- AIC -

Associazione Italiana Celiachia

Italian Society for Celiac Disease

- FC -

Fondazione Celiachia

Foundation for Celiac Disease

CALL FOR PROPOSALS 2013

AIC - Associazione Italiana Celiachia – www.celiachia.it
Italian Society for the Celiac Disease
Scientific Office
Via Caffaro 10, 16124 Genoa, Italy
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Foreword

The Fondazione Celiachia (FC) is inviting Applications **to grant three-years Italian research projects** in the area of **celiac disease** and **gluten associated pathologies**. These grants are intended to:

1. support the research of established and independent scientists, leading an existing research unit,
2. encourage talented young researchers to submit their research proposals.

The scientific activity must be carried out in a non-profit research institution located in Italy (university, hospital or other research center).

Support will be provided for **a period of three years (up to 100,000 €/year)**. **Applications exceeding € 100,000 per year will not be taken into consideration.**

The Call is open from **1st April to 15th May 2013.**

Eligibility criteria

Applicants. Applicants, henceforth defined Principal Investigators (PI), can be of any nationality. They should have achieved scientific independence, and they **must have a good track record**, as demonstrated by primary research papers (no reviews) in high level peer-reviewed journals.

FC reserves the right to reject proposals from PIs who, even if jointly affiliated to an Italian and a foreign institution, do not meet criteria for continuous presence in the Italian institution for at least 50% of their time, regardless of the "Effort on project" indicated in the application (see "Personnel Involved in the Research" section).

Hosting Institutions and affiliations. Applicants must operate in a non-profit Italian Institution for the entire duration of the grant. In the application, only the Institution where the research will be carried out must be indicated. Any change occurring in the relationship between applicant and the Hosting Institution (*e.g.* termination, retirement, leave of absence, sabbatical etc.) or in the Hosting Institution legal entity or organization (*e.g.* changes in Institution name, merging, Legal representative turn-over, changes in addresses) must be promptly notified to FC.

The Hosting Institution must be a non-profit research institution (possible revenues must be reinvested in research activities), with the mission to develop research and to disseminate its results.

Hosting Institutions must provide proper working spaces, laboratories, equipment, qualified personnel and resources to allow the project execution. FC reserves the right to verify that these conditions are met.

Research Plan. Proposals must have a clear focus on celiac disease and gluten associated pathologies: this is an eligibility factor, and projects that are not consistent with any of FC research targets will not be taken into consideration. Moreover, FC is interested into three-years research projects: this also is an eligibility factor, and the reviewers are required to evaluate whether submitted projects are consistent with a triennial duration. Finally, a grant proposal that has been rejected twice in the past cannot be resubmitted a third time. See "Resubmission of revised applications" for further details.

The research plan

Topics:

All proposed research plans must have a clear focus on one of the following **Topics** (this is an eligibility factor during the review process of submitted proposals):

1. celiac disease
2. dermatitis herpetiformis
3. wheat allergy (respiratory allergy; food allergy; wheat-dependent, exercise-induced anaphylaxis; occupational asthma and rhinitis; contact urticarial)
4. non-celiac gluten sensitivity

Research Areas:

Moreover, proposed research plans should fall into one of the following **Research Areas**:

1. Clinics (pediatrics or adult)
2. Clinical trials
3. Preclinical study
4. Epidemiology - Prevention
5. Genetics - Control of gene expression and epigenetics
6. Proteomics
7. Biology (structural, computational, signaling)

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8. Biochemistry
9. Immunology - Immunobiology
10. Nutrition
11. Oncology
12. Allergology
13. Dermatology
14. Endocrinology
15. Gynecology
16. Anatomic pathology - Histopathology
17. Drug discovery – screening - development
18. Infection and inflammation

In principle, FC believes that rigid guidelines on the research plan should not be provided for this type of grant since investigator-driven discovery is one of the most potent engines of scientific progress.

At the same time, FC feels that phenomenological, descriptive-at-best, proposals should be discouraged. 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;

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- Clinical studies that are clearly drug company-driven, in such a way that free exchange of reagents and information would be impaired, the PI or the Institution would be deprived of the intellectual property of the data, or the company could veto publications of results. This does not exclude collaborative studies with industry;
- Clinical studies that do not contribute to build or expand an original and independent line of research.

FC has mainly interest in types of studies focused on:

- proximity to find new pathogenic mechanisms;
- natural history of celiac disease (or the above mentioned disorders) by linking different phases of the disease to specific biological/genetic profiles;
- interactions between environmental risk factors, genetic profiles and intermediate biomarkers;
- proximity to cure;
- 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);

All proposals must contain appropriate provisions for study design, statistical analysis and sample size (whenever applicable), in particular for studies with human subjects (clinical and epidemiological). If such information is missing or insufficient, the research proposal will be rejected.

For clinical trials involving human subjects, and for studies with human biological samples, the approval of the local Ethics Committee/Institutional Review Board is mandatory; research proposals will not be funded in the absence of such documentation. See the "Bio-ethical requirements" section of the Guide to proposal preparation for further details on the documentation required. FC does not accept any liability for harm to participants in FC funded trials.

Proposals of clinical studies that are property of companies producing drugs or diagnostic tools and that receive economic support from such companies will not be accepted. Drug supply and economic support from companies do not preclude FC evaluation, provided that the PIs

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have the full property of data and results, and that companies have no right to veto the publication of results at any time. A statement that the management of the study, data acquisition and analysis and data property are completely independent of any company producing/marketing drugs or diagnostic tools or with any type of economic interest in the study must be clearly reported in the Proposal Main Body, together with the indication on whether the company provides its product(s) to the PI for free or not. Failure to provide such information will result in the rejection of the proposal.

