CONSENT FOR RESEARCH BIOBANKING

PURPOSE
This Policy provides a Participant consent process specific to obtaining samples from Participants in NSW Health Public Health Organisations and NSW Health Pathology (“NSW Health Controlled Entities”) for use in biobanking and the associated authorisation of medical record linkage.

Note: For defined terms, please refer to Section 1.2 Key Definitions

MANDATORY REQUIREMENTS
Each agency must ensure that:

- all human research to which this Policy Directive applies is conducted in accordance with the National Statement on Ethical Conduct in Human Research issued by the National Health & Medical Research Council (NHMRC) and all applicable NSW Health Policies
- participating Biobanks and Participating Researchers have obtained all relevant HREC approvals consistent with the requirements of this Policy Directive prior to engaging in Biobanking activities (including approaching prospective Participants for Biobanking) at NSW Health Controlled Entities;
- managers, clinicians and researchers at NSW Health Controlled Entities are informed and understand the legal requirements for obtaining consent from Participants and informing Participants with regard to biobanking in accordance with this Policy Directive;
- as a condition of accessing Samples from NSW Health Controlled Entities, Participating Biobanks, researchers and their institutions must comply with the principles and requirements set out in the provisions of this Policy Directive;
- Valid Consent is obtained from every Biobank Participant at a NSW Health Controlled Entity (Sections 3 and 4.4) in accordance with this Policy Directive;
- the storage and retention of the consent form is in accordance with all relevant laws, NSW Health Policies including PD2012_069 - Health Care Records - Documentation and Management and the National Statement;
- consent from Biobank Participants is obtained by an individual who has been approved by either the NSW Health Controlled Entity or the Participating Biobank in accordance with this Policy Directive (Section 3.2);
- Participating Biobanks have appropriate arrangements in place for recontacting biobank Participants and returning Serious and Significant Findings (Section 4);
- Samples and Data are safely and securely stored by the Participating Biobank in compliance with all relevant laws, NSW Health Policies including PD2012_069 - Health Care Records - Documentation and Management, NSW Health Privacy Manual for Health Information, PD2012_051 - Data collections-disclosure of unit record data for research or management of health services, and any additional requirements set out in the National Statement;
Participating Biobanks have effective monitoring systems to ensure their obligations as set out in this Policy are implemented and maintained within their facilities;

Participating Biobanks have in place an effective complaints management system to ensure the receipt and processing of complaints from Participants.

IMPLEMENTATION

Chief Executives:

- must ensure compliance with all aspects of this Policy Directive and ensure it is brought to the attention of all personnel engaged in biobanking at NSW Health Controlled Entities;

Facility Managers:

- must ensure the effective implementation of documented procedures to support the Policy and to respond to and investigate breaches of this Policy;
- must ensure that Participating Biobanks have provided written agreement to comply with this Policy and to implement procedures to support this Policy in their Biobanks.

REVISION HISTORY

<table>
<thead>
<tr>
<th>Version</th>
<th>Approved by</th>
<th>Amendment notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>V3</td>
<td>NSW Health</td>
<td>Consultation version 3 – December 2016</td>
</tr>
</tbody>
</table>

ATTACHMENTS

1. APPENDIX 1 – SAMPLE CONSENT FORMS
   A – Biobank Consent Form;
   B – Biobank Consent for Access to Participant MBS/PBS Data Form;

2. APPENDIX 2 – SAMPLE ADULT PARTICIPANT INFORMATION SHEET

3. APPENDIX 3 – SAMPLE GENERAL NOTICES OF A SERIOUS AND SIGNIFICANT FINDING
   A – Sample General Notice of a Serious and Significant Finding to Participant Who Electing to Receive Findings;
   B – Sample General Notice of a Serious and Significant Finding to Participant Who Did Not Elect to Receive Findings;
CONSENT FOR RESEARCH BIOBANKING

---Consultation---

Issue date: Month-2016
PD2016_XXX
Note: The Office for Health and Medical Research (OHMR) has included placeholder words for provisions relating to MBS and PBS data. OHMR is currently discussing the proposed inclusion of these provisions with the Commonwealth Department of Health. OHMR is awaiting advice as to whether these provisions, or similar provisions, will be included in the Policy Directive. Words with this colouring are placeholder only.

1 BACKGROUND.........................................................................................................................2
  1.1 About this document..................................................................................................................2
  1.2 Key definitions............................................................................................................................2
  1.3 Relevant Legislation and NSW Health Policy Directives and Guidelines.................................4

2 APPLICATION OF THIS POLICY.................................................................................................6
  2.1 Overarching Principles................................................................................................................6
  2.2 Who Does This Policy Apply To? ...............................................................................................6
  2.3 This Policy Does Not Apply To....................................................................................................7
  2.4 Participating Biobank Governance ..............................................................................................7

3 OBTAINING CONSENT.....................................................................................................................9
  3.1 Consent Requirements..................................................................................................................9
  3.2 Who Can Obtain Consent? ..........................................................................................................9
  3.3 How, When and From Whom Consent Can Be Obtained ...............................................................10
  3.4 Elements of the Biobank Consent ................................................................................................12
  3.5 Withdrawal of Consent .................................................................................................................14

4 RECONTACTING PARTICIPANTS...................................................................................................14
  4.1 Permission to Contact ..................................................................................................................14
  4.2 Limited Circumstances for the Return of Serious and Significant Findings ...............................15
  4.3 Notifying Procedures for Serious and Significant Findings Involving Adults .............................16

5 PRIVACY, INFORMATION SHARING AND DATA LINKAGE.........................................................18
  5.1 Compliance......................................................................................................................................18

LIST OF ATTACHMENTS...................................................................................................................20
APPENDIX 1 – SAMPLE CONSENT FORM FOR BIOBANKING......................................................20
APPENDIX 2 – SAMPLE PARTICIPANT INFORMATION SHEET..................................................24
APPENDIX 3 – SAMPLE GENERAL NOTICES OF A SERIOUS AND SIGNIFICANT FINDING
..........................................................................................................................................................27
1 BACKGROUND

1.1 About this document

This Policy has been developed to outline the consent processes specific to obtaining samples from Participants in NSW Health Controlled Entities for use in biobanking and the associated authorisation of medical record linkage.

1.2 Key definitions

**Biobank** – An entity that receives, stores, processes and/or distributes Samples, for approved research. It encompasses the physical location as well as the full range of activities associated with its operation.

**Biobank Consent Form** – A consent form to be signed by biobanking Participants which complies with the requirements of the Policy (a sample consent form is attached at Annexure A).

**Biobank Consent for Access to Participant MBS/PBS Data Form** – A consent form to be signed by biobanking Participants for access to Participant MBS/PBS data.

**Biobank Participant Information Sheet** – an information sheet to be provided to Participants to read, which complies with the requirements of the Policy (a sample information sheet is attached at Appendix 2).

**Clinician** – A health care provider who is trained as a health professional and who provides direct patient care.

**Confirmed research finding** – a research finding that has been confirmed (to the extent that this is reasonably possible in a research context) as being accurate and/or valid and has been verified in accordance with requirements under this Policy Directive (Section 4.2).

