FC Call for Proposals 2015

- FC -
Fondazione Celiachia
Foundation for Celiac Disease

- AIC -
Associazione Italiana Celiachia
Italian Society for Celiac Disease

FC CALL FOR PROPOSALS 2015
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1. Foreword

The Fondazione Celiachia (FC) is now releasing the **FC Call for Proposals 2015** 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 2015 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 2015 is **€ 400,000**.

The scientific activity must be carried out in public non-profit 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 2015.

Principal Investigators holding an active FC grant cannot apply to the FC Call for Proposals 2015, for neither of the above durations.

The present FC Call for Proposals 2015 will accept the resubmission of not funded Applications that were presented to the 2014 FC Call. Applications presented to the FC Call for Proposals antecedent the 2014 edition will not be accepted.

The FC Call for Proposals 2015 is opened from the 30th of January to the 24th of March 2015
2. Legend

The following abbreviations and definitions are used in the FC Call for Proposals 2015 and the other Official Documentation:

<table>
<thead>
<tr>
<th>Statement</th>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
</table>
| Principal Investigator     | PI           | → The PI is the scientist presenting the Application within the framework of the FC Call for Proposals 2015 and is the sole responsible of the whole research project  
→ The PI is a group leader, conducting a research team  
→ The PI is an independent researcher with a good track record  
→ The PI has Italian nationality and already holds a work contract with the Italian Hosting Institute |
| Hosting Institute          | HI           | → The Hosting Institute is an Italian public non-profit or private non-profit centre with the aim of performing scientific research.  
→ The PI must be affiliated to the HI in which the research presented in the Application will be performed.  
→ The HI is the institution to which FC allocates the Grant for funding the selected project. |
3. Regulation and Policies

The present FC Call for Proposals 2015 represents the regulation of the whole Call, and Applicants and their HI are required to completely adhere to it.

As well, the documents annexed to the FC Call for Proposals 2015 (the Application Form) do constitute integral part of the FC Call for Proposals 2015, and thus also are part of the regulation.

The regulation contained in the FC Call for Proposals 2015 and its documents directly derive from and are in full harmony with the Policies and Guidelines on scientific research issued by the Foundation (Regolamento FC per i Bandi), 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. The Policies and Guidelines (Regolamento FC per i Bandi) are downloadable from the web page of the FC Call for Proposals 2015.
# 4. FC Call for Proposals 2015 Official Documentation

The official documentation relevant to the FC Call for Proposals 2015 is the following:

<table>
<thead>
<tr>
<th>Document</th>
<th>Aim</th>
</tr>
</thead>
<tbody>
<tr>
<td>FC Call for Proposals 2015</td>
<td>Sets the aims and objectives of the Call, along with the rules governing the granting process</td>
</tr>
<tr>
<td>Application Form and Mandatory Annexed Documents</td>
<td>Standard Application Form and Annexed Documents to be mandatorily used for submitting projects. The documents contain all relevant instructions for filling in and completing correctly.</td>
</tr>
<tr>
<td>Regolamento FC per i Bandi</td>
<td>The Policies and Guidelines on scientific research issued by the Foundation, from which the FC Call is derived.</td>
</tr>
</tbody>
</table>

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

Application Forms using additional documents different from the provided templates will be rejected and will not be further considered for the assessment process.
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 research topic can be indicated into the Application Form.

5.2. Research Areas

Moreover, proposed research plans must fall into one 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 research area can be indicated into the Application Form.
5.3. Project Duration

The FC Call for Proposals 2015 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

FC will accept the following typologies of Applications:

<table>
<thead>
<tr>
<th>Typology of Study</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Single Research Group Studies** | → All personnel involved in the project (the research group) belong to the unity/laboratory conducted by the PI  
                                | → **NO** internal/external collaborators are thus envisaged in the Application  |
| **Collaboration Studies**  | → The research also involves **ONE OR MORE INTERNAL AND/OR EXTERNAL COLLABORATORS**  
                                | → Internal collaborators are researchers working within the same HI of the Coordinating PI, but into units/laboratories/departments different from the one conducted by the Coordinating PI  
                                | → External collaborators are researchers working in one or more other Italian Research Institutes/Centres different from the HI of the Coordinating PI  
                                | → The Application Form is presented by the Coordinating PI, and Internal/external collaborators and their role/expertise must be indicated in the Application  
                                | → **ONLY** Italian Institutions/Centres are allowed in Partnership Studies, and they must be non-profit Institutions  
                                | → **NO** funds of the FC Grant and **NO** fellowships/contracts from the FC Grant are allowed to internal/external collaborators  |
| **Multicentre Studies**    | → The research also involves **ONE OR MORE OTHER ITALIAN RESEARCH INSTITUTES/CENTRES** (Partner Centres) different from the HI of the Coordinating PI  
                                | → External Institutions and corresponding research groups are thus described into the Application  
                                | → For each Italian Partner Centre which will take part in the Multicentre Study, the chief researcher (group leader) and the role of the external group must be clearly described into the Application  
                                | → **ONLY** Italian Institutes/Centres are allowed to take part in Multicentre Studies, and they must be non-profit Institutions  
                                | → Funds of the FC Grant are allowed to the Partner Centres when forecasted in the Application Form  |

Both the consistency of the typology and the duration (one-year, two-years, three-years) of the projects will be evaluated by the Reviewers.
6.1. Special Rules for presenting Applications for Collaboration and Multicentre Studies

→ The Application Form for a Multicentre/Collaboration 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 HI of the Coordinating PI.

→ The Ethical Committee approving the Multicentre/Collaboration study is exclusively the Ethical Committee of the HI of the Coordinating PI.

→ Multicentre/ Collaboration 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/ Collaboration 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, with respect to the Regulation of the present FC Call for Proposal 2015, of the work and the conduct of all the collaborators and groups involved in the project, as well 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.

→ 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/ Collaboration study will apply following the rules reported in the Section “Number of Projects to be Presented within the FC Call for Proposals 2015” of the present Call.

→ In case of Collaboration studies, the whole grant will be allocated exclusively to the HI of the Coordinating PI. NO transfer of grant money is allowed to internal/external collaborators/partners. NO fellowships and contracts will be funded to internal/external collaborators. All costs and expenses will be held exclusively by the HI of the Coordinating PI, and the evidence of that will result from the financial reports that the PI and the HI will produce during the Grant. Only the transfer of materials will be allowed to the internal/external 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 HI of the Coordinating PI 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 2014 Applications

For Applications that were evaluated for the first time in the previous FC Call for Proposals 2014, FC allows ONLY ONE MORE resubmission to the FC Call for Proposals 2015. The present FC Call will therefore accept the resubmission of not funded Applications that were presented for the first time to the FC Call for Proposals 2014. Detailed rules for resubmission are explained here as follows:

<table>
<thead>
<tr>
<th>What you can submit to the FC Call for Proposals 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>I.</strong> Applications submitted for the first time to the FC Call for Proposals 2015</td>
</tr>
<tr>
<td><strong>What to select in the Section 6 of the Application Form:</strong></td>
</tr>
<tr>
<td><em>Is the Project Proposal Submitted for the first time?</em></td>
</tr>
<tr>
<td>YES, it is a first submission to the FC Call 2015 ✔</td>
</tr>
</tbody>
</table>

| **II.** Applications submitted for the first time to the FC Call for Proposals 2014 and not evaluated by the Reviewers (rejected at the Conformity Check) |
| **What to select in the Section 6 of the Application Form:** |
| *Is the Project Proposal Submitted for the first time?* |
| YES, it is a first and last (from the FC Call 2014) submission to the FC Call 2015 ✔ |
| **Warning:** In this case, the FC Call 2015 represents the LAST possibility to present again the Project Proposal |

| **III.** Applications submitted for the first time to the FC Call for Proposals 2014 and evaluated by the Reviewers |
| **What to select in the Section 6 of the Application Form:** |
| *Is the Project Proposal Submitted for the first time?* |
| NO, it is a resubmission from the FC Call 2014 ✗ |
| **Warning:** In this case, the FC Call 2015 represents the LAST possibility to present again the Project Proposal |

