TELETHON-UILDM CLINICAL PROJECTS – CALL 2024

GUIDELINES FOR PREPARING AND SUBMITTING THE APPLICATION ONLINE

INDEX

General Instructions

The Application form is available on the **TETRA - Telethon Projects Managements system portal** at https://projects.telethon.it.

Applicants are identified as **Lead Applicant** (in charge of creating and submitting the Application) and **Partner(s)** (invited by the Lead Applicant). Please see page 7 for details on the **Partner invitation process**.

In Multicentre projects, only the Lead Applicant can fill in the scientific contents of the Application.

Please use **English** only. For abbreviations and acronyms not universally known, spell out the term the first time it is used, with the appropriate abbreviation in parentheses; thereafter, use the abbreviation consistently.

The text should be single-spaced and should not exceed the specified character or word limits. The maximum character count for each section includes spaces.

Applicants should carefully follow these *Guidelines for preparing and submitting the Application online*, as **an Application failing to meet the requirements will be rejected**. An accurate Application will facilitate the review process.

Registration

To register, fill in and submit the Application, refer to the *TETRA Portal Instructions.pdf* - System Help 📄 available on the Home page. After the first registration, you may change your email address if needed.

Please note that the System only allows one email address per account. If you already have an account, please **do not to register with a different email**. Instead, click on 'Forgot Password?' at the bottom of the Login button to request a password change. **If your email address is no longer valid, please contact our IT Admin at projects@telethon.it to update it.**

For any question regarding the Application, click the '*Contact Us'* link on the left-hand menu to send a message.

Starting and completing the Application

On the Home page under *My Application* in the left side menu, clicking the button *New Application*, Applicants can access the page listing all the available Calls for Applications. Click *Apply* to create a new Application form.

The created Application is listed in *My Applications* (link on the left-hand menu of the Home page).
In the *My Applications* home page, at the right, the following button sections are shown:

- *'Edit'* - Click on this button if you wish to make any changes to your Application.
- *'View/Print'* - Click on this button to generate the Application form as a PDF file. A PDF of the Application can be downloaded at any time.
- *'Validate'* - Click on this button to validate the Application. The *Validation* section within the Application form will also list any errors or missing items.
- *'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'* - Click on this button if you are sure you wish to delete the Application form. Please note that once an Application has been deleted, it cannot be recovered.

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

- *'Cancel'* - Clicking on this button all modifications are not saved and you are returned to *My Application* home page.
- *'Previous'* and '*Next'* - These buttons allow you to navigate into the Application.
- *'Save'* - This button saves all modifications done, remaining within the Application page you are working on.
- *'Save and Close'* - With this button you can save your work, exit the Application page, and return to the Application form afterwards as often as you like.

To successfully submit an application, you must **complete all mandatory fields indicated by red dots**. The *Validation* section will list any missing required items.

Once the Applicant(s) have validated the Application and the Organisation Approver(s) have approved it (see detailed guidelines on page 10), the Lead Applicant may *Submit* the Application. Before the **Organisation Approval**, the Application is displayed in *My Applications* home page in the status: *Awaiting Signatory Approval*. Once submitted, the Application status will change in *Submitted* and the Lead Applicants will receive a confirmation email.

Upon Application submission, a final **Application number** will be assigned to it. Please refer to this number in any future communications regarding your Application.

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

Application Forms

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Figures

We suggest the Applicant to limit the number of figures; too many unnecessary figures are not generally appreciated by the reviewers. Additionally, avoid copying sections from already published papers.

The Application form includes two sections dedicated to figure uploads, at the end of the Preliminary Results and of the Scientific Strategy sections.

- All figures and legends to be included in a section must be placed together into a single PDF document in A4 format.
- Within the Figures PDF, include a footer indicating the name of the relevant section of the Application form followed by the label "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", and so on.
- In the PDF version of the Application, all Figure files will be automatically collected and displayed at the end of the Application form PDF as an appendix. Please ensure that the appropriate figure numbers are correctly indicated in the text.
- Please keep the PDF size below 25 MB, to avoid overloading our servers. 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 legible both on monitor and in print.

General Information

Project Title (max 150 characters) - To have full access to the Application forms you must insert the title of your proposed project. You can change it at any time. Please do not use all capital letters.

