

# NSW Health Statewide Biobank Consent Toolkit



**Health**  
Statewide Biobank

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# Purpose

The purpose of the NSW Health Statewide Biobank Consent Toolkit is to promote ethical human research and a sustainable approach to managing human biobanks.

The Consent Toolkit provides standards for biobanking on the use of broad-based consenting, the return of incidental findings, and linkage to NSW Health datasets. It will provide guidance on consent procedures to ensure the highest ethical standards are followed. The Toolkit will also improve sample and data availability for researchers.

Compliance with the Consent Toolkit is mandatory for prospective collections of the NSW Health Statewide Biobank, however it is encouraged to be used by any NSW research biobank seeking consent from potential biobanking participants.

The Consent Toolkit should be used when developing biobank documentation, such as the biobank's Human Research Ethics Committee application/amendments, Standard Operating Procedures, staff training resources, and Participant Information Sheet and Consent Form. It should be read in conjunction with [NSW Health Pathology's Biobank Certification Program's Informed Consent](#) module.

Compliance can be demonstrated using the [Compliance Checklist](#). Research biobanks must also comply with the [NHMRC National Statement on Ethical Conduct in Human Research \(2007\)](#) (National Statement), relevant NSW legislation, NSW Health Policy Directives and local Human Research Ethics Committee (HREC) requirements, collectively referred to below as 'relevant laws and guidelines'.

The Consent Toolkit contains:

1. Consent Principles and Protocol
2. Guidance for an Ethically Defensible Plan
3. Sample Participant Information Sheet
4. Sample Consent Forms for Adults and Children
5. Compliance Checklist.

The following are key terms used in the document:

*Participants/Potential Participants:* are people who are approached for consent to provide a biospecimen to the biobank for the purposes of research.

*Consenters:* are people responsible for gaining consent from participants. Consenters must have sufficient knowledge and understanding of all aspects of biobanking.

*Biobank:* for the purpose of this document the term 'biobank' refers to an entity that receives, stores, processes and/or distributes biospecimens and associated data, for approved research. It encompasses the physical location as well as the full range of activities associated with its operation.

Evaluation of this policy will provide for further enhancement.

# NSW Health Statewide Biobank Consent Principles and Protocol

## Introduction

The Consent Principles and Protocol should be used with relevant laws and guidelines.

The following sample documents have also been developed: Participant Information Sheet, Consent Form and an Ethically Defensible Plan. Case Studies that describe scenarios for the return and non-return of incidental findings are provided at the end of the Consent Principles and Protocol.

### 1.1 Principles related to biobank participants

- > Potential participants will have a right to decide whether or not to participate in biobanking and will be able to withdraw their consent to biobanking at any time without prejudicing their current or future medical treatment. Participants who withdraw will be informed that any biospecimens and data in the biobank will be destroyed. However biospecimens and data that have been provided to a researcher cannot be retrieved.
- > Potential participants who do not agree to the return of incidental findings should be advised that they will not be able to participate in the biobank.
- > Participants will have the capacity to consent, that is the ability to understand the facts and choices involved, weigh up the consequences and communicate their decision (or their parent and/or legal guardian can do so on their behalf).
- > Participants will freely give their consent, without pressure, inducement or coercion. Consenters will be aware of the impact of drugs or anaesthesia that could significantly impair a participant's judgement.
- > Participants will be provided with relevant and adequate information necessary for making an informed decision to participate in biobank research, in a way they understand.
- > Participants will be given reasonable time and opportunity to consider the information provided.

- > Participants will be provided with an opportunity to ask questions and/or seek clarification and will be provided with answers to those questions.
- > Participants will provide consent in writing on a biobank consent form.

### 1.2 Principles related to who is able to take consent

- > Individuals responsible for gaining consent from participants will have sufficient knowledge and understanding about all relevant aspects of biobanking including:
  - future unspecified research use,
  - the return of incidental findings,
  - an Ethically Defensible Plan,
  - the implications of genomic analysis,
  - how data will be collated in a manner that does not identify participants and participant privacy.
- > Records of approved consenters noting their training or experience will be kept by the participating biobank.
- > The individual who gains consent from the participant will provide their name, date, designation and the organisation that they represent and will also countersign the biobank consent form.

### 1.3 Principles related to the scope of consent that can be sought

- > Participant consent will be sought for future unspecified research to enable the broadest possible use of biospecimens and data collected to support high quality research.
- > The use of biospecimens will not occur without valid consent, defined as consent that has been undertaken in accordance with the principles of this document, and that meets all applicable legal requirements.
- > Participation in a biobank study may include access to previously collected biospecimens at the discretion of pathology services, and any proposed longitudinal collection of biospecimens over a treatment course.

