FONDAZIONE Telethon

TELETHON FALL SEED GRANT 2024 – PITTHOP

GUIDELINES for preparing and submitting the Online Application

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* System Help available on the left-hand menu on the Tetra 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.

Please note that the System enables the creation of an account associated ONLY with one email. Therefore, **if you already have an account,** you are kindly requested **not to register with a different email, but to ask for a password change** (by clicking on *Forgot Password?* - at the bottom of the Login button). **If your email address is no longer valid, you are kindly asked to contact our IT Admin (projects@telethon.it) to update your email address.**

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 Application.

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 the **My Research Output** section on the left-hand menu and refer to the instructions in the *TETRA Portal Instructions.pdf* System Help .

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, and then clicking on the **New Application** box on the right, Applicants can access the page listing all the available Calls for Applications. Select within the round **Fall Seed Grant 2024** the relevant call for the disease you are interested in and click **Apply** to create a new Application form.

Six calls are open, focusing on different diseases/syndromes; you may **apply and submit** only **one project** within the **Fall Seed Grant 2024 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 item missing before submission is 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. In case of Partner invitation, also approval from the Partner's Organisation Approver is needed (see detailed guidelines on page 10).

Before the Organisation's Approval, the Application is displayed on the **My Applications** home page with the status: *Awaiting Signatory Approval*.

The Application status will change in Submitted only after the approval by the Organisation Approver and the Submission by the Lead Applicant.

Upon Application approval by the Organisation Approver and the submission by the Lead Applicant, 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 **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
    - Administrative details
        - Personal data and Curriculum Vitae
        - Host Institution
        - Budget and Personnel
        - Other Financial Support
    - Collaborations
    - Budget
    - Other Financial Support
    - Personal Data and CV
    - Reviewers
- Notes
- 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**. The title should be inserted (and saved) by October 11ᵗʰ, 2024**. **Please note that filling in these data by October 11th, 2024 is not mandatory**. In case of title change you can modify it at any time before final submission.

Number of centres

Indicate the number of centres participating in the study. **A maximum of 2 centres are allowed**.

Project duration

The duration of the present project is **24 months**.

Type of Applicant

Please select one of the following:

- New Applicant: is a researcher who has never applied to a Telethon Call; he/she may only submit a New Application.

- Former Applicant: is a researcher who has already applied to a Telethon Call but has never been funded; he/she may submit a New or a Revised Application.

Type of Application

For this call, **New Application and Revised Application** are allowed.

Revised applications are specifically those Applications submitted, **but not funded**, to the previous PCD call. Please, indicate the **previous application number** related to it and **previous role**. An Applicant submitting a Revised Application must fill in the **Cover Letter** form in the dedicated section.

Cover Letter (max 15,000 characters) - the Cover Letter must include a detailed reply to the critiques raised upon the Full Review

Telethon Review Report of the Previous Application – Attach the Telethon Review Report of the previous Application. If needed, contact the Telethon scientific staff (telethonscience@telethon.it).

Applicant's Details

General information about the Applicant is 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)

- Broad objectives and specific aims
- Background/Rationale
- Research design and methods
- Anticipated outcomes

Role and contribution of Partner(s) in the project - Multicentre Studies only (max 4,000 characters) - The Lead Applicant must describe the contribution of all Partners, explaining why each one is necessary to the success of the project, the complementary of approaches that justifies their participation and highlighting how the synergy among them will produce results greater than the sum of their individual contributions.

Coordination and Management - Multicentre Studies only (max 4,000 characters) - The Lead Applicant should specify how the multicentre project will be managed, indicating strategies aimed at:

- monitoring activities of all centres
- facilitating communication
- promoting exchange of ideas and methodological approach

- stimulating the analysis and the integration of results.

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

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 the appropriate Research Types.

