



## FC Call for Proposals 2014

**- FC -**

*Fondazione Celiachia  
Foundation for Celiac Disease*

**- AIC -**

*Associazione Italiana Celiachia  
Italian Society for Celiac Disease*

# FC CALL FOR PROPOSALS 2014



## FC Call for Proposals 2014

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## FC Call for Proposals 2014

### 1. Foreword

The Fondazione Celiachia (FC) is glad to inform the Italian Scientific Community that, upon the successful closing of the first 2013 FC Call for Proposals that selected three research projects in the fields of Celiac Disease and Non-Celiac Gluten Sensitivity for a total of € 600,000,

**The Foundation is now releasing the FC Call for Proposals 2014** to grant Italian research projects in the following topics:

1. Celiac Disease
2. Dermatitis Herpetiformis
3. Non-Celiac Gluten Sensitivity.

The FC Call for Proposals 2014 will consider research projects of **one year, two years or three years duration**.

The Grant will be provided for fund requests not exceeding **€ 70,000 per year** for each of the above durations, provided that FC has available funds.

The total funding available for the FC Call for Proposals 2014 is € 400,000.

The scientific activity must be carried out in public or private non-profit research institutions located in Italy (university, hospital or other research centre).

Only one (1) Application per Principal Investigator can be submitted within the framework of the FC Call for Proposals 2014.

Principal Investigators holding an active FC grant cannot apply to the FC Call for Proposals 2014, for neither of the above durations.

The present FC Call for Proposals 2014 will accept the resubmission of not funded Applications that were presented to the 2013 FC Call. Applications presented to the FC Call for Proposals 2013 will not be accepted in any other later FC Call different from the present FC Call for Proposals 2014.

**The FC Call for Proposals is opened  
from the 20<sup>th</sup> of January to the 14<sup>th</sup> of March 2014**

## 2. Legend

The following abbreviations and definitions are used in the FC Call for Proposals 2014 and the other Official Documentation:

Statement	Abbreviation	Definition
<b>Principal Investigator</b>	PI	<ul style="list-style-type: none"> <li>→ The PI is the scientist presenting the Application within the framework of the FC Call for Proposals 2014 and is the sole responsible of the whole research project</li> <li>→ The PI is a group leader, conducting a research team</li> <li>→ The PI is an independent researcher with a good track record</li> <li>→ The PI has Italian nationality and already holds a work contract with the Italian Hosting Institute</li> </ul>
<b>Hosting Institute</b>	N/A	<ul style="list-style-type: none"> <li>→ The Hosting Institute is an Italian public or private non-profit centre with the aim of performing scientific research.</li> <li>→ The PI must be affiliated to the Hosting Institute in which the research presented in the Application will be performed.</li> <li>→ The Hosting Institute is the institution to which FC allocates the Grant for funding the selected project.</li> </ul>

## 3. FC Call for Proposals 2014 Official Documentation

The official documentation relevant to the FC Call for Proposals 2014 is the following:

Document	Aim
<b>FC Call for Proposals 2014</b>	Sets the aims and objectives of the Call, along with the rules governing the granting process
<b>Application Form and Mandatory Annexed Documents</b>	Standard Application Form and Annexed Documents to be mandatorily used for submitting projects under the FC Call for Proposals 2014
<b>Instructions for completing the Application Form</b>	Provides Applicants with all relevant instructions for filling in and completing correctly the Application Form and the Mandatory Annexed Documents

Only Application Forms fully respecting the format provided will be considered.

**Application Forms using additional documents different from the provided templates will be rejected without appeal and will not be further considered for the assessment process.**

#### 4. Regulation and Policies

The present FC Call for Proposals 2014 represents the regulation of the whole Call, and Applicants and their Institutes are required to completely adhere to it.

As well, the documents annexed to the FC Call for Proposals 2014 (the Application Form and the Instruction for Completing the Application Form) do constitute integral part of the FC Call for Proposals 2014, and thus also are part of the regulation.

**Disregard to the FC Call for Proposals 2014 and its official documentation automatically leads to the full rejection of the whole Application without appeal.**

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The regulation contained in the FC Call for Proposals 2014 and its documents directly derive from, and are in full harmony with, the *Policies* and *Guidelines* on scientific research issued by the Foundation, as applicable at that moment. Policies and Guidelines are issued by FC in full autonomy and independence. The FC reserves the right of integrating its Policies and Guidelines with *ad hoc* decisions in case of dissimilarities or other eventualities not contained in the Regulation even in part or completely.

#### 5. The Research Plan

##### 5.1. Research Topics

All proposed research plans must have a clear focus on one of the following research topics:

1. Celiac Disease
2. Dermatitis Herpetiformis
3. Non-Celiac Gluten Sensitivity

**ONLY ONE (1)** research topic can be indicated.

### 5.2. Research Areas

Moreover, proposed research plans must fall into one (1) of the following research areas:

1. Allergology
2. Anatomic pathology - Histopathology
3. Biochemistry
4. Biology (structural, computational, signalling)
5. Clinical trials
6. Clinics (paediatrics or adult)
7. Dermatology
8. Drug discovery – screening - development
9. Endocrinology
10. Epidemiology - Prevention
11. Genetics - Control of gene expression and epigenetics
12. Gynaecology
13. Immunology - Immunobiology
14. Infection and inflammation
15. Nutrition
16. Oncology
17. Preclinical study
18. Proteomics

**Only one (1)** research area can be indicated.

### 5.3. Project Duration

The FC Call for Proposals 2014 will consider research projects of **one year, two years or three years duration**. The duration of the project must be indicated in the Application Form.

