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# **GUIDELINES FOR HUMAN BIOBANKS, GENETIC RESEARCH DATABASES & ASSOCIATED DATA**

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**Prepared by:**

**OFFICE OF POPULATION HEALTH GENOMICS**

**PUBLIC HEALTH DIVISION**

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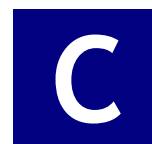
**for the**

**HEALTH DEPARTMENT OF WESTERN  
AUSTRALIA**

These Guidelines provide principles and best practices for the establishment, governance, management and use of human biobanks, genetic research databases and associated data used for research purposes.



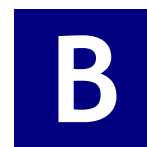
Government of **Western Australia**  
Department of **Health**



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## BACKGROUND AND CONTEXT

### RESEARCH IN HUMAN HEALTH

The completion of the first mapping of the human genome under the Human Genome Project has opened huge potential for research into the ways in which genes relate to human conditions, diseases, capacities, impairments and susceptibilities. Research involving the human genome and resulting applications open up new prospects in improving the health of individuals, families, communities and of humankind as a whole.

These advances in our understanding of genetics and genomics have moved science into the post-genomic era and led to the emergence of other science fields, such as proteomics, transcriptomics, metabolomics and epigenetics. These new areas of sciences also offer much promise for unraveling the biochemical and physiological mechanisms of complex multivariate diseases at the functional molecular level. The ability to effectively use these vast amounts of knowledge will depend in part of the bringing together of different strands of information and data within databases.

### RESEARCH INVOLVING HUMAN BIOBANKS AND GENETIC RESEARCH DATABASES

Research involving human genetic or genomic information analyzed in conjunction with other personal or health data has become increasingly important for understanding risk factors underlying complex (multi-factorial) diseases. Such research will be critical to improvements in detection, prevention, diagnosis, treatment and cures, including for new products and services. To support these research endeavours, great emphasis has been placed on the establishment and sharing of resources comprised of data, biological samples and information derived from the analysis of those samples.

Advances in biotechnology and bioinformatics afford the opportunity to store and analyse an increasingly large number and array of biological samples and genetic data.

Current uses of biobanks are already contributing significantly to our understanding of genetic and environmental factors that influence disease risk and treatment including a better understanding of the reasons for drug reactions (both positive and negative). To serve these purposes, biobanks may be established in diverse forms. For example, biobanks may be any of the following, or a combination thereof: cross-sectional, longitudinal, large-scale, disease-specific, or population-based. Such data resources may provide platforms for international collaboration on a scale not previously attained.

It is clear that wide access to such data for biomedical advances must be balanced by consideration of the interests of research participants. The ability to establish biobanks and genetic research databases will depend in part on research participants' willingness to contribute. Research must respect the participants and be conducted in ways that uphold human dignity, fundamental freedoms and human rights.

## BALANCING OPPORTUNITIES, CAPABILITY AND EMERGING ISSUES

- WA has created unique biobanks and health information collections and developed significant data linkage capability.
- The data linkage capability has been forged over the past 3 decades through strong and committed collaborations between State and academic institutions with the aim to provide better delivery of health services and health benefits to the community.
- Linkage of biobank data to population health data can provide significant academic and health services research opportunities.
- Current resources are maintained through collaboration and involve a delicate balance of health policy objectives, academic research, public good outcomes and community trust.
- Concern has been expressed by consumer, genetic disease and privacy advocacy groups for wider public consultation, increased transparency and adequate privacy safeguards.
- Academic groups have also expressed concern over the sustainability and proposed expansion of these valuable resources without:
  - Improved infrastructure;
  - Better communication;
  - Increased transparency and accountability; and
  - Sustained trust and pro-active collaborative consultation amongst stakeholders which includes public consultation.
- The potential for commercial exploitation of the unique population health resources and biobanks in WA raises complex issues for the State, academic institutions and the community.

## SCOPE OF GUIDELINES

For the purposes of the *Guidelines for Human Biobanks, Genetic Research Databases and Associated Data* (the Guidelines), the term *biobank*, is defined as

*An organised collection of human biological material and any related information stored for one or more purposes.*

It is the intention of the Guidelines to include human and population genetic research databases and collections which are also known as bio-repositories or gene-banks.

The terms *associated data*, *data*, *related information* and *associated information* are used here as synonyms and are intended to include information collected in the establishment of the database and information that is obtained through research on the material held (e.g. personal, clinical, genetic, biochemical or phenotypic information).

The Guidelines are intended for use by organisations and research personnel to assist in the establishment, governance, management and use of all human biobanks, within the custodianship or held under the auspices of WA Health and used for research purposes. This includes but is not restricted to biobanks:

- established through collaborations between WA Health, universities and research institutions;

- established by investigators with joint appointments between WA Health, universities and research institutes;
- established using biological material and/or information obtained from WA Health patients;
- established with funding in part or in full from WA Health; and
- for which researchers wish to link the biobank's data with the WA Health data collections.

## APPLICABILITY

The Guidelines are intended for use by both government and non-government organisations in WA. While they have been developed for WA Health, the Guidelines provide overarching principles that can be used by other organisations (i.e. private organisations, not for profit organisations, independent researchers or multicentre collaborations) for the establishment and management of biobanks.

It is recognised that, depending on the nature and size of the biobank, the Guidelines may be useful but they may not be directly applicable in whole. For example, some principles and best practices included in the Guidelines may not be applicable to small, highly specialised biobanks that will not be shared or linked with other datasets.

It is recognised that pre-established biobanks have scientific value. While the Guidelines are intended to be applicable to pre-established biobanks, it is also recognised that the application of some of the principles and best practices may not be fully feasible. The Guidelines may also not fully apply to biobanks established with private funding for specific commercial purposes (i.e. the development of a medical product, diagnostic or medical device) with the objective of obtaining regulatory market approval.

The Guidelines are not intended to be applicable to resources established principally for non-research purposes, such as for diagnosis, therapeutic, treatment, forensic, transplantation, transfusion, audit, public health surveillance, quality assurance purposes or for use as teaching materials. Nevertheless, where collections have been derived from materials stored in relation to therapeutic, diagnostic and clinical management purposes the Guidelines may nevertheless prove useful to the custodians.

## NATURE OF GUIDELINES

The principles and best practices within the Guidelines aim to balance the interests of all those with a stake in human biobanks, particularly between the interests of researchers (need access to human samples and information from many sources) and the needs and rights of individual participants, their relatives and the broader community (the 'general public'). The promotion of research must be balanced against maintaining public involvement, public confidence and trust in the operation of biobanks. Similarly rules and regulations are needed for guidance and protection but should not overly inhibit research that will benefit the community.

The Guidelines form part of an overarching governance and regulatory framework for biobanks in Western Australia, which was developed in consultation with stakeholders from scientific, legal, ethical, medical, health consumer and lay communities. The Guidelines cover a broad reach of activities and are intended to be interpreted as appropriate to the

circumstances. These Guidelines are not intended to cover exhaustively all aspects of biobanks. They should be used in conjunction with existing guidelines, laws and regulations.

Appropriate guidelines may include, but are not restricted to:

- NH&MRC 'National Statement on the Ethical Conduct of Research Involving Humans'. This outlines the roles, responsibilities and implications of non-compliance for researchers, Human Research Ethics Committees (HRECs) and institutions in relation to the ethical design, review, conduct and monitoring of human research.<sup>1</sup>
- NH&MRC 'Australian Code for the Responsible Conduct of Research'. Provides guidelines for institutions and researchers on their responsibilities when conducting all types of research and the implications of non-compliance.<sup>2</sup>
- WA Health 'Practice Code for the Use of Personal Health Information'. This outlines the requirements for researchers to access WA Health data collections or to request data linkage between WA Health collections and other databases.<sup>3</sup>

## ADHERENCE

It is the responsibility of institutions, departments, heads of department and researchers to be aware of and apply the principles and best practices defined in the Guidelines and be used in conjunction with other relevant guidelines, standards, general and specific legal obligations (statutory or otherwise), wherever relevant to the collection, storage, access, use of biobanks and associated data.

Biobanks that fall within the scope of the Guidelines will be required to demonstrate governance and adherence to the principles and best practices outlined in the Guidelines.

The implications of non-adherence to the Guidelines may include the inability to obtain ethics approval for the establishment and/or use of the biobank; withdrawal of funding; termination of employment contract; inability to access biological material and/or information obtained from WA Health patients; and the inability to link the biobank to WA Health data collections and databases.

## REVIEW OF GUIDELINES

The Guidelines are intended to be evolutionary in nature and should be reviewed in light of relevant scientific developments and changing public views and shared values.

A formal review of the Guidelines should be undertaken within four years of adoption at the latest, and periodically thereafter, in order to ensure that they are fostering the desired objectives.

Subsequent to the initial review, the period of review should be every 5 years.

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<sup>1</sup> [http://www.nhmrc.gov.au/publications/synopses/\\_files/e72.pdf](http://www.nhmrc.gov.au/publications/synopses/_files/e72.pdf)

<sup>2</sup> [http://www.nhmrc.gov.au/publications/synopses/\\_files/r39.pdf](http://www.nhmrc.gov.au/publications/synopses/_files/r39.pdf)

<sup>3</sup> [http://www.health.wa.gov.au/healthdata/Data\\_Services/090429\\_Practice\\_code\\_for\\_the\\_use\\_of\\_personal\\_health\\_information.pdf](http://www.health.wa.gov.au/healthdata/Data_Services/090429_Practice_code_for_the_use_of_personal_health_information.pdf)

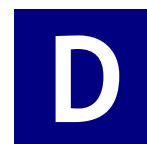
## STRUCTURE OF THE GUIDELINES

**PART I** sets out the Principles and Best Practices applicable to biobanks.

- *Principles* are overarching statements of concepts, ideals and ideas, such as “values”, “policies” and “mechanisms”.
- *Best practices* are what WA Health expects to happen in relation to the overarching ideas. For example the information that should be included in a specific policy or the structure of a specific mechanism.

