

CURE4 CYSTIC FIBROSIS INNOVATION GRANT APPLICATION GUIDELINES

About Cure4 Cystic Fibrosis Foundation (Cure4CF)

Cystic fibrosis (CF) is the most common inherited disease affecting the developed world, with one in every 2,500 children affected. It is a multi-organ disease, affecting the lungs, gut, liver, pancreas and reproductive tissues. At present about half of those with CF will die by their late 30's from loss of lung function resulting from repeated airway infection and lung tissue damage, which is the cause of death in over 90% of CF patients.

Currently, no cure is available. Existing treatments are very short lived and can only slow the inexorable destruction of the lung. The lung infections in CF patients are extremely difficult to treat, even with the strongest antibiotics and most innovative therapies the treatment can lead to debilitating side effects, destruction or malfunctioning of other organs in the body.

Cure4CF is pleased to launch its 2021 research grant program to the scientific and medical community. Since its inception Cure4CF has provided more than \$ \$2.5M in grants. Our focus is to fund research projects aiming to deliver community benefits through new innovations with therapeutic drugs, cell and gene therapies, vaccines, antimicrobials and more.

Cure4CF exists to accelerate life-extending solutions for people with CF. We are focused on research that builds on existing knowledge and has an identified path and a commitment for a strong translational impact for people living with CF.

We support research programs where theories have been demonstrated, scientific curiosity satisfied and where practical utility is evident. This means that the Foundation will not support basic or fundamental research (diagnostics, devices, observational, nutrition & exercise or epidemiology studies). We anticipate the funding provided will add commercial value to discoveries and result in therapeutic candidates progressing along the translational pathway. The Foundation is committed to provide further support to the successful recipient in their next stages of research and its successful translation, e.g. next funding source, providing commercialisation advice or assisting with translation into clinical guidelines.

An applicant should carefully consider how their project aligns with the Cure4CF vision and life mission. Please visit Cure4CF website: <u>www.cure4cf.org</u> for more information, vision statement, supporting material and current research projects information.

Guidelines

The Cure4CF 2021 grant scheme offers a total pool of up to \$500,000.00 AUD. You are invited to apply for any amount to the maximum of \$500,000.00 AUD, if you meet the following eligibility criteria and are willing to comply with the grant conditions. There is no minimum grant amount.

Eligibility Criteria

To be eligible to apply for funding through this scheme, the following conditions must be met:

- The applicant must complete and submit the application form attached herein
- The application must be led by an applicant who is an Australian resident or citizen, with research to be conducted primarily in Australian-based research facilities
- The project must clearly meet Cure4 Cystic Fibrosis Foundation's core objective: the potential to lead to the development of new therapies or cures that will result in a material increase in average life expectancy for people with cystic fibrosis

• The project must be less than 24-months in duration.

Application Submission Process and Deadline

Grant Application can be downloaded from https://www.cure4cf.org/research-grants/.

The application must be submitted via email to <u>grants@cure4cf.org</u> prior to the deadline at **5pm (ACST) on 17th of September 2021.** Late applications will not be assessed.

Recipients will receive an automated email confirming that the application has been successfully submitted.

If you have any questions regarding the application process or require technical support, please contact the team at <u>grants@cure4cf.org</u> or phone (08) 7221 8536 during office hours (Monday-Friday) 9am to 5pm (ACST).

