

## Biobanking Frequently Asked Questions



These FAQs are designed to provide additional information for biobanking participants. They should be read together with the TR-ANZGOG Biobanking Participant Information Sheet.

| Question                           | Answer/Notes  |
|------------------------------------|---|
| Taking part                        |   |
| Why am I being asked to take part? | <p>Research is an important part of our healthcare system. Across Australia, our researchers contribute to discoveries that help us lead longer, healthier lives.</p> <p>You are being asked to participate in health and medical research by:</p> <ul style="list-style-type: none"><li>• donating a sample to the TR-ANZGOG Biobank, and</li><li>• giving permission for TR-ANZGOG to link your health and personal information to the sample.</li></ul> <p>You can read more about the type of health and personal information linked to your sample in the Participant Information Sheet and in the FAQ section on <b>health and personal information and health data</b>.</p> <p>Your participation provides researchers with a valuable resource that helps them to understand and improve the way disease is detected, diagnosed and treated.</p> <p>If you choose to take part, you are encouraged to tell your family about your decision to support research in this way.</p> |
| What is a biobank?                 | <p>A biobank is a collection of human biological samples or 'biospecimens' (e.g. tissue removed during an operation, blood or bone) and/or their products (e.g. DNA). Like a bank, samples donated for health and medical research are kept under tight security and in carefully controlled conditions.</p> <p>Health data is also linked to your sample. Samples are stored securely, together with samples from many other people, for use in ethically approved health and medical research projects, now and into the future.</p> <p>Storing samples together allows researchers from across Australia to work together to find new or better treatments for illness and disease.</p>  |
| What is TR-ANZGOG                  | <p>TR-ANZGOG is an ANZGOG research initiative that will support the collection of samples from women recruited to ANZGOG trials. The main aim of TR-ANZGOG is to maximise the information gained from clinical trials by making the samples available for future research. TR-ANZGOG will ensure that research using these samples is scientifically valid, ethically approved and will prioritise research with the potential to lead to improved outcomes for women with gynaecological cancer. The types of research that TR-ANZGOG will support will include identifying factors to decide on the best treatment for individual patients; identifying ways to improve response to treatment; and understanding the underlying causes of gynaecological cancer.</p>  |

| Question                                      | Answer/Notes  |
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| What is the TR-ANZGOG Network of Laboratories | The TR-ANZGOG Biobank is comprised of a network of laboratories and biobanks across Australia. Laboratories in this network have been approved by ANZGOG as facilities that can assist with the processing, storage and distribution of samples for research. One of these facilities is the NSW Health Statewide Biobank.  |
| What is the NSW Health Statewide Biobank?     | <p>The NSW Health Statewide Biobank is a secure NSW Government facility. It's the largest facility of its kind in the Southern Hemisphere and uses robotic technology to store and process millions of biospecimens to support health and medical research.</p> <p>The Biobank provides approved researchers with access to a range of human samples (such as blood or tissue) and linked health data to help them better understand, detect and treat illness.</p> <p>You can find more information at <a href="https://biobank.health.nsw.gov.au">biobank.health.nsw.gov.au</a></p>   |
| What are the benefits of participating?       | It is not likely participants will benefit directly. Your choice to donate a sample and allow access to your health and personal information will support research that could result in discoveries that could change, improve and save the lives of others in the future.  |
| Are there any risks?                          | <p>Health information is regarded as one of the most sensitive types of personal information. For this reason, there are laws, policies and procedures in place to protect the safety and security of your sample and your health and personal information.</p> <p>While we take the greatest possible care to protect you, there are some risks associated with participating in health and medical research. This could include:</p> <ul style="list-style-type: none"> <li>• There is a rare risk that a serious incidental finding could be made. This happens when a researcher discovers something potentially serious about your health that they weren't looking for. If a finding is confirmed after further tests, there is a chance your future income protection and private health insurance policies could be affected. It might also have health implications for you or your genetic relatives. Read more about this in the FAQ section on <b>serious findings</b>.</li> <li>• There is a rare risk of breach of privacy. If this were to happen, it would be dealt with in line with strict State and Commonwealth Government privacy laws and guidelines. Read more about this in the FAQ section on <b>protecting your privacy</b>.</li> </ul> |

