2023/2024 Grants and Awards Guide

August 2023

CYSTIC FIBROSIS CANADA

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TABLE OF CONTENTS

I.	CHANGES FOR THE 2022 and 2023 COMPETITION AT A GLANCE	1
	Major Changes for the 2022 and 2023 competition	1
	Basic and Clinical Research Grants	1
	Early Career Investigator Awards	1
	Research Fellowship Awards	1
	Seed Grants	1
	Team Grants	1
п.	GENERAL INFORMATION	2
	Summary Table of Cystic Fibrosis Canada Grants and Awards	2
	Application schedule	6
	Granting process	7
	Cystic Fibrosis Canada policies	8
	Definitions	11
III.	CLINICAL GRANTS AND AWARDS	
	CLINIC INCENTIVE GRANTS	12
	CLINICAL FELLOWSHIPS	14
IV.	RESEARCH GRANTS AND AWARDS	
	BASIC SCIENCE AND CLINICAL RESEARCH GRANTS	16
	EARLY CAREER INVESTIGATOR AWARD	
	RESEARCH FELLOWSHIPS	35
	SEED GRANTS	41
	TEAM GRANTS	48
V.	OTHER GRANTS AND AWARDS	58
	EARLY STAGE TRANSLATIONAL RESEARCH PARTNERSHIPS	58
	OTHER CYSTIC FIBROSIS CANADA INITIATIVES AND PARTNERSHIPS	58

The terms of Cystic Fibrosis Canada's grants and awards are outlined in this Guide. Additional information may be obtained online or by contacting <u>research@cysticfibrosis.ca</u>.

I. CHANGES FOR THE 2022 and 2023 COMPETITION AT A GLANCE

Major Changes for the 2022 and 2023 competition

- Return to traditional October application deadline for full applications;
- Updates to the travel policy;
- Introduction of an applicant demographic self-identification section for use by Cystic Fibrosis Canada in assessing our research programs. Answers to each question are voluntary (applicant may choose 'prefer not to answer'). This information may be reported externally in aggregate form only but not on a per-applicant basis. This information will not be used as part of the review and assessment process for applications and will not be provided to reviewers.
- · Electronic signatures introduced to the application process

Basic and Clinical Research Grants

- Streamlining of the application (elimination of most attachments and inclusion of this information in the main webforms of the ProposalCentral application);
- Introduction of an EDI section for the applicant to describe how the principles of Equity, Diversity and Inclusion will be applied to recruitment of participants (where applicable to the application);
- Introduction of an EDI section for the applicant to describe how the principles of Equity, Diversity and Inclusion will be applied to recruitment of new team members including trainees during the course of the proposed research;
- Introduction of a Gantt chart to detail timelines of milestones and deliverables for the project.

Early Career Investigator Awards

- Return of the time frame for application to the traditional 60-months after first academic appointment (exceptions permitted for leaves, part-time employment or extenuating circumstances with notice before applying);
- Introduction of an LOI step, due August 15, 2023, before the full application stage;
- Extension of the award from two years to a maximum of three years and increase in the total value of the award to a maximum of \$300 000;
- Streamlining of the application (elimination of most attachments and inclusion of this information in the main webforms of the ProposalCentral application);
- · Removal of the requirement for graduate level transcripts;
- Reduction in the number of required reference letters from 3 to a minimum of 2 and maximum of 3.

Research Fellowship Awards

- Increase in the amount of the Research Fellowship Awards to \$45,000/year.
- Introduction of a \$3000/year research allowance that can be used for travel to conferences or to another lab to learn a new technique, or to purchase small equipment or supplies and reagents for the use by the Fellow;
- Permanent removal of the separate travel award application for Research Fellows;
- Streamlining of the application.

Seed Grants

- Newly introduced small, short-term grants focused on a new idea **without** other funding and **without** preliminary data;
- Grant is anticipated to allow generation of preliminary data to then use to secure additional funding from other sources;

- Not to be used to support an existing project that was not successful through the Basic Science and Clinical Research Grants competition;
- Maximum value of \$ 50 000 and a 1-year term;
- Applications open late 2022 for a submission deadline of April 1, 2023.

Team Grants

- Newly introduced large 4 year term grant;
- Grant is to support a team of researchers to address a community health priority identified by Cystic Fibrosis Canada as the topic of the current competition. The goal is to have a direct impact on people with CF by the end of the award.;
- Team grants are to fund collaborative integrated research teams working on innovative projects aligned with CR Canada community health priorities. Team grants are expected to have significant impact on CF patients within or in the near term after the four-year duration of the award.
- Maximum value of \$500,000/year for up to a 4 -year term;
- Applications open late 2023 for an LOI submission deadline of October 15, 2023.

II. GENERAL INFORMATION

Summary Table of Cystic Fibrosis Canada Grants and Awards

Clinical Grants and Awards

Type of Grant/ Award	Purpose of Grant/Award	Eligibility	Grant/ Award Amount (\$)	Max. Travel Allowance	Max. Term (Yrs)	Renewable
Clinical Fellowship award	To train physicians to become CF specialists, so that they may provide on-going clinical care to individuals with CF in Canada.	Canadian citizens or permanent residents who have an MD degree, have recently completed their clinical training, are exam eligible, and have obtained medical licensure in Canada, are eligible to apply.	\$75,000	N/A	1	No
Clinic Incentive grant	Clinic Incentive grants are intended to enhance CF clinical care by promoting on-going professional development through attendance at CF-related meetings and conferences, and by supporting entry of data into the Canadian CF Registry. Details of award amounts – based on the number of CF patients served at each clinic – will be available in <u>ProposalCentral</u> in the spring of each year, for payments to begin in the summer months.					

Research Grants and Awards

Type of Grant/Award	Purpose of Grant/ Award	Eligibility	Grant/ Award Amount (\$)	Max. Travel Allowance	Max. Term (Yrs)	Renewable
Basic Science Research grant	To support innovative basic science research projects that: (i) improve our understanding of CF and/or (ii) have a significant impact on the concepts, methods, treatments, and/ or technologies applicable to CF.	An independent researcher who holds a full-time academic or research appointment relevant to CF at a Canadian university or hospital.	The maximum budget request is \$100,000 per year	Maximum per year of the grant: \$3000 per individual (included in the budget maximum)	3	Yes, 1-3 years
Clinical Research grant	To support clinical research projects that: (i) improve the health and quality of life of CF patients and/or (ii) bridge the gap between research and clinical care.	The applicant must hold an academic or research appointment relevant to CF at a Canadian university or hospital.	The maximum budget request is \$100,000 per year	Maximum per year of the grant: \$3000 per individual (included in the budget maximum)	3	Yes, 1-3 years
Seed Grants	To support a new, innovative research idea for which the researcher doesn't yet have preliminary data or other research funding. The Program will support researchers to develop initial data on innovative new projects that can then be used to apply for new funding from other sources.	The applicant must hold an academic or research appointment relevant to CF at a Canadian university or hospital.	The maximum budget request is \$50,000 for 1 year	N/A	1	No Successful applicants may apply for further funding for the project through the Basic Science and Clinical Research Grant programs in the next annual competition.

Team Grants	To support a team of researchers to address a community health priority identified by Cystic Fibrosis Canada as the topic of the current competition. The goal is to have a direct impact on people with CF by the end of the award.	PI must be an independent researcher who holds a full-time academic or research appointment relevant to CF at a Canadian university or hospital. See program details for permissible composition of the research team.	The maximum budget request is \$500,000 per year	Maximum per year of the grant: \$3000 per individual (included in the budget maximum)	4	Possibly, 1-2 years	
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Type of Grant/Award	Purpose of Grant/ Award	Eligibility	Grant/ Award Amount (\$)	Max. Travel Allowance	Max. Term (Yrs)	Renewable
Early Career Investigator award ECI award terms are now up to 3 years and require submission of a letter of intent	To provide early career investigators an opportunity to develop outstanding CF research programs and build a team through operating grant support without having to compete against established investigators.	An independent researcher who has not held a Cystic Fibrosis Canada grant in the past and has held his/ her first full- time academic or research appointment for a period no longer than 60 months at the time of applying.	The maximum budget request is \$100,000 per year	Maximum per year of the grant: \$3000 per individual (included in the budget maximum)	3	No Successful applicants may apply for further funding for the project through the Basic Science and Clinical Research Grant programs in the next annual competition.
Research Fellowship award	To build capacity in CF research in Canada by supporting highly qualified fellows who are undertaking full- time research training in areas relevant to cystic fibrosis.	Individuals who hold MD or PhD degrees are eligible to apply. First- time applicants who, as of the application deadline have completed four or more years of training after completing their PhD or post-MD clinical training, are not eligible to apply.	\$45,000 per year salary and \$3000 per year research allowance. Research Fellowships may be held in conjunction with another award. See <u>Research</u> <u>Fellowships</u> for details on top-up, if applicable.	Maximum per year of the award: \$3000. Included as part of \$3000 annual research allowance.	2	Yes One year of additional support is available through a competitive application process.

Research Grants and Awards cont'd

Type of Grant/Award	Description
Partnered Awards with other organizations	Partnered awards with other organizations may be offered from time-to- time. These offerings will have separate requirements and generally will not follow the traditional Cystic Fibrosis Canada competition timelines. Detailed information will be published when these offerings are available.
Doctoral & Masters Studentship awards	Not available
Summer Studentship award	Not available
Special Travel Allowances for Fellows and Students	No longer available; Research Fellowships for 2022 and beyond will incorporate a research allowance that may be used for travel, equipment, and research materials by the Fellow.

Application schedule

Clinical Grants and Awards

Type of grant	Deadline	Notification					
Clinical Fellowships	October 1, 2023	Mid-March					
Research Grants and Awards							
Type of grant	Deadline	Notification					
Basic Science Research Grants							
Letter of Intent to Apply (LOI)	August 15, 2023	August					
Full Application	October 1, 2023	August					
		Mid-March					
Clinical Research Grants							
Letter of Intent to Apply (LOI)	August 15, 2023	Early August					
Full Application	October 1, 2023	Mid-March					
Early Career Investigator Awards							
NEW: Letter of Intent to Apply	August 15, 2023	Late August					
(LOI)	October 1, 2023	Mid-March					
Full Application							
Research Fellowship Awards	October 1, 2023	Mid-March					
Seed Grants	April 1, 2023	Fall					
Team Grants							
Letter of Intent to Apply (LOI)	October 15, 2023	Mid-November, 2023					
 Full Application (select applicants) 	March 1, 2024	Mid-May, 2024					
 Presentation to review panel (select applicants) 	June 15, 2024	July-August, 2024					
Project start date	October 1, 2024						

Granting process

CFC will perform a relevance review to identify eligible applications that are in alignment with the purpose and criteria of the funding opportunities. Relevant applications received by the date indicated in the <u>application schedule</u> will be assessed by Cystic Fibrosis Canada's scientific review panel. Incomplete applications and applications which are not received by the deadline will not be considered for funding.

All applications are subject to rigorous peer review by the members of the scientific review panel. Applications for Basic Science and Clinical Research grants are also reviewed by external expert reviewers, and by a panel of CF community member reviewers (people with CF and parents of those with CF). The community reviewers evaluate applications based on alignment to the CF Community research priorities, potential impact on the CF community and feasibility for participants (if applicable). Funded applications are those ranked highly by the scientific review panel, the CF community review panel and/or Cystic Fibrosis Canada.

The outcome of the competition, including the recommendations of the review panels and Cystic Fibrosis Canada, are presented to Cystic Fibrosis Canada's Board of Directors prior to notification of Applicants, usually by the middle of March. If an application is successful, a copy of the award letter is sent to the applicant and the financial officer of the institution concerned.

All grants and awards are offered subject to the availability of funds. Cystic Fibrosis Canada reserves the right to delay, reduce or terminate funding detailed in any award letter.

Grants are administered by Cystic Fibrosis Canada's office, to which all correspondence should be directed: <u>research@cysticfibrosis.ca</u>.

Cystic Fibrosis Canada policies

(i) Research involving human participants

Approval from the appropriate research ethics board (REB/IRB) is a condition of funding for any research projects involving human participants. Cystic Fibrosis Canada does not endorse the payment of participants for the purposes of human experimentation, or the payment of honoraria to persons enrolling or examining human participants. However, reasonable reimbursement for costs of participation will be considered. All successful applicants will be required to either submit proof of research ethics approval at their institution or a signed statement indicating that human participants will not be involved in the Cystic Fibrosis Canada-funded project, uploaded to ProposalCentral before funding will commence.

(ii) Research involving animals

Cystic Fibrosis Canada requires strict adherence to the policies of the Canadian Council on Animal Care. Approval from the appropriate institutional review board is a condition of funding for any research involving the use of animals. All successful applicants will be required to either submit proof of institutional approval for experiments involving animals or a signed statement indicating that animals will not be used in the Cystic Fibrosis Canada-funded project, uploaded to ProposalCentral before funding will commence.

(iii) Research involving human pluripotent stem cells

Cystic Fibrosis Canada's position on the use of human pluripotent stem cells in research follows the guidelines laid out in Canada's Tri-Council Policy Statement on the Ethical Conduct for Research Involving Humans. Canada's three federal research agencies – the Canadian Institutes of Health Research, the Natural Sciences and Engineering Council of Canada, and the Social Sciences and Humanities Research Council of Canada – jointly developed the <u>Tri-Council Policy</u> <u>Statement: Ethical Conduct for Research Involving Humans (TCPS 2 [2022])</u> as the official human research ethics policy of the Agencies. Chapter 12 (section F) provides guidance on research involving human pluripotent stem cells.

Any applicant to Cystic Fibrosis Canada who proposes the creation or use of human pluripotent stem cells must clearly indicate this fact and disclose all relevant details in the proposal. It is the applicants' and the host institutions' joint responsibility to ensure that all local ethics approvals have been obtained. All proposals are rigorously reviewed by an independent, international panel of experts, and all applicants must demonstrate strict adherence to the Tri-Council Policy Statement as laid down by the Government of Canada. All successful applicants will be required to submit a signed statement indicating whether they will use induced pluripotent stem cells in the project, and if stem cells will be used, to confirm that they will follow the principles and guidelines of the TCPS2 guidance on research involving human pluripotent stem cells. The statement must be uploaded to ProposalCentral before funding will commence.

(iv) Research involving biohazardous materials

Cystic Fibrosis Canada requires that applicants provide the appropriate certificates of approval for the use of biohazardous materials. All successful applicants will be required to either submit proof of institutional approval for experiments involving biohazardous materials or a signed statement indicating that biohazardous materials will not be used in the Cystic Fibrosis Canada-funded project, uploaded to ProposalCentral before funding will commence.

(v) Policy on patents and royalties

- a. In this policy "Invention" refers to new and useful tools, technology, processes or objects arising out of research funded in whole or in part by Cystic Fibrosis Canada ("Cystic Fibrosis Canada"), for example, diagnostic tools, proteins and genes, drugs, and methods of treatment.
- b. The Institution and the Principal Investigator shall within 10 days provide Cystic Fibrosis Canada with a copy of any Invention disclosure statement or record of like effect prepared by one or both of them, and with a copy of all patent applications and patents pertaining to Inventions made by one or both of them. In the event that none of the foregoing documents

has been prepared, the Principal Investigator shall provide Cystic Fibrosis Canada with a statement of the results of research funded in whole or in part by Cystic Fibrosis Canada upon conclusion of such research.

- c. Cystic Fibrosis Canada does not claim intellectual property ownership of Inventions, and Cystic Fibrosis Canada's name need not appear on patent applications. Therefore, title to any Invention shall belong to the Institution, the Principal Investigator, or to any other individual or organization designated by the Institution according to the Institution's established obligations at the date of grant (the "Owner"). The Institution and Principal Investigator may transfer ownership of the intellectual property only to persons agreeing to be bound by the terms of this Policy.
- d. The Institution and the Principal Investigator shall acknowledge the contributions of Cystic Fibrosis Canada, by name, to their research in all non-commercial publications and broadcasts respecting Inventions. None of the Institution, the Principal Investigator and the Owner shall use the name of Cystic Fibrosis Canada or any Cystic Fibrosis Canada trademark or official mark in any communication in a manner which states or implies an endorsement by Cystic Fibrosis Canada of any business, commercial product, or service.
- e. Cystic Fibrosis Canada expects that the Owner will seek patent protection for all commercially valuable Inventions in at least the United States of America, and that Cystic Fibrosis Canada will participate in all proceeds to the Owner arising from the transfer, licensing, or exploitation of the Inventions (the "Proceeds") while the patents remain pending or in force. The "Proceeds" shall include all monies and other benefits received less the direct out-of-pocket costs associated with patenting the Invention. Cystic Fibrosis Canada will consider waiving all or part of its share of the Proceeds where appropriate to promote the treatment, cure and control of cystic fibrosis.
- f. Cystic Fibrosis Canada's share of the Proceeds shall be determined by the mutual agreement of the Owner and Cystic Fibrosis Canada. If the parties are unable to agree, Cystic Fibrosis Canada's share of the Proceeds will correspond with the proportion of Cystic Fibrosis Canada's financial contribution to the overall costs of the research leading to and commercialization of the Invention. If Cystic Fibrosis Canada and the Owner are unable to reach an agreement as to the calculation of such proportion, the matter shall be referred for final resolution to arbitration, in accordance with the Arbitration Act, S.O. 1991, as amended.
- g. Cystic Fibrosis Canada may require the Owner or any successor in title to the Invention, and patents pertaining to it, to grant licenses to make, use or sell the Invention on a non- exclusive, royalty-free basis for academic, non-commercial research which in Cystic Fibrosis Canada's sole judgement may lead to a treatment, cure, or control for cystic fibrosis.
- h. The Owner shall require that any transfer or exclusive license of the Invention or patents pertaining thereto reserve the rights in paragraph "G" above and the rights in paragraph "I" below.
- i. Cystic Fibrosis Canada shall have the right to cancel or amend any licenses which have been granted, and to grant exclusive or non-exclusive licenses to the Invention, where an Owner or licensee subject to cancellation has (i) taken no steps to towards making the invention generally available for the past year, or (ii) not made the Invention generally available within five years of the date of making the invention, or within such further time as may be required to complete necessary antecedent steps such as clinical trials. Cystic Fibrosis Canada will consider waiving or revising its rights under this section in appropriate circumstances.
- j. The Owner shall report in writing to Cystic Fibrosis Canada annually, on the anniversary date of the first patent application respecting an Invention, as to all Proceeds received or expected by the Owner respecting the Invention. Cystic Fibrosis Canada shall have the right to audit the books and records of the Owner and those of any licensees of the Invention to verify the accuracy of the reports.