**PART II** contains explanatory Annotations which elaborate on the Principles and Best Practices found in Part One.

**PART III** contains a glossary, or definition terms, used in biobanking and database management. It also contains appendices.



## DEVELOPMENT OF THESE GUIDELINES

### INTRODUCTION

In Australia the regulation of biobanks and their associated data collections is complex and comprises a mixture of legislation, guidelines and standards. From a legal perspective various State and Commonwealth legislation, such as the Privacy Acts and Human Tissue Acts, address aspects of biobanking operations. However the ALRC-AHEC Joint Inquiry<sup>4</sup> into genetic testing and information concludes gaps exist in the legislative framework. For example in relation to the privacy of genetic samples: the lack of legal requirement for biobank participants to be informed that their tissue may be stored, disclosed to other researchers or linked with health information; and the lack of laws that specifically address the collection, use, storage, disclosure and transfer of genetic samples and information that have been collected primarily for use in research.

From an ethical perspective the National Health and Medical Research Council *National Statement on Ethical Conduct in Research Involving Humans 2007* (NH&MRC National Statement) provides a consistent and national view, albeit an advisory one, on how biobanks should be ethically established and used in the research environment. The Statement contains provisions dealing specifically with databanks and genetic samples, indicates individuals should be informed of any intention to store genetic samples or information and requires researchers to ensure the confidentiality and privacy of stored genetic information.

To date there has been a lack of overarching principles or guidelines for the governance and management of human biobanks and their associated data specific to the State of WA.

In April/May 2008 the Organisation for Economic Co-operation and Development (OECD), of which Australia is a member country, released the *Draft Guidelines for Human Biobanks and Genetic Research Databases* (OECD Draft Guidelines) for public consultation. The OECD Draft Guidelines aim to strike a balance that encourages and fosters research so as to advance knowledge and understanding, while at the same time respecting the rights of research participants and the broader community.

In 2008 an inventory of biobanks in Western Australia indicated that the North and South Metropolitan Area Health Services account for 82 human biobanks, being 85% of those known to exist in WA. Generally these biobanks were relatively small collections and most were focused towards a particular disease. Overall these biobanks represented over 180,000 research and clinical trials specimens under the custodianship of WA Health.

In June 2008 the A/Director-General of Health approved the use of the OECD Draft Guidelines as a framework for the development of overarching guidelines for the

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<sup>4</sup> Australian Law Reform Commission "Essentially Yours: The Protection of Human Genetic Information in Australia (ALRC 96)" 2003.

governance and management of human biobanks, genetic databases and associated data for WA Health.

The Office of Population Health Genomics was requested to coordinate the development of these guidelines.

## **WA HEALTH STAKEHOLDER COLLABORATION**

The Office of Population Health Genomics (OPHG) established a WA Health Stakeholder Group to consider the issues relating to human biobanks and associated databases in this State. The interdepartmental Stakeholder Group comprised the WA Health Directorates of Information Management and Reporting (IMAR), Legal and Legislative Services (LLS), the Research Development Unit (RDU) and OPHG.

### **Advisory Committees**

Two stakeholder committees, representing the professional interest groups, were established to collaborate in the development of the Guidelines. Professional interest group stakeholders from a wide spectrum of research and clinical positions nominated to be involved in a working group, (established to collect an inventory of biobanks in WA) or in an advisory group (established to assist with developing the Guidelines). The main aim of the inventory was to provide information on the types of biobanks in WA and the regulation needed.

The inventory working group included a biobank manager, a manager of a clinical based biobank, a researcher involved with a research based biobank, and one involved with a population based biobank, an indigenous representative, a data manager, a health consumer and a representative from an independent research institute.

The advisory group included a research scientist, a representative each from two independent research institutes, a hospital based researcher, an HREC member, three consumer representatives, an indigenous representative, a representative from clinical pathology services and a representative from the Department of Commerce.

We would like to acknowledge the members of the Inventory Working Group and the Advisory Group for their involvement in the development of the Guidelines.

Inventory Working Group  
Jenni Ibrahim (chairperson)  
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Michele Kosky  
Stephen Sandilands  
A/Prof Paula Edgill  
Prof Frank Christiansen  
Diana Cameron  
Sharon Humphris

## COMMUNITY CONSULTATION PROCESS

WA Health is committed to community and consumer engagement in health system policy and planning, as embodied in the WA Health *Consumer, Carer and Community Engagement Framework 2007*. WA Health has a duty to consider, reflect on and defend the shared underlying values and interests of citizens in the WA community, in relation to biobanks. Due to the nature of biobanks the community engagement process needed to be as *informed* and *wide* as possible.

*Informed consultation:* In 2006 survey research in WA (unpublished) indicated low public awareness of and knowledge about biobanks, genetic research and health data collections. Biobanks are associated with new and complex ethical, legal and social issues. There are many arguments for and against their establishment. Awareness of the competing interests and trade-offs required among value-laden options was deemed necessary, if the public were to more fully assess what is at stake for them in relation to biobanks. The need for informed public consultation was addressed through the use of deliberative public engagement forums.

*Wide consultation:* Biobanks and genetic research are of broad community interest and concern so it was important to provide all Western Australians with an opportunity to have their say. This was facilitated through the use of multiple consultation and engagement methods.

### Public Engagement Forums

Two deliberative public forums on “Biobanking in WA” were each held over four days in August and November 2008. The forums were designed in collaboration with academic experts from social psychology, law, bioethics, anthropology and political science. The format was based on similar forums on biobanking held previously in the US and Canada.

The first forum, for members of genetic support groups in WA was designed to inform policy for the Genetic Support Council of WA. The second forum involving members of the WA public was designed to inform this policy. For the public forum a stratified sample of citizens was randomly selected from the Western Australian telephone directory. Stratification was based on a number of demographics to ensure diversity of representation including: age; sex; education; ethnicity and religion.

Prior to the forum, participants received an information booklet on biobanks. The booklet provided examples of Australian biobanks and covered issues such as funding, governance, contents of biobanks, collection, storage, access, privacy protection, property rights, ownership and benefit sharing and discrimination. The booklet also included a range of perspectives on biobanks from scientists, health researchers, people with disabilities, religious communities, racial groups, indigenous groups and the general public.

On Day 1 of each forum, participants listened to a number of presentations from a range of ‘experts’, stakeholders and perspectives (e.g., biobank custodian, lawyer, health consumer, disability advocate, commercial research experience, data manager). On Days 2-4 participants discussed their hopes, concerns, values and preferences in small groups before developing a set of shared values and recommendations on how biobanks should operate as a large group.

The shared public values identified through this process included:

- ACCOUNTABILITY    ▪ COMMON GOOD    ▪ EXCELLENCE    ▪ EQUITY    ▪ INTEGRITY
- PROGRESS    ▪ PROTECTION    ▪ RESPECT    ▪ TRANSPARENCY    ▪ TRUST

These values and the public recommendations on how biobanks should operate in WA were used to inform the development of the Guidelines. A document has been developed that identifies the specific inclusion (or otherwise) in the Guidelines of the recommendations from the second deliberative forum. This document can be obtained from the following website: [www.genomics.health.wa.gov.au](http://www.genomics.health.wa.gov.au)

More information on the design, implementation and evaluation of the deliberative public engagement forums can also be obtained from the above website.

We would like to acknowledge the collaborators and personnel whom provided valuable expertise in the design and implementation of the public engagement forums.

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**The Guidelines adopt the OECD Draft Guidelines with some modifications to take account of the domestic context, stakeholder and community views, and laws.**

### BIOBANKS GENERALLY

#### OVERARCHING PRINCIPLES

- 1A. The objectives of the biobank should be:
- a. To foster research that is valued by society and conducted within applicable laws, regulations and ethical frameworks;
  - b. To ensure the collection, storage, transfer, access, use and disposal of participants' human biological materials and all data are scientifically, legally and ethically appropriate; and
  - c. To secure the sustainability of the biobank, the protection of participants' privacy, the confidentiality of data and, ongoing public trust and involvement.
- 1B. The biobank should be operated throughout its existence with integrity, transparency, accountability and respect for human rights and freedoms.
- 1C. The biobank should be established, governed and managed in accordance with applicable domestic law, guidelines and international instruments.
- 1D. The biobank should engage independent members of relevant and diverse publics and communities in decisions about its establishment, governance and use.
- 1E. The biobank should be independently monitored for compliance with applicable domestic law, guidelines and international instruments.
- 1F. Given the significant resource implications of establishing and maintaining a biobank, the scientific and financial feasibility of the biobank should be assessed, the scientific need demonstrated, and the financial resources secured prior to establishment.
- 1G. The biobank should share data and materials with others in the research community so that resources are not unnecessarily duplicated and knowledge, understanding and improved health outcomes are advanced efficiently, subject to applicable domestic laws, regulations and ethical guidelines.
- 1H. The biobank should consider and minimise risks to individuals, their families and potentially identifiable populations or groups whose specimens and data are included in the biobank and used for research.

