

The Debate on Establishing a Biobank in Taiwan

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Abstract: The purpose of a biobank is to gather and study the genetic information of a group of people to understand their genetic formation and discover whether or not some inherited diseases are present so that measures can be taken either to repair or alter these defects. In order to do this, extraction of blood from people is required. How much tissue should be taken has been an issue of concern to some ethicists while other human right groups also argue that this biobank should not be established at all because it runs the danger of breaching personal confidentiality.

This paper brings up these concerns and argues that no extra blood sample should be taken if this biobank is to be established. A survey of some medical students views on so-called "left-over tissue" was also undertaken.

Keywords: Biobank, Leftover Tissue, Human Right, Biotechnology.

The so-called economic miracle of Taiwan in the last few decades was the pride of the Taiwanese people. The rapid economic growth propelled by this miracle has however, gradually slowed down in the last several years due to the relocation of many factories from Taiwan to China as also due to the competition posed by newly - arising developing nations in the world. To ensure a continuous economic development, Taiwan therefore, needs a new direction while the computer industry is one such option that has brought much wealth in recent years yet Taiwan cannot depend solely on it; thus it has explored the emerging field of — biotechnological advancement.

To achieve this goal, fortification of biomedical research and the establishment of a biobank and other measures are considered indispensable. Projects to upgrade Taiwan's industries have been underway. The establishment of a biobank, however, has worried human rights groups as well as some scholars over issues such as,

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first, safeguarding the donors' privacy, and second, the disposal of the superfluous tissues left over from experiments. Responding to the first concern, the research institutes have indicated their awareness of the importance of this and they have promised to respect the privacy of every donor. The second concern is more complicated and controversial as the researchers insist that as long as the donors consent to the use of the leftover tissues, it should not be a problem. The human rights groups and some ethicists argue that a clause in the Consent Form that asks donors to grant researchers the right to use leftover tissues for future unknown experiments is a clear violation of ethical norms.

When asked for justification for establishing such a bank, Dr Chen Yuan Tsong, the head of the Institute of Biomedical Sciences at Academia Sinica and a key player of ELSI (ethical, legal, social issues) within the National Human Genome Research Institute, replied: "To build Taiwan's biological database in order to look into the factors causing common chronic diseases in Taiwan and to understand the impact of the interaction between genetic and environmental factors on such diseases in order to establish effective treatments and preventive strategies to safeguard the health of people in Taiwan". The study design used in developing this biological database is called a prospective cohort study, he explained, and risk factor information will be collected to observe whether those who are exposed to risk factors have a higher risk of developing a disease. Obviously, the establishment of this biobank is research-oriented but due to the long-range nature of this project, some donors may not live long enough to see the result. In that case, are their biological data to be destroyed or to become the property of the institute that carries on the research?

The underlying objective to establish such a biobank is indeed noble, yet how are we to safeguard the bioinformative privacy? One of the key members of the biobank project argued that rights have two natures, one is individualistic, and the other communitarian, meaning society owns its bioinformation. Informed consent, he argued, should be approached from both ends, namely, individual informed consent and community informed consent. He further stated that the community has the right to decide what genetic information should be shared by all and what belongs to the individual.

In order to motivate people to participate in this research, a free physical examination has been promised to those participants who consent to this study by donating their tissues for research. Again, the question is raised that this attempt to promote tissue donation violates the principle of justice that states that no coercion or enticement should be used to influence a voluntary decision.

To ensure that all the concerns are considered and explained, Taiwan's Ministry of Health has launched an attempt to formulate a research ethics for tissue procurement. No research can be carried out without being first approved by the Institutional Review Board (IRB). This proposed regulation, however, allows the leftover tissues to be used for other experiments provided that the research protocol has first been reviewed and approved by IRB. Some bioethicists worry that the clause on "leftover tissue tolerance" will surely motivate the researchers to extract more tissues than needed so that they can store them for later use. Although the regulation indicates that use of leftover tissues should also be approved by an IRB before the actual experiment, the concern remains — should a scientist be allowed to extract more tissue than needed? This "leftover" regulation seems to insinuate that the extra-tissue-taken is permissible despite the fact that the regulation emphasizes that none of the research including the procurement of organs or body tissues should violate medical ethics. This statement is vague, leaving room for subjective interpretation.

The use of fresh cadavers for research poses yet another issue. The proposed regulation indicates that cadaver tissue can only be collected after proper consent is sought and received. The representatives from the Prosecution Office participating in the discussion voiced their dissent, as this will jeopardize their criminal investigation when enforced because some criminal investigations are also research-oriented. Who owns the cadaver? Is it private property or does it belong to society? Who is to give the consent? In a Confucian society where decision-making is family-oriented, the attempt to obtain this consent may set family members at odds against one another.

