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論文 REVIEW ARTICLE

藥物基因體學的倫理、法律與社會議題：以種族考量、利益共享與專利、隱私個資保護為例

The Ethical, Legal and Social Issues of Pharmacogenomics: Considering Race, Benefit Sharing and Patents, and Privacy and Personal Data Protection as Examples

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摘要

精準醫療（precision medicine）希望透過瞭解個別病人的不同基因型、生物特徵和生活習慣，來提供對每位病人更為有效或是可避免對之造成副作用的治療方式。其中在用藥方面，很重要的是透過藥物基因體學（pharmacogenomics）的研究，依照不同病人的基因型來評估藥物選擇或劑量調整，藉以對之達成最佳療效，並降低其發生藥物不良反應的風險。雖然理論上及臨床上，藥物基因體學可能使藥物的使用更具效益，也可能更為安全，然而這個領域也有許多重要的倫理、法律與社會議題需要思考，並有許多國際組織或學會對之提出了相關的倫理準則及宣言。本文以這個領域中的「種族或族群」、「利益共享及專利」、「隱私與個人資料保護」等爭議為例，針對相關議題的爭點及其脈絡加以探討分析。(生物醫學 2025;18(4):353-368)

關鍵字：精準醫療、藥物基因體學、種族、族群、利益共享、專利、隱私、個人資料

Abstract

Precision medicine aims to provide more effective and less harmful treatments for individual patients by understanding their unique genetic makeup, biological characteristics, and lifestyle factors. In the area of medication, an essential component is pharmacogenomics, which involves studying how a patient's genetic profile affects their response to drugs. This approach helps guide the selection and dosage of medications to achieve optimal therapeutic outcomes while reducing the risk of adverse drug reactions. Although pharmacogenomics theoretically and clinically holds the potential to make pharmacotherapy more effective and safer, the field also raises a number of important ethical, legal, and social issues. Numerous international organizations and academic societies have issued relevant ethical guidelines and declarations in response. This article explores and analyzes key controversies and contextual factors within this field, focusing on issues such as race and ethnicity, benefit-sharing and patents, and privacy and personal data protection. (BioMedicine 2025;18(4):353-368)

Keywords: precision medicine、pharmacogenomics、race、ethnicity、benefit sharing、patent、privacy、personal data

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前言

精準醫療 (precision medicine) 希望將個體分類為在特定疾病易感性或對特定治療反應上有所不同的子群體，以便將預防或治療干預集中於那些能受益的人，並避免對無益者造成費用負擔和副作用。其中藥物基因體學 (pharmacogenomics) 藉由基因體技術及基因變異分析來評估不同病人對藥物的不同反應。藥物基因體學可能會為藥物的開發和處方提供相當大的助益，使之得以有效治療疾病，也可能避免開出對某些人幾乎沒有臨床效果或產生不良反應的藥物[1]。雖然理論上及臨床上，藥物基因體學可能使藥物的使用更為安全、更具成本效益，而且它也可能有助於提供新的診斷和治療資訊；然而，這個領域也有若干重要的倫理、法律與社會議題需要探討[2]，國際上並有許多文獻、專業組織準則、甚至國際宣言在在提醒：這個領域的研究者及臨床實務工作者不能輕忽這些屬於價值目標、政策規範及社會影響層面的問題，否則藥物基因體學企求的一些良善目的可能會無法真正實現，或是可能造成原先預期之外的新的問題。本文以下藉由議題導向的方式做論述，以種族或族群議題、利益共享及專利議題、隱私與個人資料保護議題為例，分析這個領域中幾個重要的倫理、法律與社會爭議。

Introduction

Precision medicine aims to classify individuals into subgroups with different susceptibilities to specific diseases or different responses to specific treatments, in order to focus preventive or therapeutic interventions on those who can benefit, while avoiding costs and side effects for those who would not benefit. Within this field, pharmacogenomics uses genomic technologies and genetic variation analysis to evaluate different patients' responses to medications. Pharmacogenomics may provide substantial benefits for drug development and prescription, enabling effective disease treatment while potentially avoiding prescribing medications that have little clinical effect or adverse reactions for certain individuals.[1] While theoretically and clinically, pharmacogenomics may make drug use safer and more cost-effective, and may help provide new diagnostic and therapeutic information, this field also has several important ethical, legal, and social issues that need to be examined.[2] International literature, professional organization guidelines, and even international declarations repeatedly remind us that researchers and clinical practitioners in this field cannot ignore these issues related to value objectives, policy regulations, and social impact dimensions. Otherwise, the well-intentioned goals of pharmacogenomics may not be fully achieved, or new, unforeseen problems could arise. This paper will use an topic-based approach to discuss and analyze several important ethical, legal, and social controversies in this field, using racial or ethnic issues, benefit sharing and patent issues, and privacy and personal data protection issues as examples.

1 Munir Pirmohamed, *Pharmacogenomics: Current Status and Future Perspectives*, 24 NATURE REVIEWS GENETICS 350 (2023).

2 何建志，藥物基因體學之政策與法律議題分析，法律與生命科學，4期，2008年1月，1-17頁。

藥物基因體學中的「種族」或「族群」議題

藥物基因體學的許多研究或臨床實務，可能涉及的「種族」或「族群」議題。國際醫藥市場上，的確有一些基於種族或族群而做治療或處方的藥物；臨床上或研究上，也曾發現不同種族／族群可能有不同的藥物反應或副作用。例如：美國食品和藥物管理局 (FDA) 於 2005 年批准了以 BiDil 為商品名的藥物，作為一種針對非洲裔美國人治療心臟衰竭的種族特異性藥物。又例如：長期以來，臨床指南都建議高血壓且無併發症的黑人患者在治療初期，使用噻嗪類利尿劑 (thiazide diuretic) 或鈣通道阻斷劑 (CCB)，而非血管張力素轉換酵素抑制劑 (ACEI) 或血管張力素受體阻斷劑 (ARB) 這些其他非黑人患者經常獲得處方而可以使用的藥物[3]。此外，一種用於治療血小板減少症的藥物 (商品名 Eltrombopag) 對東亞患者的推薦起始劑量低於所有其他患者。類似的情形又如：美國 FDA 建議亞洲患者使用一種用於降低血脂的他汀類藥物 (商品名 Crestor) 的較低起始劑量，這是基於一種造成代謝變異性的基因，儘管這種基因可能存在於任何族群中。再例如：標靶治療藥物 Iressa 是一種用於治療肺癌的藥物，儘管最初的臨床試驗顯示對美國患者的療效較低，但臨床上卻發現似乎顯著改善了亞洲患者的整體存活率，基因醫學研究顯示這跟基因變異有關：亞洲人的非小細胞肺癌患者當中有 EGFR 基因的突變者達 30~40%；歐美白種人患者有此突變的約只佔 10~15%[4]。