### ESTABLISHMENT OF BIOBANKS

#### PRINCIPLES

- 2A. The biobank should clearly articulate its current and future purpose(s) and proposed operation.
- 2B. The biobank should develop a business plan.
- 2C. The biobank should develop operational policies and procedures.
- 2D. When establishing a biobank, consideration should be given to future collaboration and cooperation, especially as regards database compatibility and interfaces.
- 2E. When establishing a biobank, the initiators should carry out consultations with stakeholders, which includes participants and in relation to population biobanks the general public.
- 2F. The WA public has a right to know that biobanks exist and the biobank should make information publicly available and easily accessible on the existence, purposes, rationale for and operation of the biobank.

#### BEST PRACTICES

##### Purpose (Principle 2A)

- 2.1. When establishing a biobank, the initiators should develop criteria for sampling and participant selection so as to ensure that the data contained in the biobank are representative of the targeted population and are scientifically appropriate for its intended use.

##### Business Plan, Financial and Human Resources (Principle 2B)

- 2.2. The biobank business plan should:
  - i) include a financial model that the biobank intends to adopt over its lifespan
  - ii) be explicit and transparent about the nature and source of its financing/funding;
  - iii) set out the financial and scientific feasibility of the biobank, examining any assumptions made or risks identified with establishing the biobank;
  - iv) ensure that the biobank has sufficient professional staff and resources to operate effectively in all aspects;
  - v) include plans for ensuring the ongoing financial and public support of the human biological materials and data throughout its existence; and

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## PART I: PRINCIPLES AND BEST PRACTICES

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- vi) include a business strategy in the event that funding is terminated or its nature changed;
- 2.3. Funding should come from ethical sources and these may be public, private or public-private partnership sources.
- 2.4. The funding model established should give consideration to ensuring the finances will be secured for the lifespan of the biobank.
- 2.5. Where a biobank foresees attracting private or foreign investment or entering in commercial or international collaborations, this should be clearly articulated, communicated especially to participants, and undertaken in accordance with applicable domestic law and regulation.
- 2.6. The biobank should ensure that it has appropriate staff and resources to preserve records, data and human biological materials appropriately, and to handle requests for access to data and human biological materials.

### Operational Policies and Procedures (Principle 2C)

Please refer to subsequent sections of the Guidelines for more information on specific policies and procedures.

### Compatibility (Principle 2D)

- 2.7. Appropriate design elements providing for compatibility and interfaces should be incorporated when creating the databases. The biobank should give consideration to using standardised approaches for the collection, storage and analyses of human biological materials and/or data so as to facilitate cross-biobank data exchange and sharing.

### Consultation (Principle 2E)

- 2.8. Consultations should be carried out with diverse stakeholders, groups and communities. As relevant for the biobank this should include the general public, patient groups, industry, scientists, ethicists, clinicians and researchers.
- 2.9. Consultations should be conducted through appropriate means. The extent and types of consultations with relevant stakeholders should be based upon considerations of the nature and design of the proposed biobank, the risks involved to participants and their families and to identifiable groups, any particular sensitivities related to the individuals and groups under study and the types of research to be conducted with the biobank.
- 2.10. Consultations should cover a variety of topics including the proposed purpose and focus of research. The initiators should articulate as much as is known about the possible future scope of the biobank.
- 2.11. The biobank initiators should clearly indicate to those consulted the manner in which their input may influence the establishment and impact the future aims of the biobank.

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## PART I: PRINCIPLES AND BEST PRACTICES

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### Information and Education (Principle 2F)

2.12. The biobank should make information publicly available and easily accessible to stakeholders, including participants and the general public, on:

- i) the background to the biobank;
- ii) the purpose(s), both current and future, including the aims and scope of research;
- iii) how the biobank is set up;
- iv) the operational policies and procedures of the biobank, including proposed security and data protection measures, and access policies;
- v) the scientific rationale underlying the biobank;
- vi) the type of research that will or is being carried out with the human biological materials and data contained within the biobank;
- vii) the research outcomes resulting from utilisation of the biobank, including any health and scientific benefits;
- viii) the scientific and business risks and uncertainties associated with the establishment, operation and use of the biobank;
- ix) any risks for members of the public, particularly public health risks, associated with the establishment, operation and use of the biobank;
- x) the nature and source of its financing/funding, especially private or foreign investment, commercial or international collaborations;
- xi) the ethics approval obtained to establish the biobank;
- xii) the proposed duration of the biobank;
- xiii) the name(s) of senior management;
- xiv) any vested interests and partnerships; and
- xv) where to find more information on the biobank including contact details for a representative who will answer questions from the public.

### GOVERNANCE, MANAGEMENT, AND OVERSIGHT

#### PRINCIPLES

- 3A. The initiators of the biobank should clearly formulate the governance structure applicable to the biobank, including management and oversight roles and responsibilities.
- 3B. The governance structure of the biobank should ensure that the rights and well-being of the participants and the common good prevail over the research interests of the initiators and users of the biobank.
- 3C. The governance structure of the biobank should be subject to independent ethical review, approval and monitoring and be administered according to the best practice principles of good corporate governance.
- 3D. The biobank should anticipate that over its lifespan the need to modify its policies, protocols and procedures will arise and should have in place a process for undertaking these modifications.
- 3E. It is the shared responsibility of all biobank personnel, researchers and partners to ensure that all biobank activities are carried out in accordance with prevailing legal norms and ethical principles.
- 3F. The biobank should make information publicly available and easily accessible on its regulatory framework, governance, management and oversight.

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## PART I: PRINCIPLES AND BEST PRACTICES

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### BEST PRACTICES

#### Governance Structure (Principle 3A)

- 3.1. The governance structure of the biobank should include mechanisms for:
- i) Independent scientific, financial and ethical oversight to ensure that the governance, management and operation of the biobank comply with applicable domestic and international legislation, regulation, ethical guidelines and applicable policies and frameworks;
  - ii) Review of applications for access to and use of the human biological materials and/or data;
  - iii) Independent auditing to monitor access to and the uses of the human biological materials and data, for adherence with research ethics approvals, access approvals and the research uses agreed to by participants during the informed consent process;
  - iv) Independent means of recourse for participants to redress breaches of the legislation, regulation, ethical guidelines and applicable policies and frameworks;
  - v) Avoiding discrimination against or stigmatisation of a person, family or group, whether or not they have contributed to the biobank.
- 3.2. In light of the nature and purpose of the biobank, the individuals involved in the oversight mechanisms and procedures set up by or for the biobank should be drawn from diverse relevant areas of expertise, including the scientific, legal, and ethical fields.
- 3.3. The oversight mechanisms set up by or for the biobank should report annually on compliance or otherwise of the biobank with applicable domestic laws, regulations and ethics guidelines; and international instruments.
- 3.4. The independent auditing mechanism should conduct regular and random auditing at appropriate stages including at the end of approved research projects and at the demise of the biobank.
- 3.5. The specific roles and chains of responsibilities of those involved in the biobank's activities should be clearly identified and delineated, including the person(s) responsible for:
- i) ensuring adherence with the governing requirements of the biobank including the legal, financial, ethical, policy, managerial and reporting requirements; and
  - ii) ensuring the security of human biological materials and data particularly the protection of privacy and confidentiality.

For best practices in relation to the review and approval of applications to access or use the biobank refer to Section 7.

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### Approval and Administration (Principle 3C)

- 3.6. The biobank's governance structure, protocols, processes and activities should be approved prior to the establishment of the biobank by an independent human research ethics committee and be subject to unbiased scientific peer review unless exempted.
- 3.7. The biobank governance structure, policies and procedures should be administered in the spirit of:
- i) The ten essential principles outlined in the Principles of Good Corporate Governance and Best Practice published by Australian Stock Exchange (ASX) Corporate Governance Council<sup>5</sup>; and
  - ii) The six essential principles of the OECD Principles of Corporate Governance<sup>6</sup>.
- 3.8. **Modifying policies, protocols and procedures (Principle 3E)**
- 3.9. The process for modifying the policies, protocols and procedures of the biobank should include a means for participants to be informed about these modifications.
- 3.10. Where policies, protocols or procedures of the biobank are significantly<sup>7</sup> modified, the biobank should ensure that a new consent is obtained from the participant or substitute decision-maker (where applicable).
- 3.11. If it is not feasible to obtain new consent for significantly modified policies, protocols or procedures, the biobank should obtain approval for the modifications from an independent human research ethics committee, unless exempted (through a waiver of consent).

### Information and Education (Principle 3G)

- 3.12. The information made publicly available and easily accessible to stakeholders, participants and the general public on governance, management and oversight should include:
- i) the ethics approval for the establishment of the biobank;
  - ii) the mechanisms and responsibilities for governance, management, oversight, review of applications for access and use, auditing and redress;
  - iii) significant modifications to the policies, protocols or procedures of the biobank;
  - iv) if applicable, the ethics approval obtained for significant modifications to the policies, protocols or procedures of the biobank;

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<sup>5</sup> [www.asx.com.au/about/corporate\\_governance/revised\\_corporate\\_governance\\_principles\\_recommendations.htm](http://www.asx.com.au/about/corporate_governance/revised_corporate_governance_principles_recommendations.htm)

<sup>6</sup> [http://www.oecd.org/document/49/0,3343,en\\_2649\\_34813\\_31530865\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/49/0,3343,en_2649_34813_31530865_1_1_1_1,00.html)

<sup>7</sup> Significant changes are defined as: changes that a reasonable person would believe the original intent had changed. Changes that a reasonable person would expect to be informed of. (Adapted from the ASX, *Ausbiotech: Code of Best Practice for Reporting by Life Science Companies, September 2005*)

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- v) key elements of applicable domestic laws, regulations and ethics guidelines; and international instruments;
- vi) the legislation, regulations and ethical guidelines that the biobank operates under, including how to access information on these, such as the implications for non-adherence (See annotation (xi) for a list of the relevant laws and regulations); and
- vii) annual reports of compliance of the biobank with applicable domestic laws, regulations and ethics guidelines; and international instruments.

