BDHP Biobanking Governance Framework

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Biobanks are powerful tools to enable medical, agricultural, and biodiversity research. The integration of existing tissue and environmental biobanks into collaborative research networks will advance scientific research by facilitating the collection, storage and analysis of highly valuable biospecimens (2016 National Research Infrastructure Roadmap). BDHP aims to capitalise on its existing biobanking networks and enhance this research capability.

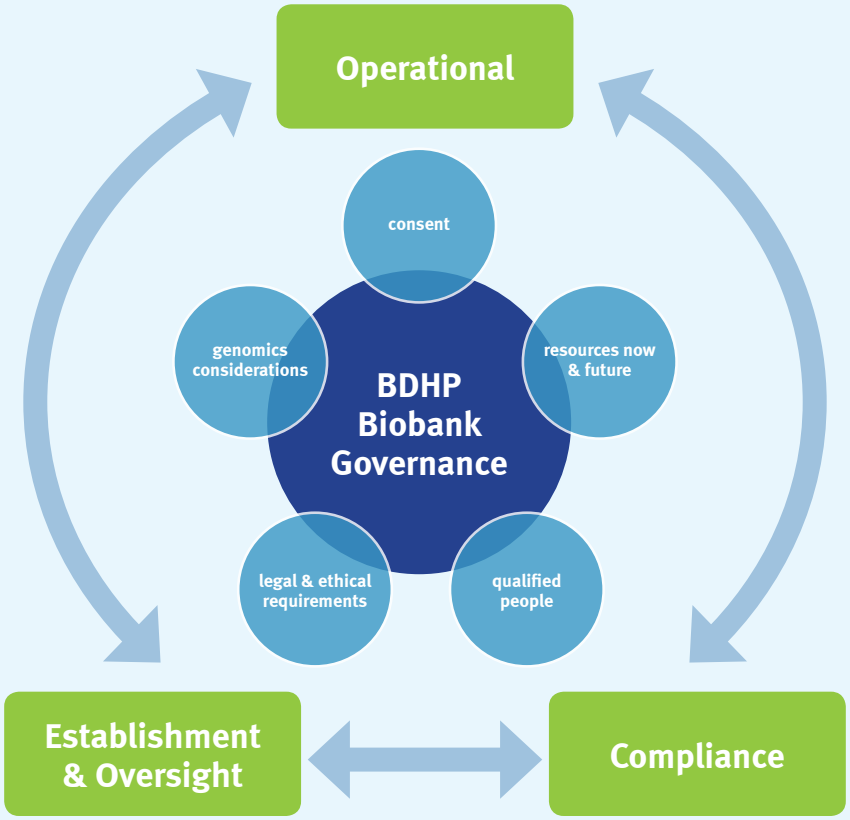
The breadth of BDHP biobanks provides an important opportunity to maximise research excellence and the potential for translating research outcomes into health care. Unified biobank governance within BDHP could improve efficiency and harmonise biobanking procedures.

The principles to achieve the uniformed governance are that a biobank;

- provide a valuable resource for researchers in partner organisations to advance our understanding of human health and disease
- harness synergies between partner organisations to provide a well governed, accountable and efficient capacity
- maximise researcher access to biological samples and associated data
- maximise collaborations between researchers, partner organisations, other research organisations and key stakeholders
- maximise collection of quality samples to increase opportunities for research and translation

The Governance framework is designed to support the establishment ,ongoing operation and compliance of a biobank with priorities of:

- Appropriate patient consent;
- Clear documentation of resources for now and into the future;
- Qualified people;
- Adherence to local / national / international legal / ethical/policy requirements;
- Special consideration for issues associated with genomics.



An agreed governance framework and principles can contribute to the quality and the success of a biobank by ensuring;

- Financial accountability and transparency
- Confidentiality of participants and security of data
- Quality of samples through optimal collection and storage processes;
- Harness synergies between existing and new biobanks, by establishing common approaches;
- Recommended compliance standards.

This document is a voluntary guideline for best practice for biobanking. Individual biobanks should comply with National and Queensland regulatory requirements.

The framework is based on the *Metro South Health Research Biorepository Governance Framework and international and national best practice documents, including- Guidelines for human biobanks, genetic research databases and associated data-Department of Health WA: Best Practices for Repositories (February 2010), and International Society for Biological and Environmental Repositories: NCI Best Practices for Biospecimen Resources (March 2016).*

Biobank Governance Framework
Establishment and Oversight

Appropriate patient consent; clear documentation of resources for now and into the future; qualified people; adherence to local / national / international legal / ethical/policy requirements; issues of genomics special consideration

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Governance Statements

1.1 Establishment of a Biobank

In establishing a biobank there should be:

- A clearly articulated objective and purpose.
- A Business plan outlining the scientific and financial feasibility and viability
- Governance and operational policies developed
- Organisational structures and charts with roles and responsibilities.
- Prior HREC approval.