## 1.4 Principles related to consenting methods

- > The consentor will ensure that the potential participant has a full understanding of the information provided to them. Typically, this will involve a verbal discussion to provide the participant with the opportunity to ask questions.
- > Where it is impractical to consent participants in person, a copy of the biobank consent form and participant information sheet will be mailed to participants. Participant questions will be responded to by a biobank consentor through written, electronic or verbal communication.
- > Information provided to participants will be tailored to individual needs and circumstances, for example for those with non-English speaking backgrounds, minors and Aboriginal people and their communities.
- > Participants who are under the age of 18 years when consent for their participation in biobanking is gained from their parent or guardian will be recontacted once they reach 18. The attempts to recontact will be recorded and the biobank will have an internal policy for circumstances where the participant cannot be recontacted. This will include whether the consent will remain valid and whether biospecimens and associated data will be retained or destroyed. Where collections involve participants aged less than 18 years, detail on participant recontact will be made explicit. After turning 18, if the adult participant does not wish to be notified of incidental findings, their sample/s and data will be withdrawn from the biobank and they will be notified as such.
- > A copy of the participant information sheet and biobank consent form will be provided to each participant. In addition, the original or a copy of the consent form will be supplied for inclusion in the patient's medical record, if the participant is a patient of a NSW public hospital.

## 1.5 Principles related to participant privacy

- > Biobanks will ensure that all participant information distributed to researchers is de-identified so that participant confidentiality is protected, and that researchers have data management systems in place to manage the safety and security of data.
- > Biobanks will ensure that procedures are in place in the event of a breach of participant privacy (accidental or intentional) by a biobank staff member or researcher that has obtained biopecimens and/or data.

- > Biobanks will ensure that procedures and mechanisms are in place for the receipt and processing of any complaints from participants.

## 1.6 Principles related to the return of incidental findings

- > By consenting to participate in the biobank, participants are consenting to be notified of incidental findings that have health implications for themselves or their genetic relatives, as per the criteria described below.
- > Only findings that meet each of the following criteria will be returned:
  - Significant: The finding indicates a life threatening health condition.
  - Clinically actionable: There are specific established therapeutic interventions or other available actions.
  - Confirmed: The finding has been checked and confirmed as accurate and/or valid, as far as reasonably possible in a research context.
- > Biobanks will ensure that adequate and appropriate arrangements are in place to return findings. This includes ensuring that researchers have a Health Research Ethics Committee-approved Ethically Defensible Plan or equivalent, and taking responsibility for findings from international researchers. An Ethically Defensible Plan outlines the steps and responsibilities for researchers, biobanks and clinicians to confirm, assess, and potentially return any findings that are discovered in the course of research.
- > A suitably qualified and experienced clinician/s will be nominated by the biobank and/or researcher. Their role and function, along with the steps and principles for evaluating possible findings and managing their return will be covered in the Ethically Defensible Plan.

# Case Studies for the Return and Non-Return of Incidental Findings

## Case Study 1: Recommended return of findings to participant

Non-syndromic isolated dilated cardiomyopathy (DCM) is characterised by left ventricular enlargement and systolic dysfunction, a reduction in the myocardial force of contraction. DCM usually presents with any one of the following:

- > heart failure with symptoms of congestion (oedema, orthopnea, paroxysmal nocturnal dyspnea) and/or reduced cardiac output (fatigue, dyspnea on exertion)
- > arrhythmias and/or conduction system disease
- > thromboembolic disease (from left ventricular mural thrombus) including stroke

Genetic DCM can be inherited in an autosomal dominant, autosomal recessive, or X-linked manner. Mitochondrial inheritance has also been reported; however, mitochondrial forms of DCM, although highly variable in presentation (including mild adult-onset forms), are usually syndromic. Genetic counselling and risk assessment depend on determination of the specific DCM subtype in an individual.

Treatment by clinicians skilled in diagnosis and management of symptomatic and asymptomatic DCM improves survival and quality of life. Treatment modalities include pharmacologic therapy, pacemakers, and/or implantable cardiac defibrillators. Cardiac transplantation remains the definitive treatment for progressive DCM and advanced heart failure refractory to medical or device therapy.

Adapted from GeneReviews® at [www.ncbi.nlm.nih.gov/books/NBK1309/](http://www.ncbi.nlm.nih.gov/books/NBK1309/)

A woman in her late thirties goes into hospital for a minor routine procedure and consents to participating in a biobank, allowing access to her health information for research purposes.

Many years later, a researcher conducting research on the biobanked sample discovers a gene variation that is pathogenic for Dilated Cardiomyopathy (DCM). The researcher had anticipated this kind of finding and had included a plan for returning results to participants in their Ethically Defensible Plan prior to obtaining samples from the biobank.

The findings are confirmed in the research laboratory and provided to the biobank. The biobank re-identifies the participant and notifies the clinician who was nominated in the Ethically Defensible Plan of the participant's name, contact details and any other relevant information.

The clinician applies the criteria for return of findings outlined in this Principles document and determines that it is significant, clinically actionable and a confirmed research finding. It is because DCM is life threatening, an effective treatment is available, and the finding has been confirmed as far as possible in a research setting.

**The clinician consults with the participant's treating clinician, and they are in agreement that the results should be returned to the participant.**

The clinician sends a letter to the participant, who later comes in to visit the clinician and obtain more information on the finding.

