

IMPORTANT NOTES TO READ BEFORE PROCEEDING

An applicant may submit only one application for a 2023 LUNGevity award. Applicants with an existing LUNGevity award that would be concurrent with a 2023 award may not apply.

LUNGevity Foundation ("LUNGevity") advises potential applicants to read this RFA in its entirety, including all eligibility requirements and other terms and conditions, before starting an application. Any applicant who is deemed ineligible for this award or does not follow the instructions for preparing the application will be disqualified and the application not reviewed.

LUNGevity Foundation Career Development Awards are intended to support biomarker-directed translational research in early detection or treatment in a career development context. Awards will be funded at a maximum of \$100,000 per year for three years, for a total award of \$300,000. Only one Career Development Award will be granted per institution, although more than one applicant from an institution may apply.

In 2023 LUNGevity is partnering with Lung Cancer Initiative; applications from North Carolina are encouraged.

A two-step application process will be used. Applicants must first submit a letter of intent (LOI). Only a subset of applicants will be invited to submit a full application after the LOIs are reviewed. The application process will be managed through proposalCENTRAL.

At the time of submission of the LOI and throughout the duration of the award term, an applicant/awardee must be employed by a U.S. institution.

Important Dates:

- February 27, 2023: Letter of Intent (LOI) deadline
- May 8, 2023: Full applications due from invited applicants
- Late Summer 2023: Award notifications made
- November 1, 2023: Awards begin

Detailed instructions for applying for this award begin on page 11.

LUNGEVITY FOUNDATION

LUNGevity Foundation is a 501(c)(3) philanthropy specifically focused on funding research for the early detection and effective treatment of lung cancer. LUNGevity's mission is to improve mortality rates of lung cancer patients through the development of protocols and tools for early detection of lung cancer, early intervention in the disease progression, and treatments, including targeted therapy and immunotherapy. LUNGevity focuses on translational science. For more information

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about LUNGevity Foundation, please visit www.LUNGevity.org.

FUNDING OPPORTUNITY DESCRIPTION

Overview

LUNGevity's Career Development Awards for Translational Research program was created with one goal: to support future research leaders who will keep the field of lung cancer research vibrant with new ideas. Research projects are restricted to translational lung cancer research, and the applicant must demonstrate the translational relevance of the research proposed. The CDAs are mentored awards; a mentoring plan is part of the required submission. The awards may be for a maximum of \$100,000 (direct and indirect) per year for three years, for a maximum award of \$300.000.

AWARD PROGRAM REQUIREMENTS

Funded projects are expected to have a direct impact on the early detection of lung cancer or on the outcomes of lung cancer, or to provide a clear conceptual or experimental foundation for the future development of methods for early detection and/or individualized treatment, including through targeted therapy and immunotherapy.

High-risk, high-return proposals will receive equal consideration. Translational research includes epidemiology studies, and clinical correlative studies are encouraged. Proposed projects must make use of human biopsies or samples. *In vivo* primary tumor explants meet these criteria, but xenografts from established cell lines do not.

Translational research includes epidemiologic, clinical/correlative, or thoracic surgical research.

The following types of research will *not* be funded:

- Pre-clinical drug development studies, such as toxicology or library of compound screening
- Purely animal models or *in vitro* models, unless it has a companion part of the study in human specimens
- Basic discovery of drug targets or disease pathogenesis

The use of existing resources is encouraged, including libraries of compounds or probes, tissue or biospecimen repositories, and other existing sets of tissue, blood, or images. It is strongly encouraged that those applying have direct and immediate access to the biospecimens necessary to complete their research.

Awardees are required during the duration of the award term to share their research progress with LUNGevity staff, members of the LUNGevity Scientific Advisory Board, study section reviewers, and other LUNGevity awardees. Awardees are also expected to attend the annual LUNGevity Fall

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Science Meeting to present on their progress and participate as *ex officio* members of the LUNGevity Scientific Advisory Board.

Eligibility

If an applicant does not currently meet an eligibility requirement at the time of application, but will meet it prior to the award start date OR has special circumstances that prevent it from being met, the applicant must notify LUNGevity at the time of LOI submission. This information should be attached to the applicant's biosketch and should be no more than one page.

