

FONDAZIONE



## 2022 FALL Seed Grant - PITTHOP

# GUIDELINES for preparing and submitting the Online APPLICATION

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## General Instructions

The Application form is available on TETRA – The Telethon Project Management system portal at <https://projects.telethon.it>.

## Registration

To register, fill in and submit the Application, refer to the *TETRA Portal Instructions.pdf*  available on the Home page.

Please click on the **Register** button and enter your email address: to complete the registration process follow the online instructions. After the first registration, you can change your email address, if you wish to.

If you have questions concerning the Application, click the **Contact Us** link on the left-hand menu to send a message.

## Personal Details

Before proceeding to complete an Application form, please check the **Manage My Details** on the left-hand menu of the Home page and update your **Basic Information and Update CV** sections. All this information will automatically populate the relevant fields of your Applications.

In the **Manage My details-Update CV** section ensure to update the following items: **Education/Training, Positions, Personal Statement/Scientific Career**, as all these are required for the submission of the Application. For the **Publication section**, please go to My Research Output section on the left-hand menu and refer to the instruction in the *Tetra Portal Instruction.pdf* document.

**You will not be able to edit this information directly from the Application form;** but you can return to the *Manage My Details* page at any time, for updates.

## New Application

On the Home page, clicking My Application on the left menu, then clicking on the New Application box on the right, Applicants can access the page listing all the available Calls for Applications (*grant rounds*). Select within the round **2022 Fall Seed Grant Initiative** the relevant call for the disease you are interested in and click **Apply** to create a new Application form.

Four calls are open focusing on different diseases/syndromes; you may **apply and submit only one project** within the **Fall Seed Grant initiative**.

## Filling in the Application

The created Applications are listed in **My Applications** (link on the left-hand menu of the Home page).

Applicants should pay careful attention to the **Guidelines and instructions**, as an Application failing to meet the requirements will be rejected. An accurate Application will facilitate the review process.

Use **English** language only. For abbreviations and acronyms not universally known, spell out the term the first time it is used, with the appropriate abbreviation in parentheses; the abbreviation should then be used thereafter.

The text must be single-spaced, not exceeding the character number limitations specified (which include spaces).

*In the **My Applications** home page, at the right, the following button sections are shown:*

**Edit** - Please click on the 'Edit' button if you wish to make any changes to your Application.

**View/Print** - Please click on the 'View/Print' button to generate the Application form as a PDF file. A PDF of the Application can be downloaded at any time by clicking on this button.

**Validate** - To validate the Application click 'Validate'. In the "Validation" section within the Application form eventual errors will be listed.

**Submit** - The Application form cannot be submitted until it has been validated to ensure that all required fields have been entered, and the data meet the submission requirements. The 'Submit' button is active once the Application has been correctly validated.

**Delete** - If you are sure you wish to delete the Application form, please click on the 'Delete' button. Please note: once an Application has been deleted it cannot be recovered.

To navigate into the Application sections, at the top of the Application page, the following buttons are shown:

**Cancel, Previous, Next, Save, Save and Close.**

Clicking the **Cancel** button all modifications are not saved, and you are returned to My Application home page.

**Previous** and **Next** buttons allow you to navigate into the Application, the **Save** button saves all modifications done, remaining on the Application page you are working on, while clicking on **Save and Close** you can save, exit the Application page and return to the Application form afterwards as often as you like.

**Mandatory fields are indicated by red dots.** To successfully submit an Application, all mandatory fields must be completed. Any items missing before submission are listed in the **Validation** section.

When the Application is validated, the Lead Applicant may **Submit** the Application, which will have to be approved by the Organisation Approver for the final submission (see detailed guidelines at page 10). Before the Organisation Approval, the Application is displayed in My Applications home page in the status: Awaiting Signatory Approval. The Application status will change in Submitted only after the approval by the Organisation Approver.

*Upon Application Approval and Submission by the Organization Approver, a final Application number will be assigned to it. Please refer to this number in any future communications related to it.*

A submitted Application cannot be further modified; should you need to apply some amendments **prior to the Call deadline date** click the **Contact Us** on the left-hand menu.

**Figures** - The Application forms include special upload fields dedicated to figures at the end of the Preliminary Results (not mandatory) and Scientific Strategy sections.