Race and Ethnicity Issues in Pharmacogenomics

Many pharmacogenomics research studies and clinical practices may involve issues related to "race" or "ethnicity." In the international pharmaceutical market, there are indeed some medications whose treatment or prescription is based on race or ethnicity; clinically and in research, different races/ethnic groups have been found to potentially have different drug responses or side effects. For example, the U.S. Food and Drug Administration (FDA) approved a drug with the brand name BiDil in 2005 as a race-specific medication for treating heart failure in African Americans. Another example: clinical guidelines have long recommended that Black patients with uncomplicated hypertension initially be treated with thiazide diuretics or calcium channel blockers (CCBs), rather than angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs) which are commonly prescribed medications used by other non-Black patients.[3] Additionally, a drug used to treat thrombocytopenia (brand name Eltrombopag) has a lower recommended starting dose for East Asian patients compared to all other patients. Similarly, the U.S. FDA recommends a lower starting dose of a statin medication for lowering blood lipids (brand name Crestor) for Asian patients, based on a gene that causes metabolic variability, although this gene may be present in any ethnic group. Another example is the targeted therapy drug Iressa used for treating lung cancer - although initial clinical trials showed lower efficacy in American patients, it was found to significantly improve overall survival rates in Asian patients clinically. Genetic medical research shows this is related to genetic variation: 30-40% of Asian non-small cell lung cancer patients have EGFR gene mutations, while only 10-15% of European and American white patients have this mutation.[4]

3 Hunter K. Holt et al., *Differences in Hypertension Medication Prescribing for Black Americans and Their Association with Hypertension Outcomes*, 35 JOURNAL OF THE AMERICAN BOARD OF FAMILY MEDICINE 26 (2022).

4 Paez JG et al., *EGFR Mutations in Lung Cancer: Correlation with Clinical Response to Gefitinib Therapy*, 304 SCIENCE 1497 (2004).

上述考量種族或族群而進行藥物基因體學的研究，或是有不同治療／處方的方式，於理論、方法或是臨床治療上，確實有其正面的價值與意義。因為國際上過去既有的基因體研究或基因醫學的相關資料或數據，在研究對象所屬族群的多樣性方面向來有很大改進空間，既有的資料與數據絕大多數僅以歐洲血統來源的族群為研究對象，因此是否能一般化推論而適用於非歐洲血統來源的病人，往往存有很大疑問[5]。加強納入其他種族或族群的病人為研究對象，可以增加基因資料及分析的多樣性，來平衡上述歐洲血統來源資料的過度代表性的問題。但值得注意的是，也有許多研究指出：以病人所屬「種族」或「族群」為研究分析上的類別或治療時的考量，可能有倫理與社會上的疑慮，甚至有時可能有害於病患利益。首先，對於以歐洲血統來源以外的其他種族為對象的基因醫學研究，目前在招募研究參與者時，通常是使用其自我陳述的種族（self-reported race）作為個體資料歸類的種族。然而「種族」或「族群」的概念，究竟有多少是社會建構的，或是有多少是屬於身分或文化認同的（這在許多人都可能有一些自知或不自知的混血血統來源時猶為明顯），而又有多少是真的基於生理上的差異？即使生理上有所差異又有多少真的是遺傳或基因變異造成的種族差異？有很多基因科學的研究顯示：許多種族內部的成員之間於基因上的差異，往往大於不同種族與種族之間的差異，生物科學上根本難以用基因型來界定不同種族[6]。

The aforementioned pharmacogenomics research that considers race or ethnicity, or employs different treatment/prescription methods, indeed holds positive value and significance in theory, methodology, and clinical treatment. This is because existing international genomic research and genetic medicine data has long presented significant opportunities for improving the diversity of study subjects' ethnic groups, with the vast majority of existing data being based on subjects of European descent, thus raising significant questions about whether findings can be generalized to patients of non-European descent.[5] Strengthening the inclusion of patients from other races or ethnic groups as research subjects can increase the diversity of genetic data and analysis, helping to balance the over-representation of European-descent data. However, it is worth noting that many studies have pointed out that using patients' "race" or "ethnicity" as categories for research analysis or treatment considerations may raise ethical and social concerns, and may sometimes even be harmful to patient interests. First, for genetic medical research targeting races other than those of European descent, participant recruitment currently typically uses self-reported race as the basis for individual data classification. However, how much of the concept of "race" or "ethnicity" is socially constructed, or tied to identity and cultural identification (especially evident when many individuals have known or unknown mixed ancestry), versus how much is truly rooted in physiological differences? Even when physiological differences are present, to what extent are they genuinely caused by genetic variations between races? Many genetic science studies have shown that genetic differences between members within the same race are often greater than differences between races, making it fundamentally difficult to define different races by genotype in biological science.[6]

5 Dragan Primorac et al., Pharmacogenomics in Clinical Practice 357 (2024).

6 蔡友月，科學本質主義的復甦？基因科技、種族／族群與人群分類，台灣社會學，23期，2012年6月，155-194頁。

簡言之，關於以種族或族群為類別的藥物基因學研究，在方法學上，事實上是將個體分組的方式決定了被歸因於這些不同組族群的基因頻率，而不是基因頻率分布決定了如何將個體做分組。研究參與者的自我陳述的種族類別，究竟是否能夠反映其於基因型上的類別，以這樣的種族「歸類」方式做基因變異的類別的研究或對之採取不同治療方式／藥物處方，是否有時候容易忽視種族內部的不同病人的差異，而有潛在可能不利於某些病人？這是近年來許多研究對之提出的既是屬於科學方法上的，也是屬於倫理及政策上的挑戰。舉例而言，關於前面提到的對於高血壓患者中的黑人族群給予有別於白人族群的第一線治療與用藥方式，其臨床指引固然有過去的一些臨床試驗數據做依據，但是 2022 年一份針對舊金山灣區 10,875 位高血壓病患兩年的電子健康記錄資料的大規模分析卻顯示：該指引可能會限制黑人病患的治療選擇，導致延遲達到最佳血壓控制，實證資料發現基於種族的處方是無效的、不必要的，長遠來說甚至可能對黑人病患不利的；該研究指出：「種族」無法替精準醫學提供有效的差異化代表，高血壓藥物的選擇應該因人而異，而不是以種族為考量，而且輕易以「種族」為考量來差異化治療或用藥方式，會忽略掉其他可能比種族更重要的因素，例如劑量、添加第二或第三種藥物、用藥依從性以及飲食和生活方式干預、後續照護等等。該研究也指出：病人是否缺乏健康食物、住房不穩定、社會孤立和付費困難等社會和環境因素，可能比他屬於哪個種族值得更多關注[7]。

