FONDAZIONE

TELETHON RESEARCH PROJECTS - 2019

GUIDELINES FOR PREPARING AND SUBMITTING THE APPLICATION ONLINE

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** (invited by the Lead Applicant, only for two-center Applications). For the **Partner invitation process**, refer to page 9 of this document.

Registration

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

Users of Telethon's discontinued grant management systems (http://proposals.telethon.it or http://webtric.telethon.it) must enter the **same email address used in their previous account** to be automatically recognized by TETRA. In case you don't remember that email address, please send an email to soffice@telethon.it. **Avoid duplication of accounts**.

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 and update your ***Basic Information*** and ***CV*** under the ***Manage My Details*** link on the left hand menu of the Home page. All this information will automatically populate the relevant fields of your Applications.

In the CV form ensure to update the following items: *Employment*, *Research Experience*, *Scientific Career*, and *Publications*, as all these are required for the submission of the Application. **You will not be able to edit this information directly from the Application form**; but you can return to the *Manage My Details* session at any time, for updates.

New Application

On the Home page under **New Grant Application**, clicking the **link *"here"*** Applicants can access the page listing all the available Calls for Applications (*grant rounds*). Click ***Apply*** to create a new Application form.

Completing 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).

The Full Application comprises the Core Project and the Supplementary Contents, which can be completed in any order.

Only the Core Project will be made available to the Telethon Scientific Committee members for the Triage Phase (see the evaluation procedure explained in the Call for Applications).

- **Core Project:**
  - General information
  - Overview
  - Cover Letter (for Revised Application only)
  - Preliminary Results
  - Scientific Approach - NOTE: from within this section, the Detail*ed Experimental Plans* and the *Figures* will be made available to Reviewers only for the Full review phase, not in the Triage.
  - Cited Literature
- **Supplementary Contents:**
  - Previous Achievements (for former Grantees – New and Renewal Applications only)
  - Feasibility, timing, clinical protocols
  - Next Generation Sequencing and High Performance Computing (NGS and HPC)
  - Administrative details, for Lead Applicant and Partner
    - Personal data and CV
    - Collaborations
    - Budget and Personnel
    - Other Financial Support
    - Host Institution
  - Reviewers
  - Notes
  - Declaration

You can download a PDF of your Application at any time by clicking on the link ***View/Print*** at the Details page of your Application.

Clicking on ***Save and Close*** you can save and return to the Application form as often as you like.

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

When the Application is validated, the Lead Applicant may ***Submit*** the Application, which is then automatically identified with the final Application number and displayed as *Under Review*. The Applicants will receive a confirmation email.

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

We strongly encourage the Applicant to limit the number of figures; too many unnecessary figures are not generally appreciated by reviewers. Do not copy sections of already published papers.

The Application forms include special upload fields dedicated to figures at the end of the Preliminary Results and Scientific Approach sections.

- All figures and legends must be placed together in one PDF document in A4 format.
- References to Figures should not be included in the Core Project (see “Core Project” section).
- 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, 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.

Core Project

This is the only part of the Application that will be made available to Reviewers during the Triage Phase. Therefore, references to figures or to other information reported in the Supplementary Contents should not be included here.

General Information

Project Title (max 150 characters) - In order 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 **-** Only one- or two-center projects are admitted to the present Call for Applications.

NOTE: **Applicants can apply** to the present Call for Applications **with one research project only, irrespectively of the role (Lead Applicant or Partner)**.

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; 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.
- *Former Grantee* is a researcher who has already been funded by Telethon in the past; he/she may submit a New, a Revised or a Renewal Application.

Type of Application **-** Choose the appropriate option among the list: *New*, *Renewal*, *Revised-past Application was triaged*, *Revised-past Application underwent full review*.

Previous Application Number and ***Previous Role*** (where relevant, on the basis of the Type of Applicant and Application. Fill in the number of your previous Application and indicate your previous role by choosing the appropriate option from the listed menu (Principal Investigator – Single Center; Coordinator – Multicenter; Partner – Multicenter).

