



MULTIROUND CALL FOR RESEARCH PROJECTS 2025-2027 – ROUND I

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General Instructions

For the Round I of the Multiround Call for research projects 2025 – 2027, Fondazione Telethon will be in partnership with “Fondazione Regionale per la Ricerca Biomedica” (FRRB) of Regione Lombardia.

The Application form is available on *Fondazione Telethon Grant Management* system portal at this [link](#).

Applicants are identified as **Lead Applicant** (in charge of creating and completing the Application) and **Partner** (invited by the Lead Applicant). Please refer to page 19 of this document for the Partner invitation process. Applicants should pay attention to the **Guidelines and Instructions, as an Application failing to meet the requirements will be rejected**. An accurate Application will facilitate the review process. Use **English** language only. For abbreviations and acronyms 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 specified character or word number limitations. **The maximum number of characters in the different sections includes spaces.**

Applicant Account

Registered Users in TETRA (the former Grant Management system)

Applicants who have already registered in TETRA – the former *Fondazione Telethon Grant Management* system – are **kindly asked NOT to create a new account**.

Please click on **Forgot Password?** and follow the instructions for setting a New Password, then enter the portal at this [link](#). Please note that the System allows the creation of an account associated with **ONLY** one email. Therefore, if the Applicant already has an account, he/she is kindly requested NOT to register with a different email, but to ask for a password change (by clicking on **Forgot Password?** - below the **Login** button).

New Applicant to Fondazione Telethon Calls

To register, Applicants should click on the **Register Here** button and enter their email address: to complete the registration process follow the online instructions.

Institution Information

Please enter the full name of the Applicant Institution. If the name of the Institution is already registered in the System, it will be shown in a dropdown menu. **Only if the Institution has not been registered yet**, Applicants have to register it by clicking on **Register New Institution** and following the instructions.

Contact Information

Please note that the System allows the creation of an account associated with **ONLY** one email. Therefore, if the Applicant already has an account, he/she is kindly requested NOT to register with a different email, but to ask for a password change (by clicking on **Forgot Password?** - below the **Login** button). In case the email address is no longer valid, the Applicant is kindly asked to contact our IT Admin (telethonscience@telethon.it) to update it. For questions concerning the Application, it is possible to send an email to: telethonscience@telethon.it or FT_FRRB_Multiround@Telethon.it. **Please note that, once the Applicant has registered on the portal for the first time, it is necessary to update the profile information** by clicking on the dedicated shortcut **Update/Edit Profile** in the dashboard. Please fill in all the mandatory fields.

In the **Department** section, select the department from the dropdown list; if the Applicant does not have a department, please select 'Not applicable' and then **Save**. If the Applicant's Department is not available among those listed, please enter only the Host Institution, and email the new department name to telethonscience@telethon.it. At the end, click on **Submit profile** so that all this information will automatically populate the Application relevant fields. Please refer to the **Personal Details** section below for more information.

Personal Details

Before starting a New Application, the Applicant must update the **My Profile – General, Department, and Biosketch** sections by clicking on the dedicated shortcut **Update/Edit Profile** in the dashboard.

The **My Profile – General** section contains the information entered during the first registration on the portal and can be updated/modified at any time.

The **My Profile – Department** section automatically reports the Institution Information inserted during the first registration on the portal.

In the **My Profile – Biosketch** section, the Applicant (and Partner) must ensure to update the following items: *Education/Training, Personal Statement, Positions, Contributions to Science, Relevant Publications, Patents (whether or not relevant for the current project), Companies (founder of or appointed by a start-up, involved in industrial partnership), Financial Interest* - as all these are **mandatory** for the submission of the Application. For further details, please read the **Biosketch** section (page 8).

Of note: keep the My Profile section updated. Please ensure to click on **Submit Profile** before creating a New Application, so that the information contained in the My Profile sections will be automatically incorporated in the relevant fields of the New Application.

My Applications section

In this section the Applicant can find his/her draft Applications, check the status of the Applications and find his/her submitted Applications and active grants (once available on the new platform).

The created Applications are listed in **My Applications**, located on the Home Page. A final Application number will be assigned to the newly created Application project once the Applicant reads and agrees with the Privacy Policies.

In the **My Applications** section, starting from the left side of the Home Page, the following tab sections are shown:

- **In progress** – In this tab the Applicant will find his/her draft Applications. To make changes to the Application, the Applicants must select the Application they want to edit.
- **Pending Signature** – In this tab the Applicant will find the Application waiting for Signature and approval by the pertinent Institution/Organization.
- **Pending Submission** – In this tab the Applicant will find the Application in pending status, i.e. waiting to be submitted.
- **Submitted** – In this tab the Applicant will find the Application that has been submitted.
- **Under Review** – In this tab the Applicant will find the list of Applications that have moved to *Under Review* status.
- **Pending activation** – In this tab the Applicant will find the list of Applications that are waiting to be activated.
- **Active grants** – In this tab the Applicant will find the list of Applications that have been activated.
- **Historical Grants** – In this tab the Applicant will find the history of all Applications.
- **Locked** – In this tab the Applicant will find the list of Applications that have been locked. This state occurs when the Call has been closed while the Application is still in progress.

Guidelines to apply with a Letter of Intent (LoI)

Creating a Letter of Intent (LoI)

NOTE: The LoI must be submitted by the Lead Applicant. In case of bi-centric projects, the Partner must fill in and sign the “Partner Biosketch and Approver” document and send it to the Lead Applicant as a pdf file. The template of the document is available on the relevant FT website page.

On the Home Page, click on the **Funding Opportunities** shortcut in the dashboard to access the page listing all available Calls.

Select, within the Call list, either **Multiround Call 2025 Basic Track – LoI** or **Multiround Call 2025 POC Track – LoI** and click **Apply** to create a New Application form. The Applicant may also read/download the related Guidelines and Privacy Policies.

