TR-ANZGOG Biobanking - Participant Information Sheet

What is TR-ANZGOG?

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.

1 This is important information to help you decide whether to donate a sample for health and medical research.

You have been given this information because you are being asked to:

- donate a sample to the TR-ANZGOG Biobank
- give permission for TR-ANZGOG to collect and link your health and personal information (data) to the sample now and into the future.

You can find more information in our Frequently Asked Questions at https://www.anzgog.org.au/research/tr-anzgog/ or through a participating biobank of the TR-ANZGOG Network of Laboratories, the NSW Health Statewide Biobank at **biobank.health.nsw.gov.au/participants**

2 You have been asked to donate a sample to support health and medical research.

Researchers use human samples to learn about illness and find better ways to help people with health problems.

Your donation will support research that may result in discoveries that can change, improve and save the lives of others in the future.

3 If you choose to donate a sample, it will be used in research studies.

A sample could be any of the below items:

- Blood
- Saliva
- Urine
- Stool/Poo
- Tissue taken from your body by a healthcare professional as part of your treatment (tumour or other cells from your body).

Your sample will be stored safely in the TR-ANZGOG Biobank which is comprised of a network of laboratories across Australia, such as the NSW Health Statewide Biobank.

4 A biobank is a secure place for storing human samples.

Samples stored in the TR-ANZGOG Biobank are used for ethically approved health and medical research. They help researchers find better ways to detect and treat illness and disease.

Like a bank, samples donated for health and medical research are kept under tight security and in carefully controlled conditions.

5 It is your choice to donate or not.

The ANZGOG clinical trial you are participating in may have samples that are required. Choosing to donate a sample that remains after the trial is completed, or donating a sample that is collected specifically for future health and medical research, is voluntary. If you do not choose to donate your sample for future health and medical research, your sample will be managed by the trial Principal Investigator as detailed in the Trial Participant Information Sheet. You should talk to your doctor, family or friends before you decide.

6 Your decision will not affect your care or treatment in any way.

If you decide not to donate a sample for TR-ANZGOG Biobanking, your participation in the ANZGOG clinical trial will not be affected.

7 You can choose to stop taking part in the biobanking component of the ANZGOG clinical trial at any time without any affect to your trial participation.

If you choose to donate a sample, but change your mind later, that is ok. The decision will not affect your medical treatment or healthcare in any way.

If you choose to stop taking part, the samples you donated that remain after the ANZGOG clinical trial is completed would be removed from the biobank and safely destroyed. Your health information, held in the biobank, will be deleted.

Some or all of your sample might have already been given to a researcher and used for a study. They will be asked to destroy any remaining sample.

If you choose to stop taking part, contact your ANZGOG trial site coordinator (details available on the TR-ANZGOG Biobanking Participant Consent Form) or the TR-ANZGOG Project Manager

Phone: 02 8004 3401
Email: tr-anzgog@anzgog.org.au

8 Ask as many questions as you like.

You can talk to:

- your doctor
- your nurse
- other people in your healthcare team, or
- the person who gave you this information sheet and is asking for your consent.

You can also contact the TR-ANZGOG Project Manager. They are in charge of safely storing samples and health and personal information (data) to support health and medical research.

9 Your sample will be linked with your health and personal information (data).

If you choose to donate a sample for health and medical research, it will be linked to health and personal information (data) collected through the ANZGOG trial and held by the local State and Commonwealth governments and by researchers.

This brings together lots of information about you and might include details about:

- your diagnosis, for example operation and test results
- the times you go to the emergency department or had to stay in hospital
- the times you go to the family doctor (based on Medicare Benefits Schedule claims)
- the prescription medicines you get from a pharmacy (based on Pharmaceutical Benefits Scheme claims)
- your personal information, such as your education, employment and lifestyle
- research that is done on your sample.

This information helps researchers better understand your health and might help develop future treatments and even cures for diseases.

With your permission, this information from the local State and Commonwealth governments and researchers will be electronically linked to your sample. Information will be stored securely without your name and contact details and used only for approved health and medical research.

10 Your name and address is removed from your sample.

Personal information, such as your name and address, is replaced with a unique number before we share it with approved researchers.