In short, regarding pharmacogenetic research that categorizes by race or ethnicity, methodologically, the grouping of individuals actually determines the gene frequencies attributed to these different ethnic groups, rather than gene frequency distribution dictating how individuals should be grouped. Whether research participants' self-reported racial categories can truly reflect their genotypic categories, and whether using such racial "classification" methods for studying genetic variations or implementing different treatment methods/drug prescriptions might sometimes easily overlook differences between patients within the same race and potentially disadvantage certain patients - these are both scientific methodological and ethical/policy challenges raised by many recent studies. For example, regarding the previously mentioned first-line treatment and medication approach that differs between Black and White hypertensive patients, while the clinical guidelines are based on past clinical trial data, a large-scale analysis in 2022 of two years of electronic health records from 10,875 hypertensive patients in the San Francisco Bay Area showed that these guidelines might limit treatment options for Black patients, leading to delays in achieving optimal blood pressure control. Empirical data revealed that race-based prescriptions were ineffective, unnecessary, and could even prove detrimental to Black patients in the long term. The study indicated that "race" cannot provide effective differentiation for precision medicine, hypertension medication choices should be individualized rather than race-based, and that easily using "race" as a consideration for differentiating treatment or medication approaches overlooks other potentially more important factors, such as dosage, addition of second or third medications, medication adherence, dietary and lifestyle interventions, and follow-up care. The study also pointed out that social and environmental factors such as whether patients lack access to healthy food, have housing instability, social isolation, and payment difficulties may deserve more attention than their racial classification.[7]

7 Hunter K. Holt et al., *supra* note 3.

本文建議：藥物基因體學的研究者及臨床工作者應該要謹記在心，這個領域真正關注的是病人「個體」與「個體」之間的基因差異及其因此可能的不同藥物反應或應有治療方式。至於「種族」至多只是基因型的粗略代表，絕對不能以之取代精準醫療或個人化醫療的真正目標，亦即個體化的用藥與治療，以至於忽略了即使所謂「同一種族」之內的個體往往可能有很大差異，不能夠基於種族的粗略區分而逕自使病人失去治療的選擇，或是逕自假設某種用藥方式或是治療一定對某種族的成員都可能比較有利。畢竟，如果個人化醫療僅僅是沿著種族界線來劃分病人的風險等級或治療方式，那麼它不但可能有時不利於病人，甚至可能進一步加劇目前存在的一些社會不平等。

最後，關於種族或族群的藥物基因體學研究，必須注意：「世界生醫倫理與人權宣言」第 6 條第 3 項特別建議，研究若是以某個群體／族群為對象，在適當情形下，除了取得參與者的個人同意外，還可尋求該群體／族群之合法代表們的同意。我們若是考量到個人與所屬族群可能有共通的遺傳組成，而該遺傳組成屬於族群的共同資產，而且基因研究所得的發現很可能影響或適用於整個族群；因研究而造成的歧視或標籤化很可能影響整個族群，並不只是參與者個人。那麼，這樣的建議確實有合理性。我國《人體研究法》第 15 條規定：「以研究原住民族為目的者，除依第 12 條至第 14 條規定外，並應諮詢、取得各該原住民族之同意；其研究結果之發表，亦同。」原住民族委員會與衛生福利部因此在 2015 年 12 月會銜發布《人體研究計畫諮詢取得原住民族同意與約定商業利益及其應用辦法》，可資參照。

This article suggests: Pharmacogenomics researchers and clinical practitioners should keep in mind that this field truly focuses on genetic differences between individual patients and their potentially different drug responses or appropriate treatment methods. As for "race," it is at most a rough proxy for genotype and absolutely cannot replace the true goals of precision medicine or personalized medicine, namely individualized medication and treatment, to the point of overlooking that even individuals within so-called "same race" often may have significant differences. We cannot, based on rough racial distinctions, arbitrarily cause patients to lose treatment options, or arbitrarily assume that certain medication or treatment methods will definitely be more beneficial to members of certain races. After all, if personalized medicine merely divides patients' risk levels or treatment methods along racial lines, it may not only sometimes be disadvantageous to patients but may further exacerbate existing social inequalities.

Finally, regarding pharmacogenomics research on race or ethnicity, it must be noted that Article 6.3 of the Universal Declaration on Bioethics and Human Rights specifically suggests that for research targeting specific groups/ethnicities, in appropriate circumstances, besides obtaining individual participants' consent, the consent of the legal representatives of that group/ethnicity may also be sought. If we consider that individuals and their ethnic groups may share common genetic compositions, and that these genetic compositions belong to the group's collective assets, and that genetic research findings are likely to affect or apply to the entire group; discrimination or stigmatization caused by research likely affects the entire group, not just individual participants. Then, such suggestions indeed have rationality. Article 15 of our country's Human Subjects Research Act stipulates: "Research targeting indigenous peoples shall, in addition to complying with Articles 12 to 14, consult with and obtain consent from the respective indigenous peoples; the same applies to the publication of research results." The Council of Indigenous Peoples and the Ministry of Health and Welfare therefore jointly issued the "Regulations for

