



## **Telethon-UILDM request for Clinical Grant Proposals – Call 2011**

### **General**

Telethon will devote funds deriving from the UILDM fund-raising campaign towards **clinical research projects aimed at improving the quality of life of patients affected by genetic muscle and nerve disorders, and by spinal muscular atrophy (SMA). Being muscular dystrophies and SMA the main pathologies addressed by the UILDM, proposals on these diseases will be considered of highest relevance.**

Multicentre and multidisciplinary projects are encouraged.

Clinical research projects in cardiology, gastroenterology, internal medicine, neurology, orthopaedics, psychology and respiratory medicine, aimed at developing preventive, diagnostic, therapeutic and rehabilitative aspects of the above listed disorders are admitted.

In particular, the research goals are:

- Controlled clinical studies for the evaluation of pharmacological and rehabilitative therapies
- Cost-benefit analysis of models for assistance outside the hospital setting
- Creation of data banks and national networks
- Development and application of new techniques and technologies aimed at improving expectoration, speech, mobility and posture
- Development of new diagnostic and therapeutic techniques for cardiology and respiratory medicine settings
- Development of protocols for evaluating muscular force and endurance
- Evaluation and treatment of cognitive and neuropsychological complications
- Evaluation and treatment of orthodontic defects and disorders in swallowing and digestive transit
- Genetic, clinical and instrumental approaches in prenatal and neonatal diagnosis
- Models for training of medical and paramedical personnel and support for caregivers
- Nutritional evaluation in relation to patients' metabolic status and body type
- Optimisation of ventilatory support in the treatment of acute and chronic respiratory insufficiency
- Prevention and treatment of limb and spinal column deformities

### **Eligibility**

#### ***Eligible Host Institutions***

Only research projects submitted by either public or private **Italian nonprofit research Institutions** are eligible.

### **Eligible applicants**

In order to be eligible for funding, the Principal investigator/Coordinator/Partner who will conduct the research must prove to be:

- scientifically independent;
- resident in Italy.

If the investigator/Coordinator/Partner 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.

### **Please note that:**

1. current Telethon grant holders may submit a Telethon-UILDM Clinical Grant proposal;
2. the submission of a Telethon-UILDM Clinical Grant proposal does not preclude the possibility of participating in another Telethon call;
3. a researcher may be funded in a maximum of 4 Telethon-UILDM Clinical Grants (either as the Principal Investigator (PI)/Coordinator for 1 project and as a Partner in 3 Multicentre studies or as a Partner in 4 Multicentre studies). If this limit is exceeded, his/her participation in newly funded studies should be discussed and reconsidered with the Telethon Scientific/Administrative Offices that will address this issue on a case by case basis.

### **New application or renewal by a Former Grantee**

A previous holder of a Telethon-UILDM clinical grant may submit a new project (or the renewal of a project expired or in progress) when all of the following apply:

- the Scientific Report of the previous project has been submitted or will be included in the Application
- the Final Administrative report has already been sent or at least minimum of 30% of the last year's funds from the previous project has been spent.

### **Revised application**

When applying with a revised project (which was not awarded funding in a previous call) a cover letter must be attached highlighting modifications and including replies to the reviewers' comments, if any.

### **Methodological support**

In agreement with experts in medical statistics of the University of Milano – Bicocca, Telethon offers the Investigator assistance on methodological aspects related to clinical protocols.

The Investigator may make use of this service if he/she deems it necessary.

The Investigator wishing to explore the appropriateness of the design or the feasibility of a study that is still in a preliminary status may send a "**Pre-Submission inquiry**". The requests received will be evaluated together with members of the UILDM Scientific Committee, who may offer support to develop those projects deemed more relevant and worthwhile to pursue, according to the objectives of this call.

**In order to receive either of the above mentioned assistance, the Pre-Submission inquiry form (available on the Telethon web site <http://proposals.telethon.it>) must be filled out in Italian specifying the type of consultancy requested and submitted via email to the Telethon Scientific Office, no later than May 3, 2011. Requests submitted after this date will not be considered (although this has no bearing on the submission of the final version of the proposal).**

Written feedback by the consultants will be sent to the Investigator by June 6, 2011.

Please note that any support received does not guarantee the success of the application.