Intellectual property

For inventions arising from a FC funded project, grant money can be used to cover the costs for filing a patent application within the European Union (EU), but not to extend a patent to non-EU countries. Intellectual property and patents resulting from research carried out with FC grants will be solely owned and managed by the grantee and/or the non-profit Hosting Institution.

Funding

Grants are for a three-year period, contingent upon the presentation of yearly renewal requests. Funding applications must not exceed € 100,000 per year. Applications exceeding € 100,000 per year will not be taken into consideration.

Applicants must indicate the requested support in the budget section of the application, providing a detailed financial breakdown of the anticipated expenditures.

The following costs are **permitted**:

- Direct research costs, inclusive of consumables and supplies, small bench instrumentation, services, maintenance contracts, publication costs, meetings/travel costs;
- Support for fellows (personnel costs). Support will be provided only for fellows at 100% of time on the project. Applicants should ascertain that their own Institution can take on fellows;
- Indirect costs. These are generated by the research project, but cannot be attributed directly and quantitatively to a specific activity. For example, they may include core facilities, personnel of the research team not directly involved in research activities (*e.g.* secretaries and core-facilities personnel, etc.). Indirect costs are **up to 15%** of the direct research costs (personnel included);

– Overheads. These are expenses that the Hosting Institution must cover so that the research can be carried out. They may include, for example, grant management costs, utilities, administrative costs etc. Overheads are **up to 10%** of the sum of direct (personnel included), and indirect costs.

Both indirect costs and overheads can be calculated by the Hosting Institution according to its own accounting standard criteria.

Once awarded, the grant is assigned to the PI to carry out the project described in the application.

Funds will be made available to the Hosting Institution under terms and conditions that FC will provide once the application is approved. Funds must be at the grantee's disposal **within 30 days** from the time the Hosting Institution has access to them.

Transfer of grant money to collaborators working in other laboratories either in Italy or abroad is not allowed.

Deadlines:

- **Renewal requests must be submitted yearly** (see Deadlines), through appropriate forms, and will be approved for the second and third year, provided that FC has available funds and that the PI and the Hosting Institution have complied with the terms and conditions of the grant.
- At the **end of the third and last year, a scientific final report will be required** and will strongly impact the evaluation of future FC grant applications.
- An **administrative final report** must be submitted within three months after the termination of the grant (see "Deadlines" section).

Please note that FC reserves the right to audit the administrative management of the project at any time.

The Review Process

All applications undergo an initial administrative review by the AIC Scientific Office for compliance with guidelines and eligibility; those that do not conform will be triaged out.

Applications from researchers who meet the eligibility requirements undergo a peer review process that ensures a fair, independent and expert evaluation of their scientific quality.

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For the evaluation of grant applications FC relies on the expertise of a panel of well-established international investigators working in institutions outside of 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 conflict of interest and appearance of conflict rules to ensure a review free from inappropriate influence (*e.g.* no application from a given research Institution is assigned to reviewers from the same Institution or the same city). When accepting to evaluate an application, reviewers agree that they will maintain the confidentiality of the application and associated materials they have received.

The **review criteria** are:

a) Significance and relevance to celiac disease and gluten associated pathologies (see the "Research Plan" section);
b) Innovation;
c) Approach and feasibility;
d) Track record and international standing of the investigator in celiac disease (or the other topics mentioned above; see the "Research Plan" section);
e) International competitiveness, independence, leadership and scientific productivity adequate to successfully complete this study;
f) Environment and standing of the Hosting Institution at the international level;
g) Adequacy of the budget requested.

When all reviews have been completed, applications are discussed by members of the AIC and FC Boards of Directors. Final Reports of previously funded applicants are also taken into account during these meetings as a measure of productivity and scientific accomplishments of the PIs. In the final plenary session, all grants are ranked in order of scientific merit. The final ranking and the financial availability of FC will determine the funding. All applicants will be notified of the final decision on their application with an official communication from FC, and they will have access to the reviewers' comments. The identity of the reviewers will not be disclosed. **The decision concerning the funding of an application cannot be appealed.**

Please note that after the awarding of a grant, **FC reserves the right to site-visit the PI's laboratories and Institutions, at any time.**

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Resubmission of revised applications

FC allows only one resubmission for applications that were not funded. The revised application must include a response to the reviewers' comments in the "Revision" section of the Application Form.

A revised application that has not been approved even after addressing all the issues raised by the reviewers is not competitive enough and therefore cannot not be submitted a third time. Applicants who fail to receive funding after two submissions (*i.e.* the original and the revised application) **may submit a new application only if its research plan is fundamentally different in content and scope from the two that were previously considered not fundable**. More specifically:

- A new application should include substantial changes in all sections of the research plan;
- There should be fundamental changes in the questions being asked and/or the outcomes examined;
- Changes to the research plan should produce a significant change in the direction and approach for the research project;
- Rewording of the Title and Abstract does not constitute substantial changes in scope, direction or content.

An application submitted for the third time (by the same or other applicants) will not be sent out for review and will automatically be rejected.