Applicants submitting a Revised Application must fill in the Cover Letter form in the dedicated section (see page 5).

Overview

Abstract (max 2,000 characters) – Organise the Abstract providing the following information:

- Broad objectives and specific aims
- Background/Rationale
- Research design and methods for achieving the stated objectives
- Anticipated output

Role and contribution of both participants to the project (max 1,000 characters) – ***accessible only for two-center projects*** **-** Describe the contribution of the Lead Applicant and the Partner, explain why they are both necessary for the success of the project, clarify the complementarity of approaches that justifies their participation and highlight how the synergy among them will produce greater results over the sum of individual contributions.

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

Impact on patients (max 1,000 characters) - describe how close to therapeutic development, or to any other potential impact on patients, the proposed studies are.

Write the **Disease Name** and provide all its 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-10 code** (if not available please indicate 'n.a.'), as given by the International Classification of Diseases (http://apps.who.int/classifications/icd10/browse/2010/en)
- the **Orpha Number** (if not available please indicate 'n.a.'), as given by Orphanet (http://www.orpha.net/orphacom/cahiers/docs/GB/List_of_rare_diseases_in_alphabetical_order.pdf);

If more than one disease is addressed, please separate names, OMIM numbers, ICD-10 codes and Orpha Numbers with semicolons.

Select the appropriate **Area(s) of Research** and the **Research Type**(s) – choose all that apply.

Select the **Research Step** that most truly represents the proposed activities:

1. Genetic studies to identify the genetic cause(s) of the disease
2. Studies of the mechanisms through which gene alterations cause the disease
3. Studies of therapeutic approaches in cellular models
4. Studies of therapeutic approaches in animal models
5. Therapeutic clinical trials
6. Diagnostic, observational and palliative clinical trials.

If your project spans more than one step, please choose the most relevant one; you may however select multiple steps if you deem it necessary to correctly describe your activities.

Cover Letter

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

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

Cover Letter (max 15,000 characters) - If the previous Application was excluded by Triage, the Cover Letter must highlight the relevant modifications made. If the previous Application underwent Full Review, the Cover Letter must include a detailed reply to the critiques.

If the Applicant is different from the previous Application, the reason must be provided in the Cover Letter.

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.

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.

Scientific Approach

Central Hypothesis, Background and Rationale (max 5,000 characters) - State the main hypothesis to be tested and 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 relevant field.

Overall Objectives (max 1,000 characters) - Describe the overall objectives that the proposed research is intended to accomplish.

Specific Aims - List the specific Aims (***Add*** button) of your project.

For each aim fill in the required information (fields):

- ***Title***
- ***Brief Description*** (max 1,000 characters per aim) - What is the question being asked? What is the general experimental design?
- ***Experimental Approach(es) and Expected Results*** (max 1,000 characters per aim) - How are you going to address this aim? What do you expect to find? What do you plan to do with those findings?
- ***Detailed Experimental Plan*** (max 3,000 characters/per aim) providing an extensive description of the experimental approaches.

Remember that the Detailed Experimental Plan will not be available to the Reviewers in the Triage Phase (Core project PDF); it will be visible only in the Full review phase (Full project PDF).

If **new methodologies** are developed or employed, state their advantages over existing methods and provide a description.

In general, planning of experiments should 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. Discuss how data will be analyzed and interpreted, and describe in detail the statistical methods to be employed.

If the study involves vertebrate animals, please refer to the "**Telethon rules and policy on animal experimentation**" section on page 13.

Explain the need for **collaborations** (if any) to achieve the scientific aims of the proposed project. Indicate how the idea of collaborating originated, the different approaches each collaborator will bring to the overall study, and how the collaboration will be conducted. Include an explicit description of the collaborative elements that are essential for the project to be carried out. Collaborators are expected to have research experience and must have an established record for independent research.

Any collaboration must be listed in the specific section (see page 10).

