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基因資料庫研究中的公眾信賴、商業介入與利益共享

Public Trust, Commercialization, and Benefit Sharing in Biobanking

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摘要

爲了促進生物醫學及生技產業發展，「建置台灣基因資料庫(Taiwan Biobank)」目前已經成爲我國政府重點推動的大型研究計畫之一，未來預計要蒐集台灣地區 20 萬名以上 40 至 70 歲民眾的血液檢體及基因資訊，並同時蒐集這些民眾的生活習慣資料、身體健康資料，再予以長期追蹤至少十年以上；追蹤調查期間，還希望透過戶籍系統、全民健保資料庫、以及調閱這些民眾就醫的病歷資料，來研究這些民眾的健康變化及罹患疾病等情形，以瞭解基因與一般常見疾病之間的關係，並進一步探究台灣地區閩南人、客家人及原住民在基因與罹病上的族群差異。由於這樣的大型人群基因資料庫，可能會對參與的民眾帶來個人自主性及隱私等權益上的影響，在群體層次也有可能帶來族群標籤化或歧視，因此在各國都引發許多討論與爭議。大部分的焦點，主要集中在採集檢體前應取得民眾的告知後同意，以及對於民眾個人資料與基因資訊應有隱私保護及保密機制等問題上。但是，本文試圖從另外一個角度切入，將焦點集中在此類研究的另一個特色上：產業界的參與和商業介入。

世界上幾個主要的人群基因資料庫計畫，雖然政府都有提供資金、或是提供行政立法上的支援，但是同時也都有產業界的參與和商業公司加入。我國的台灣基因資料庫研究計畫也不例外。本計畫在規劃之初，便有許多民間的商業公司積極參與和推動；而且正如中研院今年七月所提出的企劃書中所述：在未來的執行、以及資料庫建置完成後的利用過程中，產業界勢必也將加入。因爲事實上，促進生技產業及資訊產業發展，正是行政院科技顧問組規劃此一研究計畫的重要目標，而且研究過程中所需要的龐大人力、技術、資金等，往往也需要由民間的商業公司支援提供。並且，未來的研究發現若要轉化爲實際的醫藥產品或器材技術，通常也需要有產業界的協助，才有辦法使其具有應用性和普及性。所以，產業界的參與和商業介入，在人群基因資料庫的研究當中，幾乎是勢所難免。

但是，另外一方面，人群基因資料庫動輒需要數十萬民眾提供檢體和個人資料，而且利用到公部門的資金等公共資源來加以進行，因此，民眾的參與意願、

公眾支持及公眾信賴，往往對於此類研究的成敗居於舉足輕重的地位。若是依照台灣的生醫研究人員以往的作法，並參照中研院目前提出的企劃書中所述，台灣基因資料庫未來可能會透過以下方式來順利招募足夠的民眾參與：(1) 對民眾表示可順便接受免費的身體健康檢查，以增添民眾參與研究的動機；(2) 向民眾宣導基因研究可促進醫學進步及國人健康的價值，訴諸民眾的公益心及利他心，並在「告知後同意」的同意書當中，向民眾保證「所收集到的資料和檢體將只提供作爲學術用途」，請民眾踴躍提供檢體；(3) 透過與地方醫療院所及醫師合作，來蒐集民眾檢體，取得民眾信任。對於以上幾種招募民眾參與的方式，本文試圖從研究倫理上加以分析，並特別從前述「產業界的參與和商業介入勢所難免」的脈絡出發，討論基因資料庫研究當中可能出現的「利益衝突」(conflict of interest)及醫生的角色衝突等問題，並檢討研究者一方面對民眾訴諸公益心和利他心、保證僅供學術用途，但另一方面卻又明明有產業利益和商業化利用的事實，這兩者之間似乎呈現的矛盾，以及其對公眾信賴和公眾支持可能帶來的傷害。本文並藉由台灣及國外已經發生過的若干生物醫學研究實例、甚至訴訟，來檢討相關作法可能衍生的問題。

