**Letter of Undertaking**

I, <NAME OF PRINCIPAL INVESTIGATOR>, principal investigator of the study entitled <TITLE OF PROTOCOL> with site at <CLINIC/HOSPITAL>, request the review of Peregrine Eye and Laser Institute – Institutional Review Board (PELI-IRB) and agree to abide by the rules and regulations that the PELI-IRB follows as stated in the excerpt of Chapter 1 – 1.1.5 below:

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| * + 1. Ethical basis
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| * **The PELI-IRB is guided in its reflection, advice, and decision by the ethical principles and procedures expressed in the following international policies, guidelines and documents:**
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| * Declaration of Helsinki (2008 and subsequent revisions)
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| * CIOMS 2002 and 2009
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| * The IRB will function in accordance with PHREB’s Policy for Specialty Clinics and other national laws, regulations, and guidelines.
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| * + Memorandum of Agreement with Makati Medical Center was made last 15 Jan 2015 to able to ensure accessibility of a health facility that offers general medical services to research participants, if needed.
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| * The IRB provides its own standard operating procedures based on:
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| * PHREB Policies and Requirements for Accreditation of Research Ethics Committees
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| * Operational Guidelines for Ethics Committees That Review Biomedical Research (2000) by the World Health Organization
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| * Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011) by the World Health Organization
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| * International Conference on the Harmonization of Good Clinical Practice (ICH-GCP)
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| * National Ethical Guidelines for Health Research (2012) by the Philippine Health Research Ethics Board (PHREB)
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| * Philippine Food and Drug Authority regulations and other relevant laws and regulations
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| * The IRB adheres to national and international ethical standards and recognizes that the protocols it approves may also be approved by national and/or local ethics committees prior to their implementation in specific localities.
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| * In evaluating protocols and ethical issues, the IRB is cognizant of the diversity of laws, cultures, and practices governing health research in various countries around the world.
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| * In attempts to inform itself, whenever possible, of the regulations and requirements of sponsor countries conducting global protocols in the Philippines; and of the requirements and conditions of various localities where a proposed PELI research is being considered.
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| * The IRB will take the initiative to be informed, as appropriate, by national/local ethics committees and researches of the impact of the research that it approved.
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I also agree to provide the necessary environment to ensure safe and ethical conduct of the research, including oversight and stewardship functions and to have the PELI-IRB monitor the conduct of study, once approved, as they deem necessary.

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Signature over Printed Name Date