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Deadlines

1. Deadlines for applications to the Call 2013.

Call of Proposals and Application Form release	April 1, 2013
Submission deadline	**May 15, 2013** (by 12:00 a.m., Central European Time)
Notification of results	September 30, 2013
Assignment to the PI's Hosting Institution	October 2013
Start of grants (FC considers that assigned funds must be at the grantee's disposal **within 30 days**)	November 2013

Deadlines are strictly enforced: **applications submitted after the deadline 15th May 2013 will not be accepted.**

2. Deadlines for renewals and final reports (by 12:00 a.m., Central European Time, of the indicated dates).

Renewal for 2nd year of funding	Application Form release	April 15, 2014
	Submission deadline	May 15, 2014
Renewal for 3rd year of funding	Application Form release	April 15, 2015
	Submission deadline	May 15, 2015
Scientific final report	Form release	July 15, 2016
	Submission deadline	January 10, 2017
Administrative final report *	Form release	January 10, 2017
	Submission deadline	March 15, 2017

The deadlines for renewal requests and final reports may be subjected to changes. In this case, PIs will be notified of the new deadlines by e-mail.

* The Administrative final report ("*rendicontazione*"): conditions.

The Administrative final report is required as scan copy (to be converted into PDF files) of the form signed by the PI and the Institutional Legal Representative. Since the grant is paid with funds from revenues of the «5 per Mille», FC must send a copy of this report to the competent Ministries.

The grant is subject to **recoupment** in any of the following situations:

- if the Final administrative report is based on false statements;
- if no Final administrative report is submitted;
- in the absence of receipts and payment accounts for the amounts supplied during an audit;
- under any circumstances where the PI fails to comply to the terms and conditions indicated in this Call and in all official communications sent by FC relative to the awarded grant.

The Final administrative report and all supporting financial documentation (receipts etc.) must be related to the **research proposal carried out between the start of the Grant (approx. November 2013) and the end of the Grant (approx. October 2016)**. FC reserves the right to check at any time such documentation, which must be kept in the appropriate offices of the Host Institutions for **10 years** after the end of the grant.

***** Rendiconto amministrativo: regole di rendicontazione

Alla fine del terzo anno FC richiederà un rendiconto amministrativo. Dal momento che il progetto è finanziato con fondi provenienti dal contributo del 5 per mille, questo rendiconto dovrà essere inviato da FC ai ministeri di competenza che hanno erogato detto contributo. FC si riserva la facoltà di verificare la corrispondenza della documentazione contabile a supporto del predetto rendiconto, che dovrà essere conservata per 10 anni presso la sede legale dell'istituto ospitante e potrà essere soggetta a controlli. FC si riserva la facoltà di recuperare le somme erogate per il finanziamento del progetto qualora:

- le somme non siano state oggetto di rendicontazione;
- la rendicontazione sia determinata in base a dichiarazioni mendaci;
- non vengano rispettate le linee guida che sono stabilite nel presente Bando e nelle comunicazioni ufficiali di assegnazione dei fondi al progetto selezionato.

La rendicontazione e la relativa documentazione contabile a supporto devono fare riferimento al periodo di progetto, dall'inizio del grant (appross. Novembre 2013) al termine dello stesso (appross. Ottobre 2016).

Guide to proposal preparation

A- Registration and access to the Application Form:

To apply, go to the site www.celiachia.it/FC_E_RICERCA and click first on "FC Research" and then on "FC Call for Proposals 2013". The access to the Application Form is subjected to registration of the applicant: please provide all requested information.

B- Compilation of the Application Form:

Applications that do not conform to all the requirements in these instructions will be rejected.

1. Upon registration, the Application Form (which is an editable PDF) is downloaded and completed on the applicant's computer.
2. The Application Form is made out of different sections. **Send the completed Application Form and the other required documents to the following email address by the established deadline 15th May 2013: bandifondazione@pec.celiachia.it**
3. Secure PDF files are not allowed and will be rejected.
4. The application must be written entirely in English.
5. Do not exceed the page limit indicated for each section.

Sections of the Application Form:

1- Principal Investigator (PI)

The PI is the researcher who is primarily responsible for designing and directing the proposed research. Please fill in the requested fields, entering:

• *The PI's personal data (title, qualification, gender):* The qualification is the PI's current position (*e.g.* associate professor, staff scientist, etc.);

• *The title of the proposal*: The title must not exceed 180 characters, spaces included. It should not be too specific, nor too vague (such as "Post-translational modification of proteins"), neither it contains abbreviations of molecules names;

• *The Topic and the Research area*: First **indicate one of the Topics** listed in "The research plan" section of this Call, then **indicate one of the Research areas** provided in the same section, basing on the research activity that will be carried out with the grant.

2- Your Contact Data

Please provide the PI's Institution, Department, Address, City, Zip code, Phone, Fax and e-mail. If possible, please provide the PI's mobile phone number as well. The affiliation must correspond to the Italian research center where the PI will carry out the research activity.

Applicants may designate a Grant Officer from their Institution to assist in the preparation and submission of the application. The name of the Grant Officer must be indicated into the form. However, the PI is fully responsible of the entire proposal content.

3- Administrative Data

Please provide the requested information about the Legal representative (*Legale rappresentante*) of the Institution. The Legal representative will be responsible, along with the PI, of all the legal and administrative duties of the grant.

4- Project Keywords and Research Plan

Project keywords will be used by the AIC Scientific Office to assign each application to the most appropriate reviewers. Keywords are listed at the end of this Call.

Pick a **set of keywords (at least five)** that clearly define the key aspects of your research plan, following these instructions: use one of the Topic keywords, one of the Research Areas keywords and at least three (and no more than five) of the Detailed Description keywords.

