**VERSION CONTROL COVERSHEET**

**Approval as TR-ANZGOG Network laboratory process**

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| **APPLIES TO SECTION:** | * All |
| **DOCUMENT NUMBER:** | * 5.1.3 |
| **PURPOSE:** | * Outlines process of designating laboratories interested in participating in TR-ANZGOG Network of Labs |
| **CREATED BY:** | * Claire Davies |
| **CREATION DATE:** | * 19 May 2020 |
| **ADVISORS CONSULTED:** | * ANZGOG FNR scoresheet, GCIG lab vendor assessment template |
| **REVIEWED BY:** | * TR-ANZGOG Lab Network Working Group, Anna De Fazio, Alison Evans (high level review) |
| **REVIEW DATE:** | * 05 Feb 2020; 26 May 2020; 23 July 2020; 21 Aug 2020 |
| **LEGAL REVIEW REQUIRED?** | * No |
| **IF SPECIALIST REVIEW STILL REQUIRED, WHOM?** | * Notify ADF of V1.5 amendments (as indicated below) * Sign off by Research Management Group required |
| **VALID PERIOD:** | * Sep 2020 – Sep 2022 |

**Version Control:**

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| --- | --- | --- | --- |
| **Version** | **Date** | **Reason for Change** | **Date Effective** |
| 1.0 | 19 May 2020 | New | Draft |
| 1.2 | 26 May 2020 | Rather than S/C member review, independent review by delegated ANZGOG pathologist/ biobanker | Draft |
| 1.3 | 27 May 2020 | Minor amendment for ‘responsibilities’ wording | 27 May 2020 |
| 1.4 | 23 June 2020 | GCIG lab vendor assessment resource provided by AE. Crosschecked and a few additions included in TR-ANZGOG survey | 23 July 2020 |
| 1.5 | 21 Aug 2020 | Removal of date of submission deadline  Removal of ‘ficoll’ processing of ascites to align with amended specimen processing manual | 21 Aug 2020 |

**Approved by**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Position** | **Signature** | **Date** |
| Anna De Fazio | Chair, TR-ANZGOG | Email record 23 July 2020 | |

**Approval process to be a designated TR-ANZGOG Network laboratory**

# Application process

## EOI

A letter inviting Expressions of Interest (EOI) will be sent to laboratories who have been identified through ANZGOG Members as potential TR-ANZGOG Network laboratories or prominent biobanks within Australia.

Ideally, there would be one or two TR-ANZOG Network laboratories in each Australian state and territory. However, a suitable laboratory/ biobank has not yet been identified for ACT, NT or TAS.

Once TR-ANZGOG is established in Australia, the infrastructure will be expanded to include NZ laboratories and biobanks.

## Application form / survey

Laboratories and biobanks interested in TR-ANZGOG Network participation will be requested to complete an application form (Appendix A) to provide detail on their available infrastructure and capacity to participate as a TR-ANZGOG Network Laboratory.

TR-ANZGOG Network Laboratories will have the opportunity to accept or decline support of an ANZGOG clinical trial on a case-by-case basis. It is anticipated that a participating laboratory will have staffing capacity to process 1-2 episodes of patient samples, comprised of 3-4 x 10 mL blood tubes per week as per the standard processing manual.

# Assessment

Application forms submitted by laboratories/ biobanks applying to participate as a TR-ANZGOG Network Laboratory will be reviewed by independent, qualified ANZGOG delegates (for example, a pathologist or biobank manager) using a standardised review form (Appendix B), taking in to consideration resources and capacity such as equipment, staffing, quality measures and proximity to clinical trial sites. Recommendations will be provided to the Research Management Group for confirmation prior to notification to the TR-ANZGOG Steering Committee and ratification by the ANZGOG Board.

# Collaborative research agreement

A collaborative research agreement (CRA) will be implemented between ANZGOG and the participating TR-ANZGOG Network Laboratory’s institute. This CRA will include the following aspects:

* Responsibilities
  + Establishing an internal process for accepting/ declining trial support
  + Implementing SOPs for processing biospecimens
  + Implementing quality control/ quality assurance measures
* Cost recovery model
* Reporting requirements
* Publication policy

A sub-study service agreement will be executed prior to support of an individual trial.

Appendix A:

**Application form for participation as TR-ANZGOG Network Laboratory**

This form is to be completed by laboratories or biobanks interested in participating as a designated TR-ANZGOG Network Laboratory to assist with the collection, processing and storage of biospecimens collected in association with ANZGOG clinical trials.

The following equipment and/or resources are not essential for participation but will assist with TR-ANZGOG capacity planning.

If an SOP or equivalent covers any of the criteria, please reference the SOP, or equivalent, and provide a copy as applicable.

Applications will be reviewed by independent ANZGOG (or TR-ANZGOG) delegates and ratified by ANZGOG Board. Feedback will be provided where appropriate and if the applying laboratory is approved as a TR-ANZGOG Network Laboratory a collaborative research agreement (CRA) will be implemented between ANZGOG and the participating TR-ANZGOG Network Laboratory’s institute.

A sub-study service agreement will be executed prior to support of an individual trial.

For queries, please contact the TR-ANZGOG Project Manager via [tr-anzgog@anzgog.org.au](mailto:tr-anzgog@anzgog.org.au) Ph +61 2 8004 3401.

Please complete as fully as possible and return to the TR-ANZGOG Project Manager.