**Data** – pieces of information (as defined in the National Statement).

**Data-linkage** – a technique for creating links within and between data sources so that information that is thought to relate to the same person, family, place or event can be connected for analysis.

**Ethically Defensible Plan** – a formulated plan that, at a minimum, establishes mechanisms and procedures for assessing and evaluating the significance of results, how and to whom results should be communicated, and how to proceed with notifying results to affected parties (as required by this Policy Directive and the National Statement).

**Future Unspecified Use** – use for research in the future on any given topic, approved by a HREC and with the primary focus as health, medical, healthcare or health outcomes research.

**Genetic Relative** – as defined in the Privacy Act 1988 (Cth), means another individual who is related to the first individual by blood, including but not limited to a sibling, a parent or a descendant of the first individual.
Incidental Finding – an unanticipated discovery made in the course of research that is outside the scope of the research; also includes other terms such as ‘additional finding’ or ‘secondary finding’

Health Care Practitioner - A person authorised by a Public Health Organisation or NSW Health Pathology to provide clinical care to a patient being a registered practitioner e.g. medical practitioners, nurses and allied health professionals

Human Research Ethics Committee (HREC) – A committee registered with the National Health and Medical Research Committee (NHMRC) and established in accordance with the National Statement on Ethical Conduct in Human Research which ensures ethical standards are maintained in human research by reviewing and advising on the ethical acceptability of research including the operation of Biobanks

Medicare (MBS) – means the Medicare Benefits Schedule, a listing of the Medicare services subsidised by the Australian government

NATA Accredited Laboratory – a laboratory assessed by the National Association of Testing Authorities as competent to perform specific types of testing, inspection, calibration, and other related activities


Nominated Clinician(s) – a suitable individual(s) with appropriate clinical expertise nominated in the Ethically Defensible Plan to evaluate a Serious and Significant Finding(s)

Non-regenerative Tissue – tissue other than regenerative tissue

NSW Health Controlled Entities – NSW Health Public Health Organisations and NSW Health Pathology

Participant – a donor of Tissue to a Participating Biobank within the scope of this Policy Directive

Participating Biobanks – Biobanks authorised to approach NSW Health patients for participation in biobanking and/or Biobanks which obtain Samples from NSW Health Controlled Entities in accordance with this Policy Directive

Participating Researchers – researchers authorised to approach NSW Health patients for the prospective participation in Biobanking and/or Researchers which are obtaining Samples from Biobanks which have been collected in NSW Health Controlled Entities

Pharmaceutical Benefits Scheme (PBS) records – information on the prescription medications accessed by an individual from chemists and pharmacies at a Government-subsidised price
---Consultation---

**Public Health Organisation** – a local health district, or a statutory health corporation, or an affiliated health organisation in respect of its recognised establishments and recognised services (as defined by Section 7, Health Services Act 1997 (NSW))

**Regenerative Tissue** – Tissue that after injury or removal is replaced in the body of a living person by natural processes of growth or repair (e.g. bone marrow)

**Re-identifiable Information** – from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets

**Sample/s** – sample/s of Tissue donated by Participants for Biobanking

**Senior Available Next of Kin** – refer to definition in Section 4 of the Human Tissue Act

**Serious and Significant Finding** – information that is uncovered either directly within the scope of the research or incidental to the research that has serious and significant health implications for the Participant and/or their Genetic Relatives (Section 4.2)

**Tissue** – means tissue as defined in the Human Tissue Act - includes an organ, or part, of a human body and a substance extracted from, or part of, a human body (including blood products, regenerative or non-regenerative tissue, organs (partial or whole), bone tissue, and saliva)

**Treating Clinician** – the current or most recent clinician involved in the treatment of a Participant

**Valid Consent** – consent that is obtained in accordance with Section 3 of this Policy

### 1.3 Relevant Legislation and NSW Health Policy Directives and Guidelines

**Legislation**

- Guardianship Act 1987 (NSW)
- Health Records and Information Privacy Act 2002 (NSW) including Health Privacy Principles, Schedule 1 in Health Records and Information Privacy Act 2002 (NSW)
- Health Services Act 1997 (NSW)
- Human Tissue Act 1983 (NSW)
- Privacy Act 1988 (Cth)

**NSW Health Policy Directives and Guidelines**

This Policy Directive should be read in conjunction with the following NSW Health Policy Directives and Guidelines:

- PD2005_406 ‘Consent to Medical Treatment – Patient Information’
- PD2012_051 - Data collections-disclosure of unit record data for research or management of health services
- PD2016_001 ‘Donation, Use and Retention of Tissue from Living Persons’
Consultation

- PD2012_069 - Health Care Records - Documentation and Management, NSW Health Privacy Manual for Health Information
- PD2007_082 ‘Aboriginal Health Impact Statement and Guidelines’
- GL2006_021 ‘Human Tissue - Requirements of the Human Tissue Act 1983 in relation to research & use of tissue’
- NSW Health Privacy Manual for Health Information

National Statements and NHMRC Publications

This Policy Directive should be read in conjunction with the following publications:

- NHMRC Principles for the translation of ‘omics’-based tests from discovery to health care ['Omics']

Acronyms

ARCBS – Australian Red Cross Blood Service
HREC – Human Research Ethics Committee
MTA – Material Transfer Agreement
MBS/PBS – Medical Benefits Schedule/Pharmaceutical Benefits Scheme
NATA – National Association of Testing Authorities
NHMRC – National Health and Medical Research Council
2 APPLICATION OF THIS POLICY

2.1 Overarching Principles

- Patients have a right to decide whether or not to engage in Biobanking. This means that the collection and storage of Samples should not occur without the valid consent of the patient;
- Patients must be provided with sufficient information about Biobanking and the collection and use of Samples in order to make an informed decision about participation in Biobanking;
- Information provided to Participants needs to be tailored to the individual needs and circumstances of the Participant including taking into account cultural considerations e.g. consideration of Aboriginal people and their communities and how Biobanking might impact traditional beliefs;
- Patients have the right to refuse or withdraw consent to Biobanking at any time without prejudicing their current or future medical treatment.

2.2 Who Does This Policy Apply To?

- **NSW Health Controlled Entities**: This Policy Directive must be applied as a condition of approaching any patient of a **NSW Health Controlled Entity** for:
  - their prospective participation in biobanking or research which will involve biobanking; and
  - obtaining **Samples** for biobanking which have been collected at **NSW Health Controlled Entities**.
- **Participating Biobanks**: All existing and newly formed Biobanks seeking to obtain Tissue (see definition) Samples (see definition) from patients of NSW Health Controlled Entities must comply with this Policy. It is the responsibility of the Participating Biobank seeking to obtain Samples to ensure compliance with this Policy including the use of a Biobank Consent Form;
- A State-wide **phase in period** of 12 months following the date of publication of this Policy applies for the compliance with the Policy Directive (including the adoption of an amended Biobank Consent Form and the Participant Information Sheet). However, from the date of publication of this Policy Directive, Participating Biobanks should immediately seek requisite amended **HREC approval** with respect to any changes to any existing consent forms and consent procedures to comply with this Policy.
- **Participating Researchers**: All researchers acquiring Samples from patients of NSW Health Controlled Entities for the purpose of biobanking must use a Biobank Consent Form.
- **Other Organisations**: This Policy Directive is intended for use by both government and non-government organisations in NSW. While it has been developed for NSW Health Controlled Entities and Participating Biobanks, the Policy Directive provides overarching principles that can be adopted by other organisations (i.e. universities, not for profit organisations, independent
2.3 This Policy Does Not Apply To:

