



**Guidelines for the Submission of the Proposal Application**  
**FC Investigator Grant - Call for Proposals 2020**

**- FC -**

*Fondazione Celiachia*  
*Foundation for Celiac Disease*

**Guidelines for the Submission of the  
Proposal Application**

**FC Investigator Grant - Call for Proposals 2020**



# Guidelines for the Submission of the Proposal Application

## FC Investigator Grant - Call for Proposals 2020

### Foreword

#### IT

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

### General Info for Completing and Submitting the Proposal Application

1. **Download the Mandatory Documents:** Once entered your Project Proposal Application webpage, download the following mandatory documents from the top menu ('Mandatory Docs'):
  - The 'FC Investigator Grant - Call for Proposals 2020' (file 'Bando FC 2020') **(the Italian version of this Document is the only legally binding one; the free English translation is for consultation purposes only, and is not legally binding)**
  - The 'Regolamento FC Fellowships Call for Proposals 2020' (file 'Regolamento FC 2020') **(the Italian version of this Document is the only legally binding one; the free English translation is for consultation purposes only, and is not legally binding)**
  - The present 'Guidelines for the Submission of the Proposal Application' (file 'Guidelines FC 2020')
  - The 'Budget Plan excel forms', which must be downloaded, completed, signed, dated, colour scanned, and upload to the Project Proposal Application. The Budget Plan excel form to be downloaded (the 'Single/Partnership Budget Plan excel form', or the 'Multicentre excel form') depends on the typology of the Project, as described in the present Guidelines

**EACH OF THE ABOVE DOCUMENTS MUST MANDATORILY BE DOWNLOADED AND FULLY READ BEFORE STARTING THE COMPLETION AND THE SUBMISSION OF THE PROJECT PROPOSAL APPLICATION.**
2. **Number of Accounts and Number of Proposal Applications to be submitted to the FC Investigator Grant - Call for Proposals 2020:**
  - **Only 1 Project Proposal Application per Applicant** can be submitted (or multiple submitted) to the 'FC Investigator Grant - Call for Proposals 2020'
  - **Only 1 account per Applicant must be created on** the 'Fondazione Celiachia Calls and Proposals' Web Portal.



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→ Different Proposal Applications or the same Proposal Application submitted by the same Applicant **through different accounts** (account duplication) will lead to the **rejection of the Applicant and of all the Proposal Applications submitted by the Applicant.**

3. **Start the completion of your Proposal Application to the 'FC Investigator Grant - Call for Proposals 2020':** Complete all the required fields of each Section of the Proposal Application, and upload the required PDF files as requested in the relevant Sections of the Proposal Application and **in the present Guidelines.**
4. The Proposal Application is made of **9 Sections:** Sections from 1 to 8, plus the 'Submission' Section. You can switch from a Section to another by clicking on the corresponding Tab in top
5. When completing a Section, **always use the 'Save changes' function in the bottom of each Section** before you switch to another Section of the Proposal Application and/or you leave the 'Fondazione Celiachia Calls and Proposals' Web Portal
6. A **green check** will appear in the top Tab of each Section, when the corresponding Section is completed with required fields and data, and in case with uploaded files. Correspondingly, the same Section will appear as **green checked** and labelled as 'completed' in the 'Application Check List' reported in the 'Submission' Section
7. No green check will appear in the top Tab for those Sections that are uncompleted or partially completed or missing the upload of required files where predicted. These same uncompleted Section will appear as **red checked** and labelled as 'not completed' in the 'Application Check List' reported in the 'Submission' Section
8. Complete all the required fields of each Section of the Proposal Application, and upload the required files as requested in the relevant Sections of the Proposal Application itself. Nearby some of the fields you will find a **ⓘ**: by clicking on it, a box will appear with a brief instruction. Moreover, in most of the text field you will also find a **place-holder text** which briefly reminds you the object of the data to enter. In every case, do always refer to the Call and the present Guidelines for full instructions
9. The Proposal Application must be **completed in English** with the exception of specific fields which are indicated
10. In each Section, **mandatory fields are indicated by \***. In case of not applicability, **it is mandatory to write 'N/A' in the corresponding field, and, in every case, to follow instructions reported in the following paragraphs**
11. **Text fields** cannot exceed a fixed maximum number of characters, including spaces. A red alert will appear when you are exceeding the threshold
12. **Uncompleted** Proposal Application (with uncompleted fields and/or unchecked boxes) and/or Proposal Application missing the upload of the required mandatory files **cannot undergo submission (the Proposal Application remains as not submitted)**, since the 'Fondazione Celiachia



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'Calls and Proposals' Web Portal automatically prevents the submission of incomplete Proposal Applications

13. **Until the Deadline of the FC Investigator Grant - Call for Proposals 2020 is not expired**, you can save changes of your Proposal Application, leave the Portal whenever you like, and continue the completion and the submission of the Proposal Application in another moment
14. **Within the fixed Deadline**, you have to 1) complete your Proposal Application, 2) upload the required mandatory files (see also the 'FC Investigator Grant - Call for Proposals 2020'), 3) **download the General Info Section**, print the file, sign and date the document, **upload the file** in your Proposal Application webpage, 4) **download the appropriate 'Budget Plan excel form'**, complete and print the form, sign and date the document, **upload the file** in your Proposal Application webpage, and 5) **submit the Proposal Application** (the submission is not allowed by the Portal until all the Sections are completed and all the required files are uploaded): in the Section 'Submission', you will find the 'Submit' button
15. **Once the Deadline is expired**, it will be **not possible to enter** your Proposal Application webpage, **nor to submit** your Proposal Application. Therefore, **after the Deadline, not completed** Proposal Applications will remain **as not submitted** and will be **rejected automatically**
16. **As you complete the Proposal Application and submit it**, you will receive an automatic email containing the PDF of your submitted Proposal Application. The PDF file of the Proposal Application is labelled by i) the identification number of the Project Proposal Application (e.g.: *Proposal Identification Number: IG\_0XX\_FC\_2020*) which **is univocal to the PI Applicant (Candidate)**, ii) the date and time of the submission of the Proposal Application
17. **You can also make multiple submissions of the Project Proposal Application (re-submission of the Project Proposal Application within the fixed Deadline, upon editing or improvements)**
  - **Until the Deadline is not expired**, you are allowed to **re-submit your complete** Project Proposal Application more than once. In other words, in case you realize that your **completed and submitted** Project Proposal Application might need further improvements (a better description of the Project Proposal, attachment of improved figures, and so on), you can enter your personal webpage (login) on the 'Fondazione Celiachia Calls and Proposals' Web Portal and **re-open your Submitted Project Proposal Application** (in this case you will find the 'Complete/Edit Your Proposal' button replaced by the 'Open/Edit Your Submitted Proposal' button).
  - Once you have made the desired modifications (editing and/or attached files), **you mandatorily have to submit again the complete Project Proposal Application together with all the mandatory files** (in Section 'Submission', you will find the 'Submit' button replaced by the 'Resubmit Edited Proposal' button).
  - **Each time** you re-open, edit, complete and re-submit your Project Proposal Application **within the fixed Deadline, you will receive an automatic email** containing the PDF the last submitted Project Proposal Application. The PDF file of the re-submitted Project Proposal Application is labelled by i) the identification number of the Project Proposal Application (e.g.: *Proposal Identification Number: IG\_0XX\_FC\_2020*) which **is univocal to the PI Applicant (Candidate)**



