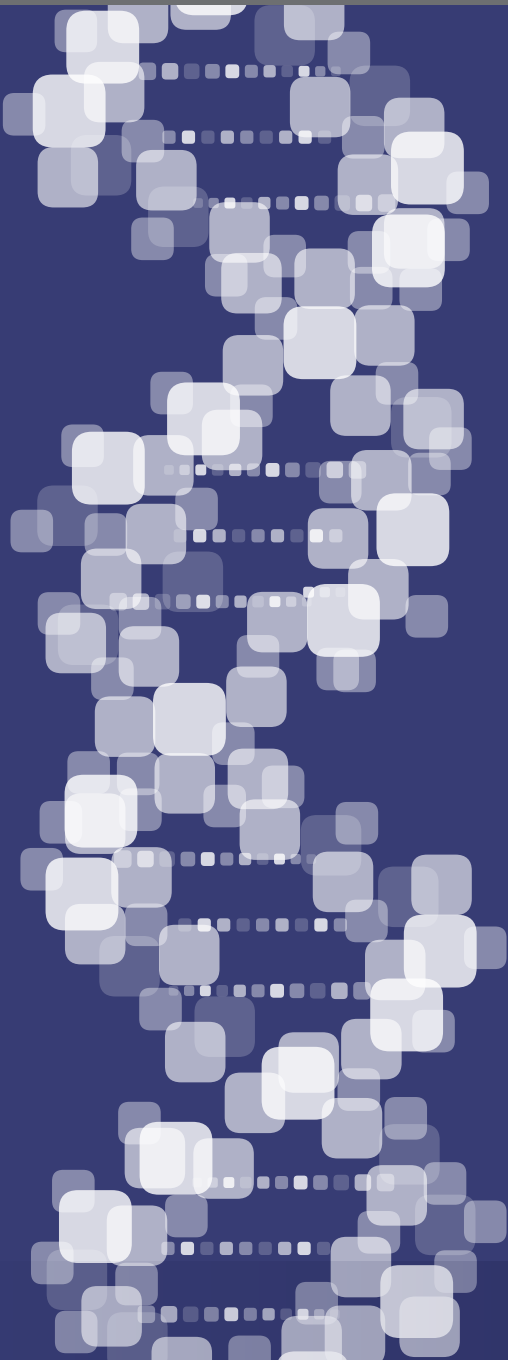





Government of **Western Australia**  
Department of **Health**

# Guidelines for human biobanks, genetic research databases and associated data



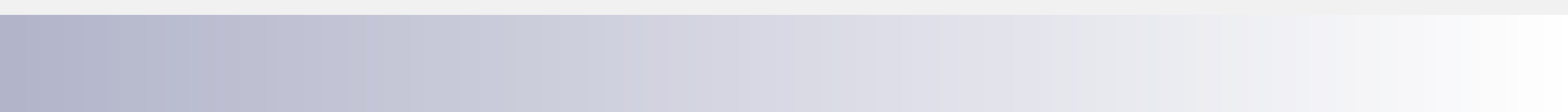


## **Guidelines for human biobanks, genetic research databases and associated data**

Prepared by:  
Office of Population Health Genomics  
Public Health Division  
February 2010

For the  
Department of Health WA

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.



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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 for 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 science also offer much promise for unraveling the biochemical and physiological mechanisms of complex diseases at the functional molecular level. The ability to effectively use these vast amounts of knowledge will depend in part on 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 analysed 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 three 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.
- Consumer, genetic disease and privacy advocacy groups have expressed their desire that there be wider public consultation, increased transparency and adequate privacy safeguards regarding the collection and use of their samples and any linked health information.
- 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

As agreed to by stakeholders and 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 and universities or research institutions;
- established by investigators with joint appointments between WA Health and universities or research institutions;
- established using samples 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.

For the purposes of the Guidelines the term 'biobank' applies to those individuals responsible for setting up the biobank, collecting the samples and data and/or those responsible for the management and daily operation of the biobank. The biobank custodian is considered by these Guidelines to have primary responsibility for the recommendations listed in Part I. This position is consistent with the NHMRC 'National Statement on Ethical Conduct in Human Research'<sup>1</sup> (National Statement) which defines:

<sup>1</sup> National Health and Medical Research Council, Australian Research Council and Australian Vice-Chancellors' Committee. National Statement on Ethical Conduct in Human Research. 2007.

*“individual researchers and the institutions within which they work hold primary responsibility for seeing that their research is ethically acceptable” (p4).*

## **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.

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 applied to resources established and used primarily for clinical purposes, such as for diagnosis, therapeutic, treatment, forensic, transplantation, transfusion, audit, public health surveillance, quality assurance purposes or for use as teaching materials. Nevertheless, for such collections the Guidelines may 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 (who 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 WA, 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 and should be used in conjunction with existing guidelines, laws and regulations (refer to Annotation 3xi for further details of relevant laws and guidelines).

Appropriate guidelines may include, but are not restricted to:

- the National Statement. This provides a framework for researchers, Human Research Ethics Committee (HRECs) and institutions for the design, review, conduct and monitoring of ethical research<sup>2</sup>;
- the National Health and Medical Research Council, Australian Research Council and Australian Vice-Chancellors' Committee *'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>3</sup>; and
- the 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>4</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. They are intended to 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 samples 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 in order to ensure they are fostering the desired objectives.

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

## 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 of terms, used in biobanking and database management. It also contains appendices and a checklist to assist in the implementation of the guidelines.

2 [http://www.nhmrc.gov.au/publications/synopses/\\_files/e72.pdf](http://www.nhmrc.gov.au/publications/synopses/_files/e72.pdf)

3 [http://www.nhmrc.gov.au/publications/synopses/\\_files/r39.pdf](http://www.nhmrc.gov.au/publications/synopses/_files/r39.pdf)

4 [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)



# 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 Act* and *Human Tissue and Transplant Act*, address aspects of biobanking operations. However the ALRC-AHEC Joint Inquiry<sup>5</sup> into genetic testing and information concluded gaps exist in the legislative framework. For example, in relation to the protection of participants' privacy there is no legal requirement for biobank participants to be informed that their tissue may be stored, disclosed to other researchers or linked with health information and there are no 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 Statement provides a consistent and national view, on how biobanks should be ethically established and used in the research environment. The National Statement provides a framework for HRECs, institutions and researchers to review, develop and perform ethical research.

