INTRODUCTION

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04	Oct. 17, 2017	Addition of Definition in the glossary of words accrued and accrual exclusion.

0.1 Introduction

Since its inception, research has been a key ingredient in Peregrine Eye and Laser Institute's (PELI) aspirations to provide excellent, modern, evidence-based quality care to its patients. Only through responsive ethical researches can up-to-date interventions and better patient options become readily available to improve health outcomes. Without the benefit of researches, Filipino patients would suffer the indignity of having to settle for prehistoric modes of treatment and stagnant choices. This is one of the prime motivations in the establishment of the PELI Institutional Review Board in CY 2012. The IRB has provided ethical guidance and patient safeguards in the pursuit of responsive clinical researches that benefit not only PELI patients but all Filipinos nationwide. It is also pioneering in that it is one of a few institutional review boards outside the confines of a hospital setting. PELI researches have contributed positively to the entry of innovative solutions in the country as well as improved patient outcomes for many Filipinos.

With the growing complexities of numerous diseases, the evolution of basic sciences in the understanding of these disorders, and the endless possibilities of interactions between and among disease entities, the approach of PELI must equally evolve to be more holistic in order to serve the needs of its patients fully. It must also be facilitative in assessing innovative new medicines, medical supplies, and therapeutic interventions. These consequently place a burden on the institution to do more researches to remain true to its goal for its patients.

The value of being patient centric is at the heart of PELI. All researches should be designed to improve the quality of lives of patients, so too should these researches assure the safety and welfare of research participants, especially those trying out innovative treatment options. Patient rights must be continuously upheld in line with local and international ethical and regulatory standards.

In this regard, the IRB must also be responsive and must evolve to safeguard the interests of patients and research participants, among others. It should remain independent, well represented, and compliant with existing non-discriminatory public policies and regulatory standards. To this end, the IRB shall be improved and developed to be able to continuously achieve its duty to facilitate innovative researches without compromising ethics, patient safety, welfare and rights.

0.2 Vision and Mission of the Institution

0.2.1 Vision:

To be Asia-Pacific's preferred eye care center by providing exceptional patient care & experience.

0.2.2 Mission:

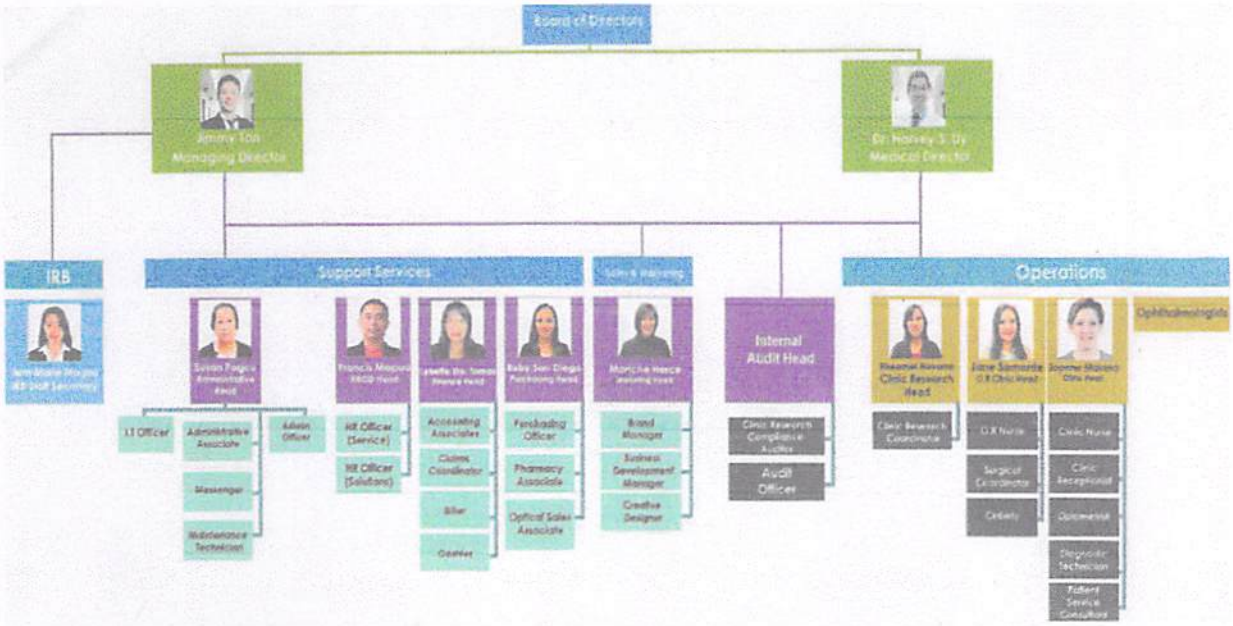
To our patients, we commit to improve quality of loge by providing exceptional eye care, through innovative technology within a safe environment, exceeding patient's expectations and ensuring delightful patient experience.