本文主張：研究者不宜任意使用「免費健康檢查」來引誘民眾提供檢體，使民眾心中混淆研究者蒐集檢體的目的及相關風險；研究者應該在蒐集檢體之前，便讓民眾清楚瞭解產業界參與及商業公司將會利用資料庫的事實，不能輕率訴諸(甚至利用)民眾的公益心和利他心；基因資料庫研究當中，研究者自身的利益衝突、或是其所合作的醫療院所及醫師的利益衝突，應該予以正視，並透過「公開」等機制加以控制。以上的研究倫理的要求，應優先由研究者設法透過自律來達成，但若是不然，在必要的範圍內，爲了保障民眾權益，亦可能有透過法律加以規定的需要。本文並且主張：聯合國教科文組織(UNESCO)的宣言、世界衛生組織(WHO)的報告近年來所一再強調的，研究者及產業界應讓參與基因資料庫研究的民眾所屬的社會或族群得到「利益共享」(benefit sharing)此一原則，應可適度平衡「要求民眾基於公益而提供檢體」以及「產業界勢將參與並將衍生商業利益」兩者間疑似呈現的矛盾，可以符合分配正義及互惠的要求，並可促進公眾的信賴與支持。而此一社會整體「利益共享」的原則，未來或可透過資料庫的管理者與申請使用者之間的契約來加以達成，或是參考國外的例子以法律加以規定。

關鍵詞：
基因資料庫、生物銀行、族群、隱私、歧視、告知後同意、自主、利益衝突、角色衝突、利益分享、產業、商業、原住民、公眾信賴、利益共享、聯合國、研究倫理

Abstract

Many countries have launched ambitious biobank projects that are backed by government agencies and/or public funding. Taiwan's government has also recently decided to sponsor a pilot biobank project conducted by the Institute of Biomedical Sciences, Academia Sinica. The pilot 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 three areas in Taiwan. Different combinations of ethnic groups, Fukien, Hukka, and indigenous people, are targeted for collection of biological samples.

Biobank projects of this magnitude need a lot of funding, logistic support and technical collaboration, and therefore the public sector increasingly depends on private industry to fund and participate in the research. However, while commercial involvement is almost inevitable, it is expected that biobank projects will benefit the society as a whole in terms of improving healthcare services and medical knowledge. Participant recruitment and sample collections usually appeal to the goodwill and altruism of individual donors. Considering the large number of participants needed, and given that these projects are backed by public funding and/or government agencies, there is a general consensus that the success of biobank research greatly depends on public trust and support. This article suggests that we should attend to issues that derive from the tension between commercial involvement and the appeal to altruism of the public, because many people have misgivings about commercial involvement in biomedical research. It is understandable that donors may feel betrayed or even cheated if they find that researchers or private companies appeal to altruism to collect their samples/data on the one hand, but make profit and *do not actually return a reasonable portion of the profit to the public* on the other. In addition to its possible adverse effects on public trust, the commercial involvement may harm scientific integrity too. This article argues that the public sector's increasing dependence on private enterprise to fund and participate in biobank research provides new opportunities for conflict of interest to arise. Also, it examined the past practices of biomedical research and controversies concerning tissue sample collection in Taiwan. Finally, the gradually emerging legal requirement of benefit sharing in genetic research in international law is discussed. The author argues that benefit sharing with populations involved is essential if the tension between commercial involvement and the appeal to altruism is to be resolved or lessened in an acceptable way, and public trust and support to be ensured.

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Public Trust, Commercialization, and Benefit Sharing in Biobanking

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Contents

1. Some Features of Biobank Research

Since the completion of the Human Genome Project, functional genomics has become a major focus in genetic studies. To understand the functions of genes and probe the complex interplay between genetic and environmental factors in causing common diseases, many researchers believe that large-scale biobanks are especially useful. Collections of biological specimens, medical records, and genealogical data become very valuable for biomedical research, especially in the areas of pharmacogenomics and population genetics.[1] Many countries, including Iceland, United Kingdom, and

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1 Jocelyn Kaiser, *Population Databases Boom, From Iceland to the U.S.*, 298 SCIENCE 1158 (2002).

Estonia, have launched ambitious biobank projects that are backed by government agencies and/or public funding.[2] Taiwan is no exception.

Taiwan's government has recently decided to sponsor a pilot project conducted by the Institute of Biomedical Sciences, Academia Sinica, Taipei. The pilot project is expected to lead, in three years, to the official development of a national-level biomedical database that will in the long run 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. Potential participants will be randomly selected on the basis of household records and approached for informed consent.[3] The database is designed for research on the genetic and environmental factors in the etiology of common diseases in Taiwan. According to the pilot project's proposal, already approved by Taiwan's National Science Council, there will be three recruitment centers located respectively in Miao-li county (in central Taiwan), Chia-yi city (in southern Taiwan), and Hua-lien county (in eastern Taiwan). Different combinations of ethnic groups are targeted for collection of biological samples: in Miao-li county, people of Fukien (19th century or earlier), Hukka (19th century or earlier), and Mainland (20th century) descents; in Chia-Yi city, people of Fukien and Mainland descents; and in Hua-lien county, people of indigenous, Fukien, and Mainland descents. Though already approved, the pilot project is required by the National Science Council *not* to get off the ground unless a proper ethical and legal regulatory framework is put in place, and for good reasons.