One-year projects may be either pilot/exploratory studies or full research projects with an annual duration. In the latter case, preliminary data should be provided into the Application Form. The nature of the one-year project must be indicated into the Application Form.

It is **not** possible to divide a project into various sub-projects coinciding with the single steps of the unitary project, or to break it down into diverse funding lines (even though a single sub-project is led by another researcher).

Also, it is **not** possible to sub-divide a two-year or three-year project into single annual projects.

### 5.4. FC's High Funding Priorities

For FC the followings are high research priorities:

- Proximity to find new pathogenic mechanisms
- Proximity to cure
- Natural history of the pathology by linking different phases of the disease to specific biological/genetic profiles
- Interactions between environmental risk factors, genetic profiles and intermediate biomarkers
- Innovation of clinical methodologies
- Evaluation in clinical practice of the efficacy of diagnostic and therapeutic approaches, in terms of outcome and quality of life
- New therapeutic drugs, procedures or strategies (pilot clinical studies)
- Critical evaluation of last generation drugs (their activity by mechanistic insights).

### 5.5. FC's Low Funding Priorities

The following kinds of proposals will receive low priority during the review process and have marginal chances of being funded:

- Studies that are essentially confirmatory in nature or represent marginal "variations-on-the theme" of well-established concepts
- Studies contemplating descriptive screenings of molecules and/or phenotypes without mechanistic insights and/or elements of innovative discovery. These include purely descriptive microarray and proteomic profiling studies that are not associated with a strong strategy for clinical application, or the generation of chemical compounds without validating their activities in pharmacological and biological studies
- Generation of reagents and/or optimization of technologies, or creation of services/technological facilities in the absence of a coherent and innovative research plan
- Chemical and/or viral studies not embodied in the framework of mechanistic studies
- Requests for on-going routine collection of current statistics, such as celiac disease registry
- Descriptive epidemiology studies
- Health economics proposals
- Clinical studies that do not contribute to build or expand an original and independent line of research.

## 6. Typologies of Applications

Within the framework of the FC Call for Proposals 2014, FC will accept the following typologies of Applications:

Typology of Study	Description
<b>Studies from a Single Research Group</b>	<ul style="list-style-type: none"> <li>→ All personnel involved in the project (the research group) belong to the unity/laboratory conducted by the PI</li> <li>→ <b>NO</b> internal/external collaborators are thus envisaged in the Application</li> </ul>
<b>Partnership Studies</b>	<ul style="list-style-type: none"> <li>→ The research also involves <b>ONE OR MORE INTERNAL AND/OR EXTERNAL COLLABORATORS</b></li> <li>→ Internal collaborators are researchers working within the same Hosting Institute of the PI, but into units/laboratories/ departments different from the one conducted by the PI</li> <li>→ External collaborators are researchers working in one or more other Italian Research Institutes/Centres different from the Hosting Institute of the PI</li> <li>→ Internal/external collaborators and their role/expertise must be indicated in the Application</li> <li>→ <b>ONLY</b> Italian Institutions/Centres are allowed in Partnership Studies</li> </ul>
<b>Multicentre Studies</b>	<ul style="list-style-type: none"> <li>→ The research also involves <b>ONE OR MORE OTHER ITALIAN RESEARCH INSTITUTES/CENTRES</b> different from the Hosting Institute of the PI</li> <li>→ External Institutions and corresponding research groups are thus provided in the Application</li> <li>→ For each Italian external institute which will take part in the Multicentre Study, the chief researcher (group leader) and the role of the external group must be indicated in the Application</li> <li>→ <b>ONLY</b> Italian Institutes/Centres are allowed to take part in Multicentre Studies</li> </ul>

The consistency of the typology of project with the project duration (one-year, two-years, three-years) will be evaluated by the Reviewers.

### 6.1. Special Rules for presenting Applications for Partnership and Multicentre Studies

- The Application Form for a Multicentre/Partnership study is unique, and is presented and signed exclusively by the Coordinating PI of the whole project proposal, and by the Legal Representative of the Hosting Institute of the Coordinating PI.

