and whose obligations include both those of a sponsor and those of an investigator. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency).
- *Sub-investigator* is any individual member of the research team designated and supervised by the investigator at a research or trial site to perform critical study-related procedures and/or to make important study-related decisions (e.g., associates, trainees, residents, and fellows).

4.6.2. Qualification is determined by education, training, and experience to assume responsibility for the proper conduct of the study.

4.6.3. Investigator should meet all the qualifications specified by the applicable regulatory requirement(s).

4.6.4. Evidence of qualification may be in the form of an updated curriculum vitae (CV)

and/or other relevant documentation requested by different stakeholders such as the research site, sponsor, the IRB/ERB/ERC, and/or regulatory authority (ies).

4.6.5. Investigators should have clearance and endorsement from his or her home institution/unit to conduct the specific research project for which ethical clearance is being sought. This clearance is attested through the signature of the head of unit in **Section III** of the **UPMREB FORM 2 (B) 2012: Registration and Application Form.**

4.6.6. Investigators should be aware of, and should comply with ethical requirements, good clinical practice requirements (as applicable), and the applicable regulatory requirements; with appropriate documentation or certifications.

4.6.7. Qualifications include the authority to facilitate institutional permissions for necessary audit of research or trial site by the sponsor, and inspection by the appropriate regulatory authority (ies).

4.7. ***Submission procedures and required documents for initial review***

4.7.1. A certification of mandatory registration of research protocols will be issued by RGAO upon receipt of completed application form and required documents, endorsing the research protocol to the UPMREB.

4.7.2. Research protocols should be guided by, but not limited to, the components indicated by **UPMREB Form 2(A) 2012: Review Checklist**.

4.7.3. All applicable documents indicated in the **UPMREB Form 2(A)2012: Review Checklist** should be included in the Protocol Submission Package. It is the responsibility of the applicant to provide copies as needed.

4.7.4. Investigators are required to submit, together with the Protocol Submission Package, proof of qualifications to conduct the research (e.g., CV, Research Ethics and GCP Training) obtained within three (3) years.

4.7.5. Specific research protocols may require additional documents, permits, and clearances. Investigators will be provided a checklist of additional documents for submission upon initial protocol screening by the UPMREB Secretariat.

4.7.6. Submissions from non-UPM researchers will not be accepted by the UPMREB unless their research site is within the scope of authority of the UP Manila.

4.7.7. UPM researcher intending to do research in a research site/facility with no local ethics review board shall submit certification to that effect signed by the administrative authority that has oversight on the study site, using the prescribed contents and format indicated in **Section IV** of the **UPMREB FORM 2 (B) 2012: Registration and Application Form (**See UPMREB SOP II).

4.8. ***Submission requirements for continuing review***

4.8.1. No amendments in an approved protocol shall be implemented without prior approval by the UPMREB.

4.8.2. Research protocol amendments need not undergo RGAO registration and are submitted directly to the UPMREB. However, UPMREB may require administrative re-review by RGAO in accordance with any UPMREB SOP (e.g. a request by PI to increase the number of research participants).

4.8.3. Operational definitions of revisions, amendments, and resubmissions will follow existing UPMREB SOPs on continuing review.

4.9. ***Review and approval of study protocols***

4.9.1. Research protocols will be reviewed based on the following elements:

- Completeness of documentation requirements
- Scientific soundness
- Ethical considerations
- Conflict of interest
- Informed consent
- Research site capability using the **UPMREB Form 2(E)2012: Site Resources Checklist for Clinical Trials Outside UP-PGH By UPM Personnel**

4.9.2. Review procedures will be in accordance with the **UPMREB SOP II**.

4.9.3. A protocol submission package shall be accomplished by the investigator and submitted to RGAO.

4.9.4. RGAO shall process the submitted documents, and register the protocol. After processing the documents, RGAO will forward the submission package to UPMREB

4.9.5. The UPMREB Secretariat shall screen the protocol and assign the protocol package to the members of the appropriate Review Panel

4.9.6. The assigned review panel shall review the submitted protocol and related documents according to **UPMREB SOP II**.

4.9.7. The Review Panel may request additional information to be included in the study protocol and related documents, such as the informed consent form, to ensure the protection of the rights, safety, and well-being of the study participants.

