General
Fondazione Telethon funds a limited number of research projects (either single or multicentre) in basic or clinical research aimed at finding therapies for 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, either monogenic or polygenic forms.

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 Fondazione Telethon]
- Multifactorial diseases; 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. 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.
If the Applicant does not hold a permanent position, the Host Institution should be aware that the salary of the Investigator cannot be requested in the Budget of the application.

A dual appointment in a foreign Institution must be notified both in the pertinent application form and in the Host Institution declaration 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 may recommend funding pending a statement by the Applicant’s Director (e.g. head of laboratory/department) 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, or three grants as Partner.**

The following scheme applies:

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<th>HOLDERS OF CURRENT TELETHON RESEARCH PROJECT GRANTS AS:</th>
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*Progression of a Telethon Exploratory Project*

A research proposal that is the progression of a Telethon Exploratory Project can be presented by its PI even if he/she is applying within the present Call with another proposal, or is holding another Telethon Research Project, on a different topic. This possibility is given for two years after the year of the Exploratory Project award; this year it applies to Exploratory Projects awarded in 2013 and 2014.

*New Application or Renewal Application by a former grantee*

The holder of a previous Telethon Research Project may submit a New or a Renewal application, only if the previous grant is completed or is in its last administrative year. In the latter case, the administrative report of the previous grant is not required at this stage.

*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 must highlight the relevant modifications of the Revised application. If the previous application underwent full review, the Cover Letter must also include a detailed reply to the critiques.

In case the Revised application is submitted by a PI/Coordinator different from the previous one, an explanation must be provided in the Cover Letter.

It is not uncommon for a project to be approved for funding at the second/third attempt. Fondazione Telethon believes, however, that resubmission of a revised application beyond the third attempt is not appropriate; therefore, **only up to two resubmissions of a previously unsuccessful application, not necessarily in consecutive years, will be accepted.**

**Research project**
The research project must contain all the scientific and administrative information required, as explained 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](http://proposals.telethon.it)) from **November 20th, 2015.**

Applications must be prepared according to the specific guidelines ([Guidelines Grant Proposals 2016.pdf](http://proposals.telethon.it)), 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 appointment at a foreign Institution, must be clearly indicated in the Host Institution section and in the related “Host Institution Agreement” document (see “Required Documents” in the Guidelines)
- All studies using biological material of human origin and/or involving human subjects must comply with the relevant Italian laws (see “Required Documents” in the Guidelines)
- 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 15th, 2016 at twelve o’clock (midday)

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).

**Access to the Cineca High Performance Computing infrastructure and services**

Fondazione Telethon and Cineca signed a collaboration agreement that will allow Telethon investigators to access Cineca’s high performance computing (HPC) infrastructure, data management
services and analysis tools for applications such as next generation sequencing (NGS) data analysis and molecular dynamics simulations. Available HPC resources and services are listed on the Cineca website: http://www.hpc.cineca.it/content/hpc-science.

Applicants requesting access to Cineca’s HPC tools and services are asked to fill in the dedicated form. Those applications that will be approved for funding by the Telethon Scientific Committee will be forwarded to Cineca for the validation of the request. The feedback from Cineca will be included in the Telethon Review Report.

THE EVALUATION

Applications that are incomplete, lack any of the mandatory documents or do not comply with the requirements stated in this Call for Applications and pertinent Guidelines will not be accepted.

Procedure

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

All accepted applications will be reviewed by the Telethon Scientific Committee (http://www.telethon.it/), 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. **Impact on patients** (how close to therapeutic development or to any other potential impact on patients 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 evident.

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/cosa-facciamo/il-metodo).

**Timetable**

Applicants whose application has been triaged will be notified by May 31st, 2016.

The awarding of funds will be discussed during the plenary Scientific Review Meeting to be held on June 20th-21st, 2016.

Applicants whose application underwent full review will be notified of the outcome by email by the end of June 2016; successful Applicants will be required to promptly provide a lay summary in both Italian and English.

All Applicants will be allowed to access their Telethon Review Report online from July 30th, 2016.

The Administrative Office will communicate all administrative details required to activate the grant to all Grantees by August 4th, 2016.

**TELETHON POLICIES AND RULES**


In addition, all Telethon Applicants and Grantees are bound to comply with the policies reported below.

**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 projects and 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 notification 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.

**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 for 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 grant 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 by the Administrative Office.

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, data sharing 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/la-ricerca/per-i-ricercatori/open-access)
- deposit data generated from research projects, including source data, in appropriate open or controlled access public databases
- submit a Final Scientific Report at the end of the project.

Development of Telethon-funded research results

Fondazione Telethon has the goal to translate research results into therapies available to patients and recognizes 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
all the steps required to ensure adequate promotion and seek opportunities of development of such research results.

Furthermore, all Telethon Grantees are required to ensure that the patentable results of 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.

Grantees and/or their Host Institutions must promptly inform Fondazione Telethon via written communication of any new patent filings and execution of agreements with for-profit entities related to Telethon’s funded research.

Upon request, Fondazione Telethon offers to Grantees and their Host Institutions advice and assistance regarding intellectual property issues and technology transfer activities through the Telethon Business Development Office (tto@telethon.it).

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 its head office in Via Varese 16b, Rome, as holder of the information, is 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.

November 20th, 2015

FONDAZIONE TELETHON
La Fondazione Telethon, con sede in Via Varese 16/b - 00185 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 che, qualora il progetto di ricerca da Lei presentato sia finanziato, i Suoi dati potranno essere diffusi per finalità di comunicazione di Telethon attraverso: i) i canali istituzionali (es. il sito internet www.telethon.it, le newsletter on-line, la rivista Telethon notizie ed ogni altro evento di comunicazione); ii) la divulgazione realizzata in occasione di eventi scientifici (es. la Convention Telethon), ovvero attraverso canali anche web di soggetti terzi quali, per esempio, enti non profit che hanno tra le loro finalità quella di informare i pazienti sulla ricerca in corso sulle loro malattie; 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 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.