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independently on the number of submissions made, *ii*) the date and time of the submission which **labels each completed submission** of the Project Proposal Application

- **Each time** you make a re-submission of your Project Proposal Application, **the last re-submission** does completely replace all the previous submitted versions of the Project Proposal Application, and does represent **the only Project Proposal Application of the Candidate that will be taken into consideration by FC** in the frame of the 'FC Investigator Grant - Call for Proposals 2020'. In no case previous submissions will be taken into consideration. **It is thus important to re-open your Submitted Project Proposal Application ONLY IF NECESSARY to edit/improve the previously submitted Project Proposal Application.** In case you re-open your Submitted Project Proposal Application and you then do not complete the re-submission procedure as described above, **the last submitted version of your Project Proposal Application will be taken into consideration by FC in the frame of the 'FC Investigator Grant - Call for Proposals 2020', with no exceptions.**
- **Be sure to complete the re-submission of the your Project Proposal Application within the fixed Deadline:** once the Deadline is expired, and you didn't complete the re-submission of the Project Proposal Application, you can neither enter your Project Proposal Application nor further re-submit the Project Proposal Application. **In this case the last submitted version of your Project Proposal Application will be taken into consideration by FC in the frame of the 'FC Investigator Grant - Call for Proposals 2020', with no exceptions.**

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

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

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

- ✓ The **General Info Section file**, which must be printed, signed, dated, and upload to the Project Proposal Application.
- ✓ The **Budget Plan excel file**, which must be downloaded, completed, signed, dated, and upload to the Project Proposal Application. The Budget Plan excel form to be downloaded (the '*Single/Partnership Budget Plan excel form*', or the '*Multicentre Budget*

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Plan excel form') depends on the typology of the Project, as reported in the present Guidelines

- ✓ In case of human and/or animal experimentation (including human and/or animal biological samples), you are required to upload **one file containing all the following documents:** **1)** a copy of the **Clearance** of the Ethical Committee/Institutional Review Board. Clearances obtained **more than 6 months** before the launch date (August 5<sup>th</sup> 2020) of the present 2020 FC Call as well as Clearances **not presenting the mandatory requirements** described in the 'FC Investigator Grant - Call for Proposals 2020' **will NOT be accepted.** **2)** Only in case the annexed Clearance of the Ethical Committee is related to other projects/studies similar or connected to the Project Proposal described in the Application Form, a specific **Amendment Document** produced by the Ethical Committee must be annexed to the Clearance. Amendments obtained **more than 6 months** before the launch date (August 5<sup>th</sup> 2020) of the present 2020 FC Call as well as Amendments **not presenting the mandatory requirements** described in the 'FC Investigator Grant - Call for Proposals 2020' **will NOT be accepted.**

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

- ✓ Should the Clearance of the Ethical Committee not be available yet at the time of the submission of the Project Proposal Application, you are required to upload **one file containing** a copy of the **Clearance SUBMISSION** to the Ethical Committee. Clearance Submissions produced **more than 6 months** before the launch date (August 5<sup>th</sup> 2020) of the present 2020 FC Call as well as Clearance Submissions **not presenting the mandatory requirements** described in the 'FC Investigator Grant - Call for Proposals 2020' **will NOT be accepted**
  - ✓ In case of Partnership or Multicentre Study, you are required to upload **one file containing all the signed and dated Collaboration Letters** according to the 'Collaboration Letter Form' downloadable from the Mandatory Documents top menu ('Mandatory Docs'). In case of a Partnership Study, each internal and external collaborator will sign and date the Collaboration Letter. **In case of a Multicentre Study, no more than 15 Spoke Centres can be involved**, and each chief researcher of the involved Spoke Centre will sign and date the Collaboration Letter. The dated and signed Collaboration Letters will be sent to the PI Applicant who will upload them **as one file** to the Proposal Application.
- **OPTIONAL FILES.** Omitted upload of the optional files will NOT hamper the completion and the submission of the Proposal Application:
- ✓ It is faculty of the Applicant to upload up to 2 PDF files of figures in the Section 'Proposal' of the Proposal Application, within the fixed Deadline



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### Section 1 – General Info

Fill in all the fields of the Section.

Data reported in this Section (e.g. 'Title of the Project Proposal', names of the PI Applicant and of the Legal Representative, etc.) will automatically appear in other Sections of the Proposal Application as not editable data. In case, editing must be done in this Section.

### Section 2 – PI Applicant

Fill in all the fields of the Section.

Please note that some of the fields appear as not editable, since these are fields automatically imported from the 'General Info' Section.

→ 'REQUIREMENTS AND ELIGIBILITY CRITERIA'/'PI Applicant's affiliation and position within the Hosting Institute (HI)'

— 'Hosting Institute (Legal name in Italian)'

It is the legal name of the Institute where the PI Applicant is affiliated and is holding an employment with.

— 'Hosting Institute (Legal name in English)'

Translate in English the name of the Institute where the PI Applicant is affiliated and is holding an employment with (i.e. University of Florence)

— 'Department', 'Laboratory/Unit': if not applicable, write 'N/A' in both 'Legal name in Italian' and 'name in English' boxes

→ 'REQUIREMENTS AND ELIGIBILITY CRITERIA'/'ACTIVE (OPEN) FC Grants'

In case you select 'The PI Applicant declares that he/she is holding or taking part to an ACTIVE (OPEN) FC Grants under the **allowed exceptions** reported in the 'FC Investigator Grant - Call for Proposals 2020'', a drop-down menu and a text field will appear both of which are **mandatory**. Select your option and complete the text field with the number of the FC Grant

→ 'OTHER MANDATORY REQUIREMENTS FOR THE PI APPLICANT AND THE OTHER RESEARCHERS/PERSONNEL INVOLVED IN THE PROJECT PROPOSAL'/'Within the frame of the present 'FC Investigator Grant - Call for Proposals 2020', any member of the PI Applicant's research team, as well as the internal/external partners of a Partnership Study and each researcher involved into a Multicentre Study are NOT holding or taking part to any kind of ACTIVE (OPEN) FC Grants under whatever role or title'

In case you select 'The PI Applicant declares that one or more members of his/her research team, and/or one or more internal/external partners of his/her Partnership Study and/or one or more researchers involved into his/her Multicentre Study ARE holding or taking part to an ACTIVE (OPEN) FC Grants under the ALLOWED EXCEPTIONS reported in the 'FC Investigator Grant - Call for Proposals 2020'', a drop-down menu and a text field will appear both of which are **mandatory**.



