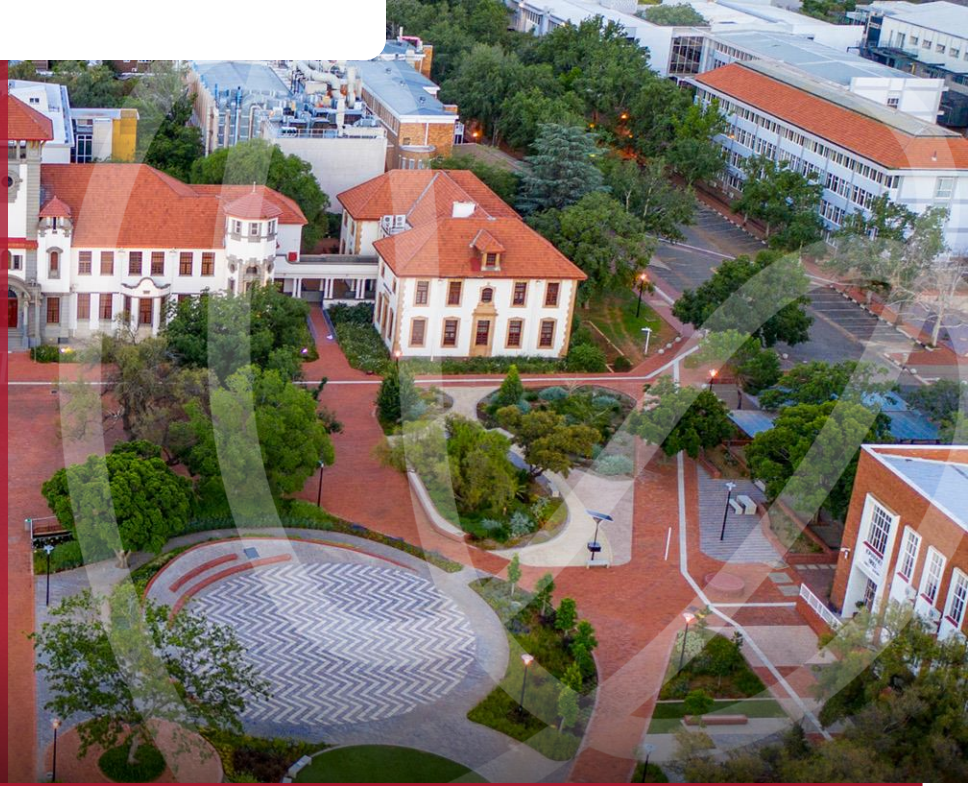
HUMAN AND ANIMAL BIOLOGICAL MATERIAL AND DATA FOR RESEARCH



2024 Third Edition
Chapter Four

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Introduction

This chapter discusses the ethical, legal, and practical considerations involved in the use of human biological material (HBM) and data in research.

It covers the collection, storage, and secondary use of HBM and data, as well as the unique aspects of genetic and genomic research.

It also addresses the use of animal biological materials and the importance of informed consent and ethical oversight in research involving HBM and data.

Use of human biological material (HBM)

Collection and storage:

HBM can be collected from living and deceased persons for diagnostic, therapeutic, research, and other purposes. Once collected, HBM and data may be stored in repositories for future research.

Ethical considerations:

Researchers and RECs must be sensitive to the values and beliefs of the donors. Consent documentation must clearly distinguish between clinical and research purposes.

Consent models for HBM collection

Specific consent:

For the current study only, with no storage or sharing.

Tiered consent:

Allows for current study and specified future uses.

Broad consent:

Permits storage and future research within the scope of the current study.

Secondary use of HBM and data

- **Conditions for secondary use**: New consent may be required if the scope of the current protocol differs from the original. If HBM or data are anonymised and pose minimal risk, new consent may not be necessary.
- **Ethical review**: RECs must review the secondary use of archived HBM and data.

Databases, storage and access

Databases, registries, and repositories

This section addresses the management of databases, registries, and repositories used for research, diagnostic, and clinical purposes. These platforms store valuable data that support current and future research, reducing duplication and fostering collaboration.

Types of repositories:
Institutional, governmental, discipline-specific, or generalist, each with unique data handling, oversight, and versioning systems.

Data security:
Repositories must ensure anonymisation, prevent re-identification, and provide high-quality, well-documented data.

Access models:
Vary from open (free access), restricted (limited to verified researchers), to controlled (with strict security measures).

Responsibilities of repositories:
Include clear terms of use, data management plans, and policies for data protection, ethical breaches, and fair attribution of credit.

Data security mechanisms:
Secure platforms, formal agreements, audit trails, and administrative safeguards to prevent misuse.

Trustworthiness:
Repositories must offer reliable, secure storage systems and protect participants' personal data.

Fair attribution of credit:
Emphasises proper citation of shared data to avoid plagiarism and ensure recognition for original researchers.

Sharing of human biological materials and data

Ethical balance: Sharing HBM and data must respect individual autonomy while enabling research benefits.

POPIA compliance: Transborder data sharing requires either similar legal protections in the recipient country, specific consent, or the necessity of contractual obligations.

Withdrawal of consent: Participants may withdraw consent, but anonymised data limits this right.

Material transfer agreements

Material transfer agreements (MTAs) are formal contracts that govern the sharing of **human biological materials (HBM)** between providers and recipients for research purposes, including clinical trials. MTAs are required whenever HBM is transferred between institutions or across borders.