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

Significance and Innovation (max 2,000 characters) - Describe which important problem will be addressed in the proposed study and how the scientific knowledge will be advanced, if the aims of the project are achieved. The objectives of the study must represent a significant step forward beyond the current state of the art and include substantial original work. Indicate if the project employs novel concepts, approaches or methods and if it challenges existing paradigms in the field or develops new methodologies or technologies.

Relevance to Telethon (max 1,000 characters) - Clearly specify how the goals of the project fit with Fondazione Telethon's aims as declared in the mission statement (http://www.telethon.it/en/what-we-do/our-mission). Please note that **diseases of proven genetic origin represent our focus**; in the proposed projects **the specific link to the genetic diseases under study needs to be clearly expressed and it will be specifically assessed by the Reviewers.**

Experimental Plan Figures – Refer to the *Figures* section (page 3 of this document) to create and upload the figures' PDF file(s). **These figures will be available to Reviewers only in the Full review phase.**

Cited Literature (max 20,000 characters)

List all references. The list must include the name of all authors, year of publication, title, book or journal, volume number and page numbers. If a bibliographic management software is being used, the format of the journal "Developmental Dynamics" may be applied.

Concise references are not allowed.

The complete list of references will be visible to Reviewers at any evaluation phase.

Supplementary Contents

This section, together with the Core Project, will be made available to the Reviewers only for those Applications that proceed to the Full Review evaluation phase.

Previous Achievements - for former Grantees only, in case of a New or a Renewal Application

Provide the **Project number and title of the most recent Telethon grant** (max 350 characters); and briefly state the original goals and the scientific **achievements**, also listing the derived publications (max 3,000 characters). Unpublished results relevant to the current Application must be reported in the Preliminary Results section.

Feasibility, Timing, Clinical protocols

Feasibility, Pitfalls and Alternative Approaches (max 3,000 characters) – Please explain how the proposal is focused on achieving specific and feasible goals. In addition, state which pitfalls could arise during the research activity and which actions could be implemented to face them.

GANNT Chart - Please upload a GANNT chart (in PDF format) describing the timeframe foreseen for the different Specific Aims and their components.

Clinical protocol **-** If applicable, clearly define:

1. Study design, i.e. blind, double blind, open, etc.
2. Study population, i.e. planned number of patients, inclusion and exclusion criteria, etc.
3. Description of the clinical procedures/medical examinations planned and the time interval between them - State the potential difficulties and limitations of the proposed procedures and discuss alternative approaches to overcome them.
4. Study medication(s)/drug(s) (if applicable): dosage, administration, blinding, etc.

5. Safety: define adverse events 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 might be advantageous to the subjects. Provide information about the Data Safety Monitoring Board that will be set in place.
6. Data management and statistical plan; discuss how data will be collected, analysed and interpreted. Describe in detail the statistical methods to be employed.
7. Provide the timetable of the study.

A clinical project must be supported by an Ethics Committee's approval in accordance with the laws of the Italian *Ministero della Salute* (http://www.aifa.gov.it/content/sperimentazione-e-ricerca).

NOTE: If the clinical protocol is already available, it has to be **uploaded** in this section. Otherwise, if the study is funded, the protocol and related documents must be provided to Telethon in order for funds to be released.

In case of doubts, please contact the Telethon scientific staff (soffice@telethon.it) before submitting the final Application.

Next Generation Sequencing and High Performance Computing

Next Generation Sequencing [NGS]

If the Applicant intends to perform NGS experiments, he/she is asked to provide additional information and to fill in the pertinent fields.

Organism name (max 250 characters) - provide the name of the organism target of sequencing. For example: Homo sapiens, Mus musculus, Drosophila melanogaster, etc.

Estimated number of samples and/or runs – provide an estimated number of samples to be sequenced or the number of sequencing runs foreseen in the project.