The project should be considered within the context of the current BDHP research environment, avoiding duplication of existing and available specimens and data.

1.2 Governance, Oversight and Management

There should be clearly formulated and documented governance structure that includes:

- Operational and compliance roles and responsibilities
- Oversight mechanisms that ensure that relevant National and State legislation and international guidelines on, accountability and Best Practice Principles are adhered to (e.g. financial, scientific and ethical guidelines and policies).

The structure should be able to be subjected to independent ethical review or auditing

1.3 Oversight Committees and Compliance

There should be, at a minimum, an oversight committee whose role is to provide expert advice to support transparent and accountable operations of a biobank.

Any committee requires a defined Terms of Reference (TOR) and also document conflict of interests (COIs) for all members.

1.4 Ethics and Participant Information and Consent Form

The framework should include:

- Strategies to communicate required information under relevant statutory guidelines to each participant to ensure consent is informed
- Consent form written in clear, concise and simple language that describes the purpose, collection, storage, and use of biospecimens.
- Conditions of withdrawal indicated, including for unspecified future research, subject to any level of restriction by the participant and approved by an Ethics Committee
- Information regarding withdrawal from the project or return of material if requested
- Clearly articulated HREC process and note of approval

Standard Operating Procedures/Guidelines topics for consideration

1.1 Establishment of a Biobank

- Business Planning Considerations – Objectives & Purpose
- Research Protocol
- Consultation with consumers and stakeholders
- Scientific and Financial Feasibility - Financial Plan and Sustainability Strategy
- Resourcing Plan
- Roles and Job Descriptions and Curriculum Vitae
- Legacy Plan
- Research Biobanking Internal Governance Structure
- Standing Operating Procedures (Review and Approval of SOPs)
- HREC approval

1.2 Governance, Oversight and Management

- Corporate Governance Principles
- Internal Governance Structure
- Strategic Oversight Committee
- Management and Scientific Review Committees
- Regulatory Management
- Financial Management
- Operational Management
- International Guidelines, ISBER, NCI, IBBL,BiobankUK

1.3 Oversight Committees and Compliance

- Strategic Oversight Committee - Membership and Accountability, Responsibilities & Functions, Risk Management, Reviewing, Internal Compliance and Audit, Breach of Legislation and Policy/Procedure
- Scientific Advisory Committee – Strategic & scientific guidance, bio-specimen resource development and management.
- Access/Complaints Committee – guidance on access and use of biospecimens through development then assessment of criteria for research projects.

1.4 Ethics and Participant Information and Consent Form

- Understanding and Consent/Relationship with Participants
- Terms of Participation
- HREC Process
- Unlimited consent
- Hereditary diseases
- Genetics & Incidental Findings (National Statement)
- Obtaining Confidentiality Disclosure Agreements
- Genome Analyses
- Study Design and Statistical Approach

Biobank Governance Framework
Operational

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Governance Statements

2.1 Operational Arrangements

A biobank requires detailed policies and procedures to cover the overall operational considerations including:

- Defined roles and responsibilities for all staff and students (either directly employed or assisting as part of other employment or study- this excludes third party employees eg private pathology, couriers) involved in the operation and management of the biobank.
- All relevant staff and students should be adequately trained to perform the tasks required, and training programs should be developed to meet standard requirements for accreditation.

2.2 Acquisition, Attainment and Recruitment

The aim of a biobank is to collect and maintain high quality biospecimens for research to advance our understanding of human health and disease. The operational model determined during the establishment of the biobank should specify the type of biospecimens to be collected, method of attainment and how the participants will be recruited. Detailed procedures on the biobanking services, operating models, and patient recruitment processes should be developed.

