



FONDAZIONE TELETHON

TELETHON RESEARCH PROJECT PROPOSALS CALL FOR APPLICATIONS 2014

General

Fondazione Telethon funds a limited number of research projects (either single- or multicentre) in basic or clinical research aimed at curing genetic diseases.

Awards are contingent upon the availability of funds.

Eligibility criteria

Eligible diseases

This call is in support of research projects focusing on **diseases of proven genetic origin**.

Non-Eligible diseases

- Cancer
- Multiple sclerosis
- Acquired immunodeficiency
- Amyotrophic Lateral Sclerosis (ALS). [Note: funding opportunities for ALS are available through AriSLA (<http://www.arisla.org/>), a dedicated Foundation supported by Telethon]
- Multifactorial diseases

Please note:

- Studies focused on **monogenic or polygenic forms of multifactorial diseases** are **ELIGIBLE**
- Studies focused on the **identification of genetic risk factors** (e.g. SNPs or other predisposing variants) **for multifactorial diseases** are **NOT ELIGIBLE**.

In case of doubt, please contact the Telethon Scientific Office (soffice@telethon.it).

Eligible Host Institutions

Only research proposals submitted by Investigators working either in public or private **Italian non-profit research Institutions** are eligible.

Investigators belonging to Telethon Institutes (TIGEM, TIGET and DTI) can apply as Partner only (see below). In the case of TIGEM or TIGET Investigators, however, no budget can be requested for their participation in the project.

Eligible Applicants

In order to be eligible for funding, all Applicants (i.e.: the Principal Investigator – PI - of a single-centre project, or the Coordinator and Partners of a multicenter project) must prove to be:

- scientifically independent
- resident in Italy.

If the Applicant does not hold a permanent position, the Host Institution is required to declare that it will provide a salary for him/her for the duration of the entire project.

A dual appointment in a foreign Institution must be notified in the Application and is allowed only if it does not conflict with the effective conduct of the Telethon research project.

If the Application is successful but the scientific independence of the Applicant is not clearly evident to the Scientific Committee, the Committee will approve funding pending a statement by the Applicant's Director (e.g. head of laboratory/department or similar), stating that the results of the funded research will belong to the Investigator, in the form of adequate authorship in any ensuing publications (last name/corresponding author).

Telethon grantees may hold a maximum of one Telethon Research Project grant as PI/Coordinator plus two further grants as Partner.

The following scheme applies:

HOLDERS OF CURRENT TELETHON RESEARCH PROJECT GRANTS AS:			MAY APPLY AS:		
<i>PI/ Coordinator</i>		<i>Partner</i>	<i>PI/ Coordinator</i>		<i>Partner</i>
0	AND	0	1	AND	2
0	AND	0	0	AND	3
1	AND	0	0	AND	2
0	AND	1	1	AND	1
0	AND	1	0	AND	2
0	AND	2	1	AND	0
0	AND	2	0	AND	1
1	AND	1	0	AND	1
1	AND	2	CANNOT APPLY		

A PI who has been holder of a Telethon Exploratory Project 2012 can submit an Application for a Research Project that represents the progression of the exploratory study, within the present Call or the 2015 Call. This does not preclude him/her from applying within the same Call with another proposal, or holding another Telethon Research project, on a different topic.

The Investigator that is submitting – as Coordinator - an Application for a multicentre Research Project that represents the progression of the Telethon Program Project 2010 can also apply within the present Call with another proposal, or hold another Telethon Research project, on a different topic.

New Application or Renewal Application by a Former Grantee

The holder of a previous Telethon Research Project or Exploratory Project may submit a new proposal (or the renewal of a project in progress) when all of the following apply:

- the Scientific Report of the previous project has already been submitted or is included in this Application
- at least 30% of the last year's funds from the previous project has been spent.

Revised Application

When submitting a revised Application, the PI/Coordinator must complete the Cover Letter Form.

If the previous Application was excluded by triage, the Cover Letter Form must highlight the relevant modifications of the revised Application.

If the previous Application received written comments, the Cover Letter Form must also include a detailed reply to the critiques.

Research Project

The research project must contain all the scientific and administrative information required in the guidelines, which must be followed carefully.

Budget

The budget description must be accurate and every item must be justified. Telethon wishes to remind Applicants and their Institutions that funds are raised through many small individual donations. Telethon therefore recognises its own special responsibility to oversee an appropriate allocation of funds.

Application Details and Forms

Application forms can be found on the Telethon website (<http://proposals.telethon.it>) from **November 15, 2013**.

Applications must be prepared according to the specific guidelines ([Guidelines Grant Proposals 2014.pdf](#)) which are an integral part of this call.