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<sup>6</sup>. The OECD Draft Guidelines aimed to strike a balance to encourage and foster 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 samples 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 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.

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

## 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.

<sup>5</sup> Australian Law Reform Commission, *Essentially Yours: The Protection of Human Genetic Information in Australia* (ALRC 96) 2003.

<sup>6</sup> The final version of this document has since been released in November 2009. Organisation for Economic Co-operation and Development, *OECD Guidelines on Human Biobanks and Genetic Research Databases*. 2009.

## 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 Aboriginal representative<sup>7</sup>, a data manager, a health consumer and a representative from an independent research institute.

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

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

Dr Jenni Ibrahim (chairperson)  
Dr Marion Macnish  
Dr Paul Caterina  
Dr Nikolajs Zeps  
Prof Lyle Palmer  
Diana Rosman  
Kathy Vial

### Advisory Group

Dr Hugh Dawkins (chairperson)  
Prof James Semmens  
Prof Ursula Kees  
Prof Lyle Palmer  
Prof Frank van Bockxmeer  
Sharon Van der Laan  
Michele Kosky  
Stephen Sandilands  
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.

---

<sup>7</sup> Throughout this document, the term 'Aboriginal' refers to Aboriginal and Torres Strait Islander people and communities.

*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 a public engagement design developed at the W. Maurice Young Centre for Applied Ethics, University of British Columbia, and previously used to inform institutional Biobanking policy 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 WA 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, Aboriginal groups and the general public.

On day one of each forum, participants listened to a number of presentations from a range of ‘experts’, stakeholders and perspectives (e.g. of biobank custodian, lawyer, health consumer, disability advocate, commercial research experience, data manager). On days two–four 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.

More information on the design, implementation and evaluation of the deliberative public engagement forums can be obtained from the following website: [www.genomics.health.wa.gov.au](http://www.genomics.health.wa.gov.au)

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

|                      |                   |                         |
|----------------------|-------------------|-------------------------|
| Prof Michael Burgess | Peter Meintjes    | A/Prof Kieran O'Doherty |
| Prof Fiona Wood      | Prof Susan Dodds  | Prof Mike Daube         |
| Dr Simon Niemeyer    | Hope Alexander    | Prof Beverley McNamara  |
| Prof Paul Waring     | Meredith Blake    | Zeliha Iscel            |
| Dr Kath Fisher       | Dr Peter O'Leary  | Prof Barbara Koenig     |
| Caron Molster        | Dr Marion Macnish | Dr Hugh Dawkins         |
| Diana Rosman         | Suzy Maxwell      | Prof John Finlay-Jones  |
| Fiona Hope           | Dr John Beilby    | Gaenor Kyne             |
| Heather D'Antoine    | Ayla Potts        | Dr Jenni Ibrahim        |
| Leanne Youngs        |                   |                         |

## Targeted and public invitations to comment

Stakeholders involved in the Inventory Working Group, the Advisory Group, and the collaborators on both public engagement forums were invited to comment on the draft Guidelines prior to their release for public comment.

For the public consultation the document was available through:

- WA Health website (<http://www.genomics.health.wa.gov.au/home/>);
- Government of Western Australia, 'Government Notice Board' published in The West Australian; and
- Government of Western Australia, 'Citizenscape, ConsultWA' website (now closed).

Interested persons and organisations were requested to make written submissions over a two week period during September 2009. Twenty written submissions were received in total and these are listed below:

### Public submissions received on the 'Guidelines for Human Biobanks, Genetic Research Databases and Associated Data'

| Name                           | Nominated Affiliation   |
|--------------------------------|---|
| Prof Fiona Stanley             | Telethon Institute for Child Health Research  |
| Dr Paul Caterina on behalf of  | Anatomical Pathology Discipline Planning Committee, PathWest Laboratory Medicine WA |
| Dr Ian Gollow                  | Princess Margaret Hospital for Children   |
| Dr Marion Macnish on behalf of | WA DNA Bank Management Committee  |
| A/Prof Melanie Ziman           | Edith Cowan University Melanoma Research Foundation                                 |
| Dr Barry Lewis                 | Clinical Biochemistry, Princess Margaret Hospital for Children                      |
| Dr Deborah Wilmoth             | Chief Professions Officer, WA Health  |
| Sharon Van der Laan            | Genetic Support Council of WA   |
| Dr Bev Hewitt                  | Park Radiology  |
| Dr Judyth Watson               | Human Research Ethics Committee, WA Health  |
| Prof Susan Dodds               | Faculty of Arts, University of Tasmania   |
| Dr Adrian Charles              | Histopathology, Princess Margaret Hospital  |
| Linda Penny                    | Research Services, Edith Cowan University, Joondalup                                |
| Prof Linda Kristjanson         | Research and Development, Curtin University of Technology                           |
| A/Prof Kieran O'Doherty        | University of British Columbia  |

Dr Nikolajs Zeps  
Prof Frank van Bockxmeer  
Margaret Ryan  
Ray Baxter  
Raymond Cheek  
Stuart Edwards

St John of God Pathology  
Royal Perth Hospital

The submissions varied substantially in size and style, ranging from short notes written by individuals or families providing personal views and experiences, to large, well-researched documents prepared by government departments and agencies, research centres and laboratories and genetic support groups.