- The Ethical Committee approving the Multicentre/Partnership study is exclusively the Ethical Committee of the Hosting Institute of the Coordinating PI.
- Multicentre/Partnership study does not mean a group of independent studies that are being carried out in a number of centres, but one single study to which more centres contribute. Special emphasis will be dedicated by the Reviewers to evaluating whether each Partner's contribution is necessary for the proposed project, and whether complementarity and synergy are a strength of the project proposal.
- In the Application Form, a dedicated Section will request detailed information about the Multicentre/Partnership study: the Coordinating PI is asked to describe the contribution of all Partners, to explain why each of them is necessary to the success of the project, to clarify the complementarity of approaches that justifies their participation and to highlight how the synergy among partners will produce greater results over the sum of individual contributions. Moreover, the Coordinating PI will specify how the Multicentre project will be managed.
- The Coordinating PI is the only responsible of the work and of the conduct of all the collaborators and groups involved in the project, with respect to the Regulation of the present FC Call for Proposal 2014.
- The Coordinating PI is the sole responsible of the whole project, including the parts deriving from the collaborators/partner groups, and thus he/she is the sole responsible for the correctness of the Application Form and the mandatory Annexed Documents for applying to the FC Call for Proposals 2014.
- The Coordinating PI is the one who will present and sign all the scientific and financial reports foreseen by the Grant, of which he/she is thus the sole responsible for.
- The Coordinating PI and the collaborators of the Multicentre/Partnership study will apply following the rules reported in the Section "*Number of Projects to be Presented within the FC Call for Proposals 2014*" of the present Call.
- In case of **Partnership studies**, the whole grant will be allocated exclusively to the Hosting Institute of the Coordinating PI. In **NO** case the transfer of grant money to the collaborators/partners working in other laboratories is allowed. All costs and expenses will be held exclusively by the Hosting Institute of the Coordinating PI, and the evidence of that will result from the financial reports that the PI and the Hosting Institute will produce during the Grant. Fellowships and contracts for personnel external to the Hosting Institute will not be funded. Only the transfer of materials will be allowed to the collaborators/partners.
- In case of **Multicentre studies**, the Group Leader and the Legal Representative of each Partner Centre, as well as the funds requested by each Partner Centre, must be indicated in the relevant section of the Application Form. Moreover, an institutional letter of acceptance will be provided by each Partner Centre to the

Coordinating PI, as indicated in the Instructions for Completing the Application Form. In case of successful project, the FC will allocate funds to the Coordinating Institute and to the other Centres as indicated in the approved Budget section of the Application Form. Financial and scientific reports of the Partner Centres will be sent to the Coordinator PI only: **NO** documents from Partner Centres will be sent to FC during the Grant. It is the responsibility of the Coordinating PI to collect progress and final administrative and scientific reports from all the Partner Centres, and to prepare, sign and send the required documents to FC within the stated deadlines.

### 7. Resubmission of 2013 Applications

- For Applications that were not funded in the previous FC Call for Proposals 2013, FC allows **ONLY ONE MORE** resubmission to the FC Call for Proposals 2014. The present FC Call will therefore accept the resubmission of not funded Applications that were presented within the framework of the FC Call for Proposals 2013. Applications presented in 2013 will not be accepted in any other next FC Call different from the present FC Call for Proposals 2014.
- Resubmitted Applications do have a dedicated Section within the Application Form, and thus within the evaluation process performed by the Peer Reviewers.
- The resubmitted Application must include a point-by-point response to the Reviewers' comments, in which the relevant modifications of the resubmitted Application are clearly highlighted.
- The Reviewers will evaluate whether the resubmitted Application is a concrete reformulation of both the research project and design, based on the comments provided by the Reviewers themselves in the past revision. Only reformulated/ameliorated Applications, with respect to Reviewers' past assessment, will merit new Peer Review.
- Applicants who fail to receive funding after two subsequent submissions (i.e. the original and the revised Application) may submit a new Application only if its research plan is fundamentally and conceptually different in content and scope (a new project) from the two that were previously considered not fundable. More specifically:
  - There should be fundamental and conceptual diversity in the questions being asked and/or the outcomes examined
  - Diversity of the research plan should produce a significant diversity in the direction and approach for the research project
  - Rewording of the Title and Abstract, as well as the mere change of the Applicant **DO NOT** constitute a new project. In these cases, the Application (presented by the same or other Applicants) is considered analogous to the

previous two submissions, and thus submitted for the third time. The Application will be rejected without appeal and will not be sent out for review.

### 8. Number of Projects to be presented to the 2014 FC Call

- The Applicant that is **NOT** holding an active FC Grant can present only one (1) Application as PI to the FC Call for Proposals 2014 **AND/OR**, in case, only one (1) Application as (internal/external) collaborator/personnel (make reference to the scheme below).
- PIs holding an active Grant from previous FC Calls **CANNOT** apply nor as PI neither as (internal/external) collaborator/personnel/partner to the FC Call for Proposals 2014.
- Internal/external collaborators/personnel/partners (not the PI) involved in funded projects with still active FC Grant **CAN** apply to the present FC Call for Proposals 2014 as either PI (only one Application) **OR** collaborator/personnel/partner (only one Application).

The following scheme applies, for whatever project duration (one-year, two-years, three-years):

Holders of still active FC Grants as:			May apply to 2014 FC Call as:		
PI (Coordinator)		Collaborator/Partner	PI (Coordinator)		Collaborator/Partner
NO	and	NO	YES (1 only)	and	YES (1 only)
NO	and	NO	YES (1 only)	and	NO
NO	and	NO	NO	and	YES (1 only)
YES	and	NOT RELEVANT	<b>CANNOT APPLY</b>		
NO	and	YES	YES (1 only)	and	NO
NO	and	YES	NO	and	YES (1 only)

### FOR COLLABORATORS/PARTNERS ONLY

- Internal/external collaborators (Partnership and Multicentre Studies) are allowed to be involved in **ONLY ONE (1)** Application **PRESENTED OR RESUBMITTED** within the framework of the FC Call for Proposals 2014. This applies for whatever project duration (one-year, two-years, three-years).
- The participation of a researcher as a collaborator in two or more Applications, included resubmitted ones, will lead to the **automatic rejection of all the Applications in which the researcher is involved**
- It is the responsibility of the PI to check out for this condition
- In the Application Form, including the resubmitted ones, each collaborator/group leader is asked to declare that he/she is not involved in other Applications presented within the framework of the FC Call for Proposals 2014.

