



# **REQUEST FOR APPLICATIONS**

# RTFCCR/LUNGevity Award for Overcoming Treatment Resistance and Technology for Detection of Recurrence of Lung Cancer

Rising Tide Foundation for Clinical Cancer Research ("RTFCCR") and LUNGevity Foundation ("LUNGevity") are issuing a request for applications (RFA) to support interventional clinical trials aimed at Overcoming Treatment Resistance or Detecting Recurrence of Lung Cancer.

Awards totaling up to USD 1,000,000 (USD 500,000 from LUNGevity and USD 500,000 from Rising Tide) for will be funded for a duration of up to 4 years. We anticipate funding at least one award through this mechanism.

RTFCCR and LUNGevity advise applicants to read the entire RFA, before starting an application. An applicant who is deemed ineligible for this award and/or does not follow the instructions for the application and the patient partners involvement plan will be disqualified and the application not reviewed.

This award application process will be managed through the RTFCCR online platform SmartSimple [SmartSimple | Rising Tide Foundation].

Rising Tide and LUNGevity are partnering to support interventional clinical trials that investigate approaches to overcoming resistance, as well as technologies for detecting recurrence.

Successful applications will be early-phase interventional clinical trials focused on:

- 1. Treatments to address or prevent resistance to the treatment of lung cancer.
- 2. Improving existing or validating new lab-developed tests (LDTs) to identify and monitor the emergence of treatment resistance and/or response to therapy.
- 3. Improving existing or validating new lab-developed tests (LDTs) to identify and monitor minimal/molecular residual disease.

#### Notes:

- 1. Projects may span any stage or histology of lung cancer.
- 2. Proof of access to a biobank to develop an LDT is required. Funds will not be provided to create a prospective biobank.
- 3. A complete clinical protocol, IRB-approved, IRB-submitted, or ready for IRB submission, is required.





The research project(s) that will be funded is expected to have a direct clinical impact on patients with lung cancer.

Final selection will be contingent on scientific review and availability of funds. If you have any questions, please contact us to clarify scope of your project.

## **Background**

Lung cancer is the largest cause of cancer-related mortality in the United States and globally. It is a highly heterogenous disease. Histologially, lung cancer is divided into non-small cell (85%) and small cell (15%) lung cancer. These histological subtypes have distinct biologies that along with the stage of the disease at diagnosis inform treatment and prognosis.

Currently, there is a paucity of tools to proactively detect emergence of resistance to targeted therapies and immunotherapy. Most approaches to targeting resistance depend on post-relapse analysis of either tumor tissue or a blood sample to determine the next course of action.

Therefore, LUNGevity and RTFCCR decided to launch the joint call for proposals to support clinical trials within this field.

## Award eligibility

Education and Experience: At the time of the award term, an applicant (who must be a principal investigator for the proposed research) must hold a doctoral degree and faculty appointment (or equivalent) with an academic institution, including research institutions that are not formally associated with a university and have completed a postdoctoral training fellowship. An applicant may be at any level of research experience.

An applicant must be an independent, self-directed researcher for whom their institution provides space and other resources customary for independent investigators. The application must convey the commitment of the institution to both the applicant and the proposed research activities. An applicant with an existing Rising Tide award or a LUNGevity award that would be concurrent with Rising Tide/LUNGevity Award is precluded from applying.

<u>Geographical Restriction</u>: International teams are highly recommended, and the Award Program does not have any geographical restrictions.

The application must be submitted in English.

**For US applicants only**: Applicants are <u>not</u> required to be U.S. citizens or to be employed by a U.S. institution. **At the time of application, if an applicant is employed by a U.S. institution**, they must be a United States citizen or a foreign national holding





one of the following visa immigration statuses: permanent resident (Green Card), exchange visitor (J-1), temporary worker in a specialty occupation (H-1, H-1B), Canadian or Mexican citizen engaging in professional activities (TC or TN), or temporary worker with extraordinary abilities in the sciences (O-1). This applicant/awardee must be employed by a U.S. institution throughout the duration of the award term.