### **Stakeholder endorsement**

A Final Draft Version (20 January 2010), incorporating changes from the targeted and public comment phase, was circulated to all stakeholders with an invitation to attend an open Stakeholder Forum (Monday 15 February 2010). The forum provided an opportunity for the stakeholders involved in the development of the Guidelines to meet and collectively endorse the document prior to its passage through the WA Health processes to become Department of Health policy. Prior to the Forum, the OPHG received a number of written comments from key stakeholders unable to attend the meeting but wanting to provide their endorsement and full support for the Guidelines. The forum was well represented by stakeholders and included researchers, human research ethics committee members, genetic support group representatives and community members. The stakeholders unanimously endorsed the Guidelines.





# Part I: Principles and best practices

# 1. Biobanks generally

## Overarching principles

- 1A The objectives of the biobank should be:
  - a. to provide a resource for 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' samples and 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 custodian should ensure data and materials are shared 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 custodian should ensure risks to individuals, their families and potentially identifiable populations or groups whose samples and data are included in the biobank and used for research are minimised.



## 2. Establishment of biobanks

### Principles

- 2A The biobank should have a clearly articulated current and future purpose(s) and proposal for operation.
- 2B The biobank custodian should ensure a business plan is developed.
- 2C The biobank custodian should ensure operational policies and procedures are developed.
- 2D When establishing a biobank, consideration should be given to maximising flexibility in the design to enable future collaboration and cooperation, especially as regards database compatibility and interfaces.
- 2E When establishing a biobank, the initiators or the custodian 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 custodian should ensure information is made 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 or the custodian should develop criteria for sampling and participant selection 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 samples and data throughout its existence; and
  - vi) include a business strategy in the event that funding is terminated or its nature changed.
- 2.3 The funding model established should give consideration to ensuring the finances will be secured for the lifespan of the biobank.
- 2.4 Where a biobank custodian foresees private or foreign investment in the biobank occurring or commercial or international collaborations being entered into, this should be clearly articulated, communicated especially to participants, and undertaken in accordance with applicable domestic law and regulation.
- 2.5 The biobank custodian should ensure there are appropriate staff and resources to preserve records, data and samples appropriately, and to handle requests for access to data and samples.

## **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)**

- 2.6 Appropriate design elements providing for compatibility and interfaces should be incorporated when creating the databases. The biobank custodian should ensure consideration is given to using standardised approaches for the collection, storage and analysis of samples and/or data to facilitate cross-biobank data exchange and sharing.

## **Consultation (Principle 2E)**

- 2.7 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.
- 2.8 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.
- 2.9 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.
- 2.10 The biobank initiators or the custodian should clearly indicate to those consulted the manner in which their input may influence the establishment and impact on the future aims of the biobank.

## **Information and education (Principle 2F)**

- 2.11 The biobank custodian should ensure information is made 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) where the biobank complies with the Best practices in the Guidelines and when it does not, reasons should be provided (refer to Biobank Checklist in Appendix II).
  - v) the operational policies and procedures of the biobank, including proposed security and data protection measures, and access policies;
  - vi) the scientific rationale underlying the biobank;
  - vii) the type of research that will or is being carried out with the samples and data contained within the biobank;
  - viii) the research outcomes resulting from utilisation of the biobank, including any health and scientific benefits;
  - ix) the scientific and business risks and uncertainties associated with the establishment, operation and use of the biobank;
  - x) any risks for members of the public, particularly public health risks, associated with the establishment, operation and use of the biobank;
  - xi) where possible the nature and source of its financing/funding, especially private or foreign investment, commercial or international collaborations;

- xii) the ethics approval obtained to establish the biobank;
- xiii) the proposed duration of the biobank;
- xiv) the name(s) of senior management;
- xv) any vested interests and partnerships; and
- xvi) where to find more information on the biobank including contact details for a representative who will answer questions from the public.

## 3. Governance, management, and oversight

### Principles

- 3A The initiators of the biobank or the custodian 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 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 (this includes but is not limited to existing and future processes for ethical review), approval and monitoring and be administered according to the best practice principles of good corporate governance.
- 3D The biobank custodian should anticipate that the need to modify the policies, protocols and procedures over the lifespan of the biobank will arise, and should ensure a process is in place for undertaking these modifications.
- 3E It is the responsibility of all biobank personnel, researchers and partners to ensure that activities related to the biobank are carried out in accordance with prevailing norms and ethical principles.
- 3F The biobank custodian should ensure information on its regulatory framework, governance, management and oversight is made publicly available and easily accessible.

### 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 samples and/or data;
  - iii) independent auditing to monitor access to and the uses of the samples 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; and
  - 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, in addition to representatives of participants and members of the public.
- 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 samples 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.

### **Approval and administration (Principle 3C)**

- 3.6 The biobank's governance structure should be approved prior to the establishment of the biobank by an independent human research ethics committee (HREC) and be subject to unbiased scientific peer review.
- 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>7</sup>; and
  - ii) the six essential principles of the '*OECD Principles of Corporate Governance*'<sup>8</sup>.

### **Modifying policies, protocols and procedures (Principle 3D)**

- 3.8 The process for modifying the policies, protocols and procedures of the biobank should include a means for participants to be informed about these modifications.
- 3.9 The biobank custodian should ensure approval is obtained from an independent HREC for modifications that significantly<sup>7</sup> alter policies, protocols and procedures.
- 3.10 Where policies, protocols or procedures of the biobank are significantly modified, the biobank custodian should ensure that new consent is obtained from the participant or substitute decision maker (unless exempted through a waiver of consent authorised by an HREC).

### **Information and education (Principle 3F)**

- 3.11 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, and complaint processes;
  - 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;
  - v) key elements of applicable domestic laws, regulations, 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 (refer to annotation 3xi for a list of relevant laws and regulations); and
  - vii) annual reports of compliance of the biobank with applicable domestic laws, regulations, ethics guidelines, and international instruments.