## 9. Funding

The following rules apply for the funding of approved Applications, for whatever project duration (one-year, two-years, three-years):

- The funds are allocated on annual instalments. In case of two-year and three-year durations, the fund allocations are contingent upon the presentation of an yearly renewal request (make reference to the Section "*Steps for Submitting Applications and Deadlines of the FC Cal for Proposals 2014*") including:
  - A **financial annual report** signed by the PI (the Coordinating PI in case of Multicentre/Partnership Studies) and the Legal Representative of the Hosting Institute of the PI
  - A **scientific annual progress report** signed by the PI (the Coordinating PI in case of Multicentre/Partnership studies).
- Funding applications **must not exceed € 70,000 per year**, for whatever project duration (one-year, two-years, three-years).
- Applicants must indicate the requested support in the Budget Section of the Application Form, providing a detailed financial breakdown of the anticipated expenditures.
- FC reserves the right of applying reductions to the proposed budget without appeal to the selected Applications. Refusal of the reformulated budget by the Applicant will automatically imply the decadence of the Application.

- Once awarded, funds will be made available to the Hosting Institute under terms and conditions that FC will provide once the Application is approved. Funds must be at the PI's disposal within 30 days from the time the Hosting Institute has access to them.
- In case of **Partnership studies**, the whole grant will be allocated exclusively to the Hosting Institute of the Coordinating PI. In **NO** case the transfer of grant money to the Collaborators/Partners working in other laboratories is allowed. All costs and expenses will be held exclusively by the Hosting Institute of the Coordinating PI, and the evidence of that will result from the financial reports that the PI and the Hosting Institute will produce during the Grant. Fellowships and contracts for personnel external to the Hosting Institute will not be funded.
- In case of **Multicentre studies**, the funds requested by each Partner Centre must be indicated in the relevant section of the Application Form. In case of successful project, the FC will allocate funds to the Coordinating Institute and to the other Centres as indicated in the approved budget section of the Application Form.
- No funds will be granted to Applications of project which are already funded (in total or in part) by other agencies and foundations, nor to Applications of project which have already applied to other grants and calls, and are thus pending for final decision (independently if they will be funded or not). The present rule also applies to Applications of projects which are overlapping for whatever part and in whatever measure to other projects already submitted to other agencies and foundations, either pending or already funded. Breaches of the principle of honesty, fairness, and good faith referred to the present rule will automatically lead to the suspension of the Grant.
- No funds will be granted to pharmaceutical or other kind of companies, nor to their employees. Applications presenting request for contracts, fellowships or other kind of funds assigned to companies and their employees will be rejected without appeal and will not be further considered for the FC Call for Proposals 2014. Breaches of the principle of honesty, fairness, and good faith referred to the present rule will automatically lead to the suspension of the Grant.
- The following rules apply for the funding of contracts/fellowships for the personnel involved in the project:
  - Salary to the PI is not permitted
  - Support will be provided only for fellows at 100% of time on the project and working **exclusively within** the research team of the PI (or, in case of Multicentre studies, of each group leader). Fellowships and contracts for personnel external to the Hosting Institute (or, in case of Multicentre studies, external to each partner centre receiving funds) will not be funded
  - Financial support can be required only for those fellows who do not have any other fellowship or equivalent source of income. Integration of the FC financial

support by the Hosting Institute is **NOT** permitted. Maximum request permitted for the contract/fellowship are reported in the Instructions for Completing the Application Form

- The fellowship support will not be awarded to fellows working in clinical areas, since, almost by definition, no clinical fellow can be listed at 100% of his/her time on a specific project.
- At the end of the grant, a **scientific final report** will be required and will strongly impact the evaluation of future FC grant applications.
- An **administrative/financial final report** must be submitted within three months after the termination of the grant.

## 10. Steps for Submitting Applications and Deadlines of the 2014 Call

### 10.1. Completing the Application Form and Mandatory Annexed Documents

For submitting an Application Form, go to the following webpage <http://www.celiachia.it/fondazione/Fondazione.aspx?SS=1007&M=1105>

Please, **download and complete the following documents:**

- Application Form (word file)
- Mandatory Annexed Documents to the Application Form (word file)
- Instructions for Completing the Application Form (PDF file)

The detailed *Instructions for Completing the Application Form* follow the same order as the *Application Form* itself. **Applicants who do not refer to these notes or who do not follow the instructions and guidance in them, risk submitting an incomplete or incorrect Application, therefore significantly reducing the chances of their application being successful.**

For any doubts concerning the FC Call for Proposals 2014 rules, the provided documents and the completion of the Application Form, please send an email with your query to the FC Scientific Office: [ufficioscienfico@celiachia.it](mailto:ufficioscienfico@celiachia.it). The FC will provide you with a written answer.