Number of Centres - Indicate the number of centres participating in the study, including the Coordinator Centre.

Project duration - Indicate the duration of the project (min 12 - max 36 months).

Type of Applicant - Choose the appropriate option according to the following descriptions:

- *New Applicant* is a researcher who has never applied to a Telethon Call
- *Former Applicant* is a researcher who has already applied to a Telethon Call but has never been funded
- *Former Grantee* is a researcher who has already been funded by Telethon (any grant round) in the past.

Please note that in case of wrong classification Telethon will modify and correct *ex officio* the Type of Applicant without informing the Applicant.

Type of Application - Choose the appropriate option among the list: *New*, *Revised*.

Previous Application Number and *Previous Role* – Fill in the number of your last Application (for Former Applicants and Former Grantees only) and indicate your previous role by choosing the appropriate option from the listed menu (Principal Investigator – Single Center; Coordinator - Multicentre; Partner - Multicentre).

Lead Applicants submitting a Revised Application must fill in the Cover Letter form in the dedicated section.

Please note that the ALL Applications will be evaluated on a competitive basis, regardless of whether they are New or Revised projects.

Applicant's details – These details are automatically retrieved from the Applicant's Basic Details (Manage My Details section).

Overview

Abstract (max 2,000 characters) - Provide the following information:

- Broad objectives and specific aims

- Background/Rationale
- Research design and methods for achieving the stated objectives
- Anticipated output.

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.

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 complementarity of approaches that justifies their participation and highlighting how the synergy among them will produce results greater than the sum of their individual contributions.

Relevance to Telethon (max 1,000 characters) - Clearly specify how the goals of the project are in line with Fondazione Telethon's and UILDM's aim of improving the quality of life of people affected by muscular dystrophy. Proposals targeting other diseases, although of proven genetic origin, will not be processed for review.

Impact on Patients (max 1,000 characters) - Describe the proximity of the proposed studies to therapeutic development or any other potential impact on patients.

Type of Research - Write the disease name and all its available codes. If more than one disease is addressed, please separate names, OMIM numbers, ICD-11 codes and Orpha Numbers with semicolons. In particular:

- the **disease OMIM number** as given by the Online Mendelian Inheritance in Man (https://omim.org/about)
- the **ICD-11 code**, as given by the International Classification of Diseases (https://icd.who.int/en)
- the **Orpha Number**, as given by Orphanet (https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN&diseaseGroup=Search+a+disease)

MeSH terms (max 250 characters) - Indicate up to five MeSH terms appropriate and specific for the proposed research (http://www.nlm.nih.gov/mesh/meshhome.html).

Select the appropriate **Research Areas** - choose all that apply.

Lay Abstract - English (max 2,000 characters) - Summarize the project using an English lay language. This description is very important, it is meant to describe the project to lay people during the review process and will eventually serve for lay communication reasons after award and, as such, it may become public information. Therefore, do not include proprietary/confidential information.

Project Title - Italian (max 200 characters) - Insert the title of the project in Italian.

Lay Abstract - Italian (max 2,000 characters) - Summarize the project using an Italian lay language. This description is very important, it is meant to describe the project to lay people during the review process and will eventually serve for lay communication reasons after award and, as such, it may become public information. Therefore, do not include any proprietary or confidential information.

Please consider that the lay abstracts are fundamental parts of the Application and that this information will be available on Fondazione Telethon website in case of projects approved for funding. Fondazione Telethon may slightly modify both Lay Abstract texts for communication purposes.

Cover Letter

(max 15,000 characters)

The Cover Letter section is accessible only for **Revised Applications.**

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***Telethon Review Report of the Previous* Application** - Attach the Telethon Review Report of the previous Application in this section. If needed, contact the Telethon Research Office for assistance (telethonscience@telethon.it).

Cover Letter – The Cover Letter must include a detailed reply to the critiques.

If the Applicant is not the same as in the previous Application, the Cover Letter must explain the reason for the change.

Scientific Strategy

(max 20,000 characters)

Background - Explain the impact of the problem addressed by the proposed project. Critically evaluate the existing knowledge and identify the specific gaps 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 in the Application is intended to accomplish. The objectives of the study must be logical, feasible and innovative; they must represent a significant step forward beyond the current state of the art and include substantial original work.

