



REGULATION

FC Investigator Grant 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.

The 'FC Investigator Grant - Call for Proposals 2020' is a **co-funding programme in the form of yearly part payment and final balance**. Thus the Hosting Institute and the Principal Investigator Applicant submitting the Investigator Proposal are asked to have **non-profit funds** both to cover part of the predicted costs involved in the accomplishment of the Research Project, and to anticipate the eligible costs of each year of the Investigator Project Proposal according to the final Budget Plan approved by FC. Non-profit funds must be available at the time of the Project Proposal Application to the 'FC Investigator Grant - Call for Proposals 2020'.

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

Legend	Description
The Principal Investigator (PI) Applicant/Candidate	The PI Applicant or Candidate is the highly qualified senior scientist presenting his/her own Investigator Project Proposal within the frame of the 'FC Investigator Grant - Call for Proposals 2020'
The Principal Investigator (PI) Grantee	The PI Grantee is the Applicant whose own Investigator Project Proposal is selected for funding at the end of the Evaluation and Selection Procedure of the 'FC Investigator Grant - Call for Proposals 2020', and that will carry out and supervise all the experimental, management and outcome issues of the Investigator Project in the Institute (Hosting Institute) indicated in the Project Proposal Application
Hosting Institute (or Institute, HI)	It is the (public or private) non-profit organization governed by Italian law and with registered office in Italy 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.



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<p>The Legal Representative (LR) of the HI (or the Director of the Department, if duly authorised to sign on the behalf of the Legal Representative of the HI)</p>	<p>The LR is the authorized representative of the Hosting 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. The Legal Representative is responsible, along with the PI Applicant, of all the legal and administrative duties and requirements related to both the application to the 'FC Investigator Grant - Call for Proposals 2020', and of the execution of the selected Investigator Research Project, and the accomplishment of all the issues reported and predicted in the FC Investigator Grant Contract and regulation.</p> <p>The LR signs for acceptance, along with the PI Grantee, all the documents related to both the execution of the selected Investigator Research Project, and the accomplishment of all the issues reported and predicted in the FC Investigator Grant Contract and regulation: the Application of the Investigator Project Proposal, the annexed mandatory documents to the Application of the Investigator Project Proposal, the FC Regulation, the FC Investigator Grant Contract, the administrative and scientific Reports produced in the course of the Investigator Research Project, and all the additional documentation required by FC at any moment.</p> <p>The LR guarantees for both the execution of the Investigator Research Project and for the accomplishment of the FC Investigator Grant Contract.</p> <p>It is allowed that the Director of the Department, where the PI Applicant is affiliated to, can act as the LR if he/she is duly authorised to sign on the behalf of the LR of the HI.</p>
<p>Project Proposal Application to the 'FC Investigator Grant - Call for Proposals 2020'</p>	<p>It is the proposal of the Investigator Research Project submitted by the PI Applicant, in the frame of the 'FC Investigator Grant - Call for Proposals 2020', accordingly to the requirements and the rules specified in the present document (Call), the Regulation and the 'Guidelines for the Submission of the Proposal Application'.</p> <p>The Project Proposal Application, which also contains the Research Project, 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 Insitute.</p> <p>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 (Hub Centre), by annexing to the Project Proposal Application the corresponding Collaboration Letters of the chief researcher of each involved Spoke Centre, and signing the Project Proposal Application also on their behalf.</p>
<p>Fondazione Celiachia Calls and Proposals' Web Portal</p>	<p>It is the FC web portal where the PI Applicants can access upon registration/login to complete and submit the Project Proposal</p>



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(callsfondazione.celiachia.it)	Application to the 'FC Investigator Grant - Call for Proposals 2020'.
The FC Investigator Grant	The funds allocated by FC to cover the eligible costs of the Investigator Project Proposal selected for funding at the end of the Evaluation and Selection Procedure of the 'FC Investigator Grant - Call for Proposals 2020', according to the final Budget Plan approved by FC during the agreement of the FC Investigator Grant Contract. The FC funds are allotted yearly to the HI, according to the final Budget Plan approved by FC, in the form of annual initial installment (part payment) and annual final balance. With the exception of the 1-year initial installment, all the other initial installments as well as all the annual final balances will be assigned to the HI only upon FC's assessment and approval of the economic annual report produced by the PI Grantee and the HI. Independently on the final Budget Plan, the actual assignments will depend on the experimental and economic course of the Project as resulting from either the Scientific and the Economic annual reports.
The PI Grantee/HI's non-profit funds	The funds allocated by the PI Grantee and/or the HI to both cover the not eligible costs of the Investigator Project Proposal, and anticipate the eligible costs of each year of the Investigator Project Proposal according to the final Budget Plan approved by FC. Funds must be: non-profit (assigned by or derived from non-profit public or private organizations), available at the time of the Project Proposal Application to the 'FC Investigator Grant - Call for Proposals 2020', and fully described by name and identification number.

Document	Description
The 'FC Investigator Grant - Call for Proposals 2020'	The document establishes: <ul style="list-style-type: none"> — the aims and objectives of the FC Call — the rules, the requirements and the eligibility criteria of the PI Applicant, the HI and the Investigator Research Project Proposal — the rules for the submission of the Project Proposal Application — the rules of the selection process
Regulation of the 'FC Investigator Grant - Call for Proposals 2020'	The (present) document comprises all the rules, policies and guidelines regarding the Funding, the requirements and the duties of the PI Grantee and the HI, including annual scientific and economic reports, publications, intellectual property and so on. The Regulation, which comprises and completes the other documents (the 'FC Investigator Grant - Call for Proposals 2020', the 'Guidelines for the Submission of the Proposal Application', the FC Investigator Grant Contract).
Guidelines for the Submission of the Proposal Application	The document, which both originates from and completes the Regulation and the 'FC Investigator Grant - Call for Proposals 2020', contains all the relevant and mandatory instructions for the completion and the submission of the Project Proposal Application on the 'Fondazione Celiachia Calls and Proposals' Web Portal (callsfondazione.celiachia.it).
FC Grant Contract	The document is agreed between FC and the PI's Hosting Institute



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	<p>(the Coordinating PI and his/her Institute, Hub Centre, in case of Multicentre Study), and 1) comprises and completes the other documents (the 'FC Investigator Grant - Call for Proposals 2020', the 'Guidelines for the Submission of the Proposal Application', the Regulation), is written in both Italian and English; 2) comprises all the rules, policies and guidelines regarding the Funding, the requirements and the duties of the PI Grantee and the HI (and of the chief researchers and the other Spoke Centres involved in the Project, in case of Multicentre Study), including annual scientific and economic reports, publications, intellectual property, the Express Termination Clause and Revocation of the FC Grant Contract, etc.; 3) is annexed to the final Budget Plan approved by FC.</p> <p>Until all the mandatory fulfillments aimed at completing the FC Grant Contract within 60 days after the agreement signature are successfully achieved by the PI and the Hosting Institute, the FC Grant Contract is considered as not fully completed, and consequently the Investigator Project cannot be started, and all the predicted costs (including the Personnel costs where applicable) will not be considered as eligible for funding/annual balance by FC.</p> <p>The document is written in Italian and is signed by the PI (the Coordinating PI, in case of Multicentre Study) and the Legal Representative of the PI's Institute (the Hosting Institute/Hub Centre in case of Multicentre Study, on the behalf of the Legal Representatives and the chief researchers of all the other Spoke Centres involved in the Project).</p>
<p>FC Grant Time Schedule (Calendario di Grant)</p>	<p>The FC Grant Time Schedule:</p> <ul style="list-style-type: none"> — sets all the dates and the deadlines of the Investigator Project: the starting date and the end date of each year of the Project, and the corresponding deadlines for the economic and scientific reports. It consequently establishes the time periods in which predicted costs are eligible: costs produced outside these periods are not eligible for funding/annual balance — is established by FC exclusively upon all the mandatory fulfillments aimed at completing the FC Grant Contract within 60 days after the agreement signature are successfully achieved by the PI and the Hosting Institute

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 averaged independently of the duration of the Project:

Published Papers (Pubmed quoted): average 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 the eligibility criteria specified into the "FC Investigator Grant - Call for Proposals 2020", to which you must refer.**

Project Proposal Applications from PI Applicants who do not meet the above requirements will be rejected.

The requirements specified into the Call for Proposals 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 "FC Grant Contract" 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

Further requirements to be met and conditions to be complied with by the PI Candidate and other researchers and/or staff and/or any member of his research team/laboratory/units involved in the Research Project are set out in the 'FC Investigator Grant - Call for Proposals 2020', to which you must refer.

It is the responsibility of the PI Candidate to verify that the requirements are met before submitting the Application Form.

6. Requirements and Eligibility Criteria of the Hosting Institute

The Hosting Institute (HI) is the (public or private) non-profit organization governed by Italian law and with registered office in Italy 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 the eligibility criteria specified into the 'FC Investigator Grant - Call for Proposals 2020', to which you may refer.**

Proposal Applications involving Hosting Institutes which do not meet the above requirements will be rejected.

The requirements specified into the Call for Proposals 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 "FC Grant Contract", 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

The requirements and eligibility criteria of the Research Project reported in the Call for Proposals concern the following aspects:

- Duration
- Research topics
- Research areas
- Adherence to the FC's Aims Priorities
- Allowed Typologies of Investigator Project Proposals and Mandatory Requirements
- The Budget Plan
- The PI Grantee/PI's non-profit funds involved into the Investigator Project Proposal Application: Mandatory Requirements

The detailed contents of these requirements and criteria are specified in the 'FC Investigator Grant - Call for Proposals 2020', to which you may refer.