(vi) Leaves

Cystic Fibrosis Canada must be contacted regarding leaves (leave of absence, maternity/ paternity, sickness, etc.).

(vii) Support of personnel

The support of graduate students and post-doctoral research fellows from Cystic Fibrosis Canada research grant proceeds will be permitted, however the organization highly encourages research fellows to apply to the Cystic Fibrosis Canada Research Fellowship award program and all trainees to apply to other funding agencies for studentship and fellowship awards, as appropriate. Fifty percent (50%) of the budgeted salary for a research fellow will be deducted on Grant awards in cases where that fellow is awarded a Cystic Fibrosis Canada Research Fellowship.

(viii) Publications by grantees and awardees

The organization requests your assistance in publicizing support of your research, as donations from the public make it possible. Any scientific communication, publication, presentation or exhibit arising out of research funded in whole or in part by Cystic Fibrosis Canada, must state, "This work was supported in whole [or, in part] by Cystic Fibrosis Canada" and display our logo, where possible, to illustrate the source of your funding. By communicating about your work and highlighting the value and impact of CF research, you will be actively helping to increase the profile of Cystic Fibrosis Canada as a research funding organization. Please provide notification to mediarelations@cysticfibrosis.ca and research@cysticfibrosis.ca within 2 weeks of acceptance of any manuscript supported in whole or in part by Cystic Fibrosis Canada so that we may promote Cystic Fibrosis Canada supported publications.

(ix) Publicity

Information conveyed to the media with respect to the program and activities of Cystic Fibrosis Canada should be met with the prior approval of the organization, and of the institution where the program is in operation.

(x) Indirect costs

Cystic Fibrosis Canada-funded research grants and awards do **not** provide for institutional overheads and/or indirect costs of research or clinical care.

(xi) Travel

Budgets for research grants, early career investigator awards and research fellowships allow a travel component. The organization encourages investigators to attend CF-related meetings in Canada or abroad, when advisable according to public health guidelines, to report on their research progress for the funded award, and to remain abreast of significant developments in CF research. Trainees working on the funded project are particularly encouraged to present their work at research conferences, participation in a scientific training course or travel to another laboratory to learn a new technique as part of their development as a future CF researcher. These are considered legitimate uses of travel funds. Personal portions of legitimate trips may not be reimbursed. This includes hotel stays for additional days beyond the duration of a research conference for sightseeing or travel to a nearby location for a holiday. The travel expenses should be for direct costs of travel, they should be as economical as reasonably possible and should not result in personal gain for members of the research team. CF Canada will permit costs of economy class tickets for flights, rail, bus or other travel to and from the valid location, such as the location for a conference, baggage fees, reasonable travel insurance costs, conference registration fees, hotel reservations, wi-fi access while travelling, etc. Meals will be reimbursed to a maximum of \$90 per day. Under no circumstances will CF Canada consider the following as valid travel expenses: alcoholic beverages, airport lounge fees, duty-free and in-flight movie charges, entertainment, in room services such as movies, room service, minibar or laundry charges, business class or first-class travel. For research grants and early career investigator awards, travel of the PI and trainees directly working on the project may be reimbursed to a

maximum of \$3000/person/award year during the term of the project or during any no-cost extension period. The total budget for the award is inclusive of any travel expenses reimbursed. No additional funds beyond the approved budget of the research grant or early career investigator award may be requested for travel. For research fellowship awards, only travel for the awardee may be reimbursed, during the award period, and the total may not exceed the maximum annual research allowance.

Definitions

Principal Investigator (PI) – an individual who is responsible for the overall direction of a research project and all proposed activities. Typically, the Principal Investigator is also the 'applicant'.

Co-Principal Investigator (co-PI) – an individual who shares with the PI the responsibility for the overall direction of a research project and all proposed activities, including meeting the reporting requirements.

Co-Investigator – an individual recognized by the PI as someone making a significant contribution to a project. The Co-Investigator is an individual that the PI relies on to assume responsibilities above those of other personnel.

Collaborator – an individual whose role in the proposed activities is to provide a specific service (e.g., access to equipment, provision of specific reagents, training in a specialized technique, statistical analysis, access to a patient population, etc.)

Clinical Fellowship applicant – a Canadian citizen or permanent resident who holds an M.D. degree at the time of application, has recently completed their clinical training, are exam eligible, and has obtained medical licensure in Canada.

Early Career Investigator Award applicant – an independent researcher who has held his/her first full- time academic or research appointment at a Canadian University, Hospital Research Institute or other equivalent institution for a period no longer than 60 months (five years) fulltime or equivalent at the time of applying, and whose intention is a career in CF research.

Research Fellowship applicant – an Individual who holds an M.D. (Medical graduates should have already completed basic residency training and must be eligible for Canadian licensure) or Ph.D. degree and has completed less than four years of post-doctoral training at the time of initial application. Applicants already holding an initial Research Fellowship may apply to the renewal stream beyond the four-year limit.

Clinic Director - Main physician who oversees clinical operations/decisions in a Canadian CF clinic.

III. CLINICAL GRANTS AND AWARDS

CLINIC INCENTIVE GRANTS

Purpose

Clinic Incentive grants are intended to enhance CF clinical care by promoting on-going professional development through attendance at CF-related meetings and conferences, and by supporting entry of data into the Canadian CF Registry. Details of award amounts – based on the number of CF patients served at each Canadian CF clinic – will be available in Proposal Central in the spring of each year, before payments for that year beginning in the summer months.

Basic support for clinical care is the responsibility of provincial governments, and Clinic Incentive grants are not intended to supplement public healthcare funding. Cystic Fibrosis Canada's Clinic Incentive Grants are based on the size of the CF population being served and are to the CF Clinic Director. Any questions can be directed to healthcare@cysticfibrosis.ca

Eligibility

Canadian hospital-based CF clinics are eligible to receive Clinic Incentive Grants.

Term

Clinic Incentive grants are awarded for a term of one year and are renewed on an annual basis (through an application process).

Criteria

Recipients must demonstrate:

- they provide specialized clinical care for cystic fibrosis;
- Information regarding the CF population served within their jurisdiction (e.g. annual outpatients served per clinic)
- the need of the institution for assistance, and its plans to attract complementary funding from other sources to develop a complete CF program;
- the desire to collaborate with Cystic Fibrosis Canada and with other Canadian CF clinics, in a collective effort to advance the objectives of CF treatment, research, and teaching.

Use of funds

(a) Payment of personnel - entry of data into the Canadian CF Registry

All personnel compensated under a grant shall be considered employees of the institution in receipt of the grant, not of Cystic Fibrosis Canada. Please note that these are incentive grants and are not intended to provide funding for clinic personnel.

(b) Professional Development

A component of Clinic Incentive Grants is allocated for professional development of personnel, via attendance at CF-related meetings or conferences. The amount of the travel component is determined by Cystic Fibrosis Canada.

Terms and conditions

(a) Payment of grants

Grant payments will be made in the second quarter of CF Canada's fiscal year, through the CF clinic's host institution. Cystic Fibrosis Canada Clinic Incentive grants are under the jurisdiction and allocated at the sole discretion of the CF Clinic Director.

(b) Cancellation of grants

Cystic Fibrosis Canada reserves the right to cancel a grant and to request the return of any

unexpended funds, for appropriate cause. A grantee institution also may cancel a Clinic Incentive grant. In either case, 90 days written notice is required.

(c) Unexpended funds

Clinic Incentive grant funds which remain unexpended at the end of each grant year must be returned to the organization

(d) Over-expenditure

Any commitment incurred by a grantee in excess of the amount of the Clinic Incentive grant is not the responsibility of Cystic Fibrosis Canada. Also, a deficit against a Clinic Incentive grant may not be carried forward from one year to the next.

(e) Canadian Cystic Fibrosis Registry

Participation in the Canadian Cystic Fibrosis Registry is a requirement for recognition as an accredited CF clinic, and for the renewal of Cystic Fibrosis Canada Clinic Incentive grants.

(f) Financial reports

Clinics in receipt of Clinic Incentive grants must provide an accounting of expenditures by 1 June. Each year, clinics are alerted when financial reporting forms are available on <u>ProposalCentral</u>; these forms are to be completed by the clinics and financial representatives, and uploaded back onto <u>ProposalCentral</u> when complete. The organization reserves the right to request interim statements.

It is expected that expenditures will be consistent with the approved budget. Any significant deviation from the approved budget must be authorized in advance by Cystic Fibrosis Canada.

Each year unexpended funds must be returned to the organization.

(g) Indirect costs

Cystic Fibrosis Canada-funded research and clinic grants and fellowship awards do not provide for institutional overheads and/or indirect costs of research or clinical care.

CLINICAL FELLOWSHIPS

Purpose

The number of people with cystic fibrosis in Canada continues to grow each year. The Cystic Fibrosis Canada Clinical Fellowship program was created to ensure that adequate numbers of highly qualified CF clinicians are available to provide patient care.

Cystic Fibrosis Canada Clinical Fellowships are intended for those physicians who have already obtained their residency training and who wish to pursue additional clinical training in CF care. The purpose is to train physicians to become CF specialists, so that they can provide on-going clinical care to individuals with CF in Canada. This training includes developing competence to allow them to participate in clinical trials. This fellowship is not intended to train individuals from other countries who will not stay in Canada but rather support CF clinicians residing in Canada. Up to two highly ranked competitive Clinical Fellowships will be offered by Cystic Fibrosis Canada each year.

Eligibility

Canadian citizens or permanent residents who have an M.D. degree, have recently completed their clinical training, are exam eligible, and have obtained medical licensure in Canada, are eligible to apply. Clinical Fellowships will not be awarded to individuals who have not completed residency training. It is intended that this experience will directly benefit the Canadian CF community.

Term

Clinical Fellowships will be awarded for a period of one year. Applications must be submitted in accordance with the deadline noted in the <u>application schedule</u>.

Tenure of a Clinical Fellowship will commence on 1 July. Upon written request, subject to the approval of the organization, the start of a Clinical Fellowship may be delayed up to twelve months.

Value

The value of a Cystic Fibrosis Canada Clinical Fellowship is \$75,000; award levels are reviewed on an annual basis and will correspond with prevailing Canadian rates.

Criteria

Clinical Fellowships are awarded based on the demonstrated merit and potential of the applicant, taking into account the applicant's academic record, clinical experience, and references. The suitability and excellence of the proposed institutional environment, along with the intrinsic value and feasibility of the proposed clinical/research program are important criteria in the evaluation process. Proposed supervisors are expected to hold an academic appointment.

One supervisor cannot submit more than two Clinical Fellowship applications to any one competition. Do not rank submitted applications.

Application requirements

Like all Cystic Fibrosis Canada grants, Clinical Fellowships are subject to the availability of funds.

Applications must be received by the organization no later than the deadline noted in the <u>application</u> <u>schedule</u>. Incomplete and/or late applications will not be considered for funding.

An application is considered to be a joint effort of the applicant and the supervisor with whom he or she intends to study.

It is essential that the application describes the clinical training program. A clinical research component to the fellowship is optional, but if included, should be described. Applicants are encouraged to spend time in a CF lung transplant centre.

Applicants must arrange to have three letters of recommendation submitted to the organization, one of which should be from the applicant's current or most recent supervisor. These one- to twopage letters should indicate the period of time and in what capacity the supervisor has known the applicant, and should elaborate on academic and clinical capabilities and competence, and should address the following: background preparation, motivation, organizational ability, demonstrated skill in clinical activity, and communication and interaction within multidisciplinary teams, etc. Also required in the application form is a description of the proposed clinical training program, including a clinical research component if applicable, and official transcripts of the applicant's complete academic record. Applications that do not include these documents will be rejected. Any questions on the Clinical Fellowships can be directed to healthcare@cysticfibrosis.ca

Use of funds

Cystic Fibrosis Canada Clinical Fellowships are solely salary awards. The payment of benefits to Cystic Fibrosis Canada Clinical Fellows, is a matter of host institutional policy.

Terms and conditions

(h) Payment of grants

Grant payments will be made in one installment, on 1 July, through the institution at which the award is being held. Fellowship income may be taxable. Cystic Fibrosis Canada reserves the right to delay, reduce or terminate funding detailed in any award letter.

(i) Institutional affiliation

Clinical Fellows are normally expected to remain with the same supervisor for the period of the award. If the Clinical Fellow leaves the institution, he or she is expected to relinquish the Clinical Fellowship.

If the Clinical Fellow transfers to another supervisor and/or institution and is continuing the same type of research and clinical activity, the award may be continued, at the discretion of Cystic Fibrosis Canada. Authorization must be sought in advance of such a transfer.

(j) Increases

Clinical Fellowship awards are subject to scale increases, in order that they remain in step with prevailing Canadian rates.

(k) Earnings from other sources

Fellows may be remunerated for other work but may not hold a second major award.

(I) Progress reports

Clinical Fellows should be prepared to submit reports on their activities at intervals, on request from Cystic Fibrosis Canada. A final progress report must be submitted following the conclusion of the award.

(m) Leaves of absence, maternity/paternity and sickness

Cystic Fibrosis Canada must be contacted regarding leaves (leave of absence, maternity/ paternity, sickness, etc.).

(n) Patents and royalties

All fellows must agree to the terms of Cystic Fibrosis Canada's policy on patents and royalties; please see the <u>Cystic Fibrosis Canada policies</u> section.

IV. RESEARCH GRANTS AND AWARDS

BASIC SCIENCE AND CLINICAL RESEARCH GRANTS

Purpose

Basic Science research grants support innovative basic science research projects that (i) improve our understanding of cystic fibrosis and/or (ii) have a significant impact on the concepts, methods, treatments, and/or technologies applicable to cystic fibrosis.

Clinical research grants support clinical research projects that (i) improve the health and/or quality of life of CF patients and/or (ii) bridge the gap between research and clinical care.

Eligibility

Applicants must be <u>independent researchers</u> who hold a full-time academic or research appointment relevant to CF at a Canadian university or hospital. Under exceptional circumstances, and at the discretion of the Office of Research with guidance from the Research Advisory Council, research grant applications from other individuals may be evaluated on a case-by-case basis, with significant emphasis placed on the degree of independence of the applicant, and on the institutional commitments to this individual. Such applications must include a statement from the applicant addressing the issue of salary support during the term of the grant, and the availability of laboratory space; and letters from the Departmental Chair and Dean of Faculty, clarifying the nature and extent of the institutional commitment to the applicant. This same eligibility criterion regarding a faculty appointment applies to any named co-investigator.

There are no limits on the number of co-investigators or collaborators that can be listed. The investigators must have clearly defined roles which are justified. The institution receiving funds indicates where the ultimate responsibility for the grant lies.

Generally, the organization funds research which is carried out in Canada, and the principal investigator must be based at a Canadian institution. While Cystic Fibrosis Canada will fund a collaboration from outside of Canada, funds must be directed through a Canadian institution and Canadian investigators intending to collaborate with individuals from outside of Canada should contact Cystic Fibrosis Canada in advance.

Grant applications submitted to the Basic Science Research Grant stream must focus on basic science research, including molecular, cellular, and animal studies aimed at better understanding the pathology of cystic fibrosis and its complications or the preclinical development of treatments for cystic fibrosis and its complications. Proposals requiring human participants or sampling of materials from human participants will be considered under the Basic Science stream only if the sampling method presents minimal patient risk (e.g. venipuncture, nasal brushings) and the sample will be used in basic or laboratory research. Projects using human samples that were collected previously, or collected as part of routine clinical care, may be considered under either the Basic Science or Clinical Research streams. All other proposals involving human participants, including interventional, observational, or epidemiological studies should be submitted to the Clinical Research Grant program.

The final decision regarding categorization of grant applications will be at the discretion of Cystic Fibrosis Canada in consultation with the chairs and vice-chairs of the Scientific Review Panel, the Research Advisory Council and the Healthcare Advisory Council, as appropriate.

Term

Basic Science research grants and Clinical research grants are awarded for a term of one to three years. They are renewable for one to three years by submission of a renewal application in the final year of the original term or to a subsequent competition.

