



*fondazione per la ricerca  
sulla fibrosi cistica - onlus*

# ITALIAN CYSTIC FIBROSIS RESEARCH FOUNDATION GRANT PROPOSALS 2011

## Call for Applications Year 2011

December 15<sup>th</sup>, 2010

The Italian Cystic Fibrosis Research Foundation (FFC) funds research projects, basic or clinical, that have the ultimate aim to treat and eventually cure cystic fibrosis (CF). Multicentre study applications combining different expertises in one project have a higher priority for this call. Besides the clinical studies, special consideration will be given to the pre-clinical ones which involve animal models. Research proposals with clear translational trend will be greatly privileged.

### 1. Priority areas

1. Pathophysiology of the basic defect in cystic fibrosis and pharmacological approaches designed to correct or compensate for the lack of functional CFTR;
2. Advanced studies on Molecular Genetics of Cystic Fibrosis;
3. Innovative antibacterial strategies in CF infection with potential of clinical applicability;
4. New approaches to understand and treating inflammation in CF;
5. Pilot studies on the feasibility and appropriateness of screening programmes for the pre-conceptual identification of CF heterozygotes;
6. Survey and revision of current key-strategies in CF care programmes, including clinical trials, epidemiological studies and systematic reviews.

- *With regard to the area 2 (Molecular Genetics) the following topics are suggested: Genomic Wide Association Studies (GWAS) and Genomic Next Generation Sequencing for detecting Modifier Genes; Next Generation Sequencing of the CFTR Region; Studies aimed at a better understanding of the role of CFTR gene mutations in the CF disease expression.*
- *With regard to area 5, the following objectives are suggested: 1. to define the most sensitive (detection rate power) panel of CFTR mutations to be tested; 2. to investigate possibilities of access and utilization of genetic services, including genetic testing and counselling in primary and secondary care settings; 3. to investigate criteria aimed at optimizing and maximizing output of such genetic services also by containing the costs; 4. to elaborate consequent recommendations for implementation of carrier screening programmes.*

### 2. Eligibility

- Scientists with proven scientific independence are eligible for a research grant assignment as Principal Investigators (PI) or Co-ordinators of multicentre studies. They must have a permanent position. Where the Applicant is not the holder of a permanent position, the Legal Representative of the Host Institution is required to declare that he will provide a salary for the duration of the entire project: copy of the contract must be anyway presented.
- The Principal Investigator or Co-ordinator of a multicentre study has to prove he is resident and working in Italy or in other European countries, provided in the last case that at least

one Partner is resident and working in Italy. Partners of a multicentre project may be co-opted even among scientists living and working in other countries.

- Partners are those scientists taking an autonomous (though co-ordinated), active and substantial contribution to a specific part of the project (we don't consider as Partners those people working in the PI's or Co-ordinator's or Partner's group or people only supplying biological material or clinical and biological data of archive; in that case they have to be considered just as internal or external Collaborators). Partners must have a permanent position, otherwise they must attach a copy of the contract with a declaration of the chief of the host institution, as specified for the PI (see also point 5).
- Scientists not demonstrating the specific and crucial role in the project presented cannot be accepted as PI or Coordinators or Partners. The only formal or prestige role must be resolutely avoided.
- An individual scientist may apply as Principal Investigator or Co-ordinator for only 1 project and may also be Partner (at the same time) in only 1 multicentre study.
- Scientists without PI or Coordinator position cannot be Partners in more than 2 projects at the same time, included those funded by FFC which are still in progress.
- 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 scientific 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 3 years, preferably 2 years), type of application (new application or renewal of a project, concluded or in advanced phase previously funded by FFC), priority research area, name of the Partners, their host institutions, name of Collaborators 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: residence, e-mail address, phone and fax numbers, tax code, both for PI and Partners.
- b. **Curriculum vitae. Form 2.** Training, previous job and research experiences, significant publications in the last 5 years (only peer-reviewed journals). For multicentre study enclose also Partners' CV
- c. **Project overview. Form 3.** It is a kind of long abstract of the project, including the main aspects: background/rationale, aims, preliminary (personal) results, project 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 of the project. This part will be regarded as absolutely necessary.
- f. **Experimental plan and methods. Form 6.** In this part you must specify: your research plan, methodology, materials you intend to use, numerosness of the sample/samples you wish examining and the statistical methods you intend to apply for result evaluation; you'll make a description of the development phases, even temporal, 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.
- g. **Facilities. Form 7.** Spaces, equipment, technical systems, technologies, services which are 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. **Length** (from 1 to 3 years: 2 years preferably) **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 between themselves, to promote exchanges of ideas and methods, to integrate research phases and results.
- k. **Lay summary. Form 11.** It must be written both in English and Italian, easily comprehensible to "lay people". It has to specify the relevance of the proposed study to FFC Mission (to promote innovative therapies for CF). This description is meant to serve as a succinct and accurate description of the proposed work. If the application was funded this summary, as it is, will become public information. The title must be translated in Italian.
- 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 adequate laboratory facilities, equipment and so on), the consent to use personal data of PI and Partners, including those documents required in form 5 and 7.