<sup>7</sup> Significant changes are defined as: changes where 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)

## 4. Terms of participation

### Principles

- 4A Participant recruitment should be carried out in a non-coercive and equitable manner.
- 4B The biobank custodian should ensure prior, free and informed consent is obtained 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 custodian should ensure clear, detailed, publicly available policies, protocols and procedures are 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 custodian should ensure careful consideration is given 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 custodian should ensure potential participants are provided 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) the nominated custodian of the biobank;
- v) any conditions where the nominated custodian may change;
- vi) storage facilities and duration of storage;
- vii) any legal or intellectual property rights that might be material to their participation;
- 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) sample or data transfer and disposal/destruction procedures;
- x) the samples and data to be collected, and which samples and data will be collected from the participants or from other sources;
- xi) if identifiable samples and/or data will be stored, the circumstances where it may be released and if samples and/or data may be released interstate or internationally;
- xii) whether third parties may be given access to samples or data and the conditions under which this will occur;

- xiii) the conditions under which law enforcement agencies may access samples and/or data and any legislation that may apply;
- xiv) the level of privacy and confidentiality protection to which their samples and data will be subject, the procedures and safeguards that will be employed for this protection, and of any specific risks of unauthorised access;
- xv) 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;
- xvi) if the biobank closes, the manner in which the samples and data will be destroyed or transferred and what will be done with the biobank assets;

#### **Implications for participation**

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

#### **Access and use**

- xxiii) the intended uses of the biobank (including if it is to be used for non-research purposes e.g. quality assurance);
- xxiv) the terms and conditions of access to the biobank samples and data;
- xxv) if specific types of tests are not allowed to be performed on the biobank samples or if specific types of data will not be recorded;
- xxvi) health and other records to be accessed and/or their intended uses (where the biobank custodian intends to access data for inclusion in the biobank 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
- xxvii) if the data collected, 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 information provided as part of the recruitment process should take into consideration the participant's cultural and/or religious beliefs.
- 4.7 The biobank custodian should ensure consideration is given to the need for certain cultures to make decisions on participation at a community or group level, in addition to, an individual level. The biobank policies, protocols and procedures 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 (refer to annotations 4xiv).

- 4.9 Throughout the lifespan of the biobank, the research use of samples 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 or the custodian 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 samples and data may only be used if a new consent is obtained, except where exempt as per domestic guidelines and laws.

### **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; and
  - iv) any consequences of withdrawal.
- 4.12 Where withdrawal is available to participants the biobank custodian should ensure traceability of the samples and data is possible.

### **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 custodian should ensure there are 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 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.



## **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 to participants is available the biobank custodian should ensure traceability of the samples and data is possible.
- 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 individual feedback is allowed, participants should be able to decide whether or not to receive feedback of individual results arising from research.
- 4.22 If individual results are given to participants the biobank custodian should ensure a trained professional gives this feedback or for counselling to be available to participants when this is appropriate.
- 4.23 The release of non-validated results (aggregated or individual) from research using the biobank to participants is not recommended. If the researcher decides it is ethically necessary to release the results advice should be given to the participant about the difference between research and clinical results, clarifying the need for clinical testing of research results.

## 5 Content of biobanks

### Principles

- 5A The biobank custodian should ensure there are 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 samples and/or data.
- 5B All samples 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 custodian should ensure there are policies on contents that include:
- i) which samples and data will be collected from the participants or from other sources;
  - ii) whether additional data will be accessed from WA Health, other health data collections or other records. The policy should describe if these data will be linked with, and/or stored in the biobank and if the 'linkage key' will be retained. Such a policy should take into account ethical and other approval processes required for any secondary use of health and other records, especially when combined with other data;
  - iii) the selection of samples. Protocols should be developed such that the least invasive approach, associated with the least risk to the participant, should be pursued. Processes to minimise the risk of invasive procedures should be in place;
  - iv) whether results from research carried out using samples 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 results will be used for and any conditions for further access to them;
  - v) the duration of storage of the samples and the data, recognising that the duration of storage may vary according to the nature and the potential uses of the samples or data. Specific conditions may apply for samples and data which form part of an application for market authorisation of a medical product or a medical device; and
  - vi) whether specific types of tests are not allowed to be performed or if specific types of data will not be entered.
- 5.2 The biobank custodian should ensure it is specified 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 samples 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 custodian should ensure the design of the policies on procurement, collection, labeling, registration, processing, storage, tracking, use and destruction of samples and data 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, sample tracking and auditing should maintain participant confidentiality.
- 5.6 The biobank's holdings should be maintained through a system that allows all the samples, data and any other information to be tracked.
- 5.7 The biobank custodian should ensure the '*OECD Best Practice Guidelines for Biological Resource Centres*' or other appropriate guidelines are followed. These 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 samples, the biobank custodian should ensure the samples and data are collected, processed, handled and stored in a manner consistent with internationally accepted technological standards and norms.

## 6 Protection of samples and data

### Principles

- 6A Processing, handling and storage of samples and data should be conducted in a manner that protects the privacy of the participant and the confidentiality of their samples and data.
- 6B The biobank custodian should ensure the biobank is established, managed and governed in such a way as to prevent any inappropriate or unauthorised, access to or use of participants' samples and data.
- 6C The biobank custodian should ensure policies and procedures are established to safeguard the privacy and confidentiality of participants, samples 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 samples and data (refer to Principle 5B).

### Best practices

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

#### Protection of privacy (Principle 6A)

- 6.1 The biobank custodian should ensure privacy and confidentiality is protected through a combination of mechanisms, as appropriate, including for example secure storage of samples and data, coding and encryption, data enclaves, and honest broker systems.
- 6.2 The biobank custodian should ensure that the data contained within the biobank databases are protected in accordance with domestic law.
- 6.3 The biobank custodian should ensure consideration is given to the extent to which the genetic data held by the biobank might allow, alone or in combination with other available samples and data, the participant to be identified. The biobank custodian should then ensure a plan is developed to manage and minimise all risks 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.

#### Unauthorised access (Principle 6B)

- 6.5 The biobank custodian should ensure a robust infrastructure is in place, consisting of both hardware and software components, so as to prevent unauthorised access to databases.
- 6.6 The biobank custodian 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 (Principle 6C)

- 6.7 The biobank custodian should ensure there are 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).