### 10.2. Submission of the Application Form

The completed Application Form must be **saved as PDF file (please, pay attention to save the file as PDF and not as image).**

In addition, the Signature Page of the Application Form must be signed in blue ink by the Principal Investigator and the Legal Representative of the Hosting Institute, and **scanned as PDF file. The signature of the Application Form implies the acceptance of all the rules governing the Call for Proposals.**



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Finally, the completed Annexed Documents to the Application Form must be **scanned as a unique PDF file**. **Single page files will not be accepted, and the Application will be rejected without appeal.**

All the above files must be **sent to FC by email** ([bandifondazione@pec.celiachia.it](mailto:bandifondazione@pec.celiachia.it)), as recapitulated in the scheme below.

Send the following **files**

- Completed Application Form, saved as PDF file (not image file)
- Completed Signature Page of the Application Form (signed in blue ink), scanned as PDF file
- Annexed Documents to the Application Form scanned as a unique PDF file

to this **email address**

[bandifondazione@pec.celiachia.it](mailto:bandifondazione@pec.celiachia.it)

**The deadline for submitting Applications is the 14<sup>th</sup> March 2014  
at 15:00 o'clock Italian time.**

**Documents received later than 14<sup>th</sup> March 2014 15:00 o'clock Italian time will be automatically rejected without appeal, and the Application will not be further considered for the selection process.**

**Once received, the Application is considered as definitive, thus no more amendable/editable/integrable.**

## 11. The Assessment Process

All Applications received by FC within the framework of the FC Call for Proposals 2014 undergo the following steps:

<b>First Step</b>	Check of Conformity
<b>Second Step</b>	Peer Reviewers' Evaluation
<b>Third Step</b>	Approval of the Ranking List by the FC Board, and funding

### 11.1. – First Step: Check of Conformity

The check of Applications represents an IN/OUT selection step, in which a well-defined group of criteria are strictly applied by FC to the Applications, the Principal Investigators (PIs) and their Institutes.

The FC holds the responsibility and authority in making the final decision on the Application's completeness and eligibility. Applications which are recognised by FC not to be eligible due to the disregard of only one of the set criteria will automatically lead to the full rejection of the whole Application without appeal. These Applications will **not** undergo the peer review process, and will receive a written communication by FC.

The **criteria** applied for checking the conformity of Applications are the followings:

- Respect of the set deadline
- The use of the standard Application Form and Annexed Documents, and the respect of the required file format
- Completeness of the Application Form and the mandatory Annexed Documents in all parts
- Signature of the Principal Investigator and the Legal Representative of the Hosting Institute in blue ink
- Respect of the maximum grant request per year (€ 70,000)
- Italian nationality of the Principal Investigator
- Contractual position of the PI within the Hosting Institute
- The guarantee of an involvement of the PI in the project equal or superior to 50% of his/her working time for the entire project duration
- No FC active funding granted in 2013 to the same PI
- Absence of research team members being employed by a company
- Italian non-profit research institute status of the Hosting Institute
- Absence of any affiliation or operation on behalf of a pharmaceutical or other kind of company by the Hosting Institute

### 11.2. Second Step: Peer Reviewers' Evaluation

Applications which are recognised by FC to be eligible based on the above reported criteria undergo a peer review process that ensures a fair, independent and expert evaluation of their scientific quality.

For the evaluation of Applications, FC relies on the expertise of a panel of well-established international investigators working in institutes outside Italy. Applications are independently reviewed by three (3) reviewers with expertise in the specific area of the research plan.

Reviewer assignments are made in compliance with disclosure of conflict of interest: reviewers disclose any conflict of interest toward the PI and the project. Moreover, when accepting to evaluate an Application for which no conflict of interest is present, reviewers

agree that they will maintain the confidentiality of the application and associated materials they have received.

Reviewers are asked to separately evaluate the following aspects of each Application:

<b>A.</b>	Triage for Scientific Competitiveness
<b>B.</b>	Score Evaluation of the Project Proposal

### A. Triage for Scientific Competitiveness

In this step, the reviewers evaluate scientific competitiveness of the project proposals and rank them as high or low priority studies, on the basis of the following criteria:

Criteria	Description
<b>Adherence to FC's main research priorities</b>	Reviewers assign a HIGH/LOW priority assessment to each evaluated project
<b>Consistency of the project with the selected duration</b>	The Reviewers evaluate the consistency of the project design, structure and purposes with the indicated duration
<b>Consistency of the project with the selected Research Topic</b>	The Reviewers assess the consistency of the project with the selected topic: 1. Celiac Disease, 2. Dermatitis Herpetiformis, 3. Non-Celiac Gluten Sensitivity
<b>Consistency of the project funding request</b>	The Reviewers assess the consistency of the funding request with FC Call Policy and the experimental plan/stated objectives
<b>ONLY in case of Resubmitted Applications</b>	The Reviewers also evaluate whether the resubmitted Application is a concrete reformulation of both the research project and design, based on the comments provided by the Reviewers themselves in the past revision. Only reformulated/ameliorated Applications, with respect to Reviewers' past assessment, will merit new peer reviewing

Applications that have received low priority will be triaged out.