Research Step

Select the research steps that best represents the proposed study:

- o genetic studies
- o studies on mechanisms
- o therapeutic approaches in vitro (studies of therapeutic approaches in in vitro models)
- o therapeutic approaches in vivo (studies of therapeutic approaches in animal models)
- o therapeutic clinical trials
- o diagnostic, observational and palliative clinical trials.

Scientific Strategy

Background and Rationale

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

Background: Clearly state the main hypothesis to be tested and the rationale of the proposed research. Critically evaluate the existing knowledge, illustrate the impact of the problem addressed by the proposed project and identify the specific gaps to be filled to progress in the field. *Rationale:* State the hypotheses to betested 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 4000 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 Applicantis 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 8,000 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 14).

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)

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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

Lead Applicant and Partners

This section is automatically generated once the Lead Applicant and Partner's Personal data are reported in the Administrative forms that follow.

Partner invitation

To enlist and invite any Partner, follow the path: Administrative Details/Lead Applicants & Partners/Partner Contact Details, and click on **Add Participant.** The Lead Applicant will then perform the following steps (if needed refer to the *TETRA Portal Instructions.pdf* System Help 🔴):

1. Add Grant Organisation – If the Partner's Organisation is not already available in the IntelliSence menu, add the new one and save it. The newly added Organisation will be displayed in the overview table.

2. Add Participant: follow the flow chart. Select your Partner *Grant Organisation******; Next >> *Select* the *Contact*, if available; if not, Next >> *Contact Search*: type the email address, click on *Search*, if available click on *Select*, if not available > *Add New Contact* – fill in the required fields and *Add Contact* > *Contact Notification*: the Invitation email is displayed, *Confirm* that you wish to send this message (check the box) and *Send the Invitation*.

*Note: due to technical issues, you cannot select a Partner belonging to your own organisation or institution. If this is the case, please register your Partner organisation as New Organisation, adding the department name (for instance Organisation, Department).

Partner confirmation

When a Partner is invited to participate in an Application, he/she will receive an email notification. The email will contain a link that, when clicked, will direct the invited Partner to a page where he/she can either **Accept** or **Decline** the invitation.

To make a decision, the invited Partner can access the related Application in the **My Co-Applications** left-hand menu and examine the Application's details. Once decided, he/she has to click **Confirm** or **Reject**, as appropriate.

Once the Partner has accepted the Invitation, the Partner will be able to register with the system and to edit the Application form.

From within the **Lead Applicant & Partner Organisation(s) table**, click on the **EDIT link beside the Organisation(s)** in order to access the **Personal Data and Curriculum Vitae** section, consisting of the following sections: *ID Research Platform, Personal Author ID, BIOSKETCH, Financial Interests Disclosure*. These Sections must **be filled in independently by both the Lead Applicant and the Partner(s).**

Administrative Details

Personal Data and Curriculum Vitae

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

Biosketch - Refer to the "Biosketch" template, compile it, and upload it as a .pdf in the *Biosketch* upload section. *A sample template will be also available to download in the header of the online application form.*

The **Biosketch** must not exceed 5 pages, including the table at the top of the first page, excluding relevant publications. Figures, tables, or graphics are not allowed.

Name – Fill in the name of the Applicant.

Position Title – Fill in the present position title of the Applicant.

Education/Training – Complete the education block. Begin with the baccalaureate or other initial professional education. Include postdoctoral, residency, and clinical fellowship training, as applicable, listing each separately. *For **each entry** provide:*

- *the name and location of the institution*
- *the degree received (if applicable)*
- *the month and year of end date (or expected end date).*
- *the field of study (for residency entries, the field of study should reflect the area of residency training)*

A. Personal Statement – Briefly describe why the Applicant is well-suited for his/her role(s) in the project. Relevant factors may include aspects of his/her training; previous experimental work on the specific topic or related topics; technical expertise; collaborators or scientific environment; and/or past performance in the field or in related fields, including ongoing and completed research projects from the past three years that the Applicant wants to draw attention to.

The Applicant may cite up to four publications or research products that highlight his/her experience and qualifications for the proposed project.