利益共享（benefit sharing）及專利議題

藥物基因體學之所以得以發展，必須倚賴病人或一般民眾捐出的基因檢體。然而，民眾是基於公益心而無償捐出檢體，科學家及醫藥業者經過研發與試驗之後，藉由產品化（例如基因檢測或個人化用藥產品）而得以營利，甚至可以將民眾檢體中分析出的基因序列申請為自己的專利，這是否會有倫理與政策上的疑慮？從美國 2003 年 Greenberg v. Miami Children’s Hospital 訴訟案的事實，似乎可以看得出來為何這可能成為公平性或分配正義問題的爭議。本案中，遺傳疾病 Canavan's Disease 的病友及家屬成立了非營利團體，對邁阿密兒童醫院無償貢獻了自己的時間、心力、金錢以及在世和已故病患的細胞組織，他們與醫院研究人員密切合作，致力於找出這種遺傳疾病的原因，並希望開發出一種檢測方法。最終，該醫院開發出對於該疾病的基因檢測，並將之申請專利，而該醫院因此可以就病人或民眾接受該基因檢測而營收獲利，其中也包括該非營利團體的病友或家屬去接受基因檢測時所須付的費用也同樣成為該醫院營收獲利的一部份。曾與研究人員密切合作、提供自己患病的孩子的檢體給醫院的 Greenberg 家族認為：他們和其他病友是無私、利他的基於「公益」而貢獻基因檢體和自己的心力時間，但最後卻成為該醫院的「私益」，而且該醫院的專利會限制該基因檢測的普及可能性，這與病友們當初同意參與的公益初衷有違且違反公平。本案法院最後判決醫院部分敗訴，認為其確實有違反公平性的不當得利[8]。

8 Greenberg v. Miami Children’s Hospital Research Institute, 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

Consultation and Obtaining Indigenous Peoples' Consent and Benefit-Sharing Agreement in Human Research Projects" in December 2015, which can be referenced.

Benefit Sharing and Patent Issues

The development of pharmacogenomics relies on genetic samples donated by patients and the general public. However, while the public donates samples altruistically for the public good, scientists and pharmaceutical companies can profit through commercialization (such as genetic testing or personalized medicine products) after research and trials, and can even patent gene sequences analyzed from public samples - does this raise ethical and policy concerns? The facts of the 2003 U.S. case Greenberg v. Miami Children's Hospital seem to illustrate why this could become a controversy about fairness or distributive justice. In this case, patients with the genetic disorder Canavan's Disease and their families formed a nonprofit organization and freely contributed their time, effort, money, and tissue samples from both living and deceased patients to Miami Children's Hospital. They worked closely with hospital researchers to identify the cause of this genetic disease and hoped to develop a testing method. Eventually, the hospital developed genetic testing for the disease and patented it, allowing them to profit from patients and the public receiving the genetic test, including fees charged to members of the nonprofit organization and their families when they needed the genetic testing. The Greenberg family, who had worked closely with researchers and provided samples from their sick child to the hospital, believed that while they and other patients had selflessly and altruistically contributed genetic samples, time and effort for the "public good," it ultimately became the hospital's "private benefit." Furthermore, the hospital's patent would limit the accessibility of genetic testing, which contradicted the patients' original public interest intentions and violated principles of fairness. The court ultimately ruled partially against the hospital, finding that there was indeed unfair unjust enrichment.[8]

從上述 Greenberg 案例的事實及原告的主張來看，病人或民眾在意的可能並不是自己可以「抽成」分配到多少錢，而是在意「當初訴諸於我的公益心，由我無償捐贈提供檢體，但為何我的公益最後卻變成你的私益」的那種覺得自己公益心被利用、信賴感被違背的不合理之感。事實上類似的情形並不罕見，因為科學研發成果若要能進一步量產和普及應用，往往需要產品化和商業化，吾人不能期待科學家的研發成果僅僅停留於實驗室就能夠進一步獲得研發和較大規模應用。但是如此一來，要怎麼去平衡一方面訴諸病人或民眾的公益心請他們無償捐贈基因檢體，但另一方面又要讓利用檢體的研究者可以將研發成果取得私人商業利益，這兩者間可能對社會大眾造成的矛盾感或不信任感呢？如果這樣的矛盾感或不信任感無法被合理化解，事實上也可能影響民眾日後捐贈檢體提供研究的意願，並會影響社會大眾對於基因研究的支持。我們可以用捐血的例子來類比：「捐血一袋，救人一命」會讓很多民眾願意捲起袖子捐血，但如果社會大眾聽到的是「捐血一袋，幫研究者賺錢一袋」或是「捐血一袋，幫研究者多一專利」，那又還剩多少民眾同樣願意捐血呢？有鑑於這個問題的重要性，有

Looking at the facts and claims of the Greenberg case mentioned above, what patients and the public care about may not be how much money they can "take a cut of," but rather their concern that "you appealed to my sense of public good, I donated specimens freely, but why did my contribution to the public good end up becoming your private benefit" - that feeling of having their altruism exploited and trust betrayed. In fact, similar situations are not uncommon, because for scientific research results to be mass-produced and widely applied, they often need to be commercialized into products. We cannot expect scientific research results to achieve further development and larger-scale applications by remaining solely in laboratories. However, this raises the question: how do we balance appealing to patients' and the public's sense of public good to donate genetic specimens for free, while allowing researchers using these specimens to obtain private commercial benefits from their research results? What kind of contradiction or distrust might this create among the general public? If such feelings of contradiction or distrust cannot be reasonably resolved, it could actually affect people's willingness to donate specimens for research in the future and impact public support for genetic research. We can draw an analogy with blood donation: "Donate one unit of blood, save one life" motivates many people to roll up their sleeves and donate blood, but if the public instead heard "Donate one unit of blood, help researchers make money" or "Donate one unit of blood, help researchers get another patent," how many people would still be willing to donate blood? Given the importance of this issue, many international ethical declarations and guidelines from international organizations have provided clear guidance on the ethical issue of whether benefits from scientists' genetic research results should involve "benefit sharing." For example, Article 19 of UNESCO's International Declaration on Human Genetic Data adopted in 2003 explicitly stipulates the requirement for "benefit sharing": "Benefits resulting from the use of human genetic data, human proteomic data or biological samples collected for medical and scientific research should