What you can NOT submit to the FC Call for Proposals 2015

| **I.** Applications already resubmitted to the FC Call for Proposals 2014, independently they were evaluated or not by the Reviewers |

| **II.** Applications already submitted to FC Calls antecedent the 2014, independently they were evaluated or not by the Reviewers |
In case of doubt, the PI is required to ask confirmation to the FC Scientific Office by email to: ufficioscientifico@celiachia.it. FC will provide you with a written answer.

→ Resubmitted Applications do have a dedicated Section within the Application Form, and are carefully evaluated 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 and will not be sent out for review.
8. **Number of Projects to be presented to the 2015 FC Call**

→ The Applicant that is NOT holding an active FC Grant CAN present only one Application as PI AND/OR, in case, only one Application as (internal/external) collaborator/personnel (Collaboration/Multicentre Studies).

→ The Applicant who is the PI of an active FC Grant CANNOT apply nor as PI neither as (internal/external) collaborator/personnel/partner (Collaboration/Multicentre Studies).

→ The Applicant who is internal/external collaborator/personnel/partner of an active FC Grant CAN present only one Application as PI OR, in case, only one Application as (internal/external) collaborator/personnel (Collaboration/Multicentre Studies).

The above rules are summarized in the following scheme which applies to all project durations (one-year, two-years, three-years) and typologies:

<table>
<thead>
<tr>
<th>Applicant:</th>
<th>Application to FC Call 2015:</th>
</tr>
</thead>
</table>
| PI (Coordinator) of an active FC Grant | CANNOT APPLY  
            NEITHER as PI NOR as Collaborator/Partner |
| Collaborator/Partner of an active FC Grant | CAN APPLY  
            as PI OR as Collaborator/Partner  
            for a total of only 1 Application |
| NOT Holder of an active FC Grant | CAN APPLY  
            as PI to 1 Application AND/OR  
            as Collaborator/Partner to 1 Application  
            for a maximum of 2 Applications |

**FOR COLLABORATORS/PARTNERS ONLY**

→ Internal/external collaborators and partner group leaders (Collaboration and Multicentre Studies) are allowed to be involved in ONLY ONE Application PRESENTED OR RESUBMITTED to the FC Call for Proposals 2015. 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 Coordinating 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 to the FC Call for Proposals 2015.
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 Call for Proposals 2015”) including:
  - A financial annual report signed by the PI (the Coordinating PI in case of Multicentre/Collaboration Studies) and the Legal Representative of the HI of the PI
  - A scientific annual progress report signed by the PI (the Coordinating PI in case of Multicentre/Collaboration 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 HI 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 HI has access to them.

→ In case of Collaboration studies, the whole grant will be allocated exclusively to the HI of the Coordinating PI. NO transfer of grant money is allowed to internal/external collaborators/partners. NO fellowships and contracts will be funded to internal/external collaborators. All costs and expenses will be held exclusively by the HI of the Coordinating PI, and the evidence of that will result from the financial reports that the PI and the HI will produce during the Grant. Only the transfer of materials will be allowed to the internal/external collaborators/partners.

→ 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 HI of the Coordinating PI 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. 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 conducted by the Coordinating PI. In the case of Collaboration and Multicentre Studies, internal collaborators (within the HI of the Coordinating PI, but not working into his/her laboratory) as well as group leaders/personnel in the Partner Centres cannot 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 Application Form
   - The fellowship support will **NOT** be awarded to fellows working in clinical areas.

