# TELETHON-UILDM CLINICAL PROJECTS - 2015

# GUIDELINES FOR PREPARING AND SUBMITTING THE APPLICATION ONLINE

## Index

## ONLINE REGISTRATION

Application forms for Telethon Research Proposals 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".

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.

## General instructions for completing the Application

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 "**Submit 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 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, Clinical Protocol.*

- For each of the three sections, all figures and legends must be placed in 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 “Sfoglia/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.**

***Centres involved in the study*** - Indicate whether the project involves a single centre or if it is a multicentre effort; in the latter case, please specify the total number of participating sites. **The number of sites can be modified at any time; if the number is reduced, the system will automatically remove the last partner and all his/her data.**

***Project duration*** - Indicate the duration of the project in years (max 3 years).

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

- New Applicant is a researcher who has never applied to a Telethon call; may only submit a New Application
- Former Applicant is a researcher who has already applied to a Telethon call 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 all types of Applications or a Renewal (extension) of a previously funded project.

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

In the case of a Revised or Renewal Application, the ***Previous Application Number*** should be reported in the specific box.

***Study classification*** - The Applicant has to indicate the kind of study proposed. “Clinical Study” applies to all studies that foresee enrolment of a number of patients determined on the basis of power calculation, whereas “General Research Study” includes projects focused on preclinical investigation or on analyses that do not necessarily involve patient recruitment. For Clinical Studies, the total number of patients expected to be enrolled in the trial should be reported.

***Scientific Report of the previous Telethon-UILDM project*** - This section must be filled out by the Principal Investigator (PI) or the Coordinator of a previous Telethon-UILDM project only, who needs to indicate whether and when the Final Report has been submitted. If not already sent, the Report has to be filled out in the proper section (“Scientific Report”).

## Methodological support and Pre-Submission inquiry

Telethon offers the Applicant assistance on methodological aspects related to the clinical protocol, a service provided by experts in medical statistics of the University of Milano - Bicocca.
Therefore, 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**”, filling out the form provided within the online Application.
The requests received may be evaluated also by the UILDM Medical Scientific Committee members, if indicated by the Applicant, who 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 type 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 needed and submitted via email to the Telethon Scientific Office, no later than **April 27, 2015.** 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 Investigators by **May 25, 2015**.

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

## Overview

***Abstract*** (max 2,000 chars) - The Applicant (PI/Coordinator) has to organise the Abstract into separate sections:

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

***Multicentre Studies only***

Role and contribution of partner(s) in the project (max 4,000 chars) - The Coordinator is asked to describe the contribution of all Partners, explain why each of them is necessary to the success of the project, clarify the complementarities of approaches that justifies their participation and to highlight how the synergy among them will produce greater results over the sum of individual contributions.

Coordination and Management (max 4,000 chars) – The Coordinator should specify in this section how the multicentre project will be managed, indicating strategies aimed at:

- monitoring activities of all centres
- facilitating communication
- promoting exchange of ideas and methodological approach
- stimulating the analysis and the integration of results.

***Keywords*** *(max 250 chars)* - Indicate a maximum of five appropriate keywords that represent the contents of the research.

***Relevance to Telethon*** *(max 1,000 chars)* - Clearly specify how the goals of the project fit with the Fondazione Telethon's and UILDM's aim of improving the quality of life of patients affected by genetic muscle and nerve disorders, and spinal muscular atrophy. Proposals targeting other diseases, although of proven genetic origin, will not be processed for review.

***Impact on patients*** *(max 1,000 chars)* - 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, OMIM number** as given by the Online Mendelian Inheritance in Man (http://www.ncbi.nlm.nih.gov/sites/entrez?db=OMIM) and **ICD-10 codes** 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) (as many as necessary).

***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 the care or therapy of the addressed diseases.

Please note that Fondazione Telethon will reserve the option to edit 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 (max 15,000 chars)

In the case of a **Revised Application,** please fill in the Cover Letter Form, specifying the previous Application number.

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

***Cover Letter*** - The Cover Letter must include a detailed reply to the critiques.

In the case the Applicant is changed with respect to the previous Application, a motivation must be provided in the Cover Letter.