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

The detailed contents are specified in the "FC Investigator Grant - Call for Proposals 2020", to which you may refer.

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. Terms and Procedures for the Submission of the Proposals Applications and Indicative Time Schedule of the “FC Investigator Grant - Call for Proposals 2020” Steps

In addition to the provisions of this Regulation, all the detailed instructions concerning the procedures and deadlines for the submission of Proposals Applications are detailed in the “FC Investigator Grant - Call for Proposals 2020” and, for aspects relating to the fulfillment of the Application Form, in the 'Guidelines for the Submission of the Proposal Application' - documents to which you may refer.

Such documents are available for download 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>

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

Therefore, please read carefully the above documents, to which you may refer for all details, instructions and mandatory requirements for the submission of the project application to the “FC Investigator Grant - Call for Proposals 2020”.

With regard to the indicative Timeline of the Call steps, it will be referred to the following dates, except for possible changes by FC and/or due to unforeseeable contingencies:

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

10. Contractual Steps of Completion and Implementation of the Funding (FC Grant Contract)

1. Upon completion of the selection process of the FC Call for Proposals, the PI and the Institute (the PI Coordinator and the Hub Centre, in the case of Multicentre Project) receive the "GRANT CONTRACT BETWEEN FC AND THE PI AND THE INSTITUTE" (shortly "FC Grant Contract"), to be signed, dated and returned to FC in original hard copy and as a color scan copy by e-mail BY THE ESSENTIAL TERM OF **30 DAYS**.
2. As an alternative to the hard copy, it is possible to proceed in totally digital (paperless) mode, by affixing your "digital signature", as long as legally valid in Italy, in the document received in PDF format, with the affixing of Time Marking or other digital instrument of time marking and return it to FC via e-mail (better if certified, P.E.C. in this case the date of the P.E.C. will be the date of the document) BY THE ESSENTIAL TERM OF **30 DAYS**.
3. The "FC Grant Contract" constitutes an essential and indispensable element for the finalization of the funding and the failure to conclude it WITHIN THE ABOVE ESSENTIAL TERM OF 30 DAYS FROM RECEPTION, with all necessary signatures by PI Candidate and HI, in the person of its Legal Representative, will be considered as a WAIVER to the GRANT FC and will result in the withdrawal of the application and the revocation of the assignment of the FC GRANT, leaving FC free to assign the GRANT to other Candidates.
4. **Within 60 days** from the signing of the "FC Grant Contract", the Institute of PI (in the persons of the Legal Representative and the PI) is required to finalize all the mandatory contractual steps listed below (points A-D), providing FC with the following documents:
 - A. The **Final Budget Plan** approved by FC, to be dated and signed.
 - B. In case it is applicable (present Regulation), **copy of the original 'Contract between the Hosting Institute and the Fellow'** for which the PI requested the funding of the Personnel Costs within the frame of the FC Grant. The copy of the original 'Contract between the Hosting Institute and the Fellow' **must mandatorily be signed and dated** by the Legal Representative of the HI and the Fellow, and **duly registered and stamped with a protocol number by the offices of the HI**. The 'Contract between the Hosting Institute and the Fellow' must **mandatorily** report **all** the following issues (**mandatory requirements**):
 - It is **mandatory** that the **starting date of the activities of the Fellow** (the contract starting date) **is placed within 60 days** after the signature of the FC Grant Contract. The duration of the 'Contract between the Hosting Institute and the Fellow' is free, but eligible Personnel Costs for the Fellow (that can be loaded on the FC Grant) are **exclusively** those for the periods placed **within** the times fixed by the *FC Grant Time Schedule (Calendario di Grant)* of the Investigator FC Project.
 - During **the whole course of the Investigator FC Grant** (times fixed by the *FC Grant Time Schedule, Calendario di Grant*), it is **mandatory** that the Fellow **does not receive any other employment income** from the Institute or any other Organization, AND the 'Contract between the Hosting Institute and the Fellow' **cannot be cumulated with any other revenue/contract** (fellowships, any kind of employment contract, collaboration contracts, supply teaching post, etc.). Thus, in case the Fellow is holding other positions, it is necessary that the Fellow **renounces and quits all open positions, including those not involving a salary, before** he/she signs the 'Contract between the Hosting Institute and the Fellow'.



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Disregarding this requirement at any moment of the FC Grant will imply the cancellation of the FC Grant Contract, the interruption of the Grant instalments, and the Institute shall pay back to FC the instalments already assigned, including the amounts already spent during the whole course of the Investigator FC Grant (Section 9 of the present Regulation - Express Termination Clause and Revocation of the FC Grant Contract)

— During **the whole course of the Investigator FC Grant** (times fixed by the *FC Grant Time Schedule, Calendario di Grant*), it is **mandatory** that the Fellow guarantees **a full time effort (100% of his/her working time) for 12 months per year** on the FC Investigator Project, and **must** perform his/her assigned research activities in the Institute and in the laboratory of the PI that were indicated in the *Proposal Application*. Disregarding this requirement at any moment of the FC Grant will imply the cancellation of the FC Grant Contract, the interruption of the Grant instalments, and the Institute shall pay back to FC the instalments already assigned, including the amounts already spent during the whole course of the Investigator FC Grant (Section 9 of the present Regulation - Express Termination Clause and Revocation of the FC Grant Contract)

IMPORTANT: In case the 'Contract between the Hosting Institute and the Fellow' does not report one or more of the above listed mandatory requirements, it is **mandatorily requested to send together with the Contract also an integrative declaration onto letterhead paper** of the Hosting Institute, which refers to the Contract (date, protocol number) and duly lists all the missing mandatory requirement. The letter is stamped, dated and signed in blue ink by the PI, the Fellow and the Legal Representative of the Hosting Institute.

- C. In case of human and/or animal experimentation (including human and/or animal biological samples), a copy of the original Clearance of the Ethical Committee/Animal Research Ethical Committee. Clearances obtained for other projects/studies similar or connected to the Project presented to the 2020 FC Call **will be accepted exclusively if annexed to a specific Amendment Document** produced for the Project presented to the 2020 FC Call by the Ethical Committee/Animal Research Ethical Committee.

The **Clearance** or the **specific Amendment Document** are required to have the following **mandatory requirements**, otherwise the document will not be accepted and the FC Grant Contract will be considered as ineffective:

— It is **an authentic/official document produced and signed** by the Ethical Committee/Animal Research Ethical Committee, and **registered by the authorities/offices**. No other types of documents or self-declaration will be accepted

— The **date** when the Ethical Committee/Animal Research Ethical Committee approval was held **must not be earlier than 6 months** before the launch of the 2020 FC Call. Clearances **obtained more than 6 months before the launch** of the 2020 FC Call will NOT be accepted

— it **must fully comply to the laws in force**. FC shall not be liable in any way for any inaccurate or incomplete or mendacious or inappropriate data or information or document or for failure to comply with the Consent or the Amendment submitted by the IP and its Institute. FC will not accept any liability for any damage to property or persons and participants in clinical trials provided for in the Consent or in the Amendment submitted by the PI and its Institute, and all civil, criminal and administrative liabilities towards anyone such as, but not limited to, injured and/or damaged parties, including the PI and the HI and the Fellow, third parties and Authorities, are and shall be borne in full by the PI and/or the HI and/or its Legal Representative and/or the Fellow, all of whom shall be jointly and severally responsible for the same, and hereby undertake to indemnify and hold FC harmless from



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any and all claims for damages and/or convictions made against it by any person, in any jurisdiction, whether judicial or extra-judicial, arbitration or other alternative dispute resolution proceedings.

These provisions relating to liability, waivers, guarantees and indemnities, will also be included and reiterated into the contract.

— Experimentation on animals (vertebrates, cephalopods and foetal forms of mammals) **must be strictly necessary, and 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>, <https://www.lav.it/aree-di-intervento/vivisezione/nuova-legge-vivisezione>, <https://www.lav.it/news/metodi-alternativi-convegno>, <https://www.ipamitalia.org/>

The **Clearance** or the **specific Amendment Document** are required to have the following **additional requirements**:

- 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)

IMPORTANT: In case the Clearance or the specific Amendment Document does not report one or more of the above listed additional requirements, it is **mandatorily requested to send together with the Clearance/specific Amendment Document also an integrative declaration onto letterhead paper** of the Hosting Institute, which refers to the Clearance/specific Amendment Document (date, protocol number) and duly lists all the missing additional requirement. The letter is stamped, dated and signed in blue ink by the PI and the Legal Representative of the Hosting Institute, under their own responsibility.

IMPORTANT: Please note that in case of **Multicentre Study**, the Clearance/specific Amendment Document approving the Multicentre study to be sent to FC in the frame of the FC Grant Contract is **exclusively** that of the Hosting institute of the Coordinating PI Applicant (**Hub Centre**).

- D. In case of **Partnership or Multicentre Study**, it is **mandatorily** required to send to FC also an **integrative declaration onto letterhead paper** of the Hosting Institute, stamped, dated and signed in blue ink by the PI and the Legal Representative of the Hosting Institute under their own responsibility. The letter duly lists and confirm all the **Collaboration Letters** attached to the Proposal Application, also duly listing all the internal/external collaborators or the Spoke Centres according to the Tables filled in the Proposal Application.