# 7 Access to biobank samples and data

## Principles

- 7A The biobank custodian should ensure there are clear, detailed, publicly available policies, protocols and procedures in place governing access to all samples and data.
- 7B Transfer, access and use of samples and data should be consistent with the terms of participation and respect the privacy of the participant, confidentiality of the samples and data, and ensure good safety and laboratory methods.
- 7C The biobank custodian should ensure the transfer of samples and data is only authorised when there are adequate standards in place regarding the privacy of the participant, confidentiality of the samples and data, and good safety and laboratory methods, and in accordance with applicable law and regulations.
- 7D The biobank custodian should ensure participants are informed of whether or not their samples 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 custodian should ensure stakeholders, including the general community and researchers, are consulted to formulate criteria for prioritising applications for access to the samples.
- 7F The biobank custodian should ensure information is publicly available on the research projects for which samples 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 samples or data are used in a manner consistent with the original informed consent process, including determining when to seek new consent;
  - ii) review the use of samples 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.
- 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 custodian should ensure there are policies on access that include:
  - i) requirements for accessing samples 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 samples or data to third parties and any legislation that may apply (refer to Annotation 7xxxiv for details of legislation); and
  - iii) requirements for the return or destruction (in a manner not permitting recovery), of samples and data provided to third parties at the completion of their research.

- 7.4 The biobank access and fee policies may be stratified but 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 objectives for the biobank, the 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 samples 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 access to the samples and data collected from participants is allowed, a material transfer agreement or other agreement appropriate for that purpose should be developed.
- 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.
- 7.10 Where results of research using the biobank are incorporated into the biobank, the biobank custodian should ensure consideration is given to 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 5.1iv).

### **Access regulations (Principle 7C)**

- 7.11 National and international access to the biobank samples and data should be 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 samples or data held by the biobank should have a collaboration agreement with the biobank custodian.

### **Third party access (Principle 7D)**

- 7.13 The biobank custodian should ensure participants are informed 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 custodian should ensure participants are informed about all the legal requirements to provide access to biobank samples or data to third parties or law enforcement agencies.
- 7.15 The biobank custodian should ensure participants' samples or data obtained for health research purposes are not accessible to, or disclosed 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.

# 8 Qualification, education and training

## Principles

- 8A The biobank custodian should ensure that all personnel are knowledgeable about the goals and mission for the biobank.
- 8B The biobank custodian should be qualified by training and experience to carry out its mandate.
- 8C The biobank custodian 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 biobank custodian should develop and implement employee training programs.
- 8E Technical staff should be responsible for the implementation of policies and procedures as established by the biobank custodian.

## Best practices

### Personnel training programs (Principle 8D)

- 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 biobank quality system and should be part of its quality manual.

# 9 Custodianship, benefit-sharing and intellectual property

## Principles

- 9A Consideration should be given to who the custodian of the biobank is and if any ownership rights (legal or ethical) apply to the samples 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 custodian should ensure there are 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 A custodian for the biobank should be nominated at the time it is created. This could be an individual researcher, Chief Executive or Executive Director of relevant institute, or head of department. If the department or institute responsible for creating the biobank is the nominated custodian the authority should be delegated to a responsible individual. The custodian may or may not be the same person as the biobank manager.
- 9.2 Current Australian legislative, regulatory and ethical systems should be considered when determining who the nominated custodian should be.
- 9.3 Consideration should be given 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 custodian should inform the participants of any legal or intellectual property rights that might be material to their participation.

### 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 custodian should ensure the exchange of information and technology is fostered.
- 9.6 The biobank custodian should ensure the general results of research conducted using the biobanks' resources are made publicly available regardless of outcome.
- 9.7 Reporting of aggregate results arising from research conducted using the biobanks' resources should not be limited to academic publications. The biobank custodian should ensure these results are made available in easily accessible forms, including a newsletter or website.



- 9.8 The biobank custodian should ensure an annual progress report and a report at the completion or termination of a research project is released. 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 resources they have used or relied on.
- 9.10 The biobank custodian should ensure researchers using its resources are provided with detailed guidance on the manner in which it wishes to be acknowledged.
- 9.11 Where appropriate, the biobank custodian should ensure there is 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 custodian should ensure participants are informed that commercial products may arise from research conducted using its resources.

### **Policies (Principle 9D)**

- 9.13 The biobank custodian should ensure there are policies on benefit sharing that cover:
  - i) any intellectual property resulting from the biobank and whom this applies to, including the researcher, the biobank custodian and the participant;
  - ii) whether research results will be added to the biobank to build it as a resource for research (refer to Best practice 5.1iv);
  - 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 occur;
  - iv) whether or not it intends to commercialise any resources (e.g. samples, 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 private or foreign investment will be allowed or commercial collaboration in the future.
- 9.14 The biobank custodian should ensure there is a policy on benefit sharing that gives consideration to how the sustainability of the biobank may be facilitated.

# 10 Demise of the biobank and disposal of samples and data

## Principles

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

## Best practices

For details of information on the disposal or transfer of samples 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 or the custodian should ensure a possible end date for the biobank is considered.
- 10.2 In the event that a biobank is no longer sustainable, the biobank custodian should ensure the transfer of the samples and data, in accordance with consent given by participants, and approval undertakings made in relation to data provision, 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 and the custodian 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 the biobank (Principle 10B)

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

### Policies (Principle 10C)

- 10.5 The biobank custodian should ensure there are policies relating to the demise of the biobank including the manner in which the samples and data that it holds will be dealt with in the event of its demise.
- 10.6 The biobank custodian should ensure the policy on the destruction and disposal of samples and data takes into consideration cultural heritage and/or religious beliefs known or disclosed by the participants, and their representative groups.
- 10.7 The biobank custodian should ensure the method of disposal of samples is explained to the participants prior to collecting informed consent (refer to Best practice 4.2) e.g. in a lawful and respectful way, particularly for retained tissue samples.