Compared with traditional biomedical research, biobank projects of this magnitude have some unprecedented features. To begin with, they aim to collect tissue samples and personal genetic data from a very large population. For instance, while Taiwan Biobank plans to collect blood samples and health data from 200,000 people, the UK Biobank forecasts a cohort of at least 500,000 men and women aged 45-69 from the United Kingdom population.[4] As Michael Yeo noted, the more extensive the collection, the more the collection becomes an issue not only for the

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2 Melissa A. Austin et al., *Genebanks: A Comparison of Eight Proposed International Genetic Databases*, 6 COMMUNITY GENETICS 37 (2003).

3 CHINA TIMES (TAIWAN), Feb. 25, 2004, at A10.

4 UK Biobank, *Protocol for the UK Biobank*, http://www.ukbiobank.ac.uk (Feb. 14, 2002).

individuals but also for the population as a whole, and the greater the challenge may be for recruitment and data security.[5]

Second, these biobank projects need a lot of funding, logistic support and technical collaboration, and therefore the public sector increasingly depends on private industry to fund and participate in the research. For instance, Iceland government relies on a private company (deCODE) to establish a large-scale biobank,[6] the Estonian Genome Project Foundation set up EGeen Inc. to market products of Estonian biobank to the global pharmaceutical industry,[7] and the UK Biobank also explicitly claims that "involvement of the pharmaceutical and biotechnology industry in the project is essential."[8] In Taiwan, the biobank project involves private industry from its early stage. Many pharmaceutical and IT companies, including HP, IBM and Vita Genomics, have eagerly pushed the government to establish a Taiwan Biobank,[9] and the government also clearly claimed that "one main purpose of the biobank project is to promote the biotech and IT industry in Taiwan."[10]

Third, while commercial involvement is almost inevitable, it is expected that biobank projects will benefit the society as a whole in terms of improving healthcare services and medical knowledge. Participant recruitment and sample collections usually appeal to the goodwill and altruism of individual donors. Considering the large number of participants needed, and given that large-scale biobanks are usually backed by public funding and/or government agencies, there is a general consensus that the success of biobank research greatly depends on public trust and support.[11]

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

6 Henry T. Greely, *Iceland's Plan for Genomics Research: Facts and Implication*, 40 JURIMETRICS JOURNAL 153, 159 (2000); 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) (*in Chinese*).

7 Austin et al., *supra* note 2.

8 UK Bibank, *supra* note 4, at 32. For example, in November 2004, the UK Biobank signed a contract with IBM for the IT design and architecture for the biobank. In the future, the UK Biobank will open access to its data and resource to pharmaceutical companies.

9 *Taiwan will build a Center of Chinese Genetic Data*, LIBERTY TIMES (TAIWAN), Mar. 19, 2004; Wei-Ling Ho (HP Taiwan), *Taiwan Should Establish a Biobank As Soon As Possible*, ECONOMIC DAILY NEWS (TAIWAN), Apr. 30, 2004, at 11.

10 COMMERCIAL TIMES (TAIWAN), Feb. 25, 2004, at 14; ECONOMIC DAILY NEWS (TAIWAN), Feb. 25, 2004, at 32; ECONOMIC DAILY NEWS (TAIWAN), Apr. 7, 2005, at C6;

11 M. G. Hansson, *Building on Relationships of Trust in Biobank Research*, 31 J. MED. ETHICS 415 (2005); Lorraine Sheremeta, *Population Biobanking in Canada: Ethical, Legal and Social Issues*, http://cbac-cccb.ca (Sept. 30, 2003); Petersen Alan, *Securing Our Genetic Health: Engendering*

2. Altruism of the Public v. Commercial Involvement: The Tension Between Them and Some Misgivings

Large-scale biobank projects and population genetics have triggered a number of controversies at both national and international levels. Most attention has been focused on issues of informed consent, privacy, and data security. This article suggests that we should pay more attention to some issues related to the above-mentioned features of biobanks, especially the issues that derive from the tension that easily arises between commercial involvement and the appeal to altruism of the public.