B. Positions, Scientific Appointments, and Honors – List in reverse chronological order all current positions and scientific appointments both domestic and foreign, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary).

List any relevant academic and professional honors.

C. Contributions to Science – Briefly describe up to five of the Applicant's most significant contributions to science. The description of each contribution should be no longer than one half page, including citations. These contributions do not have to be related to the project proposed in this Application.

For each contribution, the Applicant may cite up to four relevant publications or research products. If the Applicant is not the author of the product, indicate what his/her role or contribution was.

Note that while manuscripts that have not yet been accepted for publication may be mentioned as part of the contribution, only published papers can be cited to support each contribution.

Moreover, the Applicant may indicate the historical background that frames the scientific problem, the central finding(s), the influence of the finding(s) on the progress of science or the Application of those finding(s) to health or technology, his/her specific role in the described work.

D. Relevant Publications – Please list up to 5 personal publications relevant to the Application.

Financial interests Disclosure (max 1,000 characters) – Declare all possible financial conflicts of interest that may be perceived as relevant. Financial interests will not invalidate or automatically disqualify the Application from evaluation.

The Budget section will be visible on the left-hand menu and can be filled in only once you have completed the **Host Institution** section.

Host Institution

Provide all the information requested: the name of Host Institution and department and the relevant address. This will allow to access the Budget section (see below).

Organisation Approver

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.

In case of a Partner Invitation, also approval from the Partner's Organisation is needed.

To invite the Organisation Approver, follow these steps:

1. In the Organisation Approver section, click on *Add Participant* and follow the flow chart. Your Grant Organisation will be displayed; click on *Next* >> **Select the Contact**, if available; if not available, click on *Next* >> **Contact Search**: type the email address, click on *Search*, if available click on *Select*, if not available > **Add New Contact** – fill in the required fields and **Add Contact.** Click on **Contact Notification**, the Invitation email is displayed, confirm that you wish to send this message by checking the box and clicking on *Send*.

The *Organisation Approver* box displays the Approver's details and the approval status (Unconfirmed or Approved); in case of error the Approver can be removed by clicking on the **'Remove'** button.

The Organisation Approver will be notified that he/she has to take on the Application Approver role by an email containing the link to access the TETRA platform and all necessary clauses to approve the Application. In case of first access to the platform, the Approver should follow the registration instruction on the webpage; if already registered, clicking on the link in the invitation email, the Approver will reach a page where he/she can **Confirm the participation** or **Reject the participation.**

Organisation Approver - Approval Guidelines

After logging in, the Organisation Approver will have access, through the left-hand menu *My Co-Applications*, to the Application(s) for which he/she has been invited to approve. For each Application the reference number, the title, the name of Main Applicant are shown in a table; clicking on the lens icon on the right, the Application page will be shown.

In the central *Organisation Approver (Multi Centre Round)* box shows the Application approval status. When the Organisation Approver has accepted the invitation, *Confirmed participation YES* in green will be displayed.

On the right-hand menu, the Approver can access the following buttons:

- **'Contact Us' -** Please click on this button to get in touch with supporting team.
- **'View/Print'** - Please click on this button to view and read the Application.
- **'Approve'** - If you agree with the content of the Application click on the 'Approve' button. The Application can then be submitted to Fondazione Telethon.

- **'Reject'** - If you do not agree with the content, click on the 'Reject' button, to return the Application to the Lead Applicant or Partner for amendment.

Once the button **Approve** is clicked, in the *Submission approval status* in the central Organisation Approver (Multi Centre Round) box, *Approved* in green will be displayed.