An MTA should address the following:

- **Purpose of the transfer** of the HBM.
- **Obligations of the parties** involved.
- **Terms and conditions** for the use of the HBM.
- **Permissions for modifications** to the HBM.
- **Conditions for third-party transfers**.
- **Benefit-sharing arrangements** derived from the use of the HBM.
- **Intellectual property rights** related to research outcomes.
- **Indemnity arrangements** for legal protection.

While MTAs may include data-sharing terms, it is advisable to use a separate **data sharing agreement (DSA)** for data management, ensuring clarity and compliance with legal and ethical standards.

Data sharing agreements

Data sharing agreements (DSAs) are formal, binding contracts that govern the sharing of **data** between providers and recipients. DSAs specify the purpose of data sharing and the measures to prevent unauthorised use or breaches.

A DSA ensures

- **the protection of donor/participants' rights and interests;**
- safeguards against unauthorised data sharing and misuse;
- compliance with legal and ethical standards, including **Section 72 of POPIA** for cross-border data transfers;
- responsibilities for managing, storing, and destroying data as required;
- clear guidelines on the reuse of data, requiring prior approval;
- the protection of intellectual property rights; and
- that data shared for research purposes cannot be used for commercial gain without consent.

Genetic and genomic research

Genetic research: Studies specific genes and their effects on heredity and health.

Genomic research: Studies all genes in a genome and their interactions with the environment.

Ethical considerations: Include consent, privacy, confidentiality, and the impact on families and communities. Detailed protocols are required for ethical review.

Heritable Human Genome Editing (HHGE)

Scientific and medical justification: Must have a clear rationale focusing on preventing serious genetic disorders.

Transparency and informed consent: Essential throughout the research process.

Ethical oversight: Continuous ethical evaluation and adaptation are required.

Safety and efficacy: Prioritise safety and demonstrate scientific rigour.

Long-term monitoring: Continuous assessment of individuals born from HHGE interventions.

Informed Consent for Genetic and Genomic Research

Key elements: Include the purpose of research, storage and future use of HBM, privacy risks, and potential social harms.

Consent documentation: Must clearly explain the repository's purpose, data sharing conditions, and withdrawal rights.

Recontact of participants

Reasons for recontact: Include updating information, requesting further samples, and inviting participation in new studies.

Consent process: Must inform participants about the possibility and frequency of recontact.

Return of research results

- **Individual results**: Researchers must plan how and when to return results to participants, including incidental findings.
- **Ethical and logistical challenges**: Addressed through detailed protocols and participant consent.

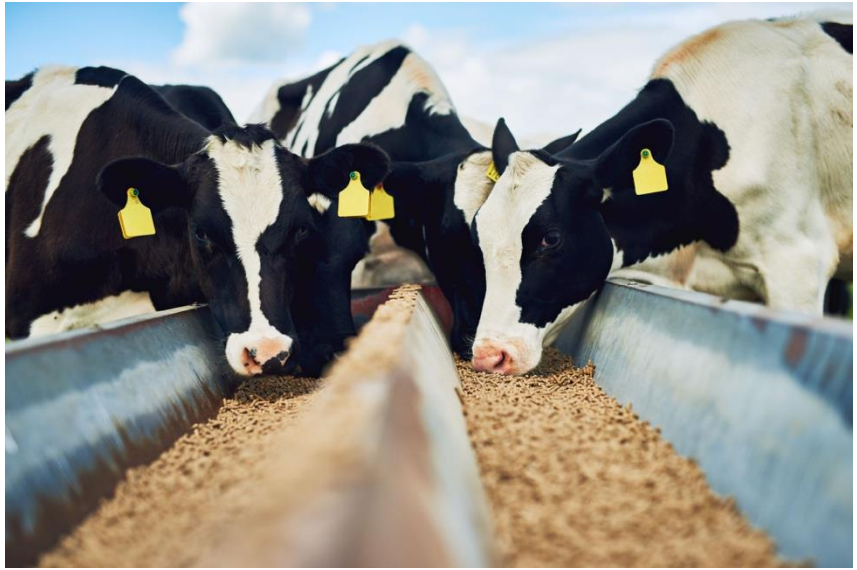
Considerations for identifiable populations and studies involving children

•**Identifiable populations**:
Address privacy, confidentiality, and potential discrimination risks.

•**Children in research**:
Consider the implications of revealing health risks and the right to receive research results upon reaching adulthood.

Use of animal biological materials

- **Principle of reduction**: Encourages optimal use and sharing of animal materials to maximise research benefits.
- **Ethical considerations**: Include the source of materials, biological safety, and sample integrity.
- **Secondary use**: Must be ethically obtained and legally compliant.



Conclusion

Key takeaways:	Ethical and legal frameworks are crucial for the responsible use of HBM and data.
	Informed consent and transparency are fundamental to maintaining trust and integrity in research.
	Continuous ethical oversight ensures that research adapts to new challenges and technological advancements.
	The balance between individual privacy and societal benefits must be carefully managed.

Final thoughts

The responsible use of HBM and data not only advances scientific knowledge but also respects the rights and dignity of participants.

Continuous dialogue between researchers, ethics committees, and the public is essential to address emerging ethical issues.

By adhering to ethical principles, researchers can contribute to meaningful and impactful scientific discoveries that benefit society as a whole.

- National Health Research Ethics Council (2024). South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, 3rd ed. National Department of Health of the Republic of South Africa. Pretoria: NDoH.
  Available from: https://www.health.gov.za/nhrec-home/