許多國際性的倫理宣言或國際組織的倫理準則，都對於科學家進行基因研究的成果的利益是否應進行「利益共享」(benefit sharing) 的倫理問題，提出了明白的指引。例如聯合國教科文組織於 2003 年通過的「國際人類基因資料宣言」(International Declaration on Human Genetic Data) 第 19 條便明文規定「利益共享」的要求：「藉由使用為醫學和科研目的而採集的人類基因資料、人類蛋白質組資料或生物樣本，而獲得的利益，應根據國家的法律或政策及國際協定，為整個社會及國際社群共享」。而國際人類基因體組織 (Human Genome Organisation, HUGO) 的倫理委員會也曾於 2000 年通過「關於利益共享的聲明」(Statement on Benefit Sharing)，其內容強調：利益共享所稱之利益並不等同於金錢或經濟意義上的利潤，利益的決定取決於需求、價值觀、優先考量和文化期望；應事先和參與的個人和社群進行協商，事前討論應包括對於最終治療、研究出的預防和診斷產品的可負擔能力和可及性；所討論的實際或未來利益不應成為參與的誘因，不應以經濟利益之獲取來吸引個人或社群參與基因研究；在研究成果進行營利的情況下，一般的利益分配應該是捐出淨利潤 (稅後) 的某個百分比給醫療保健基礎建設，或用於疫苗、檢驗、藥物和治療，或捐贈給當地、國家和國際的人道主義工作[9]。

簡言之，國際上關於基因醫學研究的「利益共享」倫理原則，一方面考量到人類基因具有代代相承的人類共同遺產的性質，另一方面考量到取自於民眾公益捐獻的檢體資料所得的研究發現，應該確實具有 (至少部分) 回歸公益的性質在內，而不能夠完全成為科學家或業者營利的工具。「利益共享」原則並不認為科學家或業者不可以將研發成果商業化並有所營利，也不認為應

be shared with the society as a whole and the international community, in accordance with domestic law and international agreements." The Ethics Committee of the Human Genome Organisation (HUGO) also adopted a "Statement on Benefit Sharing" in 2000, emphasizing that: benefits referred to in benefit sharing are not equivalent to monetary or economic profits; the determination of benefits depends on needs, values, priorities and cultural expectations; prior consultation should be conducted with participating individuals and communities, with preliminary discussions including the affordability and accessibility of final treatments, preventive and diagnostic products developed; actual or potential benefits should not serve as inducements for participation, and economic benefits should not be used to attract individuals or communities to participate in genetic research; in cases where research results are commercialized, general benefit distribution should involve donating a percentage of net profits (after tax) to healthcare infrastructure, or for vaccines, testing, medicines and treatments, or donations to local, national and international humanitarian efforts.[9]

In short, the international ethical principle of "benefit sharing" in genetic medical research considers both the nature of human genes as humanity's common heritage passed down through generations, and the notion that research findings derived from specimens donated by the public for the public good should indeed have (at least partially) a public benefit nature, rather than becoming purely a profit-making tool for scientists or businesses. The "benefit sharing" principle does not suggest that scientists or businesses cannot commercialize research results and make profits, nor does it suggest that research benefits should only be shared with specimen donors and other private individuals. Rather, it hopes that research results derived from specimens donated altruistically by patients and the public should genuinely include an element of public benefit by giving back to society and communities as a whole.

9 HUGO Ethics Committee, *Statement on Benefit Sharing*, 58 CLINICAL GENETICS 364 (2000).

該將研究利益僅分享回饋給檢體提供者等少數私人，而是希望取材於病人或民眾的公益利他心的檢體的研發成果，應該確實具有將研究成果回饋給整體社會或群體的公益的成分。

本文前面提到了美國 Greenberg 案例，然而類似的爭議也曾經發生在台灣，例如：2010 年時，國內媒體以「我的血液 你的專利 原民被犧牲？」為標題，大篇幅報導國家衛生研究院一項以台灣原住民為研究對象，探討基因變異與痛風之間的關聯性的研究，發現了所謂的「痛風基因」，該計畫主持人並與國衛院向美國專利局申請該基因之專利，但是被研究的原住民以及原住民團體對之都事先不知情，計畫主持人受訪時並表示「不需要諮詢原住民同意」，引發人權團體及原住民團體的強烈抗議。事實上該案件是由一位加拿大學者向一個非營利國際組織舉發，本事件並衍生為國際性的生醫倫理爭議案例。基於社會各界的強烈質疑與批評，最後，計畫主持人及國衛院同意向美國專利局撤銷專利申請[10]。

關於針對人類基因序列或基因變異申請專利，國際上原本對之最早採取開放性態度的國家是美國，包括美國專利局及法院判決自 1980 年代起都持較為開放的態度，但是也一再引發倫理與法律上的爭議。包括發現 DNA 雙螺旋結構而獲得諾貝爾獎之華生 (James Watson) 便強烈抨擊：只是對於自然界存在的基因序列或變異的「發現」，根本沒有所謂的「發明」，沒有資格獲得專利。另一位諾貝爾獎得主、以線蟲細胞基因組研究聞名的蘇爾斯頓爵士 (John Sulston) 也強烈表達不能接受這樣子的專利。除了倫理上的反對意見，對基因醫學研究者或相關臨床實務而言，

10 王瑞伶、林秀美，我的血液 你的專利 原民被犧牲？聯合報，2010年3月22日，A5版。

While the Greenberg case was mentioned earlier in this article, similar controversies have also occurred in Taiwan. For example, in 2010, domestic media ran extensive coverage with the headline "My Blood, Your Patent: Are Indigenous People Being Sacrificed?" regarding a National Health Research Institutes study that used Taiwanese indigenous people as research subjects to investigate the relationship between genetic variations and gout. The study discovered the so-called "gout gene," and the project director along with the NHRI applied for a patent for this gene with the US Patent Office. However, the indigenous people who were studied and indigenous groups were not informed beforehand, and when interviewed, the project director stated that "there was no need to consult with indigenous people for consent," triggering strong protests from human rights groups and indigenous organizations. In fact, this case was reported by a Canadian scholar to an international non-profit organization, and it evolved into an international biomedical ethics controversy. Due to strong questioning and criticism from various sectors of society, the project director and NHRI eventually agreed to withdraw the patent application from the US Patent Office.[10]

Regarding patent applications for human gene sequences or genetic variations, the United States was initially the most open country internationally to this practice, with both the US Patent Office and court decisions maintaining a relatively open attitude since the 1980s, though this has repeatedly sparked ethical and legal controversies. James Watson, who won the Nobel Prize for discovering the DNA double helix structure, strongly criticized this practice, arguing that merely "discovering" gene sequences or variations that exist in nature does not constitute an "invention" and thus does not qualify for patent protection. Another Nobel laureate, Sir John Sulston, known for his research on nematode cell genomics, also strongly expressed his opposition to such patents. Beyond ethical objections, for genetic medical researchers and clinical practitioners, once a gene sequence or variation is patented by someone, it means that without authorization from the patent holder, other