### **Clinical Research Project**

The research project must contain all the scientific and administrative information requested in the guidelines.

### **Budget**

The budget description must be accurate and every item must be justified. Applicants have to fill out only those items that apply to the project.

For clinical projects that foresee the enrolment of a number of patients determined on the basis of power calculation it is advisable to identify startup and other fixed costs separately from patient-related costs (variable costs). Fixed costs are incurrent regardless of the number of subjects enrolled, while variable costs are strictly related to the expected number of patients. Full reimbursement of variable costs will be dependent on the actual number of enrolled subjects.

The Principal Investigator/Coordinator may contact the Telethon Scientific Office for assistance ([soffice@telethon.it](mailto:soffice@telethon.it)).

Telethon wishes to remind Applicants that funds are raised through many small individual donations. Telethon recognizes its special responsibility to oversee a precise allocation of funds.

### **Application Details and Forms**

Application forms can be found on the Telethon website (<http://proposals.telethon.it>) from **March 31, 2011**.

**Applications must be prepared according to the specific guidelines ([Guidelines Telethon-UILDM Clinical Grants.pdf](#)), which are an integral part of this call.**

The **Pre-Submission Inquiry** has to be filled out in Italian and submitted via email to the Telethon Scientific Office, no later than May 3, 2011.

- It is mandatory that the Application be approved by the Principal Investigator's/Coordinator's/Partner's Host Institution (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).

The application forms must be:

- written in English (this applies to all online forms and uploaded documents except for the lay summary, which must be both in Italian and in English)
- submitted **by July 27, 2011 at twelve o'clock (midday)**
- completed by sending the Administrative Report (for Former Telethon-UILDM Research Project Grantees only) **to the email address [reportamministrativi@telethon.it](mailto:reportamministrativi@telethon.it) by July 27, 2011.**

**A HARD COPY OF THE ONLINE APPLICATION DOES NOT NEED TO BE SENT.**

## **Evaluation of applications**

***Applications that are incomplete or do not comply with the rules stated in the Call for application and pertinent guidelines will not be processed for evaluation.***

### **Procedure**

All complete applications will undergo a preliminary evaluation in order to verify the relevance of the project to the research goals defined in the call for proposals.

The projects identified as suitable will undergo peer review by the Telethon-UILDM Clinical Trial Evaluation Committee, an international panel of experts. The complete review process will include independent specialist opinions from appropriate international referees.

The awarding of grants will be assigned on a competitive basis according to the scientific value of the proposal and its clinical relevance. Muscular dystrophies and SMA will be considered of highest priority.

The Clinical Trial Evaluation Committee will also review the budget, which may be changed with respect to the original request.

### **Timetable**

The awarding of funds will be formally discussed during the plenary Scientific Review Meeting to be held by December 2011.

The Principal Investigator/Coordinators will be notified of the evaluation results by email first and will then be allowed to access their Telethon Review Summary online no later than December 22, 2011.

### **Awarding of research funds**

No funds will be awarded by the Comitato Telethon Fondazione Onlus to the University or Institution, until both parties have signed a specific agreement according to art. 3 of the D.P.R. 20<sup>th</sup> March 2003, n. 135.

The Comitato Telethon Fondazione Onlus only awards funds to:

- a) the Host Institution's administrative body (External management)
- b) the Fondazione Telethon, which will manage the funds according to the Principal Investigator's/Coordinator's indications (Direct management). This is a free service offered by the Fondazione Telethon.

The University or Institution entrusted with the funds commits itself to strictly adhere, in the choice between the two forms of fund management listed above, to the decision made by the Principal Investigator/Coordinator of the research grant, i.e. the funds granted by the Comitato Telethon Fondazione Onlus must be managed according to the indications of the Principal Investigator/Coordinator of the project.

The Comitato Telethon Fondazione Onlus reserves the right to ask for a copy of the Statute of the Host Institution and of the latest available Annual Statement 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 Annual Statement in the case of investigators working for non-profit organisations that have already benefited from Telethon funds in the past. The Comitato Telethon Fondazione Onlus 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 the case, to dictate the conditions of the assignment/payment of the contribution.

The Comitato Telethon Fondazione Onlus reserves the right to site visit the Centre 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.

