



FC Investigator Grant - Call for Proposals 2020

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*Fondazione Celiachia
Foundation for Celiac Disease*

FC INVESTIGATOR GRANT CALL FOR PROPOSALS 2020



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1. Foreword

The Fondazione Celiachia ONLUS (shortly FC) is releasing on **August 5th 2020 (launch date, 5 Agosto 2020)** the '**FC Investigator Grant - Call for Proposals 2020**' which is aimed at awarding excellent Research Projects on **celiac disease, dermatitis herpetiformis** and **non-celiac wheat sensitivity**, proposed by highly qualified **senior researchers** (Principal Investigator (PI) Applicant) with proved and recognized international expertise in the field of celiac disease and/or dermatitis herpetiformis. Project Proposals selected for funding will be carried out by the Principal Investigator in a **public or a private non-profit Italian research institute/organisation** (Hosting Institute, HI) where the Principal Investigator is already affiliated at the time of the present Call.

Together with this document, Candidates are invited to read carefully the "FC Investigator Grant 2020 REGULATION" whose complete reading and understanding and acceptance, together with this document, is a necessary and essential condition for the submission of Calls for Proposals.

The 'FC Investigator Grant - Call for Proposals 2020' is a **co-funding programme in the form of yearly part payment and final balance**.

The **Overall Total per Year of the Investigator Project Proposal Application** submitted to the '*FC Investigator Grant - Call for Proposals 2020*' (whatever duration and whatever typology including Multicentre Studies) **must not exceed € 70,000 per year**, considering the **sum** of the eligible costs (those covered by the FC Grant) and of the not eligible costs (those not covered by the FC Grant), and also considering (in case of Multicentre Study) the **sum** of the Overall Total per Year of each involved Centre (Hub plus the Spoke Centres).

The **total funding** presently available for the 'FC Investigator Grant - Call for Proposals 2020' is € 350,000.

The **DEADLINE** for submitting the Investigator Project Proposal Applications is **October 12th 2020 (12 Ottobre 2020), at 17:00 o'clock Italian time (ore 17:00)**.

2. Definitions and Documents

For all terminological definitions, abbreviations and references to documents, please read Section '2. Definitions and Documentation' contained in the 'FC Investigator Grant 2020 REGULATION'.

3. Expected Outcomes of the FC Investigator Grant

The following items are considered **key outcomes** of the FC Investigator Grant, and the **PI Grantee and the HI are expected to accomplish them**:

- To run the Investigator Research Project according to the plan and the aims reported in the Project Proposal Application, and yield the expected results



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→ To improve the international knowledge in the field of celiac disease/dermatitis herpetiformis, by mean of the publication of one or more papers, directly and univocally originating from the Investigator Research Project itself, into international Journals (Pubmed quoted)

The above aspects are considered directly relevant to the success of the FC Investigator Grant. The Annual Progress Reports and the Final Reports will be used by the PI Grantee to describe his/her achievements, and they will be evaluated by the Peer Reviewers. FC reserves the right in every moment to reconsider the funding and the FC Investigator Grant Contract in case of FC Investigator Grants which are not accomplishing the expected outcomes.

Statistics

In order to help the PI Applicant to pursue the expected outcomes, **statistics about previous granted FC Investigator Projects** are here reported. Statistics are over 3 years of Investigator Grant Call for Proposals, for an overall period of about 6-years. The values are avaraged independently of the duration of the Project:

Published Papers (Pubmed quoted): avarage 3,1 per closed Project

4. Requirements and Eligibility Criteria of the PI Applicant

The PI Applicant (or Candidate) is the highly qualified senior scientist presenting his/her own Investigator Project Proposal Application within the framework of the 'FC Investigator Grant - Call for Proposals 2020'.

Within the fixed Deadline for the submission of the Project Proposal Application to the present 'FC Investigator Grant - Call for Proposals 2020', the PI Applicant **is mandatorily required to have and maintain following eligibility criteria:**

1. The PI Applicant is **employed and affiliated** to an Italian public or private **non-profit Italian research institute** (the Hosting Institute, HI), where the PI will perform the selected Investigator Project
2. The PI Applicant is the **leader of a research team within the HI** and is already supplied by the HI with laboratory spaces, facilities, equipment, reagents, consumables and infrastructure
3. The PI Applicant is an **independent senior researcher** with a **good track record** and with **proved experience in the field of celiac disease and/or dermatitis herpetiformis**
4. The PI Applicant **will carry out and supervise** all the experimental, management and outcome issues of the Investigator Project if selected for FC funding
5. **Only 1 PI Applicant per research team/laboratory/unit of the same HI** can apply to the present 'FC Investigator Grant - Call for Proposals 2020'
6. Only **1 Project Proposal Application per PI Applicant**, and thus only 1 Project Proposal Application per research group/laboratory/unit of the same HI, can be submitted to the present 'FC Investigator Grant - Call for Proposals 2020'
7. The PI Applicant is **NOT** holding or taking part to **any kind of ACTIVE (OPEN) FC Grants** under whatever role or title. **Exceptions** are allowed only in the following cases:
 - The PI Applicant is taking part to an active FC Grant as an **external collaborator** who does not receive any FC funds



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- The PI Applicant is holding or taking part to **not formally closed FC Grants** (FC Grants which are concluded according to the predicted Grant time-schedule but whose scientific and economic aspects and/or final reports are still under FC evaluation). However, the Project Proposal Application of the PI Applicant who is holding or taking part to not formally closed FC Grants will undergo rules described in Section 8.3 (*Approval of the Ranking List by the FC Board of Directors, and onset of the FC Investigator Grant Contract phase*)

PROJECT PROPOSAL APPLICATIONS FROM PI APPLICANTS WHO DO NOT MEET THE ABOVE REQUIREMENTS WILL BE REJECTED.

THE ABOVE REQUIREMENTS MUST BE MET AND MAINTAINED FOR THE ENTIRE DURATION OF THE "FC INVESTIGATOR GRANT" AND FAILURE TO COMPLY WITH THESE REQUIREMENTS AT ANY TIME WILL CAUSE THE IMMEDIATE WITHDRAWAL OF THE APPLICATION AND/OR, IF AWARDED, THE REVOCATION OF THE FUNDING REFERRED TO IN THE 'FC INVESTIGATOR GRANT - CALL FOR PROPOSALS 2020' AND/OR THE TERMINATION OF THE RELEVANT CONTRACT OF GRANT FC, IF STIPULATED, IN ACCORDANCE WITH THE EXPRESS TERMINATION CLAUSE.