<u>Education and Experience</u>: At the start of the award term, the applicant, who must be the principal investigator for the proposed research, must:

- 1) hold a doctoral degree and be within the first five (5) years of his/her first faculty appointment with any academic institution, including research institutions that are not formally associated with a university
- 2) have completed a training fellowship.

An applicant may be at any level of research experience. Because the award term for the 2023 Career Development Award begins on November 1, 2023, an applicant's first faculty appointment must have begun no earlier than the start of the 2018 fall semester. The exact start date should be included in the biosketch. If an applicant has had time off for personal or family leave, this time shall not count toward the five years.

An applicant must be an independent, self-directed researcher for whom their institution must provide space and other resources customary for independent investigators. The application must convey the commitment of the institution to the applicant and the proposed research activities.

If it is not clear from an applicant's title or from the employment information in the biosketch that a position is considered to be faculty, a note of explanation/confirmation should be included in the personal statement.

If an applicant is not currently a faculty member but will be by November 1, 2023, a letter from the institution where the applicant will be a faculty member confirming the institution's commitment to the applicant and including the applicant's official start date should be attached to the LOI as well as the full application, if the applicant is invited to submit one.

<u>Support</u>: At the beginning of the grant term, an applicant may NOT have a major award, such as an RO1, DOD, or Merit review, or a Career Development Award, such as a K07, K08, K22, or K23. An applicant is not eligible for this award if the applicant has any award(s) valued at

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\$100,000 or more annually.

<u>Citizenship</u>: At the time of submission of the LOI, an applicant 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). A non-citizen must submit a notarized copy of proof of possession of a Green Card or J-1, H-1, H-1B, TC, TN or O-1 visas.

<u>Employer</u>: At the time of submission of the LOI and throughout the duration of the award term, an applicant/awardee must be employed by a U.S. institution.

AWARD INFORMATION

Award Structure

LUNGevity Career Development Awards may be for a maximum of \$100,000 (direct and indirect) per year for three (3) years. No more than 60% of the requested budget may be used for an awardee's salary and/or fringe benefits. No more than 30% of the total award budget may go to fund the purchase of permanent equipment, and no more than 15% of the total award budget may be used for overhead/indirect costs.

Award funds may be used for the salary and fringe benefit costs of personnel other than the applicant.

LUNGevity Career Development Awards are subject to annual review. The second and third years of support are based on demonstrating satisfactory progress.

Award Payment Schedule

LUNGevity will issue the first-year award payment no earlier than November 1, 2023, following receipt of the fully executed agreement documents. LUNGevity will issue the second- and third-year payments following award renewal. Second- and third-year payments will be made only after the awardee's funding balance has decreased to \$25,000 or less.

An awardee may choose to temporarily stop their research at any point during their 3-year award term if they wish to take family or personal leave. To proceed with this, the awardee will need to inform LUNGevity staff of their plan and submit a revised timeline for approval by the LUNGevity Scientific Advisory Board.

Award Selection

Final selection of the project(s) to be funded will be contingent on scientific review and availability of funds.

Some of the factors considered when reviewing applications include:

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- Candidate potential to further progress in lung cancer research
- Mentoring and career plans
- Scientific merit, innovation, and feasibility of the research plan and its relevance to the mission of LUNGevity
- Research environment support
- Appropriateness of the requested budget and timeline to complete the proposed research project

OTHER TERMS AND CONDITIONS

Following are other terms and conditions that apply to the LUNGevity Career Development Awards. A more detailed set of terms and conditions will be included in the agreement document for funded projects.

Animal Use

LUNGevity allows animal use in biomedical research only when no other means of obtaining scientifically sound, valid, and useful results are available. Applicants must ensure that only the minimum number of appropriate animals required to obtain and validate results shall be used. In cases requiring the death of an animal, only the most appropriate and humane form of euthanasia shall be used consistent with the purpose of the research.

