GLOSSARY

1	**Adverse Drug Reaction (ADR)**	All noxious or unintended responses to a new medicinal product or an already marketed product which shows that there is a causal relationship between the product and the adverse event
2	**Adverse event (AE)**	Any unintended unfavorable sign or experience associated with the use of the investigational product, whether or not related to the product
3	**Affiliated member**	Member who have official appointment with UP Manila.
4	**Amendments**	Change/changes from a previously approved study protocol requested by the Principal Investigator
5	**Approved Protocols**	Protocols that have been reviewed by the UPMREB and approved without conditions or approved after recommendations have been fulfilled
6	**Archives**	A storage for completed, inactive, or terminated protocol files documents
7	**Assent forms**	Forms asked of minor-aged children who are participants of a research or trial, aside from parents' or legal guardian's consent. The objectives of the study and procedures are explained to the child participants in a language understandable to them. See SOP II -4.1 and UPMREB FORM 2(D)2012 Informed Consent Assessment Form for additional information re "Assent".
8	**Collaborative studies**	Studies that are carried out by the UPM or UPM researchers in collaboration with other universities or institutions, in the Philippines or in other countries, which are not necessarily the sponsor of the study
9	**Completed study**	A study that was accomplished according to the study protocol and where a final report of the study had been submitted and approved
10	**Confidentiality**	Obligation not to disclose UPMREB information and documents to other than authorized individuals
11	**Confidentiality**	An agreement between the UPMREB and an individual who has been

	Agreement / Secrecy or Nondisclosure Agreement	invited to be a member of the UPMREB, or someone invited to attend a UPMREB meeting, in order to maintain confidentiality and protect trade secrets, UPMREB protected information, and other UPM-REB proceedings and files and documents. The type of information that can be included under the umbrella of confidential information is virtually unlimited. But certain types of information can be excluded from the confidentiality agreement and a disclosure time period can be included in the agreement.
12	**Conflict of interest** (COI)	Conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain). (*Thomson D. Understanding financial conflicts of Interest. NEJM [serial on the Internet]. 1993 August 19; [cited 2009 June 23]; 329:573-576. Available from http://content.nejm.org/cgi/content/full/329/8/573)*
13	**Deviation/ violation**	Occurs whenever approved protocol is not complied with as approved. ▪ **Minor or administrative deviations** do not affect the scientific soundness of the study protocol or compromise the rights, safety, or welfare of human participants in the study are classified under expedited review. ▪ **Major deviations or protocol violations** that consist of persistent protocol non-compliance with potentially serious consequences that could critically affect data analysis or put patients' safety at risk are classified under full board review.
14	**Document**	Record of studies, proceedings, communications, that include the following: ▪ Study Protocols and related documents (such as case report forms, informed consent, diary forms, scientific documents, reports, records, expert opinions or reviews); ▪ UPMREB documents (SOPs, meeting minutes, notifications, and decisions); ▪ Correspondences; or ▪ Any other forms of communications such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc.
15	**Epidemiological**	Population-based investigations that lead to improved understanding

GLOSSARY

	research	of risk factors for disease or for progression of diseases
16	**Ethics Review Board (ERB) or Ethics Review Committee (ERC)**	An independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human participants (subjects) involved in a trial/research and to provide information of that protection to any relevant body requiring it. These committees are constituted in accordance with the requirements set forth by the Philippine Health Research Ethics Board and other relevant bodies.
17	**UPMREB members**	Individuals serving as regular or alternate members in the review panels of the UPMREB
18	**Expedited review**	A review process by done by two or more designated UPMREB members for study protocols determined to be minimal risk and subsumed within the criteria set in section SOP II -4.2; results of such review are reported UPMREB panel meeting, but not necessarily discussed.
19	**Full board review**	Review and deliberation on a study protocols determined to be more than minimal risk, and discussed during a UPMREB panel meeting, thus subject to quorum requirements
20	**Informed consent document (ICD) or informed consent form (ICF)**	A written, signed, and dated form confirming a competent participant's willingness to voluntarily participate in a particular trial or research, after having been informed of all aspects that are relevant to the participant's decision to participate and given time to reflect on the decision.
21	**Initial review**	Review of a new protocol, submission to the UPMREB for the first time, for its scientific soundness and ethical considerations.
22	**Legally Authorized Representative**	An individual who can, in accordance with the law, provide consent on behalf of the research participant who is deemed incapable of giving or who has diminished capacity to give consent
23	**Medical member**	Member with education and training related to the degree of Doctor of Medicine (e.g. physician, dentist).
24	**Minimal risk**	The probability and magnitude of harm or discomfort anticipated in the research which are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (*http://bioethics.georgetown.edu/nbac/capacity/Assessment.htm#Para5, accessed 30 June 2009*)
25	**More than minimal risk**	Occurs when the participants in the course of the research would be exposed to more than a remote possibility of a "substantial or