一個基因序列或變異一旦被申請為某人的專利，就意味著若沒有取得專利權人的授權，其他研究者或臨床工作者若是去研發或施行該基因的基因檢測，將會構成專利侵權，可能嚴重影響關於該基因的進一步的研究與應用。因為其倫理上的重大爭議，也因為這類專利可能反而會限制進一步的醫學研究與應用，美國聯邦最高法院於 2013 年，針對原本擁有 BRCA1 和 BRCA2 等癌症基因的專利的 Myriad Genetics 公司，做出了 Association for Molecular Pathology v. Myriad Genetics, Inc. 的重要判決。該判決改變最高法院以往見解，轉採大幅限縮以基因或 DNA 序列申請專利的可能性的見解。該判決指出：自然發生的 DNA 片段是自然界的產物，不因為其經分離而具有可專利適格性，Myriad Genetics 公司並未創造或改變任何 BRCA1 和 BRCA2 基因編碼的遺傳資訊，即使該公司發現了一項重要且有用的基因，但該等基因從其週邊遺傳物質分離並非一種發明行為，故不具有可專利性。除非是人工合成的、非自然產物的 cDNA，才可能具有可專利性[11]。

最後，關於基因研究的商業利益及利益共享問題，本文認為特別值得我國藥物基因體學研究者及臨床工作者注意的是：我國《人體生物資料庫管理條例》第 21 條規定：「設置者及生物資料庫之商業運用產生之利益，應回饋參與者所屬之人口群或特定群體」；同法第 7 條亦明文規定：必須將「預期衍生之商業運用」列為取得檢體提供者同意的必要告知事項。此外，《人體研究法》第 14 條亦規定：研究主持人取得研究對象之參與同意時，必須以其可理解之方式告知「研究可能衍生之商業利益及其應用之約定」。這些規定都是我國法制採納前述國際宣言與國際倫理準

11 Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

researchers or clinical workers who develop or implement genetic testing for that gene would be committing patent infringement, potentially severely impacting further research and applications related to that gene. Due to these major ethical controversies and because such patents might actually restrict further medical research and applications, the US Supreme Court made an important ruling in 2013 in Association for Molecular Pathology v. Myriad Genetics, Inc., regarding Myriad Genetics, which originally held patents for cancer genes including BRCA1 and BRCA2. This ruling changed the Supreme Court's previous position, adopting an approach that greatly restricts the patentability of genes or DNA sequences. The ruling stated that naturally occurring DNA segments are products of nature and do not become patent-eligible merely by being isolated, noting that Myriad did not create or alter any genetic information encoded in the BRCA1 and BRCA2 genes. Even though the company discovered an important and useful gene, the separation of these genes from surrounding genetic material is not an act of invention, and therefore lacks patentability. Only artificially synthesized, non-natural products like cDNA may potentially be patentable.[11]

Finally, regarding the issues of commercial benefits and benefit sharing in genetic research, this article considers the following particularly noteworthy for pharmacogenomics researchers and clinical practitioners in our country: Article 21 of the "Human Biobank Management Act" stipulates that "the benefits generated from commercial applications by the operators and biobanks shall be fed back to the population or specific groups to which the participants belong"; Article 7 of the same law also explicitly states that "anticipated commercial applications" must be listed as a required disclosure item when obtaining consent from specimen donors. Furthermore, Article 14 of the "Human Subjects Research Act" also stipulates that when research directors obtain participants' consent, they must inform them in an understandable manner about "the potential commercial benefits of the research and agreements regarding their applications." These

則的要求，並希望避免國內外以往發生的社會爭議的立法結果，在世界各國的立法例中算是相當進步的立法，值得肯定[12]。

隱私與個人資料保護問題

病人或檢體提供者的隱私與個資風險，是基因醫學研究最主要的風險。而且病患或受試者的病歷、醫療、基因等健康資料不但屬於個人資料，而且屬於《個人資料保護法》 (簡稱個資法) 第 6 條所定，原則上禁止蒐集、處理、利用之「特種資料」，其資料保護更應受到重視。雖然我國藥物基因體學研究人員及醫療機構近年來多能遵循個資法規範，但仍有許多重要的概念需要釐清。

例如有關「去識別化」之用語與認定，常有混淆不清或誤解其內涵之情形，常有認為只要去除姓名、身分證字號、病歷號碼等直接可識別符碼 (direct identifiers) 便屬於已去識別化，甚至認為這些資料便不再是個人資料而不適用個資法。但此種看法誤解或忽略以下幾個重點：

(一) 個資法所稱之「個人資料」，不但包括可以直接方式識別出個人之資料，還包括可以間接方式識別出個人之資料。個資法第 2 條第 1 款對此有明確規定。

(二) 個人資料雖經處理並去除其姓名及證號等直接可識別符碼，但若依其資料型態、性質及處理方法，客觀上仍有還原其身分而得以識別出特定當事人之可能時 (如透過編碼對照、加密金

12 劉宏恩，基因資料庫研究中的公眾信賴、商業介入與利益共享，臺北大學法學論叢，57期，2005年12月，367-394頁。

regulations represent our country's legal system adopting the requirements of the aforementioned international declarations and ethical guidelines, aiming to avoid past social controversies both domestically and internationally. Among legislative examples worldwide, these can be considered quite progressive legislation worthy of recognition.[12]

Privacy and Personal Data Protection Issues

Privacy and personal data risks for patients and specimen donors represent the primary risks in genetic medical research. Moreover, patients' or research subjects' medical records, treatment, genetic, and other health data not only constitute personal data, but also fall under Article 6 of the Personal Data Protection Act (PDPA) as "special categories of data." The collection, processing, and use of such data are, in principle, prohibited, thus demanding enhanced data protection. Although pharmacogenomics researchers and medical institutions in our country have largely complied with PDPA regulations in recent years, there are still many important concepts that need clarification.

For example, regarding the terminology and determination of "de-identification," there are often confusions or misunderstandings about its implications. Many believe that simply removing direct identifiers such as names, national ID numbers, and medical record numbers constitutes de-identification, and even consider that such data is no longer personal data subject to the Personal Data Protection Act. However, this view misunderstands or overlooks several key points:

(1) "Personal data" as defined in the Personal Data Protection Act includes not only data that can directly identify an individual but also data that can indirectly identify an individual. Article 2, Paragraph 1 of the Personal Data Protection Act clearly stipulates this.