If animals will be used in the proposed research project, applicants must provide institutional endorsements that the research facility, its research, and its employees adhere to the appropriate animal welfare regulations in their country. In the U.S., these include:

- Animal Welfare Act
- USDA rules
- National Research Council Guide for the Care and Use of Laboratory Animals
- Public Health Service Policy on Humane Care and Use of Laboratory Animals

In addition to the above, applications must also include the following documents:

- Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) accreditation.
- Institutional Animal Care and Use of Committee (IACUC) approval.

A project is **not** eligible for an award if the research proposal involves animals and the institution does not have accreditation from the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC), **or** does not hold a current Public Health Service (PHS)

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Animal Welfare Assurance, **or** does not have accreditation from the United States Department of Agriculture, **or** does not have accreditation from the Institutional Animal Care and Use Committee (IACUC).

Authorized Award Holders

LUNGevity Career Development Awards are granted only to an individual; awards are not awarded to institutions. No award may be held by or transferred to another individual.

Biohazards

Biohazards are broadly defined to be recombinant and/or infectious and tumor materials that may be deleterious to normal organisms upon controlled exposure. Research involving biohazards requires one paper copy of the appropriate institutional committee approval at the time a full application is submitted.

Carryover of Funding

Carryover of funding into the next year requires prior approval by LUNGevity. All requests must be in writing and received by LUNGevity 60 days prior to the end of that funding year. When making the request, the awardee must indicate the amount and from what budget-line and to what budget-line the carryover monies are being applied. In the case of supplies or equipment, all items must be itemized.

Change in Budget

Requests for a change in budget that is 10% or more for a budget line requires prior approval by LUNGevity. All requests must be in writing and received by LUNGevity at least 60 days prior to the end of the current funding year. When requesting a change in budget, the awardee must indicate the amount to be transferred, the budget line the funds are currently included in and to where they would be transferred. In the case of supplies or equipment, all items must be itemized.

Change of Institution

Transfer of a LUNGevity award from one institution to another because of the relocation of the awardee requires prior approval by LUNGevity. All requests must be in writing and made as soon as the awardee officially knows of the relocation. A grant may not be transferred to a laboratory, clinic, hospital, or other research institution that is not affiliated with a tax-exempt not-for-profit institution. All unexpended funds must be returned to LUNGevity within 45 days of transfer approval. A grant agreement must then be executed by the new institution. After LUNGevity receives the unexpended funds from the original institution and the grant agreement has been executed with the new institution, the funds will be reissued to the new institution.

Equal Employment Opportunity

LUNGevity awards will be made to individuals working in institutions identified as Equal Opportunity Employers.

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Equipment and Supply Purchases

Upon conclusion of the award, equipment and supplies purchased with award funds become the property of the institution at which the work was done.

Equipment Expenditures

No more than 30% of the total award budget over the award term may go to fund the purchase of permanent equipment. Equipment is defined as an item that costs \$500 or more, has a primary function related to the research project, and ordinarily has a usable life expectancy of one year or greater.

Equipment Repair & Service Contracts

No portion of the award budget may be used for repair or service contract costs for institutional equipment.

Human Subjects

Whenever human subjects are a part of a LUNGevity-funded research project, the following documents must be received before any award monies are released:

- A copy of the Institutional Review Board (IRB) approval and approved patient consent forms
- A copy of the appropriate institutional committee approval for research involving human adult stem cells or use of human fetal tissue.

If the proposed research project involves human subjects, the population sampled shall be inclusive of the general population of relevance to the scientific question posed, without restriction in regard to gender, race, age, and socioeconomic status. Proposals that intentionally restrict the population sampled must include a compelling scientific rationale for such design.

LUNGevity encourages applicants to submit their projects to the appropriate human subjects Institutional Review Board at the time of application.

IRB approval and approved patient consent forms must be provided to LUNGevity before award funds will be disbursed.

Malpractice Liability

LUNGevity will not assume responsibility for and the institution will indemnify and hold LUNGevity harmless from any lawsuit, claim, judgment, damages, awards, or malpractice arising from research or investigations related to an award.