Many people have misgivings about commercial involvement in biomedical research, and empirical data show that these misgivings may affect public trust and support. For instance, public opinion data from Canada suggest that the public generally lacks trust in corporate responsibility in the biotechnology field and that it tends to mistrust researchers if they are collaborating with for-profit companies.[12] In the UK, a survey by the Human Genetics Commission (HGC) in 2000 found a clear aversion to the use of personal genetic information for commercial purposes. The same survey also shows that public ownership of new products developed from using genetic information was overwhelmingly favoured by British people.[13] In Taiwan, according to a survey made by Chou in 2005, 77.52% of interviewees worried about the possibility that their genetic information may be released for commercial purposes.[14]

It is understandable that donors may feel betrayed or even cheated if they find that researchers or private companies appeal to altruism to collect their samples/data on the one hand, but make profit and *do not actually return a reasonable portion of the profit to the public* on the other. The recent lawsuit against a researcher and Miami Children's Hospital (MCH) filed by families afflicted with Canavan disease and the Canavan Foundation can be a good example. This case involves an alliance between

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Trust in UK Biobank, 27 SOCIOLOGY OF HEALTH & ILLNESS 271 (2005).

12 Sheremeta, *supra* note 11.

13 HUMAN GENETICS COMMISSION, REPORT TO THE HUMAN GENETICS COMMISSION ON PUBLIC ATTITUDES TO THE USES OF HUMAN GENETIC INFORMATION (2000).

14 Gui-Tian Chou (周桂田), *Risk Governance of Biobank*, paper presented at the 2nd Annual Meeting of Taiwan Bioethics Association, Kaohsiung, June 26, 2005.

parents and not-for-profit organizations who sought the help of researchers to develop prenatal and carrier testing for Canavan disease, and they hoped that the testing can be made accessible and affordable to the public. From the beginning, it is obvious that they donated their blood samples and money for the common good. That is exactly why they felt betrayed and cheated when they found that the researcher and his employer MCH secretly obtained a patent for the Canavan disease gene they discovered, and began to charge royalties and limit the availability of testing. If the researcher and MCH had returned the benefit to the public and not applied for a patent, the plaintiffs might not have filed a lawsuit.[15]

In addition to its possible adverse effects on public trust, the commercial involvement may harm scientific integrity too. For instance, biomedical researchers have a tradition of free inquiry and free exchange of ideas, and objectivity is central to the scientific pursuit of truth. However, many empirical studies show that this tradition has been eroding because of the trend of commercialization.[16] Studies find that when a researcher has a financial interest in or funding by a company, results of his research tend to favor the sponsor's product, and less likely to be published (because the sponsor may prohibit him from publishing the findings that may affect business), or at least more likely to be published at a delayed time (because the sponsor may want to apply for a patent first).[17] Withholding data and findings from colleagues becomes more common, and many researchers are required by their sponsors (pharmaceutical companies) to do so because of commercial secrets or competition.[18] Commentators also worry that the focus of biomedical research will be skewed away from basic research to what is potentially very profitable.[19] In the end, the decline of scientific integrity may further hurt the public trust in biomedical research and researchers.

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15 Gina Kolata, *Sharing of Profits Is Debated as the Value of Tissue Rises*, NEW YORK TIMES, May 15, 2000, at A1.

16 SHELDON KRIMSKY, SCIENCE IN THE PRIVATE INTEREST (2003); Sheremeta, *supra* note 11.

17 Justin E. Bekelman et al., *Scope and Impact of Financial Conflicts of Interest in Biomedical Research*, 289 JAMA 454 (2003); Catherine D. DeAngelis, *Conflict of Interest and the Public Trust*, 284 JAMA 2237 (2000).

18 Eric G. Campbell, *Data Withholding in Academic Genetics: Evidence from a National Survey*, 287 JAMA 411 (2002).

19 Garrath Williams & Doris Schroeder, *Human Genetic Banking: Altruism, Benefit and Consent*, 23 NEW GENETICS AND SOCIETY 89 (2004); Sheremeta, *supra* note 11.

There are some more concerns which this article will discuss later on. As collaboration between industry and academia has been increasing and even encouraged by the government, conflict of interest situations may emerge more frequently. The public sector's increasing dependence on private enterprise to fund and participate in biobank research provides new opportunities for conflict of interest to arise.[20] May the research participants be harmed because of researchers' conflict of interest? Is it fair or equitable to ask the public to donate for the common good on the one hand, and yet let the researchers/companies have all the profits they make on the other?