- **Research that will not involve biobanking**, i.e. instances where consent is sought to use samples for specific research project(s) that will not be stored for further use in research (refer PD 2016_01-Donation, Use and Retention of Tissue from Living Persons Section 2.2 and Attachment 2);
- Repositories of human tissue that are created for diagnostic or clinical purposes;
- Repositories of animal and/or plant tissue;
- Repositories of bacterial or pathogen samples previously isolated from any human tissue;
- Where the biobank’s primary purpose is for profit and/or the Biobank is primarily a collection of samples for the purpose of obtaining regulatory approval, for example, clinical trials for new pharmaceuticals (note: compliance with existing laws, policies and guidelines is required);
- Samples obtained for the Newborn Bloodspot Screening Program, as defined by NSW Health PD2006_099 – ‘Newborn Bloodspot Screening Policy’;
- Facilities storing sperm and/or ova for clinical or therapeutic purposes;
- Consent for, and the process of coordination and retrieval of, organs and tissue from deceased donors in NSW as defined in PD2013_001 – ‘Deceased Organ and Tissue Donation - Consent and Other Procedural Requirements’ and the Human Tissue Act 1983;
- Biobanks that are part of inter-jurisdictional consortia (inter-state and international) and there is HREC approval for a single consent form to be used across multiple jurisdictions (for example, under the National Approach to Single Ethical Review established by the NHRMC and jurisdictions) (note: compliance with existing laws, policies and guidelines is required);
- **Australian Red Cross Blood Service (ARCBS)** as defined by the Deed of Agreement between the Commonwealth of Australia, acting through and represented by the National Blood Authority and the Australian Red Cross Society
- Where a Biobank is exempt due to any of the above points, the Biobank should adhere to the principles outlined in this Policy Directive as far as possible, but compliance is not mandatory.

2.4 Participating Biobank Governance

- NSW Health Controlled Entities must ensure that a binding written agreement is entered into with Participating Biobanks that requires compliance with this Policy Directive. This is to ensure the respective Participating Biobank will meet the obligations and requirements set out in this Policy Directive prior to obtaining Samples from patients of NSW Health Controlled Entities. The agreements (often referred to as **Material Transfer Agreements (MTA’s)**) should set out, at a minimum, measures pertaining to:
---Consultation---

- Participating Biobanks and Participating Researchers must have obtained all **relevant HREC approvals** consistent with the requirements of this Policy Directive prior to engaging in Biobanking activities (including approaching prospective Participants for Biobanking) at NSW Health Controlled Entities;

- obtaining consent from patients in NSW Health Controlled Entities and ensuring that all Participating Biobank personnel involved in obtaining consent from patients are aware of and comply with the requirements of this Policy Directive including the **use of a Biobank Consent Form and Participant Information Sheet**;

- consideration of issues concerning **Aboriginal people and communities** and how biobanking may be impact upon their traditional beliefs;

- ensuring the entire process of Sample procurement (Sample collection, processing and storage stages) is **compliant with all relevant laws**, NSW Health Policies and the National Statement;

- ensuring the safe and secure **storage of Participant information** in accordance with all relevant laws, NSW Health Policies and the National Statement;

- facilitating relevant and suitable clinical expertise for the assessment and the return of **Serious and Significant Findings** in accordance with all relevant laws, NSW Health Policies and the National Statement (See Sections 4.2 & 4.3 of this Policy Directive); and

- ensuring that any **third party transferee** of Samples and Data is bound by the requirements of the head MTA and this Policy Directive.
3 OBTAINING CONSENT

- Valid consent is consent that has been undertaken in accordance with the requirements of this section, and meets all applicable legal requirements.

3.1 Consent Requirements

- Biobanks must endeavour to promote Participant autonomy and respect for Participants through ensuring consent procedures are in accordance with the requirements of Valid Consent (as set out in this Policy Directive).
- Consent must be valid. Consent will be valid when the Participant is taken to have:
  - capacity to consent, that is the patient understands the facts and choices involved and can weigh up the consequences and communicate their decision, or their parent and/or legal guardian can on their behalf. Capacity to consent should be assessed with reference to PD 2016_001 ‘Donation, Use and Retention of Tissue from Living Persons’, PD2005_406 – ‘Consent to Medical Treatment – Patient Information’ and Section 7 of the Health Records and Information Privacy Act 2002 (NSW) (HRIP);
  - freely given their consent, by being under no undue pressure, inducement or coercion to consent;
  - been provided with relevant and adequate information necessary for making an informed decision to participate in Biobank research, in a way that the Participant understands;
  - been given reasonable time and opportunity to consider the information provided;
  - been provided with an opportunity to ask questions and/or seek clarification and to have been provided with satisfactory answers to those questions;
  - provided consent in writing documented on a Biobank Consent Form (refer sample at Appendix 1); and
  - provided consent in accordance with all relevant legislation including the provisions of the Human Tissue Act Part 3C relating to the consent to the use of tissue removed during medical, dental or surgical treatment for medical, scientific or research purposes and Part 3 concerning the donation of blood refer PD 2016_001 ‘Donation, Use and Retention of Tissue from Living Persons, Section 2’.
- The Participating Biobank must ensure the storage and retention of the Biobank Consent Form is in accordance with all laws, NSW Health Policies including PD2012_069 – ‘Health Care Records - Documentation and Management’ and the National Statement.

3.2 Who Can Obtain Consent?

- Consent must be obtained by an individual who has been approved by either the NSW Health Controlled Entity or the Participating Biobank to obtain consent from Participants for biobanking of Samples.
It is the responsibility of the Participating Biobank to ensure individuals responsible for obtaining consent from Participants have sufficient knowledge and understanding about all aspects of biobanking necessary to ensure that a Valid Consent is obtained e.g. medical practitioners, registered nurses, and allied health professionals (Section 3.1).

The individual who obtains consent from the Participant must also provide their name, their designation and the organisation which they represent and counter sign the Biobank Consent Form.

Any educational materials used to support consent (e.g. information sheets, videos, websites) must be in accordance with the HREC approval and should be referenced on the Biobank Consent Form.

### 3.3 How, When and From Whom Consent Can Be Obtained

A Valid Consent must always be obtained prior to the commencement of any research, and under no circumstances may research be conducted on Samples from any person who has chosen not to participate or where a Valid Consent cannot be established.

Note: The consent to the physical collection from a Participant, removal, and storage of the Sample in a NSW Health facility is also governed by the PD2005_406 _Consent to Medical Treatment - Patient Information and the Human Tissue Act_.

A copy of the Participant Information Sheet must be provided to each Participant for their retention.

A verbal discussion must take place between the individual obtaining consent and the Participant. This is to facilitate Participant understanding of the information provided to them and provide the Participant with the opportunity to seek answers to any questions they may have. A verbal discussion is not required in circumstances where the Participant expressly declines to discuss the information with the individual obtaining consent.