Value

The maximum budget request is \$100,000/year. Cystic Fibrosis Canada may accept budget requests

beyond \$100,000/year if there is a funding partner. If there is a funding partner. The amount of a grant will be approved by Cystic Fibrosis Canada with recommendations from the scientific review panel following a detailed review of the applicant's proposed budget.

Criteria

All applications must address Cystic Fibrosis Canada's Core Principles of funding the best science that has the highest probability of making an impact for CF patients. Cystic Fibrosis Canada includes community stakeholders in the review process to provide their perspective on the impact of the proposed research on those living with CF. Proposals should be directly relevant not only to CF, but also to the Research Priorities of the CF Community.

We will fund research with strong alignment to one or more of the following:

- 1. Cure CF with gene or stem cell therapies
- 2. Understand mental health and emotional wellness at different stages
- 3. Improve airway infection detection and treatment
- 4. Prevent or treat CF-related diabetes
- 5. Reduce the treatment burden
- 6. Understand health issues for people living with CF aged 50+
- 7. Predict and prevent pulmonary exacerbations
- 8. Eradicate chronic pseudomonas aeruginosa infections
- 9. Reduce hospitalizations by maximizing the therapies that can be done from home
- 10. Improve GI pain management
- 11. Help people with CF improve and sustain adherence to treatment

If there is a compelling reason why the work is uniquely applicable to the Canadian CF community, despite not aligning to these 11 priorities, it is incumbent upon Cystic Fibrosis Canada to consider funding the work. It is recommended that you discuss the proposal with the Program Director, Research, before completing the proposal letter-of-intent (LOI).

In general, there will be an emphasis on funding research that is more clinical or translational in nature and with the potential for near term impact for people with CF, but not to the exclusion of more long-term or fundamental basic research projects. Given that access to highly effective CF modulators is anticipated to significantly alter disease progression for the majority of people with CF in Canada, the organization will not be directly supporting areas such as lung transplantation research but will consider projects that help address the unmet need of individuals who will not benefit from CF modulators, such as those with mutations not responsive to modulators or those for whom modulators have become available too late. It is recommended that if there isn't a clear link in the proposed research to one of the CF Community priorities, that the applicant discuss feasibility of the topic with the Program Director, Research before completing the proposal letter-of-intent (LOI).

Application requirements: Letter-of-Intent

All applicants, for initial and renewal grants, must advise Cystic Fibrosis Canada by the deadline noted in the <u>application schedule</u> of their intent to apply for funding by completing a letter-of-intent to apply (LOI), in English, on <u>ProposalCentral</u> with the following information:

- Name and address of principal investigator;
- Name(s) and address(es) of co-investigator(s) and collaborator(s);
- Title of grant application;
- 1500 character technical summary of the proposed research in scientific language;
- Keywords of relevance to the proposal;
- One or more CF Community Research Priority areas of relevance to the Proposal;

• Suggested reviewers and name(s) of any reviewer(s) to whom you would prefer that the application not be sent.

Incomplete and/or late LOI applications will not be considered. Only documents submitted through <u>ProposalCentral</u> will be reviewed. While the PI and the majority of the proposed research team are anticipated to remain intact from LOI to full proposal, an applicant whose LOI is approved may add study team members. The applicant may also make some modifications to the proposed research program and to the lay and technical summaries, however, the basic premise of the proposal should remain unchanged from LOI to full application.

Application requirements: Full Proposal

Full applications for approved LOI topics must be submitted online, in English, through <u>ProposalCentral</u>, no later than the deadline noted in the <u>application schedule</u>. Incomplete and/or late applications will not be considered for funding. Only documents submitted through <u>ProposalCentral</u> will be reviewed.

Investigators are eligible to hold more than one research grant. It is a requirement that the focus of any additional grant application be clearly delineated from any existing ones. The specific aims of an additional grant should represent new approaches to the CF problem, and not an expansion of an existing research program.

Full applications submitted on ProposalCentral must contain the following:

- Updated carry-over information from the LOI submission (including revised title, study team members, technical abstract, keywords, research priority areas and suggested reviewers);
- A maximum 2000-character description of how the proposal aligns with the selected CF Community Research Priority (Priorities), in non-scientific, everyday language at a level no greater than Grade 10, and/or how the study has a particular Canadian relevance. If your proposal does not directly align to one of these priorities but you have been given pre-approval to submit a proposal on this topic, please describe how your proposal is relevant to CF and why it should be funded. This section should also describe the significance of the impact of the work, if successful, on the lives of CF patients. This is one of the most important sections of the proposal and should be provided to at least two individuals without a scientific background to read, to ensure that it is understandable by a lay audience;
- Demographic information on the applicant. This section must be completed but the answers to the questions are optional. The applicant may select "choose not to answer" for any or all questions. The demographic data will be used for internal assessments of our funding programs. The data will only be provided to external individuals in aggregate form, not individual responses. The responses will not be provided to reviewers;
- An ORCID ID is now required to apply. Please agree to link your ORCID profile to your CF Canada application. This will allow you to easily import certain information to your application and make the application process easier and more integrated.
- 3500-character (approx. 1 page) research proposal summary, touching on the main points of the detailed proposal, including rationale, hypothesis/objectives, specific aims and impact of the proposed research (new for 2022: this section is entered directly into ProposalCentral rather than uploading a separate completed template document);
- Research progress report: required for both renewals and new applications. In a maximum of 5000-characters (approx. 1.5 pages), applicants of renewal grants must describe their accomplishments on the previously funded Cystic Fibrosis Canada research grant. Link the discussion of progress directly to the previously stated aims for the application. For new applications, in a maximum of 5000-characters (approx. 1.5 pages), applicants must describe their past research efforts and expertise, and how these provide the necessary knowledge to conduct the currently proposed studies. (new for 2022: this section is entered directly into ProposalCentral rather than uploading a separate completed template document);

- EDI—study recruitment section. In this new section, only if the study will recruit participants, the applicant should describe in a maximum of 1,500 characters the equity, diversity, and inclusion considerations for recruitment of participants. Also indicate how you will integrate sex and gender into your recruitment and analysis, if applicable. Studies that do not involve participant recruitment should mark this response N/A. CIHR has published a significant set of resources related to EDI considerations here: https://cihr-irsc.gc.ca/e/52553.html. It is recommended that you review these materials before completing this section;
- EDI—study team. In this new section, the applicant should describe in a maximum of 1,500 characters the equity, diversity, and inclusion considerations for recruitment of study team members, including trainees. CIHR has published a significant set of resources related to EDI considerations here: <u>https://cihr-irsc.gc.ca/e/52553.html</u>. It is recommended that you review these materials before completing this section;
- Utilization of Canadian CF Registry (CCFR) Data. New for 2023. This section has been included to allow researchers to indicate if their application will utilize CF Registry data. Interested applicants can contact the CF <u>Registry team</u> if they want information about data in the CCFR, how they can leverage CCFR data for research and obtain budget estimates for using CCFR data;
- Clinical Trials- New for 2023. This section has been added for researchers to indicate if they
 are conducting a clinical trial and if they have engaged CF CanACT. <u>CF CanACT</u> can assist in
 protocol review prior to applying for a grant, and can also assist in directing you to suitable
 clinical sites to conduct your clinical trial;
- 1500 character lay summary of the proposed research in non-scientific, everyday language;
- Budget detail. A budget worksheet attachment is provided for your convenience and may be used if you wish to help develop your budget plans. Please do not upload this document. All budget details and justification must be entered directly into ProposalCentral. All budgets should be developed to an even multiple of \$100 per year and a maximum of \$100,000 per year;
- Budget justification—should align with Gantt Chart and Research proposal detail including all milestones and deliverables;
- Sources of funding. New for 2022: this section has been integrated as a webform in the ProposalCentral application platform. You may easily add any grant previously added to your profile by clicking the check box. Otherwise add a description for each existing grant/source of funding and any pending/applied grants. Indicate the amount of overlap with the current proposal and a justification.
- Relevant publications. New for 2022: this section has been integrated as a webform in the ProposalCentral application platform. You may add information and upload pdf copies of up to 5 of your recent relevant publications to the application. DOI number or Pubmed ID can be used to automatically add most details.
- Shared publication criteria/agreement: If this project is multi-centered and/or international, please indicate the shared publication criteria/agreement. Otherwise enter N/A into the field.
- Conflict of Interest Disclosure Statements: For the purpose of complete transparency, we ask that the principal investigator declare for themselves and all co-investigators and collaborators all conflicts of interest, potential conflicts of interest and perceived conflicts of interest, or expressly indicate that there are no such conflicts. Conflicts of interest may include, but are not limited to, payment for consulting services or sitting as a member of an advisory board for a for-profit company where you are proposing to employ their products or services, for example.
- Rebuttal: Optional. If this is a resubmission of a previously unsuccessful application, the applicant
 may include up to a 5000-character (approx. 1.5 page) rebuttal of previous reviewer comments.
 Include both the comment and the response as current year reviewers do not have access to past
 application reviews. If this is not a resubmission, indicate N/A in this section;
- Signatures: Signatures are now completed electronically in the ProposalCentral system. Applicant

and institutional representative who can legally bind the institution should log in and sign where indicated. The applicant may need to add access to the proposal for the institutional representative. Any Co-PI should also sign at the appropriate place. The application cannot be submitted without PI and institutional representative electronic signatures.

Attachments to be uploaded to ProposalCentral:

- Detailed program proposal (1 document, 10 pages plus table of contents, references and appendices containing data/figures);
- Gantt Chart. The Gantt Chart is a new attachment added since the 2022 competition. It is used to
 list all activities, milestones and deliverables on the project and the anticipated time required to
 complete activities and the dates for achieving deliverables and milestones. Activities listed on the
 Gantt chart should align to the research proposal and the related budget line item. Complete in
 excel format and upload as a PDF document (remove instructions tab before uploading);
- Optional: Letters of support from co-investigators and collaborators in PDF format. Include a maximum of 3;
- Signature pages, CVs and reprints of publications should **no longer** be uploaded.

The review process/evaluation criteria

Decisions concerning the amount and term of any given award are made on the basis of the following considerations:

- The quality and scientific merit of the research proposal;
- The relevance of the proposal to the CF Community Research Priorities;
- The impact of the research for people with CF, including how near-term those impacts may potentially be to benefiting people with CF;
- The translational potential for the research;
- The qualifications of the principal investigator, along with any co-investigator(s) and/or collaborator(s) named in the application, to conduct the proposed research;
- The availability to the applicant(s) of the resources necessary to conduct the proposed research;
- The degree of overlap with other operating grants held by the applicant(s);
- The potential of the proposed work to produce significant results in the field of CF.

Complete applications submitted by the deadline will be subjected to a rigorous peer review process.

(a) External Peer Review

Applications will be provided to 2-3 international experts in a relevant field of research. The list of external peer reviewers may or may not include suggestions made by the applicant. The list will generally not include the individuals expressly requested by the applicant to not be selected as reviewer, individuals who are part of the study team, or individuals from the same institution as an applicant or co-applicant. External peer reviewers comment on the strengths and weaknesses of the proposal, provide an overall impression and a recommendation on whether the application should be funded as written.

(b) Internal Peer Review

Applications will be provided to 3 individuals from the scientific review panel for rigorous review and written critique. Clinical research applications are assigned to a separate scientific review panel populated with clinical researchers. Assigned reviewers will as much as possible have knowledge or expertise in the subject matter of the given proposal, within the confines of the scientific review panel membership. The list of internal peer reviewers may or may not include suggestions made by the applicant. The list will generally not include the individuals expressly requested by the applicant to not be selected as reviewer, members of the study team,

individuals on the review panel who indicate a direct conflict with a member of the study team or individuals from the same institution as an applicant or co-applicant. Internal peer reviewers are designated as primary reviewer, secondary reviewer and reader:

- (a) Primary reviewer: summarizes the proposal, provides a score for the proposal, and answers the following questions:
 - i. Describe the track record of the principal investigator, any co-investigators and collaborators. Does the project's team have an appropriate record of success given the stage of their career(s)? Does the team have the appropriate expertise to successfully carry out the proposed research and achieve the research objectives? For renewal applications, has the applicant made appropriate progress during the term of the current grant and have they been productive? For initial applications, has the applicant adequately summarized previous studies that have prepared them to undertake the current proposal?
 - ii. Are the research aims appropriate? Do they represent a suitable avenue of CF research? Is there sufficient institutional support and resources available to carry out the proposed research?
 - iii. Is the proposal original and sufficiently innovative? Are there better ways to address the problem? Does it challenge existing paradigms in research or current clinical practices, or does it address a novel hypothesis or a critical barrier to advance the CF field?
 - iv. Is the research plan, including the design, methods, and analyses, adequately developed, well integrated, well-reasoned, and appropriate to the aims of the project? Are the timelines feasible? Are the outcomes clearly defined? Does the PI acknowledge potential problem areas and consider alternative tactics?
 - v. If successful, will the proposed work result in a significant advance in the field or benefit to the CF community? The relevance and impact of the project to CF and to the mission of Cystic Fibrosis Canada should be addressed. What is the likelihood of the study resulting in near-term impact (improvements in health and/or quality of life) for people living with CF?
 - vi. Are the budgetary requests reasonable? YES or NO. Comments and/or items to be flagged? Please list amounts to be reduced and reason, if appropriate. If the budget is recommended to be reduced, please indicate the total recommended budget for Year 1, Year 2 and Year 3.
 - vii. Do you recommend support of this project? YES, at the budget proposed; YES, at a reduced budget; or NO.

The primary reviewer scores the proposal out of 5.0, which equally reflects the applicant's track record of success, the appropriateness of the project aims, the innovativeness of the approach, feasibility of the proposal and significance/ impact to CF patients. The score reflects the following descriptors:

Score	Descriptor
4.5 - 5.0	Outstanding
4.0 - 4.4	Excellent
3.5 - 3.9	Very good
3.0 - 3.4	Good
2.0 - 2.9	Average
1.0 - 1.9	Below average
0.0 - 0.9	Not acceptable

- (b) Secondary reviewer: answers the questions indicated for the primary reviewer above and provides a score for the proposal:
- (c) Reader: reads and is prepared to discuss the proposal; optionally may complete the questions described above and score the proposal.

(c) Community Review

Applications will be provided to a committee of community reviewers (people living with CF or parents of someone living with CF) who will each review the proposal, with a major emphasis on the 'lay' sections. Community reviewers will provide a score out of 5 and provide a written critique, answering the following questions:

- i. Were the lay language sections written in language that the average member of the CF community (without a science degree) could understand? Was it well-written or confusing? Why? How could the applicant improve this section next time so that it is easier to understand or better describe what they are proposing?
- ii. Does the research sound interesting and important? Is it exciting for members of the community to hear about?
- iii. Will there be direct benefits to CF patients if the project is successful? If the project deals with subjects that are less patient-focused and more about understanding the basic science of CF, do you think if successful it will significantly improve our understanding? Will the benefits that come from the proposed research be achieved in the near-term or will it take a long time for CF patients to benefit from this research?
- iv. If the application proposes to involve patients in the research, do you think patients will participate in what is planned? Would it be easy for most patients to take part and would they think it is worth their time? Is there a better way to make things easier for the participants? If the authors are not proposing to involve patients, is there a way that patients could be included that the researchers didn't think of?
- v. What patient priorities do you think the proposal would address? Why? It is ok if your thoughts are different than what the researcher thought.
- vi. Do you think the research is aligned close enough to the community priorities? If the work does not align directly to any particular priority, do you feel the work is important specifically to Canadian CF patients? If the proposed work does not align to any priorities, do you think it is still important work that should be funded?
- vii. Do you see any problems or reasons why this project should not be funded?
- viii. If funding is limited and we can only fund a few good projects, is this one of the top three you would most like to see funded?
- (d) Review panel meeting

Internal reviewers and community reviewers meet on the same panel, in person or virtually to discuss the applications. Members of the panel holding conflicts with a member of the study team will not have access to the application, will be excused during the discussion of that application, and will not have the ability to comment or vote. Primary reviewers lead the discussion, with further critique provided by the secondary reviewer, reader, community reviewers and other members of the review panel. Comments from external reviewers are read to the committee. After discussion, the primary and secondary reviewers agree upon a 'consensus score' and scientific review panel members score the proposal within 0.5 of the consensus score. The community reviewers separately score the proposal. Where initial critiques and scores of an application are low and clearly outside of the funding range, the panel may agree to 'triage' and not discuss the application. Feedback is provided by the critiques to the applicant to assist improving the application for a future competition. Successful applications are selected based on a high average score from the scientific reviewers and a high average score from the scientific reviewers and a high average score from the community reviewers, within the confines of the budget allocation for the competition.

Use of funds

(a) Guidelines for expenditure

Grants are awarded in global annual amounts. Minor reallocations between budget categories

are permitted, provided that the global budget is not exceeded. The current maximum allowable annual budget for basic science and clinical research grants is \$100,000 CAD per year for up to a maximum of 3 years. Budget requests should be made in annual amounts rounded to an even \$100, i.e. a request could be submitted for \$299,500, but should not be submitted for \$299,498 or \$299,501.56.