5. Other Mandatory Requirements for the PI Applicant and the Other Researchers/Personnel Involved in the Investigator Project Proposal Application

1. Within the frame of the present 'FC Investigator Grant - Call for Proposals 2020', either the PI Applicant of a Project Proposal Application (including Partnership and Multicentre Studies, see below) as well as any member of his/her research team/laboratory/unit are **NOT allowed to be simultaneously involved in other Project Proposals** submitted by other PI Applicants under whatever role, including as internal/external partners into Partnership Studies submitted by other PI Applicants, as well as Multicentre Studies submitted by other PI Applicants. The involvement of a researcher (whatever his/her role) in more than one Project Proposal (**including** Partnership and Multicentre Studies) will lead to the **automatic rejection of ALL the Project Proposal Applications in which the researcher is involved. It is the responsibility of the PI Applicant of each submitted Project Proposal to check out for the compliance to this rule before submitting the Project Proposal**
2. Within the frame of the present 'FC Investigator Grant - Call for Proposals 2020', any member of the PI Applicant's research team, as well as the internal/external partners of his/her Partnership Study, and/or each researcher involved into his/her Multicentre Study are **NOT** holding or taking part to **any kind of ACTIVE (OPEN) FC Grants** under whatever role or title. **Exceptions** are allowed only in the following cases:
 - The researcher is taking part to an **active** FC Grant as an **external collaborator** who does not receive any FC funds
 - The researcher is holding or taking part to **not formally closed FC Grants** (FC Grants which are concluded according to the predicted Grant time-schedule but whose scientific and economic aspects and/or final reports are still under FC evaluation).



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However, the Project Proposal Application involving a researcher who is holding or taking part to not formally closed FC Grants will undergo rules described Section 8.3 (*Approval of the Ranking List by the FC Board of Directors, and onset of the FC Investigator Grant Contract phase*)

3. Within the frame of the present 'FC Investigator Grant - Call for Proposals 2020', either the PI Applicant of a Project Proposal as well as any member of his/her research team/laboratory/unit, the internal/external partners of his/her Partnership Study, and/or each researcher involved into his/her Multicentre Study are **NOT allowed to be simultaneously employed in a profit company/institution as well as simultaneously involved in profit company/institution activities/projects during the whole FC Investigator Grant period**

THE ABOVE REQUIREMENTS MUST BE MET AND MAINTAINED FOR THE ENTIRE DURATION OF THE "FC INVESTIGATOR GRANT" AND FAILURE TO COMPLY WITH THESE REQUIREMENTS AT ANY TIME WILL CAUSE THE IMMEDIATE WITHDRAWAL OF THE APPLICATION AND/OR, IF AWARDED, THE REVOCATION OF THE FUNDING REFERRED TO IN THE 'FC INVESTIGATOR GRANT - CALL FOR PROPOSALS 2020' AND/OR THE TERMINATION OF THE RELEVANT CONTRACT OF GRANT FC, IF STIPULATED, IN ACCORDANCE WITH THE EXPRESS TERMINATION CLAUSE.

6. Requirements and Eligibility Criteria of the Hosting Institute

The Hosting Institute (HI) is the public or private non-profit Italian research institute where the PI Applicant is already affiliated at the time of the present 'FC Investigator Grant - Call for Proposals 2020', and where the PI will perform the selected Investigator Project.

Within the fixed Deadline for the submission of the Project Proposal Application to the present 'FC Investigator Grant - Call for Proposals 2020', the HI **is mandatorily required to have and maintain following eligibility criteria:**

1. The HI is an **Italian non-profit research organisation** (such as universities, hospitals or other research centres) which, irrespective of its legal status (public or private law bodies), has the primary goal to independently conduct non-profit scientific and/or biomedical research and to disseminate its results. Possible revenues coming from non-profit research activity must be completely reinvested in the non-profit research activities. Where the Hosting Institution also pursues economic activities, the financing, the costs and the revenues of those economic activities must be accounted for separately. Shareholders, partners, companies, members or other individuals that can exert a decisive influence upon the Hosting Institution cannot enjoy any preferential access to the intellectual property of the results generated by the non-profit research activity of the Institution, and they cannot have influence over any aspect (including scientific, financial, organizational, property and/or intellectual issues) of FC granted programmes and corresponding results
2. The HI **must ensure optimal working conditions to the PI Grantee** by providing spaces, facilities, equipment, and infrastructures



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PROPOSAL APPLICATIONS INVOLVING HOSTING INSTITUTES WHICH DO NOT MEET THE ABOVE REQUIREMENTS WILL BE REJECTED.

THE ABOVE REQUIREMENTS MUST BE MET AND MAINTAINED FOR THE ENTIRE DURATION OF THE "FC INVESTIGATOR GRANT" AND FAILURE TO COMPLY WITH THESE REQUIREMENTS AT ANY TIME WILL CAUSE THE IMMEDIATE WITHDRAWAL OF THE APPLICATION AND/OR, IF AWARDED, THE REVOCATION OF THE FUNDING REFERRED TO IN THE 'FC INVESTIGATOR GRANT - CALL FOR PROPOSALS 2020' AND/OR THE TERMINATION OF THE RELEVANT CONTRACT OF GRANT FC, IF STIPULATED, IN ACCORDANCE WITH THE EXPRESS TERMINATION CLAUSE.

7. Requirements and Eligibility Criteria of the Project Proposal described in the Investigator Project Proposal Application

7.1. Duration

The present 'FC Investigator Grant - Call for Proposals 2020' is considering Investigator Project Proposals which are **one** year, **two** years or **three** years duration.

One-year Investigator Project Proposals generally are **pilot/exploratory** studies, however annual full research projects are also allowed if **preliminary data** are mandatorily provided into the Project Proposal Application.

Investigator Project Proposal Applications will receive **negative** Peer-Review assessment (Triage step, see below) in case the actual duration, according to the Peer Review evaluation, is not consistent either with none of the above durations and/or with the duration declared by the PI Applicant in the Investigator Project Proposal Application.

7.2. Research Topics

The Investigator Project Proposal must mandatorily have a **clear, complete and exclusive focus** on the following topics:

- Celiac Disease
- Dermatitis Herpetiformis
- Non-celiac wheat sensitivity

See the **Guidelines for the Submission of the Proposal Application** for detailed instructions: the Investigator Project Proposal might focus on **one or more** of the above Research Topics (and **exclusively** on them), but **only one (the predominant)** of the allowed Research Topics will be indicated in the Investigator Project Proposal Application.

Investigator Project Proposal Applications will receive **negative** Peer-Review assessment (Triage step, see below) in case the actual focus, according to the Peer Review evaluation, is not consistent either with none of the above topics and/or with the topic declared by the PI Applicant in the Investigator Project Proposal Application.



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7.3. Research Areas

The Investigator Project Proposal must mandatorily be a **biomedical or food technology study** concerning the following research areas:

- Allergology
- Anatomic pathology – Histopathology
- Biochemistry
- Biology (structural, computational, signalling)
- Clinical trials
- Clinics (paediatrics or adult)
- Dermatology
- Drug discovery – screening – development
- Endocrinology
- Epidemiology – Prevention
- Genetics - Control of gene expression and epigenetics
- Gynaecology
- Immunology – Immunobiology
- Infection and inflammation
- Nutrition
- Oncology
- Preclinical study
- Proteomics
- Psychology
- Grains chemistry and biochemistry
- Grain genomics and proteomics
- Grain processing
- Microbiology and grain biotechnology

See the **Guidelines for the Submission of the Proposal Application** for detailed instructions: the Investigator Project Proposal might focus on **one or more** of the above Research Areas, but **only one (the predominant)** of the allowed Research Areas will be indicated in the online Application Form.