## Case Study 2: Recommended *non-return of findings to participant*

Parkinson's disease is a progressive disorder of the nervous system characterised by trembling or shaking (tremor) of a limb, especially when the body is at rest. Typically, the tremor begins on one side of the body, usually in the hand or leg. Other signs include rigidity of the limbs and torso, bradykinesia or akinesia (slowness of movement), and postural instability. These symptoms worsen slowly over time. Parkinson's disease can affect emotions and thinking ability (cognition). People with Parkinson's disease also have an increased risk of developing dementia, which is a decline in intellectual functions including judgment and memory.

Generally, Parkinson's disease that begins after age 50 is called late-onset disease. More than 100 *LRRK2* gene mutations have been identified in families with late-onset disease, however it is unclear how the gene mutations lead to the movement and balance problems characteristic of Parkinson's disease.

Adapted from NIH Genetics Home Reference at <https://ghr.nlm.nih.gov/gene/LRRK2#>

Parents of a nine year old boy consent for him to participate in a biobank project, by donating a blood sample and allowing access to his health information for research purposes.

Two years later, a researcher conducting research on the boy's blood discovers a known Parkinson's disease-associated mutation in the *LRRK2* gene. The researcher had anticipated this kind of finding and had included a plan for returning results to participants in their Ethically Defensible Plan prior to obtaining samples from the biobank.

The findings are confirmed in the research laboratory and provided to the biobank. The biobank re-identifies the participant and notifies the clinician who was nominated in the Ethically Defensible Plan of the participant's name, contact details and any other relevant information.

The clinician applies the criteria for return of findings outlined in this Principles document and determines that it does not meet the listed criteria. This is because Parkinson's Disease is not directly life threatening, and cannot be cured. In addition, the boy's age is taken into consideration as *LRRK2* mutations are associated with late onset of the disease and have a variable penetrance, even in older patients.

The clinician consults with the participant's treating clinician, and they are in agreement that the results should not be returned to the participant, in light of the gene mutation not meeting the criteria, as well as the participant's young age. **The finding is not returned to the participant's parents.**



## Introduction

An Ethically Defensible Plan (EDP) is required when researchers use human biospecimens to identify information that may be clinically relevant. An EDP describes the management of disclosure to participants of any incidental findings that have been discovered during this research.

This Guidance for an Ethically Defensible Plan will guide biobanks to develop their own EDPs. The principles in this document are essential elements for an EDP. It references Section 3.4.1 of the [National Statement on Ethical Conduct in Human Research, 2007](#). The NHMRC has published draft amendments to chapters 3.1 and 3.5, which include updated guidance on incidental findings. When these amendments are finalised, this guidance document will be updated accordingly.

## Scope

This guidance document applies to research that may discover or generate information of potential importance to the future health of participants, or their genetic relatives. Researchers should follow the inclusion and exclusion criteria for the return of this information outlined in the NSW Health Statewide Biobank Consent Principles and Protocol, and should be used when deciding whether or not to return an incidental finding to participants.

Researchers accessing and using human biospecimens have responsibilities to:

- > Obtain Human Research Ethics Committee (or equivalent) approval, including approval of an EDP if required
- > Identify potential incidental findings relevant to their proposed research
- > Notify the biobank of any incidental findings
- > Work with the biobank to check and confirm any incidental findings in a timely manner.

## Method

An EDP will nominate a suitably qualified and experienced clinician(s) who will be responsible for evaluating possible findings and managing their return. This individual or group may consult with other appropriate personnel to plan a course of action, whilst protecting the biobank participant's privacy as far as possible. The implementation of the EDP will include the following:

- > The nominated clinician(s) will contact the participant's treating clinician and/or relevant head of clinical services, if appropriate
- > The nominated clinician(s) will apply the criteria outlined in the Biobank Consent Principles and Protocol for the NSW Health Statewide Biobank
- > The nominated clinician(s) will make a decision on whether to return the finding or not
- > If returning, the nominated clinician(s) will prepare a letter to the participant relevant to the circumstances
- > The nominated clinician will make reasonable attempts to ascertain that the participant is still alive
- > The nominated clinician will send the letter to the participant, requesting that the participant contact them. If there is no response, the nominated clinician(s) will attempt to contact the participant via telephone
- > When contacted, the nominated clinician will put them in touch with their treating clinician or other appropriate health practitioner and/or genetic counsellor.

## EDP elements (National Statement on Ethical Conduct in Human Research, 2007)

### 1. Circumstances in which the biospecimens are obtained, including the type of consent provided and the manner in which the consent is obtained

Participation in biobanking involves the donation of biological material by a patient, which is collected during the course of their treatment or collected previously. Patient's consent to participate will be gained for future research where the primary focus

of the research is health. The consent process will be managed by an experienced staff member and include the opportunity for the participant to ask questions.

