

Participant Information



If you need an interpreter, please let us know

You are invited to donate your tissue to the Auckland Regional Tissue Bank.

This patient information sheet and consent form explains what is involved in donating tissue samples and accompanying relevant clinical information to the Auckland Regional Tissue Bank for use in ethically approved medical research.

Why have I been chosen?

You are about to have a procedure which will take a tissue sample from your body. This tissue might be skin, blood, a lump, tumour, bone marrow and/or other body fluids.

The procedure may be a surgical operation, a bone marrow biopsy and/or a blood or body fluid sample which may be part of your treatment for a previously diagnosed condition, or may be taken as part of an investigation to confirm/ exclude a certain disease state. Tests may be used to examine your tissue sample as a routine part of your medical care and these will be unaffected, regardless of whether you decide to donate to the tissue bank or not. Should you decide to donate tissue, the tissue bank will only receive and store what is not needed for your own medical tests. The storage of your tissue will not affect these.

Along with your tissue we will also ask for your consent to access your clinical records. This information is very valuable for researchers to get the most out of using your donated tissues. This information will include, but is not limited to, your age, gender, ethnicity, medications and type of disease (if present).

Please read this information sheet and consent form carefully and ask as many questions as you like before deciding whether or not you would like to donate tissue samples and accompanying clinical information. You are encouraged to discuss this with your whānau/family or friends.

If I consent what do I need to do?

You will firstly be asked to complete and sign the consent form on page 6 of this document. Then you will be required to donate tissues which will be stored by the Auckland Regional Tissue Bank for use by ethically approved researchers in New Zealand and, if you consent, overseas.

What tissues will you take?

The types of tissue that we bank will depend on your medical situation. We will ask your consent to store a small piece of 'spare' tissue that is removed during a routine surgery. With this we may ask for a blood sample of up to 40 mL volume (~2 tablespoons). If you are undergoing a bone marrow biopsy, during the procedure we will ask to store an extra 4 mL (~1 teaspoon). If you have been diagnosed with or have a suspicion of a blood cancer, we may also ask for a sample of fingernail clippings or hair. What we ask of you will be taken during your normal clinic visit.

Who will use my tissues after I have donated them to the Auckland Regional Tissue Bank?

Only researchers who have received their own ethical approval and been reviewed by the scientific advisory board of the tissue bank will have access to your tissues.

What is a Tissue Bank?

A tissue bank is a collection of samples that are stored for scientists to access to be able to perform research. These tissues are accessed along with relevant clinical information on the donors and released for future use in ethically approved research. A tissue bank is a valuable resource to allow researchers to better understand diseases and in future improve the care of patients.

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Does the decision to donate affect my care in any way?

No. Whether you decide to donate or not is your choice and it will not affect your normal medical treatment and care.

How is my tissue collected?

Tissues are cells collected from your body. If tissues are not obtainable then none will be banked. At the time of consent, the tissue bank staff member will inform you of what type of sample is needed.

If you are about to have a surgical operation or biopsy:

We seek your consent to collect and store a small portion of the tissue, often no bigger than the size of a pea or two. This will be spare tissue that is extra to what is needed for your own medical tests and would normally be discarded. Donation makes no difference to your operation. A sample is only taken from the tissue that would normally be removed. After the tissue is removed from your body we may take a photograph of it for release to researchers.

If you are about to have a bone marrow biopsy and/or blood test:

We ask you to donate a 4 mL of bone marrow (if obtainable) which will be taken during your test. We would also ask for a sample of up to 40 mL of blood.

Other types of tissues:

In certain diseases, such as blood cancers, it is important to collect other types of healthy tissues. On such rare occasions we might ask for tissues such as fingernail clippings or a hair sample.

How often will my samples be stored?

Sometimes tissue samples are removed on more than one occasion during the treatment of your condition. We will seek your consent at each occasion before any samples are stored. On each occasion your donation is entirely voluntary and even if you have consented before you can change your mind the next time.

Where are the tissue samples stored?