No-cost Extension

A no-cost award extension requires prior approval by LUNGevity. All requests must be in writing and received by LUNGevity at least 90 days prior to the award's official termination date. When making the request, the awardee must provide a detailed rationale for the extension, project expenses to date, and a detailed revised budget. Awardees may request a no-cost extension only

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once per award. Approval of the no-cost extension is not automatic and will only be granted in exceptional circumstances.

Other Funding

LUNGevity research funds will not be awarded to duplicate any work that is being supported by other funding agencies.

Overhead/Indirect Costs

Overhead or indirect costs are permitted up to 15% of the award but are not incremental to the award. Duplication of indirect costs on subcontracts is not allowed.

Patent and Intellectual Property Policy

Inventions and discoveries from research performed during the term of a LUNGevity award will be subject to the current LUNGevity patent policy as well as to the patent policies of the institution where the work is performed. The LUNGevity policy is described in full on page 10.

Presentation Posters

Posters prepared for the LUNGevity science meeting are the responsibility of the awardee to print out. The cost of printing comes from the funds awarded.

Progress Reports and Renewal of Funding

Annual written progress and financial reports (as well as presentations at the annual LUNGevity Science Meeting) are required. Interim progress reports are the basis for the decision to award subsequent years of funding. A final progress report is also required at the conclusion of the project along with a complete financial disbursement report covering the entire award period. The financial report must reflect the award expenditures as approved by LUNGevity. All unused funds must be returned to LUNGevity. In addition, any funds used for unauthorized expenditures or unexpended funds must be returned to LUNGevity.

Project Support Expenditures

No award shall be used for the purchase of furniture or computers, repair or service contracts, the construction or renovation of facilities, payment of honoraria or membership dues, tuition for either the awardee or other project personnel, the purchase of textbooks or periodicals, or payment for secretarial support.

Public Access Policy

LUNGEVITY established a public access policy in 2012 that requires all journal articles resulting from all or partial LUNGevity funding to be made freely available in PubMed Central (PMC) within 12 months of publication. It is the responsibility of the awardee to ensure that journal articles are deposited into PMC. LUNGevityhas adopted the procedures established by the Health Research Alliance (HRA) which has partnered with the National Library of Medicine (NLM) to enable HRA member-funded awardees to deposit their publications into PMC with an embargo no longer than 12 months. LUNGevity will provide a user guide.

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Publication Expenditures

The maximum amount of funds expendable for publication costs is \$1,000. All publication costs must directly relate to the LUNGevity project.

Publications and Conference Presentations

All publications and/or presentations at scientific conferences and meetings based on research conducted from this award must include a citation of LUNGevity as a supporting entity as follows: "This study was supported by a grant from LUNGevity Foundation." Reprints of abstracts, manuscripts, or other articles that reflect research done after award acceptance must be submitted to LUNGevity.

Tobacco-Funded Research

LUNGevity will not provide research or other funding to investigators who have received direct funding or funding from agencies of the tobacco industry.

Travel Expenditures

The maximum funds expendable for awardee travel are \$1,500 per year. Travel to LUNGevity meetings is paid directly by the Foundation and is not included in the allowable \$1,500.