Investigator Project Proposal Applications will receive **negative** Peer-Review assessment (Triage step, see below) in case the actual research area, according to the Peer Review evaluation, is not consistent either with none of the above areas and/or with the area declared by the PI Applicant in the Investigator Project Proposal Application.



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7.4. Adherence to the FC's Aims Priorities

Investigator Project Proposal Applications must **mandatorily have aims and purposes** that **fully adhere** to **one or more** of the following FC's Aims 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 biomarkers. This also includes defining harmful components of gluten
- Innovation of clinical methodologies
- Evaluation of the efficacy of diagnostic and therapeutic approaches in clinical practice, in terms of outcome and quality of life. This also includes the improvement of the quality and safety of the gluten-free diet, and innovation of food products
- New therapeutic drugs, procedures or strategies (pilot clinical studies)
- Critical evaluation of last generation drugs (their activity by mechanistic insights)

Investigator Project Proposal Applications whose aims and purposes do not fully adhere to the above FC's Aims Priorities and fall into one or more of the following categories will receive **negative** Peer-Review assessment (Triage step, see below):

- 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
- Biochemical and/or biological studies not embodied in the framework of mechanistic studies
- Requests for on-going routine collection of current statistics, such as disease registry
- Descriptive epidemiology studies
- Health economics studies
- Studies that do not contribute to build or expand an original and independent line of research

7.5. Allowed Typologies of Investigator Project Proposals and Mandatory Requirements

The Investigator Project Proposal Application must mandatorily fall into **one (and only one)** of the following typologies of studies:

Typology of Investigator Project Proposal Application	Description and Mandatory Requirements
Single Research Group Study	<ul style="list-style-type: none"> — All the personnel (the research team) involved into the Investigator Project Proposal belongs to the unity/laboratory coordinated by the PI Applicant — No internal/external collaborators are thus predicted in the Investigator Project Proposal. Exceptions are of course represented by technicians and other staff involved into shared service units of the HI or employed into external service institutes/companies, such as the administration, the genomic sequencing service, and all the other services already comprised into both the overheads and indirect costs of the HI, and the service contracts between the HI and external companies. In these cases, the Project Proposal must be considered as a Single Research Group Project, and not as a Partnership or a Multicentre Project (see below) — Investigator Project Proposal Applications will receive negative Peer-Review assessment (Triage step, see below) in case they do not meet one or more of the above requirements, as well as in case they are not consistent with the Single Research Group typology declared by the PI Applicant in the Application
(Internal/External) Partnership Study	<ul style="list-style-type: none"> — The Investigator Project Proposal also involves one or more internal and/or external researchers (collaborators/partners) — Internal partners are researchers with all the following requirements: A) they are independent of the Applicant PI's research team; B) they are affiliated to the same HI of the Applicant PI, generally working into units/laboratories/departments different from the one of the Applicant PI; C) they are required by the Investigator Project Proposal by virtue of special expertise or materials that are missing into the Applicant PI's research team/laboratory/unit — External partners are researchers with all the following requirements: A) they are independent of the Applicant PI's research team; B) they are affiliated to one or more other Italian research institutes/centres different from the HI of the Applicant PI; C) they are required by the Investigator Project Proposal by virtue of special expertise or materials that are missing into the Applicant PI's research team/laboratory/unit — In case of (Internal/External) Partnership Project, the Investigator Project Proposal Application is presented by the Applicant PI who is the sole responsible of the Investigator Project. The internal/external partners and their role/expertise are mandatorily described in the Investigator Project Proposal Application, and their functionality evaluated by the Peer Reviewers — Internal/external partners affiliated to Italian non-profit Institutions/Centres



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	<p>are ONLY allowed in Partnership Project Proposals</p> <ul style="list-style-type: none"> — NO transfer of FC Grant funds are allowed between the HI of the Applicant PI and the internal/external partners. Moreover, NO kind of eligible costs predicted by the FC Grant (including personnel, fellowships, contracts, etc.) are recognised or allotted to the internal/external partners — Investigator Project Proposal Applications will receive negative Peer-Review assessment (Triage step, see below) in case they do not meet one or more of the above requirements, as well as in case they are not consistent with the (Internal/External) Partnership typology declared by the PI Applicant in the Application
<p>Multicentre Study</p>	<ul style="list-style-type: none"> — The Investigator Project Proposal is a research/clinical trial coordinated by the Applicant PI and his/her HI (Hub Centre) and conducted simultaneously in more than one Italian Research Institutes/Centres (Spoke Centres) different from the coordinating Applicant PI's HI Hub Centre. The Multicentre Study cannot involve more than 15 Spoke Centres. — Multicentre Investigator Project Proposals are generally expected to be large clinical trials, with 3-years duration, but this is not a mandatory requirement and the consistency of the Proposal is referred to the Peer Review evaluation. Moreover, the Multicentre Investigator Project Proposal is NOT a group of independent studies that will be carried out in a number of centres, but one study to which more centres adhere and contribute to. Special emphasis will be dedicated by the Peer Reviewers to evaluate whether each Spoke's contribution is necessary to the experimental outcome and the aims of the Project Proposal, and whether complementarity and synergy are a strength of the Project Proposal — Spoke centres are Italian non-profit, public or private Research Institutes — In case of Multicentre Project, the Investigator Project Proposal Application is presented by the coordinating Applicant PI who is the sole responsible of the Investigator Project. For each Spoke Centre involved into the Multicentre Study, the chief researcher (group leader), his/her role/expertise, his/her research team and the relevance of involving that specific Centre and that specific chief researcher are mandatorily described in the Investigator Project Proposal Application for the Peer Review evaluation — In case of Multicentre Investigator Project Proposals, part of the FC Grant funds are allotted to the Spoke Centres when predicted in the Budget Plan reported in the Investigator Project Proposal Application. In case of Multicentre Investigator Project Proposals, special Scientific and Economic Reporting rules are required, as described in the Regulation of the 'FC Investigator Grant - Call for Proposals 2020' — Investigator Project Proposal Applications will receive negative Peer-Review assessment (Triage step, see below) in case they are not consistent with the Multicentre typology declared by the PI Applicant in the Application



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7.6. The Budget Plan

— **THE OVERALL TOTAL PER YEAR MUST NOT EXCEED € 70,000 PER YEAR:**

The **Overall Total per Year of the Investigator Project Proposal Application** submitted to the 'FC Investigator Grant - Call for Proposals 2020' (whatever duration and whatever typology including Multicentre Studies) **must not exceed € 70,000 per year**, considering the **sum** of the eligible costs (those covered by the FC Grant) and of the not eligible costs (those not covered by the FC Grant), and also considering (in case of Multicentre Study) the **sum** of the Overall Total per Year of each involved Centre (Hub plus the Spoke Centres).