## **2. The likelihood of the research generating information that may be important for the health of the donor(s), their blood relatives or their community**

Research to be supported by the biobank will include local, interstate and international research with the primary focus as health, medical, healthcare or health outcomes. This includes but is not limited to contemporary research techniques such as genomics and personalised medicine to investigate the cause, prevention, diagnosis and treatment of disease.

The EDP will describe the biobank and the primary research supported. For example, whether this biobank primarily supports paediatric cancer research and frequently supplies samples for genomics studies that may discover genetic markers for other cancers, or infrequently, other genetic conditions such as sudden cardiac arrest.

During the course of the research, information may be discovered that represents a substantial risk of a serious health condition, is clinically actionable, and is a confirmed research finding. Inclusion and exclusion criteria for these findings can be found in the NSW Health Statewide Biobank Consent Principles and Protocol.

## **3. Whether a recognised intervention exists that can benefit or reduce the risk of harm to the donor(s), their blood relatives or their community from any health impact revealed by this information**

Only those confirmed research findings that are clinically actionable, where there are established therapeutic or preventative 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 are to be considered to be returnable to the participant.

## **4. The resource requirements and infrastructure in place to support the return of information of the kind referred to in points 2. and 3. above in an ethically appropriate manner**

The biobank will identify a clinician(s) and list them with appropriate relevant expertise to evaluate any findings.

The clinician must take into account all of the individual circumstances and the current state of health knowledge for a particular condition and the prevailing clinical practice. The clinician is responsible for:

- > contacting the participant's treating clinician and/or relevant Head of Clinical Services prior to contacting the participant, if appropriate
- > applying the criteria for the return of findings
- > making a decision to return the finding or not
- > preparing a letter relevant to the circumstances
- > making reasonable attempts to ascertain that the participant is still alive
- > sending the letter to the participant, including the clinician's contact details and
- > putting the participant in contact with their treating clinician, other appropriate health practitioner and/or genetic counsellor.

## **5. Whether participants will be given a choice to receive such information**

In consenting, participants agree to be notified of incidental findings. Participants are not given a choice on whether to be notified.

**6. Whether there is a pathway to identify and recontact the donor(s), their blood relatives or their community, taking into account the relationship between the researchers and the donor(s), if any**

As per point 4 above, the clinician(s) will, in conjunction with the biobank, identify and recontact the donor initially via letter, and then by telephone. Genetic relatives of the donor/participant will not be contacted via the plan. The clinician will make reasonable attempts to ascertain that the participant is still alive, for example checking the participant's health records, or contacting the participant's treating clinician.

**7. The potential for sampling or coding errors that may compromise the certainty that the biospecimens came from a particular donor**

The biobank and participating researchers will make every attempt to ensure that a research finding has been checked and confirmed as accurate and/or valid. This checking will include reviewing biospecimen/sample handling procedures for any misidentification and/or contamination errors as well as checks on instrument/test accuracy and repeatability within the research laboratory.

**8. Whether the findings of specific tests being undertaken as part of the research are produced or validated in an accredited laboratory**

Participants will be notified that any findings have not been validated in a NATA Accredited Laboratory (or equivalent), and should be treated as a confirmed research finding which may warrant further investigation in a clinical laboratory.

**9. Who will take responsibility for any subsequent care requirements**

Prior to contacting the participant, the clinician(s) may contact the participant's treating clinician and/or relevant Head of Clinical Service to ascertain more information. Via letter, the clinician will then offer to provide the participant with more details regarding their finding. This includes putting the participant in contact with their treating clinician, or other suitable specialist health practitioner and/or genetic counsellor (if required). For participants who live in remote or rural Australia, they will be advised that their GP or health worker is best placed to contact experts to advise and assist, and offer counselling.

**10. Whether the returned information may be used by employers or insurers to affect a participant's eligibility for employment or insurance**

The results to be returned under the EDP must meet strict inclusion criteria (must be significant, clinically actionable, and a confirmed research finding).

Depending on the finding, the use of this information in the underwriting process may or may not lead to:

- > Higher (non-standard) life insurance premiums
- > A reduced period of coverage
- > An exclusion for one or more medical conditions
- > The offer of an alternate life insurance product
- > Deferral of the decision whether to offer coverage, or
- > Outright denial of an offer for life insurance.

However, the recommendation under the Financial Services Council Standard no. 11 'Genetic Testing Policy' is for life insurance to remain available to the majority of the insurable population at standard premium rates. If participants have any concerns about the impact of biobanking on their insurance status they should be advised to contact their insurance provider.

**11. Whether there is a possibility that the participant is a minor or does not have capacity to consent and if so, the procedures for returning results to the participant and their parent or legal guardian**

The biobank will store identifiable data on all participants, including their age and if appropriate (ie. if the participant is a minor or does not have capacity), contact details for their parent/guardian. The biobank's consent form includes a section for the participant's parent or legal guardian to sign and complete. Beyond this, mechanisms for returning results remain the same as for returning results to the participant themselves.

## XXXX BIOBANK

### Investigators:

<Insert:.....>  
*Names of main investigators;.....*  
*Contact details of main investigators;.....*  
*Biobank name and/or location.....>*

You have been given this information sheet because you have been asked to provide a specimen of your biological material (biospecimen), such as urine, blood, and/or tissue to the <Insert: Biobank Name> for the purposes of research.