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### TERMS OF PARTICIPATION

#### PRINCIPLES

- 4A. Participant recruitment should be carried out in a non-coercive and equitable manner.
- 4B. The biobank should obtain prior, free and informed consent from each participant or where applicable, from an appropriate substitute decision-maker.
- 4C. Biobank participants should have a right to withdraw.
- 4D. Biobank participants should not be paid for their participation.
- 4E. The biobank should have clear, detailed, publicly available policies, protocols and procedures in place regarding recruitment, participation and the process of informed consent.
- 4F. Communication strategies should take into consideration the different needs of participants.

#### BEST PRACTICES

##### Recruitment (Principle 4A)

- 4.1. The biobank should give careful consideration to any special issues related to the participation of vulnerable populations or groups, including children, individuals with impaired decision-making capacity, and prisoners.

##### Consent Process, Scope and Information Provided (Principle 4B)

- 4.2. Prior to requesting signed consent the biobank should provide potential participants with information including (refer to the specific section for further details on these recommendations):

##### Set-up and Management

- i) background information behind, and the purpose of the biobank;
- ii) the ethical and governance framework and management responsibilities;
- iii) if the biobank has been or is being established in collaboration with the private sector or if it is involved in collaboration for commercial purposes;
- iv) who the nominated custodian of the biobank is at the time of its creation;
- v) any conditions where the nominated custodian may change through unforeseen circumstances;

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## PART I: PRINCIPLES AND BEST PRACTICES

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- vi) storage facilities and duration of storage;
- vii) whether under the current legislative, regulatory and ethical system the participants, the biobank or the nominated custodian retain any legal or ethical rights to the human biological material or data, and the nature of these rights including property rights or intellectual property rights;
- viii) policies governing the collection, storage, use and outcomes from research on samples and data and/or details of how participants can obtain further information on the policies;
- ix) biological material or data transfer and disposal/destruction procedures;
- x) the human biological material and data to be collected, and which biological material and data will be collected from the participants or from other sources;
- xi) if identifiable data will be stored, the circumstances where it may be released and if it may be released interstate or internationally;
- xii) whether third parties or law enforcement agencies may be given access to samples or data and the conditions under which this will occur;
- xiii) the level of privacy and confidentiality protection to which their human biological materials and data will be subject, the procedures and safeguards that will be employed for this protection, and of any specific risks of unauthorised access;
- xiv) of any commercialisation that will result from the research performed on the biobank, the conditions of this commercialisation and how this applies to the participants;
- xv) if the biobank closes, the manner in which the human biological material and data will be destroyed or transferred and what will be done with the biobank assets;

### Implications for Participation

- xvi) the nature of participating and the implications;
- xvii) any foreseeable risks and benefits of their participation to themselves, their blood relatives and their community;
- xviii) where to find further information including details for contacting the biobank;
- xix) if participants are entitled to withdraw from the research, conditions of withdrawal and consequences;
- xx) if the biobank will feedback results to the participants and the type of results included;
- xxi) if the biobank will re-contact the participant and the conditions of re-contact;

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### Access and Use

- xxii) the intended uses of the biobank (including if it is to be used for non-research purposes e.g. proficiency testing);
  - xxiii) the terms and conditions of access to the biobank samples and data;
  - xxiv) if the biobank will not perform specific types of tests or will not enter specific types of data;
  - xxv) health and other records to be accessed and/or their intended uses (where the biobank intends to access data from health or other records, which data will be extracted from such records, by whom and through which processes, and for which uses the data will be employed); and
  - xxvi) if the data collected by the biobank and that obtained from the research will be linked with health data collections or other data collections.
- 4.3. The informed consent materials should be written in clear, concise and simple language that is easy to understand by the participant.
  - 4.4. Information provided to participants during the informed consent process should be presented in a way so as not to constitute an improper inducement to participate in the research.
  - 4.5. Where a potential participant lacks the capacity to consent (e.g. due to age or mental incapacity), a person or appropriate statutory body exercising lawful authority for that individual should be provided with relevant information to decide whether he or she will participate.
  - 4.6. The informed consent information should take into consideration the participant's cultural and/or religious beliefs.
  - 4.7. The biobank should give consideration to the need for certain cultures to make decisions on participation at a community or group level, rather than, or in addition to, an individual level. The biobank should allow consent to be collected both ways as necessary.
  - 4.8. Consideration should be given to providing participants with graduated consent options to allow varying levels of involvement. (See annotations xiv)
  - 4.9. Throughout the lifespan of the biobank, the research use of human biological materials and data should be consistent with the original informed consent or new consent should be sought, except where otherwise provided by ethical guidelines, domestic law and consistent with state, national and international legal norms.
  - 4.10. For biobanks established from existing collections, the initiators should consider whether the intended scope and purpose of the biobank and intended research uses are consistent with the original informed consent. Where they are not within the scope of the original informed consent, the human biological materials and data may only be used if a new consent is obtained, except where exempt as per domestic guidelines and laws.

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### Conditions of Withdrawal (Principle 4C)

For details of information on withdrawal that should be provided to participants prior to collecting informed consent refer to Best Practice 4.2.

4.11. If participants may withdraw it should be clarified:

- i) if it is possible to withdraw samples, data or both;
- ii) if they may withdraw at any stage;
- iii) that there is no need to provide any explanation;
- iv) any consequences of withdrawal.

4.12. Where withdrawal is available to participants the biobank should ensure traceability of the human biological materials and data.

### Reimbursement for Participation (Principle 4D)

4.13. While participants should not be paid for their participation, reimbursement of reasonable costs incurred in order to contribute to the biobank is acceptable. Such compensation should not be of a magnitude so as to provide inducement to participate.

### Policies (Principle 4E)

4.14. The biobank should have policies on participation that include:

- i) the effects, if any, of the participant's death or loss of legal capacity;
- ii) feedback that will be provided to participants and if individual-level results and/or aggregate results will be provided;
- iii) whether participants will be re-contacted during the course of the biobank's existence, the situations for which re-contact will be permitted, and the conditions that will govern re-contact. The policy should ensure any re-contact permitted is not unduly burdensome for participants;
- iv) whether researchers using its database(s) will be allowed to contact participants directly;
- v) whether, when and how a child's assent will be obtained and including what steps, if any, will be taken once the child becomes legally competent to consent;
- vi) whether autopsy material will be collected, what will be collected and under what circumstances this will be carried out, and that the necessary legislative requirements are complied with; and
- vii) if samples and data will be made available for analyses developed from technological advancements made since the original consent was collected particularly if these analyses are not covered by the original consent.

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### Communication, Feedback and Re-contact (Principle 4F)

For details of information on feedback and re-contact that should be provided to participants prior to collecting informed consent refer to Best Practice 4.2.

- 4.15. Consideration should be given to employing different formats and modes for providing information to participants during the informed consent process and during the lifespan of the biobank.
- 4.16. Where appropriate, participants should be provided with the opportunity to communicate with representatives of the biobank, or as required designees.
- 4.17. Where re-contact is available to participants the biobank should ensure traceability of the human biological materials and data.
- 4.18. Consistent with the terms of participation, participants should only be re-contacted through a representative or designee of the biobank trained in dealing with sensitive issues and impartial in regards to the outcome of the research.
- 4.19. If the research is likely to produce information relevant to the health and wellbeing of the person from whom the tissue was derived, procedures to allow participants to be identified for follow-up should, where appropriate, be included in the research proposal.
- 4.20. Consideration should be given to providing feedback to participants of aggregated results as a minimum.
- 4.21. Where the biobank allows for individual feedback, participants should be able to decide whether or not to receive feedback of individual-level results arising from research.
- 4.22. If individual-level results are given to participants the biobank should provide a trained professional to give this feedback or for counselling to be available to participants when this is appropriate.
- 4.23. Non-validated results (aggregated or individual) from research using the biobank should not be reported back to the participants.

## CONTENT OF BIOBANKS

### PRINCIPLES

- 5A. The biobank should have clear, detailed, publicly available policies, protocols and procedures in place on the procurement, collection, labeling, registration, processing, storage, tracking, retrieval, dissemination, use, auditing and destruction of specimens and/or data.
- 5B. All human biological materials and data should be subject to proper quality control and quality assurance measures at every stage of its processing including procurement, collection, labeling, registration, processing, storage, tracking, retrieval, dissemination, use and destruction in order to ensure high standards of quality in all biobank holdings.

### BEST PRACTICES

For details of information on contents that should be provided to participants prior to collecting informed consent refer to best practice 4.2.

#### Policies (Principle 5A)

- 5.1. The biobank should have policies on contents that include:
- i) which human biological materials and data will be collected from the participants or from other sources;
  - ii) whether data will be accessed from WA Health, other health data collections or other records. The policy should cover if these data will be linked with, stored in the biobank and if the 'linkage' will be retained. Such a policy should also address the issue of secondary use of health and other records, especially when combined with other data;
  - iii) the selection of specimens. Protocols should be developed such that the least invasive approach, associated with the least risk to the participant, should be pursued. Processes to minimize the risk of invasive procedures should be in place;
  - iv) whether results from research carried out using human biological materials or data from the biobank should be incorporated into the biobank. The policy should include the standard of quality required for including research results in the biobank, what the biobank will use them for and any conditions for further access to them;
  - v) the duration of storage of the human biological materials and the data, recognising that the duration of storage may vary according to the nature and the potential uses of the specimen or data. Specific conditions may apply for human biological materials and data which form part of an

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## PART I: PRINCIPLES AND BEST PRACTICES

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application for market authorization of a medical product or a medical device;

- vi) whether the biobank will not perform specific types of tests or will not enter specific types of data.

