



DULBECCO TELETHON INSTITUTE TELETHON CAREER AWARD PROGRAM GUIDELINES FOR PREPARING AND SUBMITTING THE APPLICATION ONLINE - 2015

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ONLINE REGISTRATION

Application forms for Telethon Career Award must be completed online at the following URL:

<http://proposals.telethon.it>

If you are already a registered user, please enter your Login and Password.

If you have forgotten just your Password, please enter your Login name and click on "Forgot your Password": you will then receive an automatic email with your password.

If you have forgotten both the Login and Password, please contact the Telethon Scientific Office at soffice@telethon.it. **Please do not make multiple registrations with the same name.**

If you do not yet have a registered profile, click on "**Registration**" and fill in all the fields; you will then receive an email confirming your Login and assigned Password that will give you access to the Application forms. We encourage you to choose a Login that you can easily remember.

It is mandatory that the name inserted in the Registration Form corresponds to the Applicant's.

Please note that your Login and Password will remain the same for future Calls.

Once you have logged in, you can change your Password using the function "Change Password".

General instructions for completing the Application

Applicants should pay careful attention to the instructions, because an Application that fails to meet the requirements will be rejected. An accurate Application will facilitate the review process.

Use English language only. For terms 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).

Please remember to always click the "**Update Section**" button in order to save the data inserted in the forms. The Application must be submitted electronically once completed.

The Application forms are organized into sections, which can be completed in any order.

You do not need to complete your Application form in one session: remember to click on the "Update section" button to save your data before leaving the page.

You can download a PDF of your Application at any time by clicking on the link Download PDF at the bottom left of the page.

When you are completely satisfied with your proposal click on the "Update section" button, then on the "**Send Application**" button; a pop up window will prompt you to verify and confirm the following:

- *I have uploaded the Host Institution Agreement*
- *I have filled in the Declaration and Privacy Statement section*
- *I have downloaded the project PDF and verified that all the figures are clearly legible and readable both in print and on computer monitors.*

Once you confirm by pressing the button "Send", the Application will then be formally closed by the system. An automatic message will be sent to you acknowledging that you have completed your Application and you will receive its PDF version. Please note that you are liable for the contents and quality of your Application in its final version.

Once you have submitted your proposal, you can modify your Application at any time, prior to the deadline date, by clicking on the "**Edit Application**" button; remember to resubmit it again with the "**Submit Application**" button.

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


Formatting editor - instructions

A text-formatting editor is available only in the specific fields inside the online form where “click to edit” is shown.

The main editor’s functions are the following:

- copying and pasting text from Microsoft Word while retaining text formatting as well as tables
- easy formatting of entered text with standard intuitive buttons
- typing special characters including all Greek letters

The formatting editor allows the user to copy and paste text from Microsoft Word while retaining text formatting, with the following restrictions:

- a. You must use Microsoft Word to retain text formatting when copying and pasting: the use of other document editing software is not supported and could lead to errors in our online system
- b. In order to fully retain the original formatting in Word, use the button  [Paste from Word], to copy text into the online field
- c. Once text is pasted from Word, the default font will be automatically set to Arial with minimum size of 16 pt (corresponding to Arial 11 when printed). Please verify in the PDF output all text is clearly readable.

Hovering the mouse over the editor buttons will display a tooltip indicating their functions

Please note that the font Symbol (Greek characters) is not supported: you should use the “**Insert Special**

Character” button  in the formatting editor.

To verify that the correct text formatting has been applied check the **PDF of the Application** by clicking on the “Download PDF” button.

The Application PDF is always available while filling in the online Application; it is automatically generated every time the “Download PDF” button is clicked.

Figures

We strongly encourage the Applicant to limit the number of figures used; 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 each of the following sections**: *Scientific Strategy, Preliminary Results, Research Plan*.

- For each of the three sections, all figures and legends must be placed into one PDF document in A4 format.
- Insert the name of the relevant section followed by the indication “Figures” and the page number in the page footer (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 under a section named “Figures”. 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.

- To upload the “Figures” PDF file into the field, click the “Upload” button
- Click the “Sfogliala/Browse” button to select the PDF file from your computer
- Click the “Send File” button
- Click the “Close Window” button.

Application Forms

SCIENTIFIC CONTENTS

General Information

Project Title (max 250 chars) - **In order to have full access to the Application forms you must write the title of your proposed project. You can change it at any time, but only in this section.**

Please avoid using all capital letters.

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

- New Applicant is a researcher who has never applied to any Telethon Call; may only submit a New Application.
- Former Applicant is a researcher who has already applied to any type of Telethon Calls but has never been funded; may submit a New Application or a Revised Application.
- Former Grantee is a researcher who has already been funded by Telethon in the past; may submit a New Application or a Revised Application.