In rare cases, researchers might identify you from your information. If this happens, researchers are required by law to maintain your privacy and report any breaches to the relevant ethics committee/ privacy officers.

If needed, appropriate TR-ANZGOG staff can re-identify the sample through the trial site coordinators.

11 Your health and personal information (data) will be stored securely.

Your information is stored using strict security and privacy protocols and in line with legal and ethical requirements.

It may be stored for an unlimited period of time, but is only released to researchers for ethically approved health and medical research.

12 Your sample and health and personal information (data) might be used for a range of different health or medical research studies, now and in the future.

This could include:

- research into the cause, prevention, diagnosis and treatment of disease
- finding a cure or new treatment for a condition such as cancer, or an unrelated condition such as diabetes or dementia

- research into genetic or rare conditions
- clinical trials (an organised test of medicines and new treatments involving patients and volunteers)
- the study of human populations, or
- monitoring new treatments or medicines over time.

Cells from your sample may be grown in different laboratory models for future research.
Your sample and information can only be used in projects that have been reviewed and approved by a registered Human Research Ethics Committee. This committee checks that projects are ethically acceptable. This means that the research respects and protects you and the other people who have donated samples.

The ANZGOG Board of Directors will approve the use of samples following an application process by researchers.

13 Specimens and data can be used by approved research studies in Australia and around the world.

It is common for health and medical researchers to work together with researchers in other states or even overseas. This can help speed up the time it takes to get findings from research labs into clinics to help patients.

All research studies must be approved by a Human Research Ethics Committee (HREC) that meets international ethical standards. The expertise and experience of all researchers will be assessed as part of the HREC review process.

14 You won't be told what research studies your sample is used for.

We won't tell you when or where researchers use your sample for a research study.

All research projects that use donated samples and health and personal information (data) will be listed on the ANZGOG website www.anzgog.org.au

15 You won't be paid for your donation.

Your choice to contribute a sample and provide your health and personal information (data) is a donation.

16 Your sample could be held forever.

Or until you choose to stop taking part.

17 Your privacy will be secure and protected.

Your health and personal information (data) will be kept secure and confidential. If a breach of privacy happens, it will be dealt with in line with privacy laws and guidelines.

In very rare cases, we may have a legal obligation to make your information available to parties outside of TR-ANZGOG who are not approved researchers. For example, in the case of a new infectious disease that could affect other people both you and other parties would be informed.

18 During research, discoveries could be made that have serious and important health consequences for you or your family.

When testing your sample, researchers may find that you or your family members might be at risk of a serious health condition. For example, a gene for sudden heart attack, a type of cancer or other life-threatening condition that can be treated.

It is very rare for a serious finding to be discovered. If this happens, your nominated doctor or healthcare professional will contact you to tell you that a potential serious finding might exist and you will be referred to a medical expert or genetic counsellor. They will only contact you, or a nominated family member if you agree, if the finding is significant, confirmed and can be treated. If you are contacted about a potential serous finding, but you do not wish to be told details, see a medical expert or take further testing, you do not have to. General or non-specific health information such as evidence of a risk of high cholesterol, would not be returned to you. Please be aware that test results may affect the ability to obtain some types of insurance.

If you are not contacted about a finding, it does not mean you don't have any health issues. Researchers do not perform general testing on your sample. It is important to continue your regular health check-ups with your family doctor and other health professionals.

19 There are times we will need to contact you.

Your doctor or healthcare professional will contact you if a serious finding is discovered that has health implications for you or your family.

20 You are being asked to give your consent to:

a. Donate samples to the TR-ANZGOG biobank for ethically approved health and medical research.

b. Have your sample linked to health and personal information (data) held by the trial investigators, local State and Commonwealth governments and by researchers.

c. Have your sample and health and personal information (data) stored securely and used for ethically approved health and medical research now and into the future.

CONTACT

If you have questions, concerns or feedback, or if you would like more information, please contact either:

- The Human Research Ethics Committee that approved the study (listed on your Participant Information Sheet Cover Page)
- TR-ANZGOG Project Manager: phone +61 2 8004 3401 or email tr-anzgog@anzgog.org.au
- ANZGOG Program Manager, Clinical Trials: phone +61 2 8071 4881 or email trials@anzgog.org.au

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