## Scientific Report of the Previous Telethon-UILDM Project (for Former Grantees only)

In the case of a **Renewal Application** or of a **New Application by a Former Grantee (PI/Coordinator)**, the scientific and administrative reports are required for the previously awarded Telethon-UILDM clinical grant, if not already submitted.

***Scientific Report*** - Provide all the requested information, including the title of the completed project, the original abstract, as it appeared in the 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; 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*** – download from the left menu "Required Documents" the form ***Dichiarazione costi sostenuti.xls*** and ***Riepilogo centri.xls*** (for Coordinators of Multicentre projects only); fill it/them out according to the relevant instructions ***(Istruzioni Rendiconti Amministrativi.pdf).*** Send the completed form(s) by email to reportamministrativi@telethon.it **by July 15, 2015.**

The administrative report must prove that at least 30% of the total funds available for the final year of the previous project has been spent. Total funds include the planned budget plus residual budget from the previous year, if any.

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, Coordinators are responsible for sending both their own administrative report and the summary of the partner centres' reports. Partners of the previous project are not required to send their administrative report.

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

## Scientific Strategy (max 20,000 chars)

***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 figures' pdf file.

## Preliminary results (max 15,000 chars)

Provide an account of preliminary studies pertinent to the proposed research. This information will also help to establish the experience and competence of the Investigator to pursue the proposed project. Peer review committees generally view preliminary data as an essential part of a research grant Application, as they often aid the assessment of the likelihood of success of the proposed project.

For Multicentre Studies, preliminary results of the Centres involved in the study should be listed site by site, if applicable.

***Preliminary Results Figures*** – Refer to the "Figures" section (page 3 of this document) to create and upload the figures pdf file. Results are considered 'preliminary' only if unpublished. Published results, when deemed necessary, can be indexed as references.

## Clinical protocol and methods

*Clinical protocol* (max 30,000 chars)

Clearly define:

1) Study design, i.e. blind, double blind, open, etc.

2) Study population, i.e. number of patients based on power calculation, 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, analysed and interpreted. Describe in detail the statistical methods to be employed.

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.

Explain the need for collaboration (if any) to achieve the scientific aims of the proposed project. Indicate how the idea of collaborating originated, the different approaches which each collaborator will bring to the overall study, and how the collaboration will be conducted. Any collaboration must be listed in the specific form (page 9).

Include an explicit description of the collaborative elements that are essential for the project to be carried out. Collaborators are expected to have research experience and must have an established record for independent research.

Please note that Fondazione 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)

Provide a tentative sequence or timetable for the project.

**Methods** (max 8,000 chars)

Describe any new laboratory procedure or new methodology employed in the study and state the advantages over existing methods.

***Clinical Protocol Figures/Documents*** – Refer to the "Figures" section (page 3 of this document) to create and upload the figures pdf file.

## Cited literature (max 20,000 chars)

List all references accordingly. The list must 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**.

## Personal Data and Curriculum Vitae

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

***Unique Researcher identifying system*** – Telethon believes that the broad adoption of a researcher identification standard is key to an effective management of research. 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*** - Telethon invites Applicants to highlight possible financial conflicts of interest that might be perceived as relevant. However, these financial interests will not invalidate the Application, nor do they automatically disqualify it from being evaluated.

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

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

***Publications*** - **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.**

Provide three separate lists of your publications corresponding to:

- the most recent peer-reviewed publications, up to **20**
- the top peer-reviewed publications in your career, up to **5**
- the most relevant peer-reviewed publications related to the proposed research project, up to **5**.

The same publications may be included in more than one list.

Please note that Fondazione Telethon does not apply assessment of Candidate's CV based on journal-based metrics, such as Journal Impact Factors. The Fondazione signed and endorses the San Francisco Declaration on Research Assessment (DORA, http://am.ascb.org/dora/).

# ADMINISTRATIVE SECTION

## Personnel

Personnel (including PI/Coordinator/Partner) are defined as, and should be limited to, key individuals who contribute in a substantial way to the scientific development or execution of the project.