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

### **Scientific reports and publications**

Funded Principal Investigators/Coordinators are required to:

- acknowledge the Comitato Telethon Fondazione Onlus in all publications arising from the project by specifying the project number in the publication
- adhere to the Telethon Open Access Policy (<http://www.telethon.it/en/about-us/scientific-area/open-access>);
- submit a Final Scientific Report at the end of the project (electronic format only)
- send a list of publications ensuing from the grant and a .pdf version reprint (publications relevant to the Telethon financed project only).

Documents have to be sent by email to: [ScientificReports@telethon.it](mailto:ScientificReports@telethon.it).

### **Telethon-funded research results**

Telethon grants are contributions made to enhance Italian medical scientific research aimed at curing genetic diseases. As Telethon's goal is to translate research results into therapies and to make them available to patients, the Comitato Telethon Fondazione Onlus recognizes that the exploitation of the intellectual property rights arising from Telethon-funded research is one of the ways of pursuing this goal and is a requisite for developing results to the patients' benefit.

Consequently, all Telethon Grantees are required to contribute to Telethon's mission by ensuring that the results of the Telethon-funded research projects will be duly protected and by promptly informing Telethon of any potential intellectual property arising from those projects.

The CTFO will acknowledge full ownership of such intellectual property rights to its Grantees, while requesting that they undertake any activity to ensure their adequate valorisation and exploitation.

Any information regarding intellectual property issues may be addressed to the Telethon Technology Transfer Office ([tto@telethon.it](mailto: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, the "Comitato Telethon Fondazione Onlus" and the "Fondazione Telethon", having their head office in Via Spinola 16, 00154 Rome, as "holder" of the information, are legally bound to obtain the consent of the "Applicant" 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 (See Guidelines online) or sent by email within the submission deadline **July 27, 2011, 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 specific 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 out and upload attachment 1 (**Attachment 1.pdf**)
  2. Human samples from individuals referred to the Principal Investigator's/ Coordinator's Host Institution – fill out and upload attachment 2 (**Attachment 2.pdf**)
  3. Individuals enrolled in clinical trials - all relevant documentation (Ethics Committees' approval, Informed Consent Form and Patient Information leaflet) has to be sent to Elena Bruno, Telethon Scientific Office – Via Nino Bixio, 30 20129 Milano as soon as available.  
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 (<https://oss-sper-clin.agenziafarmaco.it/normativa.htm>)  
You can find an example of an Informed Consent Form plus a Patient Information leaflet at <http://www.telethon.it/sites/default/files/cons-inf.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 specific Application section)

### TO BE SENT BY EMAIL:

**In the case of a Renewal Application or of a New Application by a Former Telethon-UILD Clinical Project Grantee, please download the form **Dichiarazione costi sostenuti.xls** and the form **Riepilogo centri.xls** (for Multicentre Coordinators only) and fill it/them out according to the instructions provided (**Istruzioni Rendiconti Amministrativi.pdf**). Finally, send the completed form(s) by email to the address [reportamministrativi@telethon.it](mailto:reportamministrativi@telethon.it) by **July 27, 2011**.  
The Administrative Report must prove **that a minimum of 30% of the last year's funds has been spent**.**

Coordinators of a former multicentre project are responsible for sending both their own administrative report and the summary of the Partners' centres reports.  
Applicants with the role of Partners are not required to send the administrative report of their own previously funded projects.  
For single-centre projects, the administrative report is not required if the funds are directly managed by Telethon (Gestione Diretta).

**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.**

The Coordinator of a Multicentre project is responsible for both the accuracy and the completeness of all the documentation submitted to the Comitato Telethon (including the Partner Centres).

### A HARD COPY OF THE ONLINE APPLICATION DOES NOT NEED TO BE SENT.

March 31, 2011

## COMITATO TELETHON FONDAZIONE ONLUS

**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'art. 13 del D. Lgs. 196/2003**

Con l'entrata in vigore della legge n. 196/2003, recante disposizioni per la tutela delle persone e di altri soggetti rispetto al trattamento dei dati personali, il "COMITATO TELETHON FONDAZIONE ONLUS", con sede in Roma Via Spinola 16, in qualità di "titolare" del trattamento, è tenuto a fornire alcune informazioni riguardanti l'utilizzo dei dati personali.

