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Right and Duty in Biobank Research: Balancing Individual Autonomy and Social Justice

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Contents

Abstract

In this paper, the author attempts to analyze the rights and duties in biobank research by first identifying the various interests of different stakeholders in this kind of research. Then he discusses whether the paradigm of individual autonomy and informed consent established in traditional research settings should be reexamined while applied to biobank research. Finally, he remarks on the role of government and the necessity of setting up some mechanisms in this kind of project. Attention is given not only to individuals, personal rights, and substantive justice, but also groups/communities, public interest, and procedural justice.

Keywords: biobank, genetic database, privacy, autonomy, informed consent, public interest, trust, justice

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I. Introduction

A. Research Questions

Several countries (including UK, Iceland, Japan, and Taiwan) have launched ambitious biobank projects that plan to develop national-level biomedical databases that will store blood samples, genetic information, and personal lifestyle information, with linkage to health data and medical records, collected from hundreds of thousands of people.[1] Many ethical and legal controversies have been aroused by this kind of project, and some of them are unique because of its magnitude, the social/cultural contexts within which it is carried out, and its dissimilarity to traditional clinical and medical research.[2] In Taiwan, the heated controversies over the Taiwan Biobank Project, implemented mainly by the Academia Sinica, have also caused a postponement of its originally scheduled date of November 2007 for the start of sample collection.[3]

Among all the ethical and legal controversies about the biobank projects in the world, some common themes and concepts often emerge. *Right*, *duty*, *privacy*, *autonomy*, and *social justice* may be the terms most often mentioned. However, what are they and what are the relations between them in biobank research? These questions need further exploration because those terms are frequently noted in an abstract or self-evident way, or on the opposite, sometimes they are applied specifically to one party (for example, human subjects) only, without mentioning the other parties' standpoints. In this paper, I attempt to further analyze the rights and duties in biobank research by first identifying the various interests of different stakeholders in this kind of research. Then I will discuss whether the paradigm of individual autonomy and informed consent established in traditional research settings should be reexamined while applied to biobank research. Finally, I will remark on the role of government and the necessity of setting up some mechanisms in this kind of project.

More specifically, I will ask and discuss the following research questions:

- In biobank research, who are the stakeholders?
- Who has rights? Who has duties? What kind of rights, and what kind of duties? Why?
- How to build a mechanism to protect these rights and ensure the performance of these duties?

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1 Jocelyn Kaiser, *Population Databases Boom, From Iceland to the U.S.*, 298 SCIENCE 1158 (2002); UK BIOBANK, UK BIOBANK: PROTOCOL FOR A LARGE-SCALE PROSPECTIVE EPIDEMIOLOGICAL RESOURCE (2007); Hung-En Liu (劉宏恩), *A Study of the Ethical Regulation and Mechanism Design of BioBank Japan: Focusing on Its Organizational Operation and Informed Consent Requirement*, TAIWAN L. REV., Feb. 2007, at 25.

2 *See generally* RICHARD TUTTON ET AL., GENETIC DATABASES: SOCIO-ETHICAL ISSUES IN THE COLLECTION AND USE OF DNA 1-13 (2004).

3 CHINA TIMES (TAIWAN), Nov. 5, 2007, at A8.

• How to define social justice from perspectives of both substantive justice and procedural justice, from perspective of fairness, and from perspective of public health/public interest?

• How to balance the rights and duties of these stakeholders to achieve social justice?

B. The Stakeholders in Biobank Research

There are at least four groups of stakeholders in biobank research. Among them, *participants* as human subjects are most often mentioned by commentators. *Researchers* as scientific knowledge seekers and prospective intellectual property owners or business persons are obvious stakeholders in this kind of project too. Here the researchers do not only include the ones who build or operate biobanks, but also include other researchers (such as company researchers) who seek access to biobanks.

Though maybe equally important, the other two groups of stakeholders seem to be less often mentioned by some commentators. Almost all the biobank projects of the kind this paper discusses are backed by government agencies and/or public funding.[4] As the sponsor of the research and the protector/promoter of public interest, the *government* should also be an important stakeholder in biobank research.

Compared with traditional biomedical research, one of the features of biobank projects is that they aim to collect tissue samples and personal genetic data from a very large population. The more extensive the collection, the more the collection becomes an issue not only for the individuals but also for the population as a whole.[5] Furthermore, these projects usually take ethnicity as an important research factor and assume that the same ethnic group of people may have the same genes.[6] Therefore, *ethnic groups/communities* become special stakeholders in biobank research.