### What is biobank?

A biobank is a stored collection of human biological samples (e.g. tissue, blood or bone) and/or their products (e.g. DNA, associated with 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 associated health information are stored securely, and are used for medical and health-related research projects. This includes research on the cause, prevention, risks, diagnosis and treatment of disease, as well as genetics research and clinical trials.

### Being a biobank participant

Your participation in the biobank is voluntary. If you choose to participate, you will be given the opportunity to discuss any questions with an approved individual responsible for obtaining biobank consent. Your scheduled medical procedure will happen as normal. Once your questions have been answered, if you agree to participate and have completed the consent form, the following biological samples will be biobanked:

- > a small sample of tissue and/or fluid collected during your scheduled medical procedure.
- > a small blood sample (5 - 10 mls). This is generally collected during a routine blood collection before your scheduled procedure. Alternatively, or in addition, you may be asked to give a saliva sample or have a mouth swab; and

- > depending upon the treatment regimen for your current condition, the biobank may also seek approval from relevant pathology services to access samples that have been previously collected from you, and/or collect further samples over the course of your treatment.

After your treatment, any extra tissue that's not needed for clinical pathology purposes will also be stored.

### How will my privacy be protected?

Identifying personal information will be removed from your samples and replaced with a unique number for research purposes.

A separate list of identifying personal information will be stored by the biobank so that only the biobank can identify you. Your sample and information will be stored indefinitely in this way.

There may be instances where genetic information obtained from donated tissue may lead to the identification of participants, for example if genetic information derived from your donated samples was matched to previously stored genetic information and identifiers of yours.

However the biobank requires this genetic information to be kept strictly confidential and there are legal requirements for researchers to maintain your privacy.

## What does it mean to consent to biobanking?

Consenting to biobanking means you are also consenting for researchers to access and link information held by NSW Health. This health information may include details about your operation, diagnosis history, pathology results, hospital records and genetic or family history details. Your health information may be linked with other personal information (e.g. education, employment status, lifestyle factors). By consenting to link your biological sample with your health and personal information, you are providing a valuable resource for future health and medical research that will only occur after approval from a human research ethics committee. You are also consenting to be notified of incidental findings. For further information on the significance of this decision, please refer to questions 10, 11 and 12.

*[Note: If your biobank plans to routinely access data beyond that held by NSW Health, please confirm with the relevant data custodian that the wording in your Participant Information Sheet and Consent Form satisfies their requirements to access personal information.]*

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

While your sample may contribute to research that has a commercial benefit, for example the development of a new technology, you will not be entitled to receive a financial return.

## Frequently asked questions

### 1. Who is responsible for my samples?

The <Insert: Biobank Name> will be the custodian of your samples. The <Insert: Biobank Name> will be responsible for storing the samples, and the release of samples to researchers.

### 2. What will happen to my samples?

The samples collected from you will be stored in <Insert: Biobank Name> for an indefinite period of time. The samples will be used for future unspecified health and medical research after approval by a Human Research Ethics Committee, an independent committee that has ethical oversight of research involving humans.

This committee will be required to meet Australian ethical standards. The research may be published without your further consent, however you will not be identified in any way.

### 3. What does data linkage mean?

Record or data linkage, brings together information that relates to the same individual from different data sources. This helps researchers better understand people's health journey, which can improve treatment and health services delivery. For more information on how data linkage works see <http://www.cherel.org.au/how-record-linkage-works>

### 4. What will happen to my data?

All personal data will be stored using strict privacy protocols and in accordance with NSW Government requirements. All studies using biospecimens and linked data must have ethical approval.

Researchers are only provided information without identifying personal information (eg. your name and address). In the event of an incidental finding (see question 8), the biobank can de-code (ie. re-identify you) the biospecimen if necessary.

### 5. Will my samples and data 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. This will be done in such a way that you cannot be identified and only after a Human Research Ethics Committee (or an international equivalent that meets Australian ethical standards) has approved the research. Researchers will only have access to your samples, not your identifying personal information.

### 6. Are there any risks to my privacy by participating?

Your health information will be kept secure and confidential in accordance with legal requirements. Researchers are only provided information without identifying personal information (e.g. your name and address). Should any breach of privacy occur, the <Insert: Biobank Name> will ensure the situation is dealt with in accordance with existing privacy laws and guidelines.



## **7. Can anyone other than the <Insert: Biobank Name> approved researchers access my health information?**

In general, parties outside NSW Health cannot access your health information. However, there may be circumstances where a legal requirement to provide your health information outside NSW Health arises. While these situations are rare, the <Insert: Biobank Name> will be required to comply with its legal requirements and make your information available.

## **8. What if I change my mind and don't want to participate?**

Participation in biobanking is entirely voluntary. Even after you have provided the <Insert: Biobank Name> with your sample and health information, you are free to withdraw all, or part of, your consent at any time without having to give a reason by contacting the <Insert: Biobank Name>. 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 <Insert: Biobank Name> will discard your stored tissue, blood samples and health 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 retrieve these samples.

