INTRODUCTION

The **University of Perpetual Help Rizal System** established the first institutional ethics committee in October 2004 through the initiative and recommendation of Dr. Aretas P. Singson-Alday, Dean JFSM and with recommendation of Dr. Rowena Auxillos, UPHRMC Medical Director. The aim was to ensure that the clinical researches conducted at JONELTA Foundation School of Medicine and the University of Perpetual Help Rizal Medical Center conform to ICH GCP guidelines. In January 2006 the University of Perpetual Help Rizal Corporate Center was established. The Institutional Ethics Committee initially formed in 2004 was restructured to become the **University of Perpetual Help System-Institutional Ethics Review Board** under the Corporate Office for Research specifically the Corporate Vice President for Research.

The objective of the **University of Perpetual Help System-Institutional Ethics Review Board** is to ensure the protection of the rights, safety and well-being of human subjects involved in health related research and to provide public assurance of that protection. It believes in and adheres to the basic ethical principles - respect for the person and his/her autonomy, beneficence, non-maleficence and justice. It is adherent to international guidelines such as the Declaration of Helsinki, CIOMS International Guidelines, ICH-GCP and WHO Guidelines and the national laws and guidelines such as the PNHRS Act of 2013, PHREB National Ethical Guidelines for Health Research.

The **University of Perpetual Help System-Institutional Ethics Review Board** reviews all research protocols involving human participants and continues its monitoring review until the end of the study. The scope of the work of the IERB includes researches done by the University faculty members and hospital staff/trainees as well as outside clients of Perpetual Health System.

The **University of Perpetual Help System-Institutional Ethics Review Board** manual of standard operating procedures was developed in 2014 by Dr. Roy Cuison and Dr. Dulcinea Balce Santos. It has undergone three revisions, the latest version 3 was approved by Dr. Maria Leisa Magboo Gaviola, UPHS Corporate VP for Research and Dr. Daisy M. Tamayo, Chairperson Chief Executive Board on January 20,2016 and has been effective and implemented since then.

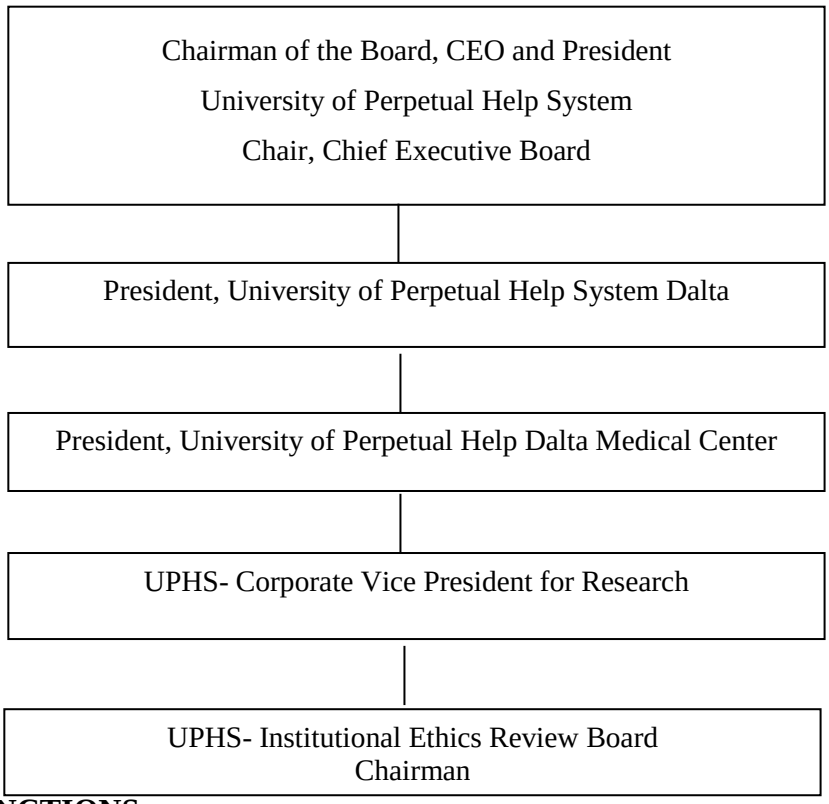
This document was prepared and will be applicable to hospital and medical staff, residents, fellows and other trainees, faculty, personnel, and students within the oversight of UPHS research system. This is designed to guide the researches as well the sponsors

regarding the Institutional Ethics Review Board requirements for review of research protocols.