Research grants may be allocated, in accordance with the approved budget, to:

- Personnel (research assistant(s), technicians, fellows, students, specified other personnel);
- Materials and supplies (expendables, animals, services);
- Data acquisition charges (i.e. Canadian CF Registry)
- Equipment (total not to exceed \$10,000, once per term grant);
- Travel (in accordance with the travel policy detailed in this guide);
- For applicants proposing to provide funds from this grant to international collaborators: While Cystic Fibrosis Canada will fund a collaboration from outside of Canada, funds must be directed through a Canadian institution. Applicants proposing to provide any funds from this grant to international collaborators must briefly describe in the budget justification section of the application why an international component is necessary for the project. Cystic Fibrosis Canada will typically allow up to \$35,000 per grant year for international collaborators. Should the applicant propose an amount beyond that, they must reasonably justify this.

Research grants do not provide support for:

- · Construction costs;
- · Institutional overheads for laboratory facilities;
- · Clinical care, including clinical care for study participants;
- · Institutional overheads and/or indirect costs of research;
- Purchase of equipment in excess of \$10,000;
- · Principal investigator salary;
- Severance pay/packages.
- (b) Clinical Trials

Cystic Fibrosis Canada recognizes the importance of strong support for clinical trials of new drugs or treatments for cystic fibrosis.

In most instances, particularly where new products are involved, funding will emanate from the manufacturer, as a normal component of the drug or product development process. In cases where such funding is not available or appropriate, the organization will entertain applications for limited support.

In no instance will Cystic Fibrosis Canada provide financial support to trials which, by their nature, should be assumed by pharmaceutical companies or equipment manufacturers.

Clinical trial funding from Cystic Fibrosis Canada will be considered for scientific merit, within the context of the overall medical/scientific budget. Given the significant costs associated with clinical trials, and the limited resources of the organization, Cystic Fibrosis Canada support for such initiatives will, of necessity, be of relatively modest proportions and, generally, will be directed to the research component of the study. In most cases, support will also be contingent upon the identification of at least one additional funding partner.

The following components of single- and multi-centre clinical trials will be considered allowable budget items in grant applications: (a) salary support for personnel involved in study design, coordination, monitoring, and analysis, including supplies and equipment needed for sample analysis; (b) meeting and travel expenses associated with study design and the data safety monitoring committee.

Funding should be requested using Cystic Fibrosis Canada's standard Research Grant application on <u>ProposalCentral</u>. In addition, the principal investigator must submit a cover letter which includes a detailed budget for the entire project, in order that the support requested from Cystic Fibrosis Canada can be placed in context; and the details of requests submitted or pending to other funding agencies, and the date on which decisions are expected.

(c) Funds received from National Support Groups

It is the organization's policy that if funds are donated by National Support Groups directly to a Cystic Fibrosis Canada-funded researcher, or to the hospital/host institution organization in the researcher's name, an equal amount will be deducted from his/her research grant in the following fiscal year.

Terms and conditions

(a) Payment of grants

Grant payments will be made at the beginning of each fiscal quarter and will coincide with the fiscal year of most universities: 1 April through 31 March. Partnered awards with other organizations, where offered, may have different payment schedules, as detailed in the Notification-of-Award. Cystic Fibrosis Canada reserves the right to delay, reduce or terminate funding detailed in any award letter.

(b) Unexpended funds

An unexpended balance at the end of each fiscal year and at the end of Cystic Fibrosis Canada support period does not immediately lapse. Grantees will have an additional one fiscal year to use unspent funds. Any funds remaining at the end of this additional one fiscal year period must be returned to Cystic Fibrosis Canada. Additional extensions will not be considered.

(c) Over-expenditure

Any commitment incurred by a grantee in excess of the amount of the Research grant is not the responsibility of Cystic Fibrosis Canada. In the case of multi-year, renewal and terminal grants, over-expenditures may be applied to the budget of the following year(s), up to a ceiling of 10%.

(d) Financial reports

Grantees must provide an annual financial report through <u>ProposalCentral</u>, within 90 days of the end of the grant period.

(e) Budget increases

The organization does not provide funds for unanticipated increases in cost, or for the expansion of a research project during the term of a grant. For multi-year grants, and subject to the availability of funds, a cost-of-living allowance may be added to Research grants.

(f) Progress reports

Grantees must submit annual progress reports, due within 90 days of the end of the grant period, and a final progress report within 90 days of the end of the project. The progress report form is available through <u>ProposalCentral</u>, and the completed document must be uploaded through that platform.

(g) Experimental approvals

All grantees must submit all required institutional approvals for experiments involving human participants and/or animals, and/or induced pluripotent stem cells and/or biohazardous materials, or signed statements indicating for each resource that they are not going to be used for the funded work, in accordance with <u>Cystic Fibrosis Canada's policies (i)-(iv)</u>, by March 31st of the year following that in which the application for a Research grant is submitted.

(h) Patents and royalties

All grantees must agree to the terms of Cystic Fibrosis Canada's policy on patents and royalties;

please see Cystic Fibrosis Canada policies section.

(i) Indirect costs

Cystic Fibrosis Canada-funded research grants do not provide for institutional overheads and/or indirect costs of research or clinical care.

(j) The Robbie Award for Most Promising New Research Project

On the recommendation of the organization's scientific review panel, an applicant for an initial research grant receiving the highest ranking in a competition will be awarded the Robbie Award. This annual award is for a one-year term. The award does not carry any supplementary monetary value.

(k) Senior Scientist Research Award

On the recommendation of the organization's scientific review panel, this award recognizes the outstanding contributions of an established cystic fibrosis investigator. This annual award is for a one-year term. The award does not carry any supplemental monetary value.

(I) Cathleen Morrison Research Impact Award

On the recommendation of the CF community review panel, this award is given to the applicant with the highest ranking for their project in terms of relevance to the community, with the greatest potential to impact those living with cystic fibrosis. This annual award is for a one-year term. The award does not carry any supplemental monetary value.

(m) Other Named Research Awards

Cystic Fibrosis Canada may create new named research awards or eliminate existing awards, including those detailed in (j)-(I) at any time at its sole discretion.

EARLY CAREER INVESTIGATOR AWARD

Program details

Cystic Fibrosis Canada's Early Career Investigator (ECI) award provides investigators who are early in their career establishment grant funds to develop and demonstrate their independence for initiating and conducting outstanding cystic fibrosis (CF) research. The award aims to build the capacity of emerging leaders in CF research in Canada and increase the impact on Cystic Fibrosis Canada's mission to end CF. Applicants may apply for this award in addition to Cystic Fibrosis Canada's Basic/ Clinical Research grants, however, they may only accept one grant/award.

An early career investigator is defined as an independent researcher who has held his/her first fulltime academic or research appointment for a period no longer than 60 months (five years) at the time of applying.

Purpose

Cystic Fibrosis Canada's ECI award provides support to a limited number of exceptional investigators, who intend on making a career in CF research. The goal of this award is to provide ECIs an opportunity to develop outstanding CF research programs and build a team through operating grant support for up to 3 years without having to compete against established investigators. The award is primarily intended as a research grant for laboratory personnel support and supplies/reagents to complete the proposed studies. However, up to 40% of the budget may be allocated to PI salary for the ECI. This salary must not replace existing institutional salary support for research activities but may be requested to enable increased protected research time.

Eligibility

At the time of application, candidates must:

- b) hold a health professional degree at a doctoral level (e.g. M.D.) or a Ph.D. degree;
- c) be within five years (60 months) of, or have a formal documented commitment to, their first full-time academic or research appointment at the time of application;
- d) never have held an operating grant from Cystic Fibrosis Canada in the past;
- e) have a written commitment from the Dean of Faculty or Research Director:
 - Guaranteeing a minimum of 0.50 FTE (full-time equivalent) protected research time for individuals with a health professional degree at a doctoral level (e.g. M.D.) who hold a license to practice in a province or territory in Canada, or a minimum of 0.75 FTE protected research time for individuals with a Ph.D. degree or health professional degree at a doctoral level who do not hold a license to practice in a province or territory in Canada (the remaining 0.25 or 0.50 FTE may be devoted to teaching and/or clinical activities);
 - Detailing the appointment, including teaching load, clinical and administrative duties, adequate research/office space, resources (equipment and/or staff), start-up funds, etc.
- f) be sponsored by a Canadian research institution or medical school;
- g) exhibit exceptional potential and demonstrate the ability to initiate and conduct independent research.

Term

The award will be for a one-, two- or three-year period and is non-renewable. Applicants may apply for further funding through Cystic Fibrosis Canada's Basic Science or Clinical Research grant programs upon completion of this award.

Value

The amount of an ECI award will be approved by Cystic Fibrosis Canada with recommendations from the scientific review panel and Research Advisory Council, following a detailed review of the applicant's proposed budget. The maximum value permitted is \$ 100,000 per year.

Criteria

All applications must address Cystic Fibrosis Canada's Core Principles of funding the best science that has the highest probability of making an impact for CF patients. Proposals must be directly relevant not only to CF, but also to the Research Priorities of the CF Community.

We will fund ECIs whose research holds a strong alignment to one or more of the following:

- 1. Cure CF with gene or stem cell therapies
- 2. Understand mental health and emotional wellness at different stages
- 3. Improve airway infection detection and treatment
- 4. Prevent or treat CF-related diabetes
- 5. Reduce the treatment burden
- 6. Understand health issues for people living with CF aged 50+
- 7. Predict and prevent pulmonary exacerbations
- 8. Eradicate chronic pseudomonas aeruginosa infections
- 9. Reduce hospitalizations by maximizing the therapies that can be done from home
- 10. Improve GI pain management
- 11. Help people with CF improve and sustain adherence to treatment

If there is a compelling reason why the work is uniquely applicable to the Canadian CF community, despite not aligning to these 11 priorities, it is incumbent upon Cystic Fibrosis Canada to consider funding the work. It is recommended that you discuss the proposal with the Program Director, Research before completing the proposal letter-of-intent (LOI).

In general, there will be an emphasis on funding research that is more clinical or translational in nature and with the potential for near term impact for people with CF, but not to the exclusion of more long-term or fundamental basic research projects. Given that access to highly effective CF modulators is anticipated to significantly alter disease progression for the majority of people with CF in Canada, the organization will not be directly supporting research or early career investigators in areas such as lung transplantation research, but will consider projects that help address the unmet need of individuals who will not benefit from CF modulators, such as those with mutations not responsive to modulators or those for whom modulators have become available too late. It is recommended that if there isn't an obvious clear link in the proposed research to one of the CF Community priorities, that the applicant discuss feasibility of the topic with the Program Director, Research before completing the proposal letter-of-intent (LOI).

Decisions concerning the amount and term of any given award are made based on the following considerations:

- Academic background, research background and future potential of the applicant for a career in cystic fibrosis research;
- · Institutional support, including research environment and start-up operating/salary support;
- · Quality, originality and scientific merit of the research program;
- The relevance of the proposal to the Research Priorities of the CF Community;
- The impact of the research for people with CF, including how near-term those impacts may potentially be to benefiting people with CF;
- The degree of overlap with other operating grants held by the applicant;
- The potential of the proposed work to produce significant results in the field of CF.

Application requirements

Multiple submissions for any given competition are not permitted. At the time of application, applicants may apply to other Cystic Fibrosis Canada grants (e.g. Basic Science Research grants,

Clinical Research grants), but they may only accept one grant/award. Applicants should not apply to the ECI award competition and the research grants competition with the same research project.

Application requirements: Letter-of-Intent

New: All applicants to the Early Career Investigator award, for initial and renewal grants, must advise Cystic Fibrosis Canada by the deadline noted in the <u>application schedule</u> of their intent to apply for funding by completing a letter-of-intent to apply (LOI), in English, on <u>ProposalCentral</u> with the following information:

- Name and address of principal investigator;
- Name(s) and address(es) of co-investigator(s) and collaborator(s);
- Title of grant application;
- 1500 character technical summary of the proposed research in scientific language;
- · Keywords of relevance to the proposal;
- One or more CF Community Research Priority areas of relevance to the Proposal;
- Suggested external reviewers and name(s) of any reviewer(s) to whom you would prefer that the application not be sent.

Incomplete and/or late LOI applications will not be considered. Only documents submitted through <u>ProposalCentral</u> will be reviewed. While the PI (ECI) and the majority of the proposed research team are anticipated to remain intact from LOI to full proposal, an applicant whose LOI is approved may add study team members. The applicant may also make some modifications to the proposed research program and to the lay and technical summaries, however the basic premise of the proposal should remain unchanged from LOI to full application.

Application requirements: Full Proposal

Full applications for approved LOI topics must be submitted online, in English, through <u>ProposalCentral</u>, no later than the deadline noted in the <u>application schedule</u>. Incomplete and/or late applications will not be considered for funding. Only documents submitted through <u>ProposalCentral</u> will be reviewed.

Full applications submitted on ProposalCentral must contain the following:

- Updated carry-over information from the LOI submission (including revised title, study team members, technical abstract, keywords, research priority areas and suggested reviewers);
- 1500 character lay summary of the proposed research in non-scientific, everyday language at a level no greater than Grade 10. It is critical that the summary be in lay language. If this application is successfully funded, this summary may be used to communicate to the public and donors about the research supported by Cystic Fibrosis Canada;
- A maximum 2000-character description of how the proposal aligns with the selected CF Community Research Priority (Priorities), in non-scientific, everyday language at a level no greater than Grade 10, and/or how the study has a particular Canadian relevance. If your proposal doesn't directly align to one of these priorities but you have been given pre-approval to submit a proposal on this topic, please describe how your proposal is relevant to CF and why it should be funded. This section should also describe the significance of the impact of the work, if successful, on the lives of CF patients. This section of the proposal should be provided to at least two individuals without a scientific background to read, to ensure that it is understandable by a lay audience;
- Demographic information on the applicant. This section must be completed but the answers to the questions are optional. The applicant may select "choose not to answer" for any or all questions. The demographic data will be used for internal assessments of our funding programs. The data will only be provided to external individuals in aggregate form, not individual responses. The responses will not be provided to reviewers;
- An ORCID ID is now required to apply. Please agree to link your ORCID profile to your CF Canada

application. This will allow you to easily import certain information to your application and make the application process easier and more integrated.

- Summary of Research to Date. Please provide a 3500 character (approx. 1-page) description of the research in which you have been engaged, prior to and since receiving your doctorate or M.D. degree, and since your first academic appointment, and the results obtained. Indicate the date, institution, and supervisor where appropriate, and, in the case of collaborative research, outline your personal contribution (new for 2022: this section is entered directly into ProposalCentral rather than uploading a separate completed template document);
- Candidate's Statement. In 3500-characters (approx. 1-page), please (1) provide an overview of your involvement in CF research; (2) outline their specific area(s) of your research interests; (3) outline your future plans for research and overall career development; and (4) include your reasons for applying for a Cystic Fibrosis Canada Early Career Investigator Award (new for 2022: this section is entered directly into ProposalCentral rather than uploading a separate completed template document);
- EDI—study recruitment section. In this new section, only if the study will recruit participants, the applicant should describe in a maximum of 1,500 characters the equity, diversity and inclusion considerations for recruitment of participants. Also indicate how you will integrate sex and gender into your recruitment and analysis, if applicable. Studies that do not involve participant recruitment should mark this response N/A. CIHR has published a significant set of resources related to EDI considerations here: https://cihr-irsc.gc.ca/e/52553.html. It is recommended that you review these materials before completing this section;
- EDI—study team. In this new section, the applicant should describe in a maximum of 1,500 characters the equity, diversity and inclusion considerations for recruitment of study team members, including trainees. CIHR has published a significant set of resources related to EDI considerations here: <u>https://cihr-irsc.gc.ca/e/52553.html</u>. It is recommended that you review these materials before completing this section;
- Utilization of Canadian CF Registry (CCFR) Data. New for 2023. This section has been included to allow researchers to indicate if their application will utilize CF Registry data. Interested applicants can contact the CF <u>Registry team</u> if they want information about data in the CCFR, how they can leverage CCFR data for research and obtain budget estimates for using CCFR data;
- Clinical Trials- New for 2023. This section has been added for researchers to indicate if they
 are conducting a clinical trial and if they have engaged CF CanACT. <u>CF CanACT</u> can assist in
 protocol review prior to applying for a grant, and can also assist in directing you to suitable
 clinical sites to conduct your clinical trial;
- Shared publication criteria/agreement: If this project is multi-centered and/or international, please indicate the shared publication criteria/agreement. Otherwise enter N/A into the field.
- Conflict of Interest Disclosure Statements: For the purpose of complete transparency, we ask
 that the principal investigator declare for themselves and all co-investigators and collaborators
 all conflicts of interest, potential conflicts of interest and perceived conflicts of interest, or
 expressly indicate that there are no such conflicts. Conflicts of interest may include, but are not
 limited to, payment for consulting services or sitting as a member of an advisory board for a forprofit company where you are proposing to employ their products or services, for example.
- Budget detail. A budget worksheet attachment is provided for your convenience and may be used if you wish to help develop your budget plans. Please do not upload this document. All budget details and justification must be entered directly into ProposalCentral. All budgets should be developed to an even multiple of \$100 per year and a maximum of \$100,000 per year. You may request up to a maximum of 40% (\$40,000 per year) of the budget total as Principal Investigator salary support. This salary support should not replace existing institutional salary support for research time but may be requested to offset increased protected research time for the applicant. This amount is to be included in the \$100,000/year budget total and is not in addition to it. (new

for 2022: an ECI award now has a maximum term of up to 3 years);

- Budget justification—should align with the Research proposal including all milestones and deliverables detailed in the proposal;
- Sources of funding. New for 2022: this section has been integrated as a webform in the ProposalCentral application platform. You may easily add any grant previously added to your profile by clicking the check box. Otherwise add a description for each existing grant/source of funding and any pending/applied grants. Indicate the amount of overlap with the current proposal and a justification.
- Relevant publications. New for 2022: this section has been integrated as a webform in the ProposalCentral application platform. You may add information and upload pdf copies of up to 5 of your recent relevant publications to the application. DOI number or Pubmed ID can be used to automatically add most details.
- References: please enter the contact information for a minimum of two and a maximum of three references. Suitable references include a PhD or Postdoctoral supervisor, a mentor, department chair, Program Head, Dean, or other individuals who can adequately comment on your research abilities and suitability as a CF Canada ECI applicant. These individuals will be able to access the ProposalCentral system to directly upload their letters. The applicant will not have access to these letters, but will be able to verify on ProposalCentral that they have been submitted.
- Signatures: Signatures are now completed electronically in the ProposalCentral system. Applicant and institutional representative who can legally bind the institution should log in and sign where indicated. The applicant may need to add access to the proposal for the institutional representative. The application cannot be submitted without PI and institutional representative electronic signatures.