IMPORTANT: FC GRANT TIME SCHEDULE (CALENDARIO DI GRANT) OF THE PROJECT AND COSTS ELIGIBILITY

5. The FC Grant Time Schedule, which sets **all the dates and the deadlines** of the Investigator Project (the starting date and the end date of each year of the Project, and the corresponding deadlines for the economic and scientific reports, including the **time periods in which predicted costs are eligible** for reporting and annual final balance by FC) is established by FC **exclusively upon** all the mandatory fulfilments aimed at completing the FC Grant Contract within 60 days after the agreement signature are successfully achieved by the PI and the Hosting Institute, according to the present Regulation and the FC Grant Contract itself. Until all the mandatory fulfilments aimed at completing the FC Grant Contract within 60 days after the agreement signature are successfully achieved by the PI and the Hosting Institute, **the FC Grant Contract is considered as not fully completed, and consequently the Investigator Project cannot be started, and all the predicted costs (including the Personnel costs where applicable) will not be considered as eligible for funding/annual balance by FC.** *Example: in case an FC Grant Contract involves both the Clearance of the Ethical Committee and the 'Contract between the Hosting Institute and the Fellow', and the latter reports a starting date for the Fellow's research activities related to the Project that is before the obtainment of the Clearance of the Ethical Committee, the FC Grant Contract is considered as not completed until the Clearance is also obtained and sent to FC, and the FC Investigator Project is considered as not started yet (no FC Grant Time Schedule is established yet), and Personnel Costs relating to the Fellow's activities (generated until the completion of all the mandatory phases of the FC Grant Contract are concluded and the FC Grant Time Schedule is established) will not be considered as eligible to be loaded on the FC Grant (economic report) and will not be paid back by FC.*
6. Failure by the PI/Institute to comply with the required documentation and the above mentioned deadlines may, in FC's sole discretion, result in the rejection of the Proposal Application and/or in refusal by FC to sign the FC Grant Contract, or, if the Contract has already been concluded, the termination of the same due to fact and cause chargeable to the PI and/or HI, who shall be responsible for the restitution and compensation of all damages, both pecuniary and non pecuniary, suffered and that will be suffered by FC. Furthermore, FC reserves the right to suspend or deny the funding and not to sign the corresponding FC Grant Contract, or, if already concluded, to invoke its termination for fact and cause attributable to PI and/or HI, which will be responsible for all restitutions and compensation for all damages, patrimonial and non patrimonial, suffered and that will be suffered by FC, for those cases in which the PI or anyone in the PI research team, collaborators and/or chief researchers (in the case of Multicentre Project) are involved in **not formally closed Grant FC** (Grant FC arrived at the end according to the Grant Calendar, but whose scientific and/or administrative aspects and related reporting are still under evaluation by FC), unless FC allows, in its sole discretion and upon specific written consent, to reach a solution - as established by FC - of the suspensive conditions of the formal closure, provided that the solution takes place within a time frame compatible with the funding procedures, otherwise the funding granted may be revoked retroactively.

11. Object and Amount of the Funding (FC Grant)

1. OBJECT OF THE FUNDING AND LOCALIZATION

Object of funding is a Research Investigator Project submitted to the “FC Investigator Grant - Call for Proposals 2020” to be carried out exclusively in ITALY in the manner and terms indicated therein and in a non-profit organization (public or private) governed by Italian law and with registered office in ITALY.

2. THE OVERALL TOTAL PER YEAR MUST NOT EXCEED € 70,000 PER YEAR:

The **Overall Total per Year of the Investigator Project Proposal** 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).

→ Example for a **Single Study** or a **Partnership Study** Investigator Project:

- ✓ **Overall Total per Year of the Investigator Project Proposal** = eligible costs (covered by the FC Grant) + not eligible costs (not covered by the FC Grant) **≤ € 70.000 per year**
- ✓ It implies that the **Overall Total of the Investigator Project Proposal (eligible costs + not eligible costs) for its whole duration** must not exceed the following ceilings:
 - € 70,000 for 1 year Projects
 - € 140,000 for 2 years Projects
 - € 210,000 for 3 years Projects

→ Example for a **Multicentre Study** Investigator Project:

- ✓ **Overall Total per Year of the Investigator Project Proposal** = eligible costs (covered by the FC Grant) of all the involved Centres (Hub Centre and Spoke Centres) + not eligible costs (not covered by the FC Grant) of all the involved Centres (Hub Centre and Spoke Centres) = Overall Total per Year of the Hub Centre + Overall Total per Year of the Spoke Centre 1 + + Overall Total per Year of the Spoke Centre N. **≤ € 70.000 per year** to be **distributed** between all the involved Centres according to the Budget Plan
- ✓ It implies that the **Overall Total of the Multicentre Investigator Project Proposal** (eligible costs + not eligible costs of all the involved Centres) **for its whole duration** must not exceed the following ceilings:
 - € 70,000 for 1 year Multicentre Projects
 - € 140,000 for 2 years Multicentre Projects
 - € 210,000 for 3 years Multicentre Projects



3. 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 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, 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 = ELIGIBLE COSTS (COVERED BY THE FC GRANT) + NOT ELIGIBLE COSTS (NOT COVERED BY THE FC GRANT)

12. ELIGIBLE COSTS AND NOT ELIGIBLE COSTS IN CASE OF SINGLE RESEARCH STUDY OR IN CASE OF PARTNERSHIP STUDY: MANDATORY REQUIREMENTS

A. ELIGIBLE COSTS

In case of Single Research Study and in case of Partnership Study Investigator Projects, the eligible costs (covered by the FC Grant) are the following:

- **Consumables and Supplies:** reagents, consumables and specific disposable plastic wares strictly necessary to the accomplishment of the Research Project as predicted in the experimental plan reported in the Proposal Application.

The followings are NOT admitted: office supplies store, generic consumables and supplies of daily/common use in the labs, including pipettes, generic disposable plastic wares

- **Services:** experimental services and methodologies that are missing in the Hosting Institute and that cannot be neither supplied by the internal/external collaborators or the Spoke Centres (in case of Partnership and Multicentre Studies), e.g.: genomic sequencing, synthesis of specific PCR primers, spectrometry, NMR, NGS (next generation sequencing), etc., if predicted by the experimental plan of the Project

The followings are NOT admitted: translation services, not experimental/methodological services

- **Publication Costs:** Only publication of **scientific papers** complying **all** the following **mandatory** requirements: **1)** papers published on indexed international Journals (Pubmed quoted); **2)** papers whose results and data are **strictly** deriving from the experimental research plan and aims of the FC Project, with the exception of not predicted new data and aims derived from the accomplishment of the FC Project itself; editorials and position statements published by the PI exclusively with the aim of sustaining/improving previous papers derived from the FC Project itself are also admitted only if complying to the above reported mandatory requirements (published on indexed international Journals (Pubmed quoted), and whose results and data are strictly deriving from the experimental research plan and aims of the FC Project)



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The followings are NOT admitted: publication costs for papers published on national journals or on not indexed journal or not Pubmed quoted; publication costs for reviews of all kinds although correlated to the item of the FC Project; translation costs; other costs not strictly related to the acceptance/publication of the paper by the journal.

- **Congress and Travel Costs: Only** Congresses and Symposia where the PI (or his/her delegate belonging to his/her research team) presents either preliminary and final data **strictly** deriving from the experimental research plan and aims of the FC Project can be loaded on the FC Grant. **The costs involve: 1)** the registration fee, **2)** back and forth travels (only economic flight and second class trains), **3)** hotel **only** in case of congresses taking more than one day or in case of long distances/unavailability of day-back travels.

The costs are recognized only to **1 personnel unit per Congress:** the PI **or** his/her delegate belonging to the research team directly involved in the FC Project (Table 'DESCRIPTION OF THE PI APPLICANT's RESEARCH TEAM' in Section 'PI Applicant' of the Proposal Application), **or 1** of his/her collaborators (partner or chief researcher in case of Multicentre Study) only if costs are paid (invoices) by the HI of the PI (Hub Centre in case of Multicentre Study).

The attendance to the Congress **must be mandatorily proved by completing the FC economic annual report with the attachment of all the followings documents:** the Proceedings of the Congress reporting the Abstract of the FC Project oral/poster presentation, the attendance certificate released by the congress organizing committee, and the relevant tickets and invoices: travel, hotel and registration fee.

IMPORTANT: It is **mandatorily required** that the Budget Plan reported in the *Proposal Application* must also include the indicative costs for multiple participations to the **Scientific AIC Congress** (travels and hotel if necessary; the registration fee to the Scientific AIC Congress is currently free). See Section 7 of the present Regulation.

The followings are NOT admitted: costs for the organisation of meeting and workshop and congresses, costs for taxi shuttling, lunches and dinners either in the hotel or outside, all these costs being charged on the PI/Institute.

- **Personnel Costs:** The PI Applicant, the technicians, the researchers and all the personnel comprising the PI's research team and involved in the Project Proposal (Table 'DESCRIPTION OF THE PI APPLICANT's RESEARCH TEAM' in Section 'PI Applicant' of the Proposal Application) are **already affiliated to and employed by the Hosting Institute** where the FC Project is carried on, they work in the same lab/unit of the PI, and they are **NOT** allowed to load their salary (including taxes) on the FC Grant.