### B. – Score Evaluation of the Project Proposals

This step is made of a series of Evaluation Areas, each Evaluation Area has a weight and is in turn composed of different criteria.

To each criterion the Reviewer assigns a score and a written comment:

Weighted Evaluation Areas	Scored Criteria
<b>Project's Purposes and Scientific Value of the Project</b> (80% weight)	<ul style="list-style-type: none"> <li>→ Clearness of the project purpose</li> <li>→ Improvement of basic/clinical comprehension of celiac disease and/or gluten related disorders stemming from this research</li> <li>→ Design and tasks of the project: background, rationale, experimental design, methodologies</li> <li>→ Preliminary data supporting the working hypothesis</li> </ul>

	<ul style="list-style-type: none"> <li>→ Appropriateness of sample sizes</li> <li>→ Methodological or conceptual innovation of the project</li> </ul>
<b>Feasibility of the Project</b> (20% weight)	<ul style="list-style-type: none"> <li>→ Potential difficulties and limitations of the project, and their impact on the success of the proposal</li> <li>→ PI's expertise, qualification, past experience and accomplishments (IF, publications track record) directly relevant to the success of the proposal</li> <li>→ Expertise of the research team</li> </ul>

The score system adopted by the Reviewers during the assessment of the project is here represented:

Score	Value
0	Unacceptable
1	Very Weak
2	Weak
3	Acceptable
4	Good
5	Very Good

For each project proposal, an 'overall review score' is obtained by summing and weighting the scores assigned by each Reviewer.

### 11.3. Third and Final Step: Approval of the Ranking List by the FC Board, and Funding

'Overall review scores' allows for the establishment of a final ranking list of the evaluated projects.

After establishing a ranking of proposed projects, FC's Board of Directors meets to decide on the allocation of funds to the most deserving projects. The ranking list and the financial availability of FC will determine the funding.

FC reserves the right of modifying the fund request of each project on the basis of Reviewers' assessment and its own autonomy.

All Applicants of selected and not-selected projects will be notified about the final decision with an official communication from FC.

For every project reviewed, FC's Scientific Office draws up a document providing a clear and detailed summary of the selection process conducted, including comments written by the reviewers. This is an important step because it attests to the system's transparency, and is an effective learning tool for the Applicant. In most cases, the criticism highlighted is constructive and contributes to the development of a new and improved project.

**The decision concerning the funding of an application cannot be appealed.**

### 12. Report Meeting at the National AIC Congress 'Network and Celiac Disease'

Only for PIs holding an active FC Grant, the Foundation reserves, in case, the right of yearly calling up the PI to report about the state of his/her research (progress report) or about the conclusion of the project (final report). In fact, every year FC and AIC organise the National AIC Congress 'Network and Celiac Disease' which is held in November. Within the Congress, a 'Progress and Final FC Grant Report Meeting' might be forecasted.

Only in case of calling up by FC, the PI will be recognised the reimbursement of the forth/back travel at the FC's conditions (in the same day, and only economy fare for train and flight).

### 13. Intellectual property

Researchers, fellows or participants in the research undertake to notify FC as soon as possible and however with the progress and final reports, in accordance with the good faith and fairness criteria, either

- a) personally
- b) or through the reference Structure

of any invention or result for which it is possible to obtain a patent, protection, industrial rights or similar, fine-tuned and/or developed by availing, even in part, of resources and/or tools procured, supplied or however made available to the Fondazione Celiachia Onlus.

It is specified that if more than one member belonging to the research team, or more than one research team, are involved in the project (Multicentre or Partnership Studies), the following provisions on intellectual property shall apply and shall therefore be accepted by each member of the research.

The above notice shall provide all relevant elements through an exhaustive and appropriate scientific report.

Being aware that the rights resulting from the invention are governed, except where agreed otherwise, by the applicable law on intellectual property (Legislative Decree nr. 30 of 10<sup>th</sup> February 2005) and, insofar as compatible, by the civil code provisions on joint ownership (Arts. 1100 – 1139 It. Civil Code), the Researcher undertakes to consider FC, in concert with the reference Structure, as their first partner for a possible joint development of the invention as regards:

- The filing of the patent application
- The economic exploitation of the research results and of their technological transfer.

The Researcher and the reference Structure recognise to FC, without prejudice to the right of the Researcher to be recognised as the author of the invention:

- a. For patents (or patent applications) filed by the same researcher and licensed by the latter, at least 40% of the net profits resulting from the exploitation of the invention. Such amount shall be due even if the Researcher sells, or assigns the right of use of, the invention patent (or patent application) to third parties
- b. For patents (or patent applications) filed in the name of FC, a percentage of the net profits resulting from the economic exploitation of the invention specifically agreed upon between the parties and however not lower than 50%.

It remains understood that, after 5 years from the filing of the application patent without any economic exploitation having begun on the part of the Researcher and/or the reference Structure or the Structure to which they belong, the Foundation shall be entitled to acquire the patent, or patent application, and the relevant right of economic exploitation of the invention, free of charge, with the right to assign and/or licence it to third parties without prejudice to the inventor's right to the attribution of authorship. If such condition occurs, the inventor shall be ready to sign all documents as may be necessary to register the transfer of ownership of the patent or patent application.