Do not copy sections of already published papers.

All figures and legends must be placed together in one PDF document in A4 format.

In the Figures PDF, insert a footer with the name of the relevant section of the Application form followed by the indication "Figures" and the page number (for example a PDF uploaded into the Application section "Preliminary Results" should have the following footer: "Preliminary Results Figures - page 1 of 2", "Preliminary Results Figures - page 2 of 2", etc.)

Important notice: in the PDF version of the Application, all Figures files will be automatically collected and displayed at the end of the Application form PDF as an Appendix. Make sure that the appropriate figure numbers are correctly indicated in the text.

Please keep the PDF size below 25 MB. Use high resolution pictures only for photographs that require details; in this case a maximum resolution setting of 300 dpi (Photoshop: Image>Image Size>Resolution) for each photo is recommended.

If you include charts or drawings in your PDF, a resolution of 100 dpi for each picture can be used.

**Make sure all the figures are perfectly readable both on the screen and printed.**

## The Application Sections

- Project Overview
  - General Information
  - Overview
  - Type of Research
- Scientific Strategy
  - Background and Rationale
  - Research Plan
  - Cited Literature
- Administrative Section
  - Host Institution and Overall Information
  - Collaborations
  - Budget
  - Other Financial Support
  - Personal Data and CV
- Declaration
- Validation

## Project Overview

This section lists the general information, the overview and type of research.

### General Information

#### Project Title

Insert the title of the project. **Please be aware that the title has to be filled in (and saved) by November 8<sup>th</sup>, 2022. In case of title change you can modify it at any time before final submission.**

#### Project duration

Select the duration of the projects in months. The maximum duration of the present project allowed is 18 months.

#### Type of Applicant

Please select one of the following:

- New Applicant (never applied to any FT grant)
- Former Applicant (applied before to FT grants but never awarded)
- Former Grantee (applied before to FT grants and awarded)

#### Type of Application

Only *New Application* are allowed to this Call and this field is automatically prefilled.

#### Applicant's Details

General information about the Applicant are automatically collected from the Applicant's account

### Overview

**Please be aware that this section will be shared with the Patients' Association dealing with the disease for which you are submitting the Application**

Abstract (max 2,000 characters spaces included)

**MeSH terms** (max 5)

Indicate up to five MeSH terms appropriate and specific for the proposed research

(<http://www.nlm.nih.gov/mesh/meshhome.html>; <https://meshb.nlm.nih.gov/MeSHonDemand>).

**Added value and unmet need** (max 1,000 characters spaces included)

Explain how the proposed study will challenge current knowledge. Clearly state the current unmet need/s in the disease/syndrome that the proposed study will contribute to fulfil.

**Lay Summary – English** (max 250 words)

Summarize the project using an English lay language. This description is meant to serve for communication reasons and, as such, it may become public information. Therefore, do not include proprietary/confidential information.

Project Title – Italian

Insert the title of the project in Italian.

**Lay Summary – Italian** (max 250 words)

Summarize the project using an Italian lay language. This description is meant to serve for communication reasons and, as such, it may become public information. Therefore, do not include proprietary/confidential information.

## Type of Research

Please be aware that the following sections have to be filled in (and saved) by November 8<sup>th</sup>, 2022. In case of change you can modify them at any time before final submission.

### Disease Name

Write the disease name.

### Disease code

Fill in all available disease codes: the **disease OMIM number** as given by the Online Mendelian Inheritance in Man (<http://www.ncbi.nlm.nih.gov/sites/entrez?db=OMIM>), the **ICD-11 code** as given by the International Classification of Diseases (<https://icd.who.int/browse11/l-m/en>) and the **Orpha Number** as given by Orphanet (<https://www.orpha.net/consor/cgi-bin/index.php?lng=EN>).

### Research Type (select all that apply)

Select the appropriate Research Type.

### Research Step

Select the research step that best represents the proposed study:

- genetic studies
- studies of the mechanisms by which gene alterations cause the disease
- studies of therapeutic approaches in cellular models
- studies of therapeutic approaches in animal models
- therapeutic clinical trials
- diagnostic, observational and palliative clinical trials.

Should your project fall within more than one research step, select all you deem necessary to properly describe the study.