After clicking **Apply**, the system will ask the Applicant to read and agree to the Privacy Policies. It is now possible to access the Application form by clicking on the **Begin Application** button. Please, refer to the **Application sections** paragraph on page 5 for details on how to fill each field in the **Application form**.

Mandatory fields are indicated by red stars. To successfully submit an Application, all mandatory fields must be completed.

The **Back** and **Next** buttons allow the Applicant to navigate into the Application, and the **Save Draft** button saves all changes and activates important functionalities within the Application (without leaving the current Application page). Make sure to save the draft Application, such that it will be possible to work on it at different times. Please, note that some fields will be populated only after clicking the **Save Draft** button. **Thus, we recommend saving the draft Application frequently, or at least every time a section has been completed.**

To exit the Application page, click on the left-hand arrow on the top of the page to return to the Home page.

The **Send for Signature** button starts the validation and submission process. **For further details about the LoI submission, please refer to the Validation and Submission Procedure section at page 10.** Please note that: a) before the application is sent for signature, it is possible to delete it by clicking on the **Delete** button at the bottom of the Application page; b) once the Application is sent for signature (the Application is in *Pending Signature* status), it can be withdrawn by clicking on the **Withdrawal** tab (the reason for withdrawal must be summarized in the text box).

A submitted Application cannot be further modified. If the Applicant needs to make any amendments before the Call deadline date, an email has to be sent to telethonscience@telethon.it

LoI Sections

- Project Overview
 - General Information
 - Type of Research
- Research Proposal
 - Stage of development
 - Letter of Intent
- Contacts
 - Approver

- Biosketch
- Declarations

Project Overview

This section comprises the General Information and Type of Research of the Lol Application.

General Information

Project Title (max 250 characters) – Enter the title of the proposed project. In case of title change, the Applicant can modify it at any time before final submission.

Number of centers – Indicate the number of centers (1 or 2) participating in the study and click on **Save Draft**. A maximum of 2 centers are allowed (Lead Applicant + 1 Partner)

Project Duration (in months) – The duration of the project is 12, 24 or 36 months.

Type of Application – Choose the appropriate option: New Application, Renewal Application, Revised Application:

- **New Application;**
- **Renewal Application:** choose this option if you are planning to ask for a renewal of a Fondazione Telethon Multiround Grant;
- **Revised Application:** choose this option if you are planning to ask for a revised version of a Fondazione Telethon Multiround Call (please, check the Call text for details about Revised applications).

Budget Lead Applicant: indicate the total amount (euros) requested by the Lead Applicant.

Budget Partner: indicate the total amount (euros) requested by the Partner.

NOTE: The maximum total budget allowed for each research project is:

- TRACK Basic Research: max 240,000 € (**max 80,000 €/year**)
- TRACK Preclinical Proof of Concept: max 360,000 € (**max 120,000 €/year**)

Partner: Name and surname of the Partner

Partner organization: organization of the Partner

Partner Biosketch and Approver: The Partner must fill in the “**Partner Biosketch and Approver**” document and read and accept the Privacy policies. The document must then be signed both by the Partner and the Institution Signatory (i.e., the Partner organization’s Approver). The Partner must send the signed document as a .pdf file to the Lead Applicant, who will upload it in the field of the Lol form.

Type of Research

Disease Name – Write the disease(s) name(s).

Fill in all available Disease Codes:

- **Disease OMIM Number** – Fill in the **OMIM number of the Disease** as given by the Online Mendelian Inheritance in Man (<https://www.ncbi.nlm.nih.gov/omim?db=OMIM>);
- **ICD-11 Code** – (if not available please indicate “n.a.”) as given by the International Classification of Diseases (<https://icd.who.int/browse/2024-01/mms/en>);

- **ORPHA Number** – (if not available please indicate “n.a.”) as given by Orphanet (<https://www.orpha.net/consor/cgi-bin/index.php?lng=EN>).

If more than one disease is addressed, please separate names, OMIM numbers, ICD-11 codes and Orpha Numbers with semicolons.

Research Type and Area of Research – select all that apply.

Research Steps – Select the research steps that best represent the proposed study (all that apply):

- genetic studies
- studies on mechanisms
- therapeutic approaches in vitro
- therapeutic approaches in vivo

Research Proposal

Stage of Development

Indicate the proposed **Starting and Ending stages of development** of the proposed project, referring to the Fondazione Telethon Development Pathway (FTDP) indicated in the Call for Application and choosing among the options below, **specific for each track**. For further details, please refer to the Call.

Basic Research track:

0. New knowledge
1. Research on mechanism/the disease
2. Target identification
3. Target Validation

Preclinical PoC track:

4. Therapeutic approach identification
5. Preclinical Proof of Concept

Letter of Intent

Fill in all the fields as follows:

Hypothesis, Background and Rationale (max 2,000 characters) – State the main hypothesis to be tested and explain the impact of the problem addressed by the proposed project. Critically evaluate the existing knowledge and identify the specific gaps to be filled to progress in the relevant field. Clarify how the project represents a significant step forward with respect to the current state of the art.

Objectives (max 2,000 characters) – Illustrate the overall objectives that the proposed research is intended to accomplish.

Preliminary data (max 2,000 characters) – Briefly describe the preliminary data supporting the proposed research. Figures are not admitted in the LoI Application.

Research Plan (max 4,000 characters) – Briefly outline how the experimental approaches will be addressed and how the results will be analyzed.

Expected outcome, significance, and innovation (max 2,000 characters) – Describe the expected results and highlight the significance and innovation of the proposed research.

Cited Literature (max 2,000 characters) – List the main references. The list must include the name of all authors, year of publication, title, book or journal, volume number and page numbers. Concise references are not allowed. The complete list of references will be visible to Reviewers.

Contacts


This section includes information about the Institution Signatory (i.e., the Lead Applicant organization's Approver). Please note that the Partner must send the approval document of his/her Organization to the Lead Applicant, who will be responsible for its upload in the Application (please refer to the **Partner Biosketch and Approver** section).

