

行政院國家科學委員會專題研究計畫 期中進度報告

Law and Ethics of Biomedical Research in the Post-Genomic Era--後基因體年代之生醫研究倫理及法制：利益衝突問題之類型、影響及其應有規範(1/3)
期中進度報告(精簡版)

計畫類別：整合型

計畫編號：NSC 97-3112-H-004-001-

執行期間：97年05月01日至98年04月30日

執行單位：國立政治大學法律科際整合研究所

計畫主持人：劉宏恩

報告附件：出席國際會議研究心得報告及發表論文

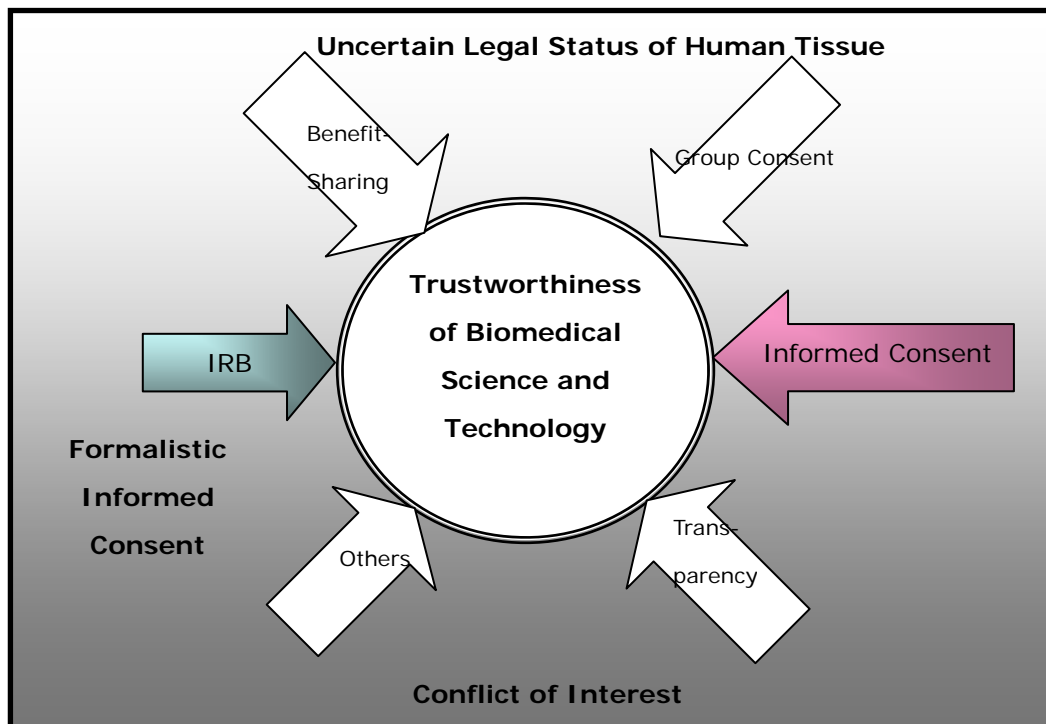
處理方式：本計畫涉及專利或其他智慧財產權，2年後可公開查詢

中華民國 98年02月28日

期中進度報告(精簡版)

Law and Ethics of Biomedical Research in the Post-Genomic Era: Exploring the Types, Implications, and Regulations of “Conflict of Interest” Issues

This project is a component of the program project “Law and Ethics of Biomedical Research in the Post-Genomic Era: Proposing a Structure of Accountability.” The research question and mechanisms we intend to study can be expressed as the following:



The “formalistic informed consent,” “uncertain legal status of human tissue,” and “conflict of interest” in biomedical research are the three major ethical and legal issues identified by the program project. Though “IRB” and “Informed Consent” have been taken as the solution for these issues, we intend to explore whether, in terms of improving accountability, they are insufficient in the post-genomic era and examine other mechanisms such as those of “transparency,” “group consent,” and “benefit-sharing.” This component project focuses its exploration and examination on the issue “conflict of interest.”

Abstract:

In the past two or three decades, one of the features of biomedical research has been the dramatic increase of industry support. As collaboration between industry and academia has been increasing, and the distinction between private and public sectors seems to be blurred in the area of biomedical research, conflict of interest situations will be seen more often.

Conflicts of interest are situations where financial and/or other personal considerations have the potential to compromise or bias professional judgment and objectivity. The “interest” does not necessarily mean “financial interest,” and a conflict of interest can happen at both individual and institutional levels. Conflict of interest issues are important not only because they may lead to harm to particular research participants, but also because they may damage scientific integrity and the pursuit of the truth. On a social level, they may reduce the trust and confidence that people generally have in research.

This project will focus on the conflict of interest situations that happen in human subjects research in biomedicine and health science, and it will pay special attention to the proper roles, responsibilities, and professional conduct of researchers. The overall goal of this project is to propose a structure of accountability that can ensure the protection of research participants, the performance of researchers’ professional responsibilities, and the objectivity and integrity of science. To accomplish that, this project needs to explore the nature and causes of conflicts of interest, examine their different types and possible different implications, analyze the existing policies/regulations that respond to these implications, and finally propose a policy and a workable mechanism if the foregoing analyses find the existing ones insufficient.

