

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 (一)*

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 (I)

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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

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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

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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.

壹、介紹

人體生物材料（human biomaterials）之可近性是健康研究其中一項關鍵組成，對我們理解健康、疾病及後續治療、疫苗及診斷（下稱「健康技術」（health-technologies））¹之發展至關重要。生物材料之獲取可以通過科學研究招募參與者直接捐贈樣本（及相關數據），或者通過生物資料庫獲得，此處生物資料庫（biobank）是指「收集生物材料及相關數據與資訊，並存儲於有組織系統中的機構，適用於某一群體或其子

1 See generally: Sameer Al Diffalha, Katherine C. Sexton, Peter H. Watson & William E. Grizzle, *The Importance of Human Tissue Bioresources in Advancing Biomedical Research*, 17 BIOPRESERVATION AND BIOBANKING 209-212 (2019); Marianna J. Bledsoe & William E. Grizzle, *The Use of Human Tissues for Research: What Investigators Need to Know*, 50 ALTERNATIVE TO LABORATORY ANIMALS 265-274 (2022).