— **THE ELIGIBLE COSTS (COVERED BY THE FC GRANT) CANNOT BE MORE THAN 70% OF THE OVERALL TOTAL PER YEAR**

The Overall Total per Year of the Investigator Project Proposal Application submitted to the 'FC Investigator Grant - Call for Proposals 2020' (whatever duration and whatever typology including Multicentre Studies) is made of the following **cost typologies**:

— **eligible costs** = covered by the FC Grant

the sum of the eligible costs **must not exceed 70% of the Overall Total per Year** of the Investigator Project Proposal Application, whatever the duration and whatever the typology including Multicentre Studies

— **not eligible costs** = not covered by the FC Grant, completely covered by the PI/Hosting Institute

OVERALL TOTAL PER YEAR OF THE INVESTIGATOR PROJECT PROPOSAL APPLICATION = ELIGIBLE COSTS (COVERED BY THE FC GRANT) + NOT ELIGIBLE COSTS (NOT COVERED BY THE FC GRANT)

— **ELIGIBLE COSTS AND NOT ELIGIBLE COSTS**

Eligibility and typology of costs depend on the typology of the Investigator Project Proposal Application, and are fully described in the mandatory document 'Regulation'

IT IS REQUIRED THAT THE REGULATION MUST MANDATORILY BE FULLY READ BEFORE STARTING THE COMPLETION AND THE SUBMISSION OF THE PROJECT PROPOSAL APPLICATION AND THE BUDGET PLAN SECTION OF THE PROJECT PROPOSAL APPLICATION.

THE REGULATION CONTAINS ALL THE DETAILS AND THE MANDATORY REQUIREMENTS ABOUT THE BUDGET PLAN, THE COSTS ELIGIBILITY AND THE FC ANNUAL INSTALMENTS, FOR EITHER SINGLE RESEARCH GROUP, PARTNERSHIP AND MULTICENTRE STUDIES.

PROJECT PROPOSAL APPLICATIONS AND BUDGET PLANS NOT FULLY COMPLYING THE RULES AND THE MANDATORY REQUIREMENTS REPORTED IN THE REGULATION WILL BE REJECTED

7.7. The PI Grantee/HI's non-profit funds involved into the Investigator Project Proposal Application: Mandatory Requirements

- The PI Applicant and/or the HI are **mandatorily required to have non-profit funds** which must be **already available at the time of the submission** of the Project Proposal Application to the 'FC Investigator Grant - Call for Proposals 2020'
- These non-profit funds will be **exclusively allotted** by the selected PI Grantee and/or the HI to both **cover the not eligible costs** of the FC Investigator Project, and **anticipate the eligible**



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costs of each year of the FC Investigator Grant according to the final Budget Plan approved by FC

MANDATORILY REFER TO THE REGULATION FOR ALL THE DETAILS AND THE MANDATORY REQUIREMENTS ABOUT THE PI/HI FUNDS. PROJECT PROPOSAL APPLICATIONS NOT FULLY COMPLYING THE RULES AND THE MANDATORY REQUIREMENTS REPORTED IN THE REGULATION WILL BE REJECTED

8. The Evaluation and the Selection Procedure

Submitted Investigator Project Proposal Applications will undergo the following steps:

1	Administrative Conformity Check
2	Peer Review Evaluation of Investigator Project Proposal Applications complying the Administrative Conformity Check, and formulation of the Ranking List
3	Approval of the Ranking List by the FC Board of Directors, and onset of the FC Investigator Grant Contract phase

8.1. Administrative Conformity Check

Submitted Investigator Project Proposal Applications first undergo an administrative check for assessing the compliance with the 'FC Investigator Grant - Call for Proposals 2020' guidelines, eligibility criteria and regulations reported in the FC Call, the Regulation and the Guidelines for the Submission of the Proposal Application.

- Project Proposal Applications that are found to be **not** consistent with any given guideline, eligibility criterion, requirement and other rules reported in the present 'FC Investigator Grant - Call for Proposals 2020', in the Regulation and in the Guidelines **will be rejected and will not undergo the Peer Review Evaluation**
- Project Proposal Applications that meet all the formal requirements (**complying Applications**) will undertake the Peer Review Evaluation
- FC holds the responsibility and the authority of making the final decision on each Application's completeness and eligibility. Whatever decision is final and without reply.

All the PI Applicants will be notified of the outcome of the Administrative Conformity Check.

8.2. Peer Review Evaluation of Investigator Project Proposal Applications complying the Administrative Conformity Check, and formulation of the Ranking List

Each complying Project Proposal Application is evaluated individually by three independent international Peer Reviewers:

- The Peer Review evaluation of each Project Proposal Application is made upon disclosure of conflict of interest
- When accepting to evaluate a Project Proposal Application, the Peer Reviewers agree that they will maintain the full confidentiality on all the data and the information contained into the Investigator Project Proposal Application and the annexed documents



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The Peer Review evaluation of each Investigator Project Proposal Application is performed by a two steps procedure:

A.	IN/OUT Triage of the Investigator Project Proposal Application
B.	Score Evaluation of the Investigator Project Proposal Application, and formulation of the Ranking List

A. IN/OUT Triage of the Investigator Project Proposal Application

In the first part of the Evaluation, the Peer Reviewers triage the Investigator Project Proposal Application as an **IN Application** or as an **OUT Application** on the basis of the following **FC's Priority Criteria**:

FC's Priority Criteria of the Triaging Evaluation of the Investigator Project Proposal Application
Adherence to the FC's Aims Priorities
Consistency with the duration declared by the PI Applicant
Consistency with the Research Topic declared by the PI Applicant
Consistency with the Research Area declared by the PI Applicant
Consistency with the Typology of study declared by the PI Applicant

Investigator Project Proposal Applications which **do not meet only one** of the above FC's Priority Criteria are **triaged OUT** by the Peer Reviewers.

Investigator Project Proposal Applications triaged OUT by **at least 2 out of 3** Peer Reviewers are **excluded** and **do NOT enter the Ranking List**.

B. Score Evaluation of the Investigator Project Proposal Application, and formulation of the Ranking List

In this second step of the Evaluation, for each Investigator Project Proposal Application, the Peer Reviewers assess the following two weighed aspects (*Evaluation Areas*): the SCIENTIFIC VALUE (60% weight) and the FEASIBILITY (40% weight).

Both the *Evaluation Areas* comprise a number of evaluation criteria, and to each criterion the Peer Reviewers assign a score and provide a written comment (see the Table below).

For each *Evaluation Area*, a weighted sub-score is obtained by summing up the scores to the evaluation criteria comprised in that *Evaluation Area* and balancing the sum by the assigned weight of that *Evaluation Area*.

The sum of the two weighted sub-scores yields the *Final Individual Peer Reviewer's Score* of the Investigator Project Proposal Application.



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The averaging of the three *Final Individual Peer Reviewer's Score* yields the *Final Overall Score* of the Investigator Project Proposal Application.

The Ranking List is prepared by positioning the Investigator Project Proposal Applications on the basis of their *Final Overall Score*.