II. Discourse on *Rights*

A. Participants

1. Privacy

In the past, many Taiwanese jurists (and maybe the general public too) tended to

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4 Melissa A. Austin et al., *Genebanks: A Comparison of Eight Proposed International Genetic Databases*, 6 COMMUNITY GENETICS 37 (2003); Kaiser, *supra* note 1; Liu, *infra* note 24.

5 Michael Yeo, *Biobank Research: The Conflict Between Privacy and Access Made Explicit*, http://cbac-cccb.ca (Feb. 10, 2004).

6 *See generally* J. L. McGregor, *Population Genomics and Research Ethics with Socially Identifiable Groups*, 35 J.L. MED. & ETHICS 356 (2007).

regard "privacy" as a synonym of "personal secrecy" or "confidentiality."[7] Recently, more attention has been paid to "individual control of personal information" and "informational self-determination."[8] Therefore the discourse on *privacy* may overlap with the one on autonomy which will be discussed in the next section. At the constitutional level, in 2005, the Grand Justices (Constitutional Court) stated in Interpretation No. 603 that:

> Although the right of privacy is not among those rights specifically enumerated in the Constitution, it should nonetheless be considered as an indispensable fundamental right and thus protected under Article 22 of the Constitution for purposes of preserving human dignity, individuality and moral integrity, as well as preventing invasions of personal privacy and maintaining self-control of personal information. As far as the right of information privacy is concerned, which regards the self-control of personal information, it is intended to guarantee that the people have the right to decide whether or not to disclose their personal information, and, if so, to what extent, at what time, in what manner and to what people such information will be disclosed. It is also designed to guarantee that the people have the right to know and control how their personal information will be used, as well as the right to correct any inaccurate entries contained in their information.[9]

At the level of law, the Computer-Processed Personal Data Protection Law was promulgated in 1995, and it regulates the collection, processing, use, and transmission of personally identifiable data. In 1999, article 195 of the Civil Code was amended to explicitly include *privacy* as a specific type of personality right. However, it should be noted that, compared with the U.S. law which tends to construe privacy as a general right to autonomy, in Taiwan the same individual interests that are protected by privacy in the U.S. may be protected by other types of personality right, such as rights of personal name, portrait, or reputation.[10]

For example, U.S. legal scholar Anita L. Allen puts privacy interests into four categories of concern: (1) informational privacy; (2) physical privacy; (3) decisional privacy; (4) proprietary privacy.[11] In Taiwan, the first two categories of individual

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7 *See, e.g.*, Taiwan ROC Grand Justices Interpretation No. 293.

8 Taiwan ROC Grand Justices Interpretation No. 603; Chen-Shan Li (李震山), *The Right to Informational Self-Determination*, *in* HUMAN DIGNITY AND HUMAN RIGHTS PROTECTION 282 (2000); Tzu-Yi Lin (林子儀), *Genetic Information and Genetic Privacy*, *in* THE CHALLENGE OF GENETIC TECHNOLOGY AND THE LEGAL RESPONSE TO IT (Tzu-Yi Lin & Ming-Cheng Tsai eds., 2003).

9 The Judicial Yuan of Republic of China, *English Translation of Grand Justices Interpretation No. 603*, http://jirs.judicial.gov.tw/ENG/FINT/FINTQRY02.asp?cno=603 (last visited May 10, 2008).

10 TEZ-CHIEN WANG (王澤鑑), QIN QUAN XING WEI FA DI YI CE (TORT LAW I) 151 (1998).

11 Anita L. Allen, *Genetic Privacy: Emerging Concepts and Values*, *in* GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA 31, 33 (Mark A. Rothstein ed., 1997).

interests may also be qualified as privacy, but the third is debatable—some Taiwanese jurists classify it as part of the residual right of personality (*i.e.* the personality right not explicitly provided in the Civil Code) instead of privacy.[12] As to the fourth category of individual interests, most Taiwanese jurists tend to classify it as a type of property right, but recently there have been some influential scholars noting it as a "right that has both the qualities of personality and property."[13] Nevertheless, these scholars may still classify it as other types of personality right instead of privacy.[14]

