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Ownership of human biological material and the protection of research participants in the context of biobanking: a bioethical analysis

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OWNERSHIP OF HUMAN BIOLOGICAL MATERIAL AND THE PROTECTION OF RESEARCH PARTICIPANTS IN THE CONTEXT OF BIOBANKING: A BIOETHICAL ANALYSIS

ABSTRACT (NOVEMBER 2021)

The effectiveness of biobanks in supplying human biological material (HBM) for human health research depends on the provision of HBM by research participants.

International and South African policy and legislation on biobanking are not clear on ownership rights of research participants in "donated" HBM and hence, on the extent to which research participants have rights in their HBM.

This ethical and legal analysis of ownership of HBM explores how informed consent, material transfer agreements (MTA) and benefit sharing arrangements protect research participants. The ethical principles as they pertain to biobanking were analysed. The South African National Health Research Ethics Council MTA template was evaluated to determine the extent to which it protects research subjects and gaps were identified. Ownership of HBM was considered.

The study concluded that:

- The principles of autonomy, beneficence, non-maleficence and care should guide informed consent processes. The principle of distributive justice and communitarianism, particularly in communities where collective ownership is a societal value, should inform benefit sharing arrangements.
- The right to privacy must be respected in biobanking.
- The South African MTA, whilst not perfect, is an effective framework for protecting research participants and is in line with global best practice.
- An act utilitarian approach was identified as being the appropriate ethical theory to take account of and find a balance between the risks and benefits of research to all stakeholders and to protect research participants. Such an approach could take account of limitations on the autonomy of the consent process and the potential for failure to protect research participant privacy in biological research whilst benefitting the societal good.

Keywords

Biobanks, bioethics, human biological material, informed consent, material transfer agreements, ownership.