Financial support by the FC Grant can be requested for **up to 1 fellow only:** upon request of the PI Applicant, the Hosting Institute is allowed to employ up to **1 and only 1 fellow whose salary will be covered by the FC Grant (personnel costs).**

The personnel costs relating to this 1 fellow are allowed to be loaded on the FC Grant exclusively under the following conditions: **1)** the personnel composing the Research Team of the Unity/Laboratory led by the PI Applicant and directly involved in the PI Applicant's Project Proposal **is considered not sufficient** in terms of units number and/or skills with respect to the Research Plan and the Aims of the Project Proposal. The Peer Reviewers will carefully evaluate this need, and FC will approve this cost only upon positive assessment of the Peer Reviewers; **2)** the fellow will work in the PI's lab and under his/her supervision, moreover the fellow is engaged on the FC Project at **100% of his/her working time (12 months per year).**



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The personnel costs relating to this 1 fellow (gross salary and taxes) **must NOT exceed the minimum gross salaries predicted by the laws in force: doctorate** (dm 40 del 25 gennaio 2018, cioè il Decreto di modifica del DM 18 giugno 2008), **post-degree/post-doctorate fellowships** (l'importo della borsa di ricerca, ragguagliato su base annua, non può essere superiore a quello minimo previsto per gli assegni di ricerca di cui all'Art. 22 della legge 240/2010, pari a € 19.367,00 annui lordo percipiente), **research contracts (assegni di ricerca art. 22 della legge n. 240/2010 e d.m. n. 102/2011)**.

The personnel costs relating to this 1 fellow are loaded on the FC Grant according to the funding system of an initial annual installment (part payment) and a final annual balance upon FC's assessment and approval of the annual economic report produced by the PI Grantee and the HI. In case of suspension of the activity of the fellow for whatever reason (including maternity leave, disease, courses, training etc.), the salary of the fellow during the suspension period will not be covered by the FC Grant funds, moreover the suspension period will not give rise to an extension of the FC Grant Time Schedule (Calendario di Grant).

All the eligible costs predicted by the Project Proposal **must be described** in the Proposal Application (Section 'BUDGET PLAN' of the Proposal Application). Description must be **detailed and provided per year**. Generic descriptions are forbidden, e.g. plastic wares, kits, etc. The PI is requested to predict and describe as exactly as possible the reagents (e.g. anti-IL2 monoclonal antibody) and the services (e.g. Next Generation Sequencing) needed to accomplish the specific research plan and aims of the Project Proposal, also including the company/provider and its present prices, the estimated quantity and the overall predicted cost for each item. Moreover, the PI is requested to list the Congresses where the Project's data will be presented.

B. NOT ELIGIBLE COSTS

In case of Single Research Study and in case of Partnership Study Investigator Projects, the not eligible costs (not covered by the FC Grant, and completely loaded on the PI/Institute) are the following:

- **Small Bench Instrumentation:** Incubators, hoods, freezer - 80°C, refrigerators, centrifuges, pipettes, etc.
- **Maintenance Contracts:** for the maintenance of whatever kind of instrumentations (small or huge) involved in the Project, including amortization costs
- **Overheads and Indirect Costs:** indirect and overheads costs absorbed by the Project itself and by the (administration staff, office supplies, personnel costs, electricity, water, other consumptions, etc.)
- **Other Costs:** other costs non listed above

13. ELIGIBLE COSTS AND NOT ELIGIBLE COSTS IN CASE OF MULTICENTRE STUDY: MANDATORY REQUIREMENTS

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, and only for some typologies of costs.

Publication and Congress costs are **exclusively** recognised to the Coordinating PI **only** (the Hub Centre). The Coordinating PI can send at his/her place **N. 1** delegate belonging to the research team directly involved in the FC Project **or 1** of his/her collaborators (partner or chief researcher in case of Multicentre Study) only if costs are paid (invoices) by the HI of the PI (Hub Centre).

A. ELIGIBLE COSTS FOR THE HOSTING INSTITUTE OF THE COORDINATING PI (HUB CENTRE)

In case of Multicentre Study, the eligible costs (covered by the FC Grant) for the Hosting Institute of the Coordinating PI (Hub Centre) are the following:

- Personnel Costs
- Consumables and Supplies
- Services
- Publication costs
- Congress and Travel costs

Eligibility requirements and not eligibility requirements are those already reported above (Section 12, *ELIGIBLE COSTS AND NOT ELIGIBLE COSTS IN CASE OF SINGLE RESEARCH STUDY OR IN CASE OF PARTNERSHIP STUDY: MANDATORY REQUIREMENTS*)

B. NOT ELIGIBLE COSTS FOR THE HOSTING INSTITUTE OF THE COORDINATING PI (HUB CENTRE)

In case of Multicentre Study, the not eligible costs (not covered by the FC Grant, and completely loaded on the PI/Institute) for the Hosting Institute of the Coordinating PI (Hub Centre) are the following:

- Small Bench Instrumentation
- Maintenance Contracts
- Overheads and Indirect Costs
- Other Costs

C. ELIGIBLE COSTS FOR EACH OF THE INVOLVED SPOKE CENTRES

In case of Multicentre Study, the eligible costs (covered by the FC Grant) for for each of the involved Spoke Centres are the following:

- Personnel Costs
- Consumables and Supplies
- Services



Eligibility requirements and not eligibility requirements are those already reported above (Section 12, *ELIGIBLE COSTS AND NOT ELIGIBLE COSTS IN CASE OF SINGLE RESEARCH STUDY OR IN CASE OF PARTNERSHIP STUDY: MANDATORY REQUIREMENTS*)

D. NOT ELIGIBLE COSTS FOR EACH OF THE INVOLVED SPOKE CENTRES

In case of Multicentre Study, the not eligible costs (not covered by the FC Grant, and completely loaded on the Spoke Centre) for each of the involved Spoke Centres are the following:

- Publication costs
- Congress and Travel costs
- Small Bench Instrumentation
- Maintenance Contracts
- Overheads and Indirect Costs
- Other Costs

14. NON-PROFIT FUNDS OF THE PI/INSTITUTE FOR THE CO-FUNDING OF THE FC INVESTIGATOR PROJECT

The funds allocated by the PI Grantee/PI to both **cover the not eligible costs** of the Investigator Project Proposal (completely loaded on the PI/PI), and **anticipate the eligible costs of each year** of the FC Investigator Project according to the final Budget Plan approved by FC.

The funds allocated by the PI/Institute for the co-funding of the FC project must have all the **following mandatory requirements**:

- **non-profit** (assigned by or deriving from **non-profit** public or private organizations): the funds must originate from and/or must be released by **non-profit Institutions** that, irrespective of their legal status (public or private law bodies), have the primary goal to independently conduct or support non-profit biomedical/scientific research and/or to disseminate its results. Shareholders, partners, companies, members or other individuals that can exert a decisive influence upon the funding Institution cannot have no influence over any aspect (including scientific, financial, organizational, property and/or intellectual issues) of FC granted programmes and corresponding results
- **already available at the time of the submission of the Project Proposal Application** to the 'FC Investigator Grant - Call for Proposals 2020', and fully described by name and identification number in the *Proposal Application* itself
- **fully adequate** to allow for a complete achievement of all the activities and the aims of the FC Investigator Project as described in the *Proposal Application*

In case of **Multicentre Study**, the above reported **mandatory** requirements are also applied to the non-profit funds allotted by each of the involved chief researchers/Spoke Centres.

15. Annual Installments of the FC Grant

1. FINAL BUDGET PLAN

FC keeps the right and privilege to **reconsider and reduce** the Budget Plan reported in the *Proposal Application* of Project Proposals selected for FC funding, leading to the **Final Budget Plan** that is signed for acceptance by the PI/Institute during the FC Grant Contract procedure.

IMPORTANT: Due to the legal entity of FC, lack/insufficiency of funds by FC at any moment will automatically imply the cancellation of the FC Grant Contract according to the *Expressed Termination Clause of FC Grant Contract* (Section 19 of the present Regulation).

2. FC GRANT TIME SCHEDULE AND FUNDS ASSIGNMENT

Upon the receipt of the required documents and the evaluation by FC of their correctness, FC keeps the right to request further documents/requirements, in case to revoke the FC Grant Contract (“CONTRATTO DI GRANT FELLOWSHIP TRA FC E L’ISTITUTO”), or to proceed with the **allocation of the pre-payment of the 1st annual instalment**.

The **FC Grant Time Schedule** sets **all the dates and the deadlines** of the Investigator Project (the starting date and the end date of each year of the Project, and the corresponding deadlines for the economic and scientific reports, including the **time periods in which predicted costs are eligible** for reporting and annual final balance by FC).

IMPORTANT: No changes of the FC Grant Time Schedule is admitted in case of delays about the annual reporting activities, actual instalment dates and other cases here not reported. In these cases, the Institute is required to anticipate the costs in order to avoid interruptions of the Project Plan. **Changes** of the FC Grant Time Schedule are admitted only in case of FC’s specific requests, as well as in case of suspensions or other issues predicted in the present Regulation (if approved by FC), and according to the Express Termination Clause.

Whatever the typology of FC Investigator Project (Single Research, Partnership, Multicentre), the funds of the FC Grant are **exclusively assigned to the Hosting Institute of the PI (the Hub Centre of the Coordinating PI in case of Multicentre Study)**.