While talking about the privacy issue in biobank research, many biomedical researchers in Taiwan seem to have two myths. First, some researchers tends to think that if the participant signed an informed consent form (ICF) in which he/she claims to transfer the ownership and other rights derived from his/her tissue sample to the researcher, then the researcher will be able to freely deal with or dispose of the sample because the participant will have no right in the sample at all.[15] This is a misunderstanding because signing the ICF at most means a transfer of property rights in the sample, but according to the law personality rights such as privacy will not and can not be transferred.[16] The participant still has personality rights in the sample he/she has donated or "transferred" to the researcher. If the researcher unwarrantedly disclose or distribute the personal information derived from the sample to others, it still may invade the participant's privacy.

The concept that A's personality right can exist in a thing owned by B is not new in the civil law system. In fact, this kind of scenarios happened quite often. For example, if a photographer takes a photo of a model, though the photographer may have both the ownership and the copyright of that photo, the model's right of portrait still (abstractly) exists in it. Similarly, a physician may own the piece of paper on which his/her patient's medical record has been written, but the patient's privacy right (abstractly) exists in it all along.

The second myth some researchers believe is that "anonymization can secure privacy in biobank research." This is a myth because, by its nature and design, the biobank research will not and cannot truly anonymize participants' data to make them personally unidentifiable. The value and fundamental design of biobank research are to *link* many different types of personal information, such as genetic information, personal lifestyle information, genealogical data, and health data and medical records, of hundreds of thousands of people. If these personal data are truly anonymized, it is impossible to link them from different databases to study the functions of genes and

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12 WANG, *supra* note 10, at 157.

13 TEZ-CHIEN WANG (王澤鑑), MIN FA ZONG ZE (GENERAL PRINCIPLES OF THE CIVIL CODE) 147 (2002).

14 *Id.*

15 Ying-Jhih Huang, A Study on the Rights that Could Be Claimed by the Human Tissue Providers in Biomedical Research 112-13 (2006) (unpublished LL.M. thesis, National Taipei University).

16 WANG, *supra* note 13。

probe the complex interplay between genetic and environmental factors in causing common diseases. At best the researchers can only encrypt or encode these data, but for linkage purpose there must be decoding keys that can make them personally identifiable when necessary, and there must be researchers who have access to these keys regularly.[17]

Even if (though impossible) the researchers would truly anonymize participants' personal data, anonymization itself still could not secure privacy.[18] For example, while reviewing an anonymous medical record, there still is a decent chance that a researcher may identify the source of the record by the information it contains. The record might show, "Female, born in 1962 in Taipei City, giving birth to a boy in 1989, giving birth to a girl in 1991, appendectomy in 1999"—just these five simple facts might be enough for a researcher who knows this participant to identify her and guesses "That must be Mary Wang!" And then the researcher might be surprised to read of Wang's medical history of mental illness, alcoholism, sexually transmitted disease, or other conditions that he/she had not known before reviewing this anonymous medical record. After all, in a relatively small country, not too many Taiwanese women have been born in the same year and same city with the same history of giving births and having an appendectomy. Moreover, by linking different types of personal information and databases by computer, this kind of privacy invasion would become more possible because of, for example, the power of cross search and multiple keywords search.

2. Autonomy

In biomedical research ethics, the *autonomy* issue is generally referred to as the issue of "informed consent" in the recruiting process on an individual level, but I would argue that it should be discussed in a broader scope. Moreover, because this paper intends to analyze the rights and duties in biobank research, from a legal perspective, it is necessary to examine what the legal ground for the protection of autonomy is and ask the question: Is there a *right* to autonomy in the law on which the participants can base their legal claims?

In the Civil Code of Taiwan R.O.C., there is no "right to autonomy" explicitly provided in the law, but generally speaking Taiwanese jurists agree that it should be protected by the Code. In cases of invasive medical treatments or research conduct without proper informed consent from the patients/participants, they can base their tort claims against the physicians/researchers on the "right of body." Furthermore, referring to German legal literature, a few scholars argue that there could be an

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17 *See* Einar Árnason, *Personal Identifiability in the Icelandic Health Sector Database*, JOURNAL OF INFORMATION, LAW & TECHNOLOGY, Sept. 2002.