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Select your option and complete the text field with the name of the personnel and the number of the FC Grant

→ 'PI's CURRICULUM VITAE AND EXPERTISE RELEVANT TO THE PROJECT PROPOSAL'

— 'EDUCATION AND TRAINING'

Please list in **reverse chronological order** the most relevant degrees, PhD and post-doctoral trainings of the PI Applicant. You can add no more than 10 fields by selecting the relevant number from the drop-down menu.

— 'RESEARCH AND PROFESSIONAL EXPERIENCE'

Please list in **reverse chronological order** the most relevant positions held by the PI Applicant. You can add no more than 10 fields by selecting the relevant number from the drop-down menu.

— 'DESCRIPTION OF THE PI APPLICANT EXPERTISE AND NARRATIVE BIOSKETCH'

Please, provide details about the PI Applicant's expertise, accomplishments, technical skills, competences, clinical activity (if applicable), and all other information of his/her biography that are **directly relevant to the Research Topic and the Aims of the present** Project Proposal.

— 'PUBLICATIONS OF THE PI APPLICANT'

✓ Please, provide in **reverse chronological order** the list of **maximum 15 published papers** where the PI Applicant is author/co-author in the **last five years (from 1 January 2015 – 1 May 2020)**. **Only published papers and only publications relevant** to the **research topic** of the present FC Call (celiac disease/dermatitis herpetiformis, non-celiac wheat sensitivity) have to be listed, as this is considered relevant for the Peer Review assessment of the relevance of the PI Applicant's expertise. In case the PI Applicant has no publications in the relevant fields, do not add row by clicking on 'add row' in the field 'PUBLICATIONS OF THE PI APPLICANT', and you have to write 'N/A' in both the following fields ('Total Impact Factor' and 'Active Impact Factor'). In case of published papers in the relevant research topics, no more than 15 rows are allowed by the system by clicking on 'add row'. Add as many rows as you actually need: adding rows without completing them yields to incomplete Section; in case you don't need added rows any more, just delete them by clicking 'del' near the empty row. Rows must be filled in reverse chronological order of publication (from the last to the oldest). For each row, **all fields are mandatory (complete all the columns displayed)**. Moreover, please note that the field 'Impact Factor of Journal' is referred to the **last version** of ISI Web of Knowledge, and for the field 'Authorship role of the Applicant' **write one of the following authorship roles**: First Author or Co-First Author, Last Author, Corresponding Author, Other.

✓ 'Total Impact Factor': It is the sum of Impact Factors of the published papers in the last five years (**1 January 2015 – 1 May 2020**) whose authors **also comprise the PI Applicant**. The impact factor must be calculated according to the last current version of ISI Web of Knowledge.

✓ 'Active Impact Factor': It is the sum of the published papers in the last five years (**1 January 2015 – 1 May 2020**) where the **PI Applicant is first, last and/or corresponding author**. The impact factor must be calculated according to the last current version of ISI Web of Knowledge.





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#### — 'DESCRIPTION OF THE FACILITIES AND EQUIPMENT AVAILABLE IN THE HI FOR THE RESEARCH'

Please, provide a detailed description of the facilities and the equipment available in the Hosting Institute and in the department/unit/laboratory of the PI Applicant where the Project Proposal will be carried out.

#### — 'DESCRIPTION OF THE PI APPLICANT'S RESEARCH TEAM'

In this field 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 fully described. These personnel units are already in force and employed under whatever title in the Hosting Institute of the PI Applicant (fellows, technicians, researchers), they work into the **same laboratory/unit of the PI Applicant within the Hosting Institute where the Project Proposal will be carried out**, and are **NOT** allowed to load their salary on the FC Grant. For this reason, the field 'Affiliation' is already completed with the HI of the PI Applicant.

- ✓ First, select the number of personnel units from the drop-down menu
- ✓ Complete the first appearing field with the data of the PI Applicant
- ✓ Complete the other appearing fields with the data of the other personnel composing the Research Team of the Unity/Laboratory led by the PI Applicant and directly involved in the PI Applicant's Project Proposal (one field for each personnel unit). Do **NOT** list administrative staff
- ✓ In the field 'Role' select one of the following admitted roles from the drop-down menu: fellow, technician, researcher
- ✓ In the field 'Expertise' please, provide a detailed description of the expertise, skills, role and tasks assigned to each personnel unit in the frame of the PI Applicant's Project Proposal
- ✓ Upon request of the PI Applicant, the Hosting Institute is allowed to employ **up to 1 and only 1 fellow whose salary will be provided by the FC Grant** (the corresponding Personnel Cost of this unit is described in the Budget Section of the Proposal Application itself). For details and mandatory requirements, see the 'FC Investigator Grant - Call for Proposals 2020' and the *Regulation*. In this case, select 'YES' in the field 'Financial support request'. The gross salary of this fellow will be described in the Budget Plan Section of the Proposal Application. As already stated above and reported in the 'FC Investigator Grant - Call for Proposals 2020' and in the *Regulation*, the other personnel units including the PI, technicians, researchers and other fellows are **NOT** allowed to load their salary on the FC Grant. For all of them, select 'NO' in the field 'Financial support request'.

## Section 3 – Institute (HI)

Fill in all the fields of the Section.

#### — 'LEGAL REPRESENTATIVE OF THE HOSTING INSTITUTE'/'Typology of the Legal Representative'

In case you select 'Director of the Department within the Hosting Institute' you are mandatorily required to check the appearing flag box



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### Section 4 – Abstract

Fill in all the fields of the Section.

### Section 5 – Project Proposal

Fill in all the fields of the Section.