Attachments to be uploaded to ProposalCentral:

- Detailed program proposal (1 document, 5 pages plus table of contents, references and appendices containing data/figures). Please see the detailed instructions for completion within the document template;
- Academic background template should be completed and uploaded to the proposal in pdf format. This template has been updated to exclude funding and publication details, as these are now entered directly into the ProposalCentral system. CVs are not needed for collaborators or personnel proposed to be paid from the successful grant.
- Nominating institution form. Please have a representative of the nominating institution such as the Chair of your Department, Research Director, Dean of Faculty or other appropriate individual in a position of oversight complete this document. Included with this document template, the individual completing the form must also provide a signed letter guaranteeing 0.5 FTE (health professional degree) or 0.75 FTE (PhD degree) protected research time and detailing the appointment including teaching load, clinical and administrative duties, lab/office space, resources (equipment, staff), start-up funds, etc. Upload the completed form and letter as a single pdf file.

The review process

Complete applications submitted by deadline will be subjected to a rigorous peer review process.

(a) Internal Peer Review

Applications will be provided to 3 individuals from the scientific review panel for rigorous review and written critique. Assigned reviewers will as much as possible have knowledge or expertise in the subject matter of the given proposal, within the confines of the scientific review panel membership. The list of internal peer reviewers may or may not include suggestions made by the applicant. The list will generally not include the individuals expressly requested by the applicant to not be selected as reviewer, members of the study team, individuals on the review panel who indicate a direct conflict with a member of the study team or individuals from the same institution as an applicant or co-applicant. Internal peer reviewers are designated as primary reviewer, secondary reviewer and reader:

- (a) Primary reviewer: summarizes the proposal, provides a score for each section as indicated, and answers the following questions:
 - i. Evaluate the applicant with respect to previous training, track record (i.e. publications in peer-reviewed journals, distinctions/awards received, etc.), career goals, future potential to become a top CF scientist/researcher, and quality of reference letters. (Score /5 weighted as 50% of final score).
 - ii. Is the nominating institution providing appropriate and sufficient support/commitment to the applicant? Is the applicant a good fit for the institution and will they receive the support they require to develop into a strong CF researcher? (Score /5 weighted as 15% of final score).
 - iii. Critique the project which should touch on the important areas of an application such as: a. Aims and hypotheses; b. background; c. previous work, including the expertise of the applicant in the proposed research area and how this program/project relates; d. experimental design and methods; and e. data analysis. Evaluate the quality and feasibility of the proposed research program/project to previous studies/research. Is the proposed research program/project appropriate for this type of award? Your score should reflect the comments above and the following: appropriateness of project aims, innovative approach and feasibility. (Score /5 weighted as 25% of final score).
 - iv. If successful, will the proposed work result in a significant advance in the field or benefit to the CF community? The relevance and impact of the project to CF and to the mission of Cystic Fibrosis Canada should be addressed. What is the likelihood of the study resulting in near-term impact (improvements in health and/or quality of life) for people living with CF? (Score /5 weighted as 10% of final score).
 - v. Are the budgetary requests reasonable? Comments and/or items to be flagged? Please list amounts to be reduced and reason, if appropriate. If budget is recommended to be reduced, please indicate the total recommended budget for Year 1, 2 and 3.
 - vi. Do you recommend support of this project? YES, at the budget proposed; YES, at a reduced budget; or NO.

The overall score is the weighted score of the above sections as indicated, and reflects the following descriptors:

Score	Descriptor
4.5 - 5.0	Outstanding
4.0 - 4.4	Excellent
3.5 - 3.9	Very good
3.0 - 3.4	Good
2.0 - 2.9	Average
1.0 - 1.9	Below average
0.0 - 0.9	Not acceptable

- (b) Secondary reviewer: answers the questions indicated for the primary reviewer above and provides a score for the proposal, weighted as described above;
- (c) Reader: reads and is prepared to discuss the proposal; optionally may complete the questions described above and score the proposal.
- (b) Review panel meeting

Internal reviewers meet in person or virtually to discuss the applications. Members of the panel holding conflicts with a member of the study team will not have access to the application, will be excused during the discussion of that application, and will not have the ability to comment or vote. Primary reviewers lead the discussion, with further critique provided by the secondary

reviewer, reader and other members of the review panel. After discussion, the primary and secondary reviewers agree upon a 'consensus score' and scientific review panel members score the proposal within 0.5 of the consensus score. Feedback is provided by the critiques to the applicant to assist improving the application for a future competition. Successful applications are selected based on a high average score from the scientific reviewers, within the confines of the budget allocation for the competition.

Use of funds

(a) Guidelines for expenditure

Early Career awards may be allocated, in accordance with the approved budget, to:

- Personnel salaries/benefits (research assistant(s), technicians, fellows, students, specified other personnel);
- Principal investigator salary in addition to, but not in lieu of, institutional support. Up to a maximum of 40% of the budget may be requested for salary support;
- Materials and supplies (expendables, animals, services);
- Equipment (total not to exceed \$10,000, once per term grant);
- Travel expenses (in accordance with the <u>travel policy</u> detailed in this guide).

Research grants do not provide support for:

- Construction costs;
- · Institutional overheads for laboratory facilities;
- · Institutional overheads and/or indirect costs of research;
- · Costs of clinical care including clinical care for participants of research studies;
- Purchase of equipment in excess of \$10,000;
- Severance pay/packages.
- (b) Clinical Trials

Cystic Fibrosis Canada recognizes the importance of strong support for clinical trials of new drugs or treatments for cystic fibrosis.

In most instances, particularly where new products are involved, funding will emanate from the manufacturer, as a normal component of the drug or product development process. In cases where such funding is not available or appropriate, the organization will entertain applications for limited support.

In no instance will Cystic Fibrosis Canada provide financial support to trials which, by their nature, should be assumed by pharmaceutical companies or equipment manufacturers.

Clinical trial funding from Cystic Fibrosis Canada will be considered for scientific merit, within the context of the overall medical/scientific budget. Given the significant costs associated with clinical trials, and the limited resources of the organization, Cystic Fibrosis Canada support for such initiatives will, of necessity, be of relatively modest proportions and, generally, will be directed to the research component of the study. In most cases, support will also be contingent upon the identification of at least one additional funding partner.

The following components of single- and multi-centre clinical trials will be considered allowable budget items in grant applications: (a) salary support for personnel involved in study design, coordination, monitoring, and analysis, including supplies and equipment needed for sample analysis; (b) meeting and travel expenses associated with study design.

(c) Travel

Early Career awards include a travel component. The organization encourages investigators to attend CF-related meetings in Canada or elsewhere, when advisable according to public health guidelines, to report on their own research and to remain abreast of significant developments in

CF research. Presentation of a paper at a reputable scientific meeting, or attendance at a major symposium or conference related to the awardee's research are considered legitimate uses of travel funds. Please see the full <u>travel policy</u> detailed earlier in this guide.

(d) Funds received from National Support Groups

It is the organization's policy that if funds are donated by National Support Groups directly to a Cystic Fibrosis Canada-funded researcher, or to the hospital/host institution organization in the researcher's name, an equal amount will be deducted from his/her research grant in the following fiscal year.

Terms and conditions

(a) Payment of ECI awards

Award payments will be made at the beginning of each fiscal quarter and will coincide with the fiscal year of most universities: 1 April through 31 March. Partnered awards with other organizations, where offered, may have different payment schedules, as detailed in the Notification-of-Award. Cystic Fibrosis Canada reserves the right to delay, reduce or terminate funding detailed in any award letter.

(b) Unexpended funds

An unexpended balance at the end of each fiscal year and at the end of Cystic Fibrosis Canada support period does not immediately lapse. Grantees will have an additional one fiscal year to use unspent funds. Any funds remaining at the end of this additional one fiscal year period must be returned to Cystic Fibrosis Canada. Additional extensions will not be considered.

(c) Over-expenditure

Any commitment incurred by a grantee in excess of the amount of the ECI award is not the responsibility of Cystic Fibrosis Canada. In the case of multi-year, renewal and terminal grants, over-expenditures may be applied to the budget of the following year(s), up to a ceiling of 10%.

(d) Financial reports

Grantees must provide an annual financial report through <u>ProposalCentral</u>, within 90 days of the end of the award period and a final financial report within 90 days of the end of the award.

(e) Budget increases

The organization does not provide funds for unanticipated increases in cost, or for the expansion of a research project during the term of an award. For multi-year awards, and subject to the availability of funds, a cost-of-living allowance may be added to ECI awards.

(f) Progress reports

Grantees must submit annual progress reports, due within 90 days of the end of the award period, and a final progress report within 90 days of the end of the award. The progress report form is available through <u>ProposalCentral</u>, and the completed document must be uploaded through that platform.

(g) Experimental approvals

All awardees must submit all required institutional approvals for experiments involving human participants and/or animals, and/or induced pluripotent stem cells and/or biohazardous materials, or signed statements indicating for each resource that they are not going to be used for the funded work, in accordance with <u>Cystic Fibrosis Canada's policies (i)-(iv)</u>, by March 31st of the year following that in which the application for a Research award is submitted.

(h) Patents and royalties

All awardees must agree to the terms of Cystic Fibrosis Canada's policy on patents and royalties; please see <u>Cystic Fibrosis Canada policies</u> section.

(i) Indirect costs

Cystic Fibrosis Canada-funded research grants & awards do not provide for institutional overheads and/or indirect costs of research or clinical care.

(j) The Marsha Morton Award for Most Promising Early Career Investigator.

On the recommendation of the organization's scientific review panel, an applicant for an ECI award receiving a high ranking in each annual competition will be awarded the Marsha Morton Award. This annual award is for a one-year term. The award does not carry any supplementary monetary value.

(k) Other Named Research Awards

Cystic Fibrosis Canada may create new named research awards or eliminate existing awards, at any time at its sole discretion.

RESEARCH FELLOWSHIPS

Purpose

A limited number of competitive fellowships are offered by the organization each year for basic or clinical research training, in areas relevant to cystic fibrosis. The goal of fellowship awards is to build capacity in CF research in Canada.

Eligibility

Individuals who hold M.D. or Ph.D. degrees are eligible to apply. Medical graduates should have already completed basic residency training and must be eligible for Canadian licensure.

Initial fellowship applicants who will have completed four or more years of training as of the application deadline, following their PhD or M.D. (post-M.D. clinical training), are not eligible for Cystic Fibrosis Canada Fellowships. Cystic Fibrosis Canada does offer flexibility on calculating years of training post-PhD or post-M.D. given parental leave, medical leave or exceptional circumstances. Applicants must contact Cystic Fibrosis Canada before submitting an application if parental leave, medical leave or exceptional circumstances.

Fellowships are tenable at approved universities, hospitals and research institutes in Canada. Canadian fellowship applicants of exceptional quality requesting funding to study abroad will be considered. Applicants will be expected to demonstrate that comparable training is not available in Canada. In addition, applications will be strengthened by indication of an intention to return to Canada upon the completion of training.

Equitable consideration will be given to fellowship applicants from outside of Canada, who intend to return to their own country on completion of a fellowship.

Term

Initial fellowships will be awarded for a period of two years. Fellows may apply for a one-year renewal. No one may receive more than three years of support under a Cystic Fibrosis Canada Fellowship.

Applications for renewal will compete on equal terms with initial applications.

Applications must be submitted in accordance with the deadline noted in the application schedule.

Tenure of a fellowship will commence on April 1st, the year following the submission of the Research Fellowship application. Upon written request, subject to the approval of Cystic Fibrosis Canada, the start of a fellowship may be delayed up to twelve months. Routine notification will be required from the supervisor by the following February 1st that the fellow plans to proceed through the second year.

Value

The value of a Cystic Fibrosis Canada Fellowship is dependent upon academic qualifications, and research experience. Award levels are reviewed on an annual basis and will correspond with prevailing Canadian rates. New: in addition to a salary component, Research Fellowships will include a research allowance to be used for travel, training or for small research expenses to enable the proposed research.

Criteria

Applications must address Cystic Fibrosis Canada's Core Principles of funding the best science that has the highest probability of making an impact for CF patients. Proposals should be directly relevant not only to CF, but also to the Research Priorities of the CF Community.

We will fund Research Fellows whose research holds a strong alignment to one or more of the following:

- 1. Cure CF with gene or stem cell therapies
- 2. Understand mental health and emotional wellness at different stages
- 3. Improve airway infection detection and treatment

- 4. Prevent or treat CF-related diabetes
- 5. Reduce the treatment burden
- 6. Understand health issues for people living with CF aged 50+
- 7. Predict and prevent pulmonary exacerbations
- 8. Eradicate chronic pseudomonas aeruginosa infections
- 9. Reduce hospitalizations by maximizing the therapies that can be done from home
- 10. Improve GI pain management
- 11. Help people with CF improve and sustain adherence to treatment

If there is a compelling reason why the work is uniquely applicable to the Canadian CF community, despite not aligning to these 11 priorities, it is incumbent upon Cystic Fibrosis Canada to consider funding the work. It is recommended that you discuss the proposal with the Program Director, Research before completing the application.

In general, there will be an emphasis on funding research that is more clinical or translational in nature and with the potential for near term impact for people with CF, but not to the exclusion of more long-term or fundamental basic research projects. Given that access to highly effective CF modulators is anticipated to significantly alter disease progression for the majority of people with CF in Canada, the organization will not be directly supporting research or research fellows in areas such as lung transplantation research but will consider projects that help address the unmet need of individuals who will not benefit from CF modulators, such as those with mutations not responsive to modulators or those for whom modulators have become available too late. It is recommended that if there isn't an obvious clear link in the proposed research to one of the CF Community priorities, that the applicant discuss feasibility of the topic with the Program Director, Research before completing the proposal letter-of-intent (LOI).

Fellowships will be awarded based on the demonstrated merit and potential of the applicant, taking into account the applicant's academic record, research ability, and references. The suitability and excellence of the proposed research environment, along with the intrinsic value and feasibility of the proposed research program, will be important criteria in the evaluation process. In addition, proposed supervisors will be expected to hold an academic appointment.

One supervisor cannot have more than two trainees submit initial fellowship applications to any one competition. Do not rank the applications submitted. Only one application is permissible per applicant.

Application requirements

Applications are considered to be a joint effort of the applicant and the supervisor with whom they intend to study. The applicant should develop the research plan in consultation with the supervisor, however the proposal itself should be written by the applicant. The supervisor may read and provide some guidance on appropriate writing quality and style but should not re-write the document. The applicant should pay particular attention to ensuring that the written quality of the research proposal, and the application overall, are high. Scientific writing ability is important to success in academia, and is an important reflection on the applicant.

Application requirements: Full Proposal

There is no letter-of-intent stage for Research Fellowships. Full applications must be submitted online, in English, through <u>ProposalCentral</u>, no later than the deadline noted in the <u>application</u> <u>schedule</u>. Incomplete and/or late applications will not be considered for funding. Only documents submitted through <u>ProposalCentral</u> will be reviewed.