3. Researchers' Conflict of Interest

A conflict of interest is a situation where financial and other personal considerations have the potential to compromise or bias professional judgment and objectivity. The "interest" does not necessarily mean "financial interest"; it can be reputation, promotion, or even the interest of advancing science. A conflict of interest can happen at both individual and institutional levels. While the investigators/researchers may have individual conflict of interest in human subjects research, there can be an institutional conflict of interest too if the interests of an institution or any of its influential officials may affect, or reasonably appear to affect, institutional processes, including the conduct, review, or oversight of human subjects research.[21]

The American Association of Medical Colleges (AAMC) has made two reports to provide guidelines and recommendations for oversight of conflict of interest in human subjects research.[22] As the reports point out,

> [Though] competing interests . . . are an inescapable fact of academic life, . . . financial interests in human subjects research are distinct from other interests inherent in academic life . . . , because financial interests are discretionary, and because the perception is widespread

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20 Sheremeta, *supra* note 11.

21 Association of American Universities (AAU), *Report on Individual and Institutional Financial Conflict of Interest*, http://www.aau.edu/research/COI.01.pdf (Oct. 2001); American Association of Medical Colleges (AAMC), *Protecting Subjects, Preserving Trust, Promoting Progress*, 78 ACADEMIC MEDICINE 225 (2003).

22 AAMC, *supra* note 21.

> that they may entail special risks. Specifically, opportunities to profit from research may affect—or appear to affect—a researcher's judgements about which subjects to enroll, the clinical care provided to subjects, even the proper use of subjects' confidential health information. Financial interests also threaten scientific integrity when they foster real or apparent biases in study design, data collection and analysis, adverse event reporting, or the presentation and publication of research findings.

While the guidelines mentioned above and government controls of conflict of interest in the U.S. focus only on financial interests,[23] there are more and more concerns about non-financial (intangible) conflict of interest issues, especially the issues of physicians' involvement in biomedical research.[24] Nowadays, biomedical research projects increasingly rely on physicians for participant recruitment and sample collection, and many physicians recruit their own patients to participate in their research.[25] This research practice may be problematic because when a physician recruits his own patients for research, there can be inherent conflict of interest due to his dual roles: A physician's primary responsibility is to ensure the welfare of his patients, but as a researcher he expects to finish the research fast and smoothly to advance science, gain a reputation, or even make a profit by collaborating with a company. When a physician recruits his own patients for research, the ethical issues include the potential for misleading the patients or even for coercion. Questions arise as to whether the patients can tell the difference between treatment and research. In fact, even if the patients can tell the difference, in many cases they may not dare to say no to the physician's invitation to participate in the research because they tend to be afraid that refusal may offend the physician or affect the treatment they will receive. When recruitment for research takes place at the same time the patient is asked to give

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23 *Id.*; Jennifer Henderson & John Smith, *Financial Conflict of Interest in Medical Research: Overview and Analysis of Federal and State Controls*, 57 FOOD & DRUG LAW JOURNAL 445 (2002); Robert Steinbrook, *Conflicts of Interest at the NIH—Resolving the Problem*, 351 NEW ENGLAND JOURNAL OF MEDICINE 955 (2004).

24 *See, e.g.*, Timothy Caulfield & Glenn Griener, *Conflicts of Interests in Clinical Research: Addressing the Issue of Physician Remuneration*, 30 JOURNAL OF LAW, MEDICINE & ETHICS 305 (2002).

25 *Id.*; Mary R. Anderlik, *Commercial Biobanks and Genetic Research: Ethical and Legal Issues*, 3 AM. J. PHARMACOGENOMICS 203, 210 (2003).

consent to surgery, the substantial stress may exert undue influence on the patient and could be coercive.[26]

In May 2005, a so-called "scandal" happened in a very prestigious military hospital in Taiwan. Several patients' families claimed that a physician collected blood samples from the patients for research without obtaining consent beforehand. However, the physician retorted that the patients had actually signed informed consent forms in advance.[27] This is a typical case of the confusion of patients and the possible conflict of interest arising from the physician's dual roles, a case which we can examine from at least three perspectives. To begin with, can the mere signatures on the forms represent genuine "informed consent"? This is highly questionable because the patients may have confused the consent to participation in research with the consent to treatment, not to mention the possibility that they may have consented under the kind of undue influences mentioned above. Second, even if the physician has obtained the patients' informed consent, the "information gap" or "knowledge gap" between the physician and the patients makes it dubious that informed consent is sufficient to protect the patients. Shouldn't there be a mechanism that can reliably monitor the physician's conflict of interest and ensure autonomy and safety of the patients? Finally, did the physician notice the likelihood of conflict of interest due to his dual roles? If physicians are generally insensitive to this issue, shouldn't there be a training program in research ethics for physicians and other biomedical researchers?