For each individual provide: name, birth date, degree, role on the project, the type of contract at the Host Institution (active or not), the annual percentage of effort in the project and whether a salary is being requested. **Please note that personnel to be recruited ("to be named") must be listed here and should be kept to a minimum.** For each person the "role on the project" must be specified in detail. For example "molecular biologist" is not satisfactory; "molecular biologist performing mutational analysis" is appropriate.

Consultants should be included only when their level of involvement meets the previous definition. **An inadequately described role on project and annual effort may result in the reduction of the budget approved.**

## Collaborations

The PI/Coordinator/Partner should list his/her national and/or international collaborations, specifying name, institution, whether the collaborator is related to the project and, *if YES*, their relative contribution.

**Collaborations must be supported by collaboration letters written in English, which have to be uploaded into the Application online.**

## Budget

The budget description must be accurate in all its parts and every item must be justified in the "Description/Justification" field and clearly related to the execution of the project. **Any omission, generic description, or miscalculation could lead to the project's rejection.** All amounts must be in Euro, please use **whole numbers** only.

Applicants have to fill out only those items that better apply to the study classification selected in the "General Information" section.

For Multicentre proposals: each partner is asked to fill out details about his/her budget in the corresponding boxes. The system will automatically create a summary section with the total budget.

For clinical projects that entail the enrolment of a number of patients necessary for power calculation it is advisable to identify start-up and other fixed costs separately from patient-related costs (variable costs). Fixed costs are incurred 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 PI/Coordinator may contact the Telethon Scientific Office for assistance (soffice@telethon.it) if deemed necessary.

The following expenses associated with the proposed research **are not allowed**:

- Salaries for the PI/Coordinator/Partner
- Full salaries for members of staff who already receive a regular wage
- Salaries, travel and/or housing related to sabbatical leaves
- Scientific Society memberships
- Organization of meetings and workshops

- Construction, alteration, maintenance, lab furnishing, rental of buildings or building spaces and utilities, fax and telephone costs
- Major basic equipment such as incubators, hoods, -80°C freezers
- Secretarial work

**DIRECT COSTS**

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

***Coordination costs*** **-** Allowed only for the Coordinator of a Multicentre project which includes at least 3 centres. This amount should be requested on a forfeit basis up to a maximum of 5,000 Euro per year and is intended to cover coordination administrative costs, which need to be well specified.

***Start-up costs***

- Database set-up
- Ethics Committee fees
- Medical supplies
- Pharmacy set-up costs
- Printing of documents (i.e. CRF, informed consent)

***Patient-related costs*** **-** Variable costs: to be filled out only for a clinical study, in which the exact number of patients is defined

- Lab work, biochemical assays, etc.
- Mailing of drug and/or specimens
- Salary for personnel dedicated to patients (examining researcher, personnel dedicated to data entry and collection, etc.). These data must correspond to those reported in the "Personnel" section. Although not encouraged by Telethon, salaries for "to be named" people may be requested
- Pharmacy and drug administration
- Physical exams and medical assessments
- Reimbursement of travel expenses to patients
- Subject screening

***Patient-related costs sum up*** **-** At the bottom of the online "Budget" section, each Partner has to report the total number of patients and the total patient-related costs of his/her centre. The cost per patient calculation will be available in the project .PDF or in the read-only mode.

***Equipment*** **-** Up to a total of **20,000 Euro** for minor essential equipment or a portion of a major piece of equipment. Each item must be clearly listed in the specific section and must be highly justified for the conduction of the proposed research.

*Personal Computer*: must be included in the "Equipment" section only. The need for a personal computer should be clearly explained according to the research needs, and must not represent a benefit for the Researcher. The amount allowed for IT equipment is up to a total of 2,500 Euro (for each Partner).
Therefore if IT equipment is requested, the total maximum amount for equipment allowed is 22.500€.

***Materials, Supplies and Services*** **-** Materials and supplies must be listed by category: glassware, chemicals, radioisotopes, etc. Services include items as *Sequencing*, *Peptide Synthesis*, etc.. Major cost items should be listed and properly justified.