The UPHS-IERB complies with the requirements of the following international and national guidelines. This guideline has been developed to protect the human participants in research and to ensure the integrity of the scientific data.

1. THE UPHS- INSTITUTIONAL ETHICS REVIEW BOARD

UPHS –IERB ORGANIZATIONAL CHART



1.1. FUNCTIONS

1.1.1. To develop, recommend and implement guidelines on the ethics review of research protocols

1.1.2. To ensure satisfactory review of submitted research protocols by following standard operating procedures

1.1.3. To issue ethics clearance to approved research protocols
1.1.4. To ensure the protection of the rights and the well- being and safety of human participants in research.
1.1.5. To address and act on concerns of research participants and other stakeholders

2. SCOPE OF POLICY

- The UPHS-IERB oversees all researches in UPHS. Institutional research includes any research conducted by residents and fellows of University of Perpetual Medical Center, UPHMC Staff and personnel, UPHS faculty members, students, clinical faculty members and other UPHS researchers. All Institutional research protocols must undergo ethics review
- All research protocols must undergo technical review prior to submission to UPHS-IERB.
- Technical review evaluates the relevance and scientific merit of research proposals and is the responsibility of the clinical department and of the college or unit endorsing a study protocol.
- Research Proposal carrying technical approvals must be endorsed by the clinical department and the college or unit to UPHS-IERB for ethics review.
- Graduate student's research must be endorsed by the Technical Review Board of the college or unit where the student is enrolled.
- Investigators must submit evidence of technical review. Applications for ethical approval without prior technical review will not be process and will be returned to the Investigator.
- All research proposals shall apply for ethics review at UPHS-IERB.
- 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 and the environment.
- All research involving human participants and clinical trials within the university and hospital shall apply to Institutional Ethics Review Board for ethical approval.

3. REVIEW OF RESEARCH PROTOCOLS

IERB APPROVAL should be obtained prior to initiation of any research related activities.

3.1. **Investigators are required to submit** a protocol package for initial review must be received together with duly signed and accomplished forms and Ten (10) sets of study related documents (as applicable) as follows:

Institutional Forms

- Application Form (FORM 2.1(A)2018)
- Certification of Technical Review approval if applicable
- Completed Study Protocol Assessment Form (FORM 2.1 (C) 2018)
- Completed Informed Consent Assessment Form (FORM 2.1 (D) 2018)

Study Related Documents

- Cover Letter
  - Full Study Protocol
  - Data collection forms (including CRFs)
  - Informed consent (for studies with human participants) already containing the institutional clause regarding contraceptive use both in English and Local Language (Pilipino and other appropriate regional dialects) where applicable.
  - Assent form in English (for studies involving minors)
  - Assent form for minors in local language (for studies involving minors)
  - SAE forms (for clinical trials)
  - Study budget
  - List of study team members with CV and current licenses of PI and study team
  - Declaration of Conflict of Interest
  - Information to participants (including advertisements)

Other Documents

- Investigator's Brochure (for clinical trials)
- Current GCP Training Certificate of PI, Co-I and Research Assistant (for clinical trials and for students, faculty, medical staff, employees of the institution, residents in training and fellows in training
- Clinical Trial Agreement (for clinical trials)
- Memorandum of Agreement (for collaborative studies)
- Previous ethical review approvals/clearances or disapprovals (for those with prior ethical clearance in other countries or other sites in the Philippines)
- Material Transfer Agreement (for genetic research)
- Other related documents i.e. indigenous people organization

- Certification of Technical Review approval for students, faculty, medical staff, employees of the institution, residents in training and fellows in training

Informed Consent Form English and Tagalog versions dated 22 November 2018

Our Institution has an existing policy regarding the "Review, Study and Supervision of the Ethical and Bioethical Policies and Programs of the System", and it fully adopts and embraces the Catholic doctrine. Consequently, because of the provision regarding the use of the contraceptive methods that the research protocol imposes on female trial subjects of child bearing potential, we therefore require that this additional paragraph be inserted and highlighted in the informed consent form that will be administered to all trial subjects recruited from our Institution.