Unfortunately, in the past, some researchers in Taiwan intentionally made use of patients' confusion mentioned above in an effort to collect blood samples or conduct research. For example, a physician in a well-known hospital in southern Taiwan ran a clinical trial on his patients while the patients thought it was part of therapy: the patients alleged that they had never known it was a clinical trial. In fact, the physician never denied their allegation, and he was later forced to resign from that hospital.[28] Another problematic research practice is that some researchers collected blood samples by offering, at the same time, "free health check" with the intention to induce lay people, especially the Taiwanese aborigines, to participate in medical research. Since the aboriginal communities in Taiwan usually lack adequate healthcare

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26 Anderlik, *supra* note 25.

27 APPLE DAILY (TAIWAN), May 22, 2005, at A1.

28 CHINA TIMES (TAIWAN), Nov. 4, 2003, at A9.

infrastructure and resources, this so-called "free health check" did attract a lot of inhabitants there. However, some of these researchers only used the free health check as a mere "bait" for promotional purposes, and they never returned any health check result to the aborigines. According to a news report, "one aborigine had been taken blood samples in the name of free health check from eight different research teams, but none of them ever told him the results," and "thereafter, these aboriginal communities strongly distrust any healthcare professionals and medical researchers."[29] The incident might actually involve a project that was explicitly intended to collect blood samples for research while at the same time promising to provide free health check. But the aborigine mentioned in the news report seems to be complaining, not only that he never received health check results, but also, worse still, that he was unaware that the health check was offered by people intending to collect blood samples.

Even the research practices of some very prestigious institutions should have paid more careful attention to ethical concerns about this unsettling mixture of sample collection with free health check. For instance, the "Super Control" study—a small-scale biobank project—carried out by Academia Sinica in 2002-2003 leaves room for the suspicion that it has unnecessarily put emphasis on "free health check" in a promotional letter sent to potential participants before coordinators went to their houses to ask for their consent to participation. This letter was the only information the potential participants could receive about the project before the coordinators' visits, but it only briefly mentioned the purposes and nature of the research after, in the very first paragraph, highlighting provision of "free health check."[30] Intentionally or not, the information provided in the letter could be misleading and unduly influence lay people's perceptions of, and their decision on, participation in the research. In addition, the practice of visiting potential participants' houses directly and asking for their consent to participation right at the first visit is also questionable, because it is rather intrusive and may not give them enough opportunity to consider the content, nature, and risk of the research. Academia Sinica may be in charge of the future Taiwan Biobank project; for this reason, its past research practices and relevant ethical issues should be carefully re-examined before inauguration of the project.

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29 CHINA TIMES (TAIWAN), Mar. 19, 2001, at 11.

30 INSTITUTE OF BIOMEDICAL SCIENCES, ACADEMIA SINICA, MANUAL FOR COORDINATORS' TRAINING IN THE SUPER CONTROL STUDY 76 (2002).

Moreover, the Taiwan Biobank project might collaborate with local hospitals and community physicians in collecting blood samples and medical records. The project should take great care not to put the physicians in a conflict of interest situation mentioned above. It must be noted that not only does physicians' conflict of interest tend to violate patients' autonomy, but it also tends to cause harm to patients because the physicians' professional judgement on the well-being of their patients may be compromised by their other roles or interests.[31] Some even worry that clinical care may be manipulated to meet the needs of the biobank.[32]

In the U.S., many regulations and court decisions have been made to control these conflict of interest situations. For instance, in a 1990 landmark case, Moore v. Regents of the University of California,[33] the Supreme Court of California stated that

> we hold that a physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment.

By contrast, Taiwanese physicians, biomedical researchers, and policy makers seem to be unaware that the conflict of interest issue could be very important from the perspectives of public trust and participants' autonomy and safety. In the past ten years, there has been only one article whose title contained the term "conflict of interest" and discussed this issue in a biomedical context.[34] Many physicians and dentists are insensitive to this issue, and a few of them even publicly recommended healthcare products and toothpaste in TV advertisement on behalf of some

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31 At times the consequence can be serious. For instance, in 1999 an American boy, Jesse Gelsinger, died because of the complications of an experimental gene therapy treatment administered by a physician who was a primary stakeholder in a biogenetics company that would stand to profit from the experiment and new technology. In fact, this physician's employer University of Pennsylvania also had financial interest in relation to the experimental study so there was an institutional conflict of interest too. *See* Lynne Smith & Jacqueline Byers, *Gene Therapy in the Post-Gelsinger Era*, 4 JONA'S HEALTHCARE LAW, ETHICS & REGULATION 104 (2002).

32 Anderlik, *supra* note 25.

33 793 P.2d 479 (Cal. 1990).