- 5.2. The biobank should specify which type of data will be collected, including personal, medical/health, biochemical, life-style, genealogical, family-history, genetic, physiological and other demographic and personal data.
- 5.3. The types of human biological materials and data collected and stored in the biobank should be justified on the basis of the scientific objectives and purposes of the biobank.
- 5.4. The biobank's policies on procurement, collection, labeling, registration, processing, storage, tracking, use and destruction of human biological material and data should take into consideration cultural heritage and/or religious beliefs known about or disclosed by participants, and their representative groups.

### Quality Management of Samples and Data (Principle 5B)

- 5.5. The quality control processes applied to the databases, specimen tracking and auditing should maintain participant confidentiality.
- 5.6. The biobank's holdings should be maintained through a system that allows all the biological material, data any other information to be tracked.
- 5.7. The biobank should follow the OECD Best Practice Guidelines for Biological Resource Centres which provide technical and practical best practices applicable for, amongst others, hygiene, equipment, storage conditions such as temperature, packaging of materials being provided, and quality audit.
- 5.8. In order to foster the interoperability of systems and facilitate the scientific exchange of data and human biological materials, the biobank should collect, process, handle and store the specimens and data in a manner consistent with internationally-accepted technological standards and norms.

### PROTECTION OF HUMAN BIOLOGICAL MATERIALS & DATA

#### PRINCIPLES

- 6A. Processing, handling and storage of human biological materials and data should be conducted in a manner that protects the privacy of the participant and the confidentiality of their specimens and data.
- 6B. The biobank should be established, managed and governed in such a way as to prevent any inappropriate or unauthorised access to, or use of participants' human biological materials and data.
- 6C. The biobank should establish policies and procedures to safeguard the privacy and confidentiality of participants, biological materials and data, especially those that may allow, directly or indirectly, the identification of the participant.
- 6D. Quality control and assurance measures should be in place to ensure, security and confidentiality during collection, storage, handling, distribution and destruction of the human biological materials and data (refer to principle 5B).

#### BEST PRACTICES

For details of information on the protection for samples and data provided to participants prior to collecting informed consent refer to best practice 4.2.

##### Protection of Privacy

- 6.1. The biobank should protect privacy and confidentiality through a combination of mechanisms, as appropriate, including for example secure storage of human biological materials and data, coding and encryption, data enclaves, and honest broker systems.
- 6.2. The biobank should ensure that the data contained within its databases are protected in accordance with domestic law.
- 6.3. The biobank should consider the extent to which the genetic data held by them might allow, alone or in combination with other available samples and data, the participant to be identified.
- 6.4. Data protection should, where appropriate, involve the separation of information that can readily identify an individual from other data, including genotypic data.

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### Unauthorised Access

- 6.5. The biobank should have in place a robust infrastructure, consisting of both hardware and software components, so as to prevent unauthorised access to databases.
- 6.6. The biobank should ensure that only a restricted number of authorised staff have access to information identifying or potentially identifying participants, that such access be monitored and documented and only be exercised when necessary for carrying out biobank-related functions.

### Protection Policies

- 6.7. The biobank should have policies on protection including whether certain data will not be available for access in order to prevent the possible identification of participants.(refer to Access section chapter 7 for further details of access considerations)

### ACCESS TO BIOBANK MATERIAL AND DATA

#### PRINCIPLES

- 7A. The biobank should have clear, detailed, publicly available policies, protocols and procedures in place governing access to all biological material and data.
- 7B. Transfer, access and use of human biological material and data should be consistent with the terms of participation and respect the privacy of the participant, confidentiality of the human biological materials and data, and ensure good safety and laboratory methods.
- 7C. The biobank should only transfer specimens and data when there are adequate standards in place regarding the privacy of the participant, confidentiality of the human biological materials and data, and good safety and laboratory methods, and in accordance with applicable law and regulations.
- 7D. The biobank should inform participants on whether or not their human biological materials and data, in whole or in part, will be made accessible to third parties or law enforcement agencies and the conditions under which this may occur.
- 7E. The biobank should consult stakeholders including the general community and researchers to formulate criteria for prioritising applications for access to the human biological materials.
- 7F. The biobank should make information publicly available on the research projects for which specimens and data are accessed, and the results of these projects.

#### BEST PRACTICES

##### Access Policies, Procedures and Processes (Principle 7A)

- 7.1. The mechanisms and processes for reviewing applications for access to and use of the biobank, including research ethics committees or other oversight mechanisms, should:
  - i) ensure human biological materials or data are used in a manner consistent with the original informed consent process, including determining when to seek re-consent;
  - ii) review the use of human biological materials and/or data which were consented using a broader or layered format for unspecified future uses, especially in the case of large-scale genetic epidemiology studies; and
  - iii) review the plan for data access and data distribution to make sure it is consistent with the informed consent provided by the participant.

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- 7.2. Where there is doubt over whether an intended use of human tissue or data is consistent with the purpose for which consent was given by a participant, legal advice should be sought by the biobank custodian or HREC through the institutional or departmental legal service. Under current law in WA, HREC approval will not make lawful an unlawful use of tissue or disclosure of identifiable tissue, nor will it negate any potential liability for such acts.
- 7.3. The biobank should have policies on access that include:
- i) requirements for accessing human biological materials and data. This should be based on objective and clearly articulated criteria considering data security and confidentiality;
  - ii) the circumstances under which they would provide access to human biological materials or data to law enforcement agencies or third parties; and
  - iii) requirements for the return or destruction (in a manner not permitting recovery), of human biological samples and data provided to third parties at the completion of their research.
- 7.4. The biobank may choose to have stratified access or fee policies. These should be fair, transparent and not inhibit research.

### Terms of Access (Principle 7B)

For details of information on access to samples and/or data that should be provided to participants prior to collecting informed consent refer to best practice 4.2.

- 7.5. Access should be assessed in light of the biobanks' objectives, participant's interest and to ensure that the proposed uses are scientifically and ethically appropriate and consistent with applicable policies, frameworks and legislation. Evidence of scientific peer review and ethical approval should be required to demonstrate this.
- 7.6. Unless strictly necessary as determined by an HREC, researchers should be provided access only to human biological materials and data or information that are coded such that the participant cannot be identified and researchers should be required to not attempt to re-identify participants.
- 7.7. The terms of access for researchers to the whole or a part of the database(s) of a biobank should be set out in an access agreement.
- 7.8. Where a biobank intends to provide access to the specimens and samples collected from participants, they should develop a material transfer agreement or other agreement appropriate for that purpose.
- 7.9. Mechanisms should be employed to ensure that researchers are not inadvertently provided access to potentially identifying data, including, for example, by only permitting the querying of the database by biobank staff who return the aggregated results to the researcher or by permitting researchers to query only certain aspects of the data held by the biobank. Users of data should sign confidentiality agreements.

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- 7.10. Where a biobank incorporates results of research into the biobank the biobank should consider how access to such results for further research should be managed, particularly if the results can be linked to other information about the participant. (Refer to Best Practice 5.1d)

### Access Regulations (Principle 7C)

- 7.11. National and international access to the biobank is contingent on recipients being subject to law or other binding requirements which are substantially similar to those applicable in this jurisdiction regarding handling, privacy and confidentiality of tissue samples and information.
- 7.12. International researchers who request access to human biological samples or data held by the biobank should have a collaboration agreement with a Western Australian researcher.

### Third Party Access (Principle 7D)

- 7.13. The biobank should inform participants whether or not samples and data will be accessible to third parties or law enforcement agencies and the purposes they may be used for including if it is for research or non-research purposes.
- 7.14. The biobank should inform participants about all the legal requirements to provide access to samples or data to third parties or law enforcement agencies.
- 7.15. The biobank should not make accessible or disclose participants' human biological materials or data obtained for health research purposes to third parties for non-research purposes, including to government departments, religious groups, lawyers, insurance providers, employers, or to law enforcement agencies, except where required by law.

### QUALIFICATION, EDUCATION AND TRAINING

#### PRINCIPLES

- 8A. The biobank should ensure that all of its personnel are knowledgeable about its goals and mission.
- 8B. The managing person(s) of the biobank should be qualified by training and experience to carry out its mandate.
- 8C. The managing person(s) of the biobank should ensure that personnel have the appropriate professional qualifications that meet recognised standards, underpinned by experience, skills, up-to-date knowledge, education and training and are assigned responsibilities commensurate with their capabilities.
- 8D. The managing person(s) of the biobank should develop and implement employee training programs.
- 8E. Technical staff should be responsible for implementation of policies and procedures as established by the managing person(s) of the biobank.

#### BEST PRACTICES

- 8.1. Training should be carried out in line with the frequency required by legislation, regulation, guidelines and practice.
- 8.2. Training should form an integral part of the biobanks quality system and should be part of its quality manual.



### CUSTODIANSHIP, BENEFIT-SHARING AND INTELLECTUAL PROPERTY

#### PRINCIPLES

- 9A. The biobank should give consideration to who the custodian of the biobank is and if any ownership rights (legal or ethical) apply to the human biological material or data in the biobank.
- 9B. Benefits from research may be shared in different ways including the sharing of financial benefits, information, licensing, or transferring of technology or materials.
- 9C. Benefits arising from research using the resources of a WA biobank should be shared as broadly as possible with the WA community.
- 9D. The biobank should have clear, detailed, publicly available policies on benefit sharing.