Weighted Evaluation Areas	Scored Criteria
Scientific Value (60% weight)	<ol style="list-style-type: none"> 1. Clearness of the Investigator Project Proposal's purposes 2. Background, rationale, preliminary data supporting the working hypothesis, aims, experimental design, research plan, methodologies of the Investigator Project Proposal. If applicable: Benefits in using animals, consistency of the sample size, power calculation 3. Expected results of the Investigator Project Proposal, impact on the scope, improvement of basic/clinical comprehension of the disease 4. Methodological or conceptual innovation, and originality of the Investigator Project Proposal
Feasibility (40% weight)	<ol style="list-style-type: none"> 1. Potential difficulties, pitfalls, caveats and limitations of the Investigator Project Proposal, and their impact on the success of the Investigator Project Proposal itself 2. The PI Applicant's expertise, qualification, research experience, accomplishments, total and active IF, publications track record (Curriculum Vitae of the PI Applicant), and their relevance to the topic/research area of the Investigator Project Proposal as well as their impact on the success of the Investigator Project Proposal itself 3. The expertise of the PI Applicant's research team involved in the Investigator Project Proposal, and the relevance to the topic/research area of the Investigator Project Proposal as well as the impact on the success of the Investigator Project Proposal itself. If applicable (Partnership and Multicentre Studies): The expertise of the internal/external researchers (collaborators/partners) or of the Spoke Centres/chief researchers (group leaders) involved in the Investigator Project Proposal, and the relevance to the topic/research area of the Investigator Project Proposal as well as the impact on the success of the Investigator Project Proposal itself. 4. The consistency of the Budget Plan with respect to the duration, the typology, the research plan, the design and the aims of the Investigator Project Proposal

The score system adopted by the Peer Reviewers is here represented:

Score	Value
0	Unacceptable <i>Fails to include a minimum amount of evidence to enable the criterion to be evaluated</i>
1	Very Weak <i>Addresses the criterion but with significant or many weaknesses</i>
2	Weak <i>Addresses the criterion but with some weaknesses</i>
3	Acceptable <i>Addresses the criterion satisfactorily</i>
4	Good <i>Addresses the criterion with some aspects of high quality</i>
5	Very Good <i>Addresses the criterion with all aspects of high quality</i>



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8.3. Approval of the Ranking List by the FC Board of Directors, and onset of the FC Investigator Grant Contract phase

Provided that funds are available, FC's Board of Directors meets to decide on the allocation of funds to the most deserving Investigator Project Proposal Applications of the Ranking List. FC holds the privilege of allocating funds to **only one** of the most deserving Investigator Project Proposal Applications, depending on either funds availability, Proposals' fund request and the outcome of the Peer Review Evaluation.

Moreover, FC keeps the privilege of suspending or rejecting the funding of those Investigator Project Proposal Applications, irrespective of their position in the Ranking List, whose PI Applicant or any other involved researcher are implicated into **not formally closed FC Grants** (FC Grants which are concluded according to the predicted Grant time-schedule but whose scientific and economic aspects and/or final reports are still under FC evaluation), until or unless suspensive conditions are clarified according to FC's decisions within times compatible with the funding procedures.

At the end of this step, the PI Applicants will be notified by FC with a communication also including the Peer Reviewers' comments. The identity of the Peer Reviewers will not be disclosed.

9. Application: Submission of the Investigator Project Proposal Application and Deadline

The present 'FC Investigator Grant - Call for Proposals 2020', the annexed Regulation and the Guidelines can be downloaded at the webpage: <https://www.celiachia.it/ricerca/bandi-di-ricerca-fc/bandi-investigatore-grant/2020>. The same webpage is available in English at the following link: <https://www.celiachia.it/ricerca/fc-call/investigatore-calls/2020-en>

Carefully read the Guidelines for all the details, the instructions and the mandatory requirements for the submission of the Project Proposal Application to the 'FC Investigator Grant - Call for Proposals 2020'.

1. **To submit an Investigator Project Proposal Application** to the 'FC Investigator Grant - Call for Proposals 2020' enter the 'Fondazione Celiachia Calls and Proposals' Web Portal at the webpage: callsfondazione.celiachia.it. Proposal Applications submitted in whichever manner different from the submission through the 'Fondazione Celiachia Calls and Proposals' Web Portal **will NOT be accepted and will be rejected**. The Project Proposal Application is submitted to the 'FC Investigator Grant - Call for Proposals 2020' exclusively through the 'Fondazione Celiachia Calls and Proposals' Web Portal (callsfondazione.celiachia.it), by the PI Applicant who completes the requested fields and data, and uploads of the mandatory and optional PDF files. The Project Proposal Application is signed by both the PI Applicant and the Legal Representative of the Hosting Institute. **In case of Multicentre Study**, the Project Proposal Application is submitted and signed exclusively by the Coordinating PI Applicant and by the Legal Representative of the HI of the Coordinating PI Applicant, who are the sole responsible with respect to the FC Call, the Regulation, the Guidelines, the work of all the collaborators and groups involved in the FC Investigator Project, as well as the whole project, including the



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parts deriving from the collaborators/partner groups, the correctness of the Project Proposal Application and the mandatory and optional files.

2. **The DEADLINE for submitting Project Proposal Applications is October 12th 2020, at 17:00 o'clock Italian time (ore 17:00).**

- **After the Deadline**, it will be **not possible to enter** the 'FC Investigator Grant - Call for Proposals 2020' Project Proposal Application webpage, **nor to submit** any Project Proposal Application in the frame of the 'FC Investigator Grant - Call for Proposals 2020'.
- Therefore, **after the Deadline, not completed** Proposal Applications will remain **as not submitted** and will be **rejected automatically**.

1. **New Users:** Once you get into the 'Fondazione Celiachia Calls and Proposals' Web Portal, you have to create your account by entering your credentials and your email address ('New Users: Create your account').

- Please, create your account using your institutional email address, and **do not** create multiple accounts (account duplication). The email address you used for the registration is your Login for future access
- You will receive an automatic communication with a temporary Password. **Always check the SPAM**
- On your first access ('Registered Users: Login') you will be asked to change the automatically generated Password (the temporary Password)
- On future access you can only change your Password using the function 'Change Password'. In case you forget it, you can click on 'Forgot your Password?' and you will then receive a new automatically generated password by email

4. **Registered Users:** Once entered the 'Fondazione Celiachia Calls and Proposals' Web Portal, use your email and Password to enter your Portal personal webpage first, and then your Project Proposal Application to the 'FC Investigator Grant - Call for Proposals 2020' ('Complete/Edit Your Proposal')

5. **Download the Mandatory Documents:** Once entered your Project Proposal Application webpage, download the following mandatory documents from the top menu:

- The 'FC Investigator Grant - Call for Proposals 2020' (**the Italian version of this Document is the only legally binding one; the free English translation is for consultation purposes only, and is not legally binding**)
- The 'Regulation FC Investigator Grant - Call for Proposals 2020' (**the Italian version of this Document is the only legally binding one; the free English translation is for consultation purposes only, and is not legally binding**)
- The 'Guidelines for the Submission of the Proposal Application'
- The 'Budget Plan excel forms', which must be downloaded, completed, signed, dated, colour scanned, and upload to the Project Proposal Application. The Budget Plan excel form to be downloaded (the 'Single/Partnership Budget Plan excel form', or the 'Multicentre excel form') depends on the typology of the Project, as described in the Guidelines



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EACH OF THE ABOVE DOCUMENTS MUST MANDATORILY BE DOWNLOADED AND FULLY READ BEFORE STARTING THE COMPLETION AND THE SUBMISSION OF THE PROJECT PROPOSAL APPLICATION.