Approver

The **Institution Signatory** is a person (**Institution's Director or Responsible Official or Administrative Representative**) representing the Organisation where the research project will be conducted and will have the **responsibility for the Application approval**.

To add an Approver, use the lookup tool and add one of the listed institutional contacts already registered in the platform as Institution Signatory. There must be at least one Institution Signatory indicated to be able submit it the application.


If an Institutional Signatory cannot be found using the lookup tool, click on **Invite New Institution Signatory** to add a new institutional contact. The registered Institution signatory will be notified via email to activate his/her account and complete the registration. If the Approver does not receive the automatic email, check the spam folder otherwise contact System admin at telethonscience@telethon.it. Personal email accounts are not accepted. Thus, please make sure that the Institution Signatory's email is the institutional account.

In case of error, the Approver can be deleted by checking the box placed on the left of the Institution Signatory's name and then by clicking on the  button.

Upon Application Submission, **the selected Institution Signatory will receive an email** containing the link to access the platform and proceed with the approval. In case of first access to the platform, please follow the registration instructions on the webpage. If already registered, clicking on the link in the invitation email the Login page of the portal will open. If the Approver does not receive the automatic email, check the spam folder otherwise contact System admin at telethonscience@telethon.it.

The Applicant is encouraged to fill in the whole Application in due time, to allow the Institution Signatory to approve and submit the application within the deadlines.

Biosketch

This section displays details added to the Applicant's profile in the system. To update details displayed here, please update, and re-submit the Applicant's system profile, by clicking on this symbol. 

Before proceeding to complete an Application form, please check the **Update/Edit Profile** shortcut on the dashboard and update the **General, Department and Biosketch Information**. Please ensure to update, in the **Biosketch** section, the following items that are required for the submission of the Application:

ID Researcher Platform and Personal Author ID – the Applicant must indicate one of the Researcher Platforms and provide their personal author ID. In case the Applicant does not have one, we suggest generating an ORCID ID (<http://orcid.org/>).

Education/Training – click on the **Edit** button and fill in the requested details. Begin with the baccalaureate or other initial professional education. Include postdoctoral, residency, and clinical fellowship training, as applicable, listing each separately. For each entry provide:

- the name and location of the institution

- the degree received (if applicable)
- the month and year of end date (or expected end date)
- the field of study (for residency entries, the field of study should reflect the area of residency training)

Personal Statement – briefly describe why the applicant is well-suited for his/her role(s) in the project. Relevant factors may include aspects of his/her training; previous experimental work on the specific topic or related topics; technical expertise; collaborators or scientific environment; past performance in the field or in related fields, including ongoing and completed research projects from the past three years that the applicant wants to draw attention to.

Positions, Scientific Appointments, and Honors – list in reverse chronological order all current positions and scientific appointments both domestic and foreign, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary). List any relevant academic and professional honors.

Contributions to Science – briefly describe up to five of the applicant’s most significant contributions to science. The description of each contribution should be no longer than one-half page, including citations. These contributions do not have to be related to the project proposed in this application. For each contribution, the applicant may cite up to four relevant publications or research products. If the applicant is not the author of the product, indicate what his/her role or contribution was. Note that while manuscripts that have not yet been accepted for publication may be mentioned as part of the contribution, only published papers can be cited to support each contribution. Moreover, the applicant may indicate the historical background that frames the scientific problem, the central finding(s), the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology, his/her specific role in the described work.

Relevant Publications – please list up to 10 publications relevant to the application.

Patents (whether relevant or not for the project) – please use this box to add any patent Applicants are owners/inventors of.

Companies (founder of or appointed by any start-up? Involved in industrial partnership?) – please use this box to add any involvement with companies (e.g. founder, involvement in industrial partnership).

Please make sure to save the updated data by clicking on *Save draft* and then by clicking on *Submit Profile* to display this information in the Biosketch tab within the Application.

Please note that, to edit the information listed above, the Applicant must return to ***Update/Edit Profile*** section at any time, for updates. It is not possible to make amendments to such information directly from the **Biosketch** tab within the Application.

Declarations

Declarations

The Lead Applicant must certify that the information included in the Application is accurate and complete, that he/she is entitled and/or authorized to disclose all the information provided within the Application, and that he/she complies with Fondazione Telethon ETS’s terms and conditions.

Lol Submission

The deadline for online submission of the Lol is **March 12th, 2025** at 1:00 PM (CEST).

Validation and Submission procedure

Once the Application has been completed in all its parts, click the **Send for Signature** button placed at the bottom-right of the page to initiate the validation and submission process.

Of note, sections/fields that are incorrect or not completed will be shown in a tab at the top of the Application page: correct/complete any highlighted fields to validate the application so that it can be properly sent for signature again.

Once validated, the Institution Signatory will receive an email with the link to approve the Application (read the **Contacts** section for important details on the approval process).

Through the link, the Institution Signatory (Approver) can access the portal and hence the application: after having accepted the *Host Institution Agreement Clauses* in the **Declarations** tab, *the Approver* can either **Submit** (approve) or **Send for Revisions** (reject) the proposal.

If the Application is **rejected** by the Institution Signatory, the Applicant will receive an email notification, and the Application will be shown in the **In Progress** tab again. Please note that once modified, the updated version of the Application will then need to be sent for signature again and approved by the Institution Signatory to be submitted.

If the Application is **approved** by the Institution Signatory, it will be automatically submitted and shown in the **Submitted** tab on the **My Applications** list in the Home Page. At this stage, the Application cannot be further modified. The Applicant can send an email to telethonscience@telethon.it if amendments are needed, **ONLY** before the Call's deadline.

APPLICANTS SHOULD MAKE SURE TO PRE-SUBMIT THEIR PROPOSAL IN DUE TIME TO ALLOW THE APPROVAL AND SUBMISSION PROCEDURES TO BE COMPLETED WITHIN THE DEADLINE.

Before final submission, the Lead Applicant is invited to download the PDF of the Application to check all the sections. Please note that the Lead Applicant is responsible for the contents and quality of the Application in its final version.