#### BEST PRACTICES

For details of information on custodianship and benefit sharing that should be provided to participants prior to collecting informed consent refer to best practice 4.2.

##### Custodianship (Principle 9A)

- 9.1. The biobank should nominate a custodian at the time it is created. This could be an individual researcher, Chief Executive or Executive Director of relevant institute, or head of department.
- 9.2. The biobank should consider the current Australian legislative, regulatory and ethical system when determining who the nominated custodian should be.
- 9.3. The biobank should give consideration to circumstances where the custodian of the biobank may change through unforeseen circumstances (e.g. privatisation, change of government) and the affects this may have on the biobank.
- 9.4. The biobank should establish if any legal or ethical rights to the human biological material and data are retained by the participants or held by the biobank or the nominated custodian. This should be determined in reference to the current legal, regulatory and ethical system. The legal rights considered should include property rights and intellectual property rights.

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### Benefit Sharing (Principle 9B)

- 9.5. In recognition that the sharing of knowledge is one of the most important benefits to be derived from biobanks, the biobank should endeavour to foster the exchange of information and technology.
- 9.6. The biobank should make the general results of research conducted using the biobanks' resources publicly available regardless of outcome.
- 9.7. Aggregate results arising from research conducted using the biobanks' resources should not be limited to academic publications but should be made available by the biobank in easily accessible forms, including a newsletter or website.
- 9.8. The biobank should release an annual progress report and a report at the completion or termination of a research project. Such reports should list publications and patents resulting from research on the biobanks' resources and should be made publicly available.
- 9.9. Researchers should acknowledge in publications, presentations, and, where relevant, patents filed, the biobank whose resources they have used or relied on.
- 9.10. The biobank should provide to researchers using its resources detailed guidance on the manner in which it wishes to be acknowledged.
- 9.11. Where appropriate, biobanks should have a system where benefit sharing agreements can be negotiated before a study begins, especially in the case of population-level studies where there may be vulnerable populations, whole communities, many participants or unique concerns.
- 9.12. Where applicable the biobank should inform participants that commercial products may arise from research conducted using its resources.

### Policies (Principle 9D)

- 9.13. The biobank should have policies on benefit sharing that cover:
  - i) any intellectual property resulting from the biobank and whom this applies to, including the researcher, the biobank and the participant;
  - ii) whether research results will be added to the biobank to build it as a resource for research (see also 5.1d);
  - iii) whether tests or products arising from research using its resources might be shared with the community and/or the general population, and how such sharing will be effected;
  - iv) whether or not it intends to commercialise any resources (e.g. biological material, data, information or the database(s)), if commercial resources may arise from research, the modalities of such commercialisation and whether participants will derive any benefits from the commercialisation; and
  - v) whether the biobank will allow private or foreign investment or commercial collaboration in the future.

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- 9.14. The biobank's policy on benefit sharing should give consideration to how this may facilitate the sustainability of the biobank.

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## DEMISE OF THE BIOBANK AND DISPOSAL OF MATERIALS & DATA

### PRINCIPLES

- 10A. The biobank should plan for a situation where it no longer meets a continued scientific need and an unforeseen demise, such as the end of its funding.
- 10B. Human biological materials and data should be disposed (destroyed or transferred) of in an appropriate way, consistent with the principles of consent and privacy.
- 10C. The biobank should have clear, detailed, publicly available policies, protocols and procedures in place for the disposal or transfer of human biological material and data in the event of the closure of the biobank.

### BEST PRACTICES

For details of information on the disposal or transfer of human biological material and data in the event of the closure of the biobank that should be provided to participants prior to collecting informed consent refer to best practice 4.2.

#### Closure of the Biobank (Principle 10A)

- 10.1. The initiators of a biobank should consider a possible end date for the project.
- 10.2. In the event that a biobank can no longer be financially supported, every effort should be made to transfer the materials and data, in accordance with consent given by participants, to another initiative or to another entity.
- 10.3. Where the demise of the biobank results from insolvency, the liquidator will be governed by applicable insolvency law. The initiators of the biobank should be aware that the liquidator may be permitted or required to sell the assets of the biobank to commercial buyers, subject to any constraints in the participants' consent or under the law.

#### Disposal or Transfer of Biobank (Principle 10B)

- 10.4. The biobank should ensure the destruction of information and data is in a manner not permitting its recovery.

#### Policies (Principle 10C)

- 10.5. The biobank should have policies relating to the demise of the biobank including the manner in which the human biological materials and data that it holds will be dealt with in the event of its demise.

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## PART I: PRINCIPLES AND BEST PRACTICES

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- 10.6. The biobanks' policy on the destruction and disposal of human biological materials and data should take into consideration cultural heritage and/or religious beliefs known or disclosed by the participants, and their representative groups.
- 10.7. The biobanks should detail the method of disposal of human biological material to the participant prior to collecting informed consent (refer to best practice 4.2). eg. in a lawful and respectful way, particularly for retained tissue samples.

Consultation Draft

### ANNOTATIONS RELEVANT TO GUIDELINES

#### 2. ESTABLISHMENT OF BIOBANKS

- (i) **Principle 2E:** The greater the breadth of targeted participants, information and data collected by the biobank, the more important that broad consultations be carried out and with diverse groups.
- (ii) **Principle 2E:** Consultations may assist in communicating information about the nature, purpose and scope of the biobank as well as identifying participant needs and concerns. Biobanks should guard against inflating the future and potential benefits of the biobank itself and of participating in the biobank.
- (iii) **Principle 2E:** Consultations may be carried out using diverse approaches and more than one approach may be used (e.g. focus groups, surveys, interviews, forums, workshops, public meetings and web-based discussions).
- (iv) **Principle 2E:** Consultations should aim to cover a variety of issues, particularly those where concerns have been identified (e.g. scientific, legal, regulatory, social and ethical issues).
- (v) **Principle 2F:** The type of information made publicly available on the financial model could include the business plan for both the short-term and the long-term.

#### 3. GOVERNANCE, MANAGEMENT, AND OVERSIGHT

- (vi) **Principle 3A:** The oversight bodies for the biobank could include representatives from medical and scientific specialties including genetics/genomics and epidemiology, as well as other fields including law, ethics and accounting in addition to representatives of participants and members of the public.
- (vii) **Principle 3B:** For research relating to a large portion of a population (e.g. looking at the correlation between a specific heritage and a specific disease) the initiators and managers of the biobank should give consideration to the potential for discrimination not only for participants but also for individuals, families and groups who have not participated. For example it should be disclosed that individual and population-based genetic data may have repercussions for a participant, his/her family, a group he/she is part of and his/her community as a whole. It should be disclosed where these repercussions may include insurance or employment difficulties or a loss of dignity.
- (viii) **Principle 3D:** The oversight groups may follow a number of models with different functions including institutional review boards, ethical review boards, scientific peer-reviewed committees or scientific advisory committees.
- (ix) **Principle 3D:** The oversight group responsible for addressing breaches of or non-adherence to relevant regulations, guidelines and frameworks may be established

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## PART II: ANNOTATIONS

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by the biobank solely for that purpose or may be an existing group (e.g. a judicial court).

- (x) **Principle 3G:** In providing information to participants about the key legislation, regulations and guidelines applicable to the biobank, the biobank should have in place a process for informing participants as these instruments are updated or changed over time.
- (xi) **Principle 3G:** Examples of the relevant legislation, regulation and guidelines that may apply to the biobank include the following:

### International

- The UNESCO, '*Universal Declaration on the Human Genome and Human Rights*' (1997) declares that the human genome is the common heritage of humanity and examines the fundamental rights of the individual and society that should be protected during research.
- The World Medical Association Declaration of Helsinki, '*Ethical Principles for Medical Research Involving Human Subjects*' (1964) provides guidance to physicians and other participants in medical research involving human subjects, including research on identifiable human material or identifiable data.
- The Council of Europe, '*Convention on Human Rights and Biomedicine*' (1997) adopted by many member countries deals primarily with protection, especially of human rights, in the context of the application of biology and medicine.
- The Council of Europe also adopted the '*Recommendation Rec2006(4) of the Committee of Ministers to member states on research on biological materials of human origin*' (2006) which applies to research activities in the health field involving the removal of biological material of human origin to be stored for research use. Within this recommendation, there is also a brief section on population biobanks.
- The HUGO Ethics Committee, '*Statement on Human Genomic Databases*' (2002) provides principles and recommendations for biobanks generally.
- Organisation for Economic Co-operation and Development '*Best Practice Guidelines for Biological Resource Centres*'. Provides guidelines for the establishment and management of access, use and security of biological material and data.

### National

- The 'Privacy Act 1988' (Cth), applies to the private sector and Commonwealth agencies. There is similar privacy legislation in various States and territories, but not currently in WA, which applies to State government entities and the private sector.
- The Common Law of Australia can be applied to property rights and to the duty of confidentiality. While this is not well defined it can be applied through case law.

