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Informed Consent and Participant Protection in Human Biobanks: Present and Future

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Abstract

Biomedical research has flourished in recent years due to the developmental needs of precision medicine, particularly through the establishment of human biobanks based on population cohorts or groups with specific diseases. Biobanks simultaneously collect biological samples, genetic information, and medical data, which significantly reduces the time and cost for participant recruitment for research and facilitates the linkage of biological and medical information from diverse sources. This has increasingly highlighted the importance of biobanks. In terms of participant autonomy, obtaining informed consent for biobanks differs from that for other types of human research. The distinct aspect of biobank participation lies in obtaining broad consent from participants, thereby placing greater emphasis on informing them about the biobank's operational mechanisms, future risks, and the impact of genetic information on the participants and their family. Consequently, the statutory requirements for biobanks regarding participant consent include more items than that for other human research; Article 7 of Taiwan's Human Biobank Management Act stipulates 17 items, exceeding the 9 items mandated for human research in the Human Subjects Research Act. Furthermore, while the physiological risks to participants in biobanks are relatively minor, other risks may seem abstract and distant, leading to their potential underestimation. Overall, ensuring participants' valid consent, complete understanding, and thorough comprehension should be undertaken from the participants' perspective to examine the explanation and consent obtaining process and whether participants can understand the information provided in the consent forms. Hence, suitable assessment methods for aiding participants' understanding should be developed. Currently, the informed consent process, including explanations in the consent forms and information disclosure, tends to be unidirectional and gives less consideration to the participants' perspective on the implications of participating in a biobank. Participant involvement is becoming more crucial as biobanks increasingly link more medical and nonmedical personal data; hence, confirming participants' genuine understanding is imperative. After all, informed consent as a means to protect participant autonomy hinges on their full understanding. Thus, incorporating varied approaches to uphold this principle is necessary.

Keywords: biobanks, autonomy, Informed consent, comprehension, research ethics

人體生物資料庫之知情同意與參與者保護：現在與未來

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摘要

近年來，由於精準醫療發展的需求，帶動生物醫學研究蓬勃發展，以人口群或疾病罹病者群體為基礎的人體生物資料庫因為同時蒐集生物檢體、基因資訊與醫療資料，可大量節省研究者於研究過程招募受試者的時間成本，而可方便於串連不同來源的生物或醫療資訊，因而越來受到重視。就生物資料庫的參與者自主權保障而言，取得參與者的知情同意(informed consent)，與其他人體研究略有不同。其不同之處在於，生物資料庫所取得的是參與者概括式同意(broad consent)因此，應告知事項更著重於生物資料庫本身運作機制、未來風險的告知、基因資訊對自己與家屬的影響等，也因此參與者同意書法定說明項目較其他人體研究更多，以我國的人體生物資料庫管理條例第7條規定應說明事項即有17項，超過人體研究法定應告知事項9項。其次，就參與者而言，參與生物資料庫面對的生理風險較小，但其他的風險又過於抽象遙遠，容易因此輕忽。整體而言，如何取得參與者有效的同意，完整的知情、充分的理解，應由參與者角度，檢視同意書提供的資訊是否適於理解，說明與取得同意過程，如何發展適合評估方式以參與者確認理解。現行知情同意的過程多較為單向，同意書的說明、資訊的告知較少由參與者角度思考參與生物資料庫的意義。當生物資料庫連結越來越多項目的醫療、非醫療個人資料資訊後，參與者參與將更為重要，亦即，如何確認參與者的真正理解。畢竟，知情同意作為保護參與者自主權，其要件之一即是充分理解，有必要與時俱進引入不同的作法。

關鍵詞： 人體生物資料庫、自主權、知情同意、理解、研究倫理