5- Abstract

Extreme care must be placed on the Abstract preparation. The Abstract must provide an immediate understanding as to why the research plan is proposed, which approach will be undertaken and the potential relevance of the whole line of research. Avoid long introductions and do not include references.

The Abstract must be structured into the following sections: Background, Hypothesis, Aims, Experimental Design, and Expected results. **The total number of words for the entire abstract must not exceed 500 (about 3,500 characters including spaces)**. The Abstract of all research projects funded by FC may be made public on AIC journals and websites.

6- Revision

Complete this section only if submitting a revised application, *i.e.* only if resubmitting an application that was not funded in a previous Call. Please provide a point-by-point reply to the criticisms and issues raised by the reviewers, explaining how they have been addressed and indicating all changes (additions, deletions, modifications) introduced in the research plan for this purpose. **Please do not exceed two pages (approx. 700 words or 4800 characters including spaces).**

The AIC Scientific Office will try to assign revised applications to the same reviewers that evaluated it in the previous Call. However, this is not always possible as some reviewers may not be available in every round of review. Therefore, please make sure to describe (or to report verbatim) all issues raised in the original evaluations, so that potentially new reviewers can understand how the application has been modified to address the criticisms.

An application submitted for the third time with the same research plan (by the same or other applicants) will not be sent out for review.

7- Proposal Main Body

This section must not exceed 10 pages (approximately 3500 words), including figures and preliminary data. Describe in detail the proposed research, intended to have a duration of three years, according to the following guidelines:

- please provide the **background and rationale** of the proposed research, along with relevant literature references; avoid lengthy, paper-like, introductions. The bibliography should be limited to only those citations essential to the application. List all references together at the end of the proposal main body, **employing the following format (for any reference, give the title and all authors):** S. Husby, S. Koletzko, I.R. Korponay-Szabo´, M.L. Mearin, A. Phillips, R. Shamir, R. Troncone, K. Giersiepen, D. Branski, C. Catassi, M. Lelgeman, M. Ma¨ki, C. Ribes-Koninckx, A. Ventura, K.P. Zimmer. European Society for Pediatric Gastroenterology, Hepatology, and Nutrition Guidelines for the Diagnosis of Coeliac Disease. JPGN 2012;54: 136–160. When available, we strongly encourage to include a paper identification code (PubMedID or doi);
- please describe the **experimental design and methodologies** that will be employed. If the methodology is new or unusual, describe it in sufficient details for evaluation. Description of cumbersome experimental details and protocols, however, is not encouraged and generally

detracts from the quality of the proposal. The research plan should be organized in *tasks*. Given existing difficulties in splitting clinical and epidemiological proposals into tasks, the task subdivision is mandatory only for proposals in laboratory research areas only. Proponents of clinical and epidemiological studies should use subdivision in *phases* whenever possible, since this facilitates the work of reviewers and, in general, results in a better appreciation of the real value of the proposal. When the description of the research can be subdivided in tasks/phases, each numbered item must describe a precise part of the project with its own experimental design and methodological approach. The objective (milestone) of each task/phase and the experimental design (including methods and time-frame) should be clearly identifiable and will be examined by the reviewers to evaluate the feasibility of the project;

- please **include a section on potential pitfalls and caveats,** discussing the potential difficulties and limitations of the proposed procedures, and **suggesting alternative approaches to achieve the purposes**;
- please describe the feasibility of the project, by providing:
  - *preliminary data*. Pay particular attention to this point, as reviewers always evaluate whether enough preliminary data are provided to support the working hypotheses. Include figures (not just written descriptions) of relevant preliminary data;
  - *power calculation*. For clinical and epidemiological studies, and whenever appropriate, make sure to have adequate sample sizes to ensure meaningful and statistically significant results;
  - *description of the PI's expertise*. Qualification, past experience and accomplishments that are directly relevant to the projected success of the proposal;
  - *description of facilities and equipment* available for the research;
  - *description of the key expertise* available in the research team.

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8- Personnel Involved in the Research

This **section must be filled out for all persons** directly involved in the project, including the PI. **Do not list** secretaries and/or administrative staff. Begin by completing the information relative to the PI; then insert other personnel.

For every unit of personnel listed there should be a description of the work that she/he will perform in the "Description of the Work for each Unit of Personnel" section. Units of personnel devoting **less than 20%** of their time to the project should not be added in this section; they should be just listed in the "Description of the work for each unit of personnel".

Please pay particular attention to the allocation of manpower: reviewers will determine whether it is reasonable for the amount and type of work proposed. PIs are expected to be involved for a significant fraction of their time. The contracts for the personnel involved in the research project must be stipulated by the Institute hosting the research, according to the law in force.

Role on project. Please choose one from the available entries:

- fellow;
- technician;
- internal collaborator (for any personnel working in the same laboratory, Department or Institution as the PI, and working/collaborating with the PI on the proposed research plan);
- external collaborator (for scientists collaborating with the PI and working in a different Institution). For external collaborators, a formal letter of collaboration is required and must be sent as PDF file to the AIC Scientific Office. In the letter, collaborators should describe in detail their role in the project and the expertise they will provide. Please note that the term "Collaboration" means a scientific collaboration, not a kind of labor contract.

Clinician. For each personnel, including the PI, indicate "clinician" only if directly involved in clinical practice (*i.e.* examining and treating patients).