The PI and the Hosting Institute of the PI (Legal Representative) are the only responsible toward FC for all of the following mandatory requirements and conditions; disregarding both this duty and the following mandatory requirements and conditions at any moment of the FC Grant will imply the cancellation of the FC Grant Contract, the interruption of the Grant instalments, and the Institute shall pay back to FC the instalments already assigned, including the amounts already spent during the whole course of the Investigator FC Grant (Section 9 of the present Regulation - Express Termination Clause and Revocation of the FC Grant Contract):

— **Single Research Studies and Partnership Studies:**

- ✓ Once assigned by credit transfer to the Institute for each year of the Grant, the funds of the FC Grant must be made available to the PI **mandatorily within 30 days** since the date of assignment



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- ✓ The funds of the FC Grant must be used **exclusively by the Institute of the PI** and **exclusively on the behalf and on demand of the PI and his/her research team** (Table 'DESCRIPTION OF THE PI APPLICANT's RESEARCH TEAM' in Section 'PI Applicant' of the Proposal Application), and **fully for the costs involved in the FC Project**
- ✓ Whatever **transfer** of the funds of the FC Grant outside the Institute of the PI is **forbidden**, and in case of **Partnership Studies**, whatever **sharing or sub-assignment** of the funds of the FC Grant to both internal (in the same Institute of the PI, including the same department) and external (in other Institutes/departments) partners (Table '*THE TYPOLOGY OF THE INVESTIGATOR PROJECT PROPOSAL*' in Section 4 – 'Project Proposal' of the *Proposal Application*) is **forbidden**
- ✓ All the **eligible costs** reported in the Final Budget Plan and described in the annual economic reports must be **exclusively held by the Institute of the PI** (Hosting Institute) and **exclusively on the behalf and on demand of the PI and his/her research team** (Table 'DESCRIPTION OF THE PI APPLICANT's RESEARCH TEAM' in Section 'PI Applicant' of the Proposal Application), and **fully for the costs involved in the FC Project**

— Multicentre Studies:

- ✓ The FC Grant Contract is agreed **exclusively** between FC and the Hosting Institute of the Coordinating PI (the Hub Centre), and the funds of the FC Grant are **exclusively** assigned to the Hub Centre whose Legal Representative and the PI are the only responsible toward FC for the management and the sub-assignment to all the involved Spoke Centres, according to the Final Budget Plan. The Hub Centre mandatorily inform each involved Spoke Centre about this instalment procedure
- ✓ Once assigned by credit transfer to the Hub Centre for each year of the Grant, the funds of the FC Grant must be made available to the Coordinating PI and to all the chief researchers of the involved Spoke Centres **mandatorily within 30 days** since the date of assignment
- ✓ The funds of the FC Grant sub-assigned to each Spoke Centre must be used **exclusively by the Spoke Centre itself** and **exclusively on the behalf and on demand of the chief researcher and his/her research team** (Table '*THE TYPOLOGY OF THE INVESTIGATOR PROJECT PROPOSAL*' in Section 'Project Proposal' of the *Proposal Application*), and **fully for the costs involved in the FC Project**
- ✓ Whatever **transfer** of the funds of the FC Grant **outside the Spoke Centre** is **forbidden**, and whatever **sharing or sub-assignment** of the funds of the FC Grant to both internal (in the same Spoke Centre, including the same department) and external (in other Institutes/departments) partners is also **forbidden**
- ✓ All the **eligible costs** reported in the Final Budget Plan and described in the annual economic reports must be **exclusively held by the Spoke Centre** and **exclusively on the behalf and on demand of the chief researcher and his/her research team** (Table '*THE TYPOLOGY OF THE INVESTIGATOR PROJECT PROPOSAL*' in Section 'Project Proposal' of the *Proposal Application*), and **fully for the costs involved in the FC Project**

3. ANNUAL INITIAL INSTALLMENT (PART PAYMENT) AND ANNUAL FINAL BALANCE

Whatever the typology of FC Investigator Project (Single Research, Partnership, Multicentre), the funds of the FC Grant are **allotted yearly** to the HI of the PI, according to the final Budget Plan approved by FC, in the **form of annual initial installment (part payment) and annual final balance**:

- The following scheme of annual initial installments (part payments) is applied to each year of the FC Project:
 - ✓ 1st year / 1 year-Projects: **50%** of the 1st year **eligible costs** reported in the Final Budget Plan approved by FC
 - ✓ 2nd year: **30%** of the 2nd year **eligible costs** reported in the Final Budget Plan approved by FC
 - ✓ 3rd year: **30%** of the 3rd year **eligible costs** reported in the Final Budget Plan approved by FC
- With the exception of the 1st year initial installment, all the other initial installments as well as all the annual final balances will be assigned to the HI only upon FC's assessment and approval of the economic annual reports produced by the PI and the HI (and the Spoke Centres, in case of Multicentre Study). **Independently on the amounts reported in the Final Budget Plan, the actual assignments will depend on the experimental and economic course of the Project as resulting from either the Scientific and the Economic annual reports**
- In the course of the Formal Closing Procedure of the FC Grant (Section 8 of the present Regulation) **all the unspent funds of the FC Grant and/or costs evaluated as not eligible by FC** as resulting from the reporting procedure **must mandatorily be returned** to FC by credit transfer **within 30 days** after the FC official communication of the conclusion date of the FC Grant.

16. Annual and Final Reports of the FC Grant

1. RULES

At the **end of each year** of the FC Project, according to the periods established by the **FC Grant Time Schedule** (*Calendario di Grant*), the PI (the Coordinating PI in case of Multicentre Study) and the LR of the PI's Institute (the Hub Centre in case of Multicentre Study) complete and sign **the annual accounting reports (scientific and economic reports)** by filling the **forms released by FC** at the beginning of each year of the FC Project. By signing the annual scientific and economic reports, the PI and the LR of the PI's Institute are the only responsible of all the data and the information there reported, they guarantee for the truthfulness of the data (also on behalf of all the Spoke Centres in case of Multicentre Studies), they also assure for the duly and full compliance to the rules and the requirements reported in the Call, the present Regulation, the FC Grant Contract, and finally they guarantee that the Project is fulfilling the aims established in the Proposal Application.

At any moment FC keeps the right to submit the annual and the final accounting reports to **independent Peer Review evaluation**, as well as to ask the PI and the Legal Representative of the Institute for further scientific and financial documents.



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Moreover, at any moment, FC keeps the right **to perform check and audit activities on documents at the Institute's location**, in order to verify the proper execution of the FC Project as well as any other contract, financial, administrative, logistic and scientific issue. FC is in the right to ask for such check and audit inspections regarding the FC Grant **within 10 (ten) years since the conclusion of the FC Grant itself**. For this reason, the Institute is required to save and file all documents concerning the FC Grant (including agreements, annual accounting reports, etc.) for 10 (ten) years since the conclusion of the Grant.

With the exception of the 1st year, the allocation of the other annual instalments is **subordinated to FC approval of the annual accounting scientific and economic reports**.

The **mandatory annual accounting reports** must be produced and sent to FC **within the fixed accounting deadlines** established by the FC Grant Time Schedule (*Calendario di Grant*), and include:

- The **Scientific Annual Report**
- The **Economic Annual Report**

IMPORTANT: In case of Multicentre Study:

For each year of the FC Project, **the annual accounting reports (scientific and economic reports) are produced and signed by the Coordinating PI and the LR of the Hub Centre** who are the **only responsible** of all the data and the information there reported, they guarantee for the truthfulness of the data **also on behalf of all the Spoke Centres** involved in the Multicentre Study. For each year of the FC Project, the Hub Centre is **mandatorily** required to collect the annual accounting scientific and economic reports (according to the forms released by FC) from all the involved Spoke Centres, including the **invoices** and the **other required fiscal documents**, and to attach them to the **Hub Centre's own annual accounting reports within the fixed accounting deadlines** established by the FC Grant Time Schedule (*Calendario di Grant*).

2. FOCUS: THE ECONOMIC ANNUAL REPORTS

- The PI, the LR and the administrative offices of the HI are **mandatorily** requested to know all the installment and accounting rules reported in the present Regulation and in the accounting scientific and economic reports released by FC, and to apply them appropriately since the beginning of the FC Grant.
- In case the economic annual report contains cost typologies and/or costs (including materials, reagents, etc.) **not predicted** in the Final Budget Plan and/or **cost amounts different** from the predicted ones, the PI (in case, also on the behalf of each Spoke Centre in case of Multicentre Study) is requested to mandatorily describe in detail the reasons of such differences and/or unpredicted costs during the annual reporting. **FC keeps the right in any moment to consider these costs and/or amount differences as not eligible.**
- In case of **plus or minus divergences** with respect to the Overall Total per Year predicted in the Final Budget Plan, the PI (in case, also on the behalf of each Spoke Centre in case of Multicentre Study) is requested to mandatorily describe in detail the reasons of such differences during the annual reporting.

— INVOICES AND ACCOUNTING PERIODS

- ✓ All the invoices and fiscal documents attached to the economic annual report, including the pay slips (*buste paga*) paid out to the Fellow **must mandatorily refer to the year** of the Grant to be accounted **and to the accounting periods** established by the FC Grant Time Schedule (*Calendario di Grant*). Invoices, fiscal documents and pay slips presenting dates outside the fixed accounting periods established by the FC Grant Time Schedule **will not be taken into consideration by FC and will be rejected** (the corresponding costs will not be accepted).
- ✓ All the invoices, fiscal documents and pay slips must **mandatorily** refer to costs **exclusively held by the PI's HI** (and each Spoke Centre in case of Multicentre Study), as described in Section 15 of the present Regulation (Point 2 - FUNDS ASSIGNMENT).
- ✓ For fiscal reasons, the only expense receipts that are considered eligible for reporting are electronic invoices (P.A. and Private individuals) or, when not required by law, paper invoices or, in any case, invoices or equivalent documents having a fiscal value, with stamp duty paid when due. **Orders, delivery documents are not accepted** as fiscal documents but they might be requested by FC to complete the evaluation of the economic annual accounting.
- ✓ The expenses reported may not be the subject of other public grants, offsets against credit taxes or reimbursements for other initiatives or projects of the Institute.
- ✓ All the rules for the eligibility of costs, the additional documents required to justify the various cost items, and the non-eligibility of costs, described for each cost item in these Regulations, will apply.
- ✓ In addition to the above, with regard to any personnel costs (where applicable and foreseen), the following supporting documents must be attached to the annual financial statement, under penalty of non-eligibility of such costs and non-recognition by FC on the Grant for the Project:
 - the personnel salary statements (which must show the name of the fellow and the Institute) relating to the fellow's salary compensation for the entire period included in the annual report of the Project;
 - Bank transfers or other fiscal documents attesting the payment of the salary: payment orders or bank transfers or other fiscal documents, showing the following data: the name of the beneficiary with the IBAN code, the date of payment, the amount of the salary paid to the fellow (in case of documents with cumulative payments, it is necessary to present the declaration signed by the legal representative indicating the part accounted);
 - for any taxes, charges and contributions: the receipts F24 or/and financial statements, showing the portion relating to the fellow (in the case of cumulative documents);
 - any additional documents that may be requested by FC.