#### Award information

#### Award Structure and Allocation:

Investigators may receive **up to** USD 1,000,000 per project, over three years.

Award funds may be used for the salary and fringe benefit costs of personnel other than the applicant. Fringe benefit costs may only be expended upon the stipulation that they cannot be obtained from another source. No more than 25% of the requested budget may be used for an investigator's salary and/or fringe benefits. Travel costs for investigators cannot be covered by this grant.

Please note that indirect costs, such as overhead, are not covered.

Allowable costs for clinical trials include: expenses related to subject recruitment (such as participation cost reimbursement, , phlebotomy charges, etc.), clinical laboratory analyses of human subjects or their samples (such as clinical laboratory assays, imaging charges, etc.), and correlative validation studies. The award may be used to help with operational costs, The investigator is required to procure funding to cover the remaining cost of the trial, a fundraising plan will be requested as part of the application. **Drug costs will not be covered**.

<u>Duration</u>: The **Rising Tide/LUNGevity Award** may be granted for up to 4 years.

The following criteria must be met for the proposed clinical trial:

- 1. The study must be an early-stage interventional clinical trial.
- 2. The study may improve existing or newly developed tests, test methods, technologies, or devices.
- 3. Population screening or companion diagnostic studies are not supported in this funding mechanism.
- 4. Patient research advocates or patient organizations (patient partners) must be involved in the proposed study from its beginning.

Final selection will be contingent on scientific review and availability of funds.

## Factors considered in evaluating applications

Some of the factors considered when reviewing applications include:

 Innovation – Does the project address a major unmet need in treatment or diagnostics?





- Scientific merit and feasibility of the research plan Does the investigator have access to the appropriate tools and samples to conduct the proposed research within a reasonable timeframe? Have they identified a strong research team?
- Impact How will the research findings from the project move to the clinic and impact patients? What plans does/do the applicant(s) have for the clinical application of the findings of the project?
- Study design and its burden on patient participation, i.e., how difficult is it for patient participants to participate in the proposed study? We recommend study designs that support the inclusion of a diverse group of patient participants
- **Research environment** Does the applicant have access to institutional resources required for the successful completion of the proposed project?
- Appropriateness of the requested budget to complete the proposed research project. Factors used to evaluate the budget include total costs of the trial, the amount requested and the plan to secure the remaining funds.
- Patient Partners involvement activities: How patient partners will be actively engaged in the study from the development of research questions through dissemination of study results. Specific guidance for preparing a Patient Involvement Plan can be found in this document and supplied upon request.





## **Application Instructions and Timeline**

Applicants will be allowed to submit their letter of intent (LOI) from December 15, 2025.

All applicants are invited to contact either of the foundations for any question or issue encountered during the application process.

#### **Application process**

The application process involves the following steps:

- Letters of Intent (LOI) are submitted online through our grant management system SmartSimple (SmartSimple | Rising Tide Foundation) with a deadline of **February 15, 2026**. They will be assessed by internal staff and advisory board members of both foundations.
- Full Grant Application: the most promising LOIs that align with our RFA topic will be invited to submit a full grant application online.
- Grant Review Committee: full grant applications are reviewed by our grant review committee, a panel of external experts that carries out a comprehensive scientific review. Each application is independently analyzed and ranked by scientific peer reviewers, patient experts and biostatisticians on the panel.
- Recommendations made by the grant review committee are submitted to the RTFCCR's and LUNGevity's boards of directors for final funding approval. Upon approval recipients will be notified of the award, no later than a month after the board meeting. Declination letters will be sent to those who were not successful in their application.