18 Henry T. Greely, *Iceland's Plan for Genomics Research: Facts and Implication*, 40 JURIMETRICS J. 153, 186 (2000).

independent "right to autonomy in body integrity" in addition to the "right of body."[19]

Some influential scholars note that the "liberty of self-determination" is protected by the "right to liberty" and "other personality interests" provided in article 195 of the Civil Code.[20] Others argue that "right to autonomy" should be construed as a positive right independent from "right of body" and "right to liberty" which are basically negative rights.[21] No matter what the legal grounds in their argument are, there is a general consensus that autonomy should and could be protected by the Civil Code and the injured person can claim for damages for emotional distress in addition to pecuniary loss.

This paper argues that the discourse on autonomy shall include (but not be limited to) the rights to choose to participate after being communicated enough information, to withdraw from participation, to know the progress of research, and to claim one's own body integrity. As noted by many commentators, informed consent should be a *communication process* between researchers and participants, not just a one-time disclosure of information to or receipt of signed ICF from the participants on recruitment occasions.[22] I also argue that in biobank research the traditional paradigm of *individual* informed consent is insufficient to ensure participants' autonomy because of the following features of this kind of research.

First, biobank research's long-term time frame and innumerous possibilities of future usages make it difficult to thoroughly inform participants while recruiting. It may seem a little dilemmatic: The clearer the informed consent is, the less the value and usage of biobank will be. Second, the complexity of this kind of research enlarges the knowledge gap between researchers and participants. The traditional paradigm of informed consent at an *individual* level sometimes may not mean much but "letting the ignorant individual decide" or even "letting the helpless individual choose by him/herself." Third, biobank research involves a great number of participants from the general public or even involves some whole communities. It is essentially more "public" or "social" than many other biomedical studies.

Because of the features above, to safeguard participants' autonomy, informed consent should be an ongoing communication process rather than a one-time event. Public communication and consultation, not just with the target participants but also with the general public and different stakeholders, should be established and held before the launch of the project. Ongoing notification of research progress and changes should be routinely given to the participants and the public, because it would be

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19 Ing-Ling Hou (侯英泠), *Yi Liao Xing Wei De Min Shi Pei Chang Ze Ren* (*Civil Liability of Medical Practice*), TAIWAN L. REV., May 2001, at 116, 121.

20 WANG, *supra* note 10, at 157.

21 Hsiu-I Yang (楊秀儀), *Patient Autonomy—Cause of Action of Informed Consent in Taiwan's Tort Law*, NAT'L TAIWAN U. L.J., June 2007, at 229, 259.

22 NEIL C. MANSON & ONORA O'NEILL, RETHINKING INFORMED CONSENT 68-96 (2007); Yang, *supra* note 21, at 263.

especially meaningful to the right to withdraw from participation. In short, public communication, consultation, and even debate may empower the prospective participants and enable them to make a better decision based on information from different viewpoints and facts—not just the one the researchers provide.

B. Researchers

In Taiwan, there has been extensive literature on researchers' interests in intellectual property and technology transfer derived from their biomedical research.[23] Since the intellectual property (IP) issue is not the main concern of this paper, I would only note that, though it is usually legitimate to let the researchers hold IP rights based on their research effort, benefit sharing to the participants' community/society should be addressed to acknowledge their contribution and achieve social justice, especially when the research is supported by public funding and/or appeals to the goodwill and altruism of participants.[24]

There are two other issues to raise. *Ownership* of biobank participants' samples/data is still a controversial and unsolved question. As for the property right in the samples/data, statutes and judicial precedents are still needed to clarify whether there is such a right on body parts and whether they are transferable and distrainable. However, regarding the personality right that (abstractly) exists in the samples/data, as discussed earlier, there is no question it belongs to the participants and will always belong to them.

Other researchers (including company researchers) who seek access to the biobank are also important stakeholders in biobank research. Given that the biobank is based on samples and data donated by the public and sponsored by the government (taxpayers), it is improper to let the researchers who build the biobank have exclusive access to it. In fact, the Government and Academia Sinica have also claimed that Taiwan Biobank should be a public resource and infrastructure.[25] But whether other researchers have a *right* to access to the biobank will depend on whether there will be a special statute which provides for it. According to the current legal system, such a right seems not existent.