When undertaking population studies and there are a large number of participants to seek consent from, and it is impractical to require them to attend a NSW Health facility solely for consent purposes, the Biobank Consent Form and Participant Information Sheet may be mailed/emailed to a prospective Participant provided that there is the contact name and details of a person approved under Clause 3.3 above, to enable the prospective Participant to seek further information and/or clarification. These arrangements must also be specifically reviewed and approved by a HREC.

When approaching prospective Participants to obtain consent, consideration of the different circumstances of Participants is required. Special attention must be given to the specific information needs of individual Participants as well as to the methods used to deliver the information and any special legal requirements with respect to obtaining a Valid Consent to biobank that Participant’s Samples. The following subgroups of Participants have additional requirements when obtaining consent for biobanking:

- consent obtained from Participants with a non-English speaking background must occur in accordance with the requirements set out in PD2005_406 ‘Consent to Medical Treatment – Patient Information’
Consultation


- assent/consent obtained from Participants who are minors and their parents or legal guardians must occur in accordance with the requirements of PD2005_406 ‘Consent to Medical Treatment – Patient Information’
(http://www0.health.nsw.gov.au/policies/pd/2016/pdf/PD2016_001.pdf) and Division 2 and Section 21Y of the Human Tissue Act 1983 and other relevant laws;

- consent obtained from Participants without capacity who are 16 years of age or over must occur in accordance with the requirements set out in PD2005_406 ‘Consent to Medical Treatment – Patient Information’ and the Guardianship Act 1987 (NSW) and Section 2 of PD2016_001 ‘Donation, Use and Retention of Tissue from Living Persons’
(http://www0.health.nsw.gov.au/policies/pd/2016/pdf/PD2016_001.pdf) and Division 2 and Section 21Z of the Human Tissue Act 1983 and other relevant laws;

- consent obtained from the Person Responsible for a Participant lacking capacity to consent due to mental illness must occur in accordance with the requirements of PD2005_406 ‘Consent to Medical Treatment – Patient Information’ and the Mental Health Act 2007 (NSW)

- consent obtained from Aboriginal and Torres Strait Islander People must occur in accordance PD2007_082 ‘Aboriginal Health Impact Statement and Guidelines’

- consent should have consideration of the different attitudes held by different cultural and religious groups towards Samples; and

- where a person was living when the Sample was removed and subsequently dies without a Valid Consent having been taken, only a Senior Available Next of Kin (or their delegate) may consent to the use of the deceased person’s Tissue (See Section 5 of PD2016_001 ‘Donation, Use and Retention of Tissue from Living Persons’ and S 21ZA of the Human Tissue Act 1983. Consent must be obtained on an HREC approved consent form. (PD2016_001 requires the use of Attachment 5 to that Policy: “Consent and Authority for the Retention and Use of Tissue Removed or Expelled During Treatment of a Now Deceased Patient”. In these circumstances the Senior Available Next of Kin should also complete a Biobanking Consent Form and provide a Valid Consent in accordance with this Policy Directive.

- If a prospective Participant’s capacity to provide consent is affected in any significant way, then the consent process must be delayed until such time that the prospective
Participant is deemed to have capacity refer PD2005_406 – ‘Consent to Medical Treatment – Patient Information’.

A prospective Participant’s ability to provide consent to biobanking may be affected by a number of different factors, and reference must be made to Clauses 21 to 28 of PD2005_406 ‘Consent to Medical Treatment – Patient Information’.

3.4 Elements of the Biobank Consent

Biobank Consent Form

The Sample Biobank Consent Forms at Appendix 1 are an example of forms that meet the requirements of this Policy Directive and the Commonwealth. These forms must be used if seeking consent to MBS/PBS data as only this form has been approved by the Commonwealth.

If an alternative form (without MBS/PBS data linkage) is to be used than the Biobank Consent Form must meet the requirements of this Policy Directive and include the following as aspects:

- the collection of Tissue & Data and associated health information for future unspecified use. Participants must be informed of the limited scope of “future unspecified use” in biobanking research, such that research must be HREC approved and must also have as its primary focus health, medical, healthcare or health outcomes to be within the scope of the Participant’s consent;
- indefinite storage and access to their donated Samples and associated information;
- the transfer and sharing of Samples and Data and associated information to other researchers/Biobanks both interstate and internationally for health and medical research; and
- the linking of the Participant’s hospital records and other health information to their Sample.
- the publication of findings from research using their Samples provided they cannot be identified;

The Biobank Consent Form must specify that Participants can elect to consent to:

- the return of a Serious and Significant Finding (in accordance with Sections 4.2 and 4.3); and
- recontact by the Participating Biobank (in accordance with Section 4.1).

Consent for MBS/PBS Data

Where the Participating Biobank seeks to obtain approval for access to Participant’s MBS and PBS information, the Biobank Consent for Access to Participant MBS/PBS Data Form must be used (Appendix 1). Participants must be informed of their right to decide whether or not their MBS and PBS information may be accessed by researchers for health and medical research.
Biobank Participant Information Sheet

- The Sample Patient Information Sheet at Appendix 2 is an example of an information sheet that meets the requirements of this Policy Directive and the Commonwealth. This information sheet must be used if seeking consent to MBS/PBS data as only this form has been approved by the Commonwealth. NB: it also explains the purpose of, and procedure(s) involved in MBS and PBS data linkage.

If an alternative is to be used (without access to MBS/PBS data linkage), than the Biobank Participant Information Sheet must appropriately explain all the aspects of consent for Biobanking listed above, in addition to:

- providing a summary of the Biobank and its functions;
- explaining the purpose of, and procedure(s) involved in, Biobanking for the participant;
- explaining the impacts the return of Serious and Significant Findings may have on some forms life and income protection insurance, employment, psychosocial coping and family dynamics for the participant;
- explain that Sample may contribute to research that has a commercial benefit and that the participant/donor will not receive a financial return;
- providing contact details for the Biobank.
3.5 Withdrawal of Consent

- Consent will remain valid until it is withdrawn by the Participant. Potential Participants must be informed of their right to withdraw their consent, and any consequences of that withdrawal. Participants must be informed that withdrawing consent will not impact their medical treatment. Participants must be informed of their right to request the withdrawal of their Data and/or Samples from the Biobank and/or for their destruction.

- Participants must be informed that it is not possible to retrieve Samples and/or Data after it has been provided to a researcher.

- Reasonable attempts **must** be made to recontact Participants who were under the age of 18 when consent for their participation in biobanking was obtained to obtain additional consent. These attempts to recontact must be recorded.

- The Participating Biobank must have developed internal policy and/or procedures, with HREC approval, that provide a process for the event that the Participant cannot be recontacted. The internal policy and/or procedures must make a determination on whether the consent will remain valid and as such whether Samples and Data and any other associated information will be retained or destroyed and how Serious and Significant Findings will be handled. The Participating Biobank’s internal policy and/or procedures relating to reconsent at 18 must be outlined explicitly in the Participant Information Sheet provided to the parent/guardian at the time consent is obtained.

- In the event of the Participant’s death, unless otherwise directed by the executor of the estate, an advance directive, or other legally binding document, the Participating Biobank will retain legal authority to continue to use the Sample and Data and any other associated information in accordance with the scope of the original Biobanking Consent Form, any subsequent consents, and in accordance with legal requirements.