Financial support. It indicates the amount of financial support for personnel (*e.g.* fellowship) requested. **Support will be provided only for fellows at 100% of time on the project**. Financial support can be required, however, 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 Institution is permitted, but two salaries are not allowed. Applicants should ascertain that their own Institution can take on fellows under this provision. The fellowship support **should not be awarded to fellows working in clinical areas**, since, almost by definition, no clinical fellow can be listed as 100% on a

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specific project. Exceptions may be possible if thoroughly justified in the "Personnel costs justifications" section of the budget form.

Man/year effort. Please indicate the percentage of time that will be devoted to the actual performance of the work. **Fellows for whom a salary is requested must be at 100% of their time on the project. FC discourages the habit of listing many units of personnel at marginal fractions of their time**: therefore, make sure to have a sizable number of units of personnel devoting **at least 75% of their time** to the project. PhD students (or equivalent) can be listed as 100%, as the time commitments to courses is not taken into account.

In general, **requests for fellowships should not exceed 50% of the total man/year effort**.

Example: for a research unit where all personnel adds up to a total of 4 man/year effort, no more than two fellowships for two fellows at 100% of their time (= 2 man/year effort) can be requested.

A short CV, **max one page**, **in English**, must be added for personnel working at more than 75% of their time, with the exclusion of technical staff. Send the CV as PDF file to the AIC Scientific Office. **The following format must be used for all CVs**:

- personal data (name, date and place of birth, citizenship, work address, phone number and email address);
- education (list, in reverse chronological order, all degrees obtained);
- research experience (list, in reverse chronological order, all positions held, describing very briefly – two sentences max – the main focus of the research activity);
- technical skills and competences;
- awards;
- publications (please provide only a selection of the most relevant, with a maximum of five).

9- Description of the Work for each Unit of Personnel

The Description of the Work for every Unit of Personnel must be attached as PDF file to the Application Form. Please **do not exceed 2 pages (700 words) for the entire staff**.

Describe in a concise, but complete manner, the work that each unit of personnel listed in the previous section will perform. Please indicate the position held by all personnel listed (*e.g.* investigator, post-doc, staff scientist, technician, etc.). **Do not list** undergraduate students, secretaries and/or administrative staff.

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10- Budget

In the three columns, one for each year of support, insert the amount needed for each of the categories allowed. Budget categories allowed:

- *Direct research costs (excluding personnel)*: The standard way of budget calculation, based on an itemized list of actual costs, must be employed. Enter the amount of money needed for research costs, divided into the following subcategories:
  - consumables and supplies (examples: plasticware, reagents, chemicals, animals if applicable, etc.);
  - small bench instrumentation (examples: electrophoresis power supplies, microcentrifuges, PCR machines etc.);
  - services (examples: sequencing, microarray, histology, patent filing costs, etc.);
  - maintenance contracts (examples: service contracts for large instruments; animal facilities contracts if outside the Hosting Institution);
  - publication costs;
  - meetings and travel costs.
- *Personnel costs*: the amount requested for the first year must be indicated in this field if one or more fellowships have been requested in the "Personnel involved in the Research" section. Remind that **requests for fellowships should not exceed 50% of the total man/year effort**. If fellowships are requested also for the second and third year of support, please fill out the relevant fields.
- *Indirect costs*: as defined in the "Funding" section of this Call, indirect costs **will be supported up to 15%** of the direct research costs (personnel included).
- *Overheads*: as defined in the "Funding" section of this Call, overheads **will be supported up to 10%** of the sum of direct (personnel included) and indirect costs.

For each budget category please provide (mandatory) a description/justification of the amounts requested. More specifically:

- for each section of the "Direct research cost", provide a financial breakdown, on an item basis;
- for "Personnel costs": describe under what type of provision (*e.g.* fellowship, contract etc.) the fellows for whom financial support is sought will be hired. Use this section to justify exceptions for requesting financial support for clinicians (see the section "Personnel involved in the research");

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– for "Indirect costs" and "Overheads": please indicate the percentage rate(s) charged by the Institution. Moreover, please include a letter in PDF file format ("Institutional Letter of Indirect Costs/Overhead") indicating the percentage rate(s) of indirect costs and/or overheads charged by the Hosting Institution, even if the rate is zero. The letter must be dated and signed by the Legal representative. Please note: the rate indicated in the letter must be consistent with the amount(s) requested in the budget form and with the limits imposed by FC for these categories of costs.

If no expenses are foreseen for any particular category of costs, **please indicate it with "n/a"**.

11- Existing/Pending Support

If the PI is receiving or expecting to receive grants from any funding agency, please list them, regardless of whether they overlap with the current proposal or not. For each ongoing and/or pending grant, indicate: the funding agency, project title, duration, level of funding (in Euros) and degree of overlap (in terms of research plan) with the project presented with this FC Grant application. In case already funded research projects overlap or are very similar to the current proposal, provide a justification for requesting additional support from FC; also, please provide name and percentage of time committed of all personnel listed in the current application (including the PI) that are also involved in the other grant. A single unit of personnel cannot be allocated for more than 100% of the time. This applies to the sum of all grants, including those from agencies other than FC.

12- Education and Training of the PI

Please list in reverse chronological order degrees and post-doctoral trainings of the PI. For each entry, please indicate the Institution, City, Field of research, time frame and name of the supervisor.

13- Research and Professional Experience of the PI

Please list in reverse chronological order all positions held by the PI. For each entry, please indicate the Institution, City, Country, time frame and the position held.

14- Research Interruptions and Justifications

This section should be completed in case the applicant's research activity has been interrupted for periods longer than 5 months between 2008 and 2013 due to parental leave, children care, illness or

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other personal issues. This section allows applicants to report prolonged periods of absence from work that may have had a negative impact on their track record. Reviewers are instructed to take this information into account when assessing the scientific productivity of an applicant.