"The Sponsor may require that an effective method of birth regulation be used by participants in this study. You may choose to participate in the study, and abide by the requirements of the Sponsors to use artificial methods of birth control, as long as you know and are fully aware of the risks involved to you and/or your baby should you become pregnant in the course of the study."

"Maaaring itakda ng Sponsor sa pag-aaral na ito ang paggamit ng isang mabisang pamamaraan ng pagpigil sa pagbubuntis. Maaari kang sumali sa pag-aaral na ito, at sumunod sa itinakda ng Sponsor na artificial na pamamaraan ng pagpigil sa pagbubuntis, hangga't nalalaman at nauunawaan mo ang panganib na maaaring idulot nito sa iyo at sa iyong sanggol kung sakaling ikaw ay mabuntis habang nasa pag-aaral na ito."

3.1.1. A summary, (if possible in non-technical language) synopsis or diagram/flowchart of the protocol.

3.1.2. Informed consent (for studies with human participants) already containing the institutional boxed clause regarding contraceptive use both in English and Local Language (Pilipino and other appropriate regional dialects) where applicable.

3.1.3. Case Reports Forms (CRF, diary cards, other questionnaires intended for the subjects).

3.1.4. Written information to be provided to the subjects or potential research participants (e.g. patient Information Sheets), clearly identified and dated, and written in the language (s) understood by them, if applicable.

3.1.5. Subject recruitment procedures (e.g. advertisements), if applicable.

3.1.6. An adequate summary of all safety pharmacological, pharmaceutical, and toxological data available on the study product (if drug trial or device under investigation.)

3.1.7. Information about payments compensation available to the subjects (including expenses and access to medical care.)

3.1.8. A description of the arrangements for indemnity, if applicable.

3.1.9. A declaration of agreement to comply with ethical principles set out in relevant guidelines.

3.1.10. Details of the Budget for the Study (including honorarium to the investigator.)

3.1.11. Philippine FDA certification of approval for clinical trial

3.1.12. List of names of the Investigators in other institutions or countries if study multinational or multicenter with contact numbers and addresses.

3.1.13. All significant previous decisions/data made by other Ethics Review Committees or regulatory authorities on the Study Protocol like reasons for the negative decisions and any modification(s) made.

4. THE IERB REVIEW PROCESS

4.1. Upon the receipt of the protocol, the Secretary-General classifies the protocol review pathway as full board review, expedited review, or exemption. (SOP Chapter 2.2 and 2.3).

4.2. If for full board review, the Principal Investigator is invited and scheduled to present in the next scheduled meeting.

4.3. For expedited review, the Secretary-General assigns one medical reviewer and one non-medical or lay member as reviewers of the protocol. Only those protocols with low risk intervention submitted by resident trainees may be classified for expedited review based on a set criterion (Form 2.1 (C).

4.4. For protocols classified as Exempted from IERB review

4.4.1. The Secretary General sends an Exemption notification letter to the investigator. The letter will include the following information:

4.4.2. That the investigator is required when applicable, to provide the UPHS-IERB written notification of changes or amendments to the protocol including any change in the title during conduct of the study.

4.4.3. That the investigator is required to submit, in a timely manner, the final paper to the UPHS-IERB

SUBMISSION REQUIREMENTS FOR CONTINUING REVIEW

4.5. The research proponent will need to submit the following reports to the committee once the Clinical Trial Protocol is Approved:

4.5.1. Serious adverse event (SAE Form 3.4) in the UPHDMC site should be reported according to the timelines specified in SOP 3.4: Reporting/Monitoring/Evaluation of Serious Adverse Events. Please forward two (2) copies of this form to the IERB office. Moreover, reporting of suspected, unexpected, serious adverse events (SUSAR) from other study sites, justification why the study should continue, is required. Submission of SUSAR may be done on a monthly basis. Any scientific update, advisory or development related to the study drug, procedure, technology or devices that will adversely affect patients enrolled in the study must be reported.

