Technical Feasibility Assessments 2023-24 Round 2 Guidelines

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 is introducing support for **Technical Feasibility Assessments** (TFAs) for Cell & Gene Therapy (CGT) research projects. Valued at $10,000, these awards will support the provision of advice on product development directly from TIA's group of CGT facilities to researchers looking to develop novel therapeutic products. Funding will be provided to TIA facilities for assessments to be provided to researchers at no cost.

The Technical Feasibility Assessments will take the form of a short-term consultancy with a TIA-supported manufacturing facility (the Provider). TIA's guidance documents[1] provide a good foundation which will maximise the value of the TFA process. Applicants should read these documents prior to applying for a TFA. These assessments will 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 manufacturing partners via the scheme is encouraged (approx. 1-2 years prior to clinical study).

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

The TFAs will generally support the following steps:

- 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 will spend 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.

[1] *The following guidance documents are available on the TIA website:*
- *Cell & Gene Therapeutics: Translation from Discovery to Market*
- *Crossing the Valley of Death: Guidance for Researchers Translating a Research Discovery into an Advanced Therapeutic Product*

- 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.

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, **Providers**, **Applicants** and **TIA**.

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 the TIA facilities and their capabilities within the Australian research community
- Incentivise collaborative projects, leading to more effective use of research infrastructure.

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

For **TIA** the aims of the scheme are to:

- Support access to facilities, their capabilities and expertise
- Increase external access to national research infrastructure enabling more collaborations

Eligibility Criteria for Applicants

The Technical Feasibility Assessment 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

Only applications that seek to access assessment by facilities external to their academic unit or host entity will be considered.

Applicants at any stage of their career can apply.

List of Providers

The project must seek to access a facility from TIA's Cell & Gene Therapy Capability (see **List of Providers** below). Applicants are encouraged to identify their preferred facility, but it is not compulsory. Projects that do not identify a preferred Provider will be assigned to the most relevant

Provider at the review stage. Funding is via a fixed-value allocation of **$10,000** ex GST. This funding will be sent directly to the Provider at assessment completion.

The following facilities are eligible for support from this scheme ("Providers").

Facility Name (click name for website)	Contact(s)
Cell & Tissue Therapies WA (Royal Perth Hospital)	Zlatibor Velickovic
Centre of Excellence in Cellular Immunotherapy (Peter Mac)	Jennifer Hollands
Q-Gen Cell Therapeutics (QIMR Berghofer)	Andrew Masel
Cell & Molecular Therapies (Royal Prince Alfred Hospital)	Sharon Sagnella
Viral Vector Manufacturing Facility (Westmead Precinct)	Michael Shum
Sydney Cell and Gene Therapy (Westmead Precinct)	Leighton Clancy
Vector and Genome Engineering Facility (CMRI, Westmead Precinct)	Betty Kao

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 in principal approval to be named in an application to this scheme, including an assurance that the facility can provide appropriate advice to the value of $10,000. TIA can advise which facility should be approached if you are not sure.*

Applicant submits a brief application for support, using the **online application form** before the closing date, which will be advised on the scheme's webpage and on the application form.

We encourage applicants to develop the application using a template application form. Once complete, simply copy and paste the text into the online form. Detailed instructions are included on the EOI 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.

TIA sends unsuccessful Applicants a letter with, if available, feedback on the application.

TIA sends successful Applicants a **Letter of Offer**, cc: the specified Provider. This letter includes the obligations of TIA, Applicant and Provider as follows:

TIA must:

- Pay invoices submitted by the named Provider totalling $10,000, plus GST, once the Applicant and Provider meet certain obligations to the satisfaction of TIA (see below).

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 3 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.

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.

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 Provider 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 on the TIA website	4 March 2024
Scheme closes for applications	26 April 2024, 5pm (AEST)
Applications assessed	May 2024
Awards made	June 2024
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.

Scheme documents

These documents make up the Application and reporting package for the **Technical Feasibility Assessments** scheme. All documents are available for download on the scheme's webpage.

1. TFAs Guidelines and application form template **(this document)**
2. TFAs **Completion Checklist** to inform TIA of project completion and trigger payment to provider