→ 'RESEARCH TOPIC KEYWORDS'

The Investigator Project Proposal might focus on one or more of the Research Topics described in the 'FC Investigator Grant - Call for Proposals 2020' (and exclusively on them), but **only one** of the allowed Research Topics (the **predominant**, the one which the Project Proposal MAINLY focuses on) must be selected in this field of the Proposal Application from the drop-down menu

→ 'RESEARCH AREA KEYWORDS'

Mandatorily select **only one** Research Area (the one the Proposal Application MAINLY focuses on) from the drop-down menu

→ 'FC's AIMS PRIORITIES'

Investigator Project Proposals must mandatorily have aims and purposes that fully adhere to one or more of the FC's Aims Priorities described in the 'FC Investigator Grant - Call for Proposals 2020', but **only one** (the **predominant**, the one which the Project Proposal MAINLY focuses on) must be selected in this field of the Proposal Application from the drop-down menu

→ 'DURATION'

In case of 1-year Project Proposals, you are required to select the typology of the study: *Pilot/ Exploratory Study* or *Full Research Study*. In the latter case, a mandatory text field will appear to describe the preliminary data of the Proposal (see the 'FC Investigator Grant - Call for Proposals 2020')

→ 'THE TYPOLOGY OF THE INVESTIGATOR PROJECT PROPOSAL'

— In case you select '*Partnership Study*' you can add up to 10 partners. For each collaborator, all the fields are mandatory.

Please, remind that **in case of Partnership Study**, you are required to upload **one PDF file containing all the signed and dated Collaboration Letters** according to the '*Collaboration Letter Form*' downloadable from the Mandatory Documents top menu ('[Mandatory Docs](#)'). In case of a Partnership Study, each internal and external collaborator will sign and date the Collaboration Letter. The dated and signed Collaboration Letters are sent to the PI Applicant who uploads them **as one PDF file** to the Proposal Application by using the '*upload*' function. **Omitted upload** of the mandatory documents to the Proposal Application and/or **uploading documents not corresponding to the required ones** will result in **incomplete** Proposal Application, consequently the submission will **not** be allowed by the Portal and, after the fixed Deadline, the incomplete Proposal Application will be **automatically rejected**. The uploaded



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documents will be evaluated during the Administrative Check of Conformity of submitted Proposal Applications.

In the field '*Expertise*' please provide a detailed description of the facilities, the equipment and the expertise missing in the PI Applicant's research team/laboratory/unit which will be supplied by the partner/collaborator.

In the field '*Role and tasks*' please provide a detailed description of the roles and the tasks assigned to the partner/collaborator within the frame of the PI Applicant's Project Proposal.

- In case you select '*Multicentre Study*' you can add up to 15 involved Spoke Centres and the corresponding chief researchers. For each Spoke Centre/chief researchers, all the fields are mandatory.

Please, remind that in case of Multicentre Study, you are required to upload **one PDF file containing all the signed and dated Collaboration Letters** according to the '*Collaboration Letter Form*' downloadable from the Mandatory Documents top menu ('*Mandatory Docs*'). **In case of a Multicentre Study, no more than 15 Spoke Centres can be involved**, and each chief researcher of the involved Spoke Centre signs and dates the Collaboration Letter. The dated and signed Collaboration Letters are sent to the PI Applicant who uploads them **as one PDF file** to the Proposal Application by using the '*upload*' function. **Omitted upload** of the mandatory documents to the Proposal Application and/or **uploading documents not corresponding to the required ones** will result in **incomplete** Proposal Application, consequently the submission will **not** be allowed by the Portal and, after the fixed Deadline, the incomplete Proposal Application will be **automatically rejected**. The uploaded documents will be evaluated during the Administrative Check of Conformity of submitted Proposal Applications.

In the field '*Expertise*' please provide a detailed description of the expertise, the facilities, the equipment and the cohort of patients provided by the Spoke Centre within the frame of the PI Applicant's Multicentre Project Proposal.

In the field '*Role and tasks*' please provide a detailed description of the roles and the tasks assigned to the Spoke Centre within the frame of the PI Applicant's Multicentre Project Proposal.

#### → '*DESCRIPTION*'

- Please, fully describe the Project Proposal in detail by filling in accurately all the fields. **All the fields are mandatory.**

#### — '*BACKGROUND*'

Describe here the **scenario** of the Project Proposal underlying the rationale of the study. Please note that relevant literature must NOT be reported here (see the '*Relevant Bibliography*' field)

#### — '*HYPOTHESIS, RATIONALE AND AIMS*'

Describe here the hypothesis and thus the rationale of the study, and the proposed aims that are expected for the study. Please give a special focus on the impact of the study on the selected topic

#### — '*RESEARCH PLAN, EXPERIMENTAL DESIGN AND METHODOLOGIES*'

Laboratory research studies should present a research plan organised in tasks.

Clinical and epidemiological studies should present a research plan organised in phases to facilitate the work of Reviewers. Moreover, whenever the methodology is new or unusual,



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please describe it in sufficient details for evaluation. The description of cumbersome experimental details and protocols, however, is not encouraged and generally detracts from the quality of the proposal. **One PDF file** containing figures/plots relating to this item can be optionally uploaded. Please note that the PDF optional file must accomplish the following mandatory requirements: A) only PDF files are allowed (in case of images, bmp, jpeg, ppt or other formats, you first have to convert/save them as PDF file, and then you can upload them); B) the PDF file must not exceed 2 MB (files larger than 2 MB will not be allowed to be uploaded on the Portal)

#### — 'POTENTIAL PITFALLS AND CAVEATS, AND ALTERNATIVE APPROACHES'

Please, discuss here the potential difficulties and limitations of the predicted procedures, and suggest any alternative approach to achieve the aims and purposes of the Project Proposal. Write 'N/A' if you think it is not applicable

#### — 'PRELIMINARY DATA'

Please provide enough preliminary data to support the working hypotheses. Please note that in case you selected *1-year Full Research Study* in the sub-Section '*Duration*', the field is already completed with the text you put in the corresponding text field in the sub-Section '*Duration*' itself. **One PDF file** containing figures/plots relating to this item can be optionally uploaded. Please note that the PDF optional file must accomplish the following mandatory requirements: A) only PDF files are allowed (in case of images, bmp, jpeg, ppt or other formats, you first have to convert/save them as PDF file, and then you can upload them); B) the PDF file must not exceed 2 MB (files larger than 2 MB will not be allowed to be uploaded on the Portal)

#### — 'FEASIBILITY AND POWER CALCULATION'

Please, discuss here the project feasibility. Also note that power calculation is **mandatory** for clinical and epidemiological studies: make sure to have adequate sample sizes to ensure meaningful and statistically significant results

#### — 'EXPECTED RESULTS AND IMPACT ON CELIAC DISEASE/DERMATITIS HERPETIFORMIS/NON-CELIAC WHEAT SENSITIVITY IN TERMS OF INNOVATION AND ORIGINALITY'

Please, take into consideration that this item must be discussed in terms of either methodological and/or conceptual approaches

#### — 'RELEVANT BIBLIOGRAPHY'

Please provide a list of **at least one and up to 5** useful references referring to the Project Proposal, including the Background and other aspects of the Proposal. You can add up to 5 bibliographies by clicking on 'add row'. Add as many rows as you actually need: adding rows without completing them yields to incomplete Section; in case you don't need added rows any more, just delete them by clicking 'del'. For each row, **all fields are mandatory (complete all the columns displayed)**.