4 RECONTACTING PARTICIPANTS

4.1 Permission to Contact

- The Participant can elect to be contacted by the Participating Biobank in the future. Participants must be informed under what conditions recontact might occur. This includes, but is not limited to situations when the Participating Biobank may need to:

  - obtain an update on the Participant’s personal information;
  - seek any additional consent that may be required by an HREC for the purposes of a particular research project; or
  - obtain additional Samples from the Participant.

- In relation to Serious and Significant Findings, the Participant must be notified that a Nominated Clinician/s may contact them to notify them of a Serious and Significant Finding in accordance with this Section 4.3 of this Policy Directive.
4.2 Limited Circumstances for the Return of Serious and Significant Findings

- When undertaking research, information may be uncovered, either directly within the scope of the research, or incidental to the research, that has health implications for the Participant (or their Genetic Relatives) such findings are defined in this Policy as Serious and Significant Findings.

- This Policy requires the return of Serious and Significant Findings where those findings satisfy the Criteria for the Return of Serious and Significant Findings (see below). In addition, consideration must be had to the Participant’s election to receive or not to receive a Serious and Significant Finding as specified on their Biobank Consent Form.

- This Policy requires the consistent application of the Criteria for the Return of Serious and Significant Findings, and requires an evaluation of all the facts by a Nominated Clinician(s), taking into account all of the individual circumstances and the current state of health knowledge for a condition and the prevailing clinical practice.

- Given this approach it is not expected that the same outcomes will always occur for the same type of Serious and Significant Findings as individual circumstances may differ even in well matched cases.

Criteria for Return of Serious and Significant Findings

- When determining whether a research and/or incidental finding should be returned to a Participant in relation to serious health conditions, only those results that adhere to all of the following criteria are to be returned:
  
  a. **Significance** i.e. a substantial risk of serious health condition. Certain types of information may have future impacts on the health of a Participant. Significant information may be the existence of a serious health condition, or genetic information revealing the existence of, or a predisposition to, a serious health condition.
    
    i. **Genetic condition**: genetic information deemed significant is that which can reveal significant risk of a condition likely to be life-threatening; can be used to avoid or ameliorate a condition likely to be grave; and can be used in reproductive decision-making to avoid significant risk for offspring of a condition, or to ameliorate a condition for offspring likely to be life-threatening or grave.

    Note: where the genetic information relates to a genetic variation, the variation must be known to be, or considered highly likely to be, a pathogenic mutation based on the latest available information, and would ordinarily be reported to a patient in a clinical setting

    ii. **Health condition**: health information deemed significant is that which can reveal the existence of a condition likely to be life-threatening and/or can be used to avoid or ameliorate a condition likely to be grave. Examples include, but are not limited to, conditions such as tuberculosis, HIV/AIDS, cancer etc.
b. **Benefit** i.e. clinically actionable, whereby there are established therapeutic or preventive interventions or other available actions, such as lifestyle changes or reproductive decisions, that have the potential to change the clinical course of the disease or improve the individual’s and/or their genetic relative’s quality of life.

c. **Confirmed research finding** i.e. a research finding that has been checked and confirmed as accurate and/or valid, as far as reasonably possible in a research context. This checking must include reviewing Sample handling procedures for any misidentification and/or contamination errors and checks on instrument/test accuracy and repeatability within the research laboratory and consistent with the Ethically Defensible Plan.

Note: As consent to diagnostic genetic testing requires pre-test counselling and other safeguards as set out in the PD2007_066 - Genetic Testing (or its successor): no diagnostic validation of the result in a NATA (or equivalent) accredited laboratory should occur until the participant has been notified and has given specific consent consistent with PD2007_066 - Genetic Testing.

Even where genetic research has been undertaken on a Sample in a NATA (or equivalent) accredited laboratory, it is unlikely that the biobanks who supplied the Samples to the laboratory operated their storage and handling procedures at clinical/diagnostic levels. Therefore these results must also be treated as a confirmed research finding requiring Notification by the clinician under this Policy Directive and any consent required for further validation managed by the clinician under the PD2007_066 - Genetic Testing.

- Participants can elect not to receive Serious and Significant Findings on the Biobank Consent Form, however, participants must be made aware that this decision may be reconfirmed by the Nominated Clinician in the event of a Serious and Significant Finding.
- Any decision to return a Serious and Significant Finding in accordance with the Criteria for the Return of Serious and Significant Findings must also take into account the Participant’s age and whether the result has current or latent clinical actionability in respect of that Participant or their Genetic Relatives.
- Genetic Relatives are not to be notified of a Serious and Significant Finding under this Policy Directive. Any further testing that has implications for Genetic Relatives is to be managed in accordance with the PD2007_066 - Genetic Testing (or its successor) and other NSW Health Policies.

### 4.3 Notifying Procedures for Serious and Significant Findings Involving Adults

**Ethically Defensible Plan**

- Researchers seeking to access Samples stored in the Participating Biobank must provide an Ethically Defensible Plan, consistent with this Policy, for the return of any Serious and Significant Findings to the Participant and the Participating Biobank (following HREC approval). The Ethically Defensible Plan will apply to all research that may discover or generate information of potential importance to the future health of Participants, or their Genetic Relatives.
Consultation

- The Ethically Defensible Plan must include:
  - details of the Nominated Clinician responsible for evaluating any Serious and Significant Findings;
  - recommendations for follow-up clinical testing and specialist genetic counselling if required;
  - whether the returned information may be used by employers or insurers to affect a Participant’s eligibility for employment or insurance; and
  - whether the Participant is a minor or does not have capacity and the procedures for returning results to the Participant and their parent or legal guardian.

Participating Researchers

- Participating Researchers must immediately notify the Participating Biobank of a confirmed Serious and Significant’ Finding.

Participating Biobanks

- The Participating Biobank must ensure that adequate and appropriate arrangements are in place to return Serious and Significant Findings.
- The Participating Biobank may develop internal policies and/or procedures for the process of returning Serious and Significant Findings to Participants (that complies with this Policy Directive and any other legal or Policy requirements), i.e. specifying requirements for the researcher to select a suitable Nominated Clinician(s) to evaluate possible Serious and Significant Findings in their Ethically Defensible Plan and manage their return.
- The Participating Biobank should consider developing their own standard HREC approved General Notice consistent with this Policy to be provided to the Nominated Clinician who will be returning the Serious and Significant Finding (see Sample Notice in Appendix 3).
- The Participating Biobank must ensure that the process for Serious and Significant Findings is followed in accordance with the Ethically Defensible Plan, including the appointment of, and instructions to, the Nominated Clinician(s).
- The Nominated Clinician(s) is responsible for:
  - applying the Criteria for the Return of Serious and Significant Findings (Section 4.2);
  - making a decision to return the Serious and Significant finding or not;
  - if returning, preparing a General Notice relevant to the circumstances (see Appendix 3);
  - making reasonable attempts to ascertain that the Participant is still alive, for example contacting the NSW Registry of Births, Deaths and Marriages, checking the Participant’s medical record, or contacting the Participant’s treating clinician
  - sending the General Notice to the Participant, with the Nominated Clinicians contact details included; and
Consultation

- if the Participant contacts the Nominated Clinician to receive further information, putting them in contact with their Treating Clinician, or other nominated Health Care Practitioner and Genetic Counsellor if required.