Methodology

Instead of studying “law in books,” this project will attempt to study the “law in action” and put issues in actual contexts of a particular society. In order to achieve so, it mainly adopts three research methods.

(1) Case Study Method: Some significant conflict of interest cases offer great opportunities for case studies. In Taiwan, many news and incidents in biomedical field also involve conflict of interest issues worth further analysis. Official documents and relevant news reports and articles from authoritative sources will be reviewed and cross-examined.

(2) Interview Research: This research will attempt to interview some biomedical researchers in Taiwan to explore their experiences and opinions in conflict

of interest situations.

(3) System-Centered Comparative Legal Studies: Traditional comparative legal studies are usually rule-centered or text-based comparison, but this project adopts a system-centered or socio-legal approach to conduct the comparative studies.

Findings and Discussions:

In this year, in order to grasp the nature, causes, types, and current regulatory status of conflicts of interest, this project has asked and tried to answer the following questions:

- What are the nature and causes of conflicts of interest?
- What are the types of conflicts of interest?
- What are the current policies and regulations on conflicts of interest in some countries where biomedical research thrives?
- Are there any significant conflict of interest cases in biomedical field in Taiwan and other countries? What do these cases reveal?

Preliminary findings show that, since 1980s, medical research collaborations between industry and academia have been increasing substantially. In the U.S., many high-profile adverse events involving biomedical researchers with significant financial interests in the results of their studies have aroused more concerns about the risks of conflict of interest situations, and therefore more regulations for controlling these situations have been promulgated. In Canada, Australia, and Europe, conflict of interest issues have also drawn more and more attention. It is noteworthy that though the U.S. seems to have more regulations on relevant issues than do the other countries, many commentators in the U.S. still believe that the existing regulations fail to adequately manage the conflict of interest problems in biomedical research and that additional measures are needed to ensure the protection of research participants and scientific integrity.

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.

While the guidelines provided by some professional groups and government controls of conflicts of interest in the U.S. focus only on financial interests, there are more and more concerns about non-financial (intangible) conflict of interest issues, especially the issues of physicians' involvement in biomedical research. 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. 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.

In Taiwan, only a few incidents have attracted attention on relevant issues. 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 participants' safety, public trust, and scientific integrity. In the past ten years, in addition to an article written by the PI of this project, there has been only one article whose title contained the term "conflict of interest" and discussed this issue in a biomedical context. Two unpublished conference papers have also coped with conflict of interest issues in scientific research, but not in the biomedical field specifically. In contrast to Taiwan government's recent plans for promoting biotechnology and encouraging the collaboration between industry and academia, this insensitivity to and ignorance of conflict of interest issues seem to be very improper.

In this year, the PI has conducted three case studies on conflicts of interest in Taiwanese medical profession. The first is the case of the former President's son-in-law Dr. Chao who received remuneration from a biotech company. The second is the case of several Taiwanese dentists who promote and make TV commercials for a specific brand of anti-sensitivity toothpaste. The third is the case of a physician who conducted a clinical trial on his own patients without proper informed consent. Preliminary finding shows that, in Taiwan, the general public and most medical professionals obviously confuse conflicts of interest with bribery and corruption and are unaware of non-financial conflict of interest situations such as physicians' involvement in biomedical research.

The preliminary finding of this study has been presented at the following conference, and is being revised for submission:

- Hung-En Liu, *Some Case Studies on Conflicts of Interest in Taiwanese Medical Profession*, the 9th World Congress of Bioethics, Sep. 3rd-8th, 2008, Rijeka, Croatia.

The following published papers have also discussed some possible conflict of interest issues in biobank (especially the Taiwan Biobank) research:

- Hung-En Liu, *Right and Duty in Biobank Research: Balancing Individual Autonomy and Social Justice*, 月旦法學雜誌, 161 期 (2008.10) .
- *Public Trust, Commercialization, and Benefit Sharing: Towards a Trustworthy Biobank in Taiwan*, in HUMAN GENETIC BIOBANKS IN ASIA: POLITICS OF TRUST AND SCIENTIFIC ADVANCEMENT (Margaret Sleeboom ed., Dec. 2008), London: Kegan Paul. (with Terence Hua Tai)

出席國際學術會議心得報告

| | |
|-------------------|--|
| 計畫編號 | 97-3112-H-004-001 |
| 計畫名稱 | 後基因體年代之生醫研究倫理及法制：利益衝突問題之類型、影響及其應有規範(1/3) |
| 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 | (1) Aug. 20-23, Rotterdam, The Netherlands. (2) Sep. 3rd-8th, 2008, Rijeka, Croatia. |
| 會議名稱 | (1) 2008 4S (Society for Social Studies of Science) Annual Meeting (2) The 9th World Congress of Bioethics, |
| 發表論文題目 | Some Case Studies on Conflicts of Interest in Taiwanese Medical Profession |