Fondazione Telethon ETS and FRRB hold the responsibility and authority to make the final decision on the Application's completeness and eligibility.

Guidelines to apply to the Full Application

Create a Full Application

On the Home Page, clicking on the **Funding Opportunities** shortcut on the dashboard, the Applicant can access the page listing all the available Calls.

Select, within the Call list, either **Multiround Call 2025 Basic Track- Full** or **Multiround Call 2025 POC Track – Full** and then click **Apply** to create a New Application form. The Applicant may read/download the related Guidelines and Privacy Policies.

Filling in the Application

After clicking **Apply**, the system will ask the Applicant to read the **Privacy Policies** and agree with them. It is now possible to access the Application form by clicking on the **Begin Application** button. Please, refer to the **Full Application sections** paragraph on page 12 for details on how to fill each field in the Application form.

Make sure to save the draft Application to be able to work on it at different times. Please, note that some fields will be populated only after clicking the **Save Draft** button. **We recommend saving the draft Application frequently, or at least every time a section has been completed.**

The created Applications are listed in **My Applications** at the bottom of the Home Page. A final Application number will be assigned to the newly created Application project.

The Back and **Next** buttons allow the Applicant to navigate into the Application, and the **Save Draft** button saves all changes and activates important functionalities within the Application (without leaving the current Application page). To exit the Application page, click on the left-hand arrow on the top of the page to return to the Application list. It is possible to delete the Application by clicking on the **Delete** button at the bottom of the Application page. Please note that the Application may be withdrawn by clicking on the **Withdrawal** tab only when the Application is in *Pending Signature* status.

Mandatory fields are indicated by red stars. To successfully submit an Application, all mandatory fields must be completed. Any item missing before submission is listed in a box that is shown at the top of the page, once the Applicant clicks on the **Send for Signature** button.

When the Application is validated, the Applicant may send the Application for signature to the Institution Signatory. Before the Institution Signatory approval, the Application is displayed on the **My Applications** page in the *Pending Signature* status.

At this point the Application will have to be **approved and signed by the Institution Signatory Approver (or Approvers, in the case of bi-center proposals)** to allow final submission. In the case of bi-center proposals, the Lead Applicant must also ensure that the Partner has completed and submitted his/her part of the Application before proceeding with the final submission. **For further details, please refer to the Validation and Submission Procedure section on page 23.**

A submitted Application cannot be further modified; if the Applicants need to make some amendments before the Call deadline date, an email should be sent to telethonscience@telethon.it.

Full Application Sections

- Project Overview
 - General Information
 - Overview
 - Type of Research
- Research Proposal
 - Stage of Development
 - Research Plan
- Ethical Documents
- Host Institution
 - Applicant Details
 - Facilities and Resources
- Contacts
 - Approver
 - Collaborators
 - Partners
- Budget
 - Application Budget
 - Other Financial support
- Biosketch
- Reviewers
 - Suggested Reviewers
 - Excluded Reviewers
- Declarations
 - Notes
 - Declarations

Figures – The Application form includes special upload fields dedicated to figures in the Research Proposal tab within the Application. Do not copy sections of already published papers.

All figures and legends must be placed together in one PDF document in A4 format.

In the Figures PDF, insert a footer with the name of the relevant section of the Application form followed by the indication “Figures” and the page number (for example a PDF uploaded into the Application section “Preliminary Results” should have the following footer: “Preliminary Results Figures - page 1 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 form PDF as an Appendix. Make sure that the appropriate figure numbers are correctly indicated in the text.

Please keep the PDF size below 50 MB. 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. A resolution of 100 dpi for each picture can be used for charts or drawings (if included).

Make sure that all figures are perfectly readable both on the screen and in print.

Project Overview

This section comprises the General Information of the Application, the Overview and the Type of Research of the Project.

General Information

Please make your preference for the funding agency to apply with (FT or FRRB).

Project Title (max 250 characters) – Enter the title of the proposed project. In case of title change, the Applicant can modify it at any time before final submission.

Number of centers – Indicate the number of centers (1 or 2) participating in the study and click on **Save Draft**. A maximum of 2 centers are allowed (Lead Applicant + 1 Partner)

Project Duration (in months) – The duration of the project is 12, 24 or 36 months.

Total Budget Requested – This field is automatically filled in once the **Budget** section is completed by the Applicant (please remember to click always on **Save Draft** to enable this functionality).

Please answer the relevant questions to state whether you participated in **previous FT and FRRB Calls** and if your project has been funded.

Type of Applicant – Please select one of the following:

- *New Applicant*: is a researcher who has never applied to a Fondazione Telethon Call; he/she may only submit a New Application.
- *Former Applicant*: is a researcher who has already applied to a Fondazione Telethon Call but has never been funded; he/she may submit a New or a Revised Application.
- *Former Grantee*: is a researcher who has already been funded by Fondazione Telethon Call in the past; he/she may submit a New, a Revised or a Renewal Application.

Type of Application – Choose the appropriate option: New Application, Renewal Application, Revised Application:

- **Renewal Application**: indicate the **Previous Application Number** of the project for which the Lead Applicant is asking for a renewal and select the **Previous role** of the Applicant. An Applicant submitting a Renewal Application must fill in the **Previous Achievements** field:

Previous Achievements (max 15,000 characters) – The Applicant must state the original goals and the scientific achievements obtained in the project for which the Applicant is asking for a renewal. The Applicant must list the derived publications, if any.
- **Revised Application**: revised proposals are specifically those Applications submitted once (but not funded) to a previous Fondazione Telethon Multiround Call. Indicate the **Previous Application Number** and the **Previous role** of the Applicant. An Applicant submitting a Revised Application must fill in the **Cover Letter** field and attach a copy of the **Review Summary of the Previous Application**:

Cover Letter (max 15,000 characters) – If the previous Application was excluded by Triage, the Cover Letter must highlight the relevant modifications made. If the previous Application underwent Full Review, the Cover Letter must include a detailed reply to the critiques.