Also, research that has been published cannot be deleted or discarded, but you will not be able to be identified in any way.

## **9. Will the <Insert: Biobank Name> contact me after I have given my consent to participate?**

Should you consent to be recontacted, the <Insert: Biobank Name> may occasionally contact you to collect further personal and health-related information. The <Insert: Biobank Name> will keep contact to a minimum.

You may also be contacted by a clinician to notify you of any new incidental findings that arise.

## **10. What happens if serious health implications are discovered in my sample?**

During research, information may be discovered that has serious and significant health implications for you (and possibly your genetic relatives). These are known as incidental findings. Only findings that are of a highly serious nature will be returned to you, such as the identification of a gene for sudden cardiac death. General health information, such as evidence of elevated risks for high cholesterol or diabetes, will not be returned.

If you are not contacted to advise you of a finding, this does not mean that you do not have any health issues. It is important to continue any regular clinical check-ups, as researchers do not perform screening on your sample during their research.

In the event that a finding is discovered, the <Insert: Biobank Name> will refer the matter to a clinical expert, 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. As the findings may impact on your genetic relatives, we encourage you to inform them of your participation in the biobank. After further testing, this information may become part of your health record as health information.

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 insurance eligibility. If you are contacted about an incidental finding, you are encouraged to seek advice from your insurer.

## **11. Where can I find more information?**

If you would like more information about the <Insert: Biobank Name> or your participation, please call 1800 XXXX or email insert: [specificbiobank@email.>](mailto:specificbiobank@email.>)

Please keep a copy of this information sheet with the copy of your signed consent form.

## **12. Who should I contact if I have concerns or complaints about the study?**

If you have any concerns or complaints about the conduct of the <Insert: Biobank Name>, these should be directed to:

XXXX Human Research Ethics Committee  
Ph: XXXXXXXX

|   |               |   |
|---|---------------|---|
| FAMILY NAME   |               | MRN   |
| GIVEN NAMES   |               | <input type="checkbox"/> MALE <input type="checkbox"/> FEMALE |
| D.O.B. ____/____/____                                   | M.O.          |   |
| <b>Facility:</b>  | ADDRESS       |   |
|   |               |   |
|   | LOCATION/WARD |   |
| <b>COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE</b> |               |   |

**SAMPLE ADULT CONSENT FORM FOR BIOBANKING**

**Authority to provide [insert name] BIOBANK (the biobank) with tissue<sup>1</sup> samples and health information**

I consent to my tissue (including blood, saliva and other tissue) removed during medical, dental or surgical treatment to be stored by the biobank and used for any current project and/or future unspecified research projects. I also consent to my health and personal information being collected, used and disclosed, for the purpose of such research.

In consenting to my tissue being stored by the biobank and used and disclosed for research purposes, **I confirm that I agree to all of the following:**

- ✓ I have read the Participant Information Sheet 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, saliva and health information collected during the course of my treatment, for use in health and medical research. This may include previously collected samples, in consultation with relevant Pathology Service/s.
- ✓ I understand that I may be contacted in the future if an incidental finding is discovered that has serious and significant health implications for me (and possibly my genetic relatives).
- ✓ 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 may not be personally informed of the general research results of studies using my samples, but these may be published, taking care not to disclose the identities of those who have contributed samples.
- ✓ I permit the biobank to store samples collected from me for an indefinite period of time and the samples will be used in an anonymous form for Human Research Ethics Committee (HREC) approved future unspecified health and medical research.
- ✓ I permit the transfer and sharing of my tissue samples and health and personal information to other researchers/biobanks both interstate and internationally for HREC approved health, medical, healthcare or health outcomes research.
- ✓ I permit the linking of my health information (e.g. clinical records, diagnosis history, pathology results, hospital and emergency department records) and other relevant information (e.g. education, employment status, lifestyle factors) for use in health and medical research, subject to HREC approval. Researchers are only provided information without identifying details (e.g. name and address).

\_\_\_\_\_

<sup>1</sup> means tissue as defined in the Human Tissue Act 1983 – includes an organ, or part, of a human body and a substance extracted from, or part of, a human body. Examples of tissue include blood products, regenerative or non-regenerative tissue, organs (partial or whole), bone tissue, and saliva.

