2022/2023 Grants and Awards Guide

June 2022

CYSTIC FIBROSIS CANADA

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Charitable registration number 106845100 RR0001



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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 COMPETITION AT A GLANCE

Major Changes for the 2022 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' to each question). 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 1, 2022, 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

- 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 and Clinical Research Grants competition;
- Maximum value of \$ 50 000 and a 1-year term;
- Applications open late 2022/early 2023 for an anticipated submission deadline of April 1, 2023. Deadline to be confirmed.
- Full application information will be provided closer to the application deadline through an update to this Grants & Awards guide.

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

Type of Grant/Award	Description
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 fall of each year, for payments to begin the following year. No application process is necessary to receive these funds.

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
NEW: Seed Grants Note: Seed Grants have a separate application deadline in Winter 2023. More information will be provided on Seed Grants in an update to this guide closer to the application deadline.	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.

Research Grants and Awards cont'd

Type of Grant/Award	Purpose of Grant/ Award	Eligibility	Grant/ Award Amount (\$)	Max. Travel Allowance	Max. Term (Yrs)	Renewable
Early Career Investigator award NEW: 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.	\$40,000 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 though a competitive application process.

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, 2022	Mid-March

Research Grants and Awards

Type of grant	Deadline	Notification
Basic Science Research Grants		
• Letter of Intent to Apply (LOI)	August 1, 2022	Early August
Full Application	October 1, 2022	Mid-March
Clinical Research Grants		
Letter of Intent to Apply (LOI)	August 1, 2022	Early August
Full Application	October 1, 2022	Mid-March
Early Career Investigator Awards		
• NEW: Letter of Intent to Apply	August 1, 2022	Early August
(LOI)	October 1, 2022	Mid-March
Full Application		
Research Fellowship Awards	October 1, 2022	Mid-March
Seed Grants	Anticipated April 1, 2023	Late May
	To be confirmed.	

Granting process

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 institutional review board (IRB/REB) 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 Canadafunded 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 [2018])</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) Maternity/Parental leave

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 sight-seeing 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 \$65 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. 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.

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 begin. No application process is necessary to receive these funds.

Basic support for clinical care is the responsibility of provincial governments, and Clinic Incentive grants are not intended to supplant public funding. Cystic Fibrosis Canada Clinic Incentive grants are based on the size of the CF population being served, and are under the jurisdiction, and allocated at the sole discretion of the CF Clinic Director.

Eligibility

Canadian hospitals and/or medical schools 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.

Criteria

Recipients must demonstrate:

- the regional need for specialized clinical care for cystic fibrosis;
- the need of the institution for assistance, and its plans to attract complementary funding from other sources to develop a complete CF program;
- the potential for the development of a comprehensive program for CF care, clinical research, and teaching;
- 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 full 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 at the beginning of each fiscal quarter, beginning 1 April, 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) Accreditation Site Visits

The organization's Healthcare department conducts an on-going program of Accreditation Site Visits, whereby each Cystic Fibrosis Canada-funded clinic is required to host a site review periodically, extenuating circumstances notwithstanding. Site reviewers are appointed by the Director, Healthcare. The full cooperation of Clinic Directors and other personnel will be sought in arranging and conducting these Accreditation Site Visits. Clinics which have hosted a site visit since submitting their last Clinic Incentive grant application are requested to comment on the resulting site visit report, and its recommendations.

(f) 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.

(g) 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.

(h) 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. 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.

Clinical Fellowships are tenable in Canada or abroad. 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 two-page 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.

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

(i) 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.

(j) 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.

(k) Increases

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

(I) Earnings from other sources

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

(m) 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.

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

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

(o) 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 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. 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.

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

Also, 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).

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.

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 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 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: <u>https://cihr-irsc.gc.ca/e/52553.html</u>. 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;
- 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 detail 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 for 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

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 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 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 particular 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 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 community reviewers and a high average score from the community reviewers and a high average score from 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);

- 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 <u>Cystic Fibrosis Canada policies</u> 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)-(l) 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

Also, 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 <u>ProposalCentral</u> 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: <u>https://cihr-irsc.gc.ca/e/52553.html</u>. 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: https://cihr-irsc.gc.ca/e/52553.html. It is recommended that you review these materials before completing this section;
- 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.

- 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 detail 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 travel policy 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 impact your number of years of training.

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

Also, 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 on the basis of 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 <u>ProposalCentral</u> 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.
- 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 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, 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 (\$40,000) and new for 2022 also include a small research allowance (\$4000). 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.

V. OTHER GRANTS AND AWARDS

SEED GRANTS

The purpose of the Seed Grants is 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. Seed Grants have a separate application deadline in Winter 2023. More information will be provided on Seed Grants in an update to this guide closer to the application deadline.

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</u>. <u>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), and other early-stage funders, and Canadian granting agencies and charities on other additional research funding opportunities. Special research initiatives and funding opportunities may 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 Cystic Fibrosis Canada website.