4.5.2. Protocol deviations/violations (Form 3.5) must be reported.

4.5.3. No amendments in an approved protocol shall be implemented without prior approval by the UPHS-IERB. Any amendment/s in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using the attached Form 3.1: Study Protocol Amendment Submission Form. The requirements prior to the review of amended protocols are:

a. Nine (9) copies of the amendment with letter of intent.
b. Summary of the amended components (Form 3.1).

c. The amended parts are highlighted.

4.5.4. Progress report using the attached Form (3.2): Continuing Review Application Form should be submitted one (1) month before the end of the approval period. Final Report (Form 3.3) is required after the completion of the protocol procedures at the study site. Failure to submit and obtain renewal of protocol approval on time will result in discontinuation of research activity when the approval expires. These should provide the following information with Letter of Intent.

a. Number of subjects enrolled in the site
b. Number of withdrawals and the reason(s) for withdrawals
c. Adverse events during conduct of the study
d. Date the study was terminated/completed (for end-of- trial reports)
e. Reasons for the study termination
f. Results of the study (for end-of- trial reports)

REVIEW AND APPROVAL OF STUDY PROTOCOLS

4.6. 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

4.7. Review procedures will be in accordance with the UPHS-IERB SOP Chapter 2.2, 2.3, 2.4, 2.5

4.8. A protocol submission package shall be accomplished by the Investigator and submitted to UPHS-IERB.

4.9. The UPHS-IERB Secretariat ensures completeness of submitted forms and documents using the checklist indicated in the IERB requirements. The Secretary General assigns an appropriate primary reviewer.

4.10. The assigned reviewer shall review the submitted protocol and related documents according to UPHS-IERB SOP 2.2 and SOP 2.3

4.11. The Board 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.

4.12. The UPHS-IERB may take any of the following decision on your protocol:

a. Approved,
b. Major revision required (WHO handbook for GCP, 2002)
   - any revision of the Informed Consent Form (ICF)
   - any change in study design
   - change in sample size
   - adding or removing procedures to improve study methods
c. Minor revision required
   - any revision not included as major revision

d. Disapproved.

4.13. In case the Board asks for modifications or additional information, the Investigator must respond to the request in writing and make a resubmission to the Board for re-evaluation prior to the final approval of the protocol.

4.14. Approved protocols duly signed by the Chair shall be send by the UPHS-IERB Secretariat for release to the PI.

4.15. In case the protocol is disapproved, investigators may appeal to the UPHS-IERB through the IERB Chair.

4.16. The conduct of approved research protocols is subject to monitoring by the UPHS-IERB.

4.17. Monitoring is done through various activities initiated by the UPHS-IERB that approved the implementation of the research protocol, in accordance with the UPHS-IERB SOP Chapter 3 such as:

- Continuing review, including review of progress report, or proposed amendments
- Site visit
- Review of reports on protocol non-compliance
- Review of completion/final report
- Review of request for early termination

- Review of adverse events, as applicable

4.18. Ethical clearance can be suspended or withdrawn from studies found to be non-compliant of in violation of UPHS-IERB terms of approval, upon determination of non-compliance or violation by the approving UPHS-IERB, based on SOP Chapter 3.7.

4.19. Clinical trials that have been approved must comply with SOPs on reporting adverse events set by the UPHS-IERB, which include reporting procedures on adverse events as defined in UPHS-IERB SOP 3.4.

UNDERGRADUATE STUDENT GUIDELINES

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

4.21. All undergraduate students research must be conducted under the supervision of a faculty member of the UPHS.

4.22. 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 comprise the security, safety, and well-being of students shall not be allowed.

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

4.24. Review of undergraduate student research shall be undertaken by the College where the student is enrolled, but must undergo UPHS-IERB review.