Full applications submitted on ProposalCentral must contain the following:

• General information including title, have you submitted previously, institutional contacts, keywords and research priorities of the CF community that the proposal aligns to;

- Demographic information on the applicant (this section must be completed but the answers to the questions are optional). The applicant may select "choose not to answer" for any or all questions. The demographic data will be used for internal assessments of our funding programs. The data will only be provided to external individuals in aggregate form, not individual responses. The responses will not be provided to reviewers. This section is new for 2022;
- An ORCID ID is now required to apply. Please agree to link your ORCID profile to your CF Canada
 application. This will allow you to easily import certain information to your application and make
 the application process easier and more integrated.
- Utilization of Canadian CF Registry (CCFR) Data. New for 2023. This section has been
 included to allow researchers to indicate if their application will utilize CF Registry data.
 Interested applicants can contact the CF <u>Registry team</u> if they want information about data in
 the CCFR, how they can leverage CCFR data for research and obtain budget estimates for
 using CCFR data.
- Clinical Trials- New for 2023. This section has been added for researchers to indicate if they are conducting a clinical trial and if they have engaged CF CanACT. <u>CF CanACT</u> can assist in protocol review prior to applying for a grant and can also assist in directing you to suitable clinical sites to conduct your clinical trial.
- Career Goals. Please provide a 3500-character (approx. 1-page) description of your career goals and explain how a Cystic Fibrosis Canada Fellowship would help to advance these goals. (New for 2022: this section has been integrated as a webform in the ProposalCentral application platform);
- Relevant publications. New for 2022: this section has been integrated as a webform in the ProposalCentral application platform. You may add information and upload pdf copies of up to 5 of your recent relevant publications to the application. DOI number or PubMed® ID can be used to automatically add most details.
- References: Applicants must arrange to have two-three letters of recommendation submitted, one of which should be from the applicant's current or most recent supervisor. Other suitable references include your proposed Postdoctoral supervisor (if different from your current or most recent supervisor), your PhD supervisor, a mentor, department chair, Program Head, Dean, or another individual who can adequately comment on your research abilities and suitability as a CF Canada Research Fellowship applicant. The one- to two-page reference letters should indicate the period of time and in what capacity the referee has known the applicant, elaborate on academic capabilities, competence and research potential and address the following: background preparation, motivation, organizational ability, demonstrated skill in the research environment, etc. Please enter the contact information for your selected references. These individuals will be able to access to these letters but will be able to verify on ProposalCentral that they have been submitted.
- Signatures: Signatures are now completed electronically in the ProposalCentral system. Applicant, proposed PI and institutional representative who can legally bind the institution should log in and sign where indicated. The applicant may need to add access to the proposal for the proposed PI and institutional representative. The application cannot be submitted without applicant, proposed PI and institutional representative electronic signatures.

Attachments to be uploaded to ProposalCentral:

- Copy of official transcripts: For initial applications, a copy of transcripts of the applicant's complete academic record from the issuing institution(s) must be uploaded in pdf format. Transcripts are not required for renewal applications.
- Detailed program proposal (1 document, 3 pages plus table of contents, references and appendices containing data/figures). Please see the detailed instructions for completion within the document template;

- Academic background of applicant template should be completed and uploaded to the proposal in pdf format.
- Proposed supervisor academic background template should be completed by the PI and uploaded by the applicant.

The review process

Complete applications submitted by deadline will be subjected to a rigorous peer review process.

(a) Internal Peer Review

Applications will be provided to 2 individuals from the scientific review panel for rigorous review and written critique. Assigned reviewers will as much as possible have knowledge or expertise in the subject matter of the given proposal, within the confines of the scientific review panel membership. The list of reviewers will not include individuals on the review panel who indicate a direct conflict with the applicant or their supervisor or individuals from the same institution as an applicant. Internal peer reviewers are designated as primary reviewer or secondary reviewer:

- (a) Primary reviewer: summarizes the proposal, provides a score for each section as indicated, and answers the following questions:
 - i. Evaluate the applicant with respect to previous training, track record (i.e. publications in peer-reviewed journals, distinctions/awards received, etc.), career goals, future potential to become a top CF scientist/researcher, and quality of reference letters. (Score /5 weighted as 40% of final score).
 - ii. Evaluate the quality of the host laboratory, training environment and proposed supervisor. Research environment and support is scored /5, weighted as 30% of the final score.
 - iii. Evaluate the quality and feasibility of the proposed research project, including the expertise of the applicant in the proposed research area. Does the applicant have the necessary skills and background? Is the proposed research project appropriate for a research fellowship award? If this is a renewal, comment on the progress and productivity of the fellow on this research project. Research proposal appropriateness of aims, innovative approach, feasibility and significance is scored /5 and is weighted as 30% of the final score.

The overall score is the weighted score of the above sections as indicated, and reflects the following descriptors:

Score	Descriptor
4.5 - 5.0	Outstanding
4.0 - 4.4	Excellent
3.5 - 3.9	Very good
3.0 - 3.4	Good
2.0 - 2.9	Average
1.0 - 1.9	Below average
0.0 - 0.9	Not acceptable

- (b) Secondary reviewer: answers the questions indicated for the primary reviewer above and provides a score for the proposal, weighted as described above;
- (b) Review panel meeting

Internal reviewers meet in person or virtually to discuss the applications. Members of the panel holding conflicts with the applicant or their proposed supervisor will not have access to the application, will be excused during the discussion of that application, and will not have the ability to comment or vote. Primary reviewers lead the discussion, with further critique provided by the secondary reviewer and other members of the review panel. After discussion, the primary and secondary reviewers agree upon a 'consensus score' and scientific review panel members score

the proposal within 0.5 of the consensus score. Feedback is provided by the critiques to the applicant to assist improving the application for a future competition. Successful applications are selected based on a high average score from the scientific reviewers, within the confines of the budget allocation for the competition.

Use of funds

Cystic Fibrosis Canada Fellowships are salary awards (\$45,000; increased in 2023) and new for 2022 also include a small research allowance (\$3000). The payment of benefits to Cystic Fibrosis Canada fellows is a matter of host institutional policy.

Terms and conditions

(a) Payment of Fellowship Awards

Award payments will be made at the beginning of each fiscal quarter through the institution at which the award is being held. Fellowship income may be taxable. Cystic Fibrosis Canada reserves the right to delay, reduce or terminate funding detailed in any award letter.

(b) Institutional affiliation

Fellows are normally expected to remain with the same supervisor for the period of the award. If the fellow leaves the university, he or she is expected to relinquish the fellowship.

If the Fellow transfers to another supervisor and/or university, and is continuing the same type of research, the award may be continued, at the discretion of Cystic Fibrosis Canada. Authorization must be sought in advance of such a transfer.

(c) Increases

Fellowship awards are subject to scale increases, in order that they remain in step with prevailing Canadian rates. In addition, subject to the availability of funds, a cost-of-living allowance may be added to the value of a Fellowship.

(d) Allocation of time

During the tenure of the award, the fellow must devote his or her full-time attention to the

research training and fellowship program.

(e) Other fellowship awards

Cystic Fibrosis Canada expects fellows to apply to other appropriate fellowship competitions, including those held by Canada's three research councils during the tenure of the award. If the applicant is successful in their application, they are expected to inform Cystic Fibrosis Canada immediately.

Cystic Fibrosis Canada Fellowships may be held in conjunction with another award. If the second award is less than \$10,000, Cystic Fibrosis Canada will provide the total value of the Cystic Fibrosis Canada Fellowship. If the second award is greater than \$10,000, Cystic Fibrosis Canada will provide top-up funding to a combined value of \$10,000 in excess of the Cystic Fibrosis Canada Fellowship value, or a total of \$50,000 in combined funding (excluding research stipend), whichever is less. Subject to the availability of funds.

(f) Kin Canada Research Fellowship

On the recommendation of the organization's scientific review panel, an applicant for an initial fellowship in the competition receiving high standing will be named the Kin Canada Research Fellow. This award does not carry any supplementary monetary value.

(g) Jennifer and Robert Sturgess Fellowship

On the recommendation of the organization's scientific review panel, an applicant for an initial fellowship in receiving high standing will be named the Jennifer and Robert Sturgess Fellow. This award does not carry any supplementary monetary value.

(h) Progress reports

Fellows should be prepared to submit reports on their activities at intervals, on request from the organization. A final progress report must be submitted within 90 days of the conclusion of the award, whether an application for renewal is submitted or not. The progress report form is available through <u>ProposalCentral</u>.

(i) Leaves of absence, maternity/paternity and sickness

Cystic Fibrosis Canada must be contacted regarding leaves (leave of absence, maternity/ paternity, sickness, etc.).

(j) Patents and royalties

All awardees must agree to the terms of Cystic Fibrosis Canada's policy on patents and royalties; please see <u>Cystic Fibrosis Canada policies</u> section.

SEED GRANTS

Purpose

Seed grants are small, short-term grants focused on a new idea without other funding and without preliminary data. While they can be in the basic science or clinical research area, it is anticipated that most will be basic science in nature given the duration of the award and available budget. Seed grants will support innovative research projects in the CF field, and it is anticipated that most will align to the current list of community health priorities. However, with sufficient justification, seed grants may focus on an emerging area relevant to CF outside of the community health priorities. It is anticipated that seed grants will help researchers generate preliminary data on promising new research areas that they can use to apply to other funders for follow-on funding, or to quickly reach a no-go decision.

Eligibility

Applicants must be <u>independent researchers</u> who hold a full-time academic or research appointment relevant to CF at a Canadian university, hospital or research institute. Under exceptional circumstances, and at the discretion of the Office of Research, seed grant applications from other individuals may be evaluated on a case-by-case basis. In making a decision on whether to permit the application, significant emphasis will be placed on the degree of independence of the applicant, and on the institutional commitments to this individual. Such applications must include a statement from the applicant addressing the issue of salary support during the term of the grant, and the availability of laboratory space; and letters from the Departmental Chair and Dean of Faculty, clarifying the nature and extent of the institutional commitment to the applicant.

There are no limits on the number of co-investigators or collaborators that can be listed, however the level of funding available should dictate the size of the research team. The investigators must have clearly defined roles which are justified. The institution receiving funds indicates where the ultimate responsibility for the grant lies.

Generally, the organization funds research which is carried out in Canada, and the principal investigator must be based at a Canadian institution. While Cystic Fibrosis Canada will fund a collaboration from outside of Canada, funds must be directed through a Canadian institution and Canadian investigators intending to collaborate with individuals from outside of Canada should contact Cystic Fibrosis Canada in advance.

Research projects should be new and should not be currently or previously funded by CF Canada or other funders. The work should not overlap with other funded research of the PI, Co-PI or co-investigator(s).

Term

Seed grants are awarded for a term of one year. They are not renewable.

Value

The amount of a grant will be approved by Cystic Fibrosis Canada with recommendations from the reviewers following a detailed review of the applicant's proposed budget. The maximum budget request is \$50,000. The research project should be designed such that the funds are spent within the one-year term of the award. Unused funds shall be returned to the organization a maximum of 2 months after the end of the award term. Upon application and with justification, a no-cost extension of a maximum of 6 months *may* be granted in rare circumstances where the research has been delayed due to reasons outside of the control of the PI (health related pandemic, delayed REB approval, etc.).

Criteria

All applications must address Cystic Fibrosis Canada's Core Principles of funding the best science that has the highest probability of making an impact for CF patients. Cystic Fibrosis Canada includes community stakeholders in the review process to provide their perspective on the impact of the

proposed research on those living with CF. Proposals should be directly relevant to CF, and generally also to the Research Priorities of the CF Community.

We will fund research with strong alignment to one or more of the following:

- 1. Cure CF with gene or stem cell therapies
- 2. Understand mental health and emotional wellness at different stages
- 3. Improve airway infection detection and treatment
- 4. Prevent or treat CF-related diabetes
- 5. Reduce the treatment burden
- 6. Understand health issues for people living with CF aged 50+
- 7. Predict and prevent pulmonary exacerbations
- 8. Eradicate chronic pseudomonas aeruginosa infections
- 9. Reduce hospitalizations by maximizing the therapies that can be done from home
- 10. Improve GI pain management
- 11. Help people with CF improve and sustain adherence to treatment

If there is a compelling reason why the work is uniquely applicable to the Canadian CF community, despite not aligning to these 11 priorities, it is incumbent upon Cystic Fibrosis Canada to consider funding the work. If your project is not relevant to the community research priorities, you should provide <u>clear justification</u> as to why it should still be funded through the seed grants competition.

In general, there will be an emphasis on funding research with the potential for near term impact for people with CF, but not to the exclusion of more fundamental basic research projects. Given that access to highly effective CF modulators is anticipated to significantly alter disease progression for the majority of people with CF in Canada, the organization will not be directly supporting areas such as lung transplantation research but will consider projects that help address the unmet need of individuals who will not benefit from CF modulators, such as those with mutations not responsive to modulators or those for whom modulators have become available too late.

Decisions concerning the support of any given award are made on the basis of the following considerations:

- The quality and scientific merit of the research proposal;
- The relevance of the proposal to the CF Community Research Priorities;
- The impact of the research for people with CF, including how near-term those impacts may potentially be to benefiting people with CF;
- The translational potential for the research;
- The qualifications of the principal investigator, along with any co-investigator(s) and/or collaborator(s) named in the application, to conduct the proposed research;
- The availability to the applicant(s) of the resources necessary to conduct the proposed research;
- The degree of overlap with other operating grants held by the applicant(s);
- Appropriateness of the proposed work to the Seed grants competition; and
- The potential of the proposed work to produce significant results in the field of CF.

Application requirements: Full Proposal

There is no letter-of-intent to apply to the Seed grants competition. All Seed grant applications must be submitted online, in English, through <u>ProposalCentral</u>, no later than the deadline noted in the <u>application schedule</u>. Incomplete and/or late applications will not be considered for funding. Only documents submitted through <u>ProposalCentral</u> will be reviewed.

Investigators are eligible to hold more than one Seed grant. It is a requirement that the focus of any additional Seed grant application be clearly delineated. The specific aims of an additional Seed grant should represent new approaches to the CF problem, and not an expansion of an existing research program.

Full applications submitted on <u>ProposalCentral</u> must contain the following:

- Name and address of principal investigator;
- Name(s) and address(es) of co-investigator(s) and collaborator(s);
- Title of Seed grant application;
- An ORCID ID is now required to apply. Please agree to link your ORCID profile to your CF Canada
 application. This will allow you to easily import certain information to your application and make
 the application process easier and more integrated;
- Keywords of relevance to the proposal;
- 1500 character technical summary of the proposed research in scientific language;
- 1500 character lay summary of the proposed research in non-scientific, everyday language;
- One or more CF Community Research Priority areas of relevance to the Proposal;
- In a maximum of 2000-characters (approximately 300 words), in non-scientific, everyday language at no greater than a Grade 10 level, describe how the proposal aligns with the selected CF Community Research Priority (Priorities), and/or how the study has a particular Canadian relevance. If your proposal doesn't directly align to one of these priorities but you feel it is in an area that should be supported, please describe how your proposal is relevant to CF and why it should be funded. This section should also describe the significance of the impact of the work, if successful, on the lives of CF patients. This is one of the most important sections of the proposal and should be provided to at least two individuals without a scientific background to read, to ensure that it is understandable by a lay audience;
- Suggested reviewers and name(s) of any reviewer(s) to whom you would prefer that the application not be sent. Please include at least 3 reviewer suggestions.
- Demographic information on the applicant. This section must be completed but the answers to the questions are optional. The applicant may select "choose not to answer" for any or all questions. The demographic data will be used for internal assessments of our funding programs. The data will only be provided to external individuals in aggregate form, not individual responses. The responses will *not* be provided to reviewers;
- EDI—study recruitment section. In this new section, only if the study will recruit participants, the applicant should describe in a maximum of 1,500 characters the equity, diversity and inclusion considerations for recruitment of participants. Also indicate how you will integrate sex and gender into your recruitment and analysis, if applicable. Studies that do not involve participant recruitment should mark this response N/A. CIHR has published a significant set of resources related to EDI considerations here: https://cihr-irsc.gc.ca/e/52553.html. It is recommended that you review these materials before completing this section;
- EDI—study team. In this new section, the applicant should describe in a maximum of 1,500 characters the equity, diversity and inclusion considerations for recruitment of study team members, including trainees. CIHR has published a significant set of resources related to EDI considerations here: <u>https://cihr-irsc.gc.ca/e/52553.html</u>. It is recommended that you review these materials before completing this section;
- Budget detail. A budget worksheet attachment is provided for your convenience and may be used if you wish to help develop your budget plans. Please do not upload this document. All budget details and justification must be entered directly into ProposalCentral. All budgets should be developed to an even multiple of \$100 per year and a maximum of \$50,000;
- Budget justification-should align with research proposal detail including all milestones and

deliverables;

- Sources of funding. You may easily add any grant previously added to your profile by clicking the check box. Otherwise add a description for each existing grant/source of funding and any pending/applied grants. Indicate the amount of overlap with the current proposal;
- Relevant publications. You may add information and upload pdf copies of up to 5 of your recent relevant publications to the application. DOI number or Pubmed ID can be used to automatically add most details.
- Shared publication criteria/agreement: If this project is multi-centered and/or international, please indicate the shared publication criteria/agreement. Otherwise enter N/A into the field;
- Conflict of Interest Disclosure Statements: For the purpose of complete transparency, we ask that the principal investigator declare for themselves and all co-investigators and collaborators all conflicts of interest, potential conflicts of interest and perceived conflicts of interest, or expressly indicate that there are no such conflicts. Conflicts of interest may include, but are not limited to, payment for consulting services or sitting as a member of an advisory board for a for-profit company where you are proposing to employ their products or services, for example.
- Signatures: Signatures are completed electronically in the ProposalCentral system. Applicant and institutional representative who can legally bind the institution should log in and sign where indicated. The applicant may need to add access to the proposal for the institutional representative. Any Co-PI should also sign at the appropriate place. The application cannot be submitted without PI and institutional representative electronic signatures.

Attachments to be uploaded to ProposalCentral:

- Detailed program proposal. Please use the word template provided on ProposalCentral and follow the instructions directly on the template. Two pages maximum are permitted for text and figures/tables. One additional page is permitted for references;
- Signature pages, CVs and reprints of publications should not be uploaded.