## **Application requirements**

Please note, all applications should include the following information as requested in the SmartSimple platform:

- The curriculum vitae (CV) of the principal investigator and co-investigators (max 2 pages each; please upload all CVs as PDF files in SmartSimple).
- A description of the proposed research project (organized in a manner similar to that required by the US National Institute of Health [PHS 398]), including:
  - Specific aims
  - Background and significance
  - Preliminary results and studies explaining the significance and potential for success
  - Experimental design and methods
  - Statement of objectives regarding how the study can change the current standardof-care for today's patients or how it will create evidence to treatment or diagnostics
  - Detailed schedule of activities for a patient participants in the study
  - Explanation of why the treatment may be helpful to patient participants
  - Description of criteria used in determining results (included quality-of-life measurements if applicable)
  - Statistical analysis section outlining approach taken to make study scientifically valid
  - Amount of time before the opening of the study upon approval for funding





- Statement of next steps for research upon achieving positive or negative results
- Description of how milestone achievements for the study are achieved
- Completed Patient Partners Involvement Plan (for more information please refer to the paragraph in this document).
- Current, active Institutional Review Board (IRB) or Ethical Committee (EC) approval letter for the study. If the IRB/EC has not been obtained at the time of proposal submission, please indicate the expected timeline for obtaining the approval [if applicable].
- Letter from department head stating institutional commitment to the project, no competing studies, and verification to accrue a valid patient participant population.
- Break-down of costs of the trial, detailing the amount of the total costs, the amount requested (including costs related to patient partners involvement) and the plan for acquiring the eventual remaining funds (fundraising-plan).
- List of other sources of financial support for the project (include all sources applied pending and/or active).
- Industry letter stating permission for the use of the investigational agent, who is supplying that agent for the study, and the in-kind amount of that contributed agent [if applicable].
- List of literature cited.

#### **RFA Timeline**

Tasks	Dates
Launch of Call	December 15 2025
Deadline for LOIs	February 15, 2026
Deadline Full Applications	March 31, 2026
Approval / rejection	End of August 2026

## Grant agreements and conditions of continued funding upon approval

- Once an award selection is made, LUNGevity Foundation and RTFCCR will each issue a separate funding award agreement that would cover 50% of the total awarded budget.
- The milestone table in the agreement will be agreed upon by the foundations and the grantee institution and will be used for demonstration of progress provided by progress reports twice/year.
- The payments are made twice a year upon demonstration of progress, as defined in grant award documentation
- Any modifications to the approved study, its Patient Involvement Plan, protocol, timeline, expectations, funding sources, patient participants status, and exact reason for any patient's discontinuation of study participation, etc. should be notified to the 2 foundation promptly





• RTFCCR and LUNGevity may require their grantees to talk to and meet staff, board members, or anyone else pertinent to the continued funding of the study (i.e. at the annual LUNGevity science meeting).

# Royalties and Intellectual Property (IP)

The processes and approaches may differ between LUNGevity and RTFCCR, and as such, LUNGevity and RTFCCR will conclude separate grant agreements with the grantee, each using its own terms and conditions.

# **Application Assistance**

For answers to questions regarding programs, eligibility, policies, terms and conditions, or instructions for the letter of intent or full application, please contact:

Upal Basu Roy Executive Director of Research ubasuroy@LUNGevity.org Karolina Werynska Scientific Program Manager Karolina.werynska@risingtide.ch

For help with the Smart Simple electronic application process, please contact:

Karolina Werynska Scientific Program Manager Karolina.werynska@risingtide.ch





## **Guidance for Planning Your Patient Partner Involvement in Research**

Throughout this document, we adopt the definition of Patient Partner provided by Patient-Centered Outcomes Research Institute (PCORI). PCORI's definition of patient partners includes patients (those with lived experience), family members, caregivers, and organizations that are representative of the population of interest in a particular study.

Early involvement of Patient Partners, based on co-design principles, allows a better formulation of relevant research questions, more credibility of the knowledge produced, identifying and solving potential challenges faced during the project, and better application of outcomes to specific contexts.