4.9.8. In case the Review Panel asks for modifications or additional information, the investigator must respond to the requests in writing and make a resubmission to the Review Panel for re-evaluation prior to the final approval of the protocol.

4.9.9. Approved protocols duly signed by the Panel Chair shall be submitted to RGAO by the UPMREB Secretariat for release to the PI.

4.9.10. In case the protocol is disapproved, investigators may appeal to the UPMREB through the UPMREB Panel Chair.

4.9.11. The conduct of approved research protocols is subject to monitoring by the UPMREB

4.9.12. Responsible and ethical conduct of approved research is the shared

responsibility of the investigator, the sponsor, and the UPMREB, to promote and protect the safety and well-being of the research participants.

4.9.13. Monitoring should ensure that research participants' interests continue to have primacy over all other interests.

4.9.14. The responsibility of monitoring of approved protocols rests on the specific UPMREB panel that reviewed and approved the protocol, subject to UPMREB oversight.

4.9.15. Monitoring is done through various activities initiated by the UPMREB panel that approved the implementation of the research protocol, in accordance with **UPMREB SOP III**, such as:

- Continuing review, including review of interval/progress report, incident report, or proposed amendment
- Site visit
- Review of reports on protocol non-compliance
- Review of completion/final report
- Review of requests for early termination
- Review of adverse events, as applicable

4.9.16. Ethical clearance can be suspended or withdrawn from studies found to be non-compliant or in violation of UPMREB terms of approval, upon determination of non-compliance or violation by the approving UPMREB Review Panel, based on **UPMREB SOP III**. The UPMREB can subsequently recommend termination of the study, if warranted.

4.9.17. Clinical trials that have been approved by any panel of UPMREB must comply with SOPs on reporting adverse events set by the UPMREB, which include reporting procedures on adverse events as defined in **UPMREB SOP III**.

4.9.18. Analysis of reported AEs is assigned to the **UPMREB Adverse Event Subcommittee**, which is tasked to investigate AEs and is composed of a Chair and at least two other members appointed by the Chancellor, upon the recommendation of the UPMREB Chair. Experts may be invited by the AEC whenever necessary. Detailed functions and procedures of the **UPMREB Adverse Event Subcommittee** may be found in **UPMREB SOP I** and **SOP III.**

5. UPMREB SPECIAL GUIDELINES

5.1. Undergraduate student research involving human participants are subject to the same general principles as outlined in this document.

5.1.1. Undergraduate students are students enrolled in a bachelor's degree program. Students enrolled in graduate programs and postgraduate programs, law, and medicine are considered postgraduate students.

5.1.2. All undergraduate student research must be conducted under the supervision of a faculty member of the UP Manila as required by **UPM Memo RLA-07- 080 (**See

Appendix 2).

5.1.3. Undergraduate students shall ONLY be allowed to do the following types of research:

- Research that is of minimal risk
- Research that fulfills the criteria for an expedited review
- Non-therapeutic or non-interventional
- Research that will compromise the security, safety, and well-being of students shall not be allowed.

5.1.4. Submission of protocols shall follow the general guidelines on protocol submission and review.

5.1.5. Review of undergraduate student research shall be undertaken by the College where the student is enrolled, but must undergo UPMREB mandatory registration procedures. Student research work is subject to the oversight and monitoring function of the UPMREB.

5.1.6. Undergraduate student research can be discontinued at any time by the faculty adviser or the UPMREB if deemed harmful to the study participants.

5.2. UPMREB Panels that review research on vulnerable populations must ensure compliance with the provisions in international ethical guidelines and the National Ethical Guidelines for Health and Health-Related Research.

5.2.1. Vulnerable populations are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. These include, but are not limited to, the following:

- Children and the elderly
- Persons suffering from mental or behavioral disorders
- Pregnant and breastfeeding women
- Prisoners and drug users
- Persons being recruited by those who teach, treat or employ them
- Very sick and desperate patients
- Underdeveloped communities, including indigenous communities

5.2.2. In general, research involving vulnerable populations must have the following minimal requirements:

- The purpose of the research is to obtain knowledge relevant to the particular health needs of the vulnerable subject population
- The assent of each subject has been obtained to the extent of his or her capabilities, and a prospective participant's refusal to participate in non-clinical research is always respected
- In the case of incompetent participants, informed consent is obtained from the legal guardian or a duly authorized person
- The degree of risk attached to interventions that are not intended to benefit the

individual participant is low and commensurate with the importance of the knowledge to be gained.

- Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual participant as an alternative.

5.2.3. UPMREB Panels that review research involving children or persons below 18 years old must have at least one member who is a pediatrician or child development expert, and with a lay member who is a parent.

5.2.4. Research involving prisoners with serious illness or at risk of serious illness should ensure that prisoners are not arbitrarily denied access to investigational drugs, vaccines, or other agents that show promise of therapeutic or preventive benefit.

5.2.5. UPMREB Panels that review research involving underdeveloped communities must have a member or consultant who is thoroughly familiar with the customs and traditions of the community being researched. The panel must ensure that research in underdeveloped communities should only be carried out with the following criteria:

- The research could be carried out reasonably well in a developed community
- The research is responsive to the health needs and the priorities of the community
- Informed consent of individual members is obtained and community permission has been secured

5.2.6. Research involving pregnant or breastfeeding women should have the following protective mechanisms:

- Pregnant or breastfeeding women should in no circumstances be the participants of non-clinical research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about pregnancy or lactation.
- As a general rule, pregnant or breastfeeding women should not be participants of any clinical trials unless designed to protect or advance the health of pregnant or nursing women, as well as fetuses or breastfeeding infants.
- Women in their reproductive years who will undergo investigational drug trials or procedures should be advised against getting pregnant and should be given options regarding contraception methods.

5.3. Research using live vertebrates other than humans shall be processed by the UPM Institutional Animal Care and Use Committee (IACUC) for review and clearance, subject to the requirements set by the **IACUC Policies and Guidelines**[13].

5.4. Guidance for other research work not detailed above may be found in specific sections of the National Ethical Guidelines for Health and Health-Related Research such as:

- Herbal Research

[13] Draft of IACUC Manual of Policies and Guidelines is available at the UPM-NIH IACUC Office

▪ Complementary and Alternative Medicine Research
▪ Research on Populations Traumatized in Emergencies and Disasters ▪ Genetic Research
▪ International Collaborative Research
▪ Research on Assisted Reproductive Technology

5.5. Material tissue transfer or transfer of blood components, human tissues, and genetic materials outside of the Philippines shall be governed by **RA 8293: An Act Prescribing the Intellectual Property Code and Establishing the Intellectual Property Office, Providing for its Powers and Functions and for other Purposes**[14]; and its implementing rules and regulations. Further information may be obtained from the Intellectual Property Office of the Philippines[15] or from the IPO of UP Manila

5.6. Research projects with biosafety implications shall be processed by the UPMREB then referred to the Institutional Biosafety and Biosecurity Committee (IBBC) for review and clearance, subject to criteria set by the **IBBC Policies and Guidelines**[16].

5.7. The UPMREB addresses participant queries and concerns in accordance with **UPMREB SOP III**.

5.7.1. Human participants in research are entitled to lodge their complaints or grievances related to research protocols approved by UPMREB Panels. Examples are:

- Research misconduct (dishonesty, disrespect, coercion, physical "abuse" not in keeping with research procedures,breach of privacy, etc)
- Discrimination in the recruitment process
- Non-compensation
- Deviation from procedures enunciated in the informed consent
- Misinformation
- Severe adverse reactions
- Injuries (physical, psychological, mental) perceived to be due to the study procedures

5.7.2. The UPMREB does not have police powers, but in view of its oversight functions, can directly receive complaints or grievances relevant to research protocols approved by UPMREB Panels, and address such complaints from participants in coordination with the approving panel.

5.7.3. UPMREB-approved informed consent forms should contain the name of the panel which reviewed and approved the protocol with the contact information of the UPMREB Office.

5.7.4. The UPMREB will process respective complaints or grievances in accordance with the UPMREB SOPs on handling complaints or grievances, and act on them in a speedy, unbiased, and confidential manner, and to recommend resolution of the

[14] https://www.officialgazette.gov.ph/1997/06/06/republic-act-no-8293/
[15] http:// www.ipophil.gov.ph 16
[16] Draft of the IBBC Manual of Policies and Guidelines is available at the IMBB, UPM-NIH

complaint according to existing policies and applicable regulations, with the option of seeking legal counsel.

5.7.5. The grievances of specific stakeholders shall be referred to the relevant authorities, as applicable.