## Section 6 – Budget Plan

→ In this Section the PI Applicant describes the Budget Plan of the Project Proposal Application, **according to the rules and the mandatory requirements reported** in the '*FC Investigator Grant - Call for Proposals 2020*' and in the *Regulation*. **All the fields are mandatory. Write 'N/A' when applicable.**

→ First, **mandatorily** download the **Budget Plan excel file** from either the Mandatory Documents top menu ('*Mandatory Docs*') or from the 'Download template' function you find in the Section: the **Budget Plan excel file** must be completed (ALL FIELDS), signed, dated, and uploaded to the Project Proposal Application by using the 'Upload' function in this Section. The Budget Plan excel form to be used (the '*Single/Partnership Budget Plan excel form*', or the '*Multicentre Budget Plan excel form*') depends on the typology of the Project Proposal selected by the PI Applicant in the Section 'Project Proposal' of the Proposal Application, and it is automatically selected by the Portal in the 'Download template' function you find in the Section. **Omitted upload** of the mandatory Budget Plan excel file to the Proposal Application and/or **uploading partially completed** Budget Plan excel file to the Proposal Application will result in **incomplete** Proposal Application, consequently the submission will **not** be allowed by the Portal and, after the fixed Deadline, the incomplete Proposal Application will be **automatically rejected**. The uploaded documents will be evaluated during the Administrative Check of Conformity of submitted Proposal Applications.

#### → **Single or Partnership Studies**

In case of either **Single or Partnership Studies**, use the '*Single/Partnership Budget Plan excel form*' and complete the corresponding mandatory fields of the Section Budget Plan ('*DESCRIPTION OF THE PREDICTED COSTS*', '*THE PI APPLICANT/HI'S NON-PROFIT FUNDS INVOLVED INTO THE INVESTIGATOR PROJECT PROPOSALS: MANDATORY REQUIREMENTS*'). All the fields are mandatory. Write 'N/A' when applicable.

— **Instructions** for the completion of the '*Single/Partnership Budget Plan excel form*':

The excel form is made of **1 sheet** containing the **two following tables**:

##### ✓ **Table '1. BUDGET PLAN':**

- The table is made of two sections: the '*ELIGIBLE COSTS (COVERED BY THE FC GRANT)*' and the '*NOT ELIGIBLE COSTS (NOT COVERED BY THE FC GRANT)*'. Costs are in Euro €
- Only fill in 'year' columns corresponding to the duration of your Project Proposal (only the '*1<sup>st</sup> year*' column for 1-year Projects, the '*1<sup>st</sup> year*' and the '*2<sup>nd</sup> year*' columns for 2-years Projects, all the 3 '*year*' columns for triennial Projects).
- For each 'year' column only fill in the fields corresponding to the predicted cost typology involved in the Project Proposal. **Leave '0,00€' for all the not used fields.**
- The '*Total per Cost*' column is auto-calculating and automatically gives the total per each row (per typology of cost).
- As described in the '*FC Investigator Grant - Call for Proposals 2020*' and in the *Regulation*, the row '*Congress and Travel Costs*' 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)
- The row '*Personnel Costs*' is dedicated to the gross personnel costs (gross salary including taxes) of the one fellow to be loaded on the FC Grant, if needed and if applicable according to the details and the mandatory requirements reported in the '*FC Investigator Grant - Call for Proposals 2020*' and in the *Regulation*. **For each year of the fellowship to be loaded on the FC Grant do not exceed the gross ceilings (gross**

salary and taxes) reported in the '*FC Investigator Grant - Call for Proposals 2020*' and in the *Regulation*.

- The '*ELIGIBLE COSTS TOTAL PER YEAR*' is an auto-calculating row and automatically gives the total of the eligible costs per year. The '*ELIGIBLE COSTS TOTAL PER YEAR*' **cannot be more than 70% of the Overall Total per Year** (see the rules and the mandatory requirements reported in the '*FC Investigator Grant - Call for Proposals 2020*' and in the *Regulation*). **In case the '*ELIGIBLE COSTS TOTAL PER YEAR*' are more than 70% of the Overall Total per Year, an error message ('Fuori Budget') will appear in the row '*CORRETTEZZA ELIGIBLE COSTS*'.** In case the '*ELIGIBLE COSTS TOTAL PER YEAR*' are equal to or less than 70% of the Overall Total per Year, the row '*CORRETTEZZA ELIGIBLE COSTS*' will return an 'OK' message.
  - The '*ELIGIBLE COSTS OVERALL TOTAL*' is an auto-calculating field which automatically gives the total of the '*ELIGIBLE COSTS TOTAL PER YEAR*' row of the whole Project Proposal (for its whole duration). This value will not exceed 70% of the Overall Total of the whole Project Proposal
  - The '*NOT ELIGIBLE COSTS TOTAL PER YEAR*' is an auto-calculating row and automatically gives the total of the NOT eligible costs per year
  - The '*NOT ELIGIBLE COSTS OVERALL TOTAL*' is an auto-calculating field which automatically gives the total of the '*NOT ELIGIBLE COSTS TOTAL PER YEAR*' row of the whole Project Proposal (for its whole duration)
  - The '*OVERALL TOTAL PER YEAR (ELIGIBLE COSTS TOTAL PER YEAR + NOT ELIGIBLE COSTS TOTAL PER YEAR)*' **must not exceed € 70,000 per year**, as described in the '*FC Investigator Grant - Call for Proposals 2020*' and in the *Regulation*. **In case the '*OVERALL TOTAL PER YEAR (ELIGIBLE COSTS TOTAL PER YEAR + NOT ELIGIBLE COSTS TOTAL PER YEAR)*' exceeds € 70,000 per year, an error message ('Fuori Budget') will appear in the row '*CORRETTEZZA OVERALL TOTAL PER YEAR*'.** In case the '*OVERALL TOTAL PER YEAR (ELIGIBLE COSTS TOTAL PER YEAR + NOT ELIGIBLE COSTS TOTAL PER YEAR)*' is equal to or less than € 70,000 per year, the row '*CORRETTEZZA OVERALL TOTAL PER YEAR*' will return an 'OK' message.
  - The '*OVERALL TOTAL (ELIGIBLE COSTS OVERALL TOTAL + NOT ELIGIBLE COSTS OVERALL TOTAL)*' is an auto-calculating field which automatically gives the total budget of the whole Project Proposal (for its whole duration). This value will not exceed the following ceilings: € 70,000 for 1-year Projects, € 140,000 for 2-years Projects, € 210,000 for triennial Projects
- ✓ **Table '2. PART PAYMENT ANNUAL INSTALLMENTS':**
- This is an auto-calculating table which returns:
- The '*ELIGIBLE COSTS TOTAL PER YEAR*' for each year of the Project Proposal, as resulting from the first table (1. BUDGET PLAN)
  - The corresponding '*PART PAYMENT INSTALLMENT PER YEAR*' for each year of the Project Proposal, as described in the '*FC Investigator Grant - Call for Proposals 2020*' and in the *Regulation*.