34 Daniel Fu-Chang Tsai (蔡甫昌), *Conflict of Interest in Medical Healthcare*, 48 JOURNAL OF TAIPEI MEDICAL ASSOCIATION 35 (2004).

pharmaceutical companies. As collaboration between industry and academia has been increasing, and the distinction between private and public sectors is blurred in the area of biomedical research, conflict of interest situations will be seen more often.[35] Thus, in the future, the government and/or professional groups in Taiwan should enact regulations or guidelines to require researchers to disclose their conflict of interest to research participants and institutional review board (IRB)—in fact, this requirement is already provided in articles 13 and 22 of the World Medical Association (WMA) Declaration of Helsinki.[36] Other monitoring mechanisms and ethical training programs for researchers may also be necessary.

4. The Inevitable Commercial Involvement v. the Necessity of Benefit Sharing

Though commercialization of biomedical research may have an adverse impact on public trust and the protection of participants' autonomy and safety, commercial involvement in biobanking is inevitable and even necessary. First of all, one of the main objectives of population genetic research is to develop new drugs and treatments for human diseases. The pharmaceutical industry will inevitably be involved in the process, and it will play a crucial role in the translation of results from basic research into tangible products and procedures that may benefit individuals and society.[37] Moreover, as discussed in a previous section, because of the large scale of biobank projects, they need a lot of funding, logistic support and technical collaboration. In every country that plans to establish a population-based biobank, the public sector increasingly depends on private industry to fund and participate in the research.

While commercial involvement in biobanking is inevitable and even necessary, this article has argued that we should curb the conflict of interest situations and design a mechanism that monitors the researchers' conduct and protects the participants' safety. Moreover, in order to ensure potential participants' autonomy and public trust, participants and the public need to be made aware that there may be possibilities for commercial exploitation in addition to any benefits for all, such as improvements in

35 Henderson & Smith, *supra* note 23; Kolata, *supra* note 15.

36 World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (2000).

37 Sheremeta, *supra* note 11.

healthcare. If researchers always appeal to the "common good" to lead the public's attention away from possible (or even inevitable) commercial involvement, then public trust and support will surely decline.

Nevertheless, merely requiring disclosure of conflict of interest, adherence to proper procedures for informed consent, and establishment of monitoring mechanisms may not be enough to gain donors' trust and increase public support of biobank research. These measures seem to be basically negative: "it can only stop unethical or unwanted research from being undertaken, but cannot pro-actively steer the usage of a DNA bank."[38]

This article argues that we should give more attention to positive measures for sharing benefits with the participant population.[39] For one thing, as biobanks rely both on donors' altruism and government support for their establishment, and the public invests a significant degree of trust in the researchers and/or their commercial partners, it is necessary to design a mechanism to vindicate this trust and let the operation of biobanks match the donors' altruism by managing and using the biobanks at least in part for the common good. As far as the researchers solicit sample donations from the public by appealing to altruistic motivation, they have a responsibility to ensure that biobanks will be used for publicly endorsed ends.[40] Benefit-sharing arrangements made before collection of samples may also ensure public trust and support because potential participants can actually know what the "common good" will be.

There is another important reason for sharing benefits with the sampled population(s). In the context of large-scale biobanking, important interests of various communities may reasonably be held to be at stake. Although personal identifiers of samples collected and stored in a biobank will be encrypted, subsequent research using the samples and genetic information derived from them will often depend on the availability of group identities—such as ethnic, gender, and occupational identities—of sample sources. Although such research holds promise for enormous

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38 Williams & Schroeder, *supra* note 19, at 98.

39 Please note that this article argues the necessity of benefit sharing with the participant *population*, not the *individual participants.*

40 Williams & Schroeder, *supra* note 19, at 97.

improvements in medical knowledge and healthcare services, it also raises serious concern that publicized research results and their implications about the genetic and environmental factors in the etiology of diseases might foster stigmatization and unjust discrimination against vulnerable communities. Since the whole population(s) may assume a risk, it is equitable that there should also be a population benefit. Benefit-sharing mechanism balances the commercial interests with interests (and burdens) of sampled populations in a way that both pays due respect to, and reflects fairly, the relative contribution of whole populations to the research endeavour.[41]

Some biomedical researchers and companies may argue that their commercial success will automatically lead to the "common good," because the improved knowledge, new drugs and new treatments developed from biobank data already count as benefits to the entire society. However, this article would rebut this argument by noting that vulnerable participant communities, such as aboriginal or poor ones, will never actually benefit from the pharmaceutical companies' new drugs or treatments as long as they cannot afford them, as they very likely cannot if no appropriate measures are taken for sharing the fruits of genetic research using biobank resources. What these communities lack may be a basic healthcare infrastructure and some fundamental medical services. It is highly doubtful that the new drugs or knowledge can benefit them and improve their conditions without social arrangements that meet the demands of distributive justice.