Applicants submitting a Revised Application must fill in the Cover Letter Form.

Scientific Report of the previous research project – This section has to be filled out only by Former Grantees. Indicate whether and when the Final Report has been submitted. If not already sent, the Final Report has to be enclosed in the proper section (“Scientific Report of the Previous Research Project”).

Overview

Abstract (max 2,000 characters) – The Applicant has to organise the Abstract into separate sections:

- Present position and prospect of career development at the proposed Host Institution
- Research project:
 - Broad objectives and specific aims
 - Background/Rationale
 - Research design and methods for achieving the stated objectives
 - Anticipated output.

MeSH terms (max 250 characters) - Indicate a maximum of five appropriate MeSH terms that represent the contents of the research (<http://www.nlm.nih.gov/mesh/meshhome.html>) and be as specific as possible.

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/about-us/mission>.

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 will be specifically assessed. Please refer to the Call for Applications for disease eligibility; projects focusing on disease that are **NOT ELIGIBLE** will not be processed for review.

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.

Type of Research - Write the **disease name**, the **OMIM** number as given by the Online Mendelian Inheritance in Man (<http://www.ncbi.nlm.nih.gov/sites/entrez?db=OMIM>) and the **ICD-10** code as given by the International Classification of Diseases (<http://apps.who.int/classifications/icd10/browse/2010/en>); if more than one disease is addressed, please separate names, OMIM numbers and ICD-10 codes with semicolons.

Indicate the **research type(s)** (all that apply).

Keeping in mind that Telethon’s mission consists primarily of moving research towards a cure for genetic diseases, please place your project on the ideal ladder of research that leads from disease to therapy, by choosing the **research step** that most 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 (which do not represent a step in the logical progression of the ladder and are listed here as step 6).

If your project falls within 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.

Lay Summary (max 2,000 characters) – This description is meant to serve as a succinct and accurate description of the proposed work when separated from the Application. If the Application is funded, this description, as is, will become public information. Therefore, do not include proprietary/confidential information.

The Applicant is asked to summarize the project (both in Italian and English) using a lay language, specifying the relevance to Telethon's mission and any progress envisaged towards a cure of the disease.

Please note that Telethon will reserve the option of editing the lay summary before posting it on the Telethon web site; this editing step is applied in order to make the content easily understandable by the lay public, while preserving its scientific accuracy.

Cover Letter

In the case of a Revised Application, please fill in the Cover Letter Form. Please specify the previously assigned Application number.

Telethon Review Summary - The Telethon Scientific Office will upload the Telethon Review Summary of the previous Application in this section.

Cover Letter (max 15,000 characters) - If the previous Application was excluded at the first stage, the Cover Letter must highlight relevant modifications made. If the previous Application underwent full review, the Cover Letter must include a detailed reply to the critiques.

Scientific Report of the previous Research Project (for Former Grantees only)

Please note that a final scientific report is required, if not already submitted, for the most recently completed Telethon research project.

Scientific Report - provide all the requested information, including the title of the completed project, the original abstract, as it appeared in the original Application, a summary of the project's achievements, the contribution of each partner (for multicentre projects only) and state any obstacle met during the research and/or any divergence from the original plan.

Provide a list of the resulting publications; if applicable, when citing papers that arise from your Telethon-funded research, also include the PMC reference number (**PMCID**) demonstrating the compliance with the [Telethon Open Access Policy](#).

Administrative report - please contact the Telethon Scientific Office (soffice@telethon.it) well ahead of the deadline for specific reporting requirements regarding your previous research project.

Scientific Strategy (max 15,000 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 PDF file with the figures, if any.

Preliminary results (max 15,000 chars)

Provide an account of preliminary studies pertinent to the proposed research performed so far. Preliminary data are an essential part of a research grant Application, as they often aid the assessment of the likelihood of success of the proposed project.

Preliminary Results Figures – Refer to the “Figures” section (page 3 of this document) to create and upload the figures’ PDF file.

Research Plan

Specific aims and Experimental plan (max 30,000 chars)

Provide a list of the specific aims and describe each one explaining its logic by answering the following questions:

- What is the question being asked?
- How are you going to address it?
- What do you expect to find?
- What will you do with those data?
- What are you going to do if it doesn’t work?

For each specific aim, provide an **experimental plan** by describing the general experimental design; 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 statistical methods to be employed.

If the study involves vertebrate animals, please refer to the **“Telethon rules and policy on vertebrate animals”** section on page 9.