6. Number of Accounts and Number of Investigator Project Proposal Applications to be submitted to the 'FC Investigator Grant - Call for Proposals 2020':

- **Only 1 Project Proposal Application per PI Applicant** can be submitted (or multiple submitted, see point 11 of the present Section) to the 'FC Investigator Grant - Call for Proposals 2020' (according to the rules reported in Section 4 of the present document '*Requirements and Eligibility Criteria of the PI Applicant*')
- **Only 1 account per PI Applicant must be created on** the 'Fondazione Celiachia Calls and Proposals' Web Portal.
- Different Project Proposal Applications or the same Project Proposal Application submitted by the same PI Applicant **through different accounts** (account duplication) will lead to the **rejection of the PI Applicant and of all the Project Proposal Applications submitted by the PI Applicant.**

7. Start the completion of your Investigator Project Proposal Application to the 'FC Investigator Grant - Call for Proposals 2020': Complete all the required fields of each Section of the Project Proposal Application, and upload the required PDF files as requested in the relevant Sections of the Project Proposal Application and **in the '*Guidelines for the Submission of the Project Proposal Application*'**.

8. Using the 'Fondazione Celiachia Calls and Proposals' Web Portal:

- After about 2 hours inactivity on your Proposal Application webpage (login), the Portal automatically goes to logout for security matters. In this case, all the changes and the data **will be lost if not saved**. Please, **be sure to use the function 'Save changes' in the bottom of each Section of your Project Proposal Application webpage, each time you fill in new data or make any change.**
- **Recommended Browsers:** The 'Fondazione Celiachia Calls and Proposals' Web Portal is compatible with the most commonly used browsers. However, we ensure its compatibility with the following browsers and versions: Chrome 40, FireFox 30, Safari 9, Internet Explorer 11, Microsoft Edge 40.
- Please note that the 'Fondazione Celiachia Calls and Proposals' Web Portal is not responsive, so **we do not guarantee a full usability of the Portal on mobile and smartphone.** Please, always access the Portal on your computer.

9. Submitting the Proposal Application to the 'FC Investigator Grant - Call for Proposals 2020'

- **Until the Deadline of the 'FC Investigator Grant - Call for Proposals 2020' is not expired**, you can save changes of your Project Proposal Application, leave the Portal whenever you like, and continue the completion and the submission of the Project Proposal Application in another moment.
- **Uncompleted** Project Proposal Application and/or Project Proposal Application missing the upload of the required PDF files **cannot undergo submission (the Project Proposal Application remains as not submitted)**, since the 'Fondazione Celiachia Calls and



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Proposals' Web Portal automatically prevents the submission of incomplete Project Proposal Applications.

- **Within the fixed Deadline**, you have to 1) complete your Project Proposal Application, 2) upload the required files, 3) **download the General Info Section**, print the file, sign and date the document, **upload the scan file** in your Project Proposal Application webpage, 4) **download the appropriate 'Budget Plan excel form'**, complete and print the form, sign and date the document, **upload the scan file** in your Proposal Application webpage, and 5) **submit the Project Proposal Application** (the submission is not allowed by the Portal until all the Sections are completed and all the required files are uploaded): in the Section 'Submission', you will find the 'Submit' button.
- **Once the Deadline is expired**, it will be **not possible to enter** your Project Proposal Application webpage, **nor to submit** your Project Proposal Application. Therefore, **after the Deadline, not completed** Project Proposal Applications will remain **as not submitted** and will be **rejected automatically**.
- **As you complete the Project Proposal Application and submit it**, you will receive an automatic email containing the PDF of your submitted Project Proposal Application. The PDF file of the Project Proposal Application is labelled by *i)* the identification number of the Project Proposal Application (e.g.: *Proposal Identification Number: IG_0XX_FC_2020*) which **is univocal to the PI Applicant (Candidate)**, *ii)* the date and time of the submission of the Project Proposal Application

10. Multiple submissions of the Project Proposal Application (re-submission of the Project Proposal Application within the fixed Deadline, upon editing or improvements):

- **Until the Deadline is not expired**, you are allowed to **re-submit your complete** Project Proposal Application more than once. In other words, in case you realize that your **completed and submitted** Project Proposal Application might need further improvements (a better description of the Project Proposal, attachment of improved figures, and so on), you can enter your personal webpage (login) on the 'Fondazione Celiachia Calls and Proposals' Web Portal and **re-open your Submitted Project Proposal Application** (in this case you will find the 'Complete/Edit Your Proposal' button replaced by the 'Open/Edit Your Submitted Proposal' button).
- Once you have made the desired modifications (editing and/or attached files), **you mandatorily have to submit again the complete Project Proposal Application together with all the mandatory files** (in Section 'Submission', you will find the 'Submit' button replaced by the 'Resubmit Edited Proposal' button).
- **Each time** you re-open, edit, complete and re-submit your Project Proposal Application **within the fixed Deadline, you will receive an automatic email** containing the PDF the last submitted Project Proposal Application. The PDF file of the re-submitted Project Proposal Application is labelled by *i)* the identification number of the Project Proposal Application (e.g.: *Proposal Identification Number: IG_0XX_FC_2020*) which **is univocal to the PI Applicant (Candidate)** independently on the number of submissions made, *ii)* the date and time of the submission which **labels each completed submission** of the Project Proposal Application
- **Each time** you make a re-submission of your Project Proposal Application, **the last re-submission** does completely replace all the previous submitted versions of the Project



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Proposal Application, and does represent **the only Project Proposal Application of the Candidate that will be taken into consideration by FC** in the frame of the 'FC Investigator Grant - Call for Proposals 2020'. In no case previous submissions will be taken into consideration. **It is thus important to re-open your Submitted Project Proposal Application ONLY IF NECESSARY to edit/improve the previously submitted Project Proposal Application.** In case you re-open your Submitted Project Proposal Application and you then do not complete the re-submission procedure as described above, **the last submitted version of your Project Proposal Application will be taken into consideration by FC in the frame of the 'FC Investigator Grant - Call for Proposals 2020', with no exceptions.**

→ **Be sure to complete the re-submission of the your Project Proposal Application within the fixed Deadline:** once the Deadline is expired, and you didn't complete the re-submission of the Project Proposal Application, you can neither enter your Project Proposal Application nor further re-submit the Project Proposal Application. **In this case the last submitted version of your Project Proposal Application will be taken into consideration by FC in the frame of the 'FC Investigator Grant - Call for Proposals 2020', with no exceptions.**

11. **Download Proposal:** In each moment, you can download the PDF file of your Project Proposal Application, although it is not completed or submitted yet. Just press the 'Download Proposal' button at the top menu of your Project Proposal Application webpage. This PDF file is just for your recording. Please, note that **the only PDF file of the Project Proposal Application that is formally legal in the frame of the 'FC Investigator Grant - Call for Proposals 2020' and that is taken into consideration by FC is the one automatically generated and sent by email by the Portal when the submission is completed.**

12. **Files to be uploaded to the Project Proposal Application:** Mandatory and optional **files** will be uploaded to the Project Proposal Application within the fixed Deadline. **Each file must accomplish mandatory requirements:** A) only PDF files are allowed in case of documents which are signed and dated in blue ink, and colour scanned; otherwise, in case of documents with digital/electronic signature, only PADES/PDF and CADES/P7M file are allowed; B) uploaded files must not exceed 2 MB (files larger than 2 MB will not be allowed to be uploaded on the Portal).