17. Scientific Reports at the AIC Congress

Upon FC's request, the PI (the Coordinating PI in case of Multicentre Study) is **mandatorily required to present the development and the results (by both Poster and/or Spoken Presentations)** of the FC Project to the Scientific AIC Congress held yearly. Generally, a **first spoken/poster presentation** is held at half of the FC Project and a **final spoken/poster presentation** is given at the end of the FC Project. In addition, the PI might be required to also present further Reports at the AIC Congress. Save-the-dates and instructions for poster and oral presentations will be communicated by FC. It is **mandatorily required** that the Budget Plan reported in the *Proposal Application* must also include **participation costs to the Scientific AIC Congress (travels and hotel if necessary;** the registration fee to the Scientific National AIC Congress is currently free).

18. The Formal Closing Procedure of the FC Grant

Upon **FC approval** of the Final Scientific and Economic Accountings of the FC Grant, FC gives rise to the **Formal Closing Procedure of the FC Grant** which comprises the following steps:

1. **FC approval** of the Final Scientific and Economic Accountings of the FC Grant
2. The **Peer Review Final Evaluation** regarding the Scientific Reports (either Progress and Final Reports) produced by the PI (the Coordinating PI in case of Multicentre Study) in the frame of the FC Grant, as well as the publication activity originated from the FC Project.
3. Communication by FC of the completion of the Formal Closing Procedure of the FC Grant to the PI/Hi.
4. Return to FC (by credit transfer and **within 30 days** after the FC official communication of the conclusion date of the FC Grant) of **all the unspent funds of the FC Grant and/or costs evaluated as not eligible by FC** as resulting from the reporting procedure. In case of Multicentre Study, it is **mandatorily required that the Hub Centre also returns to FC all the unspent funds of the FC Grant plus the not eligible costs of all the involved Spoke Centres** (when applicable) by credit transfer to FC **within 30 days** after the FC official communication of the conclusion date of the FC Grant. It is up to the Hub Centre to have the Spoke Centres return their unspent funds of the FC Grant plus the not eligible costs to the Hub Centre itself: FC has no responsibility regarding this issue, as long as the Hub Centre is the only referral of FC for any legal and economic item.
5. Following the positive outcome of the above reported steps, the **dissemination of the results and the outcomes** of the FC Project is performed by FC through the communication media of FC and AIC, in agreement with the PI.

19. Expressed Termination Clause of FC Grant Contract

Without prejudice to the commitment to carry out the project in accordance with the principles of good faith, fairness, specific diligence, responsibility and seriousness, the "FC Grant Contract" to be entered into with the selected PI and HI Candidates shall include an express termination clause pursuant to Article 1456 of the Italian Civil Code, which shall entail the legal termination of the "FC Grant Contract" itself when the party concerned declares to the other party the intention to invoke such termination clause.



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Even in the case of single clauses whose effectiveness or termination is subject to a future and uncertain event, if it is intended to invoke the termination pursuant to art. 1353 of the Italian Civil Code, the interested party shall declare to the other party that it intends to avail itself of it, indicating whether in relation to the single clause or to the entire "FC Grant Contract".

The conditions, terms and obligations that may lead to the above mentioned consequences include all those expressly indicated as "ESSENTIAL" and, by way of example but not exhaustively, the following:

- Deficiency of funds by FC within the starting of the research, according to the Grant Time Schedule;
- Any unilateral and not agreed modification in the content of the FC Grant Contract as well as of any document originating from or completing the FC Grant Contract, and in the content of the FC Project;
- Disregards of any of the requirements/duties/rules reported in this Regulation, in the FC Grant Contract and in the FC Call (including the eligibility requirements) by the PI and the Institute;
- Unilateral and not agreed modification in the use of the funds or part of them with respect to the intended use as described in the FC Call, in this Regulation, in the FC Grant Contract and for each annual installment;
- Any interruption of the activities concerning the FC Project depending on reasons or intent of the PI/Hosting Institute. This also includes items such as the voluntary waiver and interruption of the FC Project. Each case will be evaluated by FC upon requirement to the PI/Hosting Institute of formal documentation;
- Any suspension of the research activities regarding the FC Project not previously approved by FC according to the Regulation;
- non-compliance of the PI's research activities with respect to the object of the funding (Proposal Application);
- Insufficient, omitting or inadequate scientific/financial reporting activity according to the terms and conditions provided for by FC;
- non-compliance to the scientific integrity principles;
- omission of results reporting or omission of any other information required by FC;
- breach of Industrial and Intellectual Property Rights;
- Changes in the position of the PI resulting in possible incompatibility and/or conflict or however in the reduction or loss of autonomy and independence or non-compliance of the requirements provided for by the Call for Proposals;
- Changes in Hosting Institute's individuation, also regarding its nature and characteristics. It is mandatorily required that the PI/the Legal Representative do promptly notify to FC any change of the Hosting Institute legal entity or organisation (e.g. changes in Institution name, merging, Legal Representative turn-over, changes in addresses, etc.), also including events that hamper or reduce the economic stability of the Institute. FC keeps the right to evaluate each case in order to assess the compliance of the changes with the Regulation, the FC Call, the annexed documents and the FC Grant Contract, otherwise adopting the present Express Termination Clause if so considered;
- Changes in the kind and nature of the affiliations between the PI and the Hosting institute with regards to what declared into the Proposal Application;
- Conclusion/interruption of the affiliation of the PI to the Hosting institute (also refer to the Section of the present Regulation: 'Transfer of the PI to another Institute');



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- infringement by the PI/Institute of any rule set forth in the Call for Proposals, in the Regulation, in the "FC Grant Contract" and in any document complementary to or deriving from the "FC Grant Contract".

The termination and/or the loss of effectiveness of the contract implies the interruption of the financing by F and the obligation for the Institute to return all the funds received by F within 30 days from the termination.

FC shall have also the right to claim back all granted funds, without prejudice, in any case, of the right of compensation for any damage, both pecuniary and non-pecuniary, of all sorts and kind, suffered and that will be suffered by FC.

20. Suspension

In case of a temporary, and not final, stop of the activities regarding the FC Grant due to exceptional circumstances regarding the PI/Institute, the request for suspension must be urgently and formally notified to FC by the PI/ Hosting Institute, and it shall contain detailed reasons (including maternity leave, disease etc.). In this case, the PI is requested to evaluate the possibility to delegate a senior personnel unit of his/her research team, exclusively for the suspension period, in order to avoid the suspension of the FC Project.

In any case, FC keeps the right to evaluate the request for suspension which must nonetheless be approved by FC in order to be considered as operative, and the temporary delegation to a senior personnel unit of the PI's research team if applicable. FC reserves the right to accept or refuse the request. Therefore, the request for suspension shall have no effect if it is not expressly approved by FC: suspensions performed without previous written approval of FC shall have the effect of the revocation of the FC Grant Contract, according to the Express Termination Clause.

In case no delegation is possible, the suspension, when approved by FC, will yield an extension of the time schedule of the FC Grant as originally defined (update of the FC Grant Time Schedule, Calendario di Grant), as well as the suspension of payments for the whole suspension period. During the suspension period, funds of the FC Grant cannot be used in no case. Costs performed within the suspension period will not be accepted by FC.

Requests for further suspension periods (multiple requests of suspension) will be evaluated by FC, and when not approved will lead to the revocation of the FC Grant Contract (according to the Express Termination Clause).

FURTHER RULES:

For no reason (including maternity leave, disease, transfer to other Institutes, teaching, education, courses, etc.), the suspension or the interruption of the activities by any of the members of the PI's research team including the Fellow charged on the FC Grant will lead to the suspension of the FC Project and the update of the FC Grant Time Schedule, Calendario di Grant. In this case, the PI/Institute is mandatorily required to give urgent and formal notification to FC and to also guarantee for the prompt replacement of the unit/units of personnel with other personnel with the same skills and the same roles within the frame of the FC Project, and all the additional personnel costs will be exclusively charged on the PI/Institute. Moreover, in case of suspension of the activity of the fellow for whatever reason (including maternity leave, disease, courses, training etc.), the



salary of the fellow during the suspension period will not be covered by the FC Grant funds, moreover the suspension period will not give rise to an extension of the FC Grant Time Schedule (Calendario di Grant).