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 of independent research. Any collaboration must be listed in the specific form (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, 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.org>), to identify potentially useful samples.

Timetable (max 4,000 chars)

Show the time-frames foreseen for the different Specific Aims and their components (Gantt chart or similar).

If a **Clinical protocol** is proposed, 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 experiences 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, analyzed and interpreted. Describe in detail statistical methods to be employed.
7. Provide a sequence or timetable for the project.

The Clinical project must be completed with the Ethics Committee's approval in accordance with the laws of the Italian *Ministero della Salute* (<http://www.agenziafarmaco.gov.it/it/content/normativa-di-riferimento-sperimentazione-clinica>).

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

If you are unsure, please contact the Telethon Scientific Office (soffice@telethon.it) before submitting the final Application.

Research Plan Figures – Refer to the “Figures” section (page 3 of this document) to create and upload the figures pdf file.

Cited Literature (max 16,000 characters)

List all references. The list must include the names 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.**

Curriculum Vitae and Present Host Institution

Personal data - Input the personal data. Please provide telephone, fax and email address of the Office/Laboratory.

Unique Researcher identifying system – Provide your personal author ID, e.g. ORCID (<http://orcid.org/>) or ResearcherID (<http://www.researcherid.com>), if you already have one, otherwise we strongly encourage you to generate one.

Financial interests disclosure (max 1,000 chars) - Telethon requires that Applicants highlight existing or possible financial conflicts of interest. Of note, these financial interests will not invalidate the Application, nor do they automatically disqualify it from being evaluated.

Education and training (max 4,000 chars) - Organise information specifying date, place, institution, type of degree/diploma, and research field.

Employment and research experience (max 4,000 chars) - Organise information specifying period (from/to), place, institution/organization, type of employment, and field of interest.

The Applicant is asked to specify any training activity performed during his/her career (i.e. scientific supervisor for research projects, teacher, etc.), listing names, roles and current positions of the trained persons.

Present Host Institution - Input all the requested information related to the present work place including your current position. Please confirm that you do not hold a permanent position in Italy.

Publications (max 8,000 chars) - Include the names of all authors, **year of publication, title, book or journal, volume number and page numbers.** If bibliographic management software is being used, the format of the journal “Developmental Dynamics” may be applied. Concise references are not allowed.

Scientific Achievements (max 8,000 chars)

Use this section to provide a detailed account of your previous scientific achievements and/or any other information that will help to establish your experience and competence.. This section is a crucial part of the Application and will be carefully evaluated.

Host Institution

Host Institution - Please indicate the Institution where the research will be carried out and name the authorized Representative who will be legally and financially responsible for the execution of activities related to the

proposed project. Print the Host Institution Agreement document on the Institution's headed paper and have it signed by the Institution's Director or Responsible Official. The document must then be scanned, saved in PDF format and uploaded into the Application.

Host Institution Scientific Director - Indicate the Host Institution's Scientific Director, the key research areas of the Institution and its website.

A specific **Host Institution Letter of Commitment**, signed by the Scientific Director of the Institute, explaining the Host Institution's interest in recruiting the Candidate and its commitment in developing his/her career must be uploaded by the Applicant after scanning the original, signed paper version.

The Letter of Commitment should explain:

- why the Host Institution is interested in the Applicant and how his/her presence will enhance the research being carried out in the institution;
- if there has been any prior contact with the Applicant (e.g. invited seminar of the Applicant at the Host Institution, or other) and if the Applicant has had the opportunity to meet with the Institute's researchers. The outcomes of these exchanges should also be described;
- what will be made available to the Applicant if he/she is awarded the position. The letter must be very detailed in listing the lab space assigned to the successful candidate, the type and number of major pieces of equipment and facilities which he/she will have access to (as also reported in the online form of the Application) and the support personnel (including number, qualifications and fraction of dedicated time) contributed by the Host Institution to his/her research. This aspect is critical to the evaluation process. General statements such as "the necessary lab space and equipment will be made available to the candidate" will be deemed inadequate and will result in the application not being considered for funding;
- what the Host Institution's commitment is towards the successful progressive integration of the Telethon Scientist into the academic establishment. In this respect, it must be noted that one of the aims of the Telethon Career Award is to disseminate excellent scientists into the Italian scientific environment. Therefore, the Host Institution is asked to provide a plan detailing the mechanisms through which the Candidate will be considered for and allowed to progress towards a permanent position at the conclusion of their Telethon career program.

NOTE: It is mandatory to upload the Host Institution Agreement and the Host Institution Letter of Commitment, otherwise the Application will not be accepted. The original letters should be kept by the Applicant for possible future requests by the Telethon Office.