Please note that the amount under letter a) shall be granted to FC even in case of exploitation of the invention under secrecy.

The researcher also undertakes

- To mention FC in all documents or publications referred or however connected with or related to the Foundation's funding, as specified in this Regulation
- To act so as not to jeopardise in any way the suitable protection of their own and of FC's rights regarding the aforementioned results, expressly undertaking a secrecy and confidentiality obligation, also with regard to what is indicated in paragraph below ('*Publications and Printed Materials*').

## 14. Publications and Printed Materials

All researchers shall previously send the Foundation a PDF copy of the publication, report or congress papers they intend to make with regard to the research/training activities carried out through the funding of the same Foundation, first of all to keep the Foundation informed and, moreover, to permit the organisation of activities of disclosure – agreed with the same researcher/fellow – to the media and through the communication instruments of the Foundation and of the AIC. All the above is to be implemented both during and after the period of the research supported, even in part, by FC's funding.

Such materials are to be sent through transmission means allowing prompt information, at least thirty days before the date scheduled for their disclosure.

Upon sending the materials, the expected publication data and the name of the magazine are to be specified, or the date and place of the congress, where the disclosure should take place.

At any rate, and leaving aside the above indications for the protection of intellectual property, which apply to all activities supported/funded under this regulation, in each publication and disclosure activity the Foundation's contribution will always be acknowledged through a note included in the publication or materials, formulated as follows and mentioning, where possible, the identification number code of the Grant:

*'... was supported by a FC (Fondazione Celiachia Onlus) grant nr. ...'.*

Failure to comply with the procedure for preventive transmission of materials relevant to possible publications or congress lectures, as well as failure to notify the activity developments in the progress and final reports, in terms of potential results that may be the object of protection and defence, within the deadlines set forth, shall be considered a serious non-compliance liable to imply the liabilities resting on the offender as well as the block of further funding by FC.

The researcher shall ensure their availability for any press office activity organised by FC and shall therefore be ready to contact the mass media in the forms and manners deemed appropriate by the same FC. The Researcher and the Organisation or Institution where they operate undertake, at the same time, not to develop any press office activity relating to the research funded/co-funded by FC without a prior consent of FC.

### 15. Suspension, Waiver and Interruption, Revocation

Submitting a funding Application implies a commitment for the Applicant, which becomes a legally binding obligation in case of notice of acceptance, to implement the project/activity in accordance with good faith, fairness, specific diligence, responsibility and reliability criteria. Therefore, the following hypotheses of suspension, waiver, interruption shall be limited to exceptional situations.

FC in fact draws the utmost attention on the nature of the funds it destines for the funding of projects, which come from private sources, such as fund-raising, donations, legacies, or from 5 per mille and public contributions, where existent, and it consequently requires that the beneficiary is fully aware, from the moment of the submission of the Application, that if the same is accepted, the relationship originated will entail mutual obligations and commitments, as FC should and will give account of the best use of the allocations among the various stakeholders.

The beneficiary shall therefore not be allowed to withdraw, or to unilaterally modify any of the constitutive elements of the project, or to resolve all or part of the obligations undertaken, unless this occurs within the limits and at the conditions set forth in this Regulation.

The funding granted by FC shall therefore be binding, to all effects and purposes, for the researcher and the institution or reference organisation, or the organisation to which they belong, where the research takes place.

### 15.1. Suspension

Suspension shall mean a temporary, and not final, stop of the research activities. The suspension can refer to exceptional circumstances, due to personal or organisational factors, or to force majeure which may for a limited and defined period prevent or hinder the continuation of the activities, and therefore reduce or jeopardise the usefulness or validity of the research activity.

The request for suspension made by the Researcher must be accompanied by an authorisation of the reference organisation. If the suspension is accepted by FC, it will imply an extension of the time schedule as originally defined.

Requests for suspension must be made without delay, taking in view the time and manner in which the underlying circumstances have materialised, and observing the general good faith, fairness and diligence criteria.

Notwithstanding the above, based on the reasons and justifications offered by the Researcher and also in view of the rationale and of the confirmation of the targets and results of the project study despite the longer time required, FC reserves the right to accept or refuse the request. Therefore, the request for suspension shall have no effect if it is not expressly accepted by FC: failure to accept it shall have the effect of an interruption of the project under the following provisions.

The suspension of the project shall imply the suspension of payments for the period in question. Requests for suspension for further periods, in addition to those already allowed, on the same project shall not be admitted.

### 15.2. Voluntary waiver and interruption

Unless it depends on exceptional factors, of subjective or objective nature, or on force majeure, voluntary waiver of projects or fellowships has consequences on the assessment of good faith, fairness, diligence in the fulfilment of the obligations undertaken by the Applicant, and will also have a negative impact on the evaluation of any subsequent application.

In such cases, the project ends and the funding is consequently interrupted, and the Researcher shall forfeit the funding and any residual amount not yet paid will be retained by FC. If the Foundation has already made an advance payment, any amount not yet spent at the date of the waiver must be returned, within and not later than 30 days after the cessation of the project.

The scientific reporting and activity obligations referring to the period of actual performance shall remain unprejudiced.

Interruption of a project is treated in the same way as voluntary waiver if it does not depend on reasons or intent of the funding applicant, but on serious external factors of particular importance.