# Part II: Annotations

# Annotations relevant to guidelines

## Chapter 2. Establishment of biobanks

- (i) **Principle 2E:** The greater the breadth of targeted participants, information and data collected for 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. The biobank custodian should ensure the consultations do not inflate 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.

## Chapter 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.
- (vii) **Principle 3A:** 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.
- (viii) **Principle 3A:** The oversight group responsible for addressing breaches of or non-adherence to relevant regulations, guidelines and frameworks may be established solely for that purpose or may be an existing group (e.g. a judicial court).
- (ix) **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 the biobank custodian 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.
- (x) **Principle 3F:** In providing information to participants about the key legislation, regulations and guidelines applicable to the biobank, the biobank custodian should ensure there is a process in place for informing participants as these instruments are updated or changed over time.

- (xi) **Principle 3F:** 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.
- The Organisation for Economic Co-operation and Development, '*OECD Guidelines on Human Biobanks and Genetic Research Databases*' (2009) provides principles and best practices for the establishment and management of human biobanks. The draft version of the OECD guidelines were used in the development of these Guidelines.
- The Organisation for Economic Co-operation and Development, '*Best Practice Guidelines for Biological Resource Centres*' (2007) provides guidelines for the establishment and management of access, use and security of samples and data.
- The International Society for Biological and Environmental Repositories, '*2008 Best Practices for Repositories: Collection, Storage, Retrieval and Distribution of Biological Materials for Research*' 2nd Edition (2008) gives best practices for the management of all aspects of biobanks.

#### **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.

#### **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 Hospitals and Health Services Act).

- The *'Human Tissue and Transplant Act 1982'* regulates the removal and use of tissue in certain circumstances including for the purpose of transplantation. The *'Non-Coronial Post-Mortem Examination Code of Practice'* (2007) is issued under the Human Tissue and Transplant Act 1982 and provides guidelines for the access to and use of post-mortem tissue.
- The *'State Trading Concerns Act 1916'* (e.g. 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*.

## Chapter 4. Terms of participation

- (xii) **Principle 4A:** During the recruitment process there are different ways to ensure the research practices are independent of clinical practices (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 document provided 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 information 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;
  - 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 samples and data, and if applicable, linked to records from third parties; or
  - b. no further use - no further contact with the participant, no further collection of samples or data, and destruction or rendering of all 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 samples and data will continue.
- (xvii) **Principle 4E:** There are a number of ways to approach what should happen when a participant becomes incapacitated or dies. For example:
  - a. participants could be informed their samples and data will remain with the biobank;
  - b. participants could be offered the option for a legal representative to withdraw the participant; or
  - c. participants could be informed their samples and data will be made non-identifiable following notification of their death.
- (xviii) **Principle 4E:** The biobank custodian should also ensure consideration is given to whether the mental capacity of the participant will be reassessed 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).
- (xix) **Principle 4E:** Where substitute consent has been obtained from a participant lacking capacity (e.g. a child), and new consent is to be collected particular care will need to be given to respecting the individual privacy of each participant where children have been recruited into family studies.
- (xx) **Principle 4F:** When providing information various methods to provide information should be considered, 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.
- (xxi) **Principle 4F:** Decisions on the communications approaches to be employed 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.
- (xxii) **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.
- (xxiii) **Principle 4F:** If, during the informed consent process, participants meet with staff from the biobank, the biobank custodian 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.
- (xxiv) **Principle 4F:** The biobank custodian should ensure that potential participants are not placed under rushed time constraints for providing their consent.
- (xxv) **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.
- (xxvi) **Principle 4F:** Participants should be provided, at the time of consent with information about the conditions under which they will be re-contacted 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.

## Chapter 5. Content of biobanks

- (xxvii) **Principle 5A:** The biobank custodian should ensure the policy on the collection of samples and data should:
- give details of the quality and quantity of the samples and/or data to be collected;
  - indicate whether there will be direct or indirect links to identifying information;
  - provide details of the type of sample/s to be collected (e.g. blood, urine, hair, buccal swab, biopsy material);
  - indicate if immortalised cell lines will be created from the samples collected; and
  - provide details of the quantity of the samples to be collected and what each sample 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).
- (xxviii) **Principle 5A:** Where it is intended for the biobank staff to access data from the health data collections or from other collections for inclusion in the biobank data the biobank custodian should ensure participants are 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.
- (xxix) **Principle 5A:** Where there is 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.
- (xxx) **Principle 5A:** The biobank custodian should ensure policies relating to contents take into account the different attitudes held by different cultural and religious groups towards samples. 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).

## Chapter 6. Protection of samples and data

- (xxxi) **Principle 6A:** Sample and data protection may be achieved via different approaches and mechanisms, and often through the combined use of various approaches. Some examples include:
- the coding and encryption of samples and data;
  - limiting access to the collection of samples and data;
  - implementation and maintenance of security measures to block unauthorised access;
  - data enclaves (Data enclaves involve the use of secure or controlled access databases or websites. These allow the biobank custodian 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);
  - 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
  - where samples 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.
- (xxxii) **Principle 6C:** The biobank custodian should ensure the policies and procedures reflect the privacy risks for participants that may develop as technology changes. The biobank custodian should consider the risks that could result from any plan for the biobank samples or data to be linked with other data sources by the Data Linkage Unit in WA, the sharing of information with researchers and if this is provided de-identified, any risks of identification that may arise from research on rare conditions or conditions that are associated with sub-groups of the population.



## Chapter 7. Access to biobank samples and data

(xxxiii) **Principle 7A:** 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 researcher (e.g. private companies could be charged a fee when researchers from public universities and public laboratories are not).