In case of Multicentre Study, the temporary, and not final, stop of the activities regarding the FC Grant due to exceptional circumstances regarding the chief researcher/Spoke centre, the request for suspension must be urgently and formally notified to FC by the Coordinating PI/ Hub Centre (the only responsible toward FC for any legal and organization issue), and it shall contain detailed reasons (including maternity leave, disease etc.). In this case, the chief researcher is requested to evaluate the possibility to delegate a senior personnel unit of his/her research team, exclusively for the suspension period. For no reason (including maternity leave, disease, transfer to other Institutes, teaching, education, courses, etc.), the suspension of the activities by any of the involved Spoke Centres will lead to the suspension of the FC Project and the update of the FC Grant Time Schedule, Calendario di Grant. Finally, the suspension of the activities by any of the involved Spoke Centres will lead to the interruption of the FC Grant to the suspended Spoke Centre for the whole suspension period, and consequently the FC funds destined to the eligible costs of the suspended Spoke Centres will not be assigned and/or will be detracted from the subsequent annual initial instalments. During the suspension period, funds of the FC Grant already assigned to the Spoke Centre cannot be used in no case. Costs performed within the suspension period will not be accepted by FC.

In case of Multicentre Study, the interruption of the activities by any of the involved Spoke Centres will imply:

- The continuation of the FC Project, according to the established FC Grant Time Schedule (Calendario di Grant)
- The interruption of the FC Grant to the renouncing Spoke Centre. it is mandatorily required that the Hub Centre will return to FC the overall funds allocated by FC to the Spoke Centre, including those already spent all the spent and unspent funds of the FC Grant of all the renouncing Spoke Centres by credit transfer to FC within 30 days after the interruption date. It is up to the Hub Centre to have the renouncing Spoke Centres return their amounts of the FC Grant to the Hub Centre itself: FC has no responsibility regarding this issue, as long as the Hub Centre is the only referral of FC for any legal and economic item.

21. Transfer of the PI to Another Institute

In case of any conclusion/interruption/change of the affiliation of the PI to the Hosting institute, it is mandatory requested that this conclusion/interruption/change must be:

1. Communicated in advance and in writing to FC by the PI
2. Formally and urgently notified to FC by the Institute by mean of a headed notepaper of the Hosting Institute signed by the PI and the Legal Representative of the Institute

Once notified to FC the change of affiliation, the PI/Institute will be requested to provide FC with specific documents that will be carefully evaluated by FC.

In any case, FC keeps the right to determine the final decision about the prosecution of the FC Grant Programme/Project and about the conditions. FC keeps the right to revoke the FC Grant,



and to ask for paying back the overall funds allocated by FC to the Institute, including the amounts already spent, according to the Express Termination Clause.

FURTHER RULES:

The transfer to another Institute of any of the members of the PI's research team including the Fellow charged on the FC Grant will imply:

- Formal and urgent notification to FC by the PI/PI
- The PI/Institute are mandatorily required to guarantee for the prompt replacement of the unit/units of personnel with other personnel with the same skills and the same roles within the frame of the FC Project, and all the additional personnel costs will be exclusively charged on the PI/Institute
- The interruption of the salary to the fellow

22. Scientific Integrity and Conduct Code

FC pursues its institutional research missions providing for the respect of the principle of integrity in scientific research. To this end, FC acknowledges and adopts the general principles and methodologies contained in the following documents:

- i) "Singapore Statement on Research Integrity", elaborated during the 2nd World Conference on Research Integrity, held in Singapore in 2010;
- ii) 'The European Code of Conduct for Research Integrity', prepared by the international working group sponsored by the European Science Foundation.

The PI and the Institute, therefore, must recognize and comply with these principles and must perform honestly, in good faith, fairness, seriousness and responsibility all activities relating to research and study activities conducted and those related or related to them (by way of example, in the experimental design, data generation and analysis, publication of results, recognition of the direct or indirect contribution of colleagues, collaborators and others, reporting of activities and expenses, etc.) having as primary reference of its own conduct, beyond the scientific integrity, the superior interest of the research and the institutional goals pursued by FC.

Moreover, F recalls the application of the principles of Good Clinical Practice (GCP) (referred to in MD 15-07-1997 - Transposition of the European Union guidelines of good clinical practice for the conduct of clinical trials of medicinal products). Published in the Gazzetta Ufficiale 18 August 1997, n. 191, S.O. and subsequent amendments) which constitute an international standard of ethics and scientific quality for designing, conducting, recording and reporting clinical trials involving human subjects. Adherence to these GCP standards publicly guarantees not only the protection of the rights, safety and well-being of trial subjects in accordance with the principles established by the Declaration of Helsinki, but also the reliability of clinical trial data.

These Good Clinical Practice Guidelines aim to provide a common standard for the European Union (EU), Japan and the United States to facilitate mutual acceptance of clinical data by the regulatory authorities in these geographical areas and should be observed whenever clinical data are produced for submission to regulatory authorities.



Finally, the principles set out therein may also be applied in the case of other clinical trials that may have an impact on the safety and well-being of human beings.

23. INDUSTRIAL AND INTELLECTUAL PROPERTY

The PI and the Institute undertake to communicate to FC as quickly as possible (formally on the Institute's headed paper and signed by the PI and the Legal Representative), according to criteria of good faith and correctness, any invention or result in any way suitable for patent, protection, industrial property right or other similar title, developed and/or developed within the funded project.

Ownership of the rights deriving from patentable inventions resulting from Grant FC's research activity is from now on the exclusive property of FC, without prejudice to the right of the IP/Institute to be recognized as the author of the invention and therefore the moral right of authorship of the invention. FC will have the exclusive right to file the patent application.

The ownership and the rights of use and exploitation of any possible result, patentable or not, as well as the know-how deriving from the Research referred to in the Project financed by F will be exclusively due to FC, in accordance also with the provisions of art. 65, paragraph 5, C.P.I. (Legislative Decree n.30/2005).

24. Publications and Printed Materials

Before the publication of any article/paper, congress abstract of poster/oral presentation, press release as well as of any other kind of editorial issues originating from the FC Grant, the PI is mandatorily requested to send in advance to FC a copy of the corresponding text/manuscript (including submissions), in order to allow FC to:

- Verify the correctness of the FC Grant Acknowledgment statement, which should be as follows: 'This work was (also) supported by Fondazione Celiachia ONLUS - Italy [or when the new name will be effective: "This work was (also) supported by Fondazione Celiachia - Ente del Terzo Settore - Italy] Grant n° XXX'/'Lo studio è stato supportato (anche) con il Grant n° XXX di Fondazione Celiachia ONLUS - Italy [or when the new name will be effective: "Lo studio è stato supportato (anche) con il Grant di Fondazione Celiachia - Ente del Terzo Settore - Italy"]', where 'also' is intended to be used in case of involvement of other funds different from the FC Grant. The above statement must be always reported in whatever kind of publication in Italian or English or any other language of the publication itself
- In case, outfit activities of disclosure/dissemination – by previously agreeing with the researcher the appropriate moment to disseminate results or part of them – to the media and/or through the communication tools of the Foundation and of AIC. The content of any press release must be agreed with FC. Joint diffusion of press releases can also be arranged through the media tools/channels of both the researcher/Institute and of AIC/FC. The PI and the Institute undertake, at the same time, not to develop any press office activity relating to the research funded/co-funded by FC without a prior consent of FC

While sending to FC the drafts/manuscripts, the name of the magazine/journal/media and/or the date and place of the congress, where the disclosure should take place, have to be specified.



Finally, it is mandatory to provide FC also with the copy of the final publication.

All the above is to be fulfilled both during AND after the conclusion of the FC Grant for whatever kind of publication/press release/article/paper originated totally or in part from the FC Grant. In particular, for publications/press releases/articles/papers after the conclusion of the FC Grant, the PI is invited to cite the FC Grant also when the publication implies/involves even only part of data/results/outcomes originated from the past FC Grant. A possible Acknowledgment statement is suggested for such cases: 'This work was supported by XXX (XXX for the present funding Institute). Part of data and results involved in the research originates from the Fondazione Celiachia ONLUS - Italy - Grant n° XXX' [or when the new name will be effective: "Part of the data and results involved in the study are derived from the Fondazione Celiachia - Ente del Terzo Settore - Italy - Grant n° XXX"]. Copy of the original publications after the conclusion of the FC Grant should also be sent to FC.

25. Liability and Management of Personnel and Suppliers

Any liability relating to the Research and, where applicable, to the implementation of the experimentation, will be fully and exclusively borne by the "PI", the Host Institute "HI" (and/or HUB Centre and/or Spoke Centres) and the Legal Representative "LR" who, by signing the Application Form (Proposal Application), among other things, declare and guarantee that they will carry out all the planned activities in complete autonomy, independence and under their own care, supervision and responsibility.

In any case, FC is in any case excluded from any liability, whether dependent or deriving from the employment of personnel and/or collaborators (including the PI) in any capacity within the research project, as well as in relation to any supplying, serving or outsourcing contracts that may be established within or as a consequence of the research project/activity.

FC, moreover, does not assume, with respect to the staff engaged in Grant FC (including PI), any nature of employer and therefore is not liable in any way for the obligations arising from employment contracts, whether they be for contributions, social security, insurance, or related to safety in the workplace.

Consequently, after evaluating the needs arising from the research project funded in agreement with the researcher, the Institute undertakes to employ the personnel deemed necessary and appropriate to carry out the project, undertaking to ensure compliance with the regulations on employment contracts, tax and social security and safety.

These commitments and conditions are ESSENTIAL for the disbursement of funding. Failure to comply with these regulations will fall under the Express Termination Clause with the consequent revocation of the financing and the immediate restitution of the funds disbursed by FC.

In case of Partnership and Multicentre studies, the provisions of this Section are intended to be extended to all the subjects (by way of example and not exhaustive: employees, suppliers, professionals, etc.) with whom the institutions involved will enter into relations in order to exclude any hypothesis of establishment of employment and/or professional and/or direct contractual relationships with FC.