- It is mandatory that the Application be approved by the Applicant(s)' Host Institution(s)
- Any external appointments (including appointments at a foreign Institution), must be clearly indicated in the Host Institution section and in the related "Host Institution Agreement" document (see "Additional Documents" below)
- All studies including biological material of human origin and/or human subjects must comply with the relevant Italian laws (see "Additional Documents" below)
- All studies employing vertebrate animals must comply with the relevant Italian laws and adhere to Telethon's policy (reported in the Guidelines).

The Application forms must be:

- written in English (this applies to all online forms and uploaded documents)
- submitted **by January 15, 2014 at twelve o'clock (midday)**
- completed by sending the Administrative Report (for Former Grantees of Telethon Research Projects or Exploratory Projects only) to the email address reportamministrativi@telethon.it **by January 15, 2014**.

The Coordinator of a multicentre project is responsible for both the accuracy and the completeness of all the information and documentation submitted to Fondazione Telethon (including that of the Partners' Centres).

Evaluation of Applications

Applications that are incomplete or do not comply with the rules stated in the Call for Application and in the related Guidelines will be rejected.

Procedure

All Telethon staff and reviewers involved in the evaluation of Applications are bound by strict confidentiality rules defined by Telethon.

All accepted Applications will be reviewed by the Telethon Scientific Committee (<http://www.telethon.it/sites/researchers/scientificcommittee/default.aspx>), an international panel of experts.

Grants will be awarded on a competitive basis.

Reviewers are asked to separately evaluate and score the following two aspects of each Application:

1. **Scientific merit** (is the proposed research excellent?) - the following parameters will be evaluated:
 - Significance
 - Originality of science
 - Appropriateness of design and methods
 - Preliminary results
 - Feasibility/safety
 - Link to the disease
2. **Proximity to cure** (how close to therapeutic development are the proposed studies?)

The two scores will contribute to the final score of the project with a weight of 90 and 10 percent, respectively. Telethon's Guidelines for reviewers are available online - [External Reviewer Guidelines.pdf](#) and [Internal Reviewer Guidelines.pdf](#)).

For **multicentre studies**, special emphasis will be dedicated to evaluating whether each Partner's contribution is necessary for the proposed project, and whether complementarity and synergy are a strength of the proposal.

A **triage** step may be adopted if a very high number of Applications is submitted. In the triage step the Scientific Committee will preliminarily rank all the Applications, without exception, on the basis of their scientific competitiveness. Applications that have received low scores will be triaged.

All other projects will undergo **complete review** and will be evaluated by the Scientific Committee and by appropriate international external referees. Revised Applications will be assigned to the reviewers who evaluated the previous version, if deemed appropriate, and depending on their availability. The Scientific Committee will also review the budget, which may be reduced with respect to the original request. In particular, care will be taken to avoid overlap funding of scientific activities already supported by other Applicant's grants, which must be accurately described in the appropriate section of the online Application.

All information regarding the **Peer Review Process** can be found on our website (<http://www.telethon.it/en/about-us/scientific-area/funding/peer-review-process>).

Timetable

The awarding of funds will be discussed during the plenary Scientific Review Meeting to be held on June 23-24, 2014.

Applicants will be notified of the evaluation results by email by the end of June 2014. PIs/Coordinators will be allowed to access their Telethon Review Summary online from July 31, 2014.

The Telethon administration will send an administrative letter to all grantees by August 7, 2014, describing all administrative steps required to activate the grant.

Awarding of research funds

Awarded funds must contribute towards the costs of the research for which the funds were awarded. Telethon requires that the funds be used effectively and economically, and that the expenses be essential for the research for which the funds were awarded.

No funds will be awarded by Fondazione Telethon to any Host Institution, until both parties have signed a specific agreement according to art. 3 of the D.P.R. 20th March 2003, n. 135.

Fondazione Telethon awards funds to the Host Institution's administrative body (External management).

Alternatively, Fondazione Telethon can manage the funds according to the grantee's indications (Direct management). This is a free service offered by Fondazione Telethon.

The Host Institution entrusted with the funds is strongly invited to strictly adhere, in the choice between the two forms of fund management listed above, to the indication expressed by the grantee.

Fondazione Telethon reserves the right to ask for a copy of the Statute of the Host Institution and of the latest available Balance Sheet as well as the acknowledgement of the legal status for all the Investigators working for non-profit private organisations; equally, it can request updates of the Statute and of the Balance Sheet in the case of Investigators working for non-profit organisations that have already benefited from Telethon funds in the past. Fondazione Telethon reserves the right to evaluate case by case the compatibility of the statutory guidelines of the private institutions with the aim of ensuring social benefit and of the financial reliability in order, if necessary, to dictate the conditions of the assignment/payment of the contribution.