(xxxiv) **Principle 7A:** The biobank policy on third party access to samples and/or data may refer to the following legislation under which law enforcement agencies may obtain access:

- a. a written authority under the Coroner's Act. Section 33(3) of the Coroner's Act provides that a Coroner may, if the Coroner reasonably believes it necessary for the investigation, authorise a Coroner's investigator (usually a police officer)<sup>1</sup> to enter a specific place, to inspect a specified place and anything in it, take a copy of specified documents or classes of documents and seize specified things or classes of things. It is an offence for the Department to delay, obstruct or otherwise hinder the exercise of the power to take documents with written authority<sup>2</sup>;
- b. a summons under the Coroner's Act. Section 46 of the Coroner's Act provides the power for the Coroner to summon a witness to give evidence or produce documents and attendance can be compelled by the issue of a warrant for arrest<sup>3</sup>; and
- c. a search warrant under the Criminal Investigation Act 2006 (WA). If an individual dies as part of any offence under written law, then a search warrant, sought by a police officer (who is contemporaneously a Coroner's investigator) or a public officer may be used to seek biological material and related information. The search warrant can be sought for the purposes of taking the thing or class of thing relevant to the offence<sup>4</sup>. As the identity of the deceased may assist the police officer or public officer ascertain the person responsible for the commission of the crime, in certain circumstances a search warrant could be issued for the release of biological samples.

1. A police officer is contemporaneously a Coroner's investigator: section 14(2) Coroner's Act 1996 (WA)

2. Section 33(7) Coroner's Act 1996 (WA)

3. Section 46(4) Coroner's Act 1996 (WA)

4. Section 41(3)(g)(i) Criminal Investigation Act 2006 (WA).

(xxxv) **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 samples, format and timing of release);
- b. what the data and samples 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 (IPR) (e.g. whether or not IPR are asserted by the provider over existing or future intellectual property, 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) the transfer of data or samples 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).

(xxxvi) **Principle 7D:** Where samples or data may be released to third parties the biobank custodian should ensure consideration is given to the implications for the custodianship of any data derived from the analyses performed by that third party. Consideration should be given to maintaining participant's privacy and the confidentiality of any released samples and data, particularly where released samples 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 samples and data from the biobank to the researcher.

## Chapter 9. Custodianship, benefit-sharing and intellectual property

(xxxvii) **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.

(xxxviii) **Principle 9B:** To contribute towards the continued development of the biobank as a resource, the biobank custodian should aim to ensure that general results arising from research conducted using its resources are added back into its database(s).

(xxxix) **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 biobank custodian 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).

(xl) **Principle 9D:** The policy on commercialisation should be consistent with the National Statement which indicates that for commercialisation there should be no trade in human tissue for research purposes (refer to statement: 3.4.10).

(xli) **Principle 9D:** The 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.


- (xlii) **Principle 9D:** The 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 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.”* (refer to statement 20.15)

## Chapter 10. Demise of the biobank and disposal of samples and data

- (xlili) **Principle 10C:** The policy on the disposal of samples 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.





# Part III: Glossary and appendices

# 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>   | 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, genetic 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 an individual or agency nominated to be responsible for the actions of the biobank. This incorporates the authority to access, use and destroy the samples and data held. The biobank custodian is considered to be either, an individual researcher, Chief Executive, Executive Director of relevant institute, head of department, or the department or institute responsible for creating the biobank. |
| <i>Governance</i>   | The processes and structures that an organisation 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 needed to put in place internal controls and risk management systems.   |
| <i>Human Biological Material</i>  | Biological material collected from an individual at the time of inclusion in the biobank (e.g. blood, urine or tissue sample) or derived from material collected (e.g. DNA extracted).  |
| <i>Human Research Ethics Committee (HREC)</i>                                 | 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.  |
| <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 samples and associated information are collected as a link (or multiple links) exists between the participant's personal identifiers and the data (refer to Appendix I).                                     |
| <i>Independent (related to review and monitoring personnel or committees)</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 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, government entities and/or organisations involved in setting up the biobank.   |

|   |   |
|---|---|
| <i>Informed consent</i>                 | <p>A process by which information concerning the proposal and any collection, use or disclosure of an individual's samples 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. Three main elements to consent include:</p> <ul style="list-style-type: none"> <li>• full disclosure to the individual of appropriate information (e.g. the purpose, methods, risks and benefits of participation);</li> <li>• the individual must have the capacity to understand the proposal and the implications of participation in it; and</li> <li>• consent must be given voluntarily, without coercion, inducement or influence.</li> </ul> |
| <i>Management</i>                       | <p>Comprises directing and controlling a group of one or more people or entities for the purpose of coordinating and harmonising 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 organisation. Governance mechanisms ensure this management is fair and equitable.</p>  |
| <i>Material Transfer Agreement</i>      | <p>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.e. the recipient) and/or away from an entity (i.e. the provider) subject to a number of terms and conditions.</p>  |
| <i>Non-identifiable</i>                 | <p>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 (refer to Appendix I).</p>  |
| <i>Non-validated results</i>            | <p>Research results where there is insufficient evidence to clinically validate the findings.</p>   |
| <i>Oversight</i>                        | <p>An independent individual or committee responsible for reviewing and evaluating policies and practices prior to their introduction and during the operation of the biobank.</p>  |
| <i>Participant</i>                      | <p>An individual who agrees to be involved in a research study and/or biobank and provides data and/or sample/s in accordance with established medical criteria, procedures and practice and in compliance with the law including any privacy requirements.</p>   |
| <i>Private-Public Partnership (PPP)</i> | <p>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.</p>  |
| <i>Sample</i>                           | <p>A single unit obtained from one specimen or a single unit of human biological material collected or derived from material collected (refer to the definitions for Specimen and Human Biological Material).</p>   |
| <i>Specimen</i>                         | <p>A specific collection of tissue, blood or urine taken from a single individual at a specific time.</p>   |
| <i>Third party</i>                      | <p>Any person excluding the biobank participant and people involved in managing and operating the biobank.</p>  |

# Appendix I

## 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 individuals 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; and/or
- information derived from a sample 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.