Donating a sample

| Question   | Answer/Notes   |
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| <b>How and when is my sample taken?</b>  | <p>How and when your sample is collected will depend on the type of condition and/or procedure you have. It will also depend on the type of research intended for your sample and the type of sample collected through the clinical trial you participate in.</p> <p>For example, if you have surgery to remove tissue (e.g. from a cancer), with your consent, some remaining tissue from your sample after diagnosis may be stored in the Biobank. You could also be asked to donate a separate blood sample.</p> <p>The trial site coordinator can give you more information about how and when your sample is taken.</p> |
| <b>What happens to my sample after completion of the clinical trial I am participating in?</b> | <p>Your sample will be stored in in the TR-ANZGOG Laboratory Network under strict conditions to ensure it remains safe and in the highest quality condition.</p> <p>Your sample could be held indefinitely and made available to researchers with ethically approved studies, now and into the future.</p> <p>You can choose to withdraw your consent and donation at any time. If you decide to stop taking part, your sample would be removed from the Biobank and destroyed.</p>  |
| <b>What can my samples be used for?</b>  | <p>Your sample can be used for many different types of ethically approved health and medical research. For example, it could be used to help develop better treatments for people diagnosed with gynaecological cancer</p>   |
| <b>Health and personal information and health data</b>   |  |
| <b>What is health and personal information?</b>  | <p>Health and personal information is information about you and your health. It includes information that could identify you.</p> <p>Legal definitions can be found here:<br/> <a href="https://ipc.nsw.gov.au/privacy/nsw-privacy-laws/hrp-act">ipc.nsw.gov.au/privacy/nsw-privacy-laws/hrp-act</a><br/> <a href="https://ipc.nsw.gov.au/privacy/nsw-privacy-laws/ppip-act">ipc.nsw.gov.au/privacy/nsw-privacy-laws/ppip-act</a> </p>   |
| <b>What is data linkage?</b>   | <p>‘Data linkage’ is a method of bringing together information from different sources about the same person. An example of this is linking tissue or other biological samples with health data.</p> <p>When combined across numbers of people, this linked data can provide researchers with a valuable resource that helps them to investigate and improve the way disease is detected, diagnosed and treated.</p> <p>For more information, see <a href="https://cherel.org.au/how-record-linkage-works">cherel.org.au/how-record-linkage-works</a></p>   |

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| <b>Why is data linkage important for health and medical research?</b> | <p>Data linkage helps researchers to better understand health and healthcare over the life course.</p> <p>Linked data can help us to understand how lifestyle, medications, treatments, genes or other factors might affect future health in the population. It can also help to improve the delivery of healthcare, develop future treatments and even cures.</p>  |
| <b>What type of health data will be linked to my sample?</b>          | <p>The type and source of health data linked to your sample is detailed in the Participant Information Sheet.</p> <p>This might include:</p> <ul style="list-style-type: none"> <li>• your diagnosis, for example operation and test results</li> <li>• the times you go to the emergency department or had to stay in hospital</li> <li>• the times you go to the family doctor (based on Medicare Benefits Schedule claims)</li> <li>• the prescription medicines you get from a pharmacy (based on Pharmaceutical Benefits Scheme claims)</li> <li>• other information that affects health, such as your education, employment and lifestyle, and</li> <li>• research that is done on your sample.</li> </ul> <p>This will <b>not</b> include:</p> <ul style="list-style-type: none"> <li>• information from the Police</li> <li>• information from the Australian Taxation Office, or</li> <li>• information from Centrelink.</li> </ul> <p>When health data is given to researchers it will not include your name and address.</p> |
| <b>How long will my health and personal information be held for?</b>  | <p>ANZGOG could hold health and personal information forever. It is kept under strict security and privacy conditions in line with the law.</p> <p>You can choose to stop taking part at any time.</p>  |
| <b>Researcher access to samples and health data</b>                   |   |
| <b>Who can access/ use my sample and health data?</b>                 | <p>Before they can apply to use your sample, researchers must have their project reviewed and approved by a Human Research Ethics Committee. It must also be supported by the research institution or organisation where they work for.</p> <p>Only legitimate and approved health and medical researchers can apply for access to your sample and health data.</p> <p>Applications for use of your sample will be reviewed by the TR-ANZGOG Trial Support and Sample Access Committee and approved by the ANZGOG Research Advisory Committee, with notification to the ANZGOG Board of Directors.</p>  |