— 'DESCRIPTION OF THE PREDICTED COSTS'

Please describe in more detail the costs reported in the 'Single/Partnership Budget Plan excel form' by completing all the fields. **Description must be provided per year.** Complete with 'N/A' in case the corresponding cost is not predicted.

Generic descriptions are **forbidden**, e.g. plastic wares, kits, etc. You are 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) you will need 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, you are requested to report the Congresses where the Project's data are predicted to be presented.

— 'THE PI APPLICANT/HI's NON-PROFIT FUNDS INVOLVED INTO THE INVESTIGATOR PROJECT PROPOSALS: MANDATORY REQUIREMENTS'

Please describe the funds of the PI Applicant/Institute that will be used to carry out the Project Proposal, indicating the identification number/identification name of the funds (e.g. PRIN N° XXX, etc.), the full name of the charity in Italian or in the original language (e.g. Ministero della Salute, Fondazione XXX, etc.), and the amount of the funds allotted to the Project Proposals according to the requirements reported in the 'FC Investigator Grant - Call for Proposals 2020'

→ **Multicentre Studies**

In case of **Multicentre Studies**, use the 'Multicentre Budget Plan excel form' and complete the corresponding mandatory fields of the Section Budget Plan ('DESCRIPTION OF THE PREDICTED COSTS OF THE HUB CENTRE (COORDINATING APPLICANT PI)', 'THE PI APPLICANT/HUB CENTRE NON-PROFIT FUNDS INVOLVED INTO THE INVESTIGATOR PROJECT PROPOSALS: MANDATORY REQUIREMENTS', 'DESCRIPTION OF THE PREDICTED COSTS OF THE SPOKE CENTRE', 'THE CHIEF RESEARCHER/SPOKE CENTRE NON-PROFIT FUNDS INVOLVED INTO THE INVESTIGATOR PROJECT PROPOSALS: MANDATORY REQUIREMENTS'). All the fields are mandatory. Write 'N/A' when applicable.

— **Instructions** for the completion of the 'Multicentre Budget Plan excel form':

The excel form is made of **16 sheets, one for the Hub Centre** of the Coordinating PI Applicant, and **the other 15 sheets are dedicated to each of the involved Spoke Centres (one sheet for one Spoke Centre)** for up to 15 Spoke Centres (as described in the 'FC Investigator Grant - Call for Proposals 2020' and in the Regulation, **Multicentre Studies cannot involve more than 15 Spoke Centres**). Complete either the 'HUB CENTRE' sheet and as many 'SPOKE' sheets as the number of involved Spoke Centres (one sheet for one Spoke Centre).

✓ **Table '1. ALLOCATION OVER THE CENTRES':**

- All the 16 sheets contain the table '1. ALLOCATION OVER THE CENTRES' which describes the amount allocated to each Centre. The Table is **mandatory** and must be completed **only in the first sheet ('HUB CENTRE')**, since it will automatically be duplicated also in all the other 15 sheets ('SPOKES'). Costs are in Euro €.
- The column 'Legal Name of the Centre (Italian)' must be completed with the Legal Name (Italian) of each involved centre (Hub and Spokes) **as equal as reported** in 'Section 3 – Institute (HI)' of the Proposal Application for the Hub Centre, and **as equal**

**as reported** in 'Section 5 - Project Proposal' of the Proposal Application (sub-section 'THE TYPOLOGY OF THE INVESTIGATOR PROJECT PROPOSAL', table 'Multicentre Study', column 'Spoke Centres') for each of the involved Spoke Centres.

- Only fill in 'year' columns corresponding to the duration of your Project Proposal (only the '1<sup>st</sup> year Total per Centre' column for 1-year Projects, the '1<sup>st</sup> year Total per Centre' and the '2<sup>nd</sup> year Total per Centre' columns for 2-years Projects, all the 3 'year' columns for triennial Projects).
  - For each 'year' column fill in the fields with the **total amount of costs per year absorbed by each Centre. Leave '0,00€' for all the not used fields.**
  - The 'Overall Total per Centre' column is auto-calculating and automatically gives the **total per each row** which represents the **overall total costs (eligible costs + not eligible costs) absorbed by each Centre for the whole duration of the Project**
  - The 'TOTAL PER YEAR OVER THE CENTRES' is an auto-calculating column which returns the sum of the total amount of costs per year absorbed by each Centre (Hub + Spokes). The 'TOTAL PER YEAR OVER THE CENTRES' **must not exceed € 70,000 per year**, as described in the 'FC Investigator Grant - Call for Proposals 2020' and in the Regulation. **In case the 'TOTAL PER YEAR OVER THE CENTRES' exceeds € 70,000 per year, an error message ('Fuori Budget') will appear in the row 'CORRETTEZZA TOTAL PER YEAR OVER THE CENTRES'.** In case the 'TOTAL PER YEAR OVER THE CENTRES' is equal to or less than € 70,000 per year, the row 'CORRETTEZZA TOTAL PER YEAR OVER THE CENTRES' will return an 'OK' message.
  - The 'OVERALL TOTAL' is an auto-calculating field which automatically gives the total budget of the whole Multicentre Project Proposal (for its whole duration). This value will not exceed the following ceilings: € 70,000 for 1-year Multicentre Projects, € 140,000 for 2-years Multicentre Projects, € 210,000 for triennial Multicentre Projects
- ✓ **Table '2. BUDGET PLAN OF THE HUB CENTRE (COORDINATING PI APPLICANT)':**
- This table is reported in the first sheet only ('HUB CENTRE') since it describes the detailed costs of the Hub Centre.
  - The table must be completed as described above for the table '1. BUDGET PLAN' of the 'Single/Partnership Budget Plan excel form', with the due differences regarding the typologies of the 'ELIGIBLE COSTS (COVERED BY THE FC GRANT)' and the 'NOT ELIGIBLE COSTS (NOT COVERED BY THE FC GRANT)' described in the 'FC Investigator Grant - Call for Proposals 2020' and in the Regulation for Multicentre Studies.
  - As described in the 'FC Investigator Grant - Call for Proposals 2020' and in the Regulation, the row 'Congress and Travel Costs' 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)
  - The 'ELIGIBLE COSTS TOTAL PER YEAR' is an auto-calculating row and automatically gives the total of the eligible costs per year. The 'ELIGIBLE COSTS TOTAL PER YEAR' **cannot be more than 70% of the Overall Total per Year** (see the rules and the mandatory requirements reported in the 'FC Investigator Grant - Call for Proposals 2020' and in the Regulation). **In case the 'ELIGIBLE COSTS TOTAL PER YEAR' are more than 70% of the Overall Total per Year, an error message ('Fuori Budget') will appear in the row**



**'CORRETTEZZA ELIGIBLE COSTS'**. In case the *'ELIGIBLE COSTS TOTAL PER YEAR'* are equal to or less than 70% of the Overall Total per Year, the row *'CORRETTEZZA ELIGIBLE COSTS'* will return an 'OK' message.