## Scientific Strategy

### Background and Rationale

#### **Background – Rationale – Objectives** (max 4,000 characters spaces included)

**Background:** Explain the impact of the problem addressed by the proposed project. Critically evaluate the existing knowledge and identify the specific gaps to be filled to progress in the field. **Rationale:** State the hypotheses to be tested and provide a realistic description of any expected scientific, technical and economic benefits. **Objectives:** Describe the overall objectives and what the specific research proposed is intended to accomplish.

#### **Preliminary Results** (max 4,000 characters spaces included)

Preliminary results **are not requested** for this call and therefore they are not mandatory.

Results are considered ‘preliminary’ only if unpublished. Published results, when deemed necessary, can be indexed as references.

#### **Background on Intellectual Property** (max 2,000 characters spaces included)

The Applicant is asked to indicate, to the best of her/his knowledge, any intellectual property where the Applicant is an inventor and any intellectual property owned by the Applicant or by a third party that would be necessary for the development of an approach to treat the disease/syndrome based on the results of the proposed project. For Applicant’s intellectual property, please indicate freedom to operate for such development.

#### **Preliminary Results Figures**

Refer to the “Figures” section (page 2 of this document) to create and upload the Figures’ PDF file (optional).

### Research Plan

#### **Specific Aims and Experimental plan** (max 4,000 characters spaces included)

Provide a list of the specific aims explaining the scientific rationale. For each specific aim, provide an experimental plan by describing the general experimental design. Should new methodologies be developed or employed, please provide an appropriate description and state their advantages over existing methods.

The experimental plan must be based on an appropriate and accurate statistical design. State the potential difficulties and limitations of the proposed procedures and discuss alternative approaches to overcome them.

If the study involves vertebrate animals, please refer to the “Telethon rules and policy on animal experimentation” section (page 9 of this document).

Explain the need for collaborations (if any) to achieve the scientific aims of the proposed project. Include an explicit description of the collaborative elements that are essential for the project to be carried out. Any collaboration must be listed in the specific form (see page 9 of this document).

Please note that Telethon also funds a Network of Genetic Biobanks (TNGB) whose purpose is to collect, preserve and offer to the scientific community, and to Telethon-funded investigators in particular, biological samples and related clinical data from individuals affected by genetic diseases. Refer to the online catalogue of the TNGB (<http://biobanknetwork.telethon.it/>), to identify potentially useful samples.

#### **Expected Outcomes and Future Development** (max 2,000 characters spaces included)

Describe the expected outcomes of the studies and the future project development (e.g., applications to grants/awards from corporations, foundations and government agencies; development of strategic partnerships).

#### **Timetable - GANNT Chart** (PDF to upload)

Please upload a GANNT chart describing the timeframe foreseen for the achievements of the Specific Aims.

#### **Experimental Plan Figures** (PDF to upload)

Refer to the “Figures” section (page 2 of this document) to create and upload the Figures’ PDF file.

## Cited Literature

(max 20,000 characters spaces included) - List all references. The list must include the name of all authors, year of publication, title, book or journal, volume number and page numbers. Concise references are not allowed.

## Administrative Section

### Host Institution and Overall Information

Provide all the information requested. Please write the address in Italian (this address will be used for any postal deliveries addressed to you).

#### **Organisation Approver Invitation**

**The Organisation Approver will have to be a person (Institution's Director or Responsible Official or Administrative Representative) who, representing the Organisation where the research project will be performed, will have the responsibility for the Application Approval and final Submission.**

Click on *Add Contact* to invite the Organisation Approver, who will be notified by mail.

If the Organisation Approver is not already available in the menu in the IntelliSense menu, add the new one clicking on **Add Person** and save it. Personal email accounts are not accepted, please make sure that the Organisation Approver's email is the **institutional account**.

Please confirm that you wish to include this Organisational Approver then click on **Send the Invitation**.

In the *Organisation Approver* box (in the *Budget and Host Institution* section) the Approver's details and the approval status are shown; in case of error the Approver can be deleted clicking on the **Remove** button.

The selected Organisation Approver will receive an email alerting that she/he has to take on the Application Approver role.

#### **Organisation Approver Confirmation and Guidelines**

The invited Organisation Approver will receive an email containing the link to access the TETRA platform. In case of first access to the platform, please follow the registration instruction on the webpage; if already registered, clicking on the link in the invitation email opens a page where the Approver can *Confirm the participation* or *Reject the participation*.

