BIOSPECIMEN COLLECTION GRANT – Round 1
ANNUAL PROGRESS REPORT 1 – 31 July 2020 (July 2019 – June 2020)

Please complete this form and submit to the MOH-OHMRGrants@health.nsw.gov.au by **COB 28 August 2020.**

This report is to be completed by the recipient of the Biospecimen Collection Grants Program, and signed by the Organisation's representative.

As per the funding agreement, reports must be submitted on or before 30 July 2020 covering the period from the Activity Commencement Date.

Each progress Report document must include, but need not be limited to, the following information for that reporting period:

(i) The progress of your project against your project schedule you submitted in the executed Funding Agreement (Attachment C);

(ii) Any changes made to your project;

(iii) Any anticipated risks and delays; and

(iv) other grant applications submitted to support the collection or associated research and the success of these applications

The Progress Report(s) are to be signed by the Chief Investigator.

Project Information

Chief Investigator name	Professor Anna deFazio
Chief Investigator contact *Phone number:* *Email address:*	+61 2 8627 3740 anna.defazio@sydney.edu.au
Respondent name	Claire Davies
Respondent contact number	+61 2 8004 3401
Project name *As listed on the letter of agreement*	TR-ANZGOG
Host Organisation *As listed on the letter of agreement*	Australia New Zealand Gynaecological Oncology Group (ANZGOG)

Project Management

1. Please update the table below:

Phase	Start Date	Status of completion (not started, in progress, completed, no longer completing)	Revised Completion Date (if applicable)	Reasoning for delays (if applicable)	Expected effects the delay will have on activities (if applicable)	Actions taken to address delays (if applicable)
Biobanking						
Ethics application submitted for collection and research	Each ANZGOG clinical trial will require trial-specific HREC approval. Next trial submission was anticipated to be Q1 2020, now revised to Q4 2020.	In progress	(on-going trials)	Covid19 delayed the review and approval process of key TR-ANZGOG policies and documentation required prior to integration with clinical trials in development. However, new clinical trial concepts have only recently secured funding and protocols are currently being refined.	Delay in collection of trial specimens	NHMRC CTC have been requested to commence TR-ANZGOG integration into trials in development, in anticipation of policy approval at next steering committee meeting (Sept 2020)
Approval of Ethics Application	Next trial: Q2 2020, revised to Q2 2021	Not started	(on-going trials)			
Approval of RGO SSA	Next trial: Q2 2020 revised to Q2 2021	Not started	(on-going trials)			

Recruitment and consent of participants	Next trial: Q3 2020 revised to Q2 2021	Not started	(on-going trials)			
Collection of biospecimens	Next trial: Q3 2020 revised to Q2 2021	Not started	(on-going trials)			
Processing of biospecimens	Retrospective cohort, as per NSWHSB Grant application, Q4 2019	In progress	Q4 2020	Service Agreement drafted, requiring Schedule amendment. Majority of samples in NSW for delivery to NSWHSB. Awaiting samples from Monash and NZ sites.		
Research (if applicable)						
Sequencing requested and completed	n/a currently					
Data Linkage requested and completed	n/a currently					
Analysis	n/a currently					
Reporting and Publication	n/a currently					
Milestone for open access	Upon completion of the trial-associated TR sub-study					
Please add rows if necessary						

2. If applicable, please note any changes that have been made to the research project title, purpose, objectives or methodology or milestones.

Documentation:

Consent templates and resources have been revised based on feedback from the TR-ANZGOG Consent Working Group and subsequently aligned with the OHMR-recommended plain English Consent Toolkit resources.

Methodology

The TR-ANZGOG Biospecimen Processing Manual has been reviewed by representatives from sector biobankers. The methods have been agreed, with emendations recommended to ascites processing in the interests of costs and efficiency. Ascites will now be centrifuged and viably frozen, with separation to be performed only upon request (Ficoll and Dynal Magnetic Bead methods recommended).

Milestones:

The 'TR-ANZGOG Information and Resource Portal' was intended for launch at the ANZGOG Annual Scientific Meeting, March 2020. However, the ASM was cancelled due to Covid19. The launch will now coincide with ANZGOG's Annual General Meeting, October 2020.