→ 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 2015 Call

10.1. Completing the Application Form and Mandatory Annexed Documents

1. For submitting an Application Form, go to the following webpage: http://www.celiachia.it/fondazione/Fondazione.aspx?SS=1007&M=1248

2. Please, download and complete the following documents:
   → Application Form (word file)
   → Mandatory Annexed Documents to the Application Form (word file)

Detailed Instructions are contained within the Application Form. 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 2015 rules, the provided documents and the completion of the Application Form, please send an email with your query to the FC Scientific Office: ufficioscientifico@celiachia.it. The FC will provide you with a written answer. Questions will be accepted until 18th March 2015 at 15:00 o’clock Italian time. Questions and Answers will be published on the FAQ page: http://www.celiachia.it/fondazione/Fondazione.aspx?SS=1007&M=1248

10.2. Submission of the Application Form and Mandatory Annexed Documents

→ The completed Application Form must be saved as PDF file (please, pay attention to save the file as PDF and NOT as image). The file exceeding 6 MB must be sent as zipped file.

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

→ Finally, the completed Annexed Documents to the Application Form must be scanned as a unique PDF file. The file exceeding 6 MB must be sent as zipped file.

All the above files must be sent to FC by email (bandifondazione@pec.celiachia.it), as recapitulated in the scheme below. The FC pec receives emails from any other kind of addresses, including not pec email addresses.
RECAPITULATING

Send the following files

→ Completed Application Form, saved as (not image) PDF file (zipped file if higher than 6 MB)
→ 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 (zipped file if higher than 6 MB)

to this email address
bandifondazione@pec.celiachia.it

The FC pec receives emails from any other kind of addresses, including not pec email addresses.

The deadline for submitting Applications is the 24th March 2015 at 15:00 o’clock Italian time.

Documents received later than 24th March 2015 at 15:00 o’clock Italian time will be automatically rejected, 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 2015 undergo the following steps:

<table>
<thead>
<tr>
<th>First Step</th>
<th>Check of Conformity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Second Step</td>
<td>Peer Reviewers’ Evaluation</td>
</tr>
<tr>
<td>Third Step</td>
<td>Discussion Session of the Peer Reviewers</td>
</tr>
<tr>
<td>Final Step</td>
<td>Approval of the Ranking List by the FC Board, and funding</td>
</tr>
</tbody>
</table>

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 PI and the HI.

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. 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
→ Blue ink signature of the PI and the Legal Representative of the HI
→ Respect of the maximum grant request per year (€ 70,000)
→ Italian nationality of the PI
→ Contractual position of the PI within the HI
→ The guarantee of a time involvement of the PI in the project equal or superior to 4 months per year
→ No active FC funding as PI
→ The Project Proposal is a first time submission or an acceptable Resubmission of the proposal presented to the FC Call 2014
→ The respect of rules at page 15 (‘Number of Projects to be presented to the 2015 FC Call’) and page 15 (‘FOR COLLABORATORS/PARTNERS ONLY’) of the present 2015 FC Call
→ the Project Proposal submitted to FC (or whatever part of it) must NOT have any other active fundings and/or must NOT be competing for any other fundings
Absence of research team members being employed by a company
Italian non-profit research institute status of the HI (public or private)

1 By submitting the Proposal to the present FC Call and by signing the Application Form, the PI assures for the observance of this rule. However, if the PI is receiving or expecting to receive grants from any other funding agency for projects overlapping in whatever part with the current proposal, but he/she presumes that completely different results will be gained by the submitted proposal, then the PI can try to compete for the present FC Call by mandatorily completing the relevant Section 12 of the Application Form, in which he/she will describe the active/pending fundings and underline the differences with the submitted proposal. Reviewers will evaluate whether the submitted proposal is really different from the project(s) already submitted to the other agencies and thus deserves to compete for FC fundings. In case of negative evaluation, the Proposal will be rejected.