15- Publications

In this section, the PI must provide the list of papers published in **the last five years (from 2008 to 2013)**. This **PI's list of publications** is used by the AIC Scientific Office to calculate the *5-years total IF* (all papers published by a PI in the last five years) and the *5-years total active IF* (the sum of IFs of articles where the PI is first, last and/or corresponding author in the last five years). The PI's list of publications and the corresponding *5-years total IF* and *5-years total active IF* are intended as a quick assessment of the productivity in the last five years and of the international standing of the PI, in order to facilitate the work of reviewers.

Even though the Impact Factor is internationally acknowledged as an important objective criterion that allows for an estimate of peer-recognition of the work of a given investigator, FC is aware that it is not an absolute standard to evaluate scientific productivity. Indeed, several circumstances mitigate the relevance of the IF; for example, some important, recently established journals may not be impacted yet or have "artificially low" IF due to their young age. Also, for some research areas with very specialized, limited readership (*e.g.* medicinal chemistry) the best journals have low IF compared to others in more popular research arenas. **Reviewers are carefully instructed by FC to give due consideration to all caveats associated with the IF when assessing an applicant's track record and scientific productivity.**

In order to create the list of papers published in **the last five years (from 2008 to 2013)**, the PI has two possible options available:

a) The list of PubMed publications

Please strictly follow these steps on the PubMed website to **generate the final list of PI's PubMed publications from 2008 to 2013 to be included in the application**:

a.1 - Select PI's papers from 2008 to 2013 to be included in the application:

- Please launch a PubMed search with the PI's name (last name and initials);
- From this generated list of PubMed publications, select by clicking in the checkboxes the papers published by the PI and that the PI wants to include in the proposal, spanning from 2008 to 2013. Pay **special attention to potential homonyms**. **Do not include** abstracts,

conference papers, letters to the editor, book chapters and papers published in journals without IF, unless they are new journals.

a.2 - Create the PubMed page:

- After selecting all the PI's publications of interest from 2008 to 2013, click on "Display Settings" into the PubMed page and choose "Summary" and then "Apply". A new PubMed page is automatically generated in which only PI's selected publications are reported (PI's PubMed page);
- Within this PI's PubMed page, now click on "Send to" and choose "E-mail";
- A new window opens in which you may perform a number of choices: use the following default settings such as "Summary" for the "Format" menu and "Recently Added" for the "Sort by" menu; if necessary, select a "Number to send" that does contain all the PI's selected publications; finally enter your e-mail address (or another email address of your choice) and send the PI's PubMed page to the chosen email address by pushing the "E-mail" button. **Please store this email that PubMed sends to you, since it contains the PI's PubMed page with direct links to the corresponding PubMed website page**. This email is necessary to the AIC Scientific Office for the acceptance of the Application Form: **applications missing this PubMed email will be rejected.**

a.3 - Create the PubMed file:

- In the same PI's PubMed page generated in the previous point, click again on "Send to" and choose "File";
- Then choose "MEDLINE" from the "Format" menu; use the default setting "Recently Added" for the "Sort by" menu;
- Finally click on "Create File" button. Save the file as text file (.txt) with PI's name and initials **using this format**: "Rossi_M_PubMed_Medline_2008_2013". **When sending the completed Application Form, this file must be sent together with the PubMed mail of the PI's PubMed page (described in the previous point) to the AIC Scientific Office**.

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b) The list of Web of Science® publications

In case the PI has publications from 2008 to 2013 that are included in Web of Science® but not in PubMed, **it is possible to generate also a list of PI's Web of Science® publications from 2008 to 2013 to be included in the application together with the PubMed list. In this case, both lists must be sent to the AIC Scientific Office together with the Application Form.** Please strictly follow these steps on the Web of Science® website to generate the final list of PI's Web of Science® publications from 2008 to 2013 to be included in the application:

b.1 - Select PI's papers from 2008 to 2013 to be included in the application:

- Please go into the "Author Search" page of the Web of Science® website;
- Enter the PI's name (last name and initials), and choose "Exact Matches Only"; if necessary press "Select Research Domain" button, otherwise press "Finish Search" button;
- If you chose the "Select Research Domain", please select the Research Domains of your interest; then press "Select Organization" button, otherwise press "Finish Search" button;
- If you chose the "Select Organization", please select the Organizations of your interest; then press "Finish Search" button.

b.2 - Create the Web of Science® list:

- A list of Web of Science® publications is generated;
- Now refine your search by using the "Refine Results" box on the left-side of the Web of Science® page: first select only "Article" and "Review" in the "Document Types" menu; then select only years from 2008 to 2013 in the "Publication Years" menu of the box; then press the "Refine" button;
- At this point, a refined list of Web of Science® publications is generated which contains only articles and reviews from 2008 to 2013. Please select by clicking in the checkboxes **only the papers published by the PI that are not already included into the PI's PubMed list**. Pay **special attention to potential homonyms**. **Do not include** abstracts, conference papers, letters to the editor, book chapters;
- Once selected by checkboxes the appropriated papers, go to the "Output Records" box in the bottom of the page and choose "Selected Records on page" (Step 1 of the box), then choose "Full Record" (Step 2 of the box), and finally press on the "E-mail the selected records" icon (Step 3 of the box). In the "E-mail Options" page, enter your e-mail address (or another email address of your choice), select "HTML" in the "Email Style" menu, and send the PI's

Web of Science® publications list to the chosen email address by pushing the "Send E-mail" button. **Please store this email that Web of Science® sends to you, since it contains the PI's Web of Science® publications list. When sending the completed Application Form, this Web of Science® e-mail of the PI's Web of Science® publications list must be sent to the AIC Scientific Office**.