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## PART II: ANNOTATIONS

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### State

- The 'State Records Act 2000' governs the retention and disposal of State records, which applies to records created or received by government organisations or its employees. Section 78(2) provides that a government organisation employee who, without lawful authority, transfers, or offers to transfer, the possession of a government record to a person who is not entitled to possession of the record, commits an offence.
- The 'Hospitals and Health Services Act 1927' applies to the collection of information (including public and private hospital data) regarding users of the health system (see part IIIC).
- The 'Human Tissue and Transplant Act 1982' regulates the removal and use of tissue in certain circumstances including for the purpose of transplantation. See also the Non-Coronial Post-Mortem Examination Code of Practice 2007.
- The 'State Trading Concerns Act 1916' (eg. see sections 4, 4A and 4B). Essentially this Act prohibits any trading concern being carried on by WA government bodies except those expressly permitted by Statute or under the Act itself. A "trading concern" is any concern carried on with the view to making profits or producing revenue, or of competing with any trade or industry now or to be hereafter established, or of entering into any business beyond the usual functions of State Government.
- The 'Equal Opportunity Act 1985' provides regulations for the fair treatment of all people in WA.
- The Coroners Act 1996 and the Anatomy Act 1930.

### 4. TERMS OF PARTICIPATION

- (xii) **Principle 4A:** During the recruitment process there are different ways to ensure non-bias (e.g. the person performing the recruitment is independent from the lead investigator). It should always be made clear to potential participants that agreement or refusal to participate will not have any affect on their medical care.
- (xiii) **Principle 4B:** While the goal of the informed consent process should be to provide as much information as is relevant, the informed consent document should remain as straight-forward, readable and accessible as possible. Considerations should be given to the needs of participants especially for those who are less educated, elderly, or who are not native speakers. Where relevant, for the potential participants, the informed consent document should be translated into their native language/mother tongue.
- (xiv) **Principle 4B:** Where participants are offered graduated consent options these may cover issues such as:
  - a. if the samples and/or data will be used for a single research study or for multiple studies;
  - b. if the participant gives their permission to be re-contacted;

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## PART II: ANNOTATIONS

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- c. options for the participant to withdraw samples and/or data from the biobank;
  - d. participant preferences for feedback;
  - e. an option for the participant to choose if identifiable data can be accessed by researchers;
  - f. options for participants to choose for their samples and/or data to be used for particular research areas;
  - g. if or when the samples and/or data must be destroyed; and
  - h. permission to transfer samples to another registered biobank.
- (xv) **Principle 4C:** There are numerous options for a participant exercising their right of withdrawal. For example,
- a. No further contact - no further contact with the participant, but permits the continued retention and use of the previously obtained specimens, samples and data, and if applicable, linked to records from third parties.
  - b. No further use - no further contact with the participant, no further collection of specimens or data, and destruction or rendering of all specimens samples and associated data as non-identifiable.

At the time of consenting, participants should be informed of the various options.

- (xvi) **Principle 4C:** In some situations, the right to withdraw may be restricted, and participants should be informed of this. If samples have been rendered non-identifiable or distributed, or if results are in the public domain or have been published, complete withdrawal may not be possible. Participants need to be informed about these situations. However, participants should also be reassured that complete confidentiality and protection of their specimens, samples and data will continue.
- (xvii) **Principle 4E:** There are a number of ways a biobank can approach what should happen when a participant becomes incapacitated or dies. The biobank could: inform participants their samples and data will remain with the biobank; offer the option for a legal representative to withdraw the participant; inform the participant their samples and data will be made non-identifiable following notification of their death. The biobank should also consider whether they will reassess the mental capacity of the participant during any re-contact with the participant and/or what the effect of a participant being found to lack capacity on re-contact will be (e.g. further data or samples may not be lawfully collected thereafter, and whether the fact of their incapacity will be recorded and included in the research database).
- (xviii) **Principle 4E:** Where substitute consent has been obtained from a participant lacking capacity (e.g. a child), and consent is to be re-collected particular care will need to be given to respecting the individual privacy of each participant where children have been recruited into family studies.

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- (xix) **Principle 4F:** When providing information the biobank should consider various methods to provide information, whether during the consent process or to provide information to the public. Efforts should be made to employ the most environmentally-sound and cost-efficient means of communications. Information could be provided through: leaflets; annual reports; information sessions; meetings with counsellors; websites; television; radio; newspapers or internet blog sites.
- (xx) **Principle 4F:** Decisions on the communications approaches to be employed by the biobank should take into account the diversity of the targeted audience. Consideration should be given to technology issues (i.e., paper versions of the documents should be made available especially for those who are not familiar with technology), language issues (i.e. do the documents need to be translated into a language of a large segment of the population, even if it is not an official language) and diverse challenges (i.e. information may be more accessible for a portion of a population if it is made available in video format, and it may be more accessible for the visually impaired if converted into Braille script). Communication strategies should also take into account the consent process for children.
- (xxi) **Principle 4F:** While it is recognised that for certain biobanks it may not be possible for some information provided during the consent process to be made publicly available (e.g. protected or proprietary information) it should always be provided to potential participants.
- (xxii) **Principle 4F:** If, during the informed consent process, participants meet with staff from the biobank they should ensure the meetings are fair and neutral and do not, either directly or indirectly, create the potential for participants to feel pressure to participate in the biobank.
- (xxiii) **Principle 4F:** The biobank should ensure that potential participants are not placed under rushed time constraints for providing their consent.
- (xxiv) **Principle 4F:** Feedback of results to participants may be provided in different forms and in more than one form including: the publication of results; newsletters; and websites which may hold summaries of research findings and lists of publications.
- (xxv) **Principle 4F:** Participants should be provided, at the time of consent with information about the conditions under which the biobank will re-contact them if applicable. This should include the circumstances under which they will be re-contacted, whether re-contact is obligatory for participation in the biobank, and by whom they will be re-contacted.

### 5. CONTENT OF BIOBANKS

- (xxvi) **Principle 5A:** The biobank policy on the collection of biological material and data should:
- a. give details of the quality and quantity of the specimens and/or data to be collected;
  - b. indicate whether there will be direct or indirect links to identifying information;

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- c. provide details of the type of sample/s to be collected (e.g. blood, urine, hair, buccal swab, biopsy material);
  - d. indicate if immortalised cell lines will be created from the samples collected; and
  - e. provide details of the quantity of the specimens to be collected and what each specimen will be used for and the data obtained from it (e.g. 60mLs blood to extract DNA and RNA and to test for glucose and haemoglobin levels).
- (xxvii) **Principle 5A:** Where the biobank intends to access data from the health data collections or from other collections the participants should be informed before consent is collected: what the health data collections are, and the possibility that the data collected by the biobank and that obtained from the research may be linked with other data about the participants.
- (xxviii) **Principle 5A:** Where the biobank has a policy to not perform specific tests this could include things such as paternity testing, HIV/AIDS testing or testing for the use of illicit substances.
- (xxix) **Principle 5A:** The biobank policies relating to contents should take into account the different attitudes different cultural and religious groups have towards biological material. Some groups regard particular material as having a special status, particularly where it is removed post mortem, and consider special treatment should be provided (e.g. in terms of the method of disposal).

### 6. PROTECTION OF HUMAN BIOLOGICAL MATERIALS AND DATA

- (xxx) **Principle 6A:** Human biological materials and data protection may be achieved via different approaches and mechanisms, and often through the combined use of various approaches. Some examples include:
- a. the coding and encryption of human biological materials and data;
  - b. limiting access to the collection of human biological materials and data;
  - c. implementation and maintenance of security measures to block unauthorised access;
  - d. data enclaves (Data enclaves involve the use of secure or controlled access databases or websites. These allow the biobank or a third party to physically and electronically control and monitor the use of the biobanks database(s) by external users to ensure it complies with the terms of access and conforms with the participant's consent);
  - e. honest broker systems (Honest broker systems involve an independent third party who is responsible for ensuring the separation of identifying information from other data. An honest broker system may be, for example, a data protection authority); and

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- f. where human biological materials and data are collected by more than one research group, then each group could use their own code with none of them holding all the codes.

### 7. ACCESS TO BIOBANK MATERIAL AND DATA

- (xxxix) **Principle 7B:** Depending on the nature of the resource, the data/ sample provider and the end user, access agreements (including data access and material transfer agreements) may address some or all of the following:
- a. what is to be provided (specification of data and materials, format and timing of release);
  - b. what the data and materials provided can be used for (this is often limited to a specific project), and what they can't be used for (this may be everything other than the specified project, or something more specific (e.g. data linkage);
  - c. the credentials of the end user;
  - d. fees (or royalties) payable;
  - e. arrangements concerning intellectual property rights (e.g. whether or not IP rights are asserted by the provider over existing or future IP, or any licenses sought by them to future IPR);
  - f. requirement to return research findings to the resource owner to enrich the resource;
  - g. requirement to publish research findings and/or to disseminate them more generally, and to acknowledge the resource in publications;
  - h. requirement to act in accordance with participants' consent, and any procedures in the event of withdrawal of consent;
  - i. requirement to act in accordance with relevant legal and regulatory requirements, and obtain ethical approval (where applicable);
  - j. requirement to preserve confidentiality, and/or maintain non-identifiable status (and not attempt to re-identify or re-contact participants);
  - k. limits on (prohibition of or additional safeguards required for) transfer of data or materials to third parties, including cross-border;
  - l. disclaimers of responsibility for data/sample quality;
  - m. return or destruction of residual samples and data at the end of a project;
  - n. termination (e.g. for default).
- (xxxixii) **Principle 7B:** If the biobank has a policy of stratified access and fees this could be based on a number of criteria including the background or affiliation of the

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## PART II: ANNOTATIONS

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researcher (e.g. private companies could be charged a fee when researchers from public universities and public laboratories are not).