→ **MANDATORY FILES.** Omitted upload of the mandatory files to the Project Proposal Application will result in **incomplete** Project Proposal Application, consequently the submission will **not** be allowed by the Portal and, after the fixed Deadline, the incomplete Project Proposal Application will be **automatically rejected:**

- ✓ The **General Info Section file**, which must be printed, signed, dated, and upload to the Project Proposal Application.
- ✓ The **Budget Plan excel file**, which must be downloaded, completed, signed, dated, and upload to the Project Proposal Application. The Budget Plan excel file to be downloaded depends on the typology of the Project, as reported in the Guidelines
- ✓ In case of human and/or animal experimentation (including human and/or animal biological samples), you are required to upload **one file containing all the following documents: 1)** a copy of the **Clearance** of the Ethical Committee/Institutional Review Board. Clearances obtained more than 6 months before the launch date (August 5th 2020) of the present 2020 FC Call as well as Clearances not presenting the **mandatory**



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requirements described in the Appendix of the present FC Call **will NOT be accepted.**

2) Only in case the annexed Clearance of the Ethical Committee is related to other projects/studies similar or connected to the Project Proposal described in the Application Form, a specific **Amendment Document** produced by the Ethical Committee must be annexed to the Clearance. Amendments obtained more than 6 months before the launch date (August 5th 2020) of the present 2020 FC Call as well as Amendments not presenting the **mandatory requirements** described in the Appendix of the present FC Call **will NOT be accepted.** **3)** The Clearance of the Ethical Committee and/or the Amendment Document should **preferentially** contain the **additional requirements** described in the Appendix of the present 2020 FC Call. In case the document should not report the additional requirements, a completion will be required during the Administrative Conformity Check.

Please note that in case of Multicentre Study, the Clearance of the Ethical Committee approving the Multicentre study to be attached to the Proposal Application is **exclusively** that of the Hosting institute of the Coordinating PI Applicant (Hub Centre). The Clearances obtained by the Spoke Centres must **NOT** be uploaded to the Proposal Application.

- ✓ Should the Clearance of the Ethical Committee and/or the Amendment Document not be available yet at the time of the submission of the Project Proposal Application, you are required to upload **one file containing all the following documents:** **1)** a copy of the **Clearance SUBMISSION** to the Ethical Committee. Clearance Submissions produced more than 6 months before the launch date (August 5th 2020) of the present 2020 FC Call as well as Clearance Submissions not presenting the **mandatory requirements** described in the Appendix of the present 2020 FC Call **will NOT be accepted.** **2)** The Clearance Submission to the Ethical Committee should **preferentially** contain the **additional requirements** described in the Appendix of the present 2020 FC Call. In case the document should not report the additional requirements, a completion will be required during the Administrative Conformity Check.
- ✓ In case of Partnership or Multicentre Study, you are required to upload **one file containing all the signed and dated Collaboration Letters** according to the Form described in the Appendix to the present 'FC Investigator Grant - Call for Proposals 2020'. In case of a Partnership Study, each internal and external collaborator will sign and date the Collaboration Letter. **In case of a Multicentre Study, no more than 15 Spoke Centres can be involved,** and each chief researcher of the involved Spoke Centre will sign and date the Collaboration Letter. The dated and signed Collaboration Letters will be sent to the PI Applicant who will upload them **as one file** to the Proposal Application.

→ **OPTIONAL FILES.** Omitted upload of the optional files will NOT hamper the completion and the submission of the Project Proposal Application:

- ✓ It is faculty of the Applicant to upload up to 2 PDF files of figures in the Section 'Project Proposal' of the Project Proposal Application, within the fixed Deadline.



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10. The Indicative Timeline of the 'FC Investigator Grant - Call for Proposals 2020'

Step	Action	Date
1	Launch of the FC Call	August 5th 2020 (5 Agosto 2020)
2	Closure of the FC Call (DEADLINE for submitting the Investigator Proposal Applications)	October 12th 2020 (12 Ottobre 2020)
3	FC Administrative Check of Conformity of the Project Proposal Applications	October - November 2020
4	Selection of the Reviewers and Assignment of the Applications for Col disclosure	December 2020 – January 2021
5	Peer Review Evaluation Exercise	January/February - March 2021
6	FC Board Approval of the Ranking List	April - May 2021

11. Contacts and FAQs

In case of doubts regarding the participation to the present Call for Proposals, please **send an email** with your query to the FC Scientific Office: fondazione@celiachia.it

FC will provide you a written answer. Questions will be accepted until **October 12th 2020 (12 Ottobre 2020) at 15:00 o'clock Italian time (ore 15:00)**.

Questions and corresponding Answers might be published on the **FAQ page** if considered of general interest: <https://www.celiachia.it/ricerca/bandi-di-ricerca-fc/bandi-investigatore-grant/2020>. The same webpage is available in English at the following link: <https://www.celiachia.it/ricerca/fc-call/investigatore-calls/2020-en>

12. Personal Data Processing

Personal data, as defined by the laws in force, provided under the "FC Investigator Grant - Call for Proposals 2020". (e.g.: of the PI Candidate, of the HI Legal Representative, etc.) both through the



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'Fondazione Celiachia Calls and Proposals' web portal and in any other way, will be processed in compliance with the current legislation set out in the General Data Protection Regulation (EU/2016/679) (in short GDPR, containing provisions on the protection of individuals with regard to the processing of personal data, as well as rules on the free transfer of such data) and the Legislative Decree no. 196/2003 as amended by Legislative Decree no. 101 of 10/08/2018 - and the information provided pursuant to Art. 13 of the GDPR.

The data controller is Fondazione Celiachia Onlus - or "FONDAZIONE CELIACHIA – Ente del Terzo Settore", when it will be renamed -, based in Via Caffaro 10/7, 16124 Genoa, Italy.

