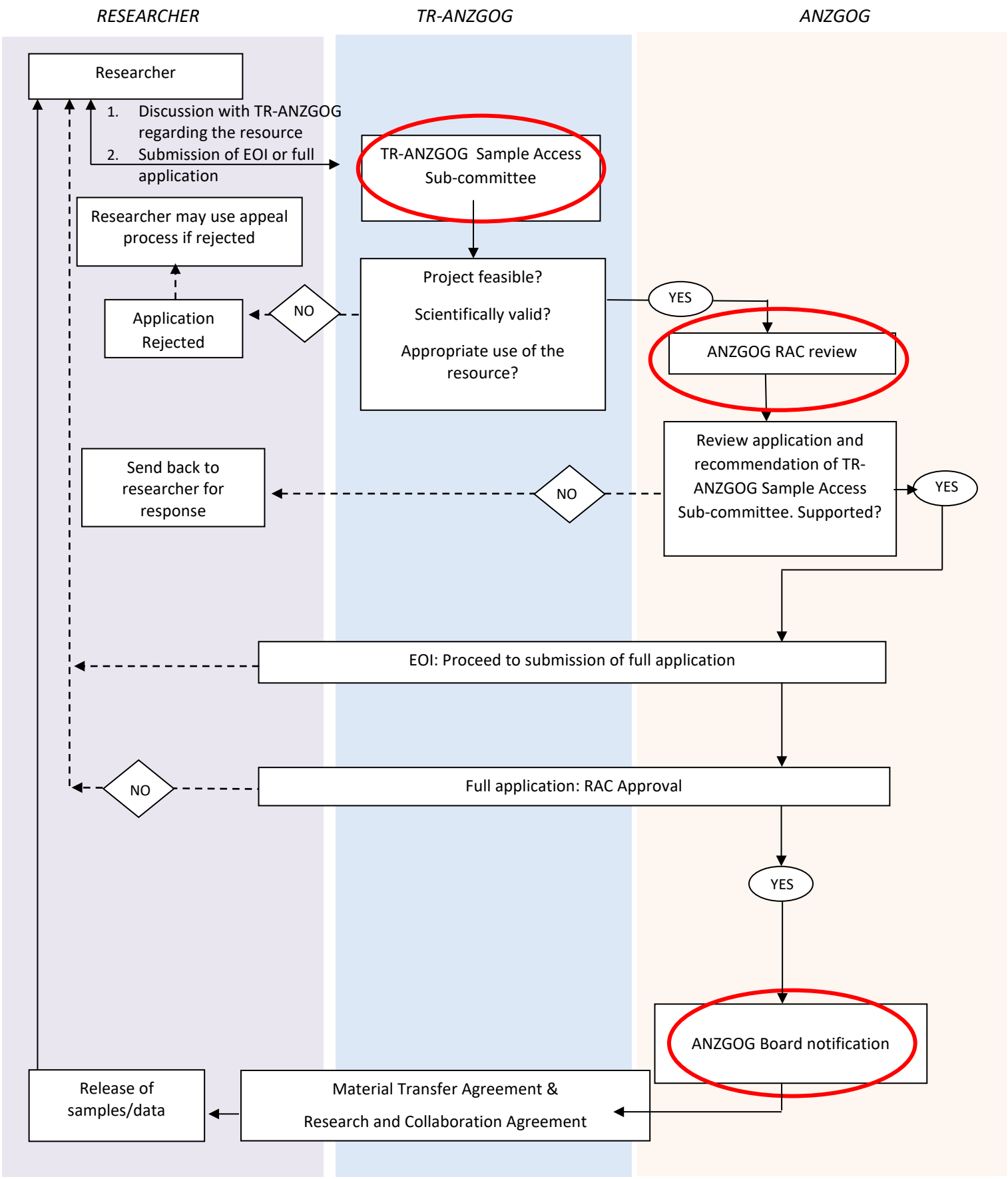
Policy on Biospecimen Access and Release
TR-ANZGOG

Contents

Access to Biological Samples and Data Flowchart



Policies and Procedures for Access to Biological Samples and Data

The TR-ANZGOG Initiative

The TR-ANZGOG Biospecimen Resource is a part of the TR-ANZGOG (Translational-ANZGOG) translational research initiative. Biological samples and data collected through this initiative are stored with patient consent for future research and provide a valuable resource for local, national and international gynaecological cancer studies. Biological samples collected for a specific clinical trial will be stored in a facility associated with the clinical trial through which the samples are collected, or an alternate, designated TR-ANZGOG facility, under the governance of the clinical trial's Principal Investigator/s (PI), ANZGOG and the trial Sponsor until the clinical trial is complete. Following this, with approvals from all parties, biological samples may be transferred to a centralised TR-ANZGOG facility for long-term management. Contractual arrangements regarding custodianship will be executed prior to trial commencement. This may entail joint custodianship between the clinical trial PI/s and ANZGOG of the biological samples and responsibility for their use in accordance with the study protocol and all other legal, regulatory and policy requirements.