Scientific Strategy Figures - Refer to the "Figures" section (page 3 of this document) to create and upload the figures' pdf file.

Preliminary Results

(max 10,000 characters)

Provide an account of preliminary unpublished studies performed in the Applicant's laboratory relevant to the proposed research. Preliminary data are an essential part of a research project Application, as they aid the assessment of the likelihood of success of the proposed project. For Multicentre Studies, preliminary results may include those of each participating Centre, if applicable.

Results are considered 'preliminary' only if unpublished.

Preliminary Results Figures - Refer to the "Figures" section (page 3 of this document) to create and upload the Figures' PDF file.

Clinical protocol

(max 30,000 characters)

Clearly define:

1) Type of study, i.e. observational or interventional, prospective or retrospective, open or randomised (if applicable), etc.

2) Study population, i.e. inclusion and exclusion criteria, number of patients based on power calculation (if applicable), etc.

3) Endpoints and clinical procedures/medical examinations planned. Indicate the time interval between examinations. State the potential difficulties and limitations of the proposed procedures and discuss alternative approaches to overcome them.

4) Study medication(s)/drug(s), i.e. dosage, administration, blinding, etc. (if applicable).

5) Safety; define potential adverse effects and how they will be monitored; describe potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness; indicate if psychological support to patients is available. Describe alternative treatments and procedures (where appropriate) that

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might be advantageous to the subjects. Provide information about the Data Safety Monitoring Board that will be set in place (if applicable).

6) Data management and statistical plan. Discuss how data will be collected, analysed and interpreted. Describe in detail the statistical methods to be employed.

The Clinical project must be completed with the Ethics Committee's approval in accordance with the laws of the Italian Ministero della Salute (https://www.aifa.gov.it/modulistica-sperimentazione-clinica).

NOTE: If a Clinical study has already been defined, the clinical protocol must be uploaded in this section. Otherwise, if the study is funded, the Telethon Scientific Office will request the protocol and related documents before releasing any funds dedicated to the clinical study.

Explain the need for collaboration (if any) to achieve the scientific aims of the proposed project. Describe how the idea of collaborating originated, the different approaches that each collaborator will bring to the overall study, and how the collaboration will be conducted. List any collaboration in the specific form (page 8 of this document). Additionally, provide a clear description of the collaborative elements that are essential for the project to be carried out.

Timetable (max 4,000 characters) - Provide a tentative sequence or timetable for the project. Please upload a GANNT chart (in PDF format) describing the timeframe foreseen for the development of the study.

Methods (max 8,000 characters) - Describe any new laboratory procedure or new methodology employed in the study and state the advantages over existing methods.

Clinical Protocol Figures/Documents/Gantt Chart - Refer to the "Figures" section (page 3 of this document) to create and upload the figures pdf file.

Cited literature

(max 20,000 characters)

List all references reported in the scientific content of the Application. The list must include the names of all authors, year of publication, title, book or journal, volume number and page numbers. **Avoid using concise references.**

Administrative Section

Lead Applicant and Partners

This section is automatically generated once the Lead Applicant and Partner 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 Researcher is invited to participate in an Application as Partner, he/she will receive an email notification. The email will contain a link that, when clicked, will direct the Researcher 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 Administrative Details sub-menu**, consisting of the following sections: *Personal Data and CV, Host Institution, Budget and Personnel, Other Financial Support.* These Sections must **be filled in independently by both the Lead Applicant and the Partner(s).**

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

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.

Once selected, Collaborators receive an *Invitation email* from the system and, upon acceptance, they **must support the Application by sending their collaboration lettersin 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 📄).

Please carefully refer to section 2 of the "**Regolamento di gestione del finanziamento**" for policies regarding **collaborations with profit entities**.

Administrative Details

The **Administrative Details** main page displays three Summary tables with information on: *Lead Applicant & Partner Organisation*, *Contact Details* and *Total Budget by Organisation* details.

In the case of Multicentre projects, the Lead Applicant invites the Partner(s) to join the Application (see *Partner invitation* section for details).

In the Lead Applicant & Partner Organisation section - Grant Organisation table - clicking on Edit (close the name of Applicant's Grant Organisation) the following sections will be shown for each Organisation:
- Personal Data and Curriculum Vitae
- Host Institution
- Budgets and Personnel
- Other Financial Support

In the *Personal Data and Curriculum Vitae* page, the Applicant can add her/his personal researcher ID, Biosketch, and Financial Interests Disclosure.

