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[Sci-tech Ethics] Taiwan Academic Chief Urges for Bill on Research Involving Human Subjects [Sci-tech Ethics] Taiwan Academic Chief Urges for Bill on Research Involving Human Subjects (Chinese Version)

China Times E-paper (2011/10/26) A biobank collecting more than one million local human biological samples is going to be destroyed in February, 2012. Academia Sinica President Chi-huey WONG said, the bill on research involving human subjects should be hastened. The controversy in Article 29 could be bypassed as long as its application to clinical experiments is prohibited.

The so-called biggest catastrophe in Taiwan biotech industries Taiwan Biobank, a biological database collecting more than one million local human biological samples will be destroyed according to the present law by February 5, 2012. Owing to the efforts by the biomedical industries, a gathering for the industries to directly negotiate with the Executive Yuan, Department of Health and lawmakers will take place next week, and the valuable assets of the biomedical industries gains a slim chance of survival.

The just-appointed Vise-President of Academia Sinica, noted Taiwan epidemiologist Chien-Jen CHEN pointed out, the biobank has great influence on the nationals' health and the development of the nation's biomedical industries. With the genetic database, we can study the long-term development of the local genetic diseases, and, based upon the studies, treatments and new drugs as well as measures of prevention could be developed. Hence, he said, we should protect and maintain the biobank.

However, according to the definition in the bill, any use of the collected biological materials, including biological samples of human cells, tissues, organs, body fluids and other recognizable derived substances via experiments that could represent the involved individuals, require the informed consent from the involved individuals. But the restriction creates a big difficulty for the clinical experiments. According to the present legal demand, all the biological samples require the involved person's consent, and the samples cannot be exported unless their genetic analyses are infeasible in Taiwan or under certain special circumstances. There is a drop between the demand and the present international practice.

Chien-Jen CHEN said, the export prohibition put Taiwan's biomedical industries in a predicament. Biological clinical experiments have to be conducted with the standard model or in core laboratory. When a research needs to export samples while the abroad lab environment is similar as the lab's in Taiwan, the export prohibition becomes a trouble that discourages international pharmaceutical factories to conduct their clinical experiments in Taiwan as well as the vise versa. This is definitely adverse to Taiwan's development of biomedial industries.

Related Historical Message: [Sci-Tech Policy][Biotch] Taiwan's BioBank Act through Third Reading 2010/01/09 [Sci-tech Policy][Biotech] Incomplete BioBank Regulations Put People at Danger of Privacy Infringement, Calls the Lawmaker 2009/07/04

Reference: <u>China Times E-paper 2011/10/26</u> (Chinese)

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