After logging, the Organisation Approver will have access, through the left hand menu *My Approval*, to the Application(s) for which he/she has been invited to approve. For each Application, clicking on the lens icon on the right, the Application page will be shown.

In the central box the *Signatories* section shows the Application approval status. When the Organisation Approver has accepted the invitation, *Confirmed participation YES* will be displayed.

While the Application is in preparation and not yet submitted by the Applicant, the *Signatory approval status* shows *Approval Not Yet Required*; when the Application will be complete and submitted by the Applicant the status will become *Approval Required*.

On the right hand menu the Approver can access the following buttons

#### **View/Print**

Please click on the 'View/Print' button to view and read the Application. If you agree with the content of the Application please approve below. The Application will then be submitted to Fondazione Telethon. If you do not agree with the content, please Reject Application to return the application to the applicant for amendment.

#### **Approve**

To approve the Application, the Approver will have to accept all the following clauses which will be shown in the Approval page:



**I, Organisation Approver, in the role of /on behalf of the Institution's Director or Responsible Official or Administrative Representative agree with the following statements:**

- The Organisation is eligible: it has to be either a public or a private Italian non-profit research Organisation.
- The Applicant is authorized to submit the Application on the Organisation's behalf.
- The Organisation undertakes to respect any and all conditions under the Call for Application and discharges Telethon from any liability related to any breach of said conditions by the Applicant and/or by the Organisation itself.
- The Organisation declares to have provided the Applicant and any researcher involved in the Application (Key Personnel or Collaborator) with the *Information to data subjects* attached to the Call for Application in Appendix 1. It also declares that the signatures/consents have been gathered to attest that any researcher involved in the Application has received *the Information to data subjects*.
- The Organisation declares to be aware that Fondazione Telethon can, at any time, request the above-mentioned documents (signed Information to data subjects and declaration of consent) and that the Organisation shall deliver any relevant document, according to Fondazione Telethon's request.
- The Organisation declares to have read the research Application pre-submitted on-line to Telethon by the Applicant and that it is complete and correct.
- The Organisation declares that it will provide the necessary facilities and personnel to carry out this research project. If the Applicant is not holder of a permanent position, the Organisation is aware that the salary of the Applicant cannot be requested within the Application as part of the Telethon Grant and that it needs to be provided through other means.
- If the Applicant has stated (see Section Budget and Host Institution - Host Institution - Box Applicant) to have a dual appointment in a foreign Institution, the Organisation acknowledges such statement and it declares that the double appointment does not conflict with the time commitment indicated by the Applicant within the Application for an effective conduct of the proposed research project.

Once approved, the Application will be automatically submitted; in the **My Application** Applicant Home page and in the **My Approval** Approver Home page, the status shown will be Submitted.

**Reject**

It is possible to explain the reasons for Rejection, which will be emailed back to the Applicant.

**Host Institution**

Provide all the information requested: the name of Host Institution and department and the relevant address.

**Applicant**

If the Applicant is not independent (i.e., is not the Head of the Laboratory) **an independence statement must be uploaded** in the dedicated box. Please note that the Independence Statement **must be provided and signed by the Head of the Lab** and should contain the name of the Applicant, the Application Title and a clear statement highlighting the Applicant's capability to carry out the proposed experiments in due time.

Please insert the **name and email address** of the Lab Head in the corresponding field.

NOTE: Applications submitted by non-independent applicants lacking the independency statement will be considered not compliant with the present Call and therefore will not be accepted.

**Should the applicant hold other appointments (including foreign appointment),** those have to be clearly indicated in "Any other Appointment" section.

**Facilities and Resources**

Provide all the information requested and list all the key facilities available for implementing the project.



## Human subjects

Indicate whether the study involves:

1. Human samples from a collaborator site or an external biobank
2. Human samples from individuals referred to the PI's Host Institution
3. Individuals enrolled in clinical trials
4. No human samples or subjects.

Should the grant be approved for funding, funds will not be provided until the pertinent Ethical documentation has been obtained. Please activate in due time all necessary procedures to obtain this approval in accordance with the relevant Italian laws (<https://www.aifa.gov.it/modulistica-sperimentazione-clinica>).