Here is a checklist to help you plan Patient Partner Involvement and complete our Patient Partner Involvement Plan table required to be submitted as part of the LOI. It encompasses points that should be considered during the application phase, implementation of the project, and beyond the project.

#### **Patient Partner Involvement in Research**

Partner Involvement Plan template required to be submitted with your Letter of Intent.		
Before the project starts  ☐ Patient Partner Involvement is planned across the entire project lifecycle ☐ The most appropriate Patient Partner Involvement model is selected ☐ The appropriate Patient Partners are involved early in formulating the concept, hypothesis ☐ Appropriate budget for patient partners involvement activities and compensation of Patient Partners is reflected in the Patient Partners Involvement Plan and the overall grant budget request		
During the project  ☐ Assessment of needs of trial participants by Patient Partners is included ☐ Adaptation of trial and procedures where necessary to meet trial participants' needs ☐ Assessment of the impact of patient partners involvement in your project at mid-term and at the end of the project is considered		
Beyond the project  ☐ Communication and dissemination activities involving patient / public partners is planned after project end  ☐ Collaboration with patient community on trial outcomes is planned		





For more information, please refer to: <a href="http://synapse.pfmd.org/resources/considerations-guide-to-implementing-patient-centric-initiatives-in-health-care-product-development/download">http://synapse.pfmd.org/resources/considerations-guide-to-implementing-patient-centric-initiatives-in-health-care-product-development/download</a>

Note: Please consider the choice of your patient advocates that you engage in order to select the ones who can best add value to this project

## **Choice of Model of Patient Partner Involvement in Research Projects**

Research teams should think carefully about the activities across the whole project lifecycle that the Patient Partners could undertake. Short term activities are easy to define upfront, but it is more challenging to think about sustained involvement across the entire project.

Therefore, depending on the research project, it is important to think about the most applicable role of a Patient Partner for contributing in a clinical research project:

Patient role	Examples	Involvement level
Team Member role	<ul> <li>Patient Partners provide a priori and continuous consultation on outcomes of importance, study design, etc.</li> <li>Patient Partners are paid investigators or consultants</li> <li>Patient Partners have a governance role – "a seat at the table"</li> </ul>	High
Advisor role	<ul> <li>Patient Partners serve as advisory committee members or provide a priori consultation on outcomes of importance and study design, but have no leadership role or governance authority</li> </ul>	Moderate
Reactor role	<ul> <li>Patient Partners input is collected distally through surveys, focus groups or interviews, but patients are not consulted directly or a priori on such things as study design and outcomes of importance</li> <li>Patient Partners are asked to react to what has been put before them rather than being the origin of the concepts of interest</li> </ul>	Low

#### **Patient Partner Involvement Plan**

We require you to submit a "Patient Partner Involvement Plan" as part of your LOI and Full Application. The plan should describe Patient Partner Involvement processes during the generation of the project application as well as during the implementation of your project. It describes Involvement e.g., how you engaged with the patient partner(s) when your research question was defined, while the proposal is written, when it is being submitted and resubmitted, and which patient partner involvement model you chose for the implementation of your project.

When developing your project budget, please make sure that adequate and realistic resources for Patient Partner Involvement are reflected in the Patient Partner Involvement Plan and the overall grant budget request. This could include e.g. appropriate budget for work time (staff or contractors in patient organizations) as well as project-related pass-through costs (e.g. travel expenses and meeting venue costs).





Different phases of research will need different activities to ensure patient partner involvement is implemented in the way defined in this document.

For the LOI and full application, please submit your Patient Partner Involvement Plan through the online submission platform.

- Each Patient Partner Involvement Plan should have: . , Activities proposed listed and properly described
- Activities proposed designed for patient partners and with patient partners
- The results of these activities are implementable in the clinical trial design or execution to ensure patient needs are met

Please be very clear at the outset about what you expect to achieve and what metrics – both quantitative and qualitative – you will use to measure progress against and achievement of both overall research goals and specific patient-centricity goals.