Recently, benefit sharing in genetic research, especially in biobank research, has gradually become an emerging legal requirement in international law.[42] Many international documents, such as the HUGO Ethics Committee "Statement on Benefit Sharing" (2000), the WHO report of "Genetic Databases: Assessing the Benefits and the Impact on Human & Patient Rights" (2003), and the UNESCO "International Declaration on Human Genetic Data" (2003), have strongly called for benefit sharing with participant populations in genetic studies. Nevertheless, benefit sharing can take different forms and is subject to varying societal and cultural values. It is not necessarily monetary. What constitute "benefit" and "sharing" would depend on needs,

41 Sheremeta, *supra* note 11; Mylène Deschênes & Geneviève Cardinal, S*urvey of National Approaches to the Development of Population Genetic Biobanks*, http://cbac-cccb.ca (Mar. 2003).

42 *Id.*

values, priorities, and cultural expectations. The public should be consulted on the issue of benefit sharing before collection of samples gets under way.

Some biobank projects already made arrangements for benefit sharing. For instance, in Iceland, deCODE and Roche reached an agreement that should Roche develops any products as a result of the database research, it would provide these products free of charge to Icelanders during the period of patent protection.[43] In Canada, Newfound Genomics promised to return a percentage of net profits to an independent foundation set up by the company for the population.[44]

It is noteworthy that article 19 of the UNESCO "International Declaration on Human Genetic Data" (2003) provides the following:

> [B]enefits resulting from the use of human genetic data, human proteomic data or biological samples collected for medical and scientific research should be shared with the society as a whole and the international community. . . . [B]enefits may take any of the following forms: (i) special assistance to the persons and groups that have taken part in the research; (ii) access to medical care; (iii) provision of new diagnostics, facilities for new treatments or drugs stemming from the research; (iv) support for health services; (v) capacity-building facilities for research purposes; (vi) development and strengthening of the capacity of developing countries to collect and process human genetic data, taking into consideration their specific problems; (vii) any other form consistent with the principles set out in this Declaration.

Such provision requires not only that benefits from genetic research using population biobanks be shared within a society, but also that they be shared internationally. Although this requirement of global justice may sound too high-minded, it is one that developing countries should not fail to press, on grounds of reciprocity or even of the

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43 Greely, *supra* note 6.

44 Bartha Maria Knoppers, *Population Genetics and Benefit Sharing*, 3 COMMUNITY GENETICS 212, 214 (2000).

human genome as "common heritage," if they involve themselves in collaboration with other countries in the collection and utilization of human genetic samples.

The author of this article wants to stress at this point the importance of grounds of *reciprocity* for benefit sharing. Large-scale biobanking creates a cooperative scheme which involves not only research institutions and profit-seeking companies, but also the population(s) from which individual sample sources come. Even if recruitment appeals to altruistic motivation on the part of donors so that they should expect no material gains in return for themselves as individuals, demands for benefit sharing with the sampled population(s) as a whole are ethically justified because every *cooperative* scheme yields benefits and burdens that must be distributed fairly or equitably, on grounds of reciprocity, among stakeholders involved in the scheme. This notion of a cooperative scheme as created by large-scale biobanking and sustained through reciprocity points further to the need of public consultation, in addition to individual consent, on any large-scale biobank project through properly designed democratic procedures of public deliberation.[45]

5. Conclusion

Most attention to biobanks from an ELSI perspective has been focused on issues of informed consent, privacy, and data security. This article argues that we should pay greater attention to issues related to the trend of commercialization of biomedical research and to the increasingly important but difficult problems raised by conflict of interest. In addition, the tension that seems hard to avoid between commercial involvement and the appeal to altruism of the general public may, if not adequately dealt with, adversely affect public trust and support. The author believes that benefit sharing with populations involved is essential if such a tension is to be resolved or lessened in an acceptable way, and public trust and support to be ensured.

In the future, the administrator or custodian of Taiwan Biobank should consider reaching an agreement with each company that applies for using the data in the biobank, and the agreement should include an article which provides that the company

[45] Terence Hua Tai (戴華), *Informed Consent and Benefit Sharing in the Context of Human Biobanking*, paper presented at the 2005 ELSI Symposium on the Legal Implication of Biobanking, Aug. 09, 2005, Taipei.

shall share benefit with Taiwanese society as a whole, to ensure that Taiwanese people receive the “common good” they have been promised.

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