3. Provide progress of your associated research (if applicable).

- TR-ANZGOG intersects clinical trials and biobanking, and there are key governance and policy issues to be considered in order to seamlessly integrate biobanking into new clinical trial design. A facilitated TR-ANZGOG Consensus Workshop was held in November 2019 with 40 attendees, representing clinical, scientific, legal, ethical and operational disciplines. Working groups were established through this workshop, in the areas of data management, consent and TR-ANZGOG laboratory network to provide expertise for refining processes and policies. A suite of required documents is nearing completion with final TR-ANZGOG Steering Committee and legal approval due in September, 2020.
- The TR-ANZGOG Laboratory Network Working Group has reviewed the Biospecimen Processing Manual, the cost recovery model and approval process for designation as a TR-ANZGOG Network Laboratory. Potential research laboratories/ biobanks will shortly be invited to apply for participation. A Collaborative Research Agreement, and trial-specific Schedule of Orders, is being prepared by ANZGOG's legal consultant.
- Laboratory Information Management Systems (LIMS) have been investigated for TR-ANZGOG suitability with quotes obtained and software trials undertaken. Procurement of a system to track biospecimens and database creation is anticipated by December 2020.
- The ANZGOG clinical trial, SOLACE2, is being utilised as a pilot study for TR-ANZGOG. Currently nearing 50% patient recruitment, management of the TR component of this trial has provided valuable learnings for TR-ANZGOG, particularly during the challenges of Covid19. SOLACE2 has a heavy translational research (TR) component. Each of the 114 patients to be recruited across the 15 trial sites in NSW, VIC, QLD, TAS and SA will have TR bloods collected at 26 time points over three years of treatment. The shipment of samples in real time to the central laboratory in Melbourne within a 24hour permissible turn-around-time (patient collection to biospecimen processing) has provided valuable cost and capacity comparisons between courier companies and tested the logistics framework of biospecimen collection from multiple trial sites.
- Vendor options for TR (Translational Research) sample kit assembly and equipment have been investigated and quotes procured.
- Retrospective TR blood samples from the internationally-led ANZGOG clinical trial, OUTBACK, are pending consolidation in NSWHSB prior to shipment to the central laboratory to complete the trial-associated TR substudy. ANZGOG is awaiting an amendment to the Schedule for this collection, with legal review of the Service Agreement requested in the interim.
- Promotion of TR-ANZGOG to internal and external stakeholders through presentations, the ANZGOG website and in hard copy formats such as flyers and Poster presentation have raised awareness, understanding and support of this initiative within the sector.
- TR-ANZGOG has commenced integration with multiple trials currently in development through NHMRC CTC, including HyNOVA, ADELE and PARAGON2, recently funded by the MRFF, with the first ethics submission anticipated in Q4 2020.

Project Outcomes

4. Provide information on how your collection has been a research asset for NSW over the last 12 months.

Invited presentations were delivered to collaborative cancer clinical trials groups, ANZUP and AGITG, to provide guidance and share learnings to assist with the development of similar translational research programs for their trial groups.

Templates and resources to support biospecimen collection and processing have been developed and will soon be available, as appropriate, via the ANZGOG website.

TR-ANZGOG has been integral for the management of TR samples for SOLACE2, with the majority of patients recruited from NSW sites.

5. Provide other grant applications submitted or approved to support the collection or associated research. Include in your answer the name of the grant, name of funding organisation, amount funded, whether the collection or the research is funded, dates funded, your role, and indicate whether the application has been submitted or approved for funding.

n/a

Project Team, Host and Partners

6. Have there been any changes to the Project Team or Partners? If so, please provide details of the changes.

n/a

7. Have there been any further collaborations since the application was submitted?

The TR-ANZGOG Consensus Workshop strengthened relationships with key stakeholders, in particular pathologists, operational centres and data managers. The formation of multiple volunteer working groups demonstrates this collaborative attitude.

In addition to ANZGOG Member research labs, relationships have been developed with the Hunter Cancer Biobank, Victoria Cancer Biobank and Western Australian Gynaecological Oncology Biobank.

Financial information

8. You should shortly recieve a financial report from the NSWHSB for the expenditure of the funds for your collection. Is the agreed project proceeding within Budget? If not, please provide an explanation and note any actions the Organisation proposes to take to address this.

No funds have been spent to date. However, three ANZGOG trials recently secured funding and are nearing ethics submission. Therefore, specimen collection is anticipated early 2021 with many more concepts in development.

Extension

9. Are you seeking an extension of time for this project? ~~**Yes or**~~ **No**

All project extensions must be approved by the Executive Director of the Office for Health and Medical Research. Please include
the reasons an extension is sought

- the length of extension sought, and
- how project funds will be managed locally throughout the proposed extension.

The extension request must be made by the Chief Investigator(s). You will be notified by return email as to whether the extension is approved and any changes to reporting timelines.

Report Sign-off

Please have this Progress Report approved by the Project's Chief Investigator(s).

Chief Investigator(s)

(Add multiple sign offs as required)

Alison Evans
CEO, ANZGOG
17 August 2020

Professor Anna DeFazio
Chief Investigator; Westmead Institute of Medical Research
28 August 2020

Associate Professor Philip Beale
Co-Investigator; ANZGOG
17 August 2020

Associate Professor Lyndal Anderson
Co-Investigator; Royal Prince Alfred Hospital
28 August 2020