Fondazione Telethon reserves the right to site visit the Host Institution before releasing any funds and at any time afterwards during the funded time period.

The release of funds is subject to the submission of all the necessary documentation as specified in the present Call for Applications and as requested in the administrative letter.

In case of two- or three-year awards, recipients will be expected to provide a detailed yearly administrative report to obtain subsequent yearly payments.

Twenty percent of the final year's budget will be reimbursed on completion of the project, upon submission of the final scientific report and approval of the administrative report, demonstrating that all granted funds have been spent.

Fondazione Telethon reserves the right to cancel payments whenever a conflict arises regarding the stipulations contained in this Call for Applications, or stipulations specifically made by Fondazione Telethon to the Investigator.

Publications and Final Scientific Reports

All grantees are required to:

- acknowledge Fondazione Telethon in all publications arising from the project by specifying the **project number** in the publication and send the relative PDF file by email to papers@telethon.it
- adhere to the Telethon **Open Access Policy** (<http://www.telethon.it/sites/default/files/policy-en-oa-july-13.pdf>)
- **Data submission to Public Databases.** Telethon supports the recommendations of the Global Alliance for sharing genomic and clinical data (http://rd-connect.eu/rdcon/files/130605_Global_Alliance_White_Paper.pdf). The Applicant is required to submit new genomic findings and clinical data to a public database, e.g. the European Genome-phenome Archive (EGA); further links to relevant databases can be obtained at Human Genome Variation Society (HGVS; <http://www.hgvs.org/dblist/dblist.html>). The Applicant should detail the database(s) to which he/she will submit the data and must confirm the status of database submission and provide the URL in his/her Final report
- submit a **Final Scientific Report** at the end of the project.

Development of Telethon-funded research results

As Telethon's goal is to translate research results into therapies and to make them available to patients, Fondazione Telethon recognises that this can be achieved through the activation of industrial collaborations and partnerships that may accomplish the development, manufacture and distribution of therapies, drugs, diagnostics and devices.

While acknowledging **full ownership of the intellectual property** rights arising from Telethon-funded research to its Grantees and/or Host Institutions, Fondazione

Telethon requests that they **undertake any necessary steps to ensure adequate valorisation** and exploitation of such research results.

Furthermore, all Telethon Grantees are required to ensure that the results of the Telethon-funded research projects are **duly protected by a patent Application** through direct collaboration with their Host Institutions' Technology Transfer Office, as this may **facilitate the full realization of the translational potential of such results**.

Telethon Grantees and/or their Host Institutions must promptly inform Fondazione Telethon via written communication of any new patent filings related to the Telethon funded research and of the related prosecution.

Telethon wishes to play a proactive role in this process and offers advice and assistance to Grantees and their Institutions through the Telethon Business Development Office, to which any request for further information regarding intellectual property issues and valorisation activities must be addressed (tto@telethon.it).

Safeguard of research integrity

Fondazione Telethon is fully committed to maintaining public trust in its research enterprise. Therefore, Applicants, Grantees and all research personnel (investigators, trainees, administrators and staff) related to any Telethon Application or Telethon project must strictly adhere to the highest standards of research integrity.

Research integrity includes:

- the use of honest and verifiable methods in proposing, performing, and reporting research results according to rules and regulations that are in force within the international scientific community
- the commonly accepted professional codes or norms.

Identification of research misconduct will result in Fondazione Telethon issuing a formal complaint to the PI's/Coordinator's/Partner's Host Institution, which should then respond according to its own policy for handling allegations of research misconduct.

Privacy of personal data

With the introduction of law 196/2003 regulating the protection of persons and other subjects with regard to the treatment of personal data, Fondazione Telethon, having their head office in Via dei Magazzini Generali 18/20, Rome, as holder of the information, are legally bound to obtain the consent of the PI/Coordinator/Partner regarding the use of the personal data included in the Application Form. See [Appendix 1](#) for further clarification.

ADDITIONAL DOCUMENTS

Please note that the following additional documents **MUST** be uploaded into the online Application or sent by email within the submission deadline **January 15, 2014, 12.00 (midday)**.

TO BE UPLOADED:

- Host Institution Agreement – Please download the form (***Host Institution Agreement.pdf***) and print it on your Host Institution headed paper before uploading the scanned version into the online proper Application section. If the project is carried out in a different Host Institution through a collaboration agreement, a PDF copy of the said agreement must be submitted.

NOTE: It is mandatory to upload the Host Institution Agreement, otherwise the Application will not be processed for review.