***Salaries*** **-** In case of a budget foreseeing patient-related costs, please report here only the salary for personnel not dedicated to patients (i.e. Clinical monitor, data manager, statistician, consultant fees, etc.) or for other project staff (post-docs, technicians, etc.) holding a temporary position.
Specify names, role on the project of the recipients, and amount under the specific section. **These data must correspond to those reported in the "Personnel" section.** Although not encouraged by Telethon, salaries for "to be named" people may be requested. Please indicate which kind of contract will be applied and the level of

seniority required. The amount requested should correspond to the level of seniority and to the annual effort declared.

***Travel costs*** **-** In the description field please split travel costs into:

- Travel costs for meetings/congresses (not more than 3,000 Euro annually)
- Project-related travel costs of personnel (which must be carefully justified: destination, purpose and travel frequency – and adequately described in the project plan).

Costs allowed in the budget for travel are the following:

- Transportation Costs (train/plane/bus/taxi/car use)
- Boarding and Lodging
- Congress Registration Fee
- Abstract Submission Fee.

***Other expenses*** **-** (each item should be detailed and justified):

- *Allowed items:* publication costs, reprints, journal subscriptions, books. If software is requested, specify the necessity for the proposed research
- *Allowed items, if overhead are not requested*: stationery (paper etc.), computer consumables (toner, CDs, etc.), repairing & maintenance of instruments, mailings.

**INDIRECT COSTS**

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

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

## Other Financial Support

It is absolutely mandatory that the Principal Investigator/Coordinator/Partner list in this section all financial resources available in direct support of his/her research endeavours, including, but not limited to, research grants, cooperative agreements, contracts, and/or institutional awards.
Indicate:

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

## Host Institution

Provide all the information requested clearly and in detail. **Please write the address in Italian and note that this address will be used for any postal deliveries addressed to you.**

Print the completed 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 online.

Please find below some general scanner settings for written documents:

- Resolution: 100 dpi
- Colors: 256 shades of grey

- Image size: A4
- Final jpeg file compression: medium.

**NOTE: It is mandatory to upload the Host Institution Agreement, otherwise the Application will not be processed for review.** The original document should be kept by the Applicant for possible future requests by Fondazione Telethon.

***Applicant*** **-** If the PI/Coordinator/Partner is not the *Chief of the Clinical Unit/Laboratory*, the information requested in the **Independence statement** should be exhaustively provided.

**It is mandatory** that **any foreign appointment** of the PI/Coordinator/Partner be clearly indicated in this section and in the "Host Institution Agreement" document**.**

***Human subjects*** - Indicate whether the study involves:

1. human samples from a collaborator site or an external biobank – fill out and upload attachment 1 (see "Required Documents")
2. human samples from individuals referred to the PI's/Coordinator's/Partner's Host Institution – fill out and upload attachment 2 (see "Required Documents")
3. individuals enrolled in clinical trials – send all relevant documentation (Ethics Committee's Approval, Informed Consent Form and Patient Information leaflet) to the Telethon Scientific Office (soffice@telethon.it) as soon as available
4. 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 Committees' Approval has been obtained. Please activate in due time all necessary procedures to obtain this approval in accordance with the relevant Italian laws (http://www.agenziafarmaco.gov.it/it/content/normativa-di-riferimento-sperimentazione-clinica).

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

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

## Suggested Reviewers

The Applicant may suggest external referees - **not currently working in Italian Institutions** - in his/her fields of research, who could competently review his/her Application. Individuals who have been associated with the Applicant within the last 3 years cannot be listed. **Should you prefer to exclude direct competitors, please indicate their names in the NOTES.** Fondazione Telethon reserves the right to choose external referees independently.

## Notes (max 8,000 chars)

Write here 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.

***Attachments*** **-** Please use this section if you need to upload any other document (PDF only) you consider relevant to the proposal.

## Declaration and Privacy Statement

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 out by the Applicant, the Application will not be processed for review.**

## Required documents to be uploaded

Additional documents to be uploaded into the proper Application's sections or emailed can be downloaded by clicking on the link "**Required documents**" on the left-hand menu bar online.

## Submitting the Application

The deadline for **online submission is July 15, 2015 - twelve o'clock (midday).**

You can modify your Application until the deadline. Click on the "**Submit 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.

The **Administrative Report** must be sent to the email address reportamministrativi@telethon.it by **July 15, 2015.**

March 20, 2015 **FONDAZIONE TELETHON**