2.3 Facility, Equipment, Storage and Security

In the planning of the design of a biobank the following should be considered;

- Sample type
- Storage requirements
- Length of the project and project growth of the samples
- Equipment purchasing and replacement schedules.
- Security of samples and equipment.
- Compliance with relevant organisational purchasing agreements

Standard Operating Procedures/Guidelines topics for consideration

2.1 Operational Arrangements

- Ownership, Custodianship and the Gift Relationship
- Management and Staffing – Director/ Custodian, Personnel Supervision, Quality Management System, Contracted Laboratory Services, Outsourcing Services, Research Manager
- Qualifications and Training – Qualifications, Training, Training Program, Trainers, Training Coordinator, Frequency of training, Cross-Training, Training Documentation, Training Records
- Infrastructure and Facilities
- Cost Management - Sustainable Funding Considerations, Identifying and Defining Costs, Cost Analysis, Financial Gain/Income Generation, Incentives, Cost Recovery/ Offset and Royalties, Financial Review and Financial Supervision i.e. Committee
- Commercial Research/Working with Industry
- Intellectual Property
- Benefit-sharing, Acknowledgement and Publication

2.2 Acquisition, Attainment and Recruitment

- Organisational Considerations
- Determination of Services to be Provided
- Tissue Attainment Service
- Tissue Banking Service
- Population-Based Collections
- Virtual Repositories
- Project Specific Collections
- Recruitment
- Acquisition, National and International, PQ AQIS - Permit to Import Quarantine Material
- Use of Diagnostic Samples/Pathology Archives Surplus to Clinical Requirements

2.3 Facility, Equipment, Storage and Security

- Facility - Heating, Ventilation and Air Conditioning, Lighting, Flooring, Backup Power
- Equipment and Storage Conditions - Liquid Nitrogen Freezers, Vapour or Liquid Storage, Storage Containers, Liquid Nitrogen Supply, Oxygen Sensors, Mechanical Freezers, Refrigerators, Ambient Temperature Storage, Dry Ice, Walk-in Environmental Storage Systems
- Equipment Maintenance, Repair and Replacement – Calibration, Verification of Equipment Functionality, Equipment Preventative Maintenance and Repair, Repair vs. Replacement
- Security – Access, Visitor Access SOP, Security Systems, Intrusion Detection Systems, Biosecurity

Governance Statements

2.4 Collection, Processing, Handling and Retrieval

There are common elements to specimen collection, processing, handling and retrieval processes, which enable maintenance of the highest quality biospecimens for research. An individual biobank may collect and process many different types of specimens (e.g., solid tissue, blood, DNA, RNA) from the same patient in a variety of ways.

Guidelines on the specific responsibilities and detailed methods should be available for staff to ensure uniformity of practice, thus guaranteeing the high quality and usability of processed biospecimens.

2.5 Disposal, Merge and Closure

A biobank should ensure management plans are in place for potential situations such as:

- When the biobank is no longer scientifically of financially viable
- Where the project has ended
- When funding has ceasedWhen consent is withdrawn by a participant for their samples

Specimens and data should then be destroyed or transferred in a manner that is consistent with the legal requirements of the state, the consent given and the specific processes approved by the HREC.

2.6 Access and Applications for Samples

To enhance research effectiveness, biobanks should maximise researcher access to biological biospecimens and associated data. Biobanks within BDHP should include access guidelines that specify the governance of the biospecimens and data for sharing that are consistent with the specified conditions of consent and HREC approval for the project.

2.7 Material Transfer Agreements, Packaging and Shipping

Any transfer of material should be covered by a MTA executed on behalf of both organisations and filled for reference.

There should be established procedures and guidelines for the packaging and shipping of specimens and data, including documentation and conditions of transfer, to ensure preservation of quality and the chain of custody between the originator and the receiver.

Standard Operating Procedures/Guidelines topics for consideration

2.4 Collection, Processing, Handling and Retrieval

- General Considerations - Timing of specimen collection specimen collection method, transportation temperature and time,
- Collection - Solid Tissues, Blood or Blood-Derived Products, Other Specimens, Post Mortem Collection (Autopsy/Necropsy), Transplant
- Processing & Handling - Tissue Processing, Human Biological Material Handling – General Considerations, Safeguards , Specimen Labelling, Transport
- Storage – Cryopreservation, Bio-preservation, Other Fixation and Preservation Methods, Liquid nitrogen (LN2) tanks, Freeze/Thaw and Cooling/Re-Warming Cycles
- Specimen Stability - Collection and Storage Containers, Sterility, Pilot Studies and Proof of Performance Studies
- Retrieval - Locating Specimens in Storage, Specimen Retrieval, Thawing, Re-warming and Aliquoting Specimens
- Carbon Dioxide/Liquid Nitrogen Safety

2.5 Disposal, Merge and Closure

- Disposal - Retention of Data in the Case of Withheld or Revoked Consent
- Culling of Collections – Audits, Specimen Destruction & Tracking and Records
- Closure, Merger or Change of Ownership - Transfer of a Collection, Relocation, Established

2.6 Access and Applications for Samples

The access guideline should be available on a website they should;

- Outline the process for application by third party researchers.
- Consideration for access should be based on scientific value and ethical soundness to manage the finite resource of a biobank.
- A recipient should have the ability/capacity to complete their proposed research.
- e.g. financial backing, access to required equipment, skill/knowledge, etc.
- State and National legislation must be complied with in developing any access documentation.
- A guideline has been developed for access procedures.