- If the study involves:

1. Human samples from a collaborator site or an external biobank – fill in and upload attachment 1 (**Attachment 1.pdf**)
2. Human samples from individuals referred to the PI's/Coordinator's/Partner's Host Institution – fill in and upload attachment 2 (**Attachment 2.pdf**)
3. Individuals enrolled in clinical trials - all relevant documentation (Ethics Committees' Approval, Informed Consent Form and Patients Information leaflet) has to be sent to Elena Bruno, Telethon Scientific Office – Piazza Cavour, 1 20121 Milano as soon as they are available (soffice@telethon.it).

Please note that in 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-di-riferimento-sperimentazione-clinica>).

You can find an example of an Informed Consent Form plus a Patient Information leaflet at <http://www.telethon.it/sites/default/files/consensoinformato.pdf>.

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

- Letters of collaboration (if any, **in English**, scanned and uploaded into the proper Application section).

TO BE SENT BY EMAIL:

In case of a **Renewal Application** or of a **New Application by a Former Grantee of a Telethon Research/Exploratory Project**, please download the form ***Dichiarazione_Spese_Sostenute.xls*** and, for Multicentre Coordinators only, the form ***Riepilogo_Dichiarazioni_Multicentri.xls***; fill it/them in according to the relevant instructions (***Istruzioni Rendiconti Amministrativi.pdf***). Finally, send the completed form(s) by email to reportamministrativi@telethon.it **by January 15, 2014.**

The Administrative report must prove **that at least 30% of the last year's funds has been spent.**

For former single-centre projects, the Administrative Report is not required if the funds are directly managed by Telethon (*Gestione Diretta*).

For former multicentre projects, the Coordinators are responsible for sending both their own administrative report and, under their own responsibility for accuracy and completeness, the summary of the Partner centre(s)' reports. Partners are not required to send their administrative report.

NOTE: If the Administrative Report is required, sending it by email within the deadline is mandatory, otherwise the Application will not be processed for review.

November 15, 2013

FONDAZIONE TELETHON

THE ATTACHED APPENDIX HAS BEEN LEFT IN ITS ORIGINAL ITALIAN AS ITS USE IN THIS CASE APPLIES ONLY TO ITALY

Appendix 1

**INFORMATIVA AI SENSI DELL'ARTICOLO 13 DEL D.LGS. 196/2003
("CODICE PRIVACY")**

La Fondazione Telethon con sede in Via dei Magazzini Generali 18/20, 00154 – Roma, titolare del trattamento (di seguito il "Titolare"), La informa che tratterà i dati da Lei forniti al fine di ufficializzare la Sua partecipazione al bando di ricerca Telethon, oltre che di consentire la valutazione del progetto di ricerca ivi presentato e, qualora finanziato, per la gestione amministrativa dello stesso.

Il Titolare la informa altresì della possibilità che, nell'ambito della comunicazione scientifica di Telethon avente ad oggetto il progetto di ricerca da Lei presentato, i Suoi dati, potranno essere diffusi attraverso: i) canali istituzionali: il sito internet www.telethon.it, le news letter on-line, il Telethon notizie ed ogni altro evento di comunicazione; ii) divulgazione scientifica: libro degli abstract, esposizione poster ecc; iii) direct marketing; iv) mezzi di comunicazione di massa.

Il Titolare tratterà i dati da Lei forniti in ottemperanza degli obblighi normativi, garantendo il pieno rispetto delle norme di legge, contrattuali e dei regolamenti. I dati personali saranno inseriti in un database di proprietà di Telethon e verranno trattati mediante strumenti manuali, informatici e telematici, con logiche e modalità volte a garantire la sicurezza e la riservatezza dei dati stessi. I dati trattati potranno essere comunicati a soggetti incaricati, interni o esterni a Telethon e/o ad altri soggetti terzi che saranno nominati Responsabili del trattamento dei dati nei limiti e nel rispetto delle finalità sopra specificate nonché nel rispetto di idonee procedure di sicurezza oltre che diffusi in coerenza a quanto sopra specificato. Il conferimento dei dati è facoltativo ma il rifiuto può comportare l'impossibilità delle finalità predette. In ogni momento Lei potrà rivolgersi al Titolare del trattamento nella persona del Direttore dell'Ufficio Scientifico presso la Fondazione Telethon, piazza Cavour 1 - 20121 Milano al fine di richiedere la cancellazione, la distruzione, l'aggiornamento, l'opposizione per motivi legittimi, la rettifica, l'accesso o per esercitare gli altri diritti di cui all'art. 7 del Codice Privacy, oppure per richiedere l'elenco aggiornato dei soggetti nominati Responsabili del trattamento.