

Clinical Trial Participant Information Sheet: TR-ANZGOG reference text

The following paragraphs are examples to be incorporated into ANZGOG clinical trial PIS; 'What will happen to my test samples?' section

If you agree, following completion of this trial, material may be utilised for future research through the ANZGOG governance mechanism, TR-ANZGOG (Translational ANZGOG). You will be provided with a separate TR-ANZGOG Biobanking Participant Information Sheet and Frequently Asked Questions resource and dedicated TR-ANZGOG Biobanking Participant Consent Form.

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.

Who is responsible for my samples?

The Principal Investigator for the ANZGOG clinical trial through which your samples have been collected and ANZGOG will be the custodians of your samples. ANZGOG will be ultimately responsible for storing the samples, and the release of samples to researchers via TR-ANZGOG processes. (the details in this response may vary between clinical trials)

What will happen to my samples?

(Trial specific information will need to be included as to what is being collected and for what purpose.) The samples collected from you will be stored at ______ or a TR-ANZGOG-designated laboratory/s for the duration of the clinical trial.

If you consent to the biobanking aspect of TR-ANZGOG, once the clinical trial and clinical trial-related research is complete, any remaining trial samples, and samples that may be collected for TR-ANZGOG, will be stored for an indefinite period of time, under the management of TR-ANZGOG. If you have also consented to the Australian Ovarian Cancer Study (AOCS), samples that are in excess of the requirements of this study may be stored with the AOCS bio-bank.

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. These committees 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.

If you do not consent to your	samples being made available for future unspecif	ied research, any
remaining samples will be	(specific to what the trial would ora	inarily perform).

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