

## Taiwan Announced the Biobanks Regulations and Management Practices

### Taiwan Has Passed “Statute of Human Biobank Management” to Maintain Privacy and Improve Medicine Industries

Due to lack of regulations, divergent opinions abounded about the establishment of Biobanks and collection of human biological specimen. For example, a researcher in an academic research organization and a hospital-based physician collected biospecimens from native Taiwanese. Although they insisted that the collections were for research only, human rights groups, ethics researchers, and groups for natives’ benefits condemned the collections as an invasion of human rights. Consequently, the Taiwanese government recognized the need for Biobanks regulation.

To investigate the relationship between disease and multiple factors and to proceed with possible prevention, The Legislative Yuan Social Welfare and Healthy Environment Committee has passed "the draft statute of human biobank management" through primary reviewing process on December 30, 2009 and subsequently passed through entire three-reading procedure on January 7, 2010. Therefore, the medical and research institute not only can set up optimal gene database for particular disease curing, but also can collect blood sample for database establishment, legally. However, the use of sample collections will be excluded from the use of judiciary purpose.

In the light of to establish large scale biobank is going to face the fundamental human right issue, from the viewpoint of biobank management, it is essential not only to set up the strict ethics regulation for operational standard, but also to make the legal environment more complete. For instance, the Department of Health, Executive Yuan had committed the earlier planning of Taiwan biobank establishment to the Academic Sinica in 2006, and planned to collect bio-specimen by recruiting volunteers. However, it has been criticized by all circles that it might be considered violating the Constitution article 8 provision 1 front paragraph, and article 22 rules; moreover, it might also infringe the personal liberty or body information privacy. Therefore, the Executive Yuan has passed the draft statute of human biobank management which was drafted and reviewed by Department of Health during the 3152nd meeting, on July 16, 2009, to achieve the goal of protecting our nation’s privacy and promoting the development of medical science by management biomedical research affairs in more effective ways. Currently, the draft statute has been passed through the primary review procedure by the Legislative Yuan.

About the draft statute, there are several important points as following: (1) Sample Definition: Types of collected sample include human somatic cell, tissues, body fluids, or other derivatives; (2) Biobank Establishment: It requires not only to be qualified and permitted, but also to set up the ethical reviewing mechanism to strengthen its management and application; (3) Sample Collection and Participant Protection: In accordance with the draft statute, bio-specimen collecting should respect the living ethics during the time and refer to the "Medical Law" article 64 provision 1; before sample collection, all related points of attention should be kept in written form, the participant should be notified accordingly, and samples can only be collected with the participant’s consent. Furthermore, regarding the restrained read right and setting up participants’ sample process way if there were death or lost of their capacity; (4) Biobank Management: The safety regulation, obligation of active notification, free to retreat, data destruction, confidentiality and obligation, and termination of operation handling are stipulated; and (5) Biobank Application: According to the new draft statute, that the biological data can’t be used for other purposes, for example, the use of inquisition result for the "Civil law", article 1063, provision 2, prosecution for denying the parent-child relationship law suit", or according to the "Criminal law", article 213, provision 6. This rule not only protects the participants’ body information and their privacy right, but also clearly defines application limits, as well as to set up the mechanism for inner control and avoid conflict of interests to prevent unnecessary disputes.

Finally, the Department of Health noted that, as many medical researches has shown that the occurrence of diseases are mostly co-effected by various factors such as multiple genes and their living environment, rather than one single gene, developed countries have actively devoted to human biological sample collection for their national biobank establishment. The construction and usage of a large-scale human bank may bring up the critical issue such as privacy protection and ethical problems; however, to meet the equilibrium biomedical research promotion and citizen privacy issue will highly depend on the cooperation and trust between the public and private sectors.

### Taiwan Department of Health Announced the Human Biobanks Information Security Regulation

The field of human biobanks will be governed by the Act of Human Biobanks (“Biobanks Act”) after its promulgation on February 3, 2010 in Taiwan. According to Article 13 of the Biobanks Act, a biobank owner should establish its directive rules based on the regulation of information security of biobanks announced by the competent authority. Thus the Department of Health announced the draft of the Human Biobanks Information Security Regulation (“Regulation”) for the due process requirement.

According to the Biobanks Act, only the government institutes, medical institutes, academic institutes, and research institutes are competent to establish biobanks (Article 4). In terms of the collecting of organisms, the participants should be informed of the relevant matters by reasonable patterns, and the collecting of organisms may be conducted after obtaining the written consent of the participants (Article 6). The relative information including the organisms and its derivatives are not allowed to be used except for biological and medical research. After all the protection of biobanks relative information above, the most important thing is the safety regulations and directive rules of the database administration lest all the restrictions of biobanks owners and the use be in vain.

The draft Regulation aims to strengthen the safety of biobanks database and assure the data, the systems, the equipments, and the web circumstances are safe for the sake of the participants' rights. The significant aspects of the draft are described as below. At first, the regulation should refer to the ISO27001, ISO27002 and other official rules. Concerning the personnel management, the security assessment is required and the database management personnel and researchers may not serve concurrently. In case some tasks are outsourced, the contractor should be responsible for the information security; the nondisclosure agreement and auditing mechanism are required. The application system should update periodically including the anti-virus and firewall programs. The biobanks database should be separated physically from internet connection, including the prohibition of information transforming by email or any other patterns through internet. The authorizing protocol of access to the biobanks should be established and all log files should be preserved in a period. The system establishment and maintenance should avoid remote control. In case the database system is physically out of the owner's control, the authorization of the officer in charge is required. If an information security accident occurred, the biobanks owner should contact the competent authority immediately and inform the participants by adequate tunnel. The biobanks owner should establish annual security auditing program and the project auditing will be conducted subject to the necessity. To sum up, while the biobanks database security regulation is fully established, the biobanks owners will have the sufficient guidance in connection with the biobank information security to comply with in the future.

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