| Question  | Answer/Notes   |
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| <b>How will I know that the researchers accessing my samples and data are legitimate?</b> | <p>Before they can access samples and linked health data, researchers must apply to the Biobank. They must provide detailed information about their research project and credentials.</p> <p>Research projects must also be approved by a Human Research Ethics Committee.</p>   |
| <b>How long can a researcher hold my sample health data?</b>                              | <p>Researchers can hold your sample and health data in accordance with the Human Research Ethics Committee approval for their research project.</p> <p>This can vary between research projects.</p>  |
| <b>Could I be identified from my health data?</b>   | <p>After your information is linked, researchers are provided with your health data. Your name and address has been removed and replaced with a unique number. This helps to protect your privacy.</p> <p>In rare cases, researchers might be able to identify you from your health data. If this happens, researchers are required by law to maintain your privacy.</p>   |
| <b>Could my sample and health data be sent interstate or overseas?</b>                    | <p>It is common in health and medical research for interstate and international researchers to work together. Your sample and health data may be sent interstate or overseas for collaborative research purposes. It will not include your name or address.</p> <p>Collaboration helps to speed up the time it takes to translate research lab discoveries into better patient care.</p> <p>Your sample and data will only ever be shared with researchers after a Human Research Ethics Committee (or an equivalent committee that meets internationally accepted ethical standards) has approved the research.</p> |
| <b>Protecting your privacy</b>  |  |
| <b>Where is my data stored?</b>   | <p>Your data will be held securely by ANZGOG or by an approved institution, for example a medical research institute or university.</p> <p>All data will need to be held securely according to the ethics approval, privacy laws and the legal contract with ANZGOG.</p>   |

| Question   | Answer/Notes  |
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| <p><b>How is my privacy protected?</b></p>                                     | <p>Your information is protected under local and Commonwealth laws, including the NSW Privacy and Personal Information Protection Act (1998) (<a href="http://ipc.nsw.gov.au/privacy/nsw-privacy-laws/ppip-act">ipc.nsw.gov.au/privacy/nsw-privacy-laws/ppip-act</a>) and the Health Records Information Privacy Act (2002) (<a href="http://ipc.nsw.gov.au/privacy/nsw-privacy-laws/hrip-act">ipc.nsw.gov.au/privacy/nsw-privacy-laws/hrip-act</a>) or international equivalent. TR-ANZGOG, and Australian and international researchers accessing the Biobank must adhere to these laws, their ethics approval and policy.</p>  |
| <p>Research projects</p>   |   |
| <p><b>Will I be told what research projects my sample is used for?</b></p>     | <p>You will not always know what research projects your sample is being used for. This is because your sample is safely stored in the TR-ANZGOG Biobank and shared with approved researchers without your identifying details, such as your name and address.</p> <p>A list of research projects that store and access samples in the TR-ANZGOG Biobank and publications from this research are available at <a href="https://www.anzgog.org.au/research/tr-anzgog/">https://www.anzgog.org.au/research/tr-anzgog/</a></p> <p>You can also find some examples of the types of research projects your samples may be used for in the Participant Information Sheet.</p>  |
| <p><b>Do I get a say in what research projects my samples are used in?</b></p> | <p>No. By making a decision to donate your sample, you are consenting for your samples to be used for ethically approved health and medical research.</p> <p>It could be used to help a number of researchers who are searching for new and better treatments, now and into the future.</p>   |
| <p>Serious findings</p>  |   |
| <p><b>What are serious findings?</b></p>                                       | <p>In this document, serious findings are also known as ‘incidental findings’. These findings happen when a researcher discovers something potentially serious about your health that they weren’t specifically looking for.</p> <p>Very rarely when tests are done on donated samples, a potentially serious and important piece of information can be discovered. For example, a change in your DNA could indicate a higher risk of a heart problem. This DNA might be something you share with your genetic relatives, such as your parents, siblings or children.</p> <p>In the consent form, we ask you to agree to be contacted, by a doctor or healthcare professional, about a potentially serious finding.</p> <p>You would only be contacted about potentially serious findings if they meet each of the following criteria</p> <ul style="list-style-type: none"> <li>• Significant: The finding indicates a potentially life-threatening health condition or affects your reproductive health.</li> </ul> |