Biological Samples and Data Available to Researchers

A range of biological specimens are collected and stored from participants consenting to involvement in ANZGOG clinical trials. Participants consent to their samples being used for future research under the auspices of TR-ANZGOG. All research using these samples must be approved by a Human Research Ethics Committee (HREC).

Biological samples routinely collected include FFPE tumour tissue and blood. The following samples may be available to researchers upon application:

- *Tissue sections, stained slides, DNA, RNA*
    - Available from FFPE and in some circumstances, frozen tumour tissue
- *Cell block sections, stained slides, DNA, RNA*
    - Available from frozen crude and purified ascites, FFPE ascites cell blocks
- *Whole blood, serum, plasma, buffy coat, cell-free plasma, viable white blood cells, germline DNA*
    - Available from blood

Data

Detailed longitudinal clinical and treatment data is also collected on TR-ANZGOG participants in accordance with the relevant ANZGOG clinical trial protocol. Molecular data is added to the resource as it is generated by ANZGOG-supported projects. Investigators using TR-ANZGOG material agree to return new information found by the project back to TR-ANZGOG so that molecular and biological information can be built up on the cases and samples over time.

Applying to Use TR-ANZGOG Biological Samples and Data

TR-ANZGOG specimens will become open access upon completion of the clinical trial and translational sub-study associated with their collection. Any investigator (not dependent on ANZGOG membership) working in gynaecological cancer research can apply to use the samples and data stored within the TR-ANZGOG Biospecimen Resource. All applications will undergo a formal review and approval process to ensure that all supported projects are scientifically and ethically sound, have HREC approval, are adequately funded and demonstrate efficient use of the finite resource.

Every effort should be made to extract the maximum amount of information from each specimen, and to avoid duplication of effort. For this reason the TR-ANZGOG Sample Access Sub-committee will review applications to ensure that duplication is avoided and to encourage and facilitate cooperation and collaboration between potential competitors wherever possible.

The unique combination of biological samples matched to specific clinical trial outcomes available through TR-ANZGOG makes this resource particularly valuable. For this reason, in the event that collaboration cannot be achieved, the ANZGOG Research Advisory Committee will decide the resolution which may involve identification of non-overlapping sample sets. Projects that require access to biological specimens only, not linked to trial outcomes, are less likely to be approved.

Applications can be submitted to the TR-ANZGOG Program Manager at any time. Investigators should submit their applications with enough time to allow project review, execution of required agreements and preparation of the required materials for dispatch.

An overview of the application process is provided in the flowchart on page 3. Full details concerning the application and review process are provided below.

Pilot Projects

Investigators may request approval to conduct a pilot project with the intent of establishing the rationale, feasibility or power of a full application.

A pilot project involves limited numbers of specimens, in general:

- < 20 DNA or RNA samples
- Slides from < 20 FFPE tissue blocks

However, the sample size will need to be sufficient to achieve the stated aims.

Investigators applying for a pilot project should complete the full Application Form and submit a short project proposal of less than two pages in length.

Procedures for Access to Biological Samples and Data for Full and Pilot Projects

- Before making an application, researchers should contact the TR-ANZGOG Program Manager (see contact details on page 9) to discuss the rationale, feasibility and the appropriateness of the resource for the proposed study.
- If deemed appropriate by the TR-ANZGOG Program Manager, the applicant will be sent the Access Policy and Application Forms, and can submit an initial Expression of Interest (EOI), or a Full Application Form, attaching all relevant supporting documents, for circulation to the TR-ANZGOG Sample Access Sub-committee. Applications will be assessed on the scope of request and scientific validity of the use of the resources.
- Applications, and the TR-ANZGOG Sample Access Sub-committee assessment reports, will be reviewed by at least two members of the ANZGOG RAC prior to ANZGOG RAC review at their next meeting or out of session by email or teleconference. Applications will be assessed on the basis of standard criteria including the novelty, significance, scientific rationale and feasibility of the project and the track record of the investigators. In addition, the appropriateness of accessing the TR-ANZGOG resource for the proposed research will be evaluated. The reviewers may suggest mechanisms and timescales for the delivery of the requested samples and/or data as well as the costs involved. They may assist with development of the study protocol and try to facilitate communication and collaboration between groups working on similar topics. The applicant may be asked to respond to the reviewers comments in writing. The Program Manager may contribute to the review process by commenting on the practicalities of the request.
- RAC reviewer recommendations will be made to the whole RAC for ratification of the decision. Members of the Committee with a conflict of interest will not participate in the review or decision-making process. Conditions on, or restrictions to, use of material or data may be made. In the event that an application is rejected, an independent appeal process will be implemented based on guidelines developed by the tissue bank network, ABN:Oncology.
- Researchers will be advised of the decision of the RAC and advised to seek HREC approval of the RAC-approved protocol, if not already approved. Upon evidence of HREC approval, the completed application will be submitted to the ANZGOG Board of Directors for notification as a TR-ANZGOG supported project.
- Upon ANZGOG RAC approval, the TR-ANZGOG Program Manager will liaise with the researcher to complete a Material Transfer Agreement (MTA). Transfer of materials is subject to terms and conditions of the MTA with ANZGOG. Any significant deviations from the agreed project must be sent by the applicants in writing for approval before proceeding.
- The TR-ANZGOG Program Manager will work with the Biobank manager of the relevant, TR-ANZGOG-designated facility to provide the researcher with the samples and/or data requested as per the agreed protocol. Whilst we take every step to ensure that TR-ANZGOG Biospecimen Resource details are up-to-date we cannot guarantee that samples requested will be available as we are constrained by the amount of sample that can be collected and stored. Additional information such as clinical outcome or assistance with data interpretation will be negotiated and will usually be provided via collaboration with the appropriate clinicians and/or researchers. Provision of such data will also be subject to HREC approval.
- Annual progress reports will be required and TR-ANZGOG reserves the right to withhold the supply of further material and /or withdraw data if the rate of progress and level of reporting is unacceptable.
-