		prolonged pain, discomfort, distress" or "clinically significant deterioration of a medical condition" (*http://bioethics.georgetown.edu/nbac/capacity/Assessment.htm#Para5, accessed 30 June 2009)*
26	**Non-affiliated member**	A panel member who is independent of the institution (UP Manila).
27	**Non-medical member**	Non-medical members refer to members who are not medical doctors.
28	**Non-scientific member**	A member whose primary area of interest is outside of any biomedical or behavioral/social scientific discipline. This includes members who may have past scientific training but has not been exercising the training or has worked in areas that does not exercise the scientific experience previously gained (e.g. retired).
29	**Protocol Package**	Study protocol plus accompanying communications, registration forms, and other documents relevant to the protocol
30	**Quorum**	Set requirements to declare a UPMREB panel meeting as official and all action emanating there from as valid
31	**Reportable Negative Events**	Experiences of researchers that involve personal safety issues (related to both research and research participant) in the conduct of research, such as sexual harassment, physical threats, stalking, and other hostile reactions.
32	**Serious Adverse Event (SAE)**	The adverse event is SERIOUS and should be reported when the patient outcome is: *Death* – if the patient's death is suspected as being a direct outcome of the adverse event *Life-Threatening* – if the patient was at substantial risk of dying at the time of the adverse event or it is suspected that the use or continued use of the product would result in the patient's death Examples: Pacemaker failure; gastrointestinal hemorrhage; bone marrow suppression; infusion pump failure which permits uncontrolled free flow resulting in excessive drug dosing *Hospitalization (initial or prolonged)* – if admission to the hospital or prolongation of a hospital stay results because of the adverse event Examples: Anaphylaxis; pseudomembranous colitis; or bleeding causing or prolonging hospitalization

		Disability – if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life Examples: Cerebrovascular accident due to drug-induced hypercoagulability; toxicity; peripheral neuropathy *Congenital Anomaly* – if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome on the child Examples: Vaginal cancer in female offspring from diethylstilbestrol during pregnancy; malformation in the offspring caused by thalidomide Requires Intervention to prevent permanent impairment or damage – Report if you suspect that the use of a medical product may result in a condition which requires medical or surgical intervention to preclude permanent impairment or damage to a patient Examples: Acetaminophen overdose-induced hepatotoxicity requiring treatment with acetylcysteine to prevent permanent damage; burns from radiation equipment requiring drug therapy; breakage of a screw requiring replacement of hardware to prevent the malfunction of a fractured long bone
32	**Scientific member**	Member who has education, training, or extensive experience in the Biomedical or Behavioral/Social Sciences.
33	**Site visit**	An action taken by the UMPREB or its representatives which involves visiting a study site to assess how the principal investigators and the site implements the approved study protocol; however this is limited to an assessment of UPMREB documents only.
34	**Standard Operating Procedure (SOP)**	Detailed, written instructions, in a certain format, describing all activities and actions undertaken by an organization to achieve uniformity of the performance of a specific function
35	**Study protocol**	A document which states the background, rationale, and objectives of the trial (investigation, research, study) and describes its design, methodology, and organization including statistical considerations and the conditions under which it is to be performed and managed.
36	**Terminated**	A study approved by the UPMREB that is being recommended for

	Study	termination before its scheduled completion.
37	**Vulnerable subjects/ participants**	A research population determined to have a substantial incapacity to protect their own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group; includes the elderly, people receiving welfare benefits or social assistance, poor and unemployed people, patients in emergency rooms, ethnic and racial minority groups, homeless persons, refugees or displaced persons, prisoners, patients with incurable disease, and individuals who are politically powerless.
38	**Witness**	A person, who is independent of the study, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.