Application Conditions

- All Australian researchers are encouraged to apply, irrespective of career stage or nominal area of research.
- Collaboration is encouraged and applicants can involve more than one research group or institution.
- Only one application will be considered from each principal researcher.
- An application will be considered incomplete if it fails to comply with the instructions or if the submitted material is insufficient to permit adequate review.
- Late applications will not be processed.
- Applications received by post will not be accepted or returned to the sender.
- Graphs and other pertinent to the application information should be embedded within the additional fields provided in the application. No attachments are allowed.
- Researchers are not to commence conduct of the project prior to receiving a grant approval confirmation and funds fully received.
- The project should be carried out within the grant funding specified dates. No extension will be granted.
- No additional funding will be provided on the top of the approved amount.
- Recipient to provide written reports every 6 months and at the end of project.
- Eligible expense items include direct costs such as salaries, consumables, equipment and travel. Please note, priority will be given to applications that do not request indirect costs such as overheads, patent costs, publication costs, capital works and non-essential items such as trade subscriptions, catering etc. Applicants should leverage this support from their institution or partners.
- It is desirable that outcomes from projects funded by Cure4CF generate sufficient data to support applications to follow-on translational funding.
- Cure4CF grants do not support research areas such as population studies, policy development, diagnostic, devices, epidemiology, nutrition & exercise or observational studies.
- Successful applicants will ensure research is conducted in accordance with all applicable laws, regulations and codes of practice and all necessary licences and approvals must have been obtained and are adhered to. This includes those concerning the use of animals and the obtaining of patient consents and ethical committee approvals.
- The goal of these grants is to translate existing and innovative technological or medical research knowledge into progressive research, enabling access to research capability and capacity beyond the existing knowledge that will result in advanced treatment discoveries, and ultimately have a significant impact on the health, lifespan and well-being of people with the CF.

Assessment Criteria and Scoring

The following scoring framework will be used to assess applications.

		SCIENTIFIC EXCELLENCE	CLINICAL RELEVANCE & IMPACT	TRANSLATIONAL POTENTIAL
0	Ineligible	A zero in any category will make the project ineligible for funding		
		Unfeasible or unjustified scientific rationale	Irrelevant or impractical in clinical practice	No commercial or translational pathway
1	Poor	Feasible project, but may be based on poor scientific rationale or planning	May be relevant in clinical practice, but likely requires significant adaptation	Potential commercial or translational pathway, but with major challenges
2	Adequate	Feasible project, sound rationale and plan, but little innovation	Relevant in clinical practice, but will not realise significant outcomes	Sound commercial or translational pathway
3	Good	Good scientific rationale and research plan, evidence of innovation	Relevant in clinical practice, potential to realise significant impact	Attractive commercial or translational pathway
4	Very good	Very good scientific rationale and research plan, innovative, good data	Highly relevant in clinical practice, highly likely to realise significant impact, potential 10+ life extension	Attractive commercial or translational pathway, clear strategies in action
5	Exceptional	Excellent rationale and plan, highly innovative, extensive evidence and data to justify potential outcomes	Addresses high need, would result in significant impact to many, clear path for clinical adoption, potential cure or 20+ life extension	Clear and attractive pathway, IP already generated, partners already in place, regulatory strategy determined

Review & Award Process

The grant review timeline is as follows:



Obligations of Grant Awardees

To Activate the Cure4 Cystic Fibrosis Innovation Grant

Successful applicants will be notified of their success through the receipt of a Notice of Success Letter and a Research Sponsorship Agreement within 6 weeks of submission deadline.

Successful applicants must formally accept the Cure4CF grant by signing and returning the Research Sponsorship Agreement. The grant will not be activated, nor any monies released until this has been received.

The grant must be activated and the project underway within 3 months of the date of the issue of the Notice of Success Letter. If the grant has not been activated within this timeframe, Cure4CF reserves the right to withdraw the offer of the grant, unless an extension has been approved.

The recipient will be paid pro-rata upon achieving the milestones and reports provided.

Reporting

The successful applicant must ensure all expenditure relating to the Cure4CF grant can be reconciled.

Cure4CF will require a verbal quarterly update and a written report every six months to ensure responsible use of the Cure4CF grant by the recipient.

For projects of more than 12 months duration, Cure4CF will require a 12-month Report in order to release funds to support activities in the second year.

A Final Report will be required from all grant recipients within 3 months of the project's end.

Grants will be closed, and any remaining balances written off 6 months after the scheduled end date of the grant unless an extension is approved in advance.

Intellectual Property

Cure4CF Foundation will not seek intellectual property rights of intellectual property from funded research. However, Cure4 Cystic Fibrosis may seek a beneficial return (e.g. repayable loan or revenue share on value realised).

Engagement in Cure4 Cystic Fibrosis Foundation Activities

Cure4CF is seeking a partnership with successful grant recipients and encourages Grantees to consider other resources, expertise and support Cure4CF may offer beyond the funding period.

Grantees must be willing to contribute to Cure4CF promotional activities as requested.