Tissue samples are stored in the Auckland Regional Tissue Bank secure facilities based at each hospital site (Middlemore, Auckland City and North Shore) and at the purpose built Auckland Regional Tissue Bank cryogenic storage facility at the University of Auckland, Grafton Campus. The tissue bank is governed by the University of Auckland, Faculty of Medical and Health Sciences. Tissues may be moved between sites and will be carefully tracked using our secure database. Unless you withdraw your consent, your tissues will be stored indefinitely until used in research.

Will my samples be sent outside of NZ?

If you approve, future research may involve sending samples for study or analysis in overseas research institutions. International researchers will be approved prior to receiving any samples.

What type of research will be done with my tissue?

We ask you to consent for your samples to be used for 'future unspecified research'. This means that we cannot be certain what types of research they will be used in and you cannot choose. All projects and research teams will be required to have their own ethical approvals from an accredited, New Zealand Ethics Committee. Applications to access tissues must also be approved by the Auckland Regional Tissue Bank Scientific Advisory Board.

Approved researchers might investigate the molecules within your cells which could include the genetic information, DNA, the biological code for every cell in your body.

What is 'Living Cell' research?

For a few tissue types it is possible to store them frozen in conditions where they can be revived at a later date for research as viable, living cells. They may continue to grow in the laboratory for ever. These cells are valuable for example in blood cancer research where they can be treated with different drugs to investigate how they may respond.

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Commercial issues?

Samples will not be 'sold for profit' to commercial organisations. Scientific research can however lead to the development of new tests or treatments. You will not benefit financially from these findings and all intellectual property rights will be owned by the researchers and their governing institutions.

Why do you need information from my health records?

For tissues to be useful for research related clinical information is vital. This information might allow a researcher to better understand the biology of disease and in turn build knowledge on how best to treat future patients. Therefore we seek your consent for authorised Auckland Regional Tissue Bank staff and researchers to access relevant information from your health records.

How will my privacy be protected?

Your identity, tissue(s) and health information will remain confidential to the Auckland Regional Tissue Bank staff and approved researchers. Donors and tissues samples will be given a coded number which only authorised Auckland Regional Tissue Bank staff can decode. Before accessing your samples and information, all researchers will be required to sign a legal document that says they will protect your privacy.

Will I receive research results?

No. Your samples may be banked for a long time before release to researchers so we cannot guarantee when they will be used or exactly what types of research they will be used for. The return of individual results is unusual in research studies. We do however encourage you to follow our webpage for updates on the projects that tissues have been released to for research.

What is an 'Incidental finding'?

Sometimes when tissues are used in research, information can be discovered that could have an impact on you, the donor, that could be important for your medical care. Some researchers have the approval to give this information back to you. We therefore seek your approval to identify you to the researcher and assist them in returning that information to you.

How might this affect my whānau/family?

Approved research studies might investigate your genetic information. This genetic information was inherited from your parents and makes you who you are. In turn we all pass our genetic information on to our children. Therefore, if a study was to find a genetic 'Incidental Finding', although your genetic information belongs to you, it can also be important for your whānau/family.

You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with storing your tissue and/or undertaking genetic analysis on them should be discussed with your whānau/family as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples and genetic testing citing whakapapa and advise their people to consult prior to participation in research where this occurs.

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Will there be Māori consultation?

Consultation with iwi nationally, regionally and locally has taken place and continues around the use of tissue for research. To date the outcome of this consultation is the belief that researchers have the responsibility to ensure participants are fully informed about the benefits and risks of such decisions. To ensure this occurs mana whenua are represented at all levels of the Auckland Regional Tissue Bank governance structure.

What if I change my mind?

You have the right to withdraw your consent at any time. If you wish to do so, please contact the Auckland Regional Tissue Bank in writing (contact details on right). You will be contacted to confirm the details of your request, e.g. disposal of your tissue sample(s), including with a karakia/blessing. You will receive written confirmation when your request has been actioned. Please note, only samples and accompanying clinical information that have not already been released to approved research can be withdrawn. The time to withdraw your consent may be short so please consider carefully before signing this form.

How will my samples be disposed of?

Samples will only be disposed of at your request or after return to the tissue bank from a researcher when small amounts of tissue remain that cannot be passed onto another study. All samples will be disposed of by cremation with an appropriate ceremony and burial at the University of Auckland plot.