Procedures for Amending or Extending TR-ANZGOG Approved Projects

Amendments to the project can be made throughout the course of the project. Amendments need to be submitted using the Amendment Form and can be submitted when requesting additional samples and/or data for previously approved projects.

The completed Amendment Form should be submitted to the TR-ANZGOG Program Manager. It will then be circulated to the relevant ANZGOG committees for approval. If the amendment is deemed substantial, a new application may be requested.

The Amendment Form can also be used to request a different use of a TR-ANZGOG resource the researcher has already accessed.

Responsibilities of Investigators Using TR-ANZGOG Materials

Researchers are requested to provide an annual research report, including abstracts and publications arising from research utilising the TR-ANZGOG Biospecimen Resource. An annual report template will be provided by the Program Manager.

Translational researcher access to the TR-ANZGOG biospecimen and data resource will be conditional to acknowledgment of ANZGOG and the TR-ANZGOG Biospecimen Resource, as outlined in ANZGOG's Publication Policy.

As a main aim of TR-ANZGOG is to benefit research into gynaecological cancer, it is requested that, once published, data obtained on individual samples is made available, to continuously add value to the biospecimens held in the resource.

Researchers will be requested to contribute to the costs associated with the preparation and supply of biospecimens and / or data according to the Biospecimen Resource Cost Recovery Policy (see page 8).

Cost Recovery Policy

The TR-ANZGOG Biospecimen Resource has a cost recovery policy in place to recoup the labour and consumable costs involved in the preparation and supply of biospecimens and clinical data. Researchers will be requested to contribute to these costs and a quotation will be provided based on the number and type of samples / data being requested.

Indicative cost recovery pricing structure:

Description	**Indicative Cost (in Australian Dollars)**
Project Management Fee	Project charged $200 minimum. This covers 3 hours of labour for project setup, contract negotiations and project management. Charged at $70/hour thereafter.
RNA extracted from tissue	$35 per sample ≥ 500 ng – 1 μg
DNA extracted from blood (add $10 per sample for tissue to cover labour and slide costs)	$15 per sample < 500 ng $25 per sample ≥ 500ng - 1 μg $40 per sample ≥ 1 – 2 μg > 2 μg - by negotiation
H&E Slide – FFPE tissue or ascites cell block	$10 per slide
Sections – FFPE tissue or ascites cell block	$10 per section
Retrieval of diagnostic block from pathology	Variable depending on pathology laboratory
Blood components (e.g. whole blood, serum, plasma)	$15/unit (n=1-5), $12 (n=6-50), $10 (n>50)
Biospecimen Shipping	To be determined based on frequency of shipments, weight of packages and mode of transport.
Data	Project charged $200 minimum. This covers 3 hours of labour for data extraction and cleaning. Charged at $70/hour thereafter.

TR-ANZGOG Sample Access Sub-committee

The TR-ANZGOG Sample Access Sub-committee is comprised of ANZGOG members with significant expertise in translational research.

TR-ANZGOG Sample Access Sub-committee structure:

- Chair of the TR-ANZGOG Steering Committee
- Members drawn from the TR-ANZGOG Steering Committee r
- ANZGOG Tumour Type Working Groups
- Principal Investigator or representative from the originating clinical trial for the biospecimens
- Independent external representative (eg NSW Health Statewide Biobank, NHMRC CTC/USyd or other appropriate institutions)
- The ANZGOG Program Manager - TR-ANZGOG will be an ex-officio member

Peer review by individuals with specific expertise may also be co-opted from ANZGOG members, site investigators or externally, if the Committee requires additional expertise or advice for the application under review.

Contact Information

For application submissions and enquiries please contact:

Claire Davies | Program Manager TR-ANZGOG
ANZGOG – Australia New Zealand Gynaecological Oncology Group
Office: Level 6, Lifehouse, 119-143 Missenden Road, Camperdown NSW 2050
Mail: Locked Bag M45 | Missenden Road | NSW | 2050
E: tr-anzgog@anzgog.org.au W: www.anzgog.org.au
T: +61 2 8004 3401 | M: 0450 449 681