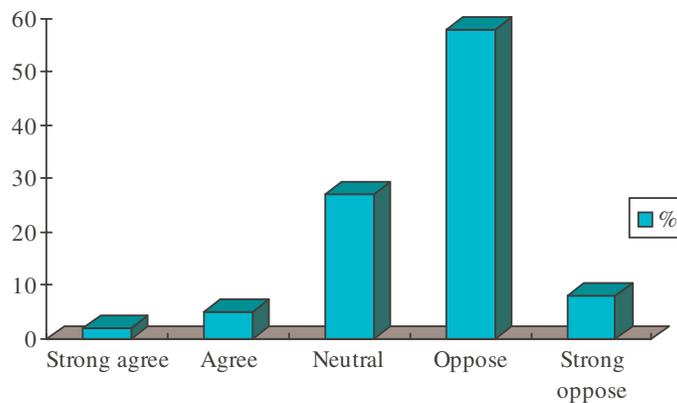
The establishment of a biobank is indispensable for the advancement of biotechnology but ethical concerns expressed by some scholars must be addressed. A public hearing to explain the purpose,

function and ways of operation needs to take place. The expressed concerns are not groundless. Irresponsibility in biomedical research must not be taken lightly.

An interesting survey in regard to this 'leftover tissue' issue was conducted in May 2006 at the Chung-kuo (China) Medical University in Taichung using 5th year medical students as respondents. This survey shows that the majority of medical students oppose the storing of leftover tissue for future research. Three scenarios were given to which varying responses were sought of 112 students in class:

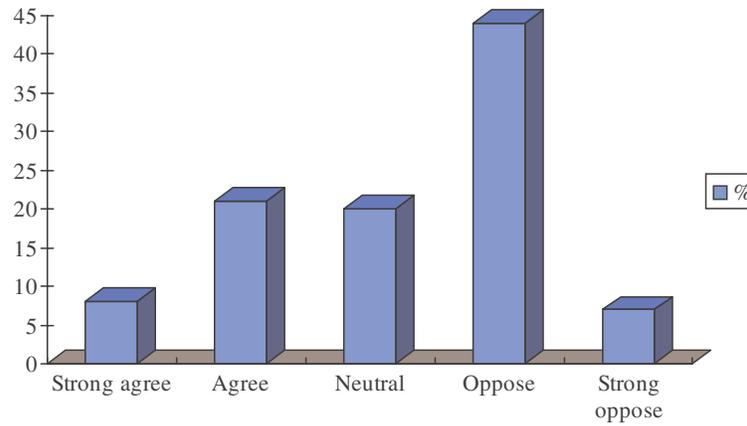
1. For biomedical progress, the research may extract more sample-tissue than needed to be stored for future experiment.

Strong agree	2 %
Agree	5 %
Neutral	27 %
Strong oppose	8 %



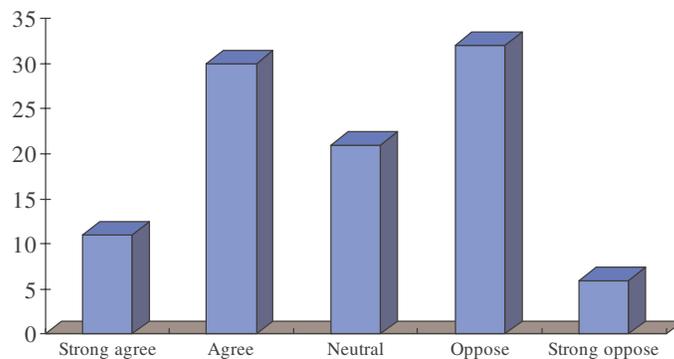
2. For biomedical progress, the researcher after telling the donors may extract more tissue than needed to be stored for future experiment.

Strong agree	8 %
Agree	21 %
Neutral	20 %
Oppose	44 %
Strong oppose	7 %



- For biomedical progress the researcher after obtaining consent from donors may extract more tissue than needed to be stored for future experiment.

Strong agree	11 %
Agree	30 %
Neutral	21 %
Oppose	32 %
Strong oppose	6 %



These ethical concerns remain unsettled. The Academia Sinica in charge of this project has tentatively suspended this project. Its IRB is still reviewing the experiment proposal presented by the researchers.

References

- Hsieh, P. H. (2005). "Taiwan Biobank". *China Times*, 13 Aug.
Yeh-dan Weekly 16 Nov, 2005.
- Reports from Taiwan Association for Human Rights. 11 April, 2006.
- Wan Joy (2006). "Taiwan Biobank being Reviewed". *Central News Agency*, 24 Jan, Taiwan.
- Liu, Mark. The Importance of Information Disclosure and Transparency in Biobank Research (Mark Liu's homepage).
www.lbms.sinica.tw
www.doh.gov.tw
- Proposed Regulation on Human Experiment, doh.gov
- Personal interviews with concerned scholars and medical students.
- Documents from National Clinical Core for Genomic Medicine.
- Liberty Times (2006). Taiwan Biobank, 25 June.