**FORM TITLE**

**FORM #**

|                       |      |   |
|-----------------------|------|---|
| FAMILY NAME           |      | MRN   |
| GIVEN NAMES           |      | <input type="checkbox"/> MALE <input type="checkbox"/> FEMALE |
| D.O.B. ____/____/____ | M.O. |   |

|   |               |
|---|---------------|
| <b>Facility:</b><br><br><b>SAMPLE ADULT CONSENT FORM FOR BIOBANKING</b> | ADDRESS       |
|   |               |
|   | LOCATION/WARD |
| <b>COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE</b>                 |               |

**Please tick the appropriate boxes:**

I permit the biobank to contact me in the future to collect further personal and health-related information:

- Yes  
 No

**Declaration:**

|                     |           |       |
|---------------------|-----------|-------|
| _____               | _____     | _____ |
| PARTICIPANT NAME    | SIGNATURE | DATE  |
| _____               | _____     | _____ |
| If applicable: NAME | SIGNATURE | DATE  |

PERSON RESPONSIBLE

SENIOR NEXT OF KIN  *(please tick appropriate box)*

|                                 |           |       |
|---------------------------------|-----------|-------|
| _____                           | _____     | _____ |
| If applicable: INTERPRETER NAME | SIGNATURE | DATE  |
|                                 |           |       |

**Person Authorised to Obtain Consent:**

|             |                      |       |
|-------------|----------------------|-------|
| _____       | _____                | _____ |
| NAME        | SIGNATURE            | DATE  |
| _____       | _____                |       |
| DESIGNATION | BIOBANK/ORGANISATION |       |

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|   |               |   |
|---|---------------|---|
| FAMILY NAME   |               | MRN   |
| GIVEN NAMES   |               | <input type="checkbox"/> MALE <input type="checkbox"/> FEMALE |
| D.O.B. ____/____/____                                   | M.O.          |   |
| <b>Facility:</b>  | ADDRESS       |   |
|   |               |   |
|   | LOCATION/WARD |   |
| <b>COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE</b> |               |   |

**SAMPLE ADULT CONSENT FORM FOR BIOBANKING**

**Authority to provide [insert name] BIOBANK (the biobank) with my child's tissue<sup>1</sup> samples and health information**

I consent to my child's tissue (including blood, saliva and other tissue) removed during medical, dental or surgical treatment to be stored by the biobank and used for any current project and/or future unspecified research projects. I also consent to my child's health and personal information being collected, used and disclosed, for the purpose of such research.

In consenting to my child's tissue being stored by the biobank and used and disclosed for research purposes, **I confirm that, on behalf of my child, I agree to all of the following:**

- ✓ I have read the Participant Information Sheet 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 my child's participation in the biobank is entirely voluntary and, acting on behalf of my child, I give my consent to donate his/her blood, tissue, saliva and health information collected during the course of my child's treatment, for use in health and medical research. This may include previously collected samples, in consultation with relevant Pathology Service/s.
- ✓ I understand that I may be contacted in the future if an incidental finding is discovered that has serious and significant health implications for my child (and possibly my genetic relatives).
- ✓ I understand that I can withdraw consent for my child's participation at any time by contacting the biobank without any impact on their treatment.
- ✓ I am aware that I may not be personally informed of the general research results of studies using my child's samples, but these may be published, taking care not to disclose the identities of those who have contributed samples.
- ✓ I permit the biobank to store samples collected from my child for an indefinite period of time and to use those samples in an anonymous form for Human Research Ethics Committee (HREC) approved future unspecified health and medical research.
- ✓ I permit the transfer and sharing of my child's tissue samples and health and personal information may be provided to other researchers/biobanks both interstate and internationally for HREC approved health, medical, healthcare or health outcomes research.
- ✓ I permit the linking of my child's health information (e.g. clinical records, diagnosis history, pathology results, hospital and emergency department records) and other relevant information (e.g. education, lifestyle factors) for use in health and medical research, subject to HREC approval. Researchers are only provided information without identifying details (eg. name and address).
- ✓ I understand that all reasonable steps will be made to contact the child once they reach 18 years of age to gain their consent.

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<sup>1</sup> means tissue as defined in the Human Tissue Act 1983 - includes an organ, or part, of a human body and a substance extracted from, or part of, a human body. Examples of tissue include blood products, regenerative or non-regenerative tissue, organs (partial or whole, bone tissue, and saliva).

**FORM TITLE**

**FORM #**

|                       |      |   |
|-----------------------|------|---|
| FAMILY NAME           |      | MRN   |
| GIVEN NAMES           |      | <input type="checkbox"/> MALE <input type="checkbox"/> FEMALE |
| D.O.B. ____/____/____ | M.O. |   |

|   |               |
|---|---------------|
| <b>Facility:</b><br><br><b>SAMPLE CHILD CONSENT FORM FOR BIOBANKING</b> | ADDRESS       |
|   |               |
|   | LOCATION/WARD |
| <b>COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE</b>                 |               |

**Please tick the appropriate boxes:**

I permit the biobank to contact me in the future to collect further personal and health-related information from my child:

- Yes  
 No

**Declaration:**

|  |                    |               |
|--|--------------------|---------------|
| _____<br>PARTICIPANT NAME  |                    |               |
| I confirm that, after reasonable inquiry, the child would not object to their tissue being stored by the biobank and used for research purposes. I also confirm that, after reasonable inquiry, no other parent or guardian would object to the child's tissue being stored by the biobank and used for research purposes. |                    |               |
| _____<br>PARENT/GUARDIAN'S NAME  | _____<br>SIGNATURE | _____<br>DATE |
| _____<br>PARENT/GUARDIAN'S NAME  | _____<br>SIGNATURE | _____<br>DATE |
| _____<br>If applicable: INTERPRETER NAME   | _____<br>SIGNATURE | _____<br>DATE |