(2) Even when personal data has been processed to remove direct identifiers such as names and ID

鑰、與其他種類資料串連比對等，藉由特定方法還原而得以間接識別該個人)，則其仍然屬於個人資料並適用個資法。我國憲法法庭 111 年憲判字第 13 號憲法判決對之有明確闡釋。

(三) 不是只有姓名、證號等明顯可直接識別出個人之符碼在資料上面時才屬於個人資料；即使沒有包含這些明顯可識別符碼之資料，但若有住址、電話、電子信箱、指紋等符碼 (性質上仍屬於直接可識別符碼)，則仍然可能屬於個人資料。

(四) 基因 (如同指紋) 的本身便屬於直接可識別符碼。因此，若認為儲存病人基因資料時並沒有同時儲存該病人之姓名或證號，便因此認為該基因資料已經去識別化而非屬個人資料，此種講法在法律上與邏輯上均無法成立。這就好比：指紋的本身就是可識別身分的個資，我們不可能說儲存指紋時沒有同時儲存具有該指紋者之姓名證號，就認為該指紋已去識別化而非個人資料。

(五) 如果資料仍然保留還原識別個人身分之方法 (無論是資料持有者或資料提供者／處理者還保留該方法)，則僅是歐盟一般資料保護規則 (General Data Protection Regulation, GDPR) 所稱之假名化 (pseudonymization)，而假名化資料仍屬於可間接識別之個人資料。與其相對應者為匿名化 (anonymization)，亦即資料經處理後，其與可供辨識特定對象之個人資料、資訊已永久不能以任何方式連結或比對，即使是資料提供者／處理者亦無法還原其身分 (相當於我國人體研究法及人體生物資料庫管理條例所稱之「去連結」)，此時候方有可能不再屬於個人資料[13]。國內生醫領

13 吳全峰、許慧瑩，健保資料目的外利用之法律爭議——從去識別化作業工具談起，月旦法學雜誌，272期，2018年1月，45-61頁；劉靜怡，淺談 GDPR 的國際衝擊及其可能因應之道，月旦法學雜誌，286期，2019年2月15日，5-31頁。

numbers, if there remains an objective possibility of restoring identity and identifying specific individuals based on the data type, nature, and processing methods (such as through code matching, encryption keys, or cross-referencing with other types of data to indirectly identify the individual), it still constitutes personal data and is subject to the Personal Data Protection Act. This has been clearly interpreted by Constitutional Court Interpretation No. 13 of 2022.

(3) Personal data is not limited to information containing obvious direct identifiers like names and ID numbers; even data without these obvious identifiers may still be considered personal data if it contains codes such as addresses, phone numbers, email addresses, or fingerprints (which are by nature direct identifiers).

(4) Genetic information (like fingerprints) itself is a direct identifier. Therefore, the argument that genetic data is de-identified and no longer personal data simply because it is stored without the patient's name or ID number is neither legally nor logically valid. This is analogous to fingerprints: since fingerprints themselves are identity-identifying personal data, we cannot claim that fingerprint data is de-identified simply because it is stored without the name and ID number of the person to whom it belongs.

(5) If methods for restoring personal identity are retained (whether by data holders or data providers/processors), this only constitutes what the EU General Data Protection Regulation (GDPR) calls pseudonymization, and pseudonymized data remains indirectly identifiable personal data. In contrast, anonymization refers to data that has been processed so that it can never be linked or matched with personally identifiable information through any means, and even data providers/processors cannot restore identity (equivalent to "de-linking" as defined in our Human Subjects Research Act and Human Biobank Management Act) - only then might it no longer be considered personal data.[13] Domestic biomedical personnel sometimes confuse the

域人員有時會將「去識別化」與「去連結」的概念或用語相互混淆使用，誤將仍然間接可識別個人、有方法可以還原追溯個人身分的資料稱為「去連結」，或是概括泛稱「匿名化」卻僅僅只做到「假名化」，忽略了間接可識別資料仍然屬於個人資料，值得特別注意。

(六) 原始蒐集取得個人資料時，若未取得當事人同意、或是符合法律其他明文規定，則便已違反個資法；且此一違法事實與狀態，法律上無法透過事後將違法取得的個人資料予以去連結，便得以治癒或合法化。倘若先是違法蒐集取得個人資料，接著又自行擅自將之「去連結」處理，然後主張去連結後的資料已非個人資料，所以就可以自由利用，這樣的作法其實屬於違反個資法的行為。

(七) 常見有基因醫學研究者誤以為：採集人體檢體或血液僅可能有極為輕微的身體傷口或侵入，因此屬於「最小風險」，或甚至於受試者同意書中直接對受試者表示無風險。然而，基因研究真正的風險並不在於身體的傷口或侵入，而是在於隱私與個資保護等資訊風險與社會風險。而且，由於基因序列（尤其是基因體資料）的本身就是直接可識別符碼，可直接用於連結與辨識個人，所以其根本無從真正「去識別化」；而藥物基因體學研究涉及被研究對象的疾病與遺傳資訊，若是被保險公司掌握可能導致其被拒保或保費增加，被就業之資方掌握可能影響其求職或升遷，於婚友交往時被對方知悉可能影響其關係，此一領域相關的社會風險絕對不是屬於定義為

concepts and terminology of "de-identification" and "de-linking," mistakenly referring to data that can still indirectly identify individuals and whose identity can be restored through certain methods as "de-linked," or broadly claiming "anonymization" when only achieving "pseudonymization," overlooking the fact that indirectly identifiable data remains personal data. This deserves special attention.

(6) If personal data is originally collected without the subject's consent or compliance with other explicit legal provisions, it violates the Personal Data Protection Act; this illegal fact and status cannot be remedied or legitimized by subsequently de-linking the illegally obtained personal data. If one illegally collects personal data, then unilaterally performs "de-linking" processing, and claims that the de-linked data is no longer personal data and thus can be freely used, such practice actually constitutes a violation of the Personal Data Protection Act.