To our employees, whom we provide a safe, professional and harmonious working environment, fair compensation, opportunities for our continuous personal and professional growth, through exposure, research, training and educational programs.

To our stakeholders, by committing to deliver a sound return on their investment, in turn, profits will be invested towards expansion research, training and innovative equipment and infrastructure.

To our community, we pledge to support the surrounding community by participating Corporate Social Responsibility (CSR) efforts that are related to research and other initiatives that will help improve and prevent vision impairment within our country and other countries surrounding the region.

0.3 Structure and Mandate



The PELI-IRB is an independent body established by the Peregrine Eye and Laser Institute under the Managing Director, to safeguard the dignity, rights, safety, and well-being of human subjects involved in health-related research and to provide public assurance of that protection. In accordance with applicable national/international regulations, the PELI-IRB has the authority to approve, require modifications to, or disapprove research protocols and related documents as well as ensure compliance with its relevant procedures after approval.

The structure and composition of PELI-IRB shall be in accordance with **Chapter 1 of PELI-IRB SOP**

Functions:

1. To ensure protection on the dignity, rights, safety and well-being of all actual or potential human subjects involved in research
2. To contribute in the development of the harmonization process of ethics review based on the national and international ethical guidelines.
3. To ensure competency and timely review of submitted protocols by following the Standard Operating Procedure
4. To ensure that researches are conducted according to Good Clinical Practice
5. To address and act on concerns of research participants and other stakeholders

0.4 Abbreviation Index

AE- Adverse Event
CFR- Code of Federal Regulations
CIOMS- Council for International Organizations of Medical Services
CTA- Clinical Trial Agreement
DOH- Department of Health
ERC- Ethics Review Committee
FDA- Food and Drug Administration
FERCAP- Forum for Ethical Review Committees in Asia and Western Pacific
GCP- Good Clinical Practice
ICH- GCP- International Conference on Harmonisation- Good Clinical Practice
ICF- Informed Consent Form
IND- Investigational New Drug
LAR- Legally Authorized Representative
NSR- Non-Significant Risk
PELI- IRB- Peregrine Eye and Laser Institute-Institutional Review Board
PHREB- Philippine Health Research Ethics Board
PI- Principal Investigator
PNHRS- Philippine National Health Research System
SAE- Serious Adverse Event
SOP- Standard Operating Procedure
SUSAR- Suspected Unexpected Serious Adverse Reaction
SR- Significant Risk
TOR- Terms of Reference

0.5 Glossary

ACCRUED - Successfully signed-up patients that meets all eligibility criteria for the study; screen failed patients are excluded or not counted.

ACCRUAL EXCLUSION – All patients excluded in the study; screen failed and withdrawal are included.

AFFILIATED MEMBER - A member of the board currently under direct employment by the institution where IRB is established.

ADVERSE EVENT - Any untoward or undesirable medical occurrence in a patient or participant in clinical investigation after use or administration of an investigational product. This is not necessarily caused by the treatment.

ASSENT- Authorization for one's own participation in research given by a minor or another participant who lacks the capability to give informed consent. The assent is requirement for research, in addition to consent, given by a parent or legal guardian. It is an agreement by an individual not competent to give legally valid informed consent like a child or cognitively impaired person to participate in research *(PNEGHR)*

BENEFITS-Any direct or indirect good effect or something of positive value to health or welfare from the research study to the participants; something that promotes or enhances well-being *(PNEGHR)*

CASE REPORT FORM- A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject *(ICH-GCP)*

CLINICAL TRIAL/ STUDY- Any investigation in human subjects intended to discover or verify the clinical, pharmacological and or other pharmacodynamics effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy *(ICH-GCP)*

CONFIDENTIALITY- Prevention of disclosure, to other than authorized individuals of, a sponsor's proprietary information or of a subject's identity

CONFLICT OF INTEREST- involves any situation a member of an ethics committee has any significant personal or financial interest in the research proposal.