C. Government

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23 *See, e.g.*, Wen-Yin Chen (陳文吟), *A Study on Gene Therapy-Related Invention Patents and Required Measures*, 93 CHENGCHI L. REV. 269 (2006); Wei-In Tsai (蔡維音), *Principles of Distributing Intellectual Property Rights in Human Genomic Technology*, 6 CHENG KUNG L. REV. 33 (2003); Wen-Yin Chen (陳文吟), *A Study on the Necessity of Moral Utility under U.S. Patent Law on Biotechnology from the Impact of Embryonic Stem Cell Research*, 49 TAIPEI U. L. REV. 179 (2001).

24 Hung-En Liu (劉宏恩), *Public Trust, Commercialization, and Benefit Sharing in Biobanking*, 57 TAIPEI U. L. REV. 367, 375 (2005).

25 *See* ACADEMIA SINICA, RESEARCH PROPOSAL OF THE FIRST STAGE OF TAIWAN BIOBANK PROJECT 10 (2005).

The Government is not a typical subject of *rights*; in fact, more often, it has the authority and even duty to protect/promote rights of the participants and public interest. It serves as the "steward" of these rights and interests. However, since the Government is the sponsor of Taiwan Biobank Project, it may claim some rights (e.g. IP or benefit sharing) based on the sponsorship contract with the researchers. Though important, there seems no clear arrangement between the Government and the researchers yet on this issue.

D. Ethnic Groups/Communities

Traditional paradigm of rights is based on *individualism*: only individuals can be subjects of rights (*Quan Li Zhu Ti*). This is especially true in the discussion on private laws such as the Civil Code, no matter whether it is regarding property rights or personality rights. Nevertheless, this paradigm has obviously been revised recently in Taiwan. In December 2007, the Legislative Yuan enacted the Statute for Protection of Indigenous Peoples' Ethnic Creative Work of Traditional Wisdom. This statute creates a new type of right: the exclusive right, both of property and personality, to a creative work of indigenous traditional wisdom. It clearly provides that the subjects of right (right holders) should be "indigenous peoples" or "ethnic groups," not individuals.[26]

Obviously, group rights or collective rights are not unprecedented in Taiwan any more. In biobank research, given that both the establishment and the effects of biobank research are essentially more "public" or "social" and that the same ethnic group share the same genes and may suffer from the same adverse consequence such as stigmatization or discrimination, it may be justifiable for ethnic groups to claim group rights (e.g. privacy, autonomy, benefit sharing), but a special biobank law which provides for such rights may be necessary for their legal claims.

III. Discourse on *Duties*

A. Participants[27]

Do participants have any *duties* in biobank research? In addition, maybe we should ask another question at an earlier stage: do individuals have a duty to participate in biobank research? The latter question might sound a little odd at first glance; obviously there has been no law which imposes a *legal* duty on individuals to

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[26] Statute for Protection of Indigenous Peoples' Ethnic Creative Work of Traditional Wisdom art. 10, 14 (Taiwan ROC).

[27] The argument and discussion in this section may also apply to the discourse on duties of ethnic groups/communities, so I will not write a specific "ethnic groups/communities" section in this part later.

participate in biobank research. However, do we have a *moral* duty to do so?

In one of his famous but controversial articles, bioethicist John Harris has argued that the answer is "yes." He contends that some biomedical research is so important because of its benefit to humankind; provided that its inconvenience, risk, or harm is minimal to individuals, we have a positive moral duty to pursue it and to participate in it.[28] He bases his argument on two reasons. First, because biomedical research is necessary to advance medical knowledge, control diseases, or even save lives, we should act to support it or otherwise we will have to accept responsibility for the harm that then occurs due to the stop of medical progress. Second, since we all in fact benefit from the social practice of medical research, it is unfair that we just accept the benefit but do not contribute to it like a "free rider."[29]

I find Harris's argument, at least in biobank research, unconvincing for several reasons. To begin with, though biobank research gives many hopes in advancing medical knowledge, the "benefit" of biobank research is still uncertain and controversial. Some scientists believe that some of the "hopes" may be just "hypes" ; even biobank researchers themselves also admit that many findings of this kind of research will not have clear or direct applications in medical practice for decades.[30] Given that the benefit is uncertain and indirect, whether there are "harm" and "unfairness" due to our not participating in biobank research becomes doubtful, and therefore Harris's argument seems to be untenable.

