

# 生物資料庫產出之 健康技術上的智慧財產權保護 對其捐贈者公益目的之追求 所造成的衝擊： 聚焦生物倫理層面 (二)\*

Biobank Donation in Search of Public Benefits and  
the Potential Impact of Intellectual Property Rights  
Over Access to Health-Technologies Developed :  
A Focus on the Bioethical Implications (II)

Aisling M. McMahon, Opeyemi I. Kolawole 著\*\*

胡芮萍 Ruei-Ping Hu \*\*\* 編譯



## 摘要

生物材料的可用性是健康研究及新健康技術（包括診斷、藥物和疫苗）開發的關鍵組成部分。生物資料庫

\*Aisling M. McMahon & Opeyemi I. Kolawole, *Biobank Donation in Search of Public Benefits and the Potential Impact of Intellectual Property Rights Over Access to Health-Technologies Developed: A Focus On The Bioethical Implications*, 32 MEDICAL LAW REVIEW 205-228 (2024), <https://doi.org/10.1093/medlaw/fwae010>

© The Author(s) 2024. Published by Oxford University Press.

This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<https://creativecommons.org/licenses/by/4.0/>), which permits unrestricted reuse, distribution, and reproduction in any medium, provided the original work is properly cited.

\*\*School of Law and Criminology, Maynooth University, Maynooth, Co. Kildare, Ireland

\*\*\*現職：美國紐約州執業律師（Practicing Attorney, JW Practice Group LLC）

經常鼓勵人們以利他主義為目的捐贈樣本。而實證證據表明，許多捐贈者的動機是為了貢獻社會，促進新健康技術的發展。然而，隨著健康技術開發，這些技術通常受到智慧財產權（包括專利）之保護，專利賦予權利人控制專利技術使用的權利，有時可能妨礙社會大眾對技術之接觸及使用。然而，歐洲現行法律並未強制要求捐贈者了解智慧財產權如何影響健康技術的後續使用，也未要求確保開發技術的社會大眾接近使用可能性。作者聚焦於生物倫理層面的挑戰，提出目前的狀況可能影響捐贈者的自主權與尊嚴利益，作者主張生物資料庫應採取更全面的捐贈策略，考量捐贈者從捐贈階段到樣本使用及技術可及性的預期與利益，並提出解決相關問題的建議。

The availability of biomaterials is a key component of health research and the development of new health-technologies (including, diagnostics, medicines, and vaccines). People are often encouraged by biobanks to donate samples altruistically to such biobanks. While empirical evidence suggests many donors are motivated by the desire to contribute towards developing new health-technologies for society. However, a tension can arise as health-technologies whose development is contributed to by donors' biomaterials will often be protected by intellectual property rights (IPRs), including patents. Patents give rightsholders control over how patented technologies are used and can be used in a way that impedes public access to technologies developed. Yet, there are no binding European legal obligations mandating disclosure to

關鍵詞：生物倫理（bioethics）、生物資料庫（biobank）、告知後同意（informed consent）、智慧財產權（intellectual property）

DOI：10.53106/241553062025080106006

donors of how IPRs can operate over downstream health-technologies and how they could impact access to health-technologies developed, nor are there legally binding obligations to ensure public accessibility of technologies developed. Focusing on the bioethical implications posed, this article argues that the current situation can impact donors' autonomy and dignity interests. A more holistic approach is needed for biobank donation, which embeds a consideration of donors' expectations/interests from the point of donation through to how such samples are used and how health-technologies developed are accessed. We put forward avenues that seek to address such issues.

---

本文上篇載於本報告第105期，112-136頁。

## 二、關於受智慧財產權保護之下游健康技術之公共可使用性之法律框架

若從生物資料庫之使用來看，目前歐洲尚無強制性法律要求權利人賦予捐贈者或生物資料庫對由此產生之智慧財產權相關的控制權，或強制要求確保使用生物資料庫樣本開發或促進受智慧財產權保護的下流技術之公共可使用性（public access）<sup>1</sup>。

現有一些一般性指導方針／建議鼓勵分享利益，例如，聯合國教育、科學及文化組織（United Nations Educational Scientific and Cultural Organisation, UNESCO）2005年《生物倫理與人權宣言》（Universal Declaration on Bioethics and Human

---

1 利益共享和生物庫方面，請參見Diane Nicol & Christine Critchley, *Benefit Sharing and Biobanking in Australia*, 21 PUBLIC UNDERSTANDING OF SCIENCE 534-555 (2011).