Technical Feasibility Assessments Guidelines 2024-25 Round 2

Early-Stage Cell and Gene Therapies Advisory Service

Background

Therapeutic Innovation Australia (TIA) is an NCRIS lead agent that supports and facilitates researcher and SME access to a diverse range of Australian translational medical research capabilities. In response to stakeholder consultation, TIA has introduced support for **Technical Feasibility Assessments** (TFAs) for Cell & Gene Therapy (CGT) research projects. Valued at $10,000, these awards support the provision of advice on product development directly from TIA's group of CGT facilities to researchers looking to develop novel therapeutic products. TIA provides funding to the TIA facilities for each assessment so that there is no cost to the researcher.

The TFAs take the form of a short-term consultancy with a TIA-supported cell and gene therapies facility (the Provider). TIA's guidance documents provide a good foundation which will maximise the value of the TFA process. Applicants should read these documents prior to applying for a TFA. The TFAs provide researchers with early information on the technical feasibility of manufacturing their therapy for clinical supply. Researchers will receive a personalised report on the product's development plan that may include (but not be limited to):

- Supply consideration for raw materials including vectors
- Transduction methods
- Cell therapy expansion platforms
- Quality control assessments that will be needed to show potency
- Regulatory considerations

Very early engagement with the Provider via the scheme is encouraged (approx. 1-2 years prior to clinical study).

The TFAs provide researchers with much needed direction for initiating translational research, building knowledge of the process and requirements and improving early-stage decisions.

The TFAs generally follow this format:

- An initial 2-hour workshop between the Applicant and the Provider. At this workshop, the Applicant should supply information on current status of the therapy including any manufacturing processes.
- After the workshop, the Provider spends time assessing this information and will compile a report containing suggestions for product development. This may include suggestions to improve processes, suggested quality assessments or other suggestions that will enable easier technology transfer to a GMP environment.
- After the Provider has given the report to the Applicant, a follow-up 2-hour workshop between Applicant and the Provider will provide an opportunity for Applicants to ask questions and seek clarity on details included in the report.
- Following this final workshop, a completion checklist is submitted to TIA (non-confidential). The checklist will not be publicised but is for TIA's internal use only.

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These assessments are designed to be short. Assessments should commence **within 3 months** of award and complete **within 6 months of commencement.** Note: this timescale applies to the supported activities only, and **not** the full completion of the project or development of a potential therapeutic.

Each TFA will be funded via a fixed-value allocation of **$10,000** ex GST. This funding will be provided directly to the Provider at the completion of the assessment. **There is no requirement for co-investment by the Applicant**.

Scheme Objectives and Key Features

TFAs are designed to respond quickly to the needs of researchers and industry by facilitating access to expertise in national research infrastructure. The scheme has three key participants, **CGT Providers**, **Applicants** and **TIA**.

1. For **Providers** (TIA-supported facilities), the general aims of the scheme are to:
   - Enable and increase external business from research groups
   - Raise the profile, knowledge and use of these facilities and their capabilities within the Australian research community
   - Incentivise collaborative projects, leading to more effective use of research infrastructure.
2. For **Applicants** the aims of the scheme are to:
   - Improve your runway to clinical manufacture by providing you with essential knowledge earlier in development
   - Improve efficiency, reducing costs of unnecessary or duplicative experiments
3. For **TIA** the aims of the scheme are to:
   - Support access to CGT Providers, their capabilities and expertise
   - Increase external access to national research infrastructure enabling more collaborations

Eligibility Criteria for Applicants

1. The Technical Feasibility Assessments scheme is open to applications from the following organisations:
   - University-based researchers and research groups
   - Research groups within Publicly Funded Research Organisations, including Medical Research Institutes (MRIs)
   - Small-to-Medium Enterprises (SMEs) including university start-ups
2. Only applications that seek to access assessment by facilities external to their academic unit or host entity will be considered.
3. Applicants at any stage of their career can apply.
4. **You may apply for a TFA voucher if you have previously been supported under either this scheme or the Pipeline Accelerator. However, you must include the completion report for the previous voucher even if it is for a different project.**

List of Providers

Applicant must select a Provider from the list of eligible Providers supported by this scheme, as listed below.