Type of experiment – please describe the type of sequencing approach. Choose the appropriate option from the following list:

- Whole Genome Sequencing (WGS)
- Whole Exome Sequencing (WES)
- Transcriptome analysis
- Epigenomics
- Metagenomics

Or, if not present in the list, provide a brief description (e.g. amplicon or custom target sequencing, etc.) in the field dedicated to ***other types of experiments*** (max 250 characters).

NGS platform – provide the name of the NGS platform to be used. Choose the appropriate option from the list:

- Illumina (MiSeq, HiSeq, Genome Analyzer, etc.)
- Ion Torrent (PGM, Proton)
- Roche/454 (FLX+, Junior)
- SOLiD
- Third Generation/Single Molecule Sequencing

Or, if not present in the list, provide a brief description in ***other NGS platforms*** (max 250 characters).

High Performance Computing [HPC] bioinformatics resources at Cineca

Fondazione Telethon partners with Cineca to offer grantees the possibility to exploit the HPC tools for the analysis of NGS data or to perform computer simulations of biological systems. HPC resources available at Cineca can be found at: http://www.hpc.cineca.it/services.

If the Applicant intends to use HPC resources, he/she is asked to provide information as follows:

For what purpose the HPC resources are requested? (max 500 characters) - specify the type of analysis, e.g. NGS analysis, molecular dynamic simulations, systems biology, docking, etc.

Systems already in use to run the Application, if applicable (max 100 characters) - provide hardware specification of the system already in use.

Application of software packages (max 100 characters) - List each Application or software package, including post-processing packages that are planned to be used. For each package, specify if it is open, proprietary or licensed and the communication and library requirements.

Estimated requirements

To fill in the following fields, please use this estimation for an experimental example as reference: "For the identification of sequence variants in a 100X human exome, 200 core hours total (parallel on 6 cores) and up to 32GB of memory are required."

Estimated number of core hours (max 100 characters) - to fill in this field the Applicant might use the experimental example to calculate: (elapsed time of a single run)* (number of cores used in a single run) * (total number of runs).

Estimated requirements for a typical run (number of nodes/cores, memory) (max 100 characters) - to fill in this field, please use as a reference guide the experimental example mentioned above, in "Estimated requirements".

Estimated storage requirements (max 100 characters) - provide an estimation assuming that the requirements for the experimental example (see "Estimated requirements") are: ~50 GB as input and ~170 GB as output.

In addition, please indicate if you are able to independently run your code or if you require a ***specialist support for using, installing or configuring new software or Application packages***.

For further details on the Cineca bioinformatics environment send an email to hpc-bioinformatics@cineca.it.

Administrative Details

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

Two-center projects - From this page, the Lead Applicant invites the Partner to join the Application.

Partner invitation

To enlist and invite the Partner, the Lead Applicant will 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: because of technical issues you cannot select a Partner belonging to your same 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

If a Researcher is invited to participate in an Application as Partner, he/she will be informed by email. Clicking on the link in the invitation email opens a page where he/she can *Accept* or *Decline* this invitation.

In order to make a decision, the invited Partner may access the related Application in the ***My Co-Applications*** left-hand menu and examine the Application's details. Once decided, 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 have access to the Administrative Details sub-menu**, consisting of the following sections: *Personal Data and CV, Collaborations, Budget and Personnel, Other Financial Support, Host Institution.* These Sections have **to be completed separately by both the Lead Applicant and the Partner.**

Personal Data and Curriculum Vitae

Personal data - Employment, Research Experience, Scientific Career and Publications are automatically embedded from the Applicant's account.

Selected Publications - Click on *"Add Publication"* to select up to 20 peer-reviewed publications from the list of publications already recorded in the Applicant's account. All references relevant to the present Application need to be marked with an asterisk (*) in the Publications section of the Applicant's account.

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 you to generate an ORCID ID (http://orcid.org/).

Financial interests disclosure (max 1,000 characters) – Declare all possible financial conflicts of interest that might be perceived as relevant. Financial interests will not invalidate the Application, nor will they automatically disqualify it from being evaluated.