Review Summary of the Previous Application – Attach the Review Report of the previous Application in this section. If needed, contact the Fondazione Telethon scientific staff (telethonscience@telethon.it).

Please, note that if a Research Project is not funded in one round, it can be re-submitted as Revised Application to another round only once. Applications submitted twice to previous rounds of this Call (Multiround Call 2021-2024) are not eligible.

Overview

Abstract (max 2,000 characters) – Provide the following information:

- Broad objectives and specific aims
- Background/Rationale
- Research design and methods
- Anticipated outcomes

For Multicenter proposals, please fill in the following two sections:

- **Coordination and Management – Multicenter Studies only** (max 4,000 characters) - The Lead Applicant should specify in this section how the multicenter project will be managed, indicating strategies aimed at:
 - monitoring activities of all centers
 - facilitating communication
 - promoting exchange of ideas and methodological approach
 - stimulating the analysis and the integration of results
- **Role and Contribution of the Partner in the Project – Multicenter Studies only** (max 4,000 characters) - The Lead Applicant is asked to describe the contribution of the Partner, explain why he/she is necessary to the success of the project, clarify the complementarities of approaches that justify his/her participation and to highlight how the synergy among them will produce greater results over the sum of individual contributions.

Lay Summary – English (max 2,000 characters) – Summarize the project using an English **lay** language. This description is meant for communication purposes and, as such, it may become public information. Therefore, do not include any proprietary/confidential information.

Project Title – Italian (max 200 characters) – Insert the title of the project in Italian.

Lay Summary – Italian (max 2,000 characters) – Summarize the project using an Italian **lay** language. This description is meant for communication purposes and as such, it may become public information. Therefore, do not include any proprietary/confidential information. *Please, consider that the lay abstracts are fundamental parts of the application and Fondazione Telethon may slightly modify both Lay Abstract texts for communication purposes and that this information will be available on Fondazione Telethon website in case of projects approved for funding.*

Of note, some fields will be populated only after clicking the *Save draft* button. We recommend saving the draft application frequently, or at least every time a section has been completed.

Type of Research

Disease Name – Write the disease(s) name(s).

Please note that this part has to be filled in and has to be consistent with what is reported in the Lol phase.

Fill in all available Disease Codes:

- **Disease OMIM Number** – Fill in the **OMIM number of the Disease** as given by the Online Mendelian Inheritance in Man (<https://www.ncbi.nlm.nih.gov/omim?db=OMIM>);
- **ICD-11 Code** – (if not available please indicate “n.a.”) as given by the International Classification of Diseases (<https://icd.who.int/browse/2024-01/mms/en>);
- **ORPHA Number** – (if not available please indicate “n.a.”) as given by Orphanet (<https://www.orpha.net/consor/cgi-bin/index.php?lng=EN>).

If more than one disease is addressed, please separate names, OMIM numbers, ICD-11 codes and Orpha Numbers with semicolons.

MeSH Terms (max 5) – Indicate up to five MeSH terms appropriate and specific for the proposed research (<http://www.nlm.nih.gov/mesh/meshhome.html>) by clicking on **Add/Edit** button. Please, be aware that the field will be visible on the Application only after clicking on **Save Draft**.

Research Type and Area of Research – Select all that apply.

Research Steps – Select the research steps that best represent the proposed study (all that apply):

- genetic studies
- studies on mechanisms
- therapeutic approaches in vitro
- therapeutic approaches in vivo

Research Proposal

Stage of Development

Indicate the proposed **Starting and Ending stages of development** of the proposed project, referring to the Fondazione Telethon Development Pathway (FTDP) indicated in the Call for Application and choosing among the options below, **specific for each track**. For further details, please refer to the Call.

Basic Research track:

0. New knowledge
1. Research on mechanism/the disease
2. Target identification
3. Target Validation

Preclinical PoC track:

4. Therapeutic approach identification
5. Preclinical Proof of Concept

Extensively justify each choice (max 1,500 characters) in the relevant text box.

Research Plan

Fill in all the fields as follows:

Hypothesis, Background and Rationale (max 8,000 characters) – State the main hypothesis to be tested and explain the impact of the problem addressed by the proposed project. Critically evaluate the existing knowledge and identify the specific gaps to be filled to progress in the relevant field.

Preliminary results (max 8,000 characters) – Provide an account of preliminary unpublished studies performed in the Applicant’s laboratory relevant to the proposed research. Preliminary data are an essential part of a research project Application, as they aid the assessment of the likelihood of success of a project. Results are considered ‘preliminary’ only if unpublished.

Figures for preliminary data – Refer to the **Figures** section (page 12) to create and upload the figures .pdf file (maximum file size is 50 MB).

Specific Aims and Experimental Plan – Click on add/edit button to enter detailed aims with a brief description, the experimental plan and the expected outcome. List the specific aims of the project and for each aim provide the following information:

- Title
- Brief Description – What is the question being asked? What is the general experimental design?
- Experimental Plan – How are you going to address this aim? Please provide an extensive description of the experimental approaches. Explain the need for collaborations (if any) to achieve the scientific aim. Indicate how the idea of collaborating originated, the different approaches each collaborator will bring to the overall study, and how the collaboration will be conducted. Include an explicit description of the collaborative elements that are essential for the project to be carried out. Collaborators are expected to have research experience and must have an established record for independent research.
- Expected Outcomes – Describe the expected outcomes.

Figures for the Research Plan – Refer to the **Figures** section (page 12) to create and upload the figures .pdf file (maximum file size is 50 MB).

Feasibility, Possible Pitfalls and Alternative Approaches (max 3,000 characters) – Please explain how the proposal is focused on achieving specific and feasible goals. In addition, please state which pitfalls could arise during the research activity and the alternative plans that will be implemented.