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These liabilities, therefore, together with any other liability for any reason or title deriving from the Research and the activities related thereto and subject of the "FC Investigator Grant 2020", shall be borne exclusively by the "PI", the Host Institute "HI" (and/or HUB Centre and/or Spoke Centres) and the Legal Representative "LR" who, by signing the Application Form (Proposal Application), expressly indemnify F from any liability, even jointly or indirectly, in this regard, assuming all administrative, civil and criminal liability, making from now on guarantors of F, obligated to indemnify and hold harmless F from any claim for damages and/or judgment against it, which may be made, at any time even after the conclusion of the Search, by any person, in any place, civil, criminal and administrative, both judicial and extra-judicial as well as arbitral or other alternative dispute resolution.

Furthermore, the care and responsibility shall be exclusively of HI (and LR) and PI, among others, by way of example and without limitation:

to obtain all necessary authorisations in accordance with the law, for the coordinating centre and for all participating centres, both as regards the execution of the trial and the creation of the related database;

to put in place and carry out, in complete autonomy and under their own complete care and responsibility, within the time limits provided, everything necessary and useful for the full execution of the research;

stipulate, when required by the type of research, the necessary insurance policies to protect the safety and well-being of patients, in accordance with the provisions of current legislation and in particular the Ministerial Decree of 14 July 2009 - Minimum requirements for insurance policies to protect subjects participating in clinical trials of medicinal products - and subsequent amendments;

These provisions relating to liability, waivers, guarantees and indemnities will also be included and reaffirmed in the "FC Grant Contract"

26. Fiscal rules and traceability of payments and financial flows

The "FC Investigator Grant 2020" is subject, inter alia, to compliance with all applicable tax, currency and financial regulations in force and the Participants undertake to comply with them under their sole responsibility and pursuant to the express termination clause.

To this effect, moreover, the PI and HI and/or LR Applicants hereby undertake to guarantee to FC and undertake to indemnify and hold harmless FC from any and all claims - including future claims up to the limit of the statute of limitations - for damages and/or sentences against it, made or to be made by any party, in any venue, whether civil, criminal or administrative, judicial or extra-judicial, as well as arbitral or other alternative dispute resolution.

In order to allow full traceability of the financial transactions relating to the financing provided for in the Investigator Grant FC 2020 call for proposals and the eligible expenses that may be recognized, the parties assume all the obligations of traceability of financial flows as well as payments, even under penalty of ineligibility of the related costs.

The failure to use the bank transfer - regardless of the limit of use of cash allowed by the applicable laws in force - or other appropriate instruments to allow full traceability of financial transactions



relating to this contract, constitutes grounds for termination of the contract and will fall under the express termination clause, without prejudice to compliance with the rules in force and applicable at the time.

Such provisions relating to liability, waivers, guarantees and indemnities shall also be included and reaffirmed in "FC Grant Contract".

27. Confidentiality

The Parties undertake to maintain, for the entire period of validity of the Contract and for a subsequent period of 10 (ten) years, the most absolute confidentiality on all technical, organizational, commercial and any other information, which the Parties themselves have become aware of as a result of their activity and, in any case, as a result of the execution of this Contract.

For the entire duration of the project and for the 10 (ten) years following its completion or expiry or the date on which, for whatever reason, the early termination of Grant's contract occurred, the PI and HI as well as the LR as well as all persons involved in the Research and/or their heads, undertake not to disclose and/or not to communicate to third parties, in any form, analogue and/or digital, written, oral or graphic or on a storage medium or in any other form, any information, data, and/or knowledge, and/or found, patented or patentable, know-how and, in general, any information of a technical-scientific, economic, commercial or administrative nature, as well as any design and/or document, owned by FC and/or concerning the latter, of which they have become aware during the execution of the Research Project referred to in the "FC Investigator Grant - Call for Proposals 2020", in accordance with these Regulations and the "FC Grant Contract", and not to use, in whole or in part, such Information, qualifying as Confidential, for purposes other than the Project. All results of the Project, of whatever nature, patentable or otherwise, shall be deemed to be Confidential Information.

This obligation of confidentiality will also be extended to their collaborators and/or employees and/or external consultants who will have access to the Confidential Information and who, for this purpose, will be duly informed of the confidential nature of the same, obtaining an express commitment, in turn, to maintain confidentiality.

It is understood that the PI and the HI as well as the LR, as well as all persons involved in the Research and/or their heads, shall be liable to FC also for the fact of their employees and/or consultants, and they shall be obliged from now on to compensate and/or indemnify FC in the event of breach of this Confidentiality Obligation and shall also be obliged, to indemnify and hold FC harmless from any and all claims - even future claims up to the limit of the statute of limitations - for damages and/or sentences against it, made by any person due to the violation of this Duty of Confidentiality, in any venue, civil, criminal and administrative, both judicial and extra-judicial as well as arbitral or other alternative dispute resolution.

Such provisions relating to Confidentiality and liability, waivers, warranties and indemnities shall also be included and reaffirmed in the "FC Grant Contract".

28. Documentation: Completeness and interpretation

In addition to the provisions of the present Regulation, Candidates will find further indications with the participation requirements and related procedures and procedures also in the "FC Investigator Grant - Call for Proposals 2020", and in the "Guidelines for the Submission of the Proposal Application" and, in case of approval of the Project, they must therefore sign the Grant Agreement, the conclusion of which is a condition precedent for obtaining the financing and whose failure to sign within the prescribed time limits prevents the completion of the FC Investigator GRANT financing, which may, in this case, be assigned to other Candidates.

The above documents, together with the correct completion and submission of the Application Form for Participation in the "FC Investigator Grant - Call for Proposals 2020" (Proposal Application), constitute the set of rules and regulations to which the PI Candidate and the Institute must adhere at each stage of the Call and, subsequently, of Grant FC if assigned.

If there are versions in languages other than Italian of the documentation relating to this "FC Investigator Grant 2020", the only binding and legally binding version to refer to in the event of litigation and/or disagreement will be the Italian language version.

FC reserves the right to execute this "FC Investigator Grant 2020" by interpreting the above mentioned documentation as, in particular, this Regulation or the "FC Investigator Grant - Call for Proposals 2020", in full autonomy and sovereignty, possibly deliberating ad hoc in case of discrepancies or events not covered in part or in whole by this Regulation, the Call for Proposals and related documents.

Any decision taken by FC at its sole discretion shall be final and binding for the Participants and Candidates.

For this purpose, please note that the signatures of the PI Candidate and the Legal Representative in the Application Form "FC Investigator Grant - Call for Proposals 2020" (Proposal Application) also apply as:

- authorization to use and process the data for the exclusive purposes of carrying out the various phases of the Call and, subsequently, Grant FC if assigned, in accordance with the European Regulation on the protection of personal data no. 679/2016 (GDPR) and Legislative Decree no. 196/2003 as amended by Legislative Decree no. 101 of 10/08/2018.
- aware and unconditional acceptance of all the rules, regulations and requirements set forth in these Regulations, in the "FC Investigator Grant - Call for Proposals 2020" and in the "Guidelines for the Submission of the Proposal Application".
- written declaration, made under its own responsibility and with the awareness of the sanctions provided for in art. 76 of the Presidential Decree no. 445 of December 28, 2000 and in accordance with such regulations, certifying the truthfulness of the information and data included in the documentation provided and, in particular, those concerning the Project, the PI Candidate and the Legal Representative of the Institute.



For anything not provided for in the above mentioned documentation, reference will be made to the Italian Civil Code and Special Italian Laws, in addition to any applicable EU rules and regulations.

29. Personal Data Processing

All persons involved and participants in this "FC Investigator Grant 2020" Call for Proposals, if they are in possession of and process personal data, as defined by the laws in force, and are required to comply with the regulations in force - provided for in the General Data Protection Regulation (EU/2016/679) (RGPD), containing provisions on the protection of individuals with regard to the processing of personal data, as well as rules on the free movement of such data, and Legislative Decree no. 196/2003 as amended by Legislative Decree no. 101 of 10/08/2018 - assume all responsibility in this regard.

Personal data, as defined by current regulations, provided by the PI, HI, LR as well as by all persons involved in the Research and/or under their control, shall be processed in compliance with current legislation as set out in the General Data Protection Regulation (EU/2016/679) (RGPD) and the Legislative Decree. 196/2003 as amended by Legislative Decree no. 101 of 10/08/2018 - and the information pursuant to Art. 13 of the General Data Protection Regulation (EU/2016/679) on the protection of individuals with regard to the processing of personal data, as well as rules on the free movement of such data.

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.

30. Governing Law, exclusive jurisdiction and competent court

The "FC Investigator Grant 2020" is exclusively dedicated to funding Research Projects in Italy and is subject to the Italian Law, which regulates all related documents - regulatory, pre-contractual and contractual - such as, by way of example, this Regulation, the "FC Investigator Grant - Call for Proposals 2020", the Grant Contract and any other document concerning the Call for Proposals, including registration and participation forms and related instructions.

Any dispute shall be submitted to the Italian Jurisdiction.

In case of conflict between the Italian version and the version in another language (e.g.: English) of any document of this "FC Investigator Grant 2020", the Italian version shall prevail, the only one valid in court and in any other alternative dispute resolution forum.

In any case, the competent Court shall be the Court of Genoa, with express recognition of the exclusive jurisdiction of such Court also in derogation of any other criterion of jurisdiction.

In order to prevent judicial litigation, the Parties undertake to find an amicable solution through alternative dispute resolution methods such as assisted negotiation or mediation.