- The *'ELIGIBLE COSTS OVERALL TOTAL'* is an auto-calculating field which automatically gives the total of the *'ELIGIBLE COSTS TOTAL PER YEAR'* row of the Hub Centre for the whole duration of the Project Proposal
- The *'NOT ELIGIBLE COSTS TOTAL PER YEAR'* is an auto-calculating row and automatically gives the total of the NOT eligible costs per year
- The *'NOT ELIGIBLE COSTS OVERALL TOTAL'* is an auto-calculating field which automatically gives the total of the *'NOT ELIGIBLE COSTS TOTAL PER YEAR'* row of the Hub Centre for the whole duration of the Project Proposal
- The *'OVERALL TOTAL PER YEAR (ELIGIBLE COSTS TOTAL PER YEAR + NOT ELIGIBLE COSTS TOTAL PER YEAR)'* must be equal to the corresponding *'Year Total per Centre'* value of the Hub Centre reported in the first Table *'1. ALLOCATION OVER THE CENTRES'*. **In case the *'OVERALL TOTAL PER YEAR (ELIGIBLE COSTS TOTAL PER YEAR + NOT ELIGIBLE COSTS TOTAL PER YEAR)'* is NOT equal to the corresponding *'Year Total per Centre'* value of the Hub Centre reported in the first Table *'1. ALLOCATION OVER THE CENTRES'*, an error message (*'Fuori Budget'*) will appear in the row *'CORRETTEZZA OVERALL TOTAL PER YEAR'*.** In case the *'OVERALL TOTAL PER YEAR (ELIGIBLE COSTS TOTAL PER YEAR + NOT ELIGIBLE COSTS TOTAL PER YEAR)'* is equal to the corresponding *'Year Total per Centre'* value of the Hub Centre reported in the first Table *'1. ALLOCATION OVER THE CENTRES'*, the row *'CORRETTEZZA OVERALL TOTAL PER YEAR'* will return an 'OK' message
- The *'OVERALL TOTAL (ELIGIBLE COSTS OVERALL TOTAL + NOT ELIGIBLE COSTS OVERALL TOTAL)'* is an auto-calculating field which automatically gives the total budget of the Hub Centre for the whole duration of the Project Proposal

✓ **Table '3. PART PAYMENT ANNUAL INSTALLMENTS TO THE COORDINATING PI APPLICANT/HUB CENTRE':**

This table is reported in the first sheet only (*'HUB CENTRE'*) and is an auto-calculating table which returns:

- The *'ELIGIBLE COSTS TOTAL PER YEAR'* for each year of the Hub Centre, as resulting from the second table of the same sheet (2. BUDGET PLAN OF THE HUB CENTRE (COORDINATING PI APPLICANT))
- The corresponding *'PART PAYMENT INSTALLMENT PER YEAR'* for each year of the Hub Centre, as described in the *'FC Investigator Grant - Call for Proposals 2020'* and in the *Regulation*.

✓ **Table '2. BUDGET PLAN OF THE SPOKE CENTRE':**

- This table is reported in each of the 15 sheet dedicated to the involved Spoke Centres, and **must be completed in each 'SPOKE' sheet for each of the involved Spoke Centres**, since it describes the detailed costs of each Spoke Centre.
- The table must be completed as described above for the table *'2. BUDGET PLAN OF THE HUB CENTRE (COORDINATING PI APPLICANT)'* with the due differences regarding the typologies of the *'ELIGIBLE COSTS (COVERED BY THE FC GRANT)'* and the *'NOT ELIGIBLE*

*COSTS (NOT COVERED BY THE FC GRANT)*' described in the '*FC Investigator Grant - Call for Proposals 2020*' and in the *Regulation for Multicentre Studies*.

✓ **Table '3. PART PAYMENT ANNUAL INSTALLMENTS TO THE SPOKE CENTRE':**

This table is reported in each of the 15 sheet dedicated to the involved Spoke Centres and is an auto-calculating table which returns:

- The '*ELIGIBLE COSTS TOTAL PER YEAR*' for each year of the Spoke Centre, as resulting from the second table of the same sheet (2. BUDGET PLAN OF THE SPOKE CENTRE)
- The corresponding '*PART PAYMENT INSTALLMENT PER YEAR*' for each year of the Spoke Centre, as described in the '*FC Investigator Grant - Call for Proposals 2020*' and in the *Regulation*.

— '*DESCRIPTION OF THE PREDICTED COSTS OF THE HUB CENTRE (COORDINATING APPLICANT PI)*'

Please describe in more detail the costs reported in the '*Multicentre Budget Plan excel form*' by completing all the fields. **Description must be provided per year.** Complete with 'N/A' in case the corresponding cost is not predicted.

Generic descriptions are **forbidden**, e.g. plastic wares, kits, etc. You are 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) you will need 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, you are requested to report the Congresses where the Project's data are predicted to be presented.

— '*THE COORDINATING PI APPLICANT/HUB CENTRE NON-PROFIT FUNDS INVOLVED INTO THE INVESTIGATOR PROJECT PROPOSALS: MANDATORY REQUIREMENTS*'

Please describe the funds of the Coordinating PI Applicant/Hub Centre that will be used to carry out the Project Proposal, indicating the identification number/identification name of the funds (e.g. PRIN N° XXX, etc.), the full name of the charity in Italian or in the original language (e.g. Ministero della Salute, Fondazione XXX, etc.), and the amount of the funds allotted to the Project Proposals according to the requirements reported in the '*FC Investigator Grant - Call for Proposals 2020*'

— '*DESCRIPTION OF THE PREDICTED COSTS OF THE SPOKE CENTRE*'

Please describe in more detail the costs reported for **each Spoke Centre** in the '*Multicentre Budget Plan excel form*' by completing all the fields. **Description must be provided per year.** Complete with 'N/A' in case the corresponding cost is not predicted.

Generic descriptions are **forbidden**, e.g. plastic wares, kits, etc. You are 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) you will need 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.