Please provide a statement explaining **the Applicant's reasons to choose that particular Host Institution**. It should be clear from this statement how the chosen Institution provides added value for the Applicant's research career in terms of scientific environment, available facilities, collaborations and mentorship.

Indicate **office and laboratory space** dedicated to the Applicant, **major equipment, core facilities and services**. Please note that all information provided in this section must be in accordance with the information written in the Letter of Agreement/Commitment by the Host Institution.

Human subjects - Indicate whether the study involves:

8. Human samples from a collaborator site or an external biobank – fill in and upload attachment 1 (see "Required Documents")
9. Human samples from individuals referred to the PI's Host Institution – fill in and upload attachment 2 (see "Required Documents")
10. Individuals enrolled in clinical trials – send all relevant documentation (Ethics Committees' Approval, Informed Consent Form and Patient Information leaflet to the Telethon Scientific Office (soffice@telethon.it) as soon as available
11. No human samples or subjects.

In the cases **2** and **3**, if the grant is approved for funding, funds WILL NOT BE AWARDED until the pertinent Ethics Committee's 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.agenziafarmaco.gov.it/it/content/normativa-3>).

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 vertebrate animals

Fondazione Telethon recognizes that experiments on animals are often necessary in many areas of biomedical research but proposals submitted for the evaluation **MUST** state precisely what will happen to the animals and that:

- the scientific objectives cannot be achieved without using animals
- the model chosen is the most appropriate
- the source of the animals, the quality of care provided and the standards to which investigations will be conducted comply with the ethical values of the scientific community
- 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.

Where experiments using animals are necessary, you are required to strictly adhere to the relevant Italian laws, rules and regulations (*Decreto Legislativo 26/2014*); 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 Rs** (**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.

Documentation must be made available upon request.

Facilities and resources - List all the key facilities available for implementing the project.

References

Clearly indicate at least three people that can provide **letters of reference** and ask them to submit the letters to Telethon.

These signed and scanned letters of references must be sent by the referees by email to soffice@telethon.it by and **no later than July 16th, 2015**. These letters will be uploaded into the Application by the Telethon Scientific Office.

It is the Applicant's responsibility to make sure that the letters of reference are sent to the Scientific Office by the deadline. Applicants will be notified if the letters are missing from the Application.

ADMINISTRATIVE SECTION

Collaborations

List all the national and/or international collaborations specifying name, institution, whether the collaborator is related to the project and if so, the relative contribution.

Collaborations must be supported by collaboration letters written in English (please see the list of required documents below), which have to be uploaded into the online Application.

Other Financial Support

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

Indicate:

- Title of the Project (max 250 characters)
- Status: Current/Pending. It is compulsory to indicate the relative period
- Gross amount
- Granting agency (max 250 characters)
- Brief description (max 2,000 characters)
- If applicable, specify possible overlaps with the proposed project (max 500 characters)

Suggested Reviewers

The Applicant may suggest referees (**not currently working in Italian Institutions**) in his/her fields of research, who could competently review his/her Application. Do not list individuals who have been associated with yourself within the last 3 years.

Should you prefer to exclude **direct competitors**, please indicate their names in the **Notes**.

Fondazione Telethon reserves the right to choose referees independently.

Notes (max 8,000 chars)

Write here any personal comments, details or additional information you wish to add to any specific sections of the Application form. Please indicate which section you are referring to and the reasons for including more information.

Please indicate in this field possible direct competitors you wish not to be involved as reviewers.

Declaration and Privacy

The Applicant has to declare that the information included in the online Application is accurate and complete, and that he/she complies with Telethon's terms and conditions. The Applicant must also agree with the personal data treatment for Telethon's institutional purposes (Italian law 196/2003).

PLEASE NOTE: If the Declaration and Privacy Statement is not filled in by the Applicant, the Application will not be accepted.

Required documents to be uploaded

Clicking on the "**Required documents**" link on the left-hand menu bar online, the following documents can be downloaded: Host Institution Agreement, Human samples' Declarations (attachments 1 and 2).

Submitting the Application

The deadline for online submission is July 16th, 2015 - twelve o'clock (midday).

You can modify your Application until the deadline. Click on the "Send Application" button to submit your completed Application.

Before the final submission, we advise downloading the PDF of your Application to check all the sections; in particular verify that all uploaded images are included in the PDF and are clearly legible.

After sending the proposal, an automatic number will be assigned to it. Please refer to this number when requesting any further information or when sending hard copy documents.

Milan, April 28th, 2015

FONDAZIONE TELETHON