(7) Genetic medical researchers often mistakenly believe that collecting human specimens or blood only involves minimal physical wounds or invasion, thus constituting "minimal risk," or even directly stating to subjects in consent forms that there is no risk. However, the real risks in genetic research lie not in physical wounds or invasion, but in privacy and personal data protection, including information and social risks. Moreover, since genetic sequences (especially genomic data) themselves are direct identifiers that can be used to link and identify individuals, true "de-identification" is fundamentally impossible. Pharmacogenomics research involves subjects' disease and genetic information, which, if obtained by insurance companies, could lead to denied coverage or increased premiums; if obtained by employers, could affect job applications or promotions; and if known by potential partners, could affect relationships. The social risks in this field absolutely exceed what is defined as "minimal risk" of "general risks existing in daily life." In particular, unlike the United States, which has the Genetic Information Nondiscrimination Act explicitly prohibiting health insurance companies from

「日常生活存在之一般風險」的「最小風險」而已。尤其，我國並不像美國，在美國聯邦法律中有「基因資訊反歧視法」 (Genetic Information Nondiscrimination Act) 明文禁止健康保險公司僅基於個人基因資訊而對民眾拒保或提高保費負擔，也禁止雇主基於個人基因資訊而決定是否雇用、解職或升遷某位職員。民眾參與藥物基因體學研究或檢測時，於我國面臨的可能隱私與個資風險，是這個領域的研究者及臨床工作者絕對不能輕忽，也不應對受試者或病人輕易承諾「無風險」或「最小風險」的議題[14]。

結語

藥物基因體學的倫理、法律與社會議題，除了本文以上特別論述的三個問題外，當然還有其他重要議題。例如：藥物基因體學的病人基因體分析可能會有偶然發現 (incidental finding) 或附帶發現 (secondary finding)，亦即原本基因檢測目的 (某疾病風險或藥物反應) 以外的其他關於該病人健康或遺傳的基因變異的發現，攸關他其他的非原本檢測分析目的之疾病，或親子血緣關係。此時是否，以及若是的話應在什麼範圍內，藥物基因體學研究者或臨床工作者有倫理或法律上的義務去通知該病人這些偶然發現或附帶發現？應如何事先透過知情同意程序告知病人此等附帶發現的可能性並取得其同意[15]？又即使是原本檢測分析目的內的發現，考量到病人的基因變異極可能屬於其家屬所共有的遺傳，在其家屬亦可能有同樣的疾病風險或藥物副作用風險的情況下，則此時是否，以及若是的話應在什麼範圍內，藥物基因體學研究者或臨床工作者有倫理或法律上的義務去通知病人的家屬[16]？此外，藥物基

denying coverage or increasing premiums based solely on genetic information, and prohibiting employers from making hiring, termination, or promotion decisions based on genetic information, the privacy and personal data risks faced by people participating in pharmacogenomics research or testing in our country are issues that researchers and clinical practitioners in this field absolutely cannot ignore, nor should they easily promise subjects or patients "no risk" or "minimal risk."[14]

Conclusion

Beyond the three issues specifically discussed in this paper, there are certainly other important ethical, legal, and social issues in pharmacogenomics. For example, pharmacogenomic patient genome analysis may yield incidental findings or secondary findings - discoveries about the patient's health or genetic variations beyond the original genetic testing purpose (such as disease risk or drug response), which may relate to diseases not initially targeted for analysis or to parent-child blood relationships. In such cases, do pharmacogenomics researchers or clinical practitioners have an ethical or legal obligation to inform patients of these incidental or secondary findings, and if so, to what extent? How should the possibility of such secondary findings be disclosed to patients through the informed consent process to obtain their agreement?[15] Moreover, even for findings within the original scope of testing, considering that a patient's genetic variations are likely shared by their family members who may face similar disease risks or drug side effect risks, do researchers or clinical practitioners have an ethical or legal obligation to inform the patient's family members, and if so, to what extent?[16] Furthermore, pharmacogenomics research often requires large-scale human biobanks or genetic databases as research foundations or data sources, but the

14 劉宏恩，精準醫療的新瓶與舊酒：大型人體生物資料庫的國際發展脈絡、爭議與國際倫理規範，收於《台灣的後基因體時代：新科技的典範轉移與挑戰》，2019年。

15 Christian Netzer & Nikola Biller-Andorno, *Pharmacogenetic Testing, Informed Consent and the Problem of Secondary Information*, 18 BIOETHICS 344 (2004).

16 Béatrice Godard et al., *Guidelines for Disclosing Genetic Information to Family Members: From Development to Use*, 5 FAMILIAL CANCER 103 (2006).

因體學的研究經常需要大型的人體生物資料庫(Biobank) 或基因資料庫作為其研究基礎或資料來源，但這類大型基因資料庫的建置與運作，在世界各國都經常引發倫理、法律與隱私人權方面的疑慮，在台灣的相關資料庫亦多次產生社會爭議，甚至遭到監察院調查而被認為有倫理上或管理上的重要缺失[17]。這些也都是藥物基因體學重要的倫理、法律與社會議題。但由這幾個議題已經有許多文獻加以探討，也限於篇幅，本文因此將論述重點放在種族或族群議題、利益共享及專利、隱私與個資保護三個主題上。或許，必須是符合倫理與法律，並能避免社會爭議取得病人與民眾信賴，讓他們願意支持及參與的藥物基因體學與精準醫療，才有可能真正長遠發展，並達成其重要的目標：讓不同的病人能分別得到最適合的治療，避免對其不必要的風險 (包括社會與心理風險而非僅指生理風險)，進而使所有的病人與民眾都可以獲益。

establishment and operation of such large-scale genetic databases frequently raise ethical, legal, and privacy concerns worldwide. In Taiwan, related databases have repeatedly generated social controversies and have even been investigated by the Control Yuan, which found significant ethical and management deficiencies.[17] These are all important ethical, legal, and social issues in pharmacogenomics. However, as these issues have been extensively discussed in existing literature, and due to space limitations, this paper has focused on three topics: racial or ethnic issues, benefit sharing and patents, and privacy and personal data protection. Perhaps only pharmacogenomics and precision medicine that comply with ethical and legal requirements, avoid social controversy, and gain patient and public trust - encouraging their support and participation - can truly develop in the long term and achieve their important goals: enabling different patients to receive the most suitable treatments, avoiding unnecessary risks (including social and psychological risks, not just physiological ones), and ultimately benefiting all patients and the public.

17 羅雨恆，台灣人體生物資料庫違法蒐集疾病檢體 中研院爆內訌，壹週刊，808期，2016年，34-39頁；監察院，113教調0053調查報告：臺灣精準醫療計畫（Taiwan Precision Medicine Initiative, TPMI）調查報告，2024年12月；劉宏恩，同前註14。