Tale legge disciplina il trattamento dei dati personali, ossia qualunque operazione o complesso di operazioni, svolti con o senza l'ausilio di mezzi elettronici o comunque automatizzati, concernenti la raccolta, la registrazione, l'organizzazione, la conservazione, l'elaborazione, la modificazione, la selezione, l'estrazione, il raffronto, l'utilizzo, l'interconnessione, il blocco, la comunicazione, la diffusione, la cancellazione e la distruzione di dati.

La legge prevede che l'"interessato" o "la persona presso la quale sono raccolti i dati personali" debbano essere previamente informati *oralmente* o per iscritto di quanto segue.

#### **Fonte dei dati personali**

I dati personali in possesso del "COMITATO TELETHON FONDAZIONE ONLUS", sono raccolti direttamente presso il *lavoratore* (da intendersi nell'accezione più ampia, ossia: il lavoratore dipendente, anche se prestatore di lavoro temporaneo o in rapporto di tirocinio, apprendistato e formazione e lavoro o qualunque soggetto che effettui prestazioni coordinate e continuative o, comunque, candidato all'instaurazione di un rapporto di lavoro).

Tutti i dati raccolti verranno ovviamente trattati con la riservatezza cui si ispira l'attività del "COMITATO TELETHON FONDAZIONE ONLUS" e nel rispetto della normativa vigente.

Il "COMITATO TELETHON FONDAZIONE ONLUS" si impegna a trattare i dati personali in modo lecito e secondo correttezza; a raccogliarli e registrarli per scopi determinati, espliciti e legittimi ed ad utilizzarli in altre operazioni del trattamento in termini non incompatibili con tali scopi.

Si impegna, altresì, a verificare che essi siano esatti, aggiornati, pertinenti, completi e non eccedenti rispetto alle finalità per le quali sono raccolti o successivamente trattati ed a conservarli in una forma che consenta l'identificazione dell'interessato per un periodo di tempo non superiore a quello necessario agli scopi per i quali essi sono stati raccolti o successivamente trattati.

#### **Dati "sensibili"**

Le precisiamo che di norma il "COMITATO TELETHON FONDAZIONE ONLUS" non richiede l'indicazione di dati definiti dalla Legge 196/2003 come "sensibili".

L'art. 4 lett. D) della Legge 196/2003 definisce dati "sensibili" i dati personali idonei a rivelare l'origine razziale ed etnica, le convinzioni religiose, filosofiche o di altro genere, le opinioni politiche, l'adesione a partiti, sindacati, associazioni od organizzazioni a carattere religioso, filosofico, politico o sindacale, nonché i dati personali idonei a rivelare lo stato di salute e la vita sessuale.

Tali dati possono essere oggetto di trattamento solo con il consenso scritto dell'interessato e previa autorizzazione del Garante.

Può accadere, tuttavia, che, solo ed esclusivamente in relazione alle "Finalità del trattamento cui sono destinati i dati", la "COMITATO TELETHON FONDAZIONE ONLUS" venga in possesso di dati che la legge definisce come "sensibili", perché da essi possono desumersi l'eventuale appartenenza del *lavoratore* a dette associazioni o informazioni sul suo stato di salute.

Per il loro trattamento la legge richiede una specifica manifestazione di consenso, che troverà nell'allegato modulo.

#### **Finalità del trattamento cui sono destinati i dati**

I dati personali del *lavoratore* saranno trattati nell'ambito della normale attività del "COMITATO TELETHON FONDAZIONE ONLUS" per adempiere a specifici obblighi o per eseguire specifici compiti previsti da leggi, da regolamenti o da contratti collettivi anche aziendali, ovvero dalla normativa comunitaria, in particolare per rispettare la normativa in materia di previdenza e assistenza anche integrativa, o in materia di igiene e sicurezza del lavoro, nonché in materia fiscale, di tutela della salute,

dell'ordine e della sicurezza pubblica, per tenere la contabilità o per la corresponsione di stipendi, assegni, premi, altri emolumenti, liberalità o benefici accessori.