- The Participant must not receive details of the result over the phone or in writing, but be asked whether they would like to obtain more information about the Serious and Significant Finding from their Treating Clinician, or other nominated Health Care Practitioner.

- If a Participant does not make contact after the General Notice has been sent, reasonable attempts to contact the Participant via phone must be made. These attempts to reconnect must be recorded.

- If a Participant, upon receiving a General Notice of the existence of a Serious and Significant Finding, explicitly declines to receive any more information (an absence of response does not constitute a decline), their wishes must be respected unless:
  
a. the refusal is by a Person Responsible on behalf of a person without capacity. In this situation, if an opinion is formed that the Person Responsible is not acting in the best interests of the Participant, legal advice should be sought and consideration given to making an application to the Guardianship Division of the NSW Civil and Administrative Tribunal to appoint a guardian for the Participant or to make a decision;

b. the refusal is by a parent or guardian of a Participant who is a minor. In this situation health workers should consider their mandatory reporting obligations under the Children and Young Persons Care and Protection Act where there are reasonable grounds to suspect the child or young person is at risk of significant harm if the Serious and Significant Finding is not actioned and consider obtaining legal advice in regard to making a Court Application in regard to the Serious and Significant Finding;

c. there exists a legal requirement to disclose under the Public Health Act 2010 (NSW).

5 PRIVACY, INFORMATION SHARING AND DATA LINKAGE

5.1 Compliance

- Participating Biobanks must ensure procedures are in place in the event of a breach of Participant privacy (accidental or intentional) by a Participating Biobank staff member or a Participating Researcher that has obtained Samples and Participant Data. These procedures must comply with the Health Records and Information Privacy Act 2002 (NSW), NSW Health Privacy Manual for Health Information Policy (PMHI) (specifically Clauses 14.3 and 14.4), Privacy and Personal Information Protection Act 1998 (NSW), and any other relevant statutory requirements.

- Participating Biobanks seeking to transfer Participant Samples and/or Data interstate or overseas must ensure that the recipient body complies with the Health Privacy Principles under the Health Records and Information Privacy Act 2002 (NSW) as defined in the NSW Health Privacy Manual for Health Information (specifically with reference to 13.2) together with clear contractual requirements within the Material Transfer Agreement (refer Section 2.4) including addressing those obligations including confidentiality, security, access, amendment and the governance of breach notifications.
---Consultation---

- Participating Biobanks must ensure procedures and mechanisms are in place for the receipt and processing of any complaints from Participants. For general principles on complaint management, refer to **PMHI Clause 14.1**.

- Participating Biobanks must ensure that there are documented procedures in place to effectively respond to and investigate any breaches of this Policy.
LIST OF ATTACHMENTS

APPENDIX 1 – SAMPLE CONSENT FORM FOR BIOBANKING

A – Biobank Consent Form: This Consent Form provides an example of how the requirements in this Policy Directive can be met.

### Sample Biobank Consent Form

**Authority to provide [insert name] BIOBANK (the Biobank) with tissue samples and health information**

I confirm that:
- I have read the information brochure relating to participation in the Biobank. I have been given the opportunity to discuss the information, ask questions and have any concerns addressed. I declare that I understand the information provided.
- I understand that participating in the Biobank is entirely voluntary and I give my consent to donate blood, tissue and other bodily fluids and health information for use in health and medical research.
- I understand that I can withdraw my consent at any time by contacting the Biobank without any impact on my treatment.
- I am aware that I will not be personally informed of the general research results of studies using my samples, but these may be published.
- I permit the Biobank to store samples collected from me for an indefinite period of time and to use those samples in a re-identifiable form for Human Research Ethics Committee (HREC) approved future unspecifed health and medical research.
- I permit the transfer and sharing of my samples and associated information to other researchers/Biobanks both interstate and internationally for HREC approved health and medical research.
- I permit the linking of re-identifiable health information (e.g. clinical records, diagnosis history, pathology results, and emergency department records) and other relevant information (e.g. education, income, lifestyle factors) for use in health and medical research subject to HREC approval.

Please tick the appropriate box:
- I permit the Biobank to contact me in the future to collect further personal and health information.
  - Yes
  - No
- I permit the Biobank to contact me in relation to serious and significant research findings that may have been validated and have specific health implications for me and/or my genetic relatives.
  - Yes
  - No
  (I understand that if a serious and significant finding is discovered I may be contacted in the future to verify my decision)

### DECLARATION

<table>
<thead>
<tr>
<th>PARTICIPANT NAME</th>
<th>SIGNATURE</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>PERSON RESPONSIBLE</td>
<td>SIGNATURE</td>
<td>DATE</td>
</tr>
<tr>
<td>SENIOR NEXT OF KIN</td>
<td>(please tick appropriate box)</td>
<td></td>
</tr>
<tr>
<td>INTERPRETER (if applicable)</td>
<td>SIGNATURE</td>
<td>DATE</td>
</tr>
<tr>
<td>PERSON AUTHORISED TO OBTAIN CONSENT</td>
<td>SIGNATURE</td>
<td>DATE</td>
</tr>
<tr>
<td>DESIGNATION</td>
<td>ORGANISATION</td>
<td></td>
</tr>
</tbody>
</table>

---

1. Tissue is defined in the Human Tissue Act - includes any organ, part of a human body and a substance extracted from, or part of, a human body (including blood products, regenerative or non-regenerative tissue, organs, partial or whole, tissue donors, and cultures).
B –Biobank Consent for Access to Participant MBS/PBS Data Form: OHMR is currently discussing the proposed Consent Form with the Commonwealth Department of Health. OHMR is awaiting advice as to whether this consent Form will be included in the Policy Directive. This Consent Form is placeholder only.
What type of information is available?

Information available from DHS includes (but is not limited to):

**Medicare (MBS)**
- Date of service (Date that the service was rendered by the provider, to the patient)
- MBS Item number (Items Numbers as per the Medicare Benefits Schedule)
- MBS Item description (describes the service as per the Medicare Benefits Schedule)
- Provider charge (the dollar amount the provider charged for the service)
- Schedule fee (fee as listed in the Medicare Benefits Schedule ie: the Governments recommended fee for that service)
- Benefit paid (this is the benefit paid to the patient)
- Patient Out of Pocket (the dollar amount the patient is out of pocket)
- Bill type (the method the benefit was claimed ie, Bulk Bill, Direct Bill, Cheque to provider via patient etc.)
- Scrambled Ordering Provider Number (a unique scrambled provider number identifying the referring provider)
- Scrambled Rendering Provider Number (a unique scrambled provider number identifying the provider who rendered the service)
- Date of referral (Date that the referral was written by the servicing provider)
- Rendering provider postcode (postcode of rendering provider’s practice location) this information may not be available on request due to privacy reasons.
- Ordering provider postcode (postcode of referring provider’s practice location) this information may not be available on request due to privacy reasons.
- Hospital Indicator (Indication of whether or not the service was provided in hospital)
- Item category (where the service sits in the hierarchical structure according to the Medicare Benefits Schedule)