The review process

Complete applications submitted by the deadline will be subjected to a rigorous peer review process.

(a) Scientific Peer Review

Applications will be provided to 2-3 scientific reviewers for rigorous review and written critique. Assigned reviewers will as much as possible have knowledge or expertise in the subject matter of the given proposal. The list of peer reviewers may or may not include suggestions made by the applicant. The list will generally not include the individuals expressly requested by the applicant to not be selected as reviewer, members of the study team, individuals who indicate a direct conflict with a member of the study team or individuals from the same institution as an applicant or co-applicant.

Each reviewer summarizes the proposal, provides a score for the proposal, and answers the following questions:

- i. Does the team have the appropriate expertise to successfully carry out the proposed research and achieve the research objectives?
- ii. Are the research aims appropriate? Do they represent a suitable avenue of CF research? Is there sufficient institutional support and resources available to carry out the proposed research?
- iii. Is the proposal original and sufficiently innovative? Are there better ways to address the problem? Does it challenge existing paradigms in research or current clinical practices, or does it address a novel hypothesis or a critical barrier to advance the CF field? Is the research new or an extension to an already funded research project?
- iv. Is the research plan, including the design, methods, and analyses, adequately developed,

well integrated, well-reasoned, and appropriate to the aims of the project? Are the timelines feasible? Are the outcomes clearly defined? Does the PI acknowledge potential problem areas and consider alternative tactics?

- v. If successful, will the proposed work result in a significant advance in the field or benefit to the CF community? The relevance and impact of the project to CF and to the mission of Cystic Fibrosis Canada should be addressed. What is the likelihood of the study resulting in near-term impact (improvements in health and/or quality of life) for people living with CF?
- vi. Are the budgetary requests reasonable? YES or NO. Comments and/or items to be flagged? Please list amounts to be reduced and reason, if appropriate. If the budget is recommended to be reduced, please indicate the total recommended budget.
- vii. Do you recommend support of this project? YES, at the budget proposed; YES, at a reduced budget; or NO.

Each reviewer scores the proposal out of 5.0, which equally reflects the applicant's track record of success, the appropriateness of the project aims, the innovativeness of the approach, feasibility of the proposal and significance/ impact to CF patients. The score reflects the following descriptors:

Score	Descriptor
4.5 - 5.0	Outstanding
4.0 - 4.4	Excellent
3.5 - 3.9	Very good
3.0 - 3.4	Good
2.0 - 2.9	Average
1.0 - 1.9	Below average
0.0 - 0.9	Not acceptable

(b) Community Review

Applications will be provided to 2-3 community reviewers (people with CF or parents of someone with CF) who will each review the proposal, with a major emphasis on the 'lay' sections. Community reviewers will provide a score out of 5 and provide a written critique, answering the following questions:

- i. Were the lay language sections written in language that the average member of the CF community (without a science degree) could understand? Was it well-written or confusing? Why? How could the applicant improve this section next time so that it is easier to understand or better describes what they are proposing?
- ii. Does the research sound interesting and important? Is it exciting for members of the community to hear about?
- iii. Will there be direct benefits to CF patients if the project is successful? If the project deals with subjects that are less patient-focused and more about understanding the basic science of CF, do you think if successful it will significantly improve our understanding? Will the benefits that come from the proposed research be achieved in the near-term or will it take a long time for CF patients to benefit from this research?
- iv. If the application proposes to involve patients in the research, do you think patients will participate in what is planned? Would it be easy for most patients to take part and would they think it is worth their time? Is there a better way to make things easier for the participants? If the authors aren't proposing to involve patients, is there a way that patients could be included that the researchers didn't think of?
- v. What patient priorities do you think the proposal would address? Why? It is ok if your thoughts are different than what the researcher thought.

- vi. Do you think the research is aligned close enough to the community priorities? If the work doesn't align directly to any priority, do you feel the work is important specifically to Canadian CF patients? If the proposed work doesn't align to any priorities, do you think it is still important work that should be funded?
- vii. Do you see any problems or reasons why this project should not be funded?
- viii. If funding is limited and we can only fund a few good projects, is this one you would most like to see funded?

CF Canada will draw from the recommendations of both the scientific peer reviewers and the community reviewers to select the successful applications. No application that is not scientifically sound will be funded, nor will any application that is not considered relevant by the community reviewers.

Use of funds

(d) Guidelines for expenditure

Grants are awarded in global amounts. Minor reallocations between budget categories are permitted, provided that the global budget is not exceeded. The current maximum allowable annual budget for Seed grants is \$50,000 CAD for 1 year. Budget requests should be made in amounts rounded to an even \$100, i.e. a request could be submitted for \$49,500, but should not be submitted for \$49,498 or \$49,501.56.

Funds from Seed grants may be allocated, in accordance with the approved budget, to:

- Personnel (research assistant(s), technicians, fellows, students, specified other personnel);
- Materials and supplies (expendables, animals, services);
- Travel (in accordance with the travel policy detailed in this guide);
- For applicants proposing to provide funds from this grant to international collaborators: While Cystic Fibrosis Canada will fund a collaboration from outside of Canada, funds must be directed through a Canadian institution. Applicants proposing to provide any funds from this grant to international collaborators must briefly describe in the budget justification section of the application why an international component is necessary for the project. Cystic Fibrosis Canada will allow up to \$20,000 per Seed grant for international collaborators, if the request is sufficiently justified.

Seed grants do not provide support for:

- · Construction costs;
- · Institutional overheads for laboratory facilities;
- · Clinical care, including clinical care for study participants;
- · Institutional overheads and/or indirect costs of research;
- Purchase of equipment;
- Principal investigator salary;
- Severance pay/packages.

Terms and conditions

(a) Payment of grants

The Seed grant award term will be July 1 – June 30, the following year. Grant payments will be made as a single payment in July following initiation of the award, provided that all required documentation is received and accepted by the deadline provided in the award letter. Cystic Fibrosis Canada reserves the right to delay, reduce or terminate funding detailed in any award letter.

(b) Unexpended funds

An unexpended balance at the end of the award term must be returned to Cystic Fibrosis Canada and is due within 2 months of the award end date.

(c) Over-expenditure

Any commitment incurred by a grantee in excess of the amount of the Seed grant is not the responsibility of Cystic Fibrosis Canada.

(d) Financial reports

Grantees must provide a financial report through <u>ProposalCentral</u>, within 60 days of the end of the grant period. Reports will not be accepted by email.

(e) Budget increases

The organization does not provide funds for unanticipated increases in cost, or for the expansion of a research project during the term of a grant.

(f) Progress reports

Grantees must submit a final progress report within 60 days of the end of the project. The progress report form is available through <u>ProposalCentral</u>, and the completed document must be uploaded through that platform. Reports will not be accepted by email.

(g) Experimental approvals

All grantees must submit all required institutional approvals for experiments involving human participants and/or animals, and/or induced pluripotent stem cells and/or biohazardous materials, or signed statements indicating for each resource that they are not going to be used for the funded work, in accordance with <u>Cystic Fibrosis Canada's policies (i)-(iv)</u>, by the deadline detailed in the award letter.

(h) Patents and royalties

All grantees must agree to the terms of Cystic Fibrosis Canada's policy on patents and royalties; please see <u>Cystic Fibrosis Canada policies</u> section.

(i) Indirect costs

Cystic Fibrosis Canada-funded Seed grants do not provide for institutional overheads and/or indirect costs of research or clinical care.

(j) Named Awards

Cystic Fibrosis Canada may create named Seed grant awards or eliminate existing awards, at any time at its sole discretion.

TEAM GRANTS

Purpose

Team grants fund collaborative, integrated research teams working on innovative projects aligned with CF Canada community health priorities. These grants address specific research questions or challenges outlined in the grant request for applications. Team grants are expected to have a significant impact on CF patients within or in the near term after the four-year duration of the award.

For 2023, the CF community health priority area chosen is:

Improve airway infection detection.

Background

Highly effective modulator therapies (HEMTs) have led to significant clinical improvements for many Cystic Fibrosis patients. However, despite the benefits of HEMTs, airway infections remain a substantial challenge for both CF patients benefiting from these therapies and those who are not. Currently the gold standard for monitoring airway infections and development of pulmonary exacerbations is analysis of patient sputum samples. Individuals on HEMTs typically produce significantly less sputum, and for some it can be challenging to produce a sputum sample on demand in the clinic. Collection of sputum can also be particularly difficult for younger CF patients. Novel airway infection detection strategies are needed to assist with routine clinical airway infection surveillance in CF patients and for monitoring pulmonary exacerbations in clinical practice. It is important that any new detection technologies undergo evaluation against the current gold standard of sputum analysis.

For this funding Opportunity Relevant Research Areas are:

- Biomarkers of airway infection
 - Identification of novel biomarkers of general airway infection of one or more specific pathogens of concern for CF using breath, blood, urine, saliva, skin or other patient samples
 - o Validation of new biomarkers for existing, improved or new devices
 - Validation of minimally invasive qualitative or quantitative diagnostics of biomarkers in clinical patient samples
 - o Application of biomarker testing to individuals on modulators or not
 - Assessment of the impact of one or more biomarkers on monitoring, treatment, or eradication of airway infections
 - o Validation of one or more biomarkers as a clinical trial outcome measure

Out of scope for this team grant:

- Improvement of protocols for collection of sputum samples that have no links to improving diagnostic methodologies or new biomarkers
- Studies of biomarkers that have no clear or proposed link to detection or quantitation of airway infection
- Development or improvement of diagnostic devices.

Eligibility

Teams must have a minimum of four (4) members (inclusive of PI, Co-PIs and co-investigators) from at least two different institutions. There may be a maximum of 2 Co-PIs. PI (or Co-PIs) must be (an) independent researcher(s) who hold(s) a full-time academic or research appointment relevant to CF at a Canadian university or hospital. This same eligibility criterion regarding a faculty appointment applies to any named co-investigator residing in Canada. Up to a maximum of 1/3 of the team (inclusive of the PI, Co-PIs and co-investigators) may be from outside of Canada, but must hold a comparable faculty appointment in their country of employment (i.e. a team with one (1) PI and five (5) co-investigators must have a Canadian PI, is permitted a maximum of two (2) co-investigators employed in a country outside of Canada and must have a minimum of three (3) Canadian co-investigators).

Teams are encouraged to include early career researchers (as co-investigator, PI or Co-PI) with appropriate, relevant expertise on the topic of the research project. Teams are expected to provide leadership and mentorship opportunities for all trainees and early career researchers on the project, to help develop the next generation of leaders in CF research. Details on the mentoring plans for trainees and early career researchers included on the team are required.

There are no limits on the maximum number of co-investigators or collaborators that can be listed. All team members must have clearly defined roles that are justified.

Teams should include, as collaborators, members of the CF community to help advise on the direction of the project (<u>https://cihr-irsc.gc.ca/e/48413.html</u>). A meaningful number of CF community perspectives should be considered, as appropriate for the project. More clinically focused studies may require more community member consultation and guidance than many basic science research projects, but in all cases advice from community members is required and anticipated to be critical for ensuring relevance and impact for the CF community.

Teams should consider <u>equity</u>, <u>diversity</u>, <u>and inclusion</u> principles in developing their study teams, both for scientists and CF community members.

Teams are encouraged to include industry partners, who will bring benefit to the project and play a valuable role in guiding the research towards a commercially viable product or bringing a product into clinical practice. Industry partners cannot directly receive funds from the project budget. Trainees or academic technicians paid through the project budget may be placed with the industry partner for a portion of the project to aid in technology transfer and development activities geared towards commercialization. Industry partners are expected to contribute actual or *in-kind* funding towards the project. In cases where industry partners are involved, a letter of support from the industry partner is required and should outline the nature of the support provided. A statement outlining the ownership and interests related to intellectual property (IP) is also required. Note the CF Canada policies on patents and IP for funded research projects in the <u>2023 Grants & Awards guide</u>.

Where industry partners are not directly involved in the project, the project team is encouraged to engage with potential partners early in the project to investigate future partnerships and next steps for the product, technology, or output from the team grant.

Teams are encouraged to include knowledge users/decision makers as appropriate to assist with adoption/uptake for the output from the team grant.

Term

Team grants may have a term of 1-4 years. It is anticipated that the nature of the research question that is the topic of the request for applications will normally dictate a study term at or near the maximum. Renewal of team grants is considered on a case-by-case basis. To apply for renewal, a written submission is required near the end of the final year of the award and upon

recommendation of the scientific advisory board. All extensions are subject to CF Canada approval and availability of funds by CF Canada and/or co-funding partner(s). More details will be provided to the successful team in advance of any such extension submission deadline.

Value

The total amount available for this funding opportunity for 2023 is **\$2,000,000**, enough to fund one team grant.

CF Canada anticipates awarding up to one (1) team grant in any offering and anticipates offering a team grant opportunity no more frequently than every second year. The amount of a team grant will be approved by Cystic Fibrosis Canada with recommendations from the scientific review panel following a detailed review of the team application proposed budget. The maximum budget request is \$500,000/year, for up to 4 years.

In accordance with policy, Cystic Fibrosis Canada-funded team grants do not provide for institutional overhead and/or indirect costs of research or clinical care. Construction/renovation expenses are not valid budget items. Equipment costs normally should not exceed 5% of the total budget (but may be included fully in year 1) and must be justified as being vital to the proposed research. Travel expenses to attend conferences and/or training opportunities are valid and must comply with the CF <u>Canada travel expense</u> <u>policy</u>. These costs should not exceed \$3000/year/person directly involved in the project and must be clearly integral to the proposed research.

A maximum of 35% of funding for the project may be directed to team members outside of Canada. The institution of the PI, or one designated Co-PI will receive all funds and disburse in accordance with the proposal budget, scientific advisory board requirements, CF Canada policies and restrictions and the restrictions of the co-funder(s). The institution receiving funds will hold ultimate financial accountability for the entire team grant. Appropriate levels of budget allocation to scientific collaborators are permissible, in line with their role in the project. Community member collaborators may be directly compensated as appropriate to their role on the project (for guidance: https://cihr-irsc.gc.ca/e/48413.html).

Co-funders

For the 2023 Team Grant competition, the Cystic Fibrosis Foundation (<u>CFF</u>) will act as a co-funding partner. The award will be administered by CF Canada, with all funding flowing directly from CF Canada.

Scientific Advisory Board

CF Canada will establish a scientific advisory board (SAB) for the successful application. The SAB will be chaired by the Chief Scientific Officer (CSO) of CF Canada, or their designate. The board will consist of 3-4 knowledgeable scientific advisors who are at arm's length from the project and team, as well as up to 3 people with CF or parents of people with CF to review and report on the progress of the project. It will also provide advice and guidance to the study team and help ensure that the project achieves its stated objectives. It is anticipated that the SAB will meet (virtually) with the study team a minimum of once annually throughout the term of the project, and at any major decision point in the work. More details will be communicated to the successful applicant team.

Criteria

All applications must address Cystic Fibrosis Canada's Core Principles of funding the best science that has the highest probability of making an impact for CF patients. Cystic Fibrosis Canada actively involves community members in the review process to provide their perspective on the impact of the proposed research on those living with CF. Applications should be directly relevant not only to CF, but also to the community health priority identified and the detailed research question(s) identified above.

Decisions concerning the amount and term of any given award are made based on the following considerations:

- The quality and scientific merit of the research proposal;
- The relevance of the proposal to the selected CF community health priority area and the research areas identified by CF Canada for the current opportunity;
- The impact of the research on people with CF, including how near-term those impacts may potentially be to benefiting people with CF;
- The translational potential for the research;
- The qualifications of the principal investigator, along with any co-investigator(s) and/or collaborator(s) named in the application, to conduct the proposed research;
- The meaningful inclusion of team members, including CF community members and early career researchers, and consideration of EDI principles in developing the team;
- The extent to which the proposal addresses how the team will engage with and leverage partners and other groups named in the application;
- The availability to the applicant(s) of the resources necessary to conduct the proposed research;
- The potential of the proposed work to produce significant results in the field of CF.

Application Process

The application process for the team grant funding opportunity is comprised of **three competitive stages.** Letter-of-Intent, Full Application, Panel Presentation.

Application requirements: Letter-of-Intent

All applicants, must advise Cystic Fibrosis Canada by the deadline noted in the key dates table above of their intent to apply for funding by completing a letter-of-intent to apply (LOI), in English, on <u>ProposalCentral</u> with the following information:

- Name and address of PI or Co-PIs;
- Name(s) and address(es) of co-investigator(s) and collaborator(s) (we recognize that there may be some changes to the study team at the full application stage);
- Title of grant application;
- 2500-character technical summary of the proposed research in scientific language with a clear link to the selected CF community health priority area and research area(s) in the request for applications;
- 2000-character lay summary of the proposed research in non-scientific, everyday language at a level no greater than Grade 10 and a clear link to the selected CF community health priority area and research area(s) in the request for applications;
- Keywords of relevance to the proposal;
- A minimum of five (5) suggested reviewers and name(s) of any reviewer(s) to whom you would prefer that the application not be sent.

Incomplete and/or late LOI applications will not be considered. Only documents submitted through <u>ProposalCentral</u> will be reviewed. CF Canada may triage LOI applications that do not align with the

intent and requirements of this request for proposals without further scientific review. While the PI and most of the proposed research team are anticipated to remain intact from LOI to full proposal, a team whose LOI is approved may add team members. The applicant may also make some modifications to the proposed research program and to the lay and technical summaries; however the basic premise of the proposal should remain unchanged from LOI to full application.