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 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:

A. Triage for Scientific Competitiveness
B. Score Evaluation of the Project Proposal

A. Triage for Scientific Competitiveness

In this step, the reviewers evaluate scientific competitiveness and strength of the project proposal on the basis of the following criteria:

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adherence to FC’s main research priorities</td>
<td>Reviewers assign a HIGH/LOW priority assessment to each evaluated project</td>
</tr>
<tr>
<td>Consistency of the project with the selected duration</td>
<td>The Reviewers evaluate the consistency of the project design, structure and purposes with the indicated duration</td>
</tr>
<tr>
<td>Consistency of the project</td>
<td>The Reviewers assess the consistency of the project with the selected topic: 1. Celiac Disease, 2. Dermatitis Herpetiformis, 3.</td>
</tr>
</tbody>
</table>
### Consistency of the project funding request

The Reviewers assess the consistency of the funding request with FC Call Policy and the experimental plan/stated objectives.

**ONLY in case of Resubmitted Applications**

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.

At the end of this evaluation step, the reviewers rank the Application as STRONG or WEAK study: WEAK studies are triaged OUT and do NOT enter the ranking list.

### B. Score Evaluation of the Project Proposals

Strong studies are further evaluated by the Reviewers.

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:

<table>
<thead>
<tr>
<th>Weighted Evaluation Areas</th>
<th>Scored Criteria</th>
</tr>
</thead>
</table>
| **Project’s Purposes and Scientific Value of the Project (80% weight)** | – Clearness of the project purpose  
– Improvement of basic/clinical comprehension of celiac disease and/or gluten related disorders stemming from this research  
– Design and tasks of the project: background, rationale, experimental design, methodologies  
– Preliminary data supporting the working hypothesis  
– Appropriateness of sample sizes  
– Methodological or conceptual innovation of the project  |
| **Feasibility of the Project (20% weight)** | – Potential difficulties and limitations of the project, and their impact on the success of the proposal  
– PI’s expertise, qualification, past experience and accomplishments (IF, publications track record) directly relevant to the success of the proposal  
– Expertise of the research team  |
The score system adopted by the Reviewers during the assessment of the project is here represented:

<table>
<thead>
<tr>
<th>Score</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>1</td>
<td>Very Weak</td>
</tr>
<tr>
<td>2</td>
<td>Weak</td>
</tr>
<tr>
<td>3</td>
<td>Acceptable</td>
</tr>
<tr>
<td>4</td>
<td>Good</td>
</tr>
<tr>
<td>5</td>
<td>Very Good</td>
</tr>
</tbody>
</table>

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

‘Overall review scores’ allows for the establishment of a ranking list of the evaluated projects.

11.3. Third Step: Discussion Session of the Peer Reviewers

The first 10 Projects in the ranking list are discussed de visu by the Reviewers in a Study Session. A final ranking list is produced at the end of the Discussion Session.

11.4. Final Step: Approval of the Final Ranking List by the FC Board, and Funding

FC’s Board of Directors meets to decide on the allocation of funds to the most deserving projects of the final ranking list.

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

All Applicants 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 ‘Rete e Celiachia’

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 ‘Rete e Celiachia’. Within the Congress, a ‘Progress and Final FC Grant Report Meeting’ might be forecasted.

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

doing the research 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 10th of 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

Ai sensi dell’art 13 del decreto legislative 30 giugno 2003 n. 196, i dati personali e sensibili forniti dai candidati sono trattati per le finalità di gestione del presente bando e per la successiva eventuale attribuzione del finanziamento. La comunicazione di tali dati è obbligatoria ai fini della valutazione sia formale che scientifica. FC s’impegna a garantire che i progetti presentati e non approvati e i relativi giudizi e valutazioni non siano divulgati, e vengano conservati in modo sicuro e non accessibile. Per i progetti finanziati, le modalità di diffusione e divulgazione saranno trattate in fase di contrattualizzazione del Grant. Firmando l’Application Form, il PI e il Rappresentante Legale s’impegnano ad accettare queste regole.

18. Competent law-court (foro competente)

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