Please note that **to confirm the role of Organisation Approver** and to have access to the Application for approval, **all the following clauses**, also highlighted in the invitation email, must be accepted:

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 that Fondazione Telethon will be appointed as data processor by the Organisation for the Direct Management of funds.
- The Organisation declares to have provided the Applicant and any researcher involved in the Application (Key Personnel or Collaborator) with the information attached to the Call for Application in Appendix 1. It also declares that the relevant consents have been gathered in order to be authorized to indicate the personal data of the Applicant and any other researcher in the Application.
- The Organisation declares to be aware that Fondazione Telethon can, at any time, request the above-mentioned documents (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 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 Investigator 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 (Section *Host Institution* - Box Applicant) to have a dual appointment in a foreign Institution, the Organisation acknowledges such statement and declares that the double appointment does not conflict with the time commitment indicated by the Investigator within the Application for an effective conduct of the proposed research project.

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:

- Human samples from a collaborator site or an external biobank
- Human samples from individuals referred to the PI's Host Institution
- Individuals enrolled in clinical trials
- 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 are just as unsatisfactory as too many.

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

Budget

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. A budget justification for each budget item is required in the "description" field and clearly related to the execution of the project. The amounts must be in Euro, please use whole numbers only. The expenses report is required at project closure and only project-related expenses will be approved.

The total budget detail is available by downloading the entire PDF application, clicking on "Details" on the left-hand menu, and then on the PDF icon.

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.
- Other expenses – any costs different from those listed above; these expenses will be approved by FT, eventually.

The Lead Applicant's Host Institution, upon the indication of the Lead Applicant, may allocate a maximum of 20% of the total budget to only one foreign collaborator (belonging to a foreign third-party institution), whose collaboration within the scope of the project should be previously evaluated and approved by the reviewers. If this is the case, the budget for the collaborator should be indicated in the "Other expenses" section. Eligible costs for the foreign collaborator are as follows:

- Materials, Supplies, Services
- Salaries

INDIRECT COSTS

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

The following expenses **are not allowed**:

- Equipment (including IT equipment)
- Full salaries for the Lead Applicant and for staff members already receiving 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 different from those indicated above
- Publication costs

Please carefully refer to section III of the "Regolamento di gestione del finanziamento" document for policies regarding costs eligibility.

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)

Please note that to leave the "Administrative Details" section and proceed with the next tab, you should click on the "Save and Close" button, and proceed with the next tab ("Collaborations") on the left-hand menu.

Collaborations

The Lead Applicant should list all the Collaborators that are **directly related to the project** and describe their contributions to the project in the dedicated field (by clicking on the Edit button). Collaborators are expected to have research experience and an established record of independent research. Furthermore, collaborations with international experts on Pitt-Hopkins syndrome are highly encouraged.

Once selected, Collaborators receive an *Invitation email* from the system and, upon acceptance, they **must support the Application by sending their collaboration letters in English to the Lead Applicant by email. The Lead Applicant is responsible for uploading these letters to the online Application** (see also *TETRA Portal Instructions.pdf* - System Help).

The Lead Applicant's Host Institution, upon the indication of the Lead Applicant, may allocate a maximum of 20% of the total budget to only one foreign collaborator (belonging to a foreign third-party institution), whose collaboration within the scope of the project should be previously evaluated and approved by the reviewers. If this is the case, the collaborator's letter must detail the work to be carried out as part of the collaboration and include information about the foreign collaborator's Host Institution. The Lead Applicant's Host Institution will be responsible for the budget transfer to the foreign collaborator.

Please see the "Budget" section for details.

Please carefully refer to section II of the "Regolamento di gestione del finanziamento" document for policies regarding collaborations with foreign collaborators and with profit entities.

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 toany 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) which can be downloaded within this section in the online Application.

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 must be completed and key data are still missing.

Application submission and Organisation Approval

The deadline for application submission is **November 28th, 2024 at 11:00 AM (CEST).**

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.

To generate a PDF file of the entire application, please click on "Details" on the left-hand menu and then on the PDF icon.

Please, note that the application's submission by the Lead Applicant is allowed only after the approval by the Organisation Approver. In case of a Partner Invitation, also approval from the Partner's Organisation is needed.

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

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

September 20th, 2024   **FONDAZIONE TELETHON ETS**