



Fondazione Ricerca
Fibrosi Cistica - Onlus
italian cystic fibrosis research foundation

ITALIAN CYSTIC FIBROSIS RESEARCH FOUNDATION (FFC) CALL FOR GRANT APPLICATIONS YEAR 2018

December 15th 2017

The Italian Cystic Fibrosis Research Foundation (FFC) funds a limited number of research projects that have the ultimate aim to improve the health status of cystic fibrosis (CF) patients. Research proposals in which translational objectives are clearly evident will be prioritized. Accordingly, research projects dealing with either clinical studies or pre-clinical studies exploiting animal models of CF are strongly encouraged. Multi-centre applications that combine different expertises in one project will be given a higher priority only if there is convincing evidence that the expected output will be more effective than the sum of individual projects.

1. Priority areas

- 1. Pathophysiology of the basic defect in cystic fibrosis and pharmacological approaches designed to correct defective CFTR or to compensate for its deficient function (*).**
- 2. Identification and validation of new and appropriate *in vivo* and *ex vivo* assays to predict and monitor the potential efficacy of new therapies finalized to correct the CFTR defect.**
- 3. Lung infection in CF: pathogenetic mechanisms and development of innovative diagnostic and antimicrobial strategies (studies clearly oriented towards possible clinical applications).**
- 4. Lung inflammation in CF: innovative strategies to reduce the inflammation-based pathology in CF and CF animal models (studies with evident translational potential).**
- 5. Clinical applications in CF prevention, diagnosis, therapy, rehabilitation, care and health organization (clinical trials, epidemiological studies and systematic reviews) (**).**

Notes.

(*) FFC will support studies aimed to identify drugs already used in the clinic to treat other diseases for their potential in the treatment of CF patients, provided there is a strong rationale to test them in the context of CF pathology. Also studies aimed to identify new compounds will be taken into consideration, provided they suggest new strategies to affect mutated CFTR function and/or CFTR-dependent mechanisms of cell pathology. Both types of studies may exploit *in vitro* or *ex vivo* primary cell models. FFC will give very low priority to studies aimed to identify hit compounds derived from lead molecules previously reported to potentiate/correct mutated CFTR unless the proposal will provide clear evidence that standard preclinical studies will be supported by the host institution, private companies or other sources. FFC will not fund formal preclinical studies with the exception of studies addressing the drug/compound effects on animal models of

CF pathology and limited to provide the proof of concept that they work in the animal models. The latter indication should also be extended to projects included in other priority areas.

*(**) Collaboration and transferring of knowledge and expertise between basic and clinical research are particularly recommended. To this aim a clinical referring consultant for basic research projects and a basic research consultant for clinical projects should be appropriately taken into account.*

2. Eligibility

Any person with the role of PI, or Coordinator, or Partner must clearly play that respective role. Proposals based only on prestige must be avoided. Therefore, here follow the eligibility criteria:

- Scientists with proven scientific independence with at least 3 experimental/clinical papers as last Author or corresponding Author or first Author in the last 5 years (these papers have to be highlighted in the P.I./Coordinator's curriculum vitae in **Form 2**) are eligible to apply as Principal Investigators (PI); in the case of a multicentre project the PI will be also the Coordinator of the project.
- **A PI must have a permanent position.** The FFC will also consider applications from non-tenured Faculty researchers (such as type A researchers) who meet the criterion of scientific independence, provided that their contract covers the intended duration of the funding period (a copy of the contract must be submitted).
- The Principal Investigator or Co-ordinator of a multicentre project, as a rule, should reside and work in Italy; if he/she lives and works in another European country, at least one Partner in the project must be resident and work in Italy.
- Partners of a multicentre project may be co-opted even among scientists living and working outside of Italy.
- Partners are those scientists taking an autonomous (though co-ordinated), active and substantial contribution to a specific part of the project. **The FFC Foundation does not consider as Partners those working as collaborators in the PI's, Co-ordinator's or Partner's group; nor people only involved in supplying biological material or clinical and biological data:** in that case they have to be considered as internal or external Collaborators.
- **Partners must have a permanent position**, otherwise they must attach a copy of their contract with a declaration of the legal representative of the host institution, as specified above for the PI (see also point 5).
- P.I. (or Coordinator) cannot be Partner or P.I or Coordinator in other FFC projects simultaneously (including projects funded by FFC which are in progress and will expire after 31st August 2018).
- The role of Partner cannot be assumed by the same individual in more than two active projects at the same time (including the ongoing projects funded by FFC which are in progress and will expire after 31st August 2018).
- For renewal application by a former grantee see paragraph 6.

3. Budget

The budget description must be accurate and every item must be justified and detailed per each Partner and per each year in the case of 2-year projects. Generic description will not be processed for evaluation.

Eligible costs (**all must be clearly related with the project**):

- a. Fellowships or research contracts (for graduated and technicians). See also point 9
- b. Consumables / animals for lab activities
- c. External and occasional professional or technical services
- d. Small research equipments or accessories and softwares (closely justified and related to the current project): not more than 7% of the total budget
- e. Travels and meeting/congress participation (overall international conferences on CF), training sessions: not more than 4% of the total budget
- f. Possible costs for patients participating in clinical trials.
- g. Publication expenses, with clear reference to the project assigned in 2018 (max 2.5% of the budget)
- h. Overheads (general expenses not provided for in the previous items): cannot exceed 4% of total funding.

Ineligible costs:

- a. Salary and wages for PI, Co-ordinators, Partners and internal or external Collaborators (with the exclusion of personnel above mentioned for fellowship or research contract)
- b. Wages for staff members already receiving salaries or grants from other sources
- c. Furniture and stationery articles
- d. PC and other hardware
- e. Software not specifically related to the project
- f. Basic lab or clinical equipment
- g. Equipment repairing or assistance fees

4. Research Project – Guidelines to fill in the forms

The research project must contain all the following information, which must be followed very carefully.

- a. **General information (Form 1).** Project title, name of the Principal Investigator, or Co-ordinator for multicentre studies, host Institution, project duration (1 to 2 years), type of application (new application or extension of both a project already concluded or in progress but in very advanced phase, previously funded by FFC), priority research area, name of the Partner/s, their host Institutions, name of Collaborators (internal and external) really involved in the project (in the case of multicentre study specify the Collaborators for each research team) and their host Institution and roles in the project. Also the main personal data have to be included in the form, both for PI and Partner/s: residence, personal e-mail address, personal phone and fax numbers, tax code.
- b. **Curriculum vitae (Form 2).** Education and training, previous job and research experiences, significant publications in the last 5 years (only peer-reviewed journals). For multicentre study enclose also Partners' CV and publications (last 5 years).

- c. **Project overview (Form 3)**. It must include: background/rationale, aims, preliminary (personal) results, design and methods description, anticipated output, relevance for CF Foundation
- d. **Aims, background and rationale (Form 4)**
- e. **Preliminary results (Form 5)**. They must be proved and convincing and refer to the results obtained by the applicant in preliminary investigations bearing the value and the rationale of the project. **This part will be regarded as absolutely necessary and decisive for the evaluation of the project.**
- f. **Experimental plan and methods (Form 6)**. In this part it must be specified in detail: the research plan, methodology, materials intended to use, justified numerosness of the samples which are going to be examined and the statistical methods that are going to be applied for results evaluation. Moreover, it is requested a description of the development phases of the project, even temporal (timeline), quality controls, and whole pertinent references. Also the organization and the management to assure quality and feasibility of the project have to be described. For clinical trials see also *Appendix 1*.
- g. **Facilities (Form 7)**. Spaces, equipment, technical systems, technologies and services available for the realization of the project must be detailed.
- h. **External and internal collaborations (Form 8)**. Define expertises and functions of each Collaborator in the project. Please note that the acceptance of collaboration must be supported by personal collaborator declaration.
- i. **Duration (from 1 to 2 years) and budget (Form 9)**. Provide a tentative timing of the study development. Specify the expenses per each year and, in case of multicentre study, also per each Partner.
- j. **Roles and contribution of the Partner(s) in the multicentre project (Form 10)**. The Coordinator has to fill in this part with a detailed description of the specific contribution of each Partner in the project, and the time/work (percentage of the personal work time) they will dedicate yearly to the study. Description of the Coordinator's strategies to monitor each team activities, to facilitate communication among one another, to promote exchanges of ideas and methods, to integrate research phases and results.
- k. **Lay summary (Form 11)**. This must be written both in English and Italian, including title, in a popular and comprehensible style. This summary is meant to serve as a succinct and accurate description of the proposed work; if the application is funded, this summary will be published in the FFC Bulletin and in any other FFC medium. The summary must state clearly the relevance of the proposed study to the FFC Mission (to promote innovative treatment for CF).
- l. **List of documents attached (Form 12)**. Letters of internal and external collaborators, letter of institutional commitments (a letter from the applicant's and Partner's host institution, signed by the legal responsible, to confirm the institutional commitment to provide the applicants with adequate laboratory facilities, equipment, etc.), the consent to use personal data of PI and Partners (see the "*Pro forma Declarations*" in the appendix).

5. Additional documents (signed)

Individual project

- Declaration of acceptance by the host Institution (*Pro forma declaration A*)
- Copy (just scanned copy) of the time contract, in case the PI or Partner has no permanent position
- Consent for use of personal data, according to the Italian law 196/2003 (See attachment B)
- Letters of commitment (signed, scanned copy) by each internal and external collaborator involved in the project and listed in the application (*Pro forma declaration C*)
- PI declaration of adherence to provisions governing laboratory animal care, if required (*Pro forma declaration E*).

Multicentre Project

The Coordinator of a multicentre project is the only responsible for both the accuracy and the completeness of all the documentation submitted to the Italian CF Research Foundation (including those of Partner Centres).

Coordinator: see documents required for individual project.

Partners: each Partner has to transmit to the Coordinator (who will send them to FFC) the following documents:

- Declaration of acceptance of Partnership (along with personal data and consent to use them, address, telephone and fax number, e-mail and fiscal code) (*Pro forma declaration D*)
- Copy (just scanned copy) of the time contract, in case of not permanent position
- Declaration of acceptance by the host institution
- Partner's declaration of adherence to provisions governing laboratory animal care, if required (*Pro forma declaration E*)
- Letters of commitment (signed, scanned copies) by each internal and external collaborator involved in the project and listed in the application (*Pro forma declaration C*).

Clinical project

A clinical or mixed project (a project implying, even just in part, diagnostic, therapeutic or rehabilitative interventions on humans, not provided for in common standard or from the personal plan of diagnosis, care and rehabilitation) needs that the following documentation is produced, in accordance with the provisions of the Italian Ministero della Salute (D.M. 15/07/1997, D.M. 18/03/1998, D.M. 19/03/1998, DL 26/05/2000 and DL 24/06/2003):

1. Ethical Committee Approval (for each Partner/Centre, if multicentre study) to be sent to FFC after award of the grant and not later than October 31st 2018;
2. "Parere Unico", released by the Ethical Committee of the Principal Investigator/Coordinator/Partner's centre (if applicable) (not later than 31st October 2018 if the project will be funded);
3. Informed consent form (for interventions and for use of personal data, in anonymous form, for research purpose, released by patients or people involved in the study) plus patient information leaflet;

4. Good Clinical Practice declaration by the Applicant (*Pro forma declaration F*).

Projects including use of animal models

Any project which includes experiments on animals must be accompanied by a specific authorization of the Ethical/Technical Committee of the Institute hosting the animal facility: to be submitted only after award of the grant and not later than October 31st 2018.

Moreover, the PI or Co-ordinator has to declare that the procedures concerning those experiments will follow the instructions included in the legislative decree 2014, n. 26, “Attuazione della direttiva 2010/63/UE sulla protezione degli animali utilizzati a fini scientifici (14G00036) (GU n.61 del 14-3-2014)” (*Pro-forma declaration G*).

NOTE. If the approval of Ethical Committee (for clinical trials) or Ethical / Technical Committee (for animals) and “Parere Unico” are not available by October 31st 2018, a follow-up report on the ongoing application either to the Italian Ministero della Salute or the Local Ethical Committee must be sent to this Foundation by email. Providing this information to the FFC Foundation is crucial for the correct management of the grant.

6. Submission of applications by former FFC grant holders

A former FFC grant holder may submit a new project or a proposal of development of a project already funded by FFC (extension project). In both cases all of the following must apply:

a. The previous project is finished and its final scientific report has been already submitted to FFC. The scientific report has to include details of the project’s achievements, the contribution of each Partner (for multicentre projects) and a list of the resulting publications and congress presentations (abstracts).

b. Applications can be considered exceptionally for an extension even before the conclusion of a previous project (only for project expiring on August 31st, 2018) providing the PI or Co-ordinator is able to show results that support the reasonableness of a development through an extension of one year, with application deadline postponed to May 25th, 2018. However, this opportunity is admitted only for “not pilot” two-year projects at their second year.

c. The application for extension of a 1-year ongoing project clearly approved by FFC as a “pilot project” in 2017 may be submitted exceptionally with a deadline postponed to May 25th, 2018, provided that at that date the project has really achieved its objectives (with adequate and convincing documentation).

d. Partners in a multicentre project financed by FFC may submit a new research proposal as PI or Coordinator (see the conditions in **2.**) provided their previous projects were finished and they are not involved in other FFC projects in accordance with the provisions of point 2.

7. Evaluation of applications

Incomplete or behind schedule applications will not be processed for evaluation.

Procedures

Grants will be awarded on a competitive basis. In particular, factors that will play a major role in determining the successful outcome of the application are: relevance to the Italian CF Research Foundation's mission and to the priority areas (see point 1); soundness and originality of the study; relevance of the preliminary results; potential value to improving the clinical and care strategies; potential value to stimulating further studies, mainly on translational basis; appropriateness of the whole design; scientific record of the participants and the host institutions/laboratories; methods reliability; feasibility within the estimated time; facilities' appropriateness. All accepted applications will undergo a preliminary review by the Scientific Committee of the Italian CF Research Foundation on the basis of their relevance to the Foundation's mission and their estimated competitiveness. Projects selected in this triage step will undergo peer review by an international panel of experts. In the final step the projects will undergo the complete review process and will be evaluated by the Scientific Committee, taking in due consideration the independent referees' comments. The Scientific Committee will also review the budget, which may be reduced with respect to the original request. Availability of co-funding, which must be declared and accurately described in the appropriate section of the application (see **Form 9**), will be considered as a privileged title.

8. Fellowship and research grants

The sum set aside for fellowship cannot exceed 27.000 euros gross per year for graduated personnel and 19.000 euros gross per year for technicians or other not graduated personnel (in any case the amount must be indicated in the budget, specified per year and per each partner centre). The life of the research grant cannot exceed the duration of the project and will expire at its end date.

Normally, the Italian CF Research Foundation will directly assign and manage the research grant. Exceptionally, other modes of administration of the grant and research collaborators must be discussed on a case by case with the FFC Foundation. On assignment of the grant, FFC will furnish to PI or Coordinators detailed information about the procedure to follow. Fellows or contract holders have to be mentioned in any documents or publications as "Italian CF Research Foundation fellow/contract holder". The Italian CF Research Foundation reserves the right to have direct contacts with the fellows or contract holders, to ask for periodical progress reports on their work in the project and to call them to participate in the annual Convention of the Italian CF Researchers in which also the Principal Investigators/Co-ordinators and Partners must participate as FFC guests. The attendance to the whole Convention is mandatory because it is a working time on research funded by FFC and not just a general update conference.

9. Awarding and management of research funds

The awarding of funds will be formally decided by the Italian CF Foundation Board of Governors and communicated on assignment. As a rule, funds are given to the PI and not to the Institution where he/she intends to carry out the funded project.

The Italian CF Foundation will manage directly the funds according to the PI's or Co-ordinator's indications. Approved PI/Co-ordinators and Partners have to keep an accurate and update accounts, in parallel to CF Foundation. With reference to budget indications, expenses will be administered per year and per each partner centre.