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|   | <ul style="list-style-type: none"> <li>• Actionable: There are specific established treatments or other available actions that might help you.</li> <li>• Confirmed: The finding has been checked as accurate and/or valid, as far as reasonably possible within a research context and to current best knowledge.</li> </ul> <p>General health information, such as evidence of increased risk of high cholesterol or diabetes, will not be returned. It is important to continue your regular health check-ups with your family doctor.</p> <p>For more information on how we deal with potentially serious findings, visit <a href="https://www.anzgog.org.au/research/tr-anzgog/">https://www.anzgog.org.au/research/tr-anzgog/</a></p> |
| <p><b>How and when will I be told about serious findings?</b></p>                                     | <p>In the rare event that a potential serious finding is discovered, the matter would be referred to clinical experts.</p> <p>If the clinical experts determine that the potential serious finding is significant, actionable and confirmed, they would inform your doctor or healthcare professional.</p> <p>The nominated clinician would contact you to tell you that a potential serious finding might exist and you may be referred to a medical expert or genetic counsellor.</p>   |
| <p><b>Why am I being contacted about a serious finding?</b></p>                                       | <p>You are being told about a potential serious finding, as this knowledge could give you early access to information that helps you understand or protect your health and wellbeing, or the health and wellbeing of your family.</p>   |
| <p><b>Could taking part impact my ability to take out health or life insurance in the future?</b></p> | <p>In rare cases, taking part in health and medical research might affect health or life insurance cover for you and your blood relatives. For example, if you have a serious and life-threatening genetic condition that you share with your family, it could affect insurance you apply for in the future (for example life insurance or income protection). A fact sheet is available at <a href="https://www.fsc.org.au/resources/1785-moratorium-key-facts">fsc.org.au/resources/1785-moratorium-key-facts</a></p> <p>You are encouraged to seek specific advice from your doctor and/or your insurer.</p>   |
| <p><b>What if I don't want to be told about a serious finding?</b></p>                                | <p>If you are contacted about a potential serious finding, but you do not wish to be told details, see a medical expert or take further testing, you do not have to.</p> <p>Even if you don't agree to be told details about your serious finding, in rare cases your doctor may contact your family members if there is a serious and imminent threat to their health.</p>   |
| <p>Payment</p>  |   |
| <p><b>Will I be paid for my samples and health and personal information?</b></p>                      | <p>No. Your decision to take part in health and medical research is voluntary and you will not receive any payment for your donation.</p>   |
| <p>Withdrawal of consent or change of details</p>   |   |

| Question  | Answer/Notes   |
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| <p><b>I've changed my mind. How do I withdraw my consent?</b></p>                                       | <p>Contact your trial site coordinator who will ask you to complete the Withdrawal of TR-ANZGOG Biobanking Consent Form. Alternatively, you can contact the TR-ANZGOG Project Manager (phone. 61 2 +61 2 8004 3401 or email <a href="mailto:tr-anzgog@anzgog.org.au">tr-anzgog@anzgog.org.au</a>).</p> <p>If you choose to stop taking part in the TR-ANZGOG biobanking component of the clinical trial, the samples you donated that remain after the clinical trial is completed will be removed from TR-ANZGOG Biobank and destroyed. Your health and personal information, held in the Biobank, will be deleted. Your sample might have already been given to a researcher and used for a study. They will be asked to destroy this sample if it has not already been used up. If you choose to stop taking part in the ANZGOG clinical trial, please contact your trial site coordinator.</p> |
| <p><b>How do I change my personal or contact details?</b></p>   | <p>Contact your trial site coordinator.</p>  |
| <p>More information</p>   |  |
| <p><b>Can I access the Participant Information Sheet, Consent Form and FAQs in other languages?</b></p> | <p>Not yet, but TR-ANZGOG, in conjunction with the NSW Health Statewide Biobank, will work to make these available in other languages.</p>   |
| <p><b>Where can I find more information?</b></p>  | <p>If you would like more information about TR-ANZGOG, the NSW Health Statewide Biobank or your participation.</p> <p><b>Phone:</b> 02 8004 3401 (TR-ANZGOG) or 02 4920 4140 (NSW Health Statewide Biobank)<br/> <b>Email:</b> <a href="mailto:tr-anzgog@anzgog.org.au">tr-anzgog@anzgog.org.au</a> or <a href="mailto:NSWPATH-Biobanking@health.nsw.gov.au">NSWPATH-Biobanking@health.nsw.gov.au</a></p> <p>Please keep a copy of your Participant Information Sheet with the copy of your signed Consent Form.</p>   |