Compensation – what if I suffer and injury during the procedure?

Procedures undertaken to collect samples for the Auckland Regional Tissue Bank will be part of standard care. No additional procedures will be undertaken. Therefore there will be no compensation from the Auckland Regional Tissue Bank if an injury occurs during one of these procedures. Your coverage by ACC or the health system will not be affected by donating your tissue.

What will my tissue be used for?

Please also view our webpage for more information on the type of research that your tissues may be used for:

www.tissuebank.ac.nz

Who may I contact if I have more questions?

The Auckland Regional Tissue Bank Manager
The University of Auckland
Faculty of Medical and Health Sciences
85 Park Road, Grafton
Auckland 1023
New Zealand

Phone: (+64) 9 923 7097

email: tissuebank@auckland.ac.nz

website: www.tissuebank.ac.nz

If you have any queries or concerns about your rights as a Tissue Bank donor, you can contact an independent Health and Disability Advocate. This is a free service provided under the Health and Disability Commissioner Act.

Phone: (NZ wide) 0800 555 050

Free Fax: (NZ wide) 0800 2787 7678
(0800 2 SUPPORT)

E-mail: (NZ wide) advocacy@hdc.org.nz

If you are unsure of your legal rights you should seek legal advice. This can be free from your community law centre, citizen's advice bureau or your lawyer which would include a fee.

Consent Form



Tick one of the boxes below

- This is the first time consent has been given.** (Please read the information below and attached and sign & date)
- Consent has been given previously and I agree to consent again.** (Please sign & date over the page)
- I do not consent for my tissue to be stored in the Auckland Regional Tissue Bank.** Please sign here if you approve:
We would like to record your decline in our database.

- By signing this form below I understand my tissue(s) and accompanying clinical information being accessed and stored in the Auckland Regional Tissue Bank for later use in ethically approved research.
- I have read the Participant Information Sheet V2, dated October 2016 about the Auckland Regional Tissue Bank.
- Where relevant, I approve the storage of one or more of the following at the Auckland Regional Tissue Bank to be stored at either; The University of Auckland – Faculty of Medical and Health Sciences, Auckland City Hospital, Middlemore Hospital or the North Shore Hospital.
 - up to 40 mL of venous blood
 - 4 mL of bone marrow biopsy
 - excess tissue from the surgical procedure that is not needed for my medical tests
 - another type of sample such as fingernail clippings
- I understand my tissue will be linked to my clinical information and for the tissue bank to access these and that this approval is entirely my choice
- I understand that the genetic material inside my cells may be studied in research
- I have had enough time to consider whether to donate my tissue and to discuss this with my whānau/family and friends.
- Any questions I had about the tissue donation process have been answered.
- I am aware that my tissue and clinical information can be withdrawn from the Auckland Regional Tissue Bank at any time on my request if not already removed for an approved research project. I understand that my samples may be used very quickly after donation and therefore the time to withdraw may be limited.
- I understand that if I choose not to donate my tissue to the Auckland Regional Tissue Bank, or later request for its removal that my medical care will not be affected.

Please turn over to sign the next page.

Consent Form



(PLACE PATIENT STICKER HERE)

Please tick the boxes below if you **do not** approve any of the following:

I **do not** consent for my tissue to be sent or used out of New Zealand

I **do not** consent for my tissue to be used in 'Living Cell' research

I **do not** consent to receive 'Incidental findings' from research using my tissues

Ethnicity: (as asked in the 2013 census)

Which ethnic group do you belong to?
(Mark the space or spaces that apply to you)

- | | |
|--|----------------------------------|
| <input type="checkbox"/> New Zealand European | <input type="checkbox"/> Tongan |
| <input type="checkbox"/> Māori | <input type="checkbox"/> Samoan |
| <input type="checkbox"/> Niuean | <input type="checkbox"/> Chinese |
| <input type="checkbox"/> Cook Island Māori | <input type="checkbox"/> Indian |
| <input type="checkbox"/> Other (such as Dutch, Japanese, Tokelauan). | |

Please State:

Patient Name: _____

Signature: _____ Date: _____

Co-signature: _____

Consent information given by (name):

Role: _____

Signature: _____ Date: _____