**Laboratory details**

|  |  |
| --- | --- |
| Laboratory name: |  |
| Primary contact name: |  |
| Role/ Position: |  |
| Phone: |  |
| Email: |  |
| Laboratory address: |  |
| Name of Laboratory Manager or equivalent (if different to Primary Contact) |  |
| Employer of Laboratory |  |

***Please answer the following questions:***

* Do you agree to the payment of standard fees to TR-ANZGOG Network laboratories as per the drafted TR-ANZGOG Cost Recovery Policy? 🞎 Yes 🞎 No
* Do you have staffing capacity to process on average 1-2 samples per week, comprised of 3-4 x 10 mL vacutainers of blood as detailed in the TR-ANZGOG Biospecimen Processing Manual (BPM)? 🞎 Yes 🞎 No
* If required, would this laboratory have staffing capacity to perform the following:
  + Formalin-fixed paraffin-embedded (FFPE) tissue block preparation 🞎 Yes 🞎 No
  + Haematoxylin & Eosin (H&E) staining 🞎 Yes 🞎 No
  + Freezing of fresh tissue 🞎 Yes 🞎 No
  + Processing of ascites (as detailed in the TR-ANZGOG BPM) 🞎 Yes 🞎 No
  + DNA extraction from microbiome swabs (SOP to be confirmed) 🞎 Yes 🞎 No
* Are laboratory staff and/or supervising scientists ANZGOG members? 🞎 Yes 🞎 No
* Are you aware of any factors which may impact the longevity of the laboratory? 🞎 Yes 🞎 No

Comments:

**Resources & Capacity**

|  |  |  |
| --- | --- | --- |
| **Facilities** | **No** | **Yes** |
| Does the laboratory perform storage and analysis of clinical research samples? |  |  |
| Is this laboratory accredited and if so, what type of accreditation does the site hold eg. PC2, Biobanking, NATA or other? Please specify: |  |  |
| If applicable, provide date of renewal of accreditation certificate: | | |
| If not accredited, describe the quality management systems the laboratory is working to: | | |
| Is access restricted? |  |  |
| Would weekend processing be possible, if required? |  |  |
| Would there be capacity to process unexpected samples? |  |  |
| If required, will ANZGOG be given access to audit the facility? |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Equipment item** | **No** | | **Yes** | **If Yes, please provide details (eg. volume, automated vs semi-automated)** |
| Liquid nitrogen (for snap freezing tissue) |  | |  |  |
| Centrifuge |  | |  |  |
| Class II Biosafety Cabinet |  | |  |  |
| Microtome, water bath and cold plate |  |  | |  |
| Cryostat |  |  | |  |
| Tissue Microarrayer |  |  | |  |
| Digital slide scanner |  |  | |  |
| Barcode reader & printer |  |  | |  |
| Can you confirm records of maintenance, servicing and calibration of equipment are available and up to date? |  |  | |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Storage equipment** | **No** | **Yes** | **If Yes, please provide capacity details** |
| Fridge |  |  |  |
| -80°C freezer storage capacity |  |  |  |
| Liquid nitrogen storage capacity |  |  |  |
| Vapour phase nitrogen storage |  |  |  |
| Ambient storage |  |  |  |

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| --- | --- | --- |
| **Quality measures** | **No** | **Yes** |
| Are staff involved in the analysis and/or evaluation of samples appropriately educated, experienced and trained? |  |  |
| Are storage facilities temperature (and volume) monitored and alarmed? |  |  |
| Do you have generator back-up in case of power failure |  |  |
| Do you have an emergency back-up plan? (if yes, please provide a copy) |  |  |
| Are records kept demonstrating the preparation of buffers and reagents? |  |  |
| Are lot numbers and batches documented? |  |  |
| Are QC checks performed, documented and retained? |  |  |
| What sample tracking system is currently in use? |  |  |
| NSW Biobanks applicable only:  Does your laboratory possess NSW Health Biobank certification? |  |  |

Contact name:

Signature:

Date:

**Appendix B:**

**TR-ANZGOG Network Laboratory - Assessment Form**

**Purpose:** This form is to be completed by a nominated, independent, ANZGOG (or TR-ANZGOG) delegate for each laboratory or biobank that expresses interest in participating within the TR-ANZGOG Network of Laboratories. The reviewers will be nominated by the TR-ANZGOG Steering Committee Chair.

|  |  |  |
| --- | --- | --- |
|  | **Laboratory name:** | |
|  | **Laboratory State/ Territory location:** | |
|  | Does the laboratory have adequate and secure facilities to process and store biospecimens? | 🞎 Yes 🞎 No |
|  | Comment: | |
|  | Does the laboratory have adequate equipment to meet the basic biospecimen processing requirements, as outlined in the Biospecimen Processing Manual? | 🞎 Yes 🞎 No |
|  | Comment: | |
|  | Does the laboratory have capacity to cater for all biospecimen storage method requirements? | 🞎 Yes 🞎 No |
|  | Comment: | |
|  | Does the laboratory have capacity to process and store, at a minimum, an estimated 1-2 patient samples per week, as outlined in the Biospecimen Processing Manual? | 🞎 Yes 🞎 No |
|  | Comment: | |
|  | Does the laboratory have quality control and quality assurance measures in place? | 🞎 Yes 🞎 No |
|  | Comment: | |
|  | Does the laboratory have longevity for the foreseeable future? | 🞎 Yes 🞎 No |
|  | Comment: | |
|  | Other comments: | |

**Assessor Recommendation**

|  |  |
| --- | --- |
| A. | Laboratory recommended for TR-ANZGOG Laboratory Network participation 🞎 Yes 🞎 No |
|  | Summary of recommendation: |
| B. | Decision to be deferred until further information provided 🞎 Yes 🞎 No |
|  | Summary of information required: |
| C. | Suitability of laboratory:  🞎 High suitability  🞎 Moderate suitability  🞎 Low suitability |
| E. | Assessment completed by:  Name: …… ………………………………………………………………………. Position: ……………………………………………  Organisation: ……………………. Date: ………………………………. |