*The project leader (PI or Coordinator) has to write a cover letter, accompanying the whole documentation: it has to be signed and written 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 or 3-year projects. Generic description will not be processed for evaluation.

The following entries will be allowed:

- a. Fellowship or time contract on project (for graduated and technicians). See also point 9.
- b. Consumables for lab activity;
- c. External and occasional professional or technical services;
- d. Research equipment (small devices or accessories at a very limited extent, whose usage is in keeping with the project; some software could be accepted if specifically related to the study);
- e. Travel, training sessions and publications expenses, closely related to the project (cannot exceed 5% of total funding)

The following expenses are not allowed:

- Salary and wages for the PI or Co-ordinators and Partners
- Wages for staff members already receiving salaries or grants from other sources
- Furniture and stationery articles
- PC and other hardwares
- Basic lab or clinical equipment

## **5. Additional documents** (in signed hard copy).

### Monocentre project

- 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 A.
- Declaration of acceptance by the host institution
- PI declaration of adherence to provisions governing laboratory animals care, if required (*Pro forma declaration D*);
- Letters of commitment from internal and external collaborators involved in the project and listed in the application (*Pro forma declaration B*)

### Multicentre Project

The Coordinator of a Multicentre project is responsible for both the accuracy and the completeness of all the documentation submitted to the 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 to the 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 C*).
- 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 D*)
- letters of support by internal and external collaborators involved in the project and listed in the Application (*Pro forma declaration B*)

### 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 centre, if multicentre study).
- 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.
- "Parere Unico", released by the Ethical Committee of the Principal Investigator/Coordinator/Partner's centre (if applicable)
- Good Clinical Practice declaration by the Applicant (*Pro forma declaration E*)

### 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. Moreover the PI or Co-ordinator has to declare that the procedures concerning those experiments will follow the instructions included in the legislative decree of the Italian Government 27 January

1992, n. 116 and the Health Minister memorandum 14 May 2001, n. 6 (*see the pro-forma declaration F*).

*Whenever the authorisations of the Ethical Committees are not available at the moment of the project's submission, the Principal Investigator/Coordinator must send the above-mentioned documentation to the Italian CF Research Foundation as soon as he receives them, in the meanwhile he has to declare in a separated signed letter the commitment to furnish them not later than June 20, 2011. For cell/gene therapy trials, please adhere to the specific guidelines issued by the Italian Istituto Superiore di Sanità.*

## **6. Submission of applications by previous holder of a FFC research grant**

A previous holder of an Italian CF Research Foundation's grant may submit a new project or a renewal of a project funded by FFC still in progress. For the last all of the following must apply:

- a. The previous project is finished or its final scientific and administrative report has been already submitted or is going to be included in the application. In any case, the PI or Coordinator has to prove in an administrative report that at least 80% of the previous grant has been spent at 15<sup>th</sup> January 2011. Please note that salaries and wages for personnel have to be considered as the whole sum assigned. Coordinators of a former multicentre project are responsible for sending their own administrative reports and those of the Partners. The scientific report has to include a summary of the project's achievements, the contribution of each Partner (for multicentre projects) and a list of the resulting publications and congress presentations.
- b. Partners in a multicentre project financed by FFC may submit a new research proposal as PI or Coordinator;
- c. Partners of multicentre project financed by FFC may be also Partners in a new project, if all the conditions in a. are satisfied.

