The Physiology of the Ethics Review Board

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As health professionals, we are bound by a set of ethical rules that we swore to follow. The Practice of Nursing is governed by a declaration of Gretter in 1935 known as the Nightingale Pledge – *I will abstain from whatever is deleterious and mischievous and will not take or administer any harmful drug*. Physicians are likewise bound by the Oath of Hippocrates – *I will prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone.* Both declarations point to firstly, Beneficence[1] ("ensure the benefits, safety and welfare promotion of patients") and secondly, Non-maleficence[1] ("reduction of risk for patients and provide necessary services for such risks"). This obviously applies to the conduct of any research study and must be reminded often to health research investigators. Patients come in for consultation and admissions to be treated of their ailments. Hospital consent forms for consultations and admissions are used for the purpose of medical treatment and should not take the place of a research protocol's informed consent. If this happens, the patient unknowingly enrolls himself into such a study thus it can be a ground for deception and maleficence on the part of the principal investigator.

Any study with clinical trials, devices, interventions and diagnostics and involving human participants is particularly subject to the appraisal of an Ethics Review Board. Also known as Institutional Review Board (IRB) or Institutional Ethics Committee (IEC) the purpose of an ERB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in a research study. ERBs attempt to ensure protection of subjects by reviewing research protocols and related materials. ERB protocol review assesses the ethics of the research and its methods, promotes fully informed and voluntary participation by prospective subjects capable of making such choices and if such is not possible, a written informed permission given by a suitable proxy via dissent and/or proxy consent is legally requested for, and seeks to maximize the safety of subjects.

Special attention should be paid to trials and/or interventions that may include vulnerable subjects, such as pregnant women (patients of the obstetrics and gynecology department),children (pediatric patients and adolescents), the elderly, or persons with diminished comprehension. The primary ethical principles in human subjects review are outlined in the Belmont Report and include "respect for persons," "beneficence," and "justice." The ERB may only approve such research for which there is a

bonafide “Informed Consent Process” for participants, for which the selection of subjects presents a fair or just distribution of risks and benefits to eligible participants. Both the informed consents and study results are legal obligations of the principal investigator which must be periodically submitted at least four times – before the conduct of the research study commences, during the research process for any amendments and modifications by the ERB, before finalization of the research document and before inclusion into a publication. Any adverse event that may occur during the entire process must be reported in writing and submitted to the ERB at the soonest possible time. Because of the idiosyncrasies of different clinical research topics, informed consent should be tailored made for each individual research study and should be translated to the vernacular for the research participant’s understanding of the contents of the informed consent form.

The following list will serve as an informed consent guide for principal investigators (1) a statement that the study involves research, (2) statement that the study is being undertaken by a principal investigator (full name) under the supervision of a co-author (full name), including the department, (3) an explanation of the purpose of the research[2], (4) duration of the research’s subject participation, (5) the number of research participants involved in the study[2] ,(6) the step by step description of the drug administration or procedures to be used, (7) a description of expected or foreseeable risks to the risk subjects, (8) a description of benefits to the subject or to others which may be reasonably expected from the research, and any compensation for the research participant’s family or relative in case of disability or loss of life related to the research study, (9) a disclosure of alternative procedures or courses of treatment, if any, that may be advantageous to the subject, (10) a description of the measures that the investigator will follow to ensure the confidentiality of records that may identify each subject by name and or identification number[2] , an explanation how to contact the principal investigator and co-author for any questions about the research study[3], (12) an explanation of whom to contact regarding the research subject’s rights and research-related injury, (13) a statement that the participant’s involvement is voluntary, the participant may refuse to participate before the study begins, discontinue at any time, or skip any questions that may make him/her feel uncomfortable, with no penalty to him/her, and no effects on the compensation earned before withdrawing, (14) a description of whom to go to, be it the principal investigator or hospital for any research related risk or injury, (15) a statement indicating that the research participant will be given copy of the dated informed consent[3], a description of what will be done with the data once the research study is finished, (17) a line for the printed name and signature of the principal investigator followed by the date of signing.

The ERB should be furnished with trial protocols/amendments, written informed consent forms and consent form updates the investigator proposes for use in the trial, subject recruitment procedures, written information to be provided the subjects, investigator's brochures, available safety information, service or current treatment available for the study participant, hospital's financial role and compensation for any adverse event or risk that may occur during the conduct of the research, information about payments and compensation available to subjects, the investigator's current curriculum vitae and/or other documentation evidencing qualifications, and any other documents the ERB may need to fulfill its responsibilities. Thus, it is at the level of the principal investigator and the clinical departments to submit to the hospital's ERB such documents for the latest modifications and amendments to such protocols. Our hospital's research manual contains provisions and *aide memoire* cues for the ethical review of research papers. Research is always and will always be a path towards achieving standards of treatment, putting in consideration the four guiding principles of ethics – autonomy, beneficence, non-maleficence, and justice.

1. National Ethical Guidelines for Health research, Philippine Health Research Ethics Board. Philipine National Health Research Systems, 2011.
1. Education and Research, Elements of the Informed Consent. American Academy of Otolaryngology
2. Additional elements of the informed consent. Research Administration Office, University of California, Irvine.

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