- (xxxiii) **Principle 7D:** Where the biobank releases biological material or data to third parties consideration should be given to the implications for the custodianship of any data derived from the analysis performed by that third party. Consideration should be given to maintaining participant's privacy and the confidentiality of any released biological material and data, particularly where released material or data can be linked to other data on the same participants. This may require suitable provisions managing the use of the data being included in the terms of material transfer agreements (MTAs) which govern the release of the human biological materials and data from the biobank to the researcher.

### 9. CUSTODIANSHIP, BENEFIT-SHARING AND INTELLECTUAL PROPERTY

- (xxxiv) **Principle 9B:** Information and technology exchange may occur through various ways including: technology transfer, material transfer, licensing, or joint development activities. The OECD Guidelines for the Licensing of Genetic Inventions (2006) provide guidance so as to ensure that licensing and transferring agreements as well as joint development activities are carried out in a balanced manner and are based on economically rational practices that help eliminate high transaction costs and that serve the interests of society.
- (xxxv) **Principle 9B:** To contribute towards the continued development of the biobank as a resource the biobank should aim to ensure that general results arising from research conducted using its resources be added back into its database(s).
- (xxxvi) **Principle 9B:** Where the biobank has been developed with input from researchers from resource-poor settings, it may be appropriate for the users of the resources or the initiators of the biobank to identify ways in which those contributors can be supported (e.g. through the exchange of knowledge or know-how to develop research capacity in such settings).
- (xxxvii) **Principle 9D:** The biobank policy on commercialisation should be consistent with the National Health and Medical Research Council '*National Statement on Ethical Conduct in Human Research*' which indicates that for commercialisation there should be no trade in human tissue for research purposes (ref: 3.4.10).
- (xxxviii) **Principle 9D:** The biobank policy on intellectual property rights should cover any property rights that arise directly or indirectly from use of the biobank. The policy may include to whom the property rights accrue, and who will ensure their protection or enforcement, if necessary. There may also be intellectual property rights that arise pursuant to research carried out using the biobank and this should also be considered in the policy.

**Principle 9D:** The biobank policy on intellectual property rights should give consideration to existing legislation, regulations, and ethical guidelines on this. The ALRC report 96 '*Essentially Yours: The Protection of Human Genetic Information in Australia*' (2003) provides the following on the legal position regarding property rights in human tissue samples in Australia -

- "The recognition of property rights has implications for access, storage and use of such samples. However, the cases to date have only dealt with very limited fact situations. The courts have not produced any

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## PART II: ANNOTATIONS

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clear ruling on the particular property rights that may be held over tissue samples, beyond a right of possession - the violation of which may constitute theft only in specific circumstances. It is not clear what other property rights exist in relation to tissue samples, though it could be argued that the common law has implicitly accepted the existence of other property rights in tissue, such as the right to use, by allowing continued possession by hospitals, laboratories and museums.” (20.15).

### 10. DEMISE OF THE BIOBANK AND DISPOSAL OF MATERIALS AND DATA

- (xxxix) **Principle 10C:** The biobank policy on the disposal of biological material and data at the demise of the biobank should consider how samples and data that have been provided to third parties will be managed. Depending how long the biobank has been running the destruction of all data may also be quite difficult given that back-up files may cover a lengthy period (e.g. 30 years). While the biobank will retrieve and destroy as much of the data as possible, there may be circumstances where this is not feasible (e.g. if pooled samples have been prepared or cells lines have been developed and disseminated in a non-identifiable form). Information on these conditions should be provided before collecting informed consent as indicated in Best Practice 4.2.

GLOSSARY

DEFINITIONS

The following definitions are provided for ease of reference. Some of these definitions are drawn from commonly used international documents and do not represent an effort to agree on interpretation of these definitions or develop new ones.

<i>Assent</i>	Herein this term is used in the context of a child participant in research. It implies an act involving understanding. Even though a child may not be considered legally competent to consent to participate in research, the child may be considered competent to give his/her assent, that is - their opinion on whether they wish to participate in the research.
<i>Associated Data (Information)</i>	Personal, clinical, biochemical and phenotypic information about the participant.
<i>Biobank (Biorepository, Genebank)</i>	An organised collection of human biological material and any related information stored for one or more purposes.
<i>Custodian</i>	The custodian of a biobank is considered to be either, an individual researcher, Chief Executive or Executive Director of relevant institute, or head of department as nominated by the biobank.
<i>Double-Coded</i>	Double coded data employs the use of two coding keys to ensure additional protection of privacy and confidentiality.
<i>End-User</i>	A health care practitioner, scientist, or laboratory personnel who performs an appropriate procedure, test or archival function for the specimen
<i>Governance</i>	The processes and structures that an entity uses to set its objectives/goals, appoint the management whose responsibility it is to achieve these goals and to oversee management in its pursuit of these goals.  Governance mechanisms are also needed to put in place internal controls and risk management systems. Management is accountable to the governance bodies that in turn are accountable to those who have appointed them.
<i>Human Biological Material</i>	Includes specimen, samples and aliquots
<i>Identifying information (identified)</i>	Information where the identity of an individual is apparent or can reasonably be ascertained by the holder of the information. Information that may directly, or indirectly, lead to identifying individuals from whom the human biological material and associated information are collected as a link (or multiple links) exists between the participant's personal identifiers and the data. (See Appendix 1)
<i>Independent (related to review)</i>	Identified as having no conflict of interest. Having no association with the governance or running of the biobank, no association with the funding for

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## PART III: GLOSSARY & APPENDICES

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and monitoring personnel or committees)	the biobank, not being a researcher using the biobank and not being associated with any government institutions associated with the biobank or these guidelines.
<i>Initiators</i>	The researchers, governmental entities and/or organisations involved in setting up the HBGRD.
<i>Informed consent</i>	<p>A process by which information concerning the proposal and any collection, use or disclosure of an individual's human biological material or associated data is presented to the participant or participant's substitute decision-maker with an opportunity for them to ask questions, after which specific approval is documented. The three main elements to consent are -</p> <ul style="list-style-type: none"><li>▪ There must be full disclosure to the individual of the purpose, methods, demands, material risks and potential benefits of participation</li><li>▪ The individual must have the capacity to understand the proposal and the implications of participation in it</li><li>▪ It must be given voluntarily, without coercion, inducement or influence.</li></ul>
<i>Management</i>	Comprises directing and controlling a group of one or more people or entities for the purpose of coordinating and harmonizing that group towards accomplishing a goal. Management often encompasses the deployment and manipulation of human resources, financial resources, technological resources, and natural resources. Management is responsible for achieving the objectives/goals set for the organization and is given considerable leeway to undertake this task. While this may be operationally efficient, there is a possibility that management might act only in their own interests, hence the need for governance mechanisms.
<i>Material Transfer Agreement</i>	Generally signed between a provider and a recipient, is used to document the transfer of materials, with or without information, either to an entity ( <i>i.e.</i> , the recipient) and/or away from an entity ( <i>i.e.</i> , the provider) subject to a number of terms and conditions.
<i>Non-identifiable</i>	Information from which the holder of the information cannot reasonably ascertain the identity of a specific individual. This includes information that has never been labeled with individual identifiers or from which they have been permanently removed. (See Appendix 1)
<i>Non-validated results</i>	Research results where there is insufficient evidence to clinically validate the findings.
<i>Oversight</i>	Is based on the notion that there is usually a difference between setting policy and objectives for an entity and overseeing or monitoring how these are being executed or put into operation.
<i>Participant</i>	Individual who is the source of the specimen in accordance with established medical criteria, procedures and practice and in compliance with the law including any privacy requirements.
<i>Private entity</i>	May cover for-profit entities but may also cover legal entities not publicly held or traded.
<i>Private-Public Partnership (PPP)</i>	Is a cooperative venture between the public and private sectors, built on the expertise of each partner and involves the allocation of resources, risks and rewards.
<i>Human Research Ethics Committee (HREC)</i>	Is a local authority that evaluates research projects involving human beings, including genetic research. The primary function of an HREC is to protect the welfare and rights of human participants in research.

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## PART III: GLOSSARY & APPENDICES

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<i>Sample</i>	A single unit containing material derived from one specimen.
<i>Specimen</i>	A specific tissue, blood sample, urine sample, <i>etc.</i> taken from a single individual at a specific time.
<i>Third party</i>	Any person excluding the biobank participant and people involved in managing and operating the biobank.

Consultation Draft

#### IDENTIFICATION

There is growing recognition that the concepts of identification and anonymity in relation to health data and in particular to biobanks is not easily defined and terms such as de-identified and anonymised are misnomers. The concept of personal or identifying information is perhaps best viewed as a spectrum or continuum from unidentified to identified.

An individual will be identifiable if:

- the information is identified with the individual's name, image, date of birth, address or other personal identifier
- the information contains a unique personal identifier and the holder of the information also has a master list linking the identifiers to individuals
- the number of different pieces of information known about a particular individual enables someone to link the known pieces and complete the (re) identification of some or all those in the data list
- the person holding the information can merge or link it to other information which will enable them to identify the individual/s
- the identity of the individual can be established from aggregated data because of the small number of persons within a particular category
- information derived from a human biological material can be used to identify an individual, or enable (re) identification.

In every case a judgement must be made as to whether the identity of an individual can reasonably be ascertained by the holder of the information.

This decision on **identifiability** of data depends on the probability that a specific individual can be identified from the information. Equally important is that **identifiability** is dependent on both the amount of information held and on the skills and technology employed by the holder.

Separation between non-identifiable and identifiable data is thus technology and information based but is also highly dependent upon the ethical conduct, adherence to good governance practices and an understanding of the duties owed, by custodians and responsible officers, in relation to the biobanks, associated data and other databases.