# Appendix II

## Biobank checklist

This checklist is designed to provide biobank custodians with a summary of the recommendations included in the Guidelines. For further details relating to each recommendation please refer to the specific principle or best practice indicated in the brackets or the full Guidelines document.

### Establishment of biobanks

- 1 The initiators or custodian should develop criteria for sampling and participant selection to ensure data are representative of the targeted population. (2.1)
- 2 The biobank should have a business plan. (2.2)
- 3 Consultations should be carried out with diverse stakeholders, groups and communities. The initiators or the custodian should clearly indicate to those consulted how their input may influence the establishment and/or future aims of the biobank. (2.7, 2.10)
- 4 The biobank custodian should ensure information on the biobank is made publicly available and easily accessible to stakeholders, including participants and the general public. (2.11, 3.11)

### Governance, management and oversight

- 5 The initiators or the custodian should develop an applicable governance structure. (3A, 3.1)
- 6 The biobank's governance structure should be approved prior to its establishment by an independent human research ethics committee. (3.6)
- 7 The oversight mechanisms should report annually on compliance with applicable laws, regulations, ethics guidelines and international instruments. (3.3)
- 8 The independent auditing mechanism should conduct regular and random auditing at appropriate stages. (3.4)
- 9 The specific roles and responsibilities of those involved in the biobank's activities should be clearly identified. (3.5)
- 10 The biobank should obtain approval for modifications that significantly alter policies, protocols and procedures from an independent human research ethics committee. (3.9)
- 11 Where policies, procedures and protocols are significantly modified the biobank custodian should ensure that a new consent is obtained from the participant. (3.10)

### Terms of participation

- 12 Prior to requesting signed consent the biobank custodian should ensure participants are provided with detailed information. (4.2)
- 13 The biobank custodian should ensure there are policies on participation. (4.14)

### Content of biobanks

- 14 The biobank custodian should ensure there are policies on contents. (5.1)
- 15 The biobank custodian should ensure it is specified which type of data and samples will be collected. This should be justified on the basis of the scientific objectives and purposes of the biobank. (5.2, 5.3)

- 16 The biobank should have a quality management process that maintains participant confidentiality. (5.5)
- 17 The biobank's holdings should be maintained through a system that allows all the biological material, data and any other information to be tracked. (5.6)
- 18 The biobank custodian should ensure the OECD Best Practice Guidelines for Biological Resource Centres or other appropriate guidelines are followed. (5.7)

### **Protection of human biological materials and data**

- 19 The biobank custodian should ensure privacy and confidentiality is protected through a combination of mechanisms as appropriate. (6.1)
- 20 The biobank custodian should ensure that the data contained within the biobank databases are protected in accordance with domestic law. (6.2)
- 21 Data protection should where appropriate involve the separation of information that can readily identify an individual from other data (e.g. genotypic data). (6.4)
- 22 The biobank custodian should ensure a robust infrastructure is in place consisting of both hardware and software components, to prevent unauthorized access. (6.5)
- 23 The biobank custodian should ensure only a restricted number of authorised staff have access to information identifying or potentially identifying participants and that this is monitored and documented. (6.6)
- 24 The biobank custodian should ensure there are policies on protection. (6.7)

### **Access to biobank material and data**

- 25 The biobank custodian should ensure there are policies on access to all samples and data. (7.3)
- 26 Researchers should be provided access only to coded samples and data unless determined otherwise by an HREC. (7.6)
- 27 The terms of access for researchers should be set out in an access agreement. (7.7)
- 28 Where access to the samples and data collected from participants is allowed, a material transfer agreement or other appropriate agreement should be developed. (7.8)
- 29 Mechanisms should be employed to ensure that researchers are not inadvertently provided access to potentially identifying data. (7.9)
- 30 National and international access to biobank samples and data should be contingent on recipients being subject to law or other binding requirements substantially similar to those applicable in Western Australia. (7.11)
- 31 International researchers who request access to samples or data should have a collaboration agreement with the biobank custodian. (7.12)
- 32 The biobank custodian should ensure participants are informed whether or not samples and data will be accessible to third parties or law enforcement agencies and if there are legal requirements to do so. (7.13, 7.14)
- 33 The biobank custodian should ensure samples and data collected for health research purposes are not accessible to or disclosed to third parties for non-research purposes. (7.15)

## **Custodianship, benefit-sharing and intellectual property**

- 34 A custodian for the biobank should be nominated at the time it is created. (9.1)
- 35 The biobank custodian should inform the participants of any legal or intellectual property rights that might be material to their participation (9.4)
- 36 The biobank custodian should ensure the general results of research conducted using the biobank are made publicly available regardless of outcome. (9.6)
- 37 The biobank custodian should ensure aggregate results from research using the biobank are not limited to academic publications and are made available in easily accessible forms. (9.7)
- 38 The biobank custodian should ensure an annual progress report and a report at the completion or termination of a research project is released and made publicly available. (9.8)
- 39 Researchers should acknowledge in publications, presentations, and where relevant, patents filed, the biobank resources they have used. (9.9)
- 40 The biobank custodian should ensure researchers using the biobank are provided with detailed guidance on the manner in which it wishes to be acknowledged. (9.10)
- 41 Where appropriate, the biobank custodian should ensure there is a system where benefit sharing agreements can be negotiated before a study begins. (9.11)
- 42 Where applicable the biobank custodian should ensure participants are informed that commercial products may arise from research conducted using the biobank. (9.12)
- 43 The biobank custodian should ensure there are policies on benefit sharing. (9.13)

## **Demise of the biobank and disposal of materials and data**

- 44 The biobank custodian should ensure there is a plan for a situation where the biobank no longer meets a continued scientific need. (10A)
- 45 The initiators or the custodian should ensure a possible end date for the biobank is considered. (10.1)
- 46 The biobank custodian should ensure the destruction of information and data is in a manner not permitting its recovery. (10.4)
- 47 The biobank custodian should ensure there are policies relating to the demise of the biobank including the manner in which the samples and data will be dealt with. (10.5)



# Delivering a **Healthy WA**