Significance and Innovation (max 3,000 characters) – Describe how the scientific knowledge will be advanced if the aims of the project are achieved. Indicate if the project employs novel concepts, approaches or methods and if it challenges existing paradigms in the field or develops new methodologies or technologies.

Possible evolution of research, if successful (max 3,000 characters) – Please provide details for future development of the proposed research.

Unmet medical need and relevance to Fondazione Telethon’s mission (max 3,000 characters) – Please explain how the results of this research fill a gap in knowledge and will have impact on an unmet medical need for the disease under study. Clearly specify how the goals of the project fit with Fondazione Telethon’s mission (<http://www.telethon.it/en/what-we-do/ourmission>).

Background Intellectual Property (max 3,000 characters) – Indicate any intellectual property where the Applicant is an inventor, and any intellectual property owned by the Applicant or by a third party that would be necessary for the development of an approach to treat the disease/syndrome based on the results of the proposed project. For Applicant’s intellectual property, please indicate freedom to operate for such development.

Gantt Chart – Upload a GANTT chart describing the timeframe foreseen for the different specific aims and their components (max 50 MB).

Cited Literature (max 20,000 characters) – Please list all references. The list must include the name of all authors, year of publication, title, book or journal, volume number and page numbers. Concise references are not allowed. The complete list of references will be visible to Reviewers.

Ethical Documents

Human Subjects – Indicate whether the study involves (consider both Applicant and collaborator(s) activities):

1. Human samples not requiring an Ethical Committee approval (e.g. samples from external biobanks, commercial cell lines, etc.);
2. Human samples/data requiring an Ethical Committee approval (e.g. biological/genetic material, health/genetic information, etc.);
3. Individuals enrolled in clinical studies (e.g. clinical trials, registries); **NOT APPLICABLE for this call**
4. No human samples or subjects.

Please, note:

- If 2 applies, indicate if the Ethical Authorization is already in place (or not) or is in progress.
- If 1 or 2 applies, also specify the origin of the samples in the mandatory box (max 2,000 characters). If the study involves patient-derived samples, the Applicant must also include a summary of patients' details (e.g., age, sex, origin, genetics).

Vertebrate animals – Specify whether or not experiments involving vertebrate animals are planned at any time during the proposed project (Yes/No). If Yes, please indicate if the Ethical Authorization is already in place (or not) or is in progress.

Should the grant be approved for funding, funds will not be provided until the pertinent Ethical documentation has been obtained. Please activate in due time all necessary procedures to obtain this approval in accordance with the relevant Italian laws (<https://www.aifa.gov.it/modulistica-sperimentazione-clinica>). Be aware that the relevant approval documents must be provided for grant activation. For further details, please refer to “Regolamento di Gestione del finanziamento” of this Call and “FRRB - Linee guida Bando”

Host Institution

Applicant Details

Please provide all the information required in this section of the Application.

If the Applicant is not independent (i.e., he/she is not the Chief of the Laboratory), the name of the Chief of the Laboratory must be inserted in the corresponding field and **an Independence statement must be uploaded** in the dedicated box. Please note that the Independence Statement **must be provided and signed by the Chief of the Laboratory** and should contain the name of the Applicant, the Application Title and a clear statement highlighting the Applicant's capability to carry out the proposed experiments in due time. Applications lacking the independence statement (when required) will not be accepted.

Should the Applicant hold other appointments (including foreign appointments), those must be indicated in the **Other Appointment** section.

Financial Interests disclosure (max 1,000 characters) – Declare all possible financial conflicts of interest that might be perceived as relevant. Financial interests will not invalidate the Application, nor will they automatically disqualify it from being evaluated.

Facilities and Resources

Laboratory Space, Clinical Resources, Office Space, Major Equipment, Core Facilities and Services, Other –

Provide all the information requested and list all the key facilities available for implementing the project.


Contacts

This section includes information about the Institution Signatory, the Collaborators, and the Partners (in case of multicenter proposals) allowing to invite them, respectively, as Organization Approver, Project Collaborator(s), and Partner(s).

Approver

The **Institution Signatory** will have to be a person (**Institution’s Director or Responsible Official or Administrative Representative**) who, representing the Organisation where the research project will be performed, will have the **responsibility for the Application approval**.

The Applicant must use the lookup tool to add as Institution Signatory role one of the listed institutional contacts already registered in the platform. There must be at least one Institution Signatory indicated on the Application in order to submit it.

If an Institutional Signatory cannot be found using the lookup tool, please click on **Invite New Institution Signatory** to add a new institutional contact. The registered signatory will be notified via email to activate his/her account and complete the registration. If the Approver cannot find the automatic email, please check the spam folder as well (otherwise contact System admin at telethonscience@telethon.it). Personal email accounts are not accepted, please make sure that the Institution Signatory’s email is the institutional account. In case of error, the Approver can be deleted by checking the box placed on the left of the Institution Signatory’s name and then clicking on the  button.

By clicking on the **Send for Signature** button, the selected Institution Signatory will receive an email alerting that she/he has to take on the Application Approval role. The email contains the link to access the Smart Simple platform. In case of first access to the platform, please follow the registration instructions on the webpage; if already registered, clicking on the link in the invitation email will open the Login page of the portal.


The Applicant is invited to fill in the whole Application in due time, to allow the Institution Signatory to approve the Application to proceed for the final submission within the deadlines.

Please refer to the **Validation and Submission Procedure** section on page 23 for more detailed instructions on the Full Application approval process.

Collaborators


Collaborators are subjects involved in the project and, as such, their active contribution must be carefully described and justified in the Application.

Please note that collaborators cannot request a budget.

Use the icon  to select and invite collaborators. Once invited, collaborators will receive an email (please, check also the spam) containing a link through which they can accept or decline their role. The Applicant has to make sure each collaborator will accept his/her role through the automatic email. Once the invitation is accepted, “Active” collaborators will be able to see the online Application; additionally, they will have to send a **Collaboration letter** written in English to the Lead Applicant, properly dated and signed, exhaustively illustrating their role and contribution to the project.