**Pharmaceutical Benefits Scheme (PBS)**
- Date of supply (Date the prescription was supplied by the pharmacy)
- Date of Prescribing (Date that the prescription was prescribed by a Medical Practitioner to a patient)
- PBS Item Number (Items Numbers reflected in the Pharmaceutical Benefits Scheme)
- PBS Item Description (the Item description as noted in the Pharmaceutical Benefits Scheme Book)
- Patient category e.g. general, concession, safety net, doctor’s bag (Patient’s eligibility status at the time of supply)
- Patient contribution (the contribution paid by the patient)
- PBS Net Benefit (Amount paid by the Government)
- Scrambled Prescriber Number (a unique scrambled number identifying the particular prescriber of the PBS Item)
- Pharmacy postcode (postcode of the pharmacy) this information may not be available on request due to privacy reasons.
- Form category (Original or repeat prescription)
- ATC Code (the code allocated by the World Health Organisation Collaborating Centre for Drug statistics Methodology)
- ATC Name (the group the drug falls under in the Anatomical Therapeutic Chemical (ATC) classification system)
### XXXX Biobank Consent Form

A sample of the information that may be included in your Medicare claims history:

<table>
<thead>
<tr>
<th>Date of service</th>
<th>Item number</th>
<th>Item description</th>
<th>Provider charge</th>
<th>Schedule Fee</th>
<th>Benefit paid</th>
<th>Patient out of pocket</th>
<th>Bill type</th>
</tr>
</thead>
<tbody>
<tr>
<td>20/04/09</td>
<td>00023</td>
<td>Level B consultation</td>
<td>$36.30</td>
<td>$34.30</td>
<td>$34.30</td>
<td>$4.00</td>
<td>Cash</td>
</tr>
<tr>
<td>22/06/09</td>
<td>11700</td>
<td>ECG</td>
<td>$29.50</td>
<td>$29.50</td>
<td>$29.50</td>
<td></td>
<td>Bulk Bill</td>
</tr>
</tbody>
</table>

* Scrambled Provider number refers to a unique scrambled provider number identifying the doctor who provided/referred the service. Generally, each individual provider number will be scrambled and the identity of that provider will not be disclosed.

### A sample of the information that may be included in your PBS claims history:

<table>
<thead>
<tr>
<th>Date of supply</th>
<th>Date of prescribing</th>
<th>PBS item code</th>
<th>Item description</th>
<th>Patient category</th>
<th>Patient contribution (this includes under copayment amounts)</th>
<th>Net Benefit (this includes under copayment amounts)</th>
<th>Scrambled Prescriber number</th>
<th>Pharmacy postcode</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/03/09</td>
<td>01/03/09</td>
<td>03133X</td>
<td>Cefalexin Tablet 30 mg</td>
<td>Concessional Ordinary</td>
<td>$5.30</td>
<td>$25.55</td>
<td>999999999</td>
<td>2560</td>
</tr>
<tr>
<td>04/07/09</td>
<td>28/05/09</td>
<td>03161J</td>
<td>Diazepam Tablet 2 mg</td>
<td>General Ordinary</td>
<td>$30.85</td>
<td></td>
<td>999999999</td>
<td>2530</td>
</tr>
</tbody>
</table>

* Scrambled Prescriber number refers to a unique scrambled prescriber number identifying the doctor who prescribed the prescription. Generally, each individual prescriber number will be scrambled and the identity of that prescriber will not be disclosed.

** Under copayments can now be provided for data after 1 June 2012.
APPENDIX 2 – SAMPLE PARTICIPANT INFORMATION SHEET

PARTICIPANT INFORMATION SHEET FOR BIOBANKING IN MEDICAL RESEARCH

Note – This is an example of a Tissue Bank Specific Participant Information Sheet only and will need to be appropriately altered to suit each Biobank. This Participant Information Sheet is an example of how all the Policy Requirements have been met, and its use as far as possible is recommended.

XXXX BIOBANK

Investigators:

<Insert:
Names of main investigators;
Contact details of main investigators;
Biobank location>

A biobank is a stored collection of human biological samples (tissue, blood or bone) linked to personal information. Biobanks are an important resource for medical researchers to improve the understanding of diseases and to help find better ways to prevent or treat them.

The samples and health information stored are used for medical and health-related research projects. These may include research on the prevention, diagnosis and treatment of disease, as well as for genetics, understanding the characteristics of people with disease and for use in clinical trials.

Being a Biobank Participant

If you choose to participate, a biobank representative will meet with you to go through your details and discuss any questions you have. Once your questions have been answered and you have completed the consent form the biobank will collect:

1. A small sample of tissue and/or fluid collected during your scheduled procedure; and
2. A small blood sample. This is generally collected during a routine blood collection prior to your scheduled procedure. If a blood sample is unavailable, you may be asked to give a saliva sample or have a mouth swab.

Any identifying information will be removed from your samples before researchers can use them for research. The biobank will store your sample and information in such a way that ordinarily only the biobank can identify you, thus protecting your confidentiality and researchers are not normally able to identify you. Occasionally genetic information obtained from donated tissue may allow for the identification of participants. The Biobank requires this information to be kept strictly confidential and there are legal requirements for researchers to maintain your privacy.

In order for researchers to better conduct research it is important that they are able to link your samples to information about you. This type of information might include details collected during your treatment, such as your operation, diagnosis history, pathology results, emergency department records and genetic or family history details. Depending on the nature of their ethics approved research project, researchers may want to access information dated from before or after you consented. Some research projects involve investigating other impacts on health, such as a person’s lifestyle, education and level of income. By consenting for biobanking, you are
permitting access to information that will be attached to your donated sample, as well as other relevant information held by other agencies for use in health and medical research that has ethics approval.

If you decide to participate in the biobank, you are encouraged to tell your family of your decision and why you chose to support medical research in this way.

Your Sample may contribute to research that has a commercial benefit; however, you will not receive a financial return.

Most frequently asked questions

1. **What will happen to my samples?**
   The samples collected from you will be stored in the biobank for an indefinite period of time; to be used for [Human Research Ethics Committee approved health and medical research](#).

2. **Will my samples only be used for Australian based research?**
   It is common in health and medical research for international and interstate based researchers to collaborate. If you agree to participate, your samples and associated information may be sent interstate or overseas for collaborative research purposes in such a way that you cannot be identified and only after a [Human Research Ethics Committee](#) has approved the research.

3. **Are there any risks to my privacy by participating?**
   Your health information will be kept secure and confidential in accordance with legal requirements. Generally, only information without identifying marks (e.g. your name and address) is provided to researchers. However, should a breach of privacy occur, the biobank will ensure the situation is dealt with in accordance with existing privacy principles and guidelines. Occasionally genetic information derived from donated tissue may allow for the identification of participants. The Biobank requires this information to be kept strictly confidential and there are legal requirements for researchers to maintain your privacy.

4. **Can anyone other than biobank approved researchers access my health information?**
   Generally, third parties cannot access your health information. However, there may be circumstances where a legal requirement to provide your health information to third parties arises, such as law enforcement agencies. While these situations are rare, the biobank will be required to comply with its legal requirements and make available your information.