— '*THE CHIEF RESEARCHER/SPOKE CENTRE NON-PROFIT FUNDS INVOLVED INTO THE INVESTIGATOR PROJECT PROPOSALS: MANDATORY REQUIREMENTS*'

Please describe the funds of the Chief Researcher and the Spoke Centre that will be used to carry out the Project Proposal, indicating the identification number/identification name of the funds (e.g. PRIN N° XXX, etc.), the full name of the charity in Italian or in the original language (e.g. Ministero della Salute, Fondazione XXX, etc.), and the amount of the funds allotted to the



## Guidelines for the Submission of the Proposal Application

### FC Investigator Grant - Call for Proposals 2020

Project Proposals according to the requirements reported in the 'FC Investigator Grant - Call for Proposals 2020'

#### Section 7 – BioEthics

In case **NEITHER human NOR animal experimentation** is involved in the Project Proposal, **please select BOTH options (on the contrary the Section is incomplete):**

*'The PI Applicant and the HI declare that the present Project Proposal **DOES NOT** include trials on patients and/or healthy volunteers, and/or **DOES NOT** involve the use of biological samples, genetic material or data collection, as well as whatever activity that involve the Clearance of the Ethical Committee'* under the sub-Section 'Human Experimentation'

**And** *'The PI Applicant and the HI declare that the present Project Proposal **DOES NOT** include Animal Experimentation (including biological samples), as well as **DOES NOT** include whatever activity that involve the Clearance of the Animal Research Ethical Committee'* under the sub-Section 'Animal Experimentation'

**In case of human and/or animal experimentation**, the required documents must be produced as reported in the 'FC Investigator Grant - Call for Proposals 2020'.

In case you select either *'The PI Applicant and the HI declare that the present Project Proposal **DOES** include trials on patients and/or healthy volunteers, and/or **DOES** involve the use of biological samples, genetic material or data collection, as well as whatever activity that involve the Clearance of the Ethical Committee'* **and/or** *'The PI Applicant and the HI declare that the present Project Proposal **DOES** include Animal Experimentation (including biological samples), as well as **DOES** include whatever activity that involve the Clearance of the Animal Research Ethical Committee'*, you also have to **mandatorily** complete the additional fields as indicated in the Proposal Application. Depending on the choices selected by the PI Applicant, you are required to upload **one file containing all the following documents: 1)** a copy of the **Clearance** of the Ethical Committee/Institutional Review Board. Clearances obtained **more than 6 months** before the launch date (August 5<sup>th</sup> 2020) of the present 2020 FC Call as well as Clearances **not presenting the mandatory requirements** described in the 'FC Investigator Grant - Call for Proposals 2020' **will NOT be accepted. 2)** Only in case the annexed Clearance of the Ethical Committee is related to other projects/studies similar or connected to the Project Proposal described in the Application Form, a specific **Amendment Document** produced by the Ethical Committee must be annexed to the Clearance. Amendments obtained **more than 6 months** before the launch date (August 5<sup>th</sup> 2020) of the present 2020 FC Call as well as Amendments **not presenting the mandatory requirements** described in the 'FC Investigator Grant - Call for Proposals 2020' **will NOT be accepted.**

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

Should the Clearance of the Ethical Committee not be available yet at the time of the submission of the Project Proposal Application, you are required to upload **one file containing** a copy of the **Clearance SUBMISSION** to the Ethical Committee. Clearance Submissions obtained **more than 6 months** before the launch date (August 5<sup>th</sup> 2020) of the present 2020 FC Call as well as Clearance



## Guidelines for the Submission of the Proposal Application

### FC Investigator Grant - Call for Proposals 2020

Submissions **not presenting the mandatory requirements** described in the 'FC Investigator Grant - Call for Proposals 2020' **will NOT be accepted**.

**Omitted upload** of the mandatory documents to the Proposal Application and/or **uploading documents not corresponding to the required ones** will result in **incomplete** Proposal Application, consequently the submission will **not** be allowed by the Portal and, after the fixed Deadline, the incomplete Proposal Application will be **automatically rejected**. The uploaded documents will be evaluated during the Administrative Check of Conformity of submitted Proposal Applications.

Proposal Applications involving **BOTH** human **and** animal experimentation are also allowed. In this case you have to select **BOTH** 'The PI Applicant and the HI declare that the present Project Proposal DOES include trials on patients and/or healthy volunteers, and/or DOES involve the use of biological samples, genetic material or data collection, as well as whatever activity that involve the Clearance of the Ethical Committee' **and** 'The PI Applicant and the HI declare that the present Project Proposal DOES include Animal Experimentation (including biological samples), as well as DOES include whatever activity that involve the Clearance of the Animal Research Ethical Committee' sub-Sections, and follow the above reported instructions for BOTH sub-Sections, overall **uploading 1 file containing all the required documents**.

In case you select 'The PI Applicant and the HI declare that the present Project Proposal DOES include Animal Experimentation (including biological samples), as well as DOES include whatever activity that involve the Clearance of the Animal Research Ethical Committee', a field appears to be **mandatorily** completed. 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 required by national and international rules. Please describe how the Three Rs have been implemented in the research plan (e.g. explain why the anticipated results and benefits of the proposed research justify the use of animals, and why methods avoiding the use of living animals cannot be used; provide details and justification on the number of animals proposed for the research plan; describe all actions that will be taken to avoid or minimize pain and distress; etc.).

## Section 8 – Signature

This is a mandatory Section.

Once **completed**, download here the 'General Info' Section. A PDF file will be generated (named 'Proposal Summary and Signature\_2020.pdf'), which is the 'FC Investigator Grant - Call for Proposals 2020 - Project Proposal Summary and Signature' page. The PDF document must then be printed, signed. The signed document must **mandatorily** be uploaded by using the function 'Upload' contained in the present 'Signature' Section.

**Omitted upload** of the mandatory documents to the Proposal Application and/or **uploading documents not corresponding to the required ones** will result in **incomplete** Proposal Application, consequently the submission will **not** be allowed by the Portal and, after the fixed Deadline, the incomplete Proposal Application will be **automatically rejected**. The uploaded documents will be evaluated during the Administrative Check of Conformity of submitted Proposal Applications.



## Guidelines for the Submission of the Proposal Application

### FC Investigator Grant - Call for Proposals 2020

#### Section – Submission

This is a mandatory Section.

Once you have checked the status of each Section of the Proposal Application, click on the 'Submit' button in this Section.

Please note that the 'Submit' button is not working until all the Sections of the Proposal Application are completed as required, and until all the required mandatory files are uploaded, as also indicated in the 'Application Check List' in the bottom of this Section.

Once you have pressed the 'Submit' button, the Proposal Application is formally closed by the FC Portal. You are going to receive an automatic confirmation email containing the PDF of your Proposal Application. **Always check your SPAM.**