In the *Host Institution* page, the Applicant invites her/his Organisation Approver (see below for details) and fills in Host Institution information.

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In the **Budgets and Personnel** page, the Applicant inserts the costs to perform the project (see below for details).

In the **Other Financial Support,** the Applicant lists the financial resources available in direct support of her/his research endeavors (see below for 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 (**Errore. L'origine riferimento non è stata trovata.**doc), 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 10 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.

Host Institution

Organisation Approver Invitation and Confirmation

The Organisation Approver is a person (Institution's Director or Responsible Official or Administrative Representative) representing the Organisation where the research project will be performed, who has the responsibility to approve the Application.

To invite the Organisation Approver, follow these steps: 1. click on Administrative Details in the Lead Applicant & Partner Organisation section; 2. in the Grant Organisation table, click on Edit next to the name of the Applicant's Grant Organisation; 3. click on Host Institution. 4. 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

Provide all the information requested.

Applicant - If the Applicant is not the Chief of the Laboratory/Clinical Unit, the **Independence statement** must be completed (max 1,000 characters).

It is mandatory that any **foreign appointment** of the Applicant be clearly indicated in this 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 studies
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 documents must be provided for grant activation.

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Budgets and Personnel

Awards are contingent upon the availability of funds.

Telethon wishes to remind Applicants and their Institutions that funds are raised through many small individual donations. Telethon therefore bears a special responsibility to oversee an appropriate allocation of funds.

This call does not apply a budget cap to projects, also taking into account the possibility of multicentre Applications. The mean total budget for projects is typically between 180-300 K€, even for multicentre projects. Lead Applicants are invited to contact the Telethon Research Office (telethonscience@telethon.it) if the total budget planned exceeds 300 K€ or if they need to address any budget issues.

The *Budget* description must be accurate in all its parts, every item must be justified in the "Description/Justification" field and clearly related to the execution of the project. **Any omission, generic description, or miscalculation could result in project rejection**.

Please express all amounts in **Euro** using **whole numbers** only.

Personnel (including the Lead Applicant and Partner) are defined as, and should be limited to, key individuals whose contribution is deemed significant for the scientific development or execution of the project. Please note that **personnel to be recruited ("to be named") must be listed here and should be kept to a minimum**.

For clinical projects that entail the enrolment of a defined number of patients necessary for power calculation, it is advisable to identify start-up and other fixed costs separately from patient-related costs (variable costs). Fixed costs are incurred regardless of the number of subjects enrolled, while variable costs are strictly related to the expected number of patients. Full reimbursement of variable costs will be dependent on the actual number of enrolled subjects. The PI may contact the Telethon Research Office for assistance (telethonscience@telethon.it) if deemed necessary.

To **ADD** an Item, click on the corresponding button and fill in the required information.

Direct costs

The following expenses associated with the proposed research **are allowed**:

Coordination costs - Allowed only for the Lead Applicant of a Multicentre project (Coordinator) that includes at least 3 centres. The maximum amount that can be requested is 5,000 Euro per year, and it is intended to cover coordination administrative costs. These costs must be well specified.

Start-up costs
- Database set-up
- Ethics Committee fees
- Medical supplies
- Pharmacy set-up costs
- Printing of documents (i.e. CRF, informed consent)

Patient-related Costs - these costs may be related to "Materials, Supplies, Services" or to "Salaries" categories when they are closely dependent on the number of patients the Centre intends to include in the study. The total number of patients (of each centre in case of multicentre study) should also be reported here.

Equipment - up to a total of 20,000 Euro for minor essential equipment or a portion of a major piece of equipment. Each item must be clearly listed in the specific section and must be highly justified for the conduct of the proposed research.

IT equipment - the request for a personal computer should be clearly justified according to the research needs. The maximum amount allowed for IT equipment is 2,500 Euro.

Materials, Supplies, Services - materials and supplies must be **listed by category**: consumables, antibodies, reagents, etc. Sequencing, peptide synthesis, biological material from biobanks (e.g., for TNGB refer to the cost recovery list http://biobanknetwork.telethon.it/Pages/View/pricelist), etc. Please specify if any service will be provided by a company. Major cost items should be listed and properly justified.