5. **What if I change my mind and don’t want to participate?**
   Participation in the biobank is entirely voluntary. Even after you have provided the biobank with your sample and health information, you are free to withdraw all, or part of, your consent at any time by contacting the Biobank. Choosing not to participate, or withdrawing your consent to participate, will not affect your medical treatment in any way.

   Should you choose to withdraw your consent; the biobank will discard your stored tissue, blood samples and medical information collected about you. However, if some or all of your tissue or blood samples have been provided to a research project, it will not be possible to withdraw these samples. Research that has been published cannot be deleted or discarded.

6. **Why is my Medicare and PBS claims information useful for research?**
   The ability to link to data stored in various locations provides biobanks with a lot of research opportunities. By completing the consent form you will be providing your permission to link your data held in Medicare (MBS) or Pharmaceutical Benefits Scheme (PBS) records to your samples stored by the biobank, for research purposes. Each research project seeking to use your MBS and/or PBS data will request information within a certain time period. For example,
a project may only want your information for a 3 year period 01/01/2013 – 01/01/2016. The biobank will ensure your confidentiality is maintained through removing any identifying information before allowing access to researchers. At the end of the research project, the MBS and PBS information provided to the researcher will be destroyed.

The paragraph below is mandatory if seeking data linkage to MBS/PBS

You will be asked to fill out a consent form authorising the study access to your complete Medicare and Pharmaceutical Benefits Scheme (PBS) data as outlined on the back of the consent form. Medicare collects information on your medical visits and procedures, and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. The consent form is sent securely to the Commonwealth Department of Human Services which holds this information confidentially.

7. Will the biobank contact me after I have given my consent to participate?
Should you decide you would like to be recontacted on the consent form; the biobank may occasionally contact you to collect further personal and health-related information. The biobank will try to keep contact to a minimum.

You may also be contacted by a clinician to notify you of a serious and significant research finding (see below).

8. Will any research findings be returned to me?
During research, information may be discovered that has serious and significant health implications for you (and possibly your genetic relatives). These are known as serious and significant findings. Their occurrences are rare since only findings that are of a highly serious nature will be returned to you. General health information, such as elevated risks for high cholesterol or diabetes, will not be returned.

The absence of any recontact does not necessarily indicate a lack of health issues, nor should you assume that your sample will automatically undergo testing or analysis. Researchers are not screening for disease.

9. What happens if I choose to receive serious and significant findings?
In the event that a serious and significant finding is discovered and you have ticked ‘Yes’ on the Consent Form, the biobank will refer the matter to an individual(s) with the appropriate clinical expertise, who will evaluate the result to determine whether it is a serious and significant finding and whether it should be returned to you for further action. This may involve further tests, genetic or otherwise, to ensure the validity of the finding.

After this further testing, this information may become part of your medical record as health information and you may be required by law to disclose this information to any future insurer. The results of a genetic test may affect your future income protection and travel insurance eligibility.

10. What happens if I don’t want to receive any serious and significant findings?
In the event that a serious and significant finding is discovered and you have ticked ‘No’ on the Consent Form, you may still be contacted to confirm this prior decision.

If you confirm that you still do not wish to know about any serious and significant findings, no further clinical tests aimed at validating the finding will be undertaken on your sample so that you will not be informed of the finding unless you request further information about it.

11. Where can I find more information?
If you would like more information about the biobank, or your participation, please call 1800 B-I-O-B-A -N-K or email the biobank at specificbiobank@email.com.au.

Please keep a copy of this information sheet with the copy of your signed consent form.
APPENDIX 3 – SAMPLE GENERAL NOTICES OF A SERIOUS AND SIGNIFICANT FINDING

These General Notices provide an illustration of how a letter can be composed. This is an example only, however the use of these General Notices is recommended.

A – Sample General Notice of a Serious and Significant Finding to Participant Who Electing to Receive Findings

Sample letter to participant
It is suggested that this letter be marked — Private and Confidential.

Dear XXXX

You may recall that you donated a sample to the XXXX Biobank, for researchers to undertake health and medical research. We note that you consented to receiving serious and significant findings on your consent form.

Whilst research was being undertaken on your sample, a finding was discovered, that may have serious health implications for you. This finding has been passed on to me to evaluate it based on my clinical expertise.

At this stage, it is not a clinically confirmed diagnosis. In order to diagnose whether or not you have a serious health condition I need to discuss this with you in person, and possibly run further tests. This may involve taking an additional blood sample, or a biopsy.

Please take this letter to your GP if you would like him or her to make contact with me on your behalf, or are in a rural area and cannot come in person to my clinic. Or you may want to call the contact number listed below to arrange a meeting.

This letter does not give you any details of this disease, but allows you to decide for yourself whether you wish to have more information. If you do, I would be pleased to provide you with more details. Any information you give me will be treated confidentially.

Appointments can be organised for discussions with suitable specialists and/or a genetic counsellor. If you live in remote or rural Australia, your GP or health worker is best placed to contact experts to advise and assist, and offer counselling if you would like more information. It is important for us to know that you have received this letter. Even though you may not want to act on this information, please acknowledge receipt by telephoning the number below or returning the enclosed acknowledgement slip in the stamped addressed envelope provided.

I urge you to take this matter seriously as this information could be very important for the health of you (optional: and your close relatives). Further, it is important to note that receiving further information and/or undertaking further testing may affect your future income protection and travel insurance eligibility.

Yours sincerely

Disclosing Health Practitioner

Phone number
Sample letter to participant

It is suggested that this letter be marked — Private and Confidential.

Dear XXXX

You may recall that you donated a sample to the XXXX Biobank, for researchers to undertake health and medical research. We note that you did not consent to receive any findings.

However, whilst research was being undertaken on your sample, a result has arisen that we believe will be in your best medical interests to know. At this stage, it is not a clinically confirmed diagnosis.

I would need like to offer to meet with you to discuss your decision not to receive any findings and to make sure this decision stands.

Please take this letter to your GP if you would like him or her to make contact with me on your behalf, or are in a rural area and cannot come in person to my clinic. Or you may want to call the contact number listed below to arrange a meeting.

This letter allows you to decide for yourself whether you wish to have more information. Any information you give me will be treated confidentially, and you may ask general questions without details of the finding being revealed.

If you choose to make an inquiry, you are not committed to do anything more than receive more detailed information. Further testing can be done for some conditions but that would only take place after allowing time to consider the full implications for you, at your request and with your consent.

Appointments can be organised for discussions with suitable specialists and/or a genetic counsellor. If you live in remote or rural Australia, your GP or health worker is best placed to contact experts to advise and assist, and offer counselling if you would like more information. It is important for us to know that you have received this letter. Even though you may not want to act on this information, please acknowledge receipt by telephoning the number below or returning the enclosed acknowledgement slip in the stamped addressed envelope provided.

I urge you to take this matter seriously as this information could be very important for the health of you (optional: and your close relatives). Further, it is important to note that receiving further information and/or undertaking genetic testing may affect your future income protection and travel insurance eligibility. This will be discussed with you before any further tests are undertaken.

Yours sincerely

Disclosing Health Practitioner

Phone number