一、參加會議經過及與會心得

本次至荷蘭及克羅埃西亞參與兩個國際研討會，是與同一整合型計畫「後基因體年代之生醫研究倫理及法制」之其他子計畫主持人楊秀儀教授、雷文政教授共同前往參與。出發之前，我們整合性計畫內部曾多次聚會，共同討論每個人即將前往發表的論文。八月二十日首先抵達荷蘭鹿特丹參與「科技之社會研究」學會 (Society for Social Studies of Science, 4S) 的 2008 年全球年會。本次 4S 年會並與歐洲相關學會 European Association for the Study of Science and Technology 聯合舉辦，規模及國際多元性都相當驚人，總共有約兩百五十場次的論文發表與討論會，分散在將近三十個會議室舉行。本研討會的總主題 “Acting with Science, Technology and Medicine”，跟我們整合型計畫的主題密切相關，所以有非常多論文場次都令我們感到興趣。但因為同一時段有二十幾場次同時舉行，我們只能選擇特別相關的場次參與。我參加了 “Different Kinds of Translation: How Genomics Challenges Health Care”、 “Ethics as Practice in Science and Technology”、 “Regulating Emerging Technologies: Subpolitics in the Making”、 “Assisted Reproductive Technologies and New Perceptions of the Body” ... 等約十個場次。這個研討會是典型的跨領域研討會，論文作者及與會來賓包括社會學、歷史學、自然科學、法律學、哲學.... 等各個領域的學者，其中有非常多與會者長期參與科技與社會 STS 的研究。我個人深切感受到：我們從事 ELSI 研究的學者有非常多可以跟 STS 學者合作，或是向他們學習的地方。例如經驗實證的研究方法，對於歷史上許多現象演變的追蹤及文化意涵的分析。許多 STS 的方法與視角，對我們 ELSI 研究極有啟發性；對我們法律學者而言，尤其提供了極為寶貴的思考脈絡。此外，參與這次研討會讓我有機會與舊識 Margaret Sleeboom 等數位國際學者再次碰面與交換意見，是另一收穫。

同一赴歐行程中，九月三日我們抵達克羅埃西亞參與第九屆世界生命倫理年會 (9th World Congress of Bioethics)。其規模及國際多元性同樣令人印象深刻，但相較於之前於荷蘭參與的會議，克羅埃西亞的主辦單位顯然在行政協調方面比較欠缺經驗。本次會議的總主題為 “The Challenge of Cross-Cultural Bioethics in the 21st Century”，特別強調跨文化或不同文化的比較觀點，有非常多有趣的論文場次。我個人共計參與了 “Ethics of Clinical Trials”、“Ethics in Clinical Genetics”、“Cultural Bioethics”、“Law and Cultural Diversity”....等數個場次的討論，比較特別的收穫是：得以有機會認識東歐、南亞等國家的現況及 ELSI 研究者。在台灣，關於美國、西歐等所謂第一世界國家的文獻資料很容易取得，但是我們對於發展中國家的情形及研究成果極為陌生～不只是對於距離較遠的東歐如此，甚至對於距離台灣較近的菲律賓及印度的 ELSI 議題，我們也都幾乎毫無所悉。我自己的論文發表是在九月六日下午的場次，論文題目為 “Some Case Studies on Conflicts of Interest in Taiwanese Medical Profession”。坦白說，並不是每一位與會者都對台灣的狀況特別感興趣，但從討論中也可發現：隨著生物科技帶來的商機，「利益衝突」問題在世界各國都逐漸受到更多重視。此外，參與這次研討會讓我有機會與 Alastair Campbell 等數位國際學者再次碰面與交換意見，是另一收穫。

二、個人發表論文摘要：

Some Case Studies on Conflicts of Interest in Taiwanese Medical Profession

Hung-En Liu

National ChengChi University
Taipei, Taiwan

Conflicts of interest are situations where financial and other personal considerations have the potential to compromise or bias professional judgment and objectivity. Relevant issues are important in medical profession not only because conflicts of interest may lead to harm to particular patients or research participants, but also because it may damage professional and scientific integrity. On a social level, it may reduce the trust and confidence that people generally have in medical profession. In Taiwan, only a few incidents have attracted attention on relevant issues, and most physicians, biomedical researchers, and policy makers still seem to be unfamiliar with them. In this paper, the author conducts three case studies on conflicts of interest in Taiwanese medical profession. The first is the case of the former President's son-in-law Dr. Chao who received remuneration from a biotech company. The second is the case of several Taiwanese dentists who promote and make TV commercials for

a specific brand of anti-sensitivity toothpaste. The third is the case of a physician who conducted a clinical trial on his own patients without proper informed consent. This paper concludes that, in Taiwan, the general public and most medical professionals obviously confuse conflicts of interest with bribery and corruption and are unaware of non-financial conflict of interest situations such as physicians' involvement in biomedical research. In contrast to Taiwan government's recent plans for promoting biotechnology and encouraging the collaboration between industry and academia, this insensitivity to and ignorance of conflict of interest issues seem to be very improper.