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LUNGEVITY PATENT AND INTELLECTUAL PROPERTY POLICY

- a. All inventions or intellectual property made with support in whole or in part by research or training grants or awards from LUNGEVITY must be reported at the earliest practical time to the Research and Program Services Division. The grantee institution or individual awardee agrees to notify LUNGEVITY immediately of the decision to apply for letters patent or other legal protection for intellectual property, and to consider seriously and in good faith any comments or objections LUNGEVITY may have concerning such applications. LUNGEVITY agrees to keep all information confidential and to not release any information relating to such inventions, intellectual property or applications. All patenting expenses shall be borne by the grantee institution or individual awardee unless the intellectual property is ceded to LUNGEVITY (see paragraphs b and c).
- b. Title to any invention or intellectual property shall reside in the grantee institution to the extent that such title is claimed by the institution under its patent policy or procedure and paragraphs c-e shall apply. If a grantee institution has no established patent policy or procedure for administering inventions or intellectual property, or if the institutional patent policy or procedure does not claim rights for the institution or individual inventor, then LUNGEVITY shall have the right to determine the disposition of invention or intellectual property rights and paragraphs c-d shall not apply.
- c. No patent, patent application or other type of protection shall be abandoned without first notifying the Research and Program Services Division. At such time, the grantee institution and individual awardee shall give LUNGEVITY the opportunity to take title to the invention or other intellectual property.
- d. The grantee institution shall agree that when it licenses any invention or intellectual property it will obligate the licensee as follows: The licensee agrees to exert its best efforts to commercialize or cause to be commercialized the invention or intellectual property as rapidly as practical, consistent with sound and reasonable business practices and judgment. In the event that the licensee has failed to commercialize the invention or intellectual property within the number of years determined to be reasonable for the invention or intellectual property, the grantee institution upon conferring with LUNGEVITY shall have the right to convert an exclusive license to a non-exclusive license or to terminate a non-exclusive license. If the licensee or grantee institution has an ongoing and active research, development, manufacturing, marketing or licensing program as appropriately directed toward the production and sale of the invention or intellectual property, the same would be deemed to be sufficient evidence that the licensee or grantee institution has commercialized the invention or intellectual property.
- e. LUNGEVITY reserves the right to public acknowledgment for inventions or intellectual property resulting from support by LUNGEVITY; however, LUNGEVITY name and logo may not be used in association with an invention or intellectual property without prior approval of LUNGEVITY.

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APPLICATION INSTRUCTIONS AND TIMELINE

Templates and detailed instructions for required information/materials can be found at https://proposalcentral.com. Be sure to read those instructions in case any instructions were changed, added, or deleted after this RFA was issued.

Letter of Intent (LOI)

The letter of intent **must** include a narrative that contains:

- Rationale for the project
- Planned **specific aims** (these may be modified slightly if invited to submit a full application)
- Brief statement of the overall experimental approach
- Brief statement of career and mentoring plan
- A few pertinent **references**

The narrative should be typed in Arial 11-point type, single-spaced, with .5" margins. Identifying information, per the template, must be included at the top of each page. The narrative should not exceed a total of **three pages**, including the references. **Your LOI will not be considered if these instructions are not followed.**

The following items should be included as part of the LOI:

- An NIH biosketch (OMB No. 0925-0001 and 0925-0002) of the applicant only. Double-check that the information included is current and thorough. We will not be contacting you to clarify any information.
- If a non-citizen, **proof of visa immigration status**, as described under "Award Eligibility." This should be attached to the end of the biosketch.

No budget information or other supporting materials should be included with the LOI. A sponsoring institution signature is not required.

Templates and detailed instructions can be found at https://proposalcentral.com.

Letters of Intent are due by February 27, 2023 (11:59pm EST) via proposalCENTRAL. Extensions will not be given. Once an LOI has been submitted it cannot be changed.

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Applicants will be notified by email no earlier than **March 31**, **2023**, whether they will be invited to submit full application. LUNGevity will **not** provide feedback regarding results of the review of any Letter of Intent submitted.

Full Application

Only invited applicants may prepare and submit a full application. Instructions for how to proceed will accompany the invitation. Among other materials, the full application must include:

- A narrative to include these components:
 - Lay Abstract that explains your project completely in lay terms that will be clear to individuals who do not have a scientific background.
 - Scientific Abstract version that would be appropriate for a reviewer of a peer-review iournal.
 - **Background**: Present the ideas and reasoning behind the proposed research, to include relevant literature citations. Describe previous experience most pertinent to this application.
 - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
 - **Specific Aims:** Concisely explain the project's specific aims.
 - Research Strategy: Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches.
 - Statistical analysis plan: A detailed statistical analysis plan is required for all applications and is limited to one single-spaced page. The analysis plan should define the primary objectives, study design, and planned analyses supporting the study hypotheses. Justification of the proposed sample size or number of patient samples to be analyzed should be stated and include all parameters required for calculation: the type I error rate, power, and target effect size. Detail regarding analysis methods, groups to be compared, and other assumptions made (for example, regarding accrual rates, follow-up, