fondazione per la ricerca
sulla fibrosi cistica - onlus
italian cystic fibrosis research foundation

ITALIAN CYSTIC FIBROSIS RESEARCH FOUNDATION (FFC)
CALL FOR GRANT APPLICATIONS YEAR 2016

December 15th 2015

The Italian Cystic Fibrosis Research Foundation (FFC) funds a limited number of research projects, from basic to clinical, 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 given higher priority. 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 total output will be more effective than the sum of the parts.

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 vitro*, *ex vivo* and *in vivo* assays to predict and monitor the potential efficacy of new therapies finalized to correct the CFTR defect.
3. Development of new animal models to investigate CF pathophysiology and therapy.
4. Infections in CF: pathogenetic mechanism and development of innovative diagnostic and antimicrobial strategies.
5. Lung inflammation in CF: innovative strategies to reduce the inflammation-based pathology in CF and CF animal models.
6. Clinical application in CF prevention, diagnosis, therapy, care and health organization: clinical trials, epidemiological studies and systematic reviews.
Note. Clinical research projects will be welcome and encouraged.

2. Eligibility

- Scientists with proven scientific independence are eligible to apply as Principal Investigators (PI); in the case of a multicentre study the PI will be also the Coordinator of the study. **Normally a PI must have a permanent position**. Where the Applicant is not the holder of a permanent position, the legal representative of the Host Institution or a Responsible Official is required to declare that a **salary will be provided for the duration of the entire project**: in any case, a copy of the contract must be submitted.
- The Principal Investigator or Co-ordinator of a multicentre study, as a rule, must 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 CF 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 for the PI (see also point 5).
- **Any person with the role of PI, or Coordinator, or Partner must clearly play that respective role. Appointments based only on prestige or interpreted as a formality are absolutely excluded.**
- P.I. (or Coordinator) cannot be Partner or P.I. in other project simultaneously (including ongoing projects funded by FFC).
- 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**).
- For renewal application by a former grantee see paragraph 6.

3. 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 a project already concluded or in progress but in advanced phase, previously funded by FFC), priority research area, name of the Partners, 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 Partners: residence, e-mail address, 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 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: the research plan, methodology, materials intended to use, numerousness 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, even temporal (timeline), of the project, 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 declarations.

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 the case of multicentre study, per each Partner. See also point 4.

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. As a test that the summary can be understood by lay people, please **submit it for review to at least two independent lay people** who you know. The summary must clearly state the relevance of the proposed study to the FFC Mission (to promote innovative therapies 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, including those documents required in form 5 and 7.
See the "*Pro forma Declarations*" in the appendix.

The project leader (PI or Coordinator) has to write a cover letter, accompanying the whole documentation: it has to be written and signed on institution headed paper.

4. 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:

a. Fellowship or time contract on project (for graduated and technicians). See also point 9;
b. Consumables for lab activities;
c. External and occasional professional or technical services;
d. Research equipment: small devices or accessories at a very limited extent, whose usage is in clear keeping with the project; some software could be accepted if specifically related to the study;
e. Overheads: project-related travels and meeting/congress participation (overall international conferences on CF), training sessions and publications expenses closely related to the project, general costs. These items cannot exceed 7% of total funding.

Ineligible costs:

- Salary and wages for PI, Co-ordinators, Partners and internal or external collaborators (with the exclusion of personnel mentioned in 4.a.
- Wages for staff members already receiving salaries or grants from other sources
- Furniture and stationery articles
- PC and other hardware
- Software not specifically related to the project
- Basic lab or clinical equipment
- Equipment repairing or assistance

5. Additional documents (in signed hard copy)

Monocentre project

- Declaration of acceptance by the host Institution (*Pro forma declaration A*)
- Authenticated copy of the time contract, in case the P.I. has no permanent position;
- Consent for use of personal data, according to the Italian law 196/2003 (See *attachment B*).
- Letters of commitment (signed) from 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 animals 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 monocentre project.