Application requirements: Full Application

LOIs will be reviewed, and a subset of teams will be invited to submit full applications. Full applications for approved LOI topics must be submitted online, in English, through <u>ProposalCentral</u>, no later than the deadline noted in the key dates table above. Incomplete and/or late applications will not be considered for funding. Only documents submitted through <u>ProposalCentral</u> will be reviewed.

Investigators are eligible to hold other CF Canada funding while participating on a team grant. It is a requirement that the focus of any additional grant be clearly delineated from the team grant proposal.

Full applications submitted on ProposalCentral must contain the following:

- Updated carry-over information from the LOI submission (including revised title, study team members, technical abstract, lay abstract, keywords, research priority areas and suggested reviewers);
- A maximum 2500-character description of how the proposal aligns with the selected CF community health priority area and question(s) of focus of the team grant opportunity, in non-scientific, everyday language at a level no greater than Grade 10. This section should also describe the significance of the impact of the work, if successful, on the lives of CF patients. This is one of the most important sections of the proposal and should be provided to at least two individuals without a scientific background to read, to ensure that it is understandable by a lay audience;
- Demographic information on the PI (or selected Co-PI who will be financially responsible for the team). This section must be completed but the answers to the questions are optional. The applicant may select "choose not to answer" for any or all questions. The demographic data will be used for internal assessments of our funding programs. The data will only be provided to external individuals in aggregate form, not individual responses. The responses will not be provided to reviewers;
- An ORCID ID is now required to apply. The PI or designated Co-PI should agree to link their ORCID profile to their CF Canada application. This will allow you to easily import certain information to the application and make the application process easier and more integrated.
- 3500-character (approx. 1 page) research proposal summary, touching on the main points of the detailed proposal, including rationale, hypothesis/objectives, specific aims, and impact of the proposed research. Describe the deliverables that will be realized by the end of the project that have the potential to be translated into significant promise and benefit for people living with CF.
- Team research expertise report: In a maximum of 7000-characters (approx. 2 pages), teams must describe their past research efforts and expertise, and how these provide the necessary knowledge to conduct the currently proposed studies. Describe briefly how each team member contributes to the collective knowledge and expertise of the team. This section is entered directly into ProposalCentral rather than uploading a separate completed template document;
- Equity, Diversity and Inclusion (EDI)—study recruitment section. In this section, only if the study will recruit participants, the applicant should describe in a maximum of 1,500 characters the equity, diversity, and inclusion considerations for recruitment of participants. Also indicate how you will integrate sex and gender into your recruitment and analysis, if applicable. Studies that do not involve participant recruitment should mark this response N/A. CIHR has published a significant set of resources related to EDI considerations here: https://cihr-example.com

<u>irsc.gc.ca/e/52553.html</u>. It is recommended that you review these materials before completing this section;

- EDI—study team. In this section, the applicant should describe in a maximum of 1,500 characters the equity, diversity, and inclusion considerations for recruitment of study team members, including trainees. CIHR has published a significant set of resources related to EDI considerations here: <u>https://cihr-irsc.gc.ca/e/52553.html</u>. It is recommended that you review these materials before completing this section;
- Utilization of Canadian CF Registry (CCFR) Data. This section has been included to allow researchers to indicate if their application will utilize CF Registry data. Interested applicants can contact the CF <u>Registry team</u> if they want information about data in the CCFR, how they can leverage CCFR data for research and obtain budget estimates for using CCFR data;
- Clinical Trials. This section has been included for researchers to indicate if they are conducting a clinical trial and if they have engaged CF CanACT. <u>CF CanACT</u> can assist in protocol review prior to applying for a grant, and can also assist in directing you to suitable clinical sites to conduct your clinical trial;
- 2000 character lay summary of the proposed research in non-scientific, everyday language;
- Team management and governance plan: in a maximum of 7000 characters (approximately 2 pages), describe how the team will be effectively managed and integrated. Describe the roles and responsibilities of the PI and/or Co-PIs as well as any project managers or activity leaders. Provide details on the process for decision-making, how disputes will be resolved and how momentum will be maintained on the project. Ensure there is a clear connection between the management plan and the activities described in the Gantt chart. Describe how early career researchers will be integrated into the team and if/how they will be involved in the management of the team. Describe any mentoring/training plans for early career researchers and trainees. Describe how the CF community representatives will be meaningfully incorporated into the team and how their views will impact the design and conduct of the research. The successful team will be advised by a scientific advisory board (SAB) that will meet regularly with the team to review the team's progress and advise on the current and future directions. Describe how the team plans to interact with the SAB and take advantage of their guidance and expertise to achieve success.
- Adoption and/or commercialization description: in a maximum of 7000 characters (approximately 2 pages) describe how the work that the team is proposing will be advanced towards impact on CF patients or clinical practice. Over what time frame? If the team is proposing to develop a new therapy, or validation of a device, or product, describe how the invention will progress towards commercialization. Who will you involve to assist in the process? How will you fund the next steps in development? If you are proposing a new process, tool, or care model, how will you achieve adoption into clinical practice? Describe the role of knowledge users/decision makers as appropriate. Describe your knowledge translation efforts.
- Budget detail. For your convenience, we have included a budget worksheet attachment that you can utilize to aid in developing your budget plans. However, please note that you should not upload this document. All budget details and justifications must be entered directly into ProposalCentral. When creating your budget, ensure that it is rounded to an even multiple of \$100 per year and does not exceed \$500,000 per year.
- Budget justification—should align with Gantt Chart and Research proposal details including all milestones and deliverables. The budget justification should clarify the exact level of funding provided to each study team member and the total funding for the team that will be directed outside of Canada;
- Sources of funding. This section has been integrated as a webform in the ProposalCentral application platform. You may easily add any grant previously added to your profile by clicking the check box. Otherwise add a description for each existing grant/source of funding and any pending/applied grants. Indicate the amount of overlap with the current proposal and a justification.

- CVs for the PI and Co-PIs (maximum 10 pg.).
- Relevant publications. This section has been integrated as a webform in the ProposalCentral application platform. You may add information and upload pdf copies of up to 10 of your team members' recent relevant publications to the application. DOI number or Pubmed ID can be used to automatically add most details.
- Shared publication criteria/agreement: Please indicate the plan the team has agreed to on how publication authorship will be determined/shared.
- Conflict of Interest Disclosure Statements: For complete transparency we ask that the principal investigator declare for themselves and all co-investigators and collaborators all conflicts of interest, potential conflicts of interest and perceived conflicts of interest, or expressly indicate that there are no such conflicts for each study team member. Conflicts of interest may include, but are not limited to, payment for consulting services or sitting as a member of an advisory board for a for-profit company where you are proposing to employ their products or services, for example.
- Signatures: Signatures are now completed electronically in the ProposalCentral system. PI and institutional representatives who can legally bind the institution should log in and sign where indicated. The applicant may need to add access to the proposal for the institutional representative. Any Co-PI should also sign at the appropriate place. The application cannot be submitted without PI and institutional representative electronic signatures. Any ProposalCentral cover pages for ink signatures are no longer required or accepted. Only electronic signatures will be accepted.

Attachments to be uploaded to ProposalCentral:

- Detailed program proposal (1 document, maximum 15 pages plus table of contents, references and appendices containing data/figures);
- Gantt Chart. The Gantt Chart is used to list all activities, milestones and deliverables on the project and the anticipated time required to complete activities and the dates for achieving deliverables and milestones. Activities listed on the Gantt chart should indicate which team members are responsible and align to the research proposal and the related budget line item. Complete in excel format and upload as a PDF document (remove instructions tab before uploading);
- Optional: Letters of support from co-investigators, collaborators and partners in PDF format. Include a maximum of 5; Letters should include specific incremental cash or in-kind contributions being provided in support of the proposed research. For industry partner's the letter should outline the nature of the support provided. A statement outlining the ownership and interests related to intellectual property (IP) is also required.
- Signature pages and reprints of publications should no longer be uploaded.

Application requirements: Presentation

Top ranked teams at the Full Application stage will be invited to the Presentation stage. Teams will be expected to consider the review panel feedback and develop a presentation for the panel on the final project. The presentation will be conducted virtually via Zoom or Teams and should last approximately 45 minutes. Following the presentation, the team should be ready to answer questions for about 30 to 45 minutes. Questions may cover various aspects of the proposal, such as the work plan, team integration, budget allocations, and if applicable, the commercialization plan. Additional information regarding the presentation stage will be provided to the invited team(s).

The LOI review process

CF Canada will initially perform a relevance review to identify eligible applications that are in alignment with the purpose, research

areas and criteria of the funding opportunity. Complete LOIs submitted by the deadline and meet the requirements and objectives of this call will be subjected to a rigorous peer review process.

(e) External Peer Review

Applications will be provided to approx. 5 international scientific experts in a relevant field of research and approx. 5 community reviewers. The list of external peer reviewers may or may not include suggestions made by the applicant. The list will generally not include the individuals expressly requested by the applicant to not be selected as reviewer, individuals who are part of the study team, or individuals from the same institution as an applicant or co-applicant. External peer reviewers comment on the strengths and weaknesses of the proposal, provide an overall impression and a recommendation on whether the application should advance to the full application stage. CF Canada will determine which applications advance based on the advice of the reviewers.

The Full Application review process

Complete applications submitted by the deadline by teams invited to submit full applications will be subjected to a rigorous peer review process.

(a) External Peer Review

Applications will be provided to international experts in a relevant field of research. The list of external peer reviewers may or may not include suggestions made by the applicant. The list will generally not include the individuals expressly requested by the applicant to not be selected as reviewer, individuals who are part of the study team, or individuals from the same institution as an applicant or co-applicant. External peer reviewers comment on the strengths and weaknesses of the proposal, provide an overall impression and a recommendation on whether the application should be funded as written.

(b) Internal Peer Review

Applications will be provided to scientific reviewers for rigorous review and written critique. Assigned reviewers will, as much as possible, have knowledge or expertise in the subject matter of the given proposal. The list of internal peer reviewers may or may not include suggestions made by the applicant. The list will generally not include the individuals requested by the applicant to not be selected as reviewer, members of the study team, individuals who indicate a direct conflict with a member of the study team or individuals from the same institution as an applicant or co-applicant.

- (a) Internal reviewers: summarize the proposal, provide a score for the proposal, and answer the following questions:
 - i. Describe the track record of the principal investigator, co-investigators, and collaborators. Does the project's team have an appropriate record of success given the stage of their career(s)? Does the team have the appropriate expertise to successfully conduct the proposed research and achieve the research objectives? Has the team adequately described previous studies that have prepared them to undertake the current proposal? Does the team seem integrated? Are there key participants missing? Is the role given to early career researchers appropriate and valuable? Has the PI considered EDI principles in developing the team?
 - ii. Is the proposed team management and governance structure sound? Are the roles and responsibilities and processes clear and appropriate? Is the role of people with CF well described and integrated in the team?
 - iii. Are the research aims appropriate? Do they represent a suitable avenue for CF research? Is there sufficient institutional support and resources available to conduct the proposed research?
 - iv. Is the proposal original and sufficiently innovative? Are there better ways to address the

problem? Does it challenge existing paradigms in research or current clinical practices, or does it address a novel hypothesis or a critical barrier to advance the CF field?

- v. Is the research plan, including the design, methods, and analyses, adequately developed, well integrated, well-reasoned, and appropriate to the aims of the project? Are the timelines feasible? Are the outcomes clearly defined? Is the pathway to impact feasible? Does the PI acknowledge potential problem areas and consider alternative tactics?
- vi. If successful, will the proposed work result in a significant advance in the field or benefit to the CF community? Is there sufficient relevance and impact of the project to CF and to the research question(s) of the request for applications? What is the likelihood of the study resulting in near-term impact (improvements in health and/or quality of life) for people living with CF?
- vii. Are the budgetary requests reasonable? YES or NO. Comments and/or items to be flagged? Please list amounts to be reduced and reason, if appropriate. If budget is recommended to be reduced, please indicate the total recommended budget for Year 1, Year 2, Year 3, and Year 4.
- viii. Do you recommend support for this project? YES, at the budget proposed; YES, at a reduced budget; or NO.

Each reviewer scores the proposal out of 5.0, which equally reflects the applicant's track record of success, the appropriateness of the project aims, the innovativeness of the approach, feasibility of the proposal and significance/ impact to CF patients. The score reflects the following descriptors:

Score	Descriptor
4.5 - 5.0	Outstanding
4.0 - 4.4	Excellent
3.5 - 3.9	Very good
3.0 - 3.4	Good
2.0 - 2.9	Average
1.0 - 1.9	Below average
0.0 - 0.9	Not acceptable

(b) Community Reviewers:

Applications will be provided to a committee of community reviewers (people living with CF or parents of someone living with CF) who will each review the proposal, with a major emphasis on the 'lay' sections. Community reviewers will provide a score out of 5 and provide a written critique, answering the following questions:

- ix. Were the lay language sections written in language that the average member of the CF community (without a science degree) could understand? Was it well-written or confusing? Why? How could the applicant improve this section next time so that it is easier to understand or better describe what they are proposing?
- x. Does the research sound interesting and important? Is it exciting for members of the community to hear about?
- xi. Will there be direct benefits to CF patients if the project is successful? If the project deals with subjects that are less patient-focused and more about understanding the basic science of CF, do you think if successful it will significantly improve our understanding? Will the benefits that come from the proposed research be achieved in the near-term or will it take a long time for CF patients to benefit from this research?
 If the application proposes to involve patients in the research, do you think patients will participate in what is planned? Would it be easy for most patients to take part, and would they think it is worth their time? Is there a better way to make things easier for the participants? If the applicants are not proposing to involve patients, is there a way that

patients could be included that the researchers did not think of? Are the perspectives of CF community members appropriately integrated into the team?

- xii. Will the proposed research address the major research question(s) of the request for applications?
- xiii. Do you see any problems or reasons why this project should not be funded?
- xiv. Are people with CF meaningfully engaged throughout the proposal? Does the proposal outline how people with CF will be engaged?
- (c) Review panel meeting

Internal reviewers and community reviewers will meet on the same panel, in person or virtually to discuss the applications. Members of the panel holding conflicts with a member of the study team will not have access to the application, will be excused during the discussion of that application, and will not have the ability to comment or vote. A designated internal reviewer will lead the discussion, with further critique provided by all scientific and community reviewers. Comments from external reviewers are read to the committee. After discussion, the scientific review panel members score the proposal. The community reviewers separately score the proposal. Where initial critiques and scores of an application are low and clearly outside of the funding range, the panel may agree to 'triage' and not discuss the application. Feedback is provided by the critiques to the applicant. Only very highly ranked applications will be selected to move onto the next stage of the process (presentation) based on a high average score from the scientific reviewers and a high average score from the community reviewers.

The presentation review process

Review panel and community reviewers will attend (virtually) team presentations and provide written feedback on the presentations and proposed research. Review panel members, CF Canada representatives and co-funder representatives (if applicable) will have an opportunity to ask questions and ask for clarifications from the study team. CF Canada (and co-funder(s)) will decide on the funded application based on feedback from reviewers (scientific and community) at all stages of the process and CF Canada's (and co-funders) goals and priorities. CF Canada may request or require changes or adjustments to the budget and project work plans before electing to fund a winning proposal.

CF Canada policies

The successful application will be subject to all applicable CF Canada policies detailed in the current version of the <u>Grants & Awards guide</u>, including the policy on IP and patents. Additional requirements and policies described in the request for applications will also be applicable to the successful applicatio

V. OTHER GRANTS AND AWARDS

EARLY STAGE TRANSLATIONAL RESEARCH PARTNERSHIPS

In accordance with our <u>2020-2023 Strategic Plan</u>, CF Canada is increasing its focus on translational research that has a potential for near-term impact. Individuals and/or early-stage biotechnology companies that have a potential product, therapy, device, or intervention beyond the basic research proof-of-concept stage with direct relevance to the CF research community that requires investments for transition to the next phase of commercial development should contact

<u>research@cysticfibrosis.ca</u> to discuss the project and funding requirements. CF Canada will make available, through a formal and reviewed out-of-cycle proposal process, funding to support promising early-stage translational research & development directly relevant to better health outcomes for CF patients.

OTHER CYSTIC FIBROSIS CANADA INITIATIVES AND PARTNERSHIPS

From time to time, Cystic Fibrosis Canada may fund special research initiatives in line with our mission and strategic directions. Cystic Fibrosis Canada will conduct appropriate levels of due diligence, including the use of expert panels, strategic consultations, and third-party reports to evaluate these initiatives.

Cystic Fibrosis Canada may partner with various other funders, including Canadian Centres of Excellence for Commercialization and Research (CECR), other early-stage funders, Canadian granting agencies and charities on other research funding opportunities. Special research initiatives and funding opportunities will be subject to the requirements detailed in this guide including all <u>Cystic Fibrosis Canada policies</u> and financial and scientific reporting requirements, or any other requirements as may be explicitly stated and described in the funding opportunity.

These opportunities will be communicated through the <u>Cystic Fibrosis Canada website</u>, or standard Cystic Fibrosis Canada research communications channels.