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Taiwan: Law on Research Using Human Subjects

(Jan. 23, 2012) On December 9, 2011, Taiwan's legislature adopted a new law on the use of human subjects in research projects. Previously, research involving humans was governed by the non-binding Ethical Guidelines for Human Research, formulated by the Department of Health in 2007. (*Taiwan Legislature Greenlights New Human Subject Research Law*, TAIWAN TODAY (Dec. 12, 2011).) One key feature of the new law is that it makes informed consent by aborigines a precondition for any research involving them and for release of the research results. (Shih Hsiu-chuan, *Legislature Passes Act on Using Human Subjects in Research*, TAIPEI TIMES (Dec. 10, 2011).)

The purpose of the Act on Human Research Subjects is to better protect the subjects' rights, because those rights "tend to be neglected and thus impinged upon, due to such factors as differential access to information and conflicts of interest between subjects and researchers." (*Id*.) The Act stipulates that research conducted on humans must respect the subjects' decision-making power, ensure a balance between risks and benefits, minimize infringements, and also attend to the fair assignment of the research burdens and the achievements alike, in order to safeguard the subjects' rights. (Jen-t'i yen-chiu fa [Act on Research Involving Human Subjects] (Dec. 9, 2011) arts. 1 & 2, Parliamentary Library Legislative Yuan website.)

Definitions

The Act defines research on human subjects as engaging in research on behavioral ecology, physiology, psychology, genetics, medicine, and the like by obtaining, investigating, analyzing, and applying data related to human specimens or individuals.

"Human specimens" refers to human organs (including those from fetuses and corpses), tissue, cells, body fluids, or materials derived from test results. (*Id*. art. 4, items 1 & 2).) The Act also contains a definition for delinking, whereby once the research material or data has been coded or handled by other means, it will become impossible to link or compare it with any identifiable human research subjects. (*Id*. item 3.)

Ethics Review

The Act prescribes that a research plan must be approved by an ethics review committee before a research project that involves human subjects can proceed. The committee, to be set up by the research institute concerned, is to comprise a minimum of five disinterested persons of whom at least two-fifths are from outside the institution; neither gender, moreover, may exceed two-thirds of the membership. The Act requires that approved research projects undergo annual reviews. Should irregularities be discovered that affect the rights or safety of the participants, the ethics review committee may suspend the given project until the situation is corrected or cancel it. Any committee member who violates legal procedures during a review or who is found to be involved in the research project will be subject to a fine of from NT$60,000 (about US$1,982) to NT$600,000. (*Taiwan Legislature Greenlights New Human Subject Research Law*, *supra*; Act, Ch. 2, Review of Research Plan, arts. 5-11.)

Consent

Generally speaking, research subjects are to be limited to adults with the capacity of intent. This restriction will not apply, however, in cases where the research is "clearly beneficial" to a specific population or when "it is not possible to find another research subject as a replacement" for such persons (art. 12, ¶ 1). The Act requires that the informed consent of the adult subjects targeted for research be obtained (art. 12, ¶ 2). For participants who are minors, parental consent is necessary; in the case of research involving corpses, the person's pre-death permission or their relatives' consent is required; where fetuses are used, the mothers' consent must be obtained (arts. 12, 13). A research organization that fails to obtain informed consent or that obtains data through force or inducement will be subject to a fine of from NT$50,000 (about US$1,679) to NT$500,000 (art. 24). (*Taiwan Legislature Greenlights New Human Subject Research Law*, *supra*.)

Before obtaining the consent of participants, those in charge of research projects must clearly inform them of such matters as the project's purpose, research methods, mechanisms for protection of the subjects' rights, measures of remedy against possible risks,

and potential revenue from the research and methods for its allocation (art. 14, ¶ 1). (Shih Hsiu-chuan, *Draft on Human Research Approved*, TAIPEI TIMES (June 4, 2010).)

Aborigines

The Act prescribes that before aborigines may be used as research subjects, they must be consulted and their individual consent obtained (with certain exceptions, where the other articles on the protection of research subjects' rights apply); these conditions also apply to the release of the research results. Such matters as the arrangements for consultation and consent and for the commercial benefits resulting from the research and their use are to be handled by the central Council of Indigenous Peoples, along with the competent authorities. (*Legislature Passes Act on Using Human Subjects in Research*, *supra*; Act, art. 15.) The relevant article in the Act was not in the draft legislation submitted to the legislature by the Executive Yuan (Cabinet); the two legislators who sponsored its introduction deemed it necessary after several cases came to light involving the misuse of genetic material. For example, aborigines' blood samples collected for health research were subsequently used for genetic studies or sold to an overseas genetic database. (*Legislature Passes Act on Using Human Subjects in Research*, *supra*.)

Some Related Legislation

A number of provisions in the Act on Research Involving Human Subjects are mirrored in the Human Biobank Management Act of 2010. (Human Biobank Management Act [in English & toggle Chinese] (Feb. 3, 2010), Laws & Regulations Database of the Republic of China; Wendy Zeldin, *Taiwan: Human Biological Database Management Statute Enacted*, GLOBAL LEGAL MONITOR (Mar. 2, 2010).)

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