In the Application, Active collaborators will be listed in a table displayed in the **Collaborators** section: the Applicant must click on the **Edit details** button of this section to complete the required collaborators' data and to upload the Collaboration Letters (pdf).

Please, carefully refer also to “Regolamento di Gestione del finanziamento” section 2 for policy related to collaborations with for-profit entities.

To remove invited Collaborators, click on  and then on ✕ icons displayed next to their names in the list.


Please, remember to save the draft through the *Save Draft* button.

Partners


Partners are subjects equally involved and equally responsible in the Application preparation and submission as Co-Applicant. Partners should pay attention to the **Guidelines and instructions**, as an Application failing to meet the requirements will be rejected.

Please note that, similarly to the Lead Applicant, if the Partner is not a holder of a permanent position, he/she can ask for a salary budget (please see the **Budget** section below).

Please be aware that for this Call the Applicant may add up to 1 Partner on the Application. **The Applicant will not be able to submit the Application if the number of Partners exceeds this limit.**

Use the icon  to select and invite a Partner. Once invited, the Partner will receive an email (please, check also the spam) containing a link through which he/she can accept the role. For registration to the portal, please refer to the **Applicant Account** paragraph on page 3.

Once accepted the invitation, the Partner will be able to see his/her Application, indicated by **the same grant code of the Lead Applicant's Application but in Pre-Draft status and with blank Call Name**. By clicking on it and upon acceptance of the Privacy Policies, the Partner can start working on his/her specific part of the Application package (indicated by the grant code followed by an “A”, e.g. GMR25B001 A) by following the Guideline Instructions. Within the Application, the Lead Applicant will be able to open the Partner Application within the **Partner Applications** tab, and vice versa.

To remove invited Partners, click on  and then on ✕ icons displayed next to their names in the list.

Of note, some fields will be populated only after clicking the *Save draft* button. We recommend saving the draft application frequently, or at least every time a section has been completed.

The Partner must click the **Send for Signature** button for the Institution Signatory approval. As for the Applicant, the Partner is invited to fill in his/her part of the Application in due time, to allow the Institution Signatory to approve the Application to proceed with the final submission within the deadline. The Partner must **Submit to Lead Applicant** to allow final submission of the Application package that will have to be completed by the Lead Applicant (please refer to the **Validation and Submission Procedure** section instructions on page 23).

Budget

Application Budget

Click on the **Edit Budget** button to open a new window where the Applicant will be able to enter the budget details.

The maximum total budget allowed for each research project is:

- TRACK Basic Research: max 240,000 € (**max 80,000 €/year**)
- TRACK Preclinical Proof of Concept: max 360,000 € (**max 120,000 €/year**)

Awards are contingent upon the availability of funds.

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 expressed in Euro; please use whole numbers only. Personnel (including the Lead Applicant or Partner) are defined as and should be limited to, key individuals whose contribution is deemed significant for the scientific development or execution of the project. Please note that personnel to be recruited (“to be named”) must be listed here and should be kept to a minimum to avoid delays in the project activation. To ADD an item, click on the relative button and fill in the required information.

DIRECT COSTS

The following expenses associated with the research project are **allowed** (for further details please see the document “Regolamento di Gestione del finanziamento”):

Scientific Equipment – Up to 20,000 € over the whole project period can be requested 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 conduct of the proposed research.

IT equipment – Up to 2,500 € over the whole project period can be requested. The requests for a personal computer should be clearly justified according to the research needs.

Materials, Supplies and Services – Materials and supplies must be listed by category: consumables, antibodies, reagents, etc. Services include items as animal housing (please provide the total number of animals and the cost per diem in the justification field), animal production (please specify if the service will be provided by a company), sequencing, peptide synthesis, biological material from biobanks, etc. Major cost items should be listed and properly justified.

Personnel & Salaries – Please include personnel (including the Lead Applicant or Partner), defined as key individuals whose contribution is deemed significant for the scientific development or execution of the project, and indicate for whom a salary coverage is requested.

For each person, the “role on the project” must be detailed (as an example, “molecular biologist performing mutational analysis” is appropriate, while “molecular biologist” is not sufficient). An inadequately described role in the project and/or a mismatch with the effort, as also expressed in the budget, may result in the reduction of the budget approved. Please note that personnel to be recruited (“to be named”) must be listed here and should be kept to a minimum. Consultants should be included only when their level of involvement meets the previous definition.

Budget can cover salaries up to 50% of the direct costs of the total budget, for personnel (including the Lead Applicant or Partner) not holding a permanent position.

Please enter these amounts only after having completed all the other fields included in the direct costs for the correct percentage calculation.

For each person requiring a salary, salaries must be proportionate to the effort dedicated to the project (i.e., Full Time Equivalent). Although not encouraged, salaries for “to be named” people may be requested. In this case, indicate the type of contract that will be applied, and the level of seniority required. The salary requested should correspond to the level of seniority and to the annual effort declared. The amount must refer to the total employee cost (gross amount plus employment taxes). If a salary is not required, enter 0 in the Salary field.

Travel – Travel costs for meetings/congresses (up to 3,000 € per year). Travel costs must be carefully justified (destination, purpose, and travel frequency) and adequately described in the project plan.

Project-related travel costs – Travels for collaboration/training purposes. Project-related travel costs must be carefully justified (destination, purpose, and travel frequency) and adequately described in the project plan. Costs allowed for travel are:

- o Transportation (train/airplane/car, etc.)
- o Lodging
- o Meals
- o Congress registration fees
- o Costs for producing posters related to participation in Congresses
- o Fees for submission of Abstracts to Congresses.

Other expenses – Each item cost should be detailed and justified.

- Allowed items: publication costs, reprints, journal subscriptions, books, samples and animal shipments. If software is requested, specify the necessity for the proposed research. Each item cost should be detailed and justified.
- Allowed items if overheads are not requested: repairing and maintenance of instruments, stationery, computer consumables (toner, external memory devices), mailing. Please detail the cost by item.

