Human Subject Protection

Full heart to treat, the subjects can rest assured

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About Human trial

- Human trial is an important and obligatory step advancing from scientific research results to actual clinical applications. It is called "human trial" in the Medical Care Act, or "clinical trial" in Pharmaceutical Affairs Act.
- The levels of risk exposed to the subjects within the scope of human trial and human research may be categorized as follow:

Level	Research Scope	Risk Level
A	Human trials that require prior approval from the Department of Health	The risk level that the subject is exposed to is higher, thus it requires prior approval. The management is based on the Medical Care Act and the Pharmaceutical Affairs Act. In the event of any violation, it is punishable by fines in accordance with the provisions of the administrative sanctions.
B	Human trials that do not require prior approval from the Department of Health	The risk level that the subject is exposed to is lower, thus is monitored and controlled independently by the hospital. In order to ensure that hospitals have proper protection measures for the subject, the Department of Health has published "Guidelines for the Organization and Operation of Medical Institutional Review Board," and "Guidelines for Good Clinical Practice," which outline, in detail, the provisions governing the items to be implemented by hospitals when conducting clinical trials.
C	Non-invasive academic research with human as subjects, such as questionnaires, interviews, etc.	The risk level is mostly the impact on the psychological level, and issues regarding the violations of patient rights
D	Human related researches without direct contact with the subject, for example, researches on tissues already extracted from the body or analysis of medical history document.	There is only a question of potential violation of the subject's rights. Under certain circumstances, some research does not require an informed consent form. The Department of Health has published "Guidelines for Collection and Use of Human Specimens for Research," "Human Research Ethics Policy Guidelines," and "Policy Instructions on the Ethics of Human Embryo and Embryonic Stem Cell Research" to be used as reference for researchers.

- The "Helsinki Declaration" is an important source of reference for medical research ethics guidelines worldwide. Its content explains the responsibilities arising from human research should be held by qualified medical staff. Even if the consent has been obtained from the subject, the medical staff should still be held accountable for any medical injuries caused by the experimentation. Doctors should fully inform the patient about what medical care is related to the experimentation. A patient's refusal to participate the trial should not affect the doctor-patient relationship.

About the Ethic Review Committee

- The Committee to ensure whether or not the medical research is ethically acceptable is called Human subject committee. In Europe, it is referred to as the Ethics Committee (EC); in the US, it is called the "Institutional Review Board (IRB).
- According to article 78 of the Medical Care Act, the composition of the review personnel of the Ethic Review Committee should be accordance with the ratio of one single sex should be no less than one-third. Apart from the medical science and technology personnel, at least one-third of the personnel should be legal experts, social justice, civic social representatives, and other non-medical professionals. They appropriately report the opinion of general public and non-medical views. The Ethic Review Committees in Taiwan already have had a mature history and most have been acknowledged by international certification.
- The Ethic Review Committee's operation includes expedite review and general review. The purpose of the review is to ensure that the rights, safety, and wellbeing of the subject are protected, and in particular, to pay special attention to subjects who might be vulnerable to trials.

To ensure subject's rights

- According to the amended announcement of the section 2 of article 42 of the Pharmaceutical Affairs Act "Guidelines for Good Clinical Practice," the spirit is to confirm the credibility of clinical trial results, and to ensure subject's rights. The content describes, in detail, the responsibilities of medical institutions, investigator, Ethic Review Committee and trial sponsor in clinical trials.
- "Informed Consent Form" is the evidence that proves the doctor has fulfilled his obligation to inform, it is an important tool to ensure subject's rights, and also one of the important review items for the Ethic Review Committee. The Informed Consent Form must be compiled carefully and properly. Taking into consideration that the readers of the Informed Consent Form are patients or a legal representative, its content should adopted the narrative writing method, be friendly and in the colloquial language, avoid specialized terminology, and be based on a junior middle school grade 3 (basic obligatory education level) language level in principle.
- The subject consent not only agreed in writing, but also the consent of the subject, after understanding the purpose, objective, risk, and values of the trial, to agree and be willing to participate. Good interaction between the researcher and the subject is an important factor that influences the subject's signing of the consent form and the smooth operation of the clinical trial that follows.

Legal responsibility of human trial

- Article 79 of the Medical Care Acts requires that on the Informed Consent Form, it must state that when the damage occurs during the human trial, the subject will receive compensation or be covered by insurance. It cannot be denied that the subject participating in human trial has given a great contribution to medical progress, in spite that the indemnity, compensation and insurance is the last resort of the remedial measures. However, it is our common goal in developing Taiwanese human trial that we seek to reach a consensus on indemnity and compensation to the subject, between hospitals, doctors, human trial sponsor and the subject him/herself.