2.7 Material Transfer Agreements, Packaging and Shipping

- Material Transfer Agreement - Material Transfer Agreement for Specimens, Data Transfer Agreement, Confidentiality, Access regulations, Incorporation of Results
- Packaging - Review of Packaging Test Report
- Shipping – Risks, Transport Specifications, Regulatory Requirements, Technical Instructions and in the IATA Dangerous Goods, Temperature Requirements, Humidity Requirements, Arrival Time Requirements, Specimen Quantities, Test Shipments, International Shipments, Invoicing, Notification of Shipment, Shipping Manifest, Confirmation of Receipt, Tracking Shipments During Transport

Biobank Governance Framework
Compliance

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Governance Statements

3.1 Emergency Preparedness and Work Health and Safety

A biobank should have a business continuity management plan to maintain the viability and quality of biospecimens. This should address threats posed by disasters as well as minor incidents or situations could affect sample integrity. This may be as part of the host institutions emergency or business continuity planning.

A biobank will be governed by the host institutions work place health and safety and HR requirements.

3.2 Databases, Tracking, Records and Documentation

The privacy and confidentiality of a participant's samples and data should be safeguarded.

- There should be procedures developed to prevent any inappropriate or unauthorized identification of participants.
- It may be a requirement that a participant be re-identified in the case of longitudinal studies or incidental findings.
- The Database systems should be secure, encrypted, robust and backed-up to prevent any data loss, unauthorized or unapproved access or hacking.

3.3 Quality Management System (Assurance and Control)

A quality management system should not only assure the protection of the specimens it should also maintain confidentiality. The system should be integrated and contain documented assurance/quality control principles and SOPs.

Standard Operating Procedures/Guidelines topics for consideration

3.1 Emergency Preparedness and Work Health and Safety

- Emergency Preparedness - Emergency Response Planning, Business Continuity Plan , On Call, Security Systems, Evacuation, Splitting Stored Specimens, Back-up Storage Capacity, Malfunctioning Units. Plans should be tested yearly.
- Work Health and Safety Considerations - Reliant on host organisation and legislative requirements

3.2 Databases, Tracking, Records and Documentation

- Privacy and Confidentiality - Consent for the Collection Use and Disclosure of Personal Information, Protection of Privacy and Data, Ensuring Safeguards for Personal Information, Identifying Purposes for the Collection of Personal Information, Accountability for Personal Information, Limiting Collection, Accuracy of Personal Information,
- Individual Access to Own Personal Information & Complaints
- Transmission of Information and Data, Physical Storage of Information and Data and Retaining Information and Data
- Databases & Systems - Data Management and Informatics Security, Sample Records, Restricted Access, Integration and Interoperability, Quality Control and Assurance, Custodianship of Tissue Data & Backup
- Human Biological Material Tracking - Inventory Systems, Specimen Location, Informatics – Collection and Handling, Specimen Annotations and Data Collection, Additional Specimen Descriptors, Additional Information for Research Biorepositories, Additional Information for Non-Human Specimens, Audit Trail, Reporting, Validation, Labels, Labels for Specimens, Barcoding, Annotations on Stored Specimen, Shipping Log
- Obtaining Confidentiality Disclosure Agreements

3.3 Quality Management System (Assurance and Control)

A list of considerations that if implemented will aid the scientific results, ensure the safety of personnel and efficient operations of a biobanks

- Quality Management System - Quality Assurance (QA) & Quality Control (QC)
- Quality Standards - Current Good Practices, Best Practices, International Organisation for Standardisation, Clinical and Laboratory Standards Institute (CLSI), Quality management of samples and data, Accreditation Processes
- Auditing - Operational Audits & Annual Audits
- Quality Control - Validation of Quality Control Methods, Pre-analytical Variations
- Standards of Samples & Validation of Sample Processing Methods

Governance Statements

3.4 Standard Operating Procedures (SOPs)

As under 2.1 Operational arrangements, SOPs should be developed to ensure compliance with the relevant National. State and institution legislative and regulatory frameworks. All SOPs developed should be available for review and audit, both biobank and institution specific.

Standard Operating Procedures/Guidelines topics for consideration

3.4 Standard Operating Procedures (SOPs)

The SOPs that are developed are likely to be required to be modified over the lifespan of a biobank and a process of review and modification should be developed. A SOP is a controlled document and a list of all SOP should be maintained with review dates outlined.