Collaborations

The Applicant should list all his/her national and/or international collaborations with the required information.

Actively involved collaborators are those directly related to the project and, as such, their contribution to the project must be described in the dedicated field. Once selected, the actively involved collaborators receive an Invitation email and, upon acceptance, they **must support the Application by sending collaboration letters, written in English, which have to be uploaded in the online Application by the Applicant**.

Budget and Personnel

For single-center Applications a maximum of 100,000 €/year is allowed.

For two-center Applications a total budget of 160,000 €/year is allowed; the Coordinator may ask for a maximum of 100,000 €/year.

The ***Budget*** description must be accurate in all its parts and 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 lead to the project's rejection**.

All amounts must be expressed in Euro; please use **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 studies**: Applicants are encouraged to contact the Telethon scientific staff for assistance in defining the budget (soffice@telethon.it).

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

Direct costs

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.

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

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 and must be included in the "Equipment" section.

Materials, Supplies, Services - materials and supplies must be **listed by category**: consumables, antibodies, reagents, etc. Services include items as animal housing (please provide the total number of animals and the cost per diem in the justification field), animal production (please specify if the service will be provided by a company), 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. 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 (postgraduates, PhD students, junior/senior post-docs, technicians) 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.

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
- congress registration fee
- abstract submission fee.

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.

Travel costs **-** travel costs for meetings/congresses (not more than 3,000 Euro annually/center).

Coordination costs (1,000 Euro annually) – Lead Applicant only

Indirect costs

Overheads - should be indicated up to 10% of the **direct research cost per year** and include for example: mailing, photocopying, office supplies, telephone expenses, equipment maintenance and repair, services such as radioactive waste and discarded solvent.

Please note that the percentage must not be calculated on the total budget requested but on the direct costs subtotal.

Other Financial Support

It is mandatory that each Applicant lists in this section all 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.

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).

Host Institution

Host Institution **-** Download the HI Agreement document, print it on the Institution's headed paper, fill in the information and have it signed by the Institution's Director or Responsible Official. The document

must be provided in PDF format and uploaded in the Application. The original document should be kept by the Applicant for possible future requests by the Telethon Office.

NOTE: Applications with an incomplete Host Institution Agreement will be considered not compliant with the present Call and therefore will not be accepted.

Applicant – Provide all the information requested.

If the Applicant is not the Chief of the Laboratory, 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 and in the "Host Institution Agreement" document.

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 – download, fill in and upload Attachment 1
2. Human samples from individuals referred to the PI's Host Institution - download, fill in and upload Attachment 2
3. Individuals enrolled in clinical trials - send all relevant documentation (Ethics Committee's Approval, Informed Consent Form and Patient Information leaflet) to the Telethon scientific staff (soffice@telethon.it) as soon as available
4. No human samples or subjects.

In cases **2** and **3**, if the grant is approved for funding, funds will not be provided until the pertinent Ethics Committees' Approval has been obtained. Please activate in due time all necessary procedures to obtain this approval in accordance with the relevant Italian laws (http://www.aifa.gov.it/content/modulistica-sperimentazione-clinica).

Telethon reserves the right to ask for a copy of all the relevant approval documentation.

Vertebrate animals - Specify whether or not activities 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 116/92); moreover, approval by your Institutional 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 R**s (**R**eduction, **R**eplacement and **R**efinement, 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.

Documentation must be made available upon request.

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. Co-authors in scientific publications and/or individuals who have been associated with the Applicant and/or his/her collaborators within the last 3 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 declare that the information included in the Application is accurate and complete and that he/she complies with Telethon's terms and conditions.

Submitting the Application

The deadline for **online submission is February 12th, 2019 at 1:00 p.m**.

Before the final 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 you are liable for the contents and quality of your Application in its final version.

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

After submitting the Application, a final Application number will be assigned to it. Please refer to this number in any future communications related to it.

December 12th, 2018 **FONDAZIONE TELETHON**