All publications retrieved from any of the above options will be listed by the applicant in the present "Publications" section of the Application Form. In particular, for each publication retrieved from PubMed or Web of Science®, the applicant will indicate:

- title
- list of authors
- year, volume, pages
- publication date (**from 2008 to 2013**)
- DOI number
- the database (PubMed or Web of Science®)
- the authorship role of the PI in the published work.

The **authorship role of the PI in each published work must be indicated** with one of the followings:

- *first author* or *co-first author*
- *last author*
- *first corresponding author* or *corresponding author*
- *none* (meaning that the PI is not the first/co-first author, nor the last author, neither the corresponding author). This option also includes publications stemming from a consortium in which the relative contribution of each author is the same.

For those publications where the PI is co-first author or first corresponding author, **a PDF copy of the page of the paper(s) where it is stated that the PI "equally contributed to this work" or that the PI is the corresponding author, respectively**, must be added to the Application Form (do not attach the entire manuscript, only the relevant page).

In case of **papers in press that are already accepted** for publication but not yet available online, please provide the title, list of authors, journal, year, authorship of the PI (as described above), abstract and keywords describing the relevance to the Topics of the present Call (see the Research Plan section). Please include a PDF file with the **letter of acceptance from the journal**. Do not attach the entire manuscript.

Additional papers that are published or accepted for publication **after the submission deadline** of the present Call **will not be taken into consideration**.

16- Bio-Ethical Requirements

a) Research on humans

Please note that human experimentation is not limited to clinical studies with healthy volunteers and/or patients. It includes use of human biological samples (commercially available human cell lines *e.g.* from ATCC are exempt), human genetic material and human data collection (*e.g.* genetic information, health, etc.).

For clinical trials involving human subjects, and for studies with human biological samples, the **approval of the local Ethics Committee/Institutional Review Board** (IRB) together with a copy of the informed consent (if requested by the Ethics Committee) is **mandatory**. If available at the time of submission, the documentation must be included in the application as PDF file with "Clearance from Ethic Committee" header. The approval document issued by the Ethics Committee MUST indicate:

- the date when the IRB meeting was held: **approvals obtained more than 3 years ago (*i.e.* prior to 2010) are NOT acceptable**;
- the name of the applicant;
- a clear reference to the studies described in the proposal (*e.g.* the title of the application).

In case biospecimens have been obtained by external sources/collaborators, the clearance documents must be provided by the collaborator's research center. In any case, if the research deals with human biological samples, genetic materials or data collection, the research proposal should include information about:

- how the samples, materials or data are collected;
- whether the samples, materials or data are collected specifically for the proposed research project;
- how the samples, materials or data are dismissed.

If the approval from the Ethics Committee is not available by the submission deadline, the PI must obtain it **by September 8th 2013** and send it as PDF file to the AIC Scientific Office by e-mail (bandifondazione@pec.celiachia.it).

b) Research on animals

Animal experimentation must conform to all regulations protecting animals used for research purposes according to current international and national rules. If the research plan involves animal experimentation, the applicant must select one of the available options in the Application Form:

- I have obtained the clearance from the competent animal research ethics committee to carry out the described animal experimentation, and I am attaching it to the application;
- I have not obtained the clearance from the competent animal research ethics committee yet, but Ihave requested it and will send it to the AIC Scientific Office by September 8th 2013;
- There is not active Ethical Committee for animal research at my Institute, but the procedures related to animal use have been communicated to the Italian Ministry of Health and a copy of this communication is attached to the current application;
- There is not an active animal research ethics committee in my Institute; I have yet to communicate the procedures related to animal use to the Italian Ministry of Health but I will do so and I will send a copy of this communication to the AIC Scientific Office by September 8th 2013.

In any case, by signing the Bio-Ethical requirements page the applicant declares that the research studies are accurately described in the proposal and conform to all regulations protecting animals used for research purposes, including those of the DL 116/92. The experiments described in the proposal will be performed following the guidelines described in: Workman P. et al.: "Guidelines for the welfare and use of animals in cancer research". Br. J. Cancer (2010) 102: 1555-1577.

The required documentation for animal experimentation, if not available by the submission deadline, must be sent to the AIC Scientific Office (bandifondazione@pec.celiachia.it) **by September 8th 2013**.

Please note: Ethics Committee(s) approval(s) for human and/or animal research are not necessary for the assessment of the scientific merit of an application **during the review**; however, if the application is approved, **funds will be granted only if the required Ethical Committee certifications have been sent to FC**. FC is not responsible for any inaccuracy in the ethical

documentation provided and does not accept any liability for harm to participants in FC funded trials.

17- Final full proposal submission (by e-mail)

Before submitting the completed Application Form, complete the "Check List" section of the application, and **check that all sections have been correctly filled out** and **that all required additional documents have been included into the Application Form**.

Recapitulating, the **final submission is made of the following 6 parts**:

1. The whole Application Form, completed as editable PDF by computer; deadline 15th May 2013;

2. The following Sections of the completed Application Form must **also** be printed, signed, dated and finally PDF scanned, and must be e-mailed together with the completed Application Form file by deadline 15th May 2013 (by signing these Sections, the PI and the Legal Representative acknowledge and agree to all terms and conditions of this Call):
   - **Section 1 – Principal Investigator**, signed by the PI and the Institutional Legal Representative;
   - **Section 10 - Budget**, signed by the PI and the Institutional Legal Representative;
   - **Section 16 - Bio-ethical Requirements**, signed by the PI.