4.25. Undergraduate student research can be discontinued at any time by the faculty adviser or the UPHS-IERB if deemed harmful to the study participants.

5. REVIEW AND INDEMNIFICATION FEE

5.1. The IERB charges Fifty Thousand pesos (**Php 50,000 NET of TAX**) IERB Application and Initial Review Fee for all Sponsored Researches and Clinical

Trials regardless of the design of the study. Check payable to University of Perpetual Help Rizal Inc. (Note: Application and Review fee payment should be given on the same day the study protocol is submitted otherwise the protocol will not be reviewed).

Non-UPHS Researches

1. For pharmaceutical -sponsored clinical researches
- Initial or Application Review Fee Php 50,000.00 plus incidentals*
- Continuing Review Fee Php 20,000.00

2. For Students' researches:
- Initial or Application Review Fee Php 15,000.00 plus incidentals*
- Continuing Review Fee Php 5,000.00 plus incidentals*

* Incidentals include expenses incurred during site visits.

5.2. Other Expenses needed after the final IERB Protocol approval;

- Ten percent (10%) of the total budget of the study computed based on a minimum of five (5) patients or **Php 100,000.00** whichever is higher, as Institutional Fee, check payable to University of Perpetual Help Rizal Inc. This must be paid prior to the conduction of the research in the **institution (For UPHS Institutional Research Works- Hospitals and Universities and for non- UPHS Students' Researches or Investigators' initiated researches, pls. refer to Corporate VP's Memo regarding guidelines on the charging of fees for UPHS-IERB ethical review of research protocols).**
- A monthly rental fee of **Php 7,000.00** for the clinical trial room per study subject to yearly increase of 5% as stated in the Memorandum of Agreement between Institution and Sponsor.
- There will be a yearly **Continuing IERB Review Fee of Php 20,000.00** for every renewal of IERB Protocol approval until study termination or end of study. Check payable to University of Perpetual Help Rizal Inc.
- **Protocol Amendment Fee of Php 10,000.00**. Check payable to University of Perpetual Help Rizal Inc.
- **Clinical Trial Agreement Amendment Fee of Php 15,000.00**. Check payable to University of Perpetual Help Rizal Inc.

- **Memorandum of Agreement (MOA)** signing Fee minimum of **Php 50,00.00** maximum of **Php 100,000.00** for non- institutional clinical trial depending on the design of the study.
- Expedited or Additional Meeting, the IERB charges Twenty-Five Thousand pesos (**Php 25,000 NET of TAX**) IERB Application and Initial Review Fee for all Sponsored Researches and Clinical Trials regardless of the design of the study. Check payable to University of Perpetual Help Rizal Inc. (Note: Application and Review fee payment should be given on the same day the study protocol is submitted otherwise the protocol will not be reviewed).

REMINDERS:

1. All communication with the IERB will be done in writing.
2. Protocols (with corresponding payment) for IERB review must be submitted by the investigator **on or before the 5th day each month** so that they may be calendared for review on the next regular monthly IERB meeting. This will allow adequate time for dissemination and review of the materials otherwise these protocols will be included in the next scheduled regular meeting.
3. The IERB will require the submission of Ten (10) copies each (or the equivalent of the number of current regular committee members) of a research proposal.
4. No study/clinical trial should begin without IERB approval (examples: patient/volunteer recruitment and enrollment)
5. No protocol changes or deviations without IERB approval can be done except in conditions like immediate hazards
6. Prompt reports for adverse drug reactions (ADR) that are serious and life-threatening or unexpected ADR's, new developments that may affect subject's safety, should be reported by the investigator to the IERB office through the chairperson.
7. Principal Investigators, Sub-Investigators and Clinical Study Coordinators must be trained in GCP Guidelines.

For inquiries regarding the protocol review, you may call or email at:

BIENVENIDO JOSE V. TIANCO, MD
Chairman
University of Perpetual Help System- Institutional Ethics Review Board

or for other Administrative concerns:

ADRIEN R. QUIDLAT, MD
Executive Medical Director
University of Perpetual Help DALTA Medical Center

Thru:
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