Tale trattamento è effettuato con riferimento alle sole categorie di dati, di interessati e di destinatari della comunicazione e della diffusione strettamente collegate a tali adempimenti, conservando inoltre i dati non oltre il periodo necessario all'adempimento medesimo.

I dati personali possono essere comunicati, e ove necessario diffusi, nei limiti strettamente pertinenti agli obblighi, ai compiti o alle finalità predette, a soggetti pubblici o privati, ivi compresi organismi sanitari, casse e fondi di previdenza e assistenza sanitaria integrativa anche aziendale, agenzie di intermediazione, associazioni di datori di lavoro, liberi professionisti, società esterne titolari di un autonomo trattamento di dati e familiari dell'interessato.

Il conferimento dei dati personali necessari a tali finalità non è obbligatorio, ma il rifiuto di fornirli può comportare, in relazione alla peculiarità del rapporto tra il dato e la finalità per cui lo stesso è richiesto - l'impossibilità del "COMITATO TELETHON FONDAZIONE ONLUS" ad adempiere a specifici obblighi od adempimenti imposti dalla legge (per es obblighi contabili, retributivi, previdenziali, assistenziali e fiscali).

#### **Modalità di trattamento dei dati**

In relazione alle indicate finalità, il trattamento dei dati personali avviene mediante strumenti manuali, informatici e telematici con logiche strettamente correlate alle finalità stesse e, comunque, in modo da garantire la sicurezza e la riservatezza dei dati stessi.

In ogni caso la protezione dei dati personali è assicurata dal "COMITATO TELETHON FONDAZIONE ONLUS".

#### **Categorie di soggetti ai quali i dati possono essere comunicati**

Per lo svolgimento della sua attività il "COMITATO TELETHON FONDAZIONE ONLUS" comunica i dati agli incaricati studi di consulenza sul lavoro che si occupano della gestione delle paghe e contributi, espressamente nominati Responsabili del Trattamento, e ove necessario diffonde i dati personali dei *lavoratori*, nei limiti strettamente pertinenti agli obblighi, ai compiti o alle finalità indicate nelle "**Finalità del trattamento cui sono destinati i dati**", a soggetti pubblici o privati, ivi compresi organismi sanitari, casse e fondi di previdenza e assistenza sanitaria integrativa anche aziendale, agenzie di intermediazione, associazioni di datori di lavoro, liberi professionisti, società esterne titolari di un autonomo trattamento di dati e familiari dell'interessato.

Ne segue che, senza il consenso dell'interessato alle comunicazioni a terzi e ai correlati trattamenti, il "COMITATO TELETHON FONDAZIONE ONLUS" non potrà effettuare le sopracitate comunicazioni dei dati personali.

I soggetti appartenenti alle categorie ai quali i dati possono essere comunicati utilizzeranno i dati in qualità di "*titolari*" ai sensi della legge, in piena autonomia, essendo estranei all'originario trattamento effettuato presso "COMITATO TELETHON FONDAZIONE ONLUS", con sede in Roma, Via Spinola 16.

#### **Titolari e Responsabili del trattamento**

Il Titolare del Trattamento dei Vostri dati personali è il Comitato Telethon Fondazione ONLUS con sede in Via Spinola 16, 00154 - Roma.

Responsabile del trattamento dei Vostri dati personali è il responsabile della Direzione Scientifica, Via Nino Bixio, 30, 20129 - Milano.

#### **Diritti di cui all'art. 7**

Informiamo, inoltre, che l'art. 7 della legge conferisce ai cittadini l'esercizio di specifici diritti. In particolare, l'interessato può ottenere dal titolare la conferma dell'esistenza dei propri dati personali e che tali dati vengano messi a sua disposizione in forma intelligibile.

L'interessato può altresì chiedere di conoscere l'origine dei dati nonché la logica e le finalità su cui si basa il trattamento; di ottenere la cancellazione, la trasformazione in forma anonima o il blocco dei dati trattati in violazione di legge nonché l'aggiornamento, la rettificazione se vi è interesse, l'integrazione dei dati di opporsi, per motivi legittimi, al trattamento stesso.

Ulteriori informazioni potranno essere richieste direttamente presso il "COMITATO TELETHON FONDAZIONE ONLUS", con sede in Roma, Via Spinola 16.