Personnel and Salaries - For each person, the "role on the project" must be detailed. As an example, "molecular biologist performing mutational analysis" is appropriate, while "molecular biologist" is not sufficient. Consultants should be included only when their level of involvement meets the previous definition. **An inadequately described role in the project and/or a mismatch with the annual effort, as also expressed in the budget, may result in the reduction of the budget approved.**

Salaries for the project's staff holding a **temporary position** must be proportionate to the effort dedicated to the project (i.e. Full Time Equivalent). Although not encouraged by Telethon, salaries for "to be named" people may be requested. Indicate the type of contract that will be applied and the level of seniority required. The salary requested should correspond to the level of seniority and to the annual effort declared. The amount must refer to the total employee cost (gross amount plus employment taxes). If a salary is not required, enter 0 in the Salary field.

Travel costs - travel costs for meetings/congresses (not more than 3,000 Euro annually/centre). Costs allowed for travel are:
- transportation costs (train/plane/bus/taxi/car use, etc.)
- meals and lodging
- congress registration fee
- abstract submission fee.

Project-related travel costs must be carefully justified (destination, purpose, and travel frequency) and adequately described in the project plan. Costs allowed for travel are:
- transportation costs (train/plane/bus/taxi/car use, etc.)
- meals and lodging.

Other expenses (each item should be detailed and justified):
- Allowed items: publication costs, reprints, journal subscriptions, books, sample and animal shipments. If software is requested, specify the necessity for the proposed research. Please detail the cost by item.
- Allowed items if overheads are not requested: repairing and maintenance of instruments, stationery, computer consumables (toner, external memory devices), mailing. Please detail the cost by item.

The following expenses associated with the proposed research are **not allowed**:
- Salary for the Lead Applicant/Partner
- Full salaries 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
- Major basic equipment such as incubators, hoods, -80°C freezers.

Indirect costs

Overheads - should be indicated up to 10% of the **direct research cost per year**.

Note that the percentage should not be calculated based on the total budget requested, but on the subtotal of direct costs.

Other Financial Support

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

Click on the **'Add'** button and Indicate:

- Granting agency (max 250 characters)
- Title of the Project (max 250 characters)
- Status: Current/Pending. If *current*, it is compulsory to indicate the relative period (Start - End date)
- Gross amount, Currency
- Brief description (max 1,000 characters)
- If applicable, specify possible overlaps with the proposed project (max 500 characters).

Reviewers

Suggested Reviewers - External referees who are not currently affiliated with Italian institutions may be suggested by the Applicant to competently review the application.
It is recommended to avoid co-authors in scientific publications and individuals who have been associated with the Applicant(s) and/or their collaborators within the last 5 years. Telethon reserves the right to independently choose external referees.

Excluded Reviewers - If the Applicant wishes to **exclude direct competitors** from being selected as reviewers, they can provide their names here. Any exclusion request that is not clearly justified will be disregarded by Telethon.

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 must certify that the information included in the Application is accurate and complete.
- The Applicant certifies that he/she is entitled and/or authorized to disclose all information provided within the Application.
- The Applicant declares to have provided any Key Personnel/Collaborator involved in the Application with the information about Data processing attached to the Call for Application in Appendix 1. He/She also declares that the relevant consents have been gathered to be authorized to indicate the personal data of any other collaborator in the Application.

Please duly fill in, sign, and upload the Applicant's Information about Data Processing (see Call Document – Appendix 1) which can be downloaded within this section in the online Application.

Validation

Upon clicking the *Validate* button on the **My Application** Home Page, this section will be automatically generated. Green highlights indicate completed sections, while red highlights indicate sections with missing key data.

Application submission

The deadline for **online submission is April 10, 2024 at 1:00 pm Italian time**.

Versione gennaio 2024

Prior to submission, download the PDF of your Application to review all sections, ensuring that all uploaded images are included in the PDF and are clearly legible. Please note that the Lead Applicant is liable for the content and quality of the final version of the Application.

Once the Application is validated by the Applicant(s) and approved by the Organisation Approver(s) (see detailed guidelines above), the Lead Applicant can *Submit* it. Upon submission, the Application status will change to '*Submitted*' and the Lead Applicant will receive a confirmation email.

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

January 30, 2024   **FONDAZIONE TELETHON ETS**