13. Appendix

13.1. Requirements for the Clearance/Amendment of the Ethical Committee, and for the Clearance Submission to the Ethical Committee

MANDATORY REQUIREMENTS for the Clearance (and the Amendment to the Clearance, if applicable):

- It is an **authentic/official document** produced, dated and signed by the Ethical Committee, and **registered by the authorities/offices**. No other kind of documents or self-declarations will be accepted
- The **date** must be indicated and **must not be earlier than 6 months** before the launch date (August 5th 2020) of the present 2020 FC Call. Clearances obtained more than 6 months before the launch date (August 5th 2020) of the present 2020 FC Call **will NOT be accepted**
- Clearances **obtained for other projects/studies** similar or connected to the Project Proposal presented in the frame of the 'FC Investigator Grant - Call for Proposals 2020' **will be accepted exclusively if annexed to specific Amendment Documents** produced by the Ethical Committee specifically for the submitted Project Proposal. Amendments obtained more than 6 months before the launch date (August 5th 2020) of the present 2020 FC Call **will NOT be accepted**
- Moreover, it is intended that the **Clearance and the Amendment of the Ethical Committee must completely adhere to the laws in force**. FC is not responsible for any inaccuracy, incompleteness, mendacity, unsuitability to the submitted Project Proposal or law non-fulfilment. FC does not accept any liability neither for harm to participants in FC funded trials nor for any damage to others: all the civil and penal responsibilities toward the Authorities and third parties lie on the PI and the Legal Representative of the Institute.
- Experimentation on animals (vertebrates, cephalopods and foetal forms of mammals) **must conform to all regulations protecting animals used for research purposes and aimed at avoiding pain and stress of the animals**. Research supported by FC that involves animal experimentation must comply with the principle of the Three Rs (3Rs) to Replace, Reduce and Refine the use of animals in research, as well as with national and international rules. Please refer to the following web sites for further information:
<https://www.eurogroupforanimals.org/>, <https://www.eurogroupforanimals.org/what-we-do/policy-areas/animals-science>,
<https://3rs.ccac.ca/en/about/three-rs.html>,



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<https://www.lav.it/aree-di-intervento/vivisezione/nuova-legge-vivisezione>,
<https://www.lav.it/news/metodi-alternativi-convegno>, <https://www.ipamitalia.org/>

MANDATORY REQUIREMENTS for the Clearance Submission:

- It is an **authentic/official document** produced, dated and signed by the Proponent Researcher, it is written on the Hosting Institute letterhead paper and it is forwarded to the Ethical Committee. If possible, the document is labelled with an authentic/official protocol identification number released by the Ethical Committee or by the authorised offices, and/or is associated to a receipt of the authorised offices. In case the authentic/official protocol identification number released by the Ethical Committee or by the authorised offices, and/or the receipt of the authorised offices are missing, they will be required during the Administrative Conformity Check.
- The **date** must be indicated and **must not be earlier than 6 months** before the launch date (August 5th 2020) of the present 2020 FC Call. Clearance Submissions obtained more than 6 months before the launch date (August 5th 2020) of the present 2020 FC Call **will NOT be accepted**

ADDITIONAL REQUIREMENTS for the Clearance (and the Amendment to the Clearance, if applicable), as well as for the Clearance Submission:

- Reporting **the exact English Title** of the Project Proposal (as reported in the *Proposal Application*)
- Referring **unequivocally to the Project Proposal** (as described in the *Proposal Application*)
- Reporting **the name of the PI Applicant as the researcher that will carry out the Project Proposal (ALSO** in case the researcher who submitted the Clearance/Clearance Submission is not the PI Applicant, as in case of Clinical Studies/collection of samples being performed in authorized medical centers and/or departments)

In case the documents should not report the above reported additional requirements, a completion will be required during the Administrative Conformity Check.

13.2. Collaboration Letters in case of Partnership or Multicentre Study

In case of Partnership or Multicentre Study, the PI Applicant is required to upload to the Proposal Application **one file containing all the signed and dated Collaboration Letters** according to the Collaboration Letter Form here described. The **Form is downloadable from the Mandatory Documents top menu of your Proposal Application webpage**, at the 'Fondazione Celiachia Calls and Proposals' Web Portal. In case of Partnership Study, each internal and external collaborator will sign and date his/her Collaboration Letter. In case of a Multicentre Study, each chief researcher of the involved Spoke Centre will sign and date his/her Collaboration Letter. **For each internal/external collaborator, as well as for each Spoke Centre, the corresponding Collaboration Letter must be produced.** The dated and signed Collaboration Letters will be sent by the collaborators/Spoke Centres to the PI Applicant who will collect them **as one file**, and **will attach the file to the Proposal Application.**

Instructions to complete the Collaboration Letter Form



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The letter must be written on the Hosting Institute letterhead paper of each collaborator/chief researcher of the Spoke Centre, dated and signed in blue ink or digitally signed by the collaborator/chief researcher of the Spoke Centre and the corresponding Legal Representative. The stamp of the Institute of the collaborator/chief researcher must also be added to the signed letter. The red parts in italic square brackets must be replaced with the required data.



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Fondazione Celiachia Onlus,
Via Caffaro 10,
16124 Genova, Italia

[luogo], [data]

Oggetto Lettera di Collaborazione al Progetto di Ricerca presentato al Bando FC 2020 dal Candidato PI (PI Applicant) [cognome e nome del PI Applicant] e intitolato [esatto titolo in Inglese del Progetto così come riportato nella Domanda di Partecipazione –Proposal Application]

Il sottoscritto [cognome e nome del collaboratore/chief researcher dello Spoke Centre], sotto la propria responsabilità, dichiara di aver concordato con il Candidato PI ovvero con il Candidato PI Coordinatore (nel caso di studio Multicentrico) [cognome e nome del PI Applicant] la propria partecipazione al Progetto di Ricerca [esatto titolo in Inglese del Progetto così come riportato nella Domanda di Partecipazione –Proposal Application] presentato al Bando 'FC Investigator Grant - Call for Proposals 2020', in qualità di [indicare la qualifica del caso: collaboratore interno ovvero collaboratore esterno, indicare il nome legale dell'istituto del collaboratore; OVVERO IN CASO DI STUDIO MULTICENTRICO chief researcher dello Spoke Centre indicare il nome legale dello Spoke Centre].

Di seguito i motivi che richiedono la partecipazione del sottoscritto al Progetto di Ricerca [da riportare in inglese]:

→ Expertise area	
→ Added value to the project	
→ Facilities	

Dichiaro di aver letto e preso atto di tutti i requisiti obbligatori, le norme e le regole riportati nel Bando 'FC Investigator Grant - Call for Proposals 2020', nel Regolamento del Bando 'FC Investigator Grant - Call for Proposals 2020' e nelle Guidelines, e li accetto in pieno. Confermo e sottoscrivo il Bando 'FC Investigator Grant - Call for Proposals 2020', il Regolamento del Bando 'FC Investigator Grant - Call for Proposals 2020' e le Guidelines.

Confermo e sottoscrivo le dichiarazioni e i dati riportati nella Domanda di Partecipazione (Proposal Application) presentata dal Candidato PI.

[da aggiungere in caso di Progetto Multicentre:

Confermo e sottoscrivo le dichiarazioni e i dati riportati in tutte le sezioni della Domanda di Partecipazione (Proposal Application) presentata dal Candidato PI, inclusa la Sezione Budget Plan della Domanda di Partecipazione e I relativi file excel di Budget allegati.

In fede,

Cognome e nome del collaboratore/chief researcher dello Spoke Centre (computer typing):	
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Firma del collaboratore/chief researcher dello Spoke Centre (in inchiostro blu o digitale)	
Cognome e nome del Legale Reppresentante dell'Istituto del collaboratore/del chief researcher (Spoke Centre) (by computer typing):	
Cognome e nome del Legale Reppresentante dell'Istituto del collaboratore/del chief researcher (Spoke Centre) (in inchiostro blu o digitale)	

Luogo e Data

Timbro dell'Istituto

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