INDIRECT COSTS

Overheads – Up to 10% of the direct research costs per year.

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

- Full salaries for personnel with a permanent position
- 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.

Please remember to click on the *Save Draft* button placed on the right side of the page to display the Total Budget Requested on the Project Overview tab.

Other Financial Support

It is mandatory that the Applicant lists all the additional financial resources – active/current or pending grants (also from Fondazione Telethon) in direct support of his/her research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, and/or institutional awards. Please click on the **View/Edit** button to add or update Financial Support records.

Indicate:

- Project title
- Status: Current/Pending. If current, it is compulsory to indicate the relative period (From Date – to

Date)

- Gross amount
- Currency
- Granting agency
- Brief description of the project
- Overlaps with this Application, if any

Please, remember to click on the **Save Draft** button placed on the right side of the page to display the resume table.

Biosketch

The Applicant must complete/update the Biosketch according to the instructions at page 8.

In addition, it is **mandatory for the Applicant to download the Biosketch template** from the Reference Documents on top of the Application, fill it out and **upload it as a .pdf** in the relevant box. The Biosketch may not exceed 5 pages, including the table at the top of the first page, excluding relevant publications. Figures, tables, or graphics are not allowed.

Reviewers

Please click on **Add/Edit** button to add or update reviewers.

Suggested Reviewers – The Applicant may suggest reviewers **not currently working in Italian Institutions** and experts in their fields of research, who could competently review the Application. Co-authors in scientific publications and/or individuals who have been associated with the Applicants within the last 5 years will not be considered suitable. Fondazione Telethon reserves the right to choose reviewers independently.

Excluded Reviewers – Should the Applicant prefer to exclude direct competitors from being chosen as reviewers, their names can be indicated here.

Click Save and Save Draft to update the suggested/excluded reviewers. This insertion will be then displayed in a dedicated table on the Reviewers tab within the Application.

Declarations

Notes

(max 5,000 characters) - Any personal comments, details or additional information the Applicant wishes to add to any specific sections of the Application can be inserted here. The Applicant must indicate which section they are referring to and the reasons for including more information.

Supporting documents

Please attach any supporting documentation (if any). It is possible to upload .pdf files and .jpg files.

Declarations

The Applicant must certify that the information included in the Application is accurate and complete, that they are entitled and/or authorized to disclose all the information provided within the Application and that they comply with Fondazione Telethon ETS's terms and conditions.

Full Application Submission

The deadline for online submission is by the **end of June 2025** (the date will be confirmed in the letter of invitation to submit the Full Application).

Validation and Submission procedure

Single- and bi-center proposals follow two separate procedures for submission, which are explained in this section. Please follow the relevant instructions, according to the specific case.

For single-center proposals:

Once the Application has been completed in all its parts by the Lead Applicant, clicking on the **Send for Signature** button placed at the bottom-right of the page will initiate the submission procedure.

Please, note that if there are sections that need completion or are wrongly completed, these will be shown in a tab at the top of the Application page during this phase: complete/correct all the highlighted fields before sending for signature again.

Once validated, the Application will be sent to the Institution Signatory email for approval (for further details, please refer to the **Contacts** section on page 18).

The Institution Signatory (Approver), after having accepted the *Host Institution Agreement Clauses* in the **Declarations** tab, can either **Submit** (approve) or **Send for Revisions** (reject) the proposal.

If the Application is **rejected** by the Institution Signatory, the Applicant will receive an email notification and the Application will be shown in the **In Progress** tab again. Please note that once modified, the updated version of the Application will then need to be sent for signature again and approved by the Institution Signatory to be submitted.

If the Application is **approved** by the Institution Signatory, this will be automatically shown in the **Submitted** tab on the **My Applications** Home Page and it cannot be further modified. Should the Applicants need to make some amendments before the Call deadline date, they are asked to write an email to telethonscience@telethon.it.

For Bi-center proposals:

Once the Application has been completed in all its parts, the Lead Applicant and the Partner can initiate the submission procedure of their respective part of the Application by clicking on the **Send for Signature** button placed at the bottom-right of the page.

Please, note that if there are sections that need completion or are wrongly completed, these will be shown in a tab at the top of the Application page during this phase: complete/correct all the highlighted fields before sending for signature again.

Once validated, the Application will be sent to the respective Institution Signatory emails for approval (for further details, please refer to the **Contacts** section at page 18).

The Institution Signatory (Approver), after having accepted the *Host Institution Agreement Clauses* in the **Declarations** tab, can either **Sign Application** (approve) or **Send for Revisions** (reject) the proposal.

If the Application is **rejected** by the Institution Signatory, the Applicant (or Partner) will receive an email notification and the Application will return in the **In Progress** tab again. Please note that once modified, the updated version of the Application will then need to be sent for signature again and approved by the Institution Signatory to be submitted.

If the Application is **approved** by the Institution Signatory, this will be automatically shown in the **Pending Submission** tab on the **My Applications** Home Page. At this point, the Lead Applicant will be able to submit the final version of the Application by clicking on the **Submit** button within the Application. The submitted Application will be automatically shown in the **Submitted** tab in the **My Applications** Home Page and it cannot

be further modified. Should the Applicants need to make some amendments before the Call deadline date, they are asked to write an email to telethonscience@telethon.it.

APPLICANTS SHOULD MAKE SURE TO PRE-SUBMIT THEIR PROPOSAL IN DUE TIME TO ALLOW THE APPROVAL AND SUBMISSION PROCEDURES TO BE COMPLETED WITHIN THE DEADLINE.

Before final submission, Applicants are invited to download the PDF of their Application to check all the sections; in particular check that all uploaded images are included in the PDF and are clearly legible. Please note that Applicants are liable for the contents and quality of the Application in its final version.

Fondazione Telethon ETS and FRRB hold the responsibility and authority to make the final decision on the Application's completeness and eligibility.

Rome and Milan – February 18, 2025

FONDAZIONE TELETHON ETS and FRRB