## **7. Evaluation of applications**

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

### Procedure

Grants will be awarded on a competitive basis. In particular, will play a major role in determining the successful outcome of the application: relevance to Italian CF Research Foundation's mission and to priority areas (see point 1), creativity and originality of the study, relevance of the preliminary results, potential value to improve the clinical outcome and the care-clinical spin-off, potential value to stimulate further studies, mainly on translational basis, appropriateness of the whole design, scientific solidity of the participants and the hosting institutions/laboratories, methods reliability, feasibility within the estimated time, facilities' appropriateness. Great importance will be given to multicentre clinical proposals, to the organisational/managerial model adopted to guarantee the quality and feasibility of the project. 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 competitiveness relative to their scientific quality. 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**

Applications must be submitted **by February 15, 2011** both by e-mail and by post (the postage or courier stamp is valid for the date).

**By post.** The complete documentation must be sent in duplicate hard copy to the Fondazione per la Ricerca sulla Fibrosi Cistica – c/o Ospedale Civile Maggiore – P.le A. Stefani, 1 – 37126 Verona (Phone +39 045 8123438-3597; fax +39 045 8123568). A registered package or a courier service is preferable.

**By e-mail.** Only the forms listed in the point 3 must be sent by e-mail. Please use one single Word file (or pdf), attaching a separated letter signed by 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 in English, the title has to be translated in Italian too), using single paragraph and not exceeding the number of characters, spacing included, required in each form. Any images must be in JPG format, not too heavy, and they must be inserted in the Word text.

## **9. Fellowship or time contracts on project (graduated and technicians)**

The sum set aside for fellowship cannot exceed 22.000 euros pre-tax per year for graduated personnel and 17.000 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 contract cannot exceed the length of the project and will expire at its end date.

The Italian CF Research Foundation will directly assign and manage fellowships or contracts. 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 to the annual Convention of the Italian CF Researchers (also all the Principal Investigators/Co-ordinators and Partners have to participate in the Convention 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-coordinator and Partners have to keep an accurate and update accounts, in parallel to CF Foundation.

With reference to budget indications, expenses will be kept per year and per each centre.

In case of 2-years or 3-years projects award recipients will be expected to provide a detailed yearly administrative report, as well as a satisfying 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 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 must be paid by PI or Coordinator.

## 11. Scientific and administrative reports, publications, patents and products

At the end of each 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 presentations relevant to the FFC financed project. The Italian CF Research Foundation - Onlus must be acknowledged in all publications arising from the grant (congress abstracts, book chapters, scientific articles, congress slides...) by specifying the project number on the publication and inserting the FFC logo on slides. Also the adopters of a project, as indicated by FFC, have to be mentioned. A copy of publications and congress abstracts must be sent in duplicate to FFC in a good time.

Scientific discoveries or products from a financed project may be patented or exploited for commercial purposes only after FFC formal consent and they will show, in official acts, the total or partial financing source and thanks to whom they have been obtained.

The deadline for submission is **February 15, 2011**. Applications must be submitted by two modalities. By post (the postage or courier stamp date is valid): the complete documentation must be sent in duplicate hard copy to the Fondazione per la Ricerca sulla Fibrosi Cistica – c/o Ospedale Civile Maggiore – P.le A. Stefani, 1 – 37126 Verona (Phone +39 045 8123438-3597; fax +39 045 8123568). A registered package or a courier service is preferable. By e-mail: only the forms listed in the point 3 must be sent by this way to [fondazione.ricercafc@ospedaleuniverona.it](mailto: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 grant proposals and the forms have been also issued on the CF Research Foundation web site: [www.fibrosicisticaricerca.it](http://www.fibrosicisticaricerca.it) (on page “Bandi” > “Bando per Progetti di Ricerca 2011”).