Partner: 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 tax code) *(Pro forma declaration D).*
- Authenticated copy of the time contract, in case of non permanent position.
- Declaration of acceptance by the host institution.
- Partner's declaration of adherence to provisions governing laboratory animals care, if required *(Pro forma declaration E).*
- Letters of support (signed) by each internal and external collaborator involved in the project and listed in the Application *(Pro forma declaration C).*

Clinical project

Please note that 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), approved for funding will not be administratively activated until 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):

- Ethical Committee Approval (for each Partner/Centre, if multicentre study) and to be submitted to FFC after award of the grant and not later than October 30th 2016;
- "Parere Unico", released by the Ethical Committee of the Principal Investigator/Coordinator/Partner's centre (if applicable);
- 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;
- 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 30th 2016. 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 March 4th, 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).*

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. 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, when indicated, a list of the resulting publications and congress presentations.
b. Applications can be considered exceptionally even before the conclusion of a previous project (February 15, 2106) providing the PI or Co-ordinator is able to show results that support the reasonableness of a development through an extension. However, this opportunity is admitted only for 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 2015 may be submitted exceptionally with a deadline postponed to May 15, 2016, 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. However, they may participate only as partners in one or two new or extension projects.

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 solidity of the participants and the host institutions/laboratories, methods reliability, feasibility within the estimated time, facilities' appropriateness. All accepted applications will be first reviewed 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 be submitted to 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 international referees' comments. The Scientific Committee will also review the budget, which may be reduced with respect to the original request. Availability of other funds declared, which must be accurately described in the appropriate section of the Application (see **Form 9**), will be considered as a privileged title.

8. Application details and Form forwarding

The documentation must be accompanied by a cover letter, signed by the applicant, in which he declares the acceptance of all the conditions specified in the call for application.

Applications must be submitted **by February 15th 2016 both by e-mail and by post** (a registered package or a courier service is preferable, the postage or courier stamp is valid for the date).
By post. The complete documentation must be sent in a hard copy to the Fondazione per la Ricerca sulla Fibrosi Cistica – c/o Ospedale Civile Maggiore – Pad. 40, Edificio Geriatrico, Lato Mameli, 3° Piano – P.le A. Stefani, 1 – 37126 Verona (Phone +39 045 8123438; fax +39 045 8123568).
By e-mail. Only the forms listed in the point 3 (Form from 1 to 12) must be sent by e-mail. Please use **one single Word file (or PDF)**, attaching a separated letter signed by the PI or Coordinator.

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. Any images must be not too heavy, and they must be inserted in the text.

9. Fellowship and research grants

The sum set aside for fellowship cannot exceed 26.000 euros pre-tax per year for graduated personnel and 18.500 euros pre-tax 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. Other modes of engagement and administration of 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 invite 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.

10. 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.

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-years 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.

11. 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: *"Progetti 2016*"), have to be mentioned. A copy of publications and congress abstracts must be promptly sent by email to fondazione.ricercafc@ospedaleuniverona.it.

12. 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 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. Ownership of inventions will reside within the funded scientists' institutions, unless differently agreed with FFC. The FFC reserves the right to negotiate in good faith with the funded scientists' institutions 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.

The deadline for submission is **February 15th 2016**

Applications must be submitted both by:

- **post** (the postage or courier stamp date is valid): the complete documentation must be sent in single hard copy to the **Fondazione per la Ricerca sulla Fibrosi Cistica – c/o Ospedale Civile Maggiore, PAD. 40, Edificio Geriatrico, Lato Mameli, 3° Piano – P.le A. Stefani, 1 – 37126 Verona** (Phone +39 045 8123438; fax +39 045 8123568). A registered package or a courier service is preferable;
- **e-mail**: only the forms listed in the point 3 (Form 1 to 12) must be sent by email to fondazione.ricercafc@ospedaleuniverona.it (please use only one Word or PDF file, not too heavy and attach a separated and signed covering letter edited by the PI or Coordinator).

This call for proposals and all relative forms are available on the Italian CF Research Foundation web site: www.fibrosicisticaricerca.it (on page page "Area ricercatori" >"Bando per progetti di ricerca FFC">"Scarica la documentazione ">"Bando FFC 2016 " and "Forms FFC 2016").