**Be aware that the relevant approval docs must be provided for grant activation.**

## Vertebrate animals

Specify whether or not experiments involving vertebrate animals are planned at any time during the proposed project.

### *Telethon rules and policy on animal experimentation*

Telethon recognizes that experiments on animals are often necessary in many areas of biomedical research. Proposals submitted for the evaluation **MUST** explain why the scientific objectives cannot be achieved without using animals.

Where experiments using animals are necessary, you are required to strictly adhere to the relevant Italian laws, rules and regulations (D.to L.vo 26/2014); moreover, **approval by your Institution Ethics Review Body is mandatory**. The ethical review process is a means of ensuring that any use of animals within lab animal facilities is carefully considered, adequately justified and carried out as humanely as possible, so that any adverse effects experienced by the animals are more than offset by the benefits that arise from the study.

Measures should be put in place to avoid unnecessary duplication of research/testing and fully implement the *Three Rs* (Reduction, Replacement and Refinement, from The Principles of Humane Experimental Technique, Russell and Burch, 1959), from the moment it is recognized that an animal experiment will take place, through the period where the animals are sourced and arrive at the facility, and up to the time they are either dead or have been re-homed. This includes optimizing standards of animal husbandry and care and effective training, supervision and management of all personnel involved. Microbiological status is important not only because there are welfare imperatives in minimizing the incidence of disease but also to avoid the risk that subclinical infections affect research results.

Provide a detailed description of the proposed use of the animals in the work outlined and identify the species, strains, ages, and sex of animals to be used in the proposed work. Provide information on the veterinary care of the animals involved.

Make sure that the fewest animals compatible with obtaining a valid scientific result are used. In this regard, in planning your experiments you should carefully estimate the number of animals needed. You should take into account the likely magnitude of the effect you will be studying and the frequency with which that effect will be achieved for given levels of statistical significance and power. It is unacceptable to base the number of animals to be used solely on the calculation of the number of experiments that can be carried out at any given time. It is also unacceptable to state that the numbers are based on "previous experience" without additional justification, or to answer the question on numbers of animals to be used by paraphrases such as "these numbers are chosen as the minimum necessary to achieve statistical significance". Too few animals is just as unsatisfactory as too many.

**Be aware that the relevant approval docs must be provided for grant activation.**

## Collaborations

The Applicant should list all the collaborators and the required information.

Once added, the collaborator/s will receive an Invitation email and, upon acceptance, they have to support the Application by sending a collaboration letter directly to the Applicant, written in English, which will be uploaded online by the Applicant (see also TETRA Portal Instructions.pdf document).

## Budget

Clicking on **Edit** the pop-up **Other Expenses** will be made available. Please note that the **Budget** section will appear on the left-hand menu and can be filled in properly only once you insert the Host Institution name. Budget allocated to each item does not need to be pre-specified in the application.

The amounts must be in Euro, please use whole numbers only. **Please, insert the whole budget amount request in the first-year section, leaving the second-year section empty.**

The expenses report is required at project closure and only project-related expenses will be approved.

## DIRECT COSTS

The following expenses **are allowed** as long as they will be instrumental to achieve the project goals:

- Materials, Supplies, Services
- Salaries
- Travel costs for collaborations and learning purposes or to attend Patient's Association Meetings.

## INDIRECT COSTS

**Overhead** - up to 5% of the **direct research cost per year**

The following expenses associated with the proposed research **are not allowed**:

- Equipments (including IT equipments)
- Full salaries for the Lead Applicant and for members of staff who already receive a regular wage
- Salaries, travel and/or housing related to sabbatical leaves
- Scientific Society memberships
- Organization of meetings and workshops
- Construction, alteration, maintenance, lab furnishing, rental of buildings or building spaces and utilities, fax and telephone costs
- Travel Costs (except those defined below)
- Publication costs

## Other Financial Support

It is important that the Applicant lists all the additional financial resources available in direct support of his/her research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, and/or institutional awards.