### 15.3. Revocation

In case of serious non-compliance, for a long time, with the obligations under this Regulation, particularly as regards the compliance of the project activities with the object of the funding, the reporting activity, the observance of provisions concerning scientific integrity, notice of the results, protection of property, and any derived charters and, more generally, with all requirements under Law, FC reserves the right to revoke the project with the same effects as those resulting from waiver and/or interruption.

Revocation will also be possible if impediments or significant changes, either of objective or of subjective nature, are found to affect relevant and significant aspects of the project to be approved, regardless of any specific faults of the Researcher or of the reference organisation; in no event shall the Researchers and their respective reference organisations/hosting institutes modify elements liable to affect the contents subject to assessment.

The following may, for example and without limitation, constitute cases of change/impediment which FC may consider as reasons for revocation:

- Changes in the position of the Researcher resulting in possible incompatibility and/or conflict or however in the reduction or loss of autonomy and independence
- Changes in the identification of the reference/hosting institute, also in view of the nature and characteristics of the same
- Change in the type and nature of the relation between the Researcher and the hosting institute
- Subjective and/or objective impediments preventing actions for a period exceeding the maximum admitted suspension.

Revocation may take place only after a written notice has been sent by FC, indicating the serious non-compliance or the change/impediment found and provided that no arguments or justifications deemed acceptable by FC have been given in writing within the stated period, of no less than 15 days.

The situations resulting in the revocation, insofar as they may be ascribed to the Researchers or reference/hosting institutes, may imply liability to FC and are unfavourably considered in the assessment of any subsequent application; participation in the subsequent Call is however excluded.

## 16. Code of Conduct and Scientific Integrity

Researchers will act with honesty, fairness, seriousness and responsibility and in good faith in each activity relating to research and study activities conducted by the same, as well as those connected therewith (such as, for example and without limitation, during trial design, data generation and analysis, funding applications, publication of results, recognition of direct or indirect contributions of colleagues, collaborators and others, reports on activities and costs, etc.), always keeping scientific integrity and the superior

interest of research as their primary reference in their conduct in view of the institutional objectives of FC.

Please note, in particular, that:

1. Plagiarism, deception and falsification of results amount to serious non-compliance under this Regulation
2. Researchers are encouraged to notify any misconduct in a responsible and appropriate manner
3. Researchers are bound to inform FC of any actual or prospective conflict of interest, either predating or arising during the research activity.

Researchers shall remain independent from any internal and external influence.

## 17. Privacy Law

### INFORMATIVA AI SENSI DELL'ART. 13 DEL D.LGS 196/03

*(THE ATTACHED APPENDIX HAS BEEN LEFT IN ITS ORIGINAL ITALIAN VERSION AS ITS USE IN THIS CASE APPLIES ONLY TO ITALY)*

La Fondazione Celiachia Onlus con sede in Via Caffaro 10, 16124 – Genova, titolare del trattamento (di seguito il "Titolare"), La informa che tratterà i dati da Lei forniti al fine di ufficializzare la Sua partecipazione al bando di ricerca FC, oltre che di consentire la valutazione del progetto di ricerca ivi presentato e, qualora finanziato, per la gestione amministrativa dello stesso.

Il Titolare la informa altresì della possibilità che, nell'ambito della comunicazione scientifica di FC avente ad oggetto il progetto di ricerca da Lei presentato, i Suoi dati, potranno essere diffusi attraverso: i) canali istituzionali: il sito internet [www.celiachia.it](http://www.celiachia.it), le newsletter on-line ed ogni altro evento di comunicazione; ii) divulgazione scientifica: libro degli *abstract*, esposizione poster, ecc.; iii) *direct marketing*; iv) mezzi di comunicazione di massa.

Il Titolare tratterà i dati da Lei forniti in ottemperanza degli obblighi normativi, garantendo il pieno rispetto delle norme di legge, contrattuali e dei regolamenti. I dati personali saranno inseriti in un database di proprietà di FC e verranno trattati mediante strumenti manuali, informatici e telematici, con logiche e modalità volte a garantire la sicurezza e la riservatezza dei dati stessi. I dati trattati potranno essere comunicati a soggetti incaricati, interni o esterni a FC e/o ad altri soggetti terzi che saranno nominati Responsabili del trattamento dei dati nei limiti e nel rispetto delle finalità sopra specificate nonché nel rispetto di idonee procedure di sicurezza oltre che diffusi in coerenza a quanto sopra specificato. Il conferimento dei dati è facoltativo ma il rifiuto può comportare l'impossibilità delle finalità predette. In ogni momento Lei potrà rivolgersi al Titolare del trattamento nella persona del Presidente di FC presso la Celiachia Onlus con sede in Via Caffaro 10, 16124 – Genova al fine di richiedere la cancellazione, la distruzione, l'aggiornamento, l'opposizione per motivi legittimi, la rettifica, l'accesso o per esercitare



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gli altri diritti di cui all'art. 7 del Codice Privacy, oppure per richiedere l'elenco aggiornato dei soggetti nominati Responsabili del trattamento.

### 18. Competent law-court (*foro competente*)

For whatever controversy, the competent law-court is the one sited in Genova, Italy.