Provider Name (click name for website)	Contact(s)
Cell & Molecular Therapies (Royal Prince Alfred Hospital)	Sharon Sagnella
Cell & Tissue Therapies WA (Royal Perth Hospital)	Zlatibor Velickovic
Centre of Excellence in Cellular Immunotherapy (Peter Mac)	Gretchen Poortinga
Cell Therapies Pty Ltd	Jennifer Hollands

Provider Name (click name for website)	Contact(s)
Q-Gen Cell Therapeutics (QIMR Berghofer)	Darron Laing
Sydney Cell and Gene Therapy (Westmead Precinct)	Leighton Clancy

Eligibility of Projects

To achieve support, the Project application must:

- Involve a cell or gene therapy
- Briefly articulate the current state of development of the CGT, including
  - the type of therapy,
  - your understanding of what intellectual property is contained in the invention,
  - what ambition you have for progressing this therapy to clinical trials.
- Be regarded as meritorious by an assessment committee with external members appointed by TIA

Application and Funding Process

1. *Applications open*

TIA publishes a call for applications through a variety of channels.

IMPORTANT**: Applicants should approach a facility and seek their assurance in writing that the facility can provide appropriate advice to the maximum value of $10,000. TIA can advise which facility should be approached if you are not sure. **Correspondence from the facility must be attached to the application.

Applicant submits application using the **online application form** before the closing date, which is advised on the scheme's webpage and on the application form.

We encourage applicants to develop the application using a **template application form** provided as the form cannot be saved and returned to later. Once complete, simply copy and paste the text into the online form. Detailed instructions are included on the application form template.

2. *Applications close*

3. *Project selection*

A panel, including internal and independent external experts, assesses applications and decide on awards. The assessment process may be staged, depending on the number of applications received.

All outcomes will be notified via email, including unsuccessful applications. For successful applications, a **Letter of Offer** will be sent to the Applicants, cc: the specified Provider(s).

4. *Project commencement*

- The Provider and the Applicant agree dates for initial and final workshops. These should be approx. 1-2 months apart, to allow time for the Provider to undertake assessment.

The Applicant must:

- Co-sign with the Provider the received letter of offer and return to indicate agreement with the terms.

- Enter into a confidentiality agreement with the Provider (**NOT** with TIA) to receive specific guidance on technical feasibility of a cell or gene therapy.
- Provide a **Completion Checklist** (download the template on TIA website)

The Provider must:

- Co-sign with the Applicant the received letter of offer and return to indicate agreement with the terms.
- Enter into an appropriate confidentiality agreement with the Applicant (**NOT** with TIA) to provide specific guidance on technical feasibility of a cell or gene therapy.
- Ordinarily, TIA would expect the project to commence within **three months** of award of the voucher. Because of the nature of this scheme, ***offers may be withdrawn if projects do not commence within six months of award without a reasonable explanation.***
- Schedule a mutually agreeable time for initial workshop, establish a time frame for the report and schedule a time for the final workshop.
- After the initial workshop, the Provider will compile a written report to the Applicant within an agreed time window, and a **Completion Checklist** to TIA.
- Upon completion of project, submit an invoice to TIA for $10,000 +GST.

Note:

- The voucher awarded is **not transferable** to another project.
- TIA **does not** need to see the agreement between Provider and Applicant.
- TIA **does not** seek any ownership or beneficial interest in supported projects but reserves the right to receive brief project updates (~1/2 page) on request.
- In the event of early termination and/or significant project scope change, the Applicant must notify TIA in writing at the earliest possible opportunity. Depending on the scenario, TIA will advise the Provider on the next steps.

5. Project completion

Once the work of the Provider is complete, Provider and Applicant must meet the following conditions:

- The Applicant and Provider have provided **written proof** that the services have completed. This proof shall be a TIA-provided template **Completion Checklist** from the Applicant (counter-signed by the Provider) describing the capability provided. This template includes instructions for a brief completion report.
- As noted above, submission of a **Completion Checklist** is required to ensure ongoing eligibility of Providers.

Once the Project has Assessment has completed, the Provider is directly reimbursed by TIA according to the following conditions:

- The Provider has sent to TIA a copy of a proper invoice for $10,000 plus GST, that references the Project and the Applicant
- The Invoice must have extended payment terms (60 days) to allow TIA to assess whether payment conditions have been met
- The Invoice accompanies **written notice** that the services have completed. This proof shall be via a TIA-provided template **Completion Checklist** from the Applicant (counter-signed by the Provider) stating that the services have been completed and briefly outlining the findings.

Scheme timelines

The scheme's approximate timelines, which will remain subject to change, are listed below:

Stage	Timeframe
Scheme opens for applications	4 March 2025
Scheme closes for applications	2 May 2025, 5pm (AEST)
Applications assessed	May -June 2025
Awards made	June/July 2025
Projects commence	**Strictly** within 6 months of award*
Projects complete	Within 12 months of commencement

*Offers may be withdrawn if projects have not commenced within six months without an explanation satisfactory to TIA.