Indicate:

- Title of the Project
- Status: Current/Pending. It is compulsory to indicate the relative Period
- Gross amount (in Euro)
- Granting agency
- Brief description of the project (max 2,000 characters spaces included)
- Specify overlaps with this application, if any (max 1,000 characters spaces included)

## Personal Data and CV

Before proceeding to complete an Application form, please check the **Manage My Details** on the left-hand menu of the Home page and update your **Basic Information** and **Update CV** sections. All this information will automatically populate the relevant fields of your Applications. In the Manage **My details-Update CV** section ensure to update the following items: *Education/Training, Positions, Personal Statement/Scientific Career* as all

these are required for the submission of the Application. For the **Publication** section, please go to **My Research Output** section on the left-hand menu and refer to the instruction in the Tetra Portal Instruction.pdf document. You will not be able to edit this information directly from the Application form; but you can return to the **Manage My Details** page at any time, for updates.

**Additional Info:** please use this box to add any additional information that you may consider relevant; (e.g.; honors, membership...).

**Financial interest disclosure:** Fondazione Telethon requires that Applicants declare all possible financial conflicts of interest that might be perceived as relevant (such as, for example, collaborations or direct involvement in profit or no-profit entities). However, these financial interests will not invalidate the Application, nor do they automatically disqualify it from being evaluated.

**ID Researcher Platform and Personal ID:** Indicate one of the Researcher Platforms and provide your personal author ID. If you do not have one, we suggest you to generate an ORCID ID (<http://orcid.org/>).

**Select publications relevant to this proposal-** Click on “Add Publication” to select up to 5 peer-reviewed publications from the list of publications already recorded in the Applicant’s account. The selected publications will be automatically listed in the **Publications relevant to this proposal** section.

## Reviewers

**Suggested Reviewers** - The Applicant may suggest external referees - **not currently working in Italian Institutions** - expert in their own fields of research, who could competently review the Application. Coauthors in scientific publications and/or individuals who have been associated with the Applicant and/or his/her collaborators within the last 5 years should be avoided. Telethon reserves the right to choose external referees independently.

**Excluded Reviewers** - Should the Applicant prefer to exclude direct competitors from being chosen as reviewers, their names can be indicated here. If the indications were not clearly justified, Telethon will disregard any exclusion request.

## Notes

(max 5,000 characters) - Any personal comments, details or additional information the Applicant wishes to add to any specific sections of the Application can be inserted here. Please indicate which section you are referring to and the reasons for including more information.

## Declaration

The Applicant has to certify that the information included in the Application is accurate and complete, that he/she is entitled and/or authorized to disclose all the information provided within the Application and that he/she complies with Telethon’s terms and conditions, as reported in the “Specific Requirement” section of the Call.

Please duly fill in, sign and upload the Information about Data Processing (see Call Document - Appendix 1).

## Validation

This section will be automatically compiled, once the *Validate* action in the **My Application** Home Page has been done. Please note that the sections highlighted in green are those correctly filled in, while those in red have to be completed and key data are still missing.

## Application submission and Organisation Approval

The deadline for **online submission** is **November 28<sup>th</sup>, at 1:00 PM (CEST)**.

**Please make sure to have inserted (and saved) the title by November 8<sup>th</sup>, 2022.**

Please consider that clicking the **Submit** button, will generate a Pre-Submission Application which cannot be further modified.

The Pre-Submission will then automatically be notified to the Grant Organization Approver who, after having checked and accepted the *Host Institution Agreement Clauses* will approve or reject the proposal. If **approved**, the Application will be automatically submitted by the Organization Approver; if **rejected** (the reasons for rejecting may be written back to the Applicant) the Applicant will receive a notification in order to eventually amend the Application. The updated Pre-Submission will then need to be further approved.

**FOR THESE REASONS, PLEASE MAKE SURE TO PRESUBMIT YOUR PROPOSAL IN DUE TIME TO ALLOW THE APPROVAL PROCEDURE TO BE CARRIED OUT.**

**THE DEADLINE IS INTENDED FOR THE APPROVAL OF THE APPLICATION by the Organisation Approver.**

Before the Pre-Submission, download the PDF of your Application to check all the sections; in particular check that all uploaded images are included in the PDF and are clearly legible. Please note that the Applicant is liable for the contents and quality of the Application in its final version.

Fondazione Telethon holds the responsibility and authority in making the final decision on the Application's completeness and eligibility.

October 24<sup>th</sup>, 2022

FONDAZIONE TELETHON