**Person Authorised to Obtain Consent:**

|                      |                               |               |
|----------------------|-------------------------------|---------------|
| _____<br>NAME        | _____<br>SIGNATURE            | _____<br>DATE |
| _____<br>DESIGNATION | _____<br>BIOBANK/ORGANISATION |               |

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# NSW Health Statewide Biobank Compliance Checklist



This checklist has been developed for biobanks to demonstrate that the criteria outlined in the NSW Health Statewide Biobank Principles and Protocol document have been met. A completed checklist will be mandatory for prospective collections housed in the NSW Health Statewide Biobank, however other biobanks are encouraged to use the checklist for their own record keeping.

| NSW Health criteria<br>(see NSW Health Statewide Biobank Consent Principles and Protocol for further information)   | Describe biobank procedures and attach copies of relevant materials in order to meet each criteria <i>(to be completed by the applicant)</i> | NSW Health assessment:<br>Does the applicant comply with the criteria?<br>(Yes/No/not applicable) |
|---|--|---|
| <b>Biobank Participants</b>   |  |   |
| Details of the biobank's consenting method and participant rights are included in biobank HREC application and are adequate.  |  | Yes <input type="checkbox"/><br>No <input type="checkbox"/><br>N/A <input type="checkbox"/>       |
| Information on participation and withdrawal is described in the Participant Information Sheet and Consent Form.   |  | Yes <input type="checkbox"/><br>No <input type="checkbox"/><br>N/A <input type="checkbox"/>       |
| <b>Consenters</b>   |  |   |
| The biobank keeps records of training and/or experience of biobank consent staff.   |  | Yes <input type="checkbox"/><br>No <input type="checkbox"/><br>N/A <input type="checkbox"/>       |
| The biobank Consent Form has provision for the biobank consentor to counter-sign.   |  | Yes <input type="checkbox"/><br>No <input type="checkbox"/><br>N/A <input type="checkbox"/>       |
| All consent staff have undertaken training or are experienced to judge participant capacity, avoid coercion, ensure valid and informed consent, and ensure that cultural considerations are taken into account. |  | Yes <input type="checkbox"/><br>No <input type="checkbox"/><br>N/A <input type="checkbox"/>       |

| NSW Health criteria<br>(see NSW Health Statewide<br>Biobank Consent Principles and<br>Protocol for further information)  | Describe biobank procedures and attach copies of relevant materials in order to meet each<br>criteria <i>(to be completed by the applicant)</i> | NSW Health<br>assessment:<br><i>Does the<br/>applicant comply<br/>with the criteria?<br/>(Yes/No/not<br/>applicable)</i> |
|--|---|--|
| <b>Scope of Consent</b>  |   |  |
| Biobank data management practices are strictly administered to mitigate against biospecimen use without consent.   |   | <input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> N/A                              |
| The biobank Participation Information Sheet and Consent Form clearly outline the scope of the biospecimens to be biobanked.  |   | <input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> N/A                              |
| <b>Consenting Methods</b>  |   |  |
| HREC approval will be sought to consent potential participants in writing (email or mail as appropriate). This includes the provision of further information to participants if requested. |   | <input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> N/A                              |
| HREC approval will be sought for the biobank's policy on re-contacting participants at the age of 18 (if relevant).  |   | <input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> N/A                              |
| The Participant Information Sheet contains information on re-contact at the age of 18 (if relevant).   |   | <input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> N/A                              |
| The biobank has procedures in place to ensure that a copy of participant Consent Forms are included in the patient's medical record.   |   | <input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> N/A                              |

| NSW Health criteria<br>(see NSW Health Statewide<br>Biobank Consent Principles and<br>Protocol for further information)  | Describe biobank procedures and attach copies of relevant materials in order to meet each<br>criteria (to be completed by the applicant) | NSW Health<br>assessment:<br>Does the<br>applicant comply<br>with the criteria?<br>(Yes/No/not<br>applicable) |
|--|--|---|
| <b>Participant Privacy</b>   |  |   |
| The biobank has adequate and appropriate procedures in place to remove identifiers and re-identify participants if required.   |  | <input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> N/A                   |
| The biobank has procedures in place to manage breaches of participant privacy.   |  | <input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> N/A                   |
| The biobank has procedures in place to manage complaints.  |  | <input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> N/A                   |
| <b>Return of Incidental Findings</b>   |  |   |
| Details of the biobank's management of incidental findings are included in biobank HREC application.   |  | <input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> N/A                   |
| The Participant Information Sheet and Consent Form contains adequate information on incidental findings.   |  | <input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> N/A                   |
| The biobank has procedures in place to ensure that each application for a biospecimen has an appropriate Ethically Defensible Plan or equivalent, and if not, to assist researchers in the development of one. |  | <input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> N/A                   |