3. The following additional PDF documents must be e-mailed together with the completed Application Form by deadline 15th May 2013:
   - For external collaborators, a formal letter of collaboration is required (**Section 8 - Personnel Involved in the Research**);
   - A short CV, max one page, in English, must be added for personnel working at more than 75% of their time, with the exclusion of technical staff (**Section 8 - Personnel Involved in the Research**);

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- The Description of the Work for every Unit of Personnel must be attached as PDF file to the Application Form. Please do not exceed 2 pages (700 words) for the entire staff (**Section 9 - Description of the Work for each Unit of Personnel**);
- A letter ("Institutional Letter of Indirect Costs/Overhead") indicating the percentage rate(s) of indirect costs and/or overheads charged by the Hosting Institution, even if the rate is zero. The letter must be dated and signed by the Legal Representative (**Section 10 - Budget**);
- A Table (as PDF file) produced by the applicant and containing all publications reported in the PI's PubMed Publications list and, in case, in the PI's Web of Science® Publications list (**Section 15 - Publications**).
- For those publications where the PI is co-first author or first corresponding author, a PDF copy of the page of the paper(s) where it is stated that the PI "equally contributed to this work" or that the PI is the corresponding author, respectively, must be added to the Application Form (do not attach the entire manuscript, only the relevant page; see **Section 15 - Publications**).
- In case of papers in press that are already accepted for publication but not yet available online, please include a PDF file with the letter of acceptance from the journal. Do not attach the entire manuscript (**Section 15 - Publications**).
- (In case of human and/or animal experimentations) The approval of the local Ethics Committee/Institutional Review Board together with a copy of the informed consent (if requested by the Ethics Committee) as PDF file with "Clearance from Ethic Committee" header (**Section 16 - Bio-Ethical Requirements**).

4. The list of PI's PubMed Publications (generated in PubMed as text file) must be sent by e-mail together with the completed Application Form by deadline 15th May 2013.

5. the PubMed mail of the PI's PubMed page must be sent by deadline 15th May 2013 **(please, send the PubMed e-mail only when you are also sending the e-mail with the Application Form and the other required documents)**

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6. in case, the Web of Science® e-mail of the PI's Web of Science® publications list by deadline 15th May 2013 **(please, send the Web of Science® e-mail only when you are also sending the e-mail with the Application Form and the other required documents)**

Send all documentation and the completed Application Form at latest by 15th May 2013 to the following email address: bandifondazione@pec.celiachia.it

If these documents are not sent by the indicated deadline 15th May 2013, or if FC does not receive them, applications will not be reviewed.

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Keywords for describing the research subject of submitted Projects

By <u>Research Topic</u> (Please, <u>use only one</u> of the followings):

- celiac disease
- dermatitis herpetiformis
- wheat allergy (use one of the following):
  - respiratory allergy
  - food allergy
  - wheat-dependent, exercise-induced anaphylaxis
  - occupational asthma and rhinitis
  - contact urticarial
- non-celiac gluten sensitivity

By <u>Research Area</u> of the Project (Please, <u>use only one</u> of the followings):

- Allergology
- Anatomic pathology - Histopathology
- Biochemistry
- Biology (structural, computational, signaling)
- Clinics (pediatrics or adult)
- Clinical trials
- Dermatology
- Drug discovery – screening - development
- Endocrinology
- Epidemiology - Prevention
- Genetics - Control of gene expression and epigenetics
- Gynecology
- Immunology - Immunobiology
- Infection - Inflammation
- Nutrition
- Oncology
- Preclinical study
- Proteomics

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CALL FOR PROPOSALS 2013

By Detailed Description of the Project

(Please, use at least three and no more than five of the followings)

- Autoimmunity/Autoantibodies
- B cells
- Bioinformatics
- Biomarkers
- Biophysics
- Body mass index (BMI) and/or obesity
- Carcinogenesis
- Cell adhesion and/or cell adhesion molecules
- Cell cycle
- Chemistry
- Chemokines
- Clinical practice guidelines
- Clinical trials
- Costimulatory molecules
- Crystallography
- Cytokines/Interleukins
- Dendritic cells
- Diet
- Drug discovery and/or development
- Drug screening
- Endocrinology
- Enzyme-linked immunosorbent assay (ELISA)
- Flow cytometry
- Gene expression and/or profile
- Gene regulation
- Genomics
- Gliadins
- Gluten
- Glutenins
- High Performance Liquid Chromatography (HPLC)
- HLA/Major Histocompatibility Complex (MHC)
- Immunohistochemistry
- Immunosuppression and/or suppressor cells
- Immunotherapy

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- In vitro imaging and/or live cell imaging
- Inflammation and/or inflammatory cytokines
- Innate immunity
- Integrins
- Interferons
- Lymphocyte differentiation
- Mass spectrometry
- Membrane biology
- Microarrays
- Microenvironment
- microRNA
- Microscopy
- Monoclonal antibodies (mAbs) and/or immunoconjugates
- mRNA processing/translation
- Next generation sequencing
- Pharmacogenetics/Pharmacogenomics
- Polymorphisms/SNPs
- Preclinical studies
- Risk factors
- Statistics
- T cells/TCR
- T helpers
- Transcription
- Treg cells
- Vaccine

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