In case of 2-year projects award recipients will be expected to provide a detailed yearly administrative report, as well as a full progress report, to obtain subsequent payments.

Any changes of the original destination of budget formalized on assignment, occurring during the fulfilment of the project, must be formally asked and agreed with FFC.

The Italian CF Foundation will not pay any expenses made after the date of conclusion of the project or exceeding the budget assigned. Any costs in excess will be charged personally to the PI or Co-ordinator.

10. Scientific and administrative reports, publications

At the end of each project-year the PI or Coordinator must provide a detailed scientific and administrative progress report. At the end of the project, investigators are asked to submit a Final Scientific Report including a list of publications and congress presentations plus the reprints of publications and congress abstracts relevant to the FFC funded project. The Italian CF Research Foundation - Onlus must be acknowledged in all publications arising from the funded project (congress abstracts, book chapters, scientific articles, congress slides, press releases...) by specifying the code of the related grant and by inserting the FFC logo both on slides and posters. Also, the adopters of a project, as indicated by FFC (see in www.fibrosicisticaricerca.it/area-ricercatori/i-progetti-di-ricerca/), have to be mentioned. Contextually, the FFC Foundation requires to receive a copy of publications and congress abstracts at the following email: fondazione.ricercafc@aovr.veneto.it.

FFC may ask investigators to collaborate to public engagement and dissemination of their research results, in order to support fund raising. For this purpose it is up to FFC the task of contacting investigators.

11. Research results and intellectual property

One of FFC's goals is to translate research results into clinical applications available to CF patients. This can be achieved by establishing partnerships with industry, so that the most promising research results can be fully developed into drugs, therapies, devices and diagnostics.

For this reason, FFC requests that all scientific results derived from an FFC funded project, that have importance for a possible development, are assessed for patent protection and/or commercial valorization. This can be performed by the funded scientists' institutional dedicated offices (for example Technology Transfer Offices), providing support and assistance on intellectual property matters and technology transfer activities. In any case, the request for a patent relating to results from projects funded by FFC must first be discussed with FFC and authorized by it. The FFC reserves the right to negotiate in good faith with the funded scientists' institutions its participation in the ownership of intellectual property of inventions derived from funded projects. The funded scientists must promptly inform FFC in writing of any new patent filings and execution of agreements with for-profit

entities related to FFC funded research results.

FFC is confident that FFC-funded researchers will operate with clarity and honesty concerning the attribution of merits relative to any work, invention or discovery. FFC is confident that FFC researchers will always remember that all funds supporting CF research are coming from voluntary donations.

12. Cover letter and forwarding of application

The documentation must be accompanied by a **separated cover letter**, (signed by the applicant on institution headed paper), in which the PI or Coordinator declares the acceptance of all the conditions specified in the call for application. Moreover, he/she has to summarize the reasons of CF specificity of the proposal, its originality/innovation/significance in the CF field, and its compliance to the Mission of the Foundation (possible transfer of results to the management and care of CF patients). He will also have to declare if he/she has any other grants and awards connected with the matter of the proposed project.

Applications must be submitted **by February 15th 2018 by Certified Email (PEC)** through three PDF files: cover letter, application (forms 1-12), administrative documents (declarations, etc.).

Please pay careful attention to the general guidelines in filling in the application forms. The application forms must be written in English (except for the lay summary, which must be both in Italian and English), using single paragraph and not exceeding the number of characters, spacing included, required in each form. Images must be not too heavy, and they must be inserted inside the text near the point to which they relate.

The deadline for submission is **February 15th 2018** (at 12 pm)

Applications must be submitted by **Certified Email (PEC)** through three PDF files: cover letter, application (forms 1-12), administrative documents (declarations, etc.) to

fondazioneffe@pcert.postecert.it

This call for proposals and all relative forms are also available on the Italian CF Research Foundation website: www.fibrosicisticaricerca.it (on page “*Area ricercatori*” > “*Bando per progetti di ricerca FFC 2018*”).