INDEPENDENT CONSULTANTS- are individuals with expertise in special areas to assist in the review of protocols that require such expertise in addition to those available within the IRB

INFORMED CONSENT- A process by which a subject voluntarily confirms his/her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

INVESTIGATOR - a person responsible for the conduct of the clinical trial at a trial site.
If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. *ICH-GCP E6 (R1)*

INSTITUTIONAL REVIEW BOARD - An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects. *ICH-GCP E6 (R1)*

MEMBER SECRETARY - a scientific member of the board that has secretarial roles, one of which is to oversee the full-time staff secretariat

LEGALLY ACCEPTABLE REPRESENTATIVE- an individual or juridical or other body authorized under the applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial *ICH-GCP E6 (R1)*

MAJOR MODIFICATION – Changes that involve altering study design, decreasing or increasing no. of subjects, change in inclusion/exclusion, adding or changing investigational drug/device, adding serious privacy risks and many others. (http://cphs.berkeley.edu/amendment.pdf)

MINIMAL OR NONSIGNIFICANT RISK- The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

MINOR MODIFICATION - Include personnel changes; minor procedural changes; changes that reduce risks; changes that add minor risks (e.g., risks of small blood draws); changes to wording in the application, consent form, or

other documents; modifications to questionnaires/surveys that don't increase risk, etc. (http://cphs.berkeley.edu/amendment.pdf)

NON-AFFILIATED MEMBER - A member of the board not under direct employment by the institution where IRB is established.

NON-MEDICAL OR NON-SCIENTIFIC OR LAY MEMBER - A member who represents the interest and concerns of the community

PROTOCOL -a document that describes the objective(s), design, methodology, statistical consideration, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents *ICH-GCP E6 (R1)*

PROTOCOL AMENDMENT-A written description of a change(s) to, or formal clarification of a protocol and changes on any other supporting documentation made from the originally approved protocol by the research ethics review body after the study has begun. *PNEGHR*

SAE REVIEWER – is a scientific reviewer that assess serious adverse event reports

SCIENTIFIC MEMBER – are technically qualified experts in their field, such as clinical medicine, engineering, biological sciences, physical sciences, biostatistics and many others. (US-FDA)

SERIOUS ADVERSE EVENT (SAE) - any untoward medical occurrence that at any dose:

- Results in death,
- is life threatening,
- requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/ incapacity, or
- congenital anomaly/birth defect *ICH-GCP E6 (R1)*

SIGNIFICANT RISK - involves conditions where the risk of harm is greater, or is potentially greater, than that encountered in everyday life. (http://youthscience.ca/policy/participation-humans-research-significant-risk)

STAFF SECRETARIAT – a full-time staff employed by the institution responsible for administrative groundwork support under the supervision of the board.

SUSPECTED UNEXPECTED SERIOUS ADVERSE REACTION (SUSAR) - is a serious event the nature and severity of which is not consistent with the applicable product information.

TECHNICAL REVIEWER COMMITTEE – is a committee independent of the IRB that is composed of technical reviewers with clearly defined expertise in research methodology responsible in reviewing the technicalities of protocol study design

VULNERABLE SUBJECTS- individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in the case of refusal to retaliate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent

References

- Declaration of Helsinki (2008 and subsequent revisions)
- CIOMS 2002 and 2009
- Operational Guidelines for Ethics Committees That Review Biomedical Research (2000) by the World Health Organization
- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011) by the World Health Organization
- International Conference on the Harmonization of Good Clinical Practice (ICH-GCP)
- National Ethical Guidelines for Health Research (2012) by the Philippine Health Research Ethics Board (PHREB)
- Philippine Food and Drug Authority regulations and other relevant laws and regulations
- `http://cphs.berkeley.edu/amendment.pdf`
- http://youthscience.ca/policy/participation-humans-research-significant-risk