Second, Harris supposes that inconvenience or risk of participating in biobank research is minimal to individuals, therefore we have a positive moral duty to participate in it. Nevertheless, his supposition is questionable. As a longitudinal cohort study, the researchers of Taiwan Biobank project will follow and observe the 200,000 participants' health conditions, medical records, and lifestyles for at least ten years, and the researchers also plan to access the records from the Government's computerized registry system of Taiwanese families/residents and the National Health Insurance system. It is not just a one-time blood donation, and the point of this project is not "blood" but "information"—many different kinds of personal information.[31] The inconvenience or risk of donating a little blood for once may be minimal, but is it still so to be collected so many kinds of private information and be tracked for ten years or more? Considering that Taiwan's Computer-Processed Personal Data Protection Law is pretty loose[32] and there is no truly independent oversight committee of Taiwan

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28 John Harris, *Scientific Research is a Moral Duty*, 31 J. MED. ETHICS 242 (2005).

29 *Id.* at 242-43.

30 Kaiser, *supra* note 1, at 1158, 1160; Hung-En Liu (劉宏恩), *A Study on the Legal Policy of Iceland's Population Databases and Biobanks*, 54 TAIPEI U. L. REV. 45 (2004); *Ethical Concerns at the DNA Bank*, WIRED NEWS, May 6, 2002, *at* http://www.wired.com/news/medtech/0,1286,52716,00.html.

31 *See* ACADEMIA SINICA, *supra* note 25; CHINA TIMES (TAIWAN), July 2, 2007, at A5.

32 Tyng-Ruey Chuang (莊庭瑞), *Personal Data Protection in Taiwan: Whose Business?* NAT'L POL'Y Q., Mar. 2003, at 53.

Biobank yet, it would be too bold to simply claim "yes."

Third, even if we have a moral duty to participate in biomedical research, Harris's argument does not demonstrate that we should participate in any specific kind of biomedical research such as the biobank. Since that there are many other medical studies more promising and/or trustworthy than biobank and that it is impossible to oblige us to participate in *all* medical studies, we can simply participate in other medical studies, not the biobank, to discharge the so-called "duty" argued by Harris.[33]

Finally, so long as "fairness" is concerned, since commercial involvement is essential in Taiwan Biobank project,[34] it will be obviously unfair and unjust to oblige only individuals to contribute to common good but not the private companies or for-profit researchers involved to do so. Harris himself also emphasizes that his argument is based on the premise that there is a benefit sharing mechanism ensuring the widest and fairest possible availability of the products of the research.[35] Nevertheless, such a mechanism does not exist yet and hence (at least at this stage) it is implausible to say individuals have a moral duty to participate in the research for "fairness."

Though individuals have neither a legal nor a moral duty to participate in the biobank research, suppose that any individuals *choose* to participate, surely they have a moral duty thereafter to give correct personal information to researchers in order not to damage the research.

B. Researchers

In biomedical research, since the participants have the rights to privacy and autonomy as discussed earlier, the researchers have the complementary duties corresponding with these rights on the same object. In short, the researchers are obliged to respect and protect the participants' privacy and autonomy. It should be noted that many of these duties are *legal* duties, not just moral duties. We can find the legal grounds for these duties in many statutes, such as the Civil Code (in both tort and contract sections of it), the Computer-Processed Personal Data Protection Law, the Medical Care Act, and many regulation laws on health professionals.[36]

What remains a question is whether there is a legal ground for the researchers' duty to consult and communicate with the public. I have argued the necessity of public communication and consultation before and after launching the biobank research, but the law which might oblige the researchers to do so seems incomplete on this issue. Article 21 of the Basic Law on Indigenous Peoples (promulgated in 2005) stipulates that

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33 *See also* Sandra Shapshay & Kenneth D Pimple, *Participation in Biomedical Research Is an Imperfect Moral Duty: A Response to John Harris*, 33 J. MED. ETHICS 414 (2007).

34 *See* ACADEMIA SINICA, *supra* note 25, at 9-10; Liu, *supra* note 24, at 374-75.

35 John Harris, *supra* note 28, at 246.

36 *See* Yang, *supra* note 21, at 239-62.

"The agents of both the public and the private sectors should consult with, receive consent from, and share benefit with indigenous peoples, whenever they develop land, utilize resources, promote ecological conservation, and conduct research in indigenous peoples' land areas." Though this could be a legal ground for obliging the researchers to consult and share benefit with the participants in biobank research, it applies only to indigenous participants

Considering that biobank is a public funded but controversial project which appeals to public interest and that, as mentioned earlier, proper informed consent needs public consultation and communication to ensure participants' autonomy, I believe we should impose a duty on the researchers to consult and communicate with the public before and after launching the biobank research. Similarly, because it is a public funded research which appeals to participants' altruism and public interest, the researchers who build the biobank shall also have the duty to share the benefit of research result to the general public or communities and to share the resource of biobank with other researchers.

C. Government

As a steward and safeguard of citizens' rights and public interest, and also as the sponsor (using taxpayers' money) who funds the biobank project, I believe it is government's unavoidable responsibility to ensure the protection of the rights and the performance of the duties mentioned above. The government has the responsibility to set up (or at least help to set up) a mechanism to balance these rights and duties and settle controversies. It is irresponsible and unfair of the government to let the researchers (or even the IRB of researcher's institute) distribute rights and duties and solve the controversies alone.

For instance, to safeguard public interest and win public trust, all the governments of the other countries (including Iceland, U.K, and Japan) that launched biobank projects have come forward to establish a special independent oversight committee of biobank research.[37] Nevertheless, in Taiwan, this kind of committee is still inexistent. It seems that the government[38] still expects the Academia Sinica to establish this committee itself, and it seems to confuse this committee with IRB.[39]

The government's expectation is improper because letting the biobank researchers themselves choose their overseers may damage the committee's independence or at least lead to some public distrust in it. This approach is also unfair to the Academia Sinica

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37 *See* UK BIOBANK, *supra* note 1, at 40; Liu, *supra* note 1; Liu, *supra* note 30.

38 To be more precisely, Department of Health (DOH) is the sponsor and funding source of Taiwan Biobank Project.

39 This is an observation from the statement of a DOH representative in the ELSI Conference of the National Research Program for Genomic Medicine, Dec. 07, 2007, Academia Sinica, Taipei.

because it is just one of the four institutes that carry out this project,[40] the burden of establishing a special independent oversight committee of Taiwan Biobank project should not be imposed on the Academia Sinica only, not to mentioned that the IRB or any other committees affiliated to the Academia Sinica could oversee merely the research conducted by the Academia Sinica, so this approach may leave a big hole in terms of overseeing this project.

This paper argues that a study of this magnitude, time frame, complexity, and controversiality needs a special *independent* oversight committee. It should not be the IRB or other similar committees affiliated to the researchers' institutes. The government as both the sponsor of this project and the steward and safeguard of citizens' rights and public interest should come forward to establish a special independent oversight committee on Taiwan Biobank, just as all the governments of the other countries that launched biobank projects have done.

IV. Final Remarks

Biobank research involves multiple stakeholders who may have consistent and inconsistent substantive rights and duties. Moreover, not only does biobank research appeals to public interest, but it does in fact need public trust and support.[41] To protect the rights and ensure the performance of the duties mentioned above, to balance the possible conflict and inconsistency among them, and to win public support and settle controversies, it is necessary to set up mechanisms for at least the following issues:

(1) A mechanism to review the performance and trustworthiness of public consultation and communication.

(2) A mechanism to ensure the protection of participants' rights and the performance of researchers' duties. We may further develop it into two sub-mechanisms: an *oversight* mechanism which oversees researchers' conduct and performance and a *compliance* mechanism which holds researchers accountable.

(3) A mechanism to decide and monitor the fair access to the biobank.

(4) A mechanism to decide the benefit sharing policy and standard and to monitor their implementation.

Many of these mechanisms are more related to transparent and trustworthy *procedures*. These procedures can further help to decide the substantive standards that are necessary and acceptable by the society. This paper has argued that the

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[40] The other three institutes are Institute for Information Industry (資策會), Development Center for Biotechnology (生物技術開發中心), and Foundation of Medical Professionals Alliance in Taiwan (台灣醫界聯盟). *See* ACADEMIA SINICA, *supra* note 25; Official Website of Taiwan Biobank Project, http://www.twbiobank.org.tw (last visited May 10, 2008).

[41] M. G. Hansson, *Building on Relationships of Trust in Biobank Research*, 31 J. MED. ETHICS 415 (2005); Liu, *supra* note 24.

government has a duty to help establish these mechanisms, especially the oversight and compliance mechanism. Although legislated standards are important, they must be supported by an independent oversight and compliance mechanism, otherwise the standards would be merely ineffectual statements of good intent.[42] Moreover, the procedures and mechanisms are essential to the public trust and support that the biobank research needs. Unfortunately, while the researchers seem to determined to start sample collection soon,[43] those procedures, mechanisms, and public trust and support appear to remain underdeveloped in Taiwan.

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42 *See also* BRUCE PHILLIPS, THE PRIVACY COMMISSIONER OF CANADA ANNUAL REPORT 6 (1995).

43 Central News Agency (Taiwan), *Start of Taiwan Biobank Triggers Sensitivity*, Aug. 13, 2007, *at* http://news.yam.com/cna/healthy/200708/20070813599669.html.

出席國際學術會議心得報告

計畫編號	96-3112-H-004-002
計畫名稱	基因醫療之新權利義務觀：自主權與社會正義之協調--基因醫療之新權利義務觀：生醫資料庫中的個人自主與社會正義(3/3)
出國人員姓名 服務機關及職稱	劉宏恩，國立政治大學法律科際整合研究所助理教授
會議時間地點	July 25-28, 2007 ／ Berlin, Germany
會議名稱	2007 Law & Society Association Annual Meeting: Law and Society in the 21st Century International Conference
發表論文題目	The Ethical and Legal Controversies and Governance of Biobank Projects in Taiwan and Japan

一、參加會議經過

本次至德國參與國際研討會，是與同一整合型計畫「基因醫療之新權利義務觀：自主權與社會正義之協調」下各個子計畫的主持人楊秀儀教授、雷文玫教授、牛惠之教授共同前往參與，而且數月之前大家就曾聚會多次，共同討論每個人即將前往發表的論文。七月廿五日抵達會議地點之後，即每日參加數個場次、聽取來自各國的學者的報告，並向他們提出問題。我個人共計參加“Global Challenges in Health Care”、“Emerging Questions in Technology and Law”、“Alternative Regulation in Health Care”、“Governing Science and Technology”、“The Intersection of Bioethics and Law”... 等十餘個場次。我自己的論文發表是在七月廿八日的“The Legal and Ethical Issues of Biobank Research in Different Contexts”的場次中進行，美國華盛頓大學法學院的 Patricia Kuszler 教授並到場參與討論並提供評論。

二、與會心得

Law & Society Association 的國際年會規模極為龐大，參與的人數多達上千人，並有極多大師級的學者與精彩的報告，很令人激賞。雖然這已經是我第三次參加 Law & Society Association 的年會，但卻是第一次跟整合型計畫下的其他子計畫主持人大家共同參與這個年會。從各國與會者的報告看來，醫學或生物科技與法律之間的關係，很顯然在世界許多國家都成為法學者關注的焦點，而且大家都是同時在面對許多「新」的問題，所以沒有哪一個國家敢說自己已經有完全確定的典範可以供其他國家參考依循。換言之，各國法律學者進行研究的「立足點」在許多方面是平等的，也因此，彼此交換自己國家的經驗與問題就顯得更有意義。

底下是我發表的論文的摘要：

The Ethical and Legal Controversies and Governance of Biobank Projects in Taiwan and Japan

Hung-En Liu

Abstract

Many countries have launched ambitious biobank projects that are backed by government agencies and/or public funding. Both Taiwan's and Japan's governments have also recently decided to sponsor biobank projects conducted by public academic institutes. In Taiwan, the project is expected to develop a national-level biomedical database that will store blood samples, genetic information derived from them, and personal lifestyle information, with linkage to health data and medical records, collected from 200,000 people aged 40-70. In Japan, the project was launched in 2003 and aims to collect blood samples and medical information from 300,000 patients of 47 diseases. Its goal is to link single-nucleotide polymorphisms to diseases and adverse drug reactions and develop personalized medicine. Both projects aroused some controversies in Taiwan's and Japan's societies, but compared with Iceland and UK experiences theses controversies seem less bitter, partly because (especially in Taiwan) there had been lack of information transparency and public discussion. The paternalistic culture towards decision-making and policy in the scientific and medical spheres may also explain the difference. In these contexts, this paper argues that Taiwan and Japan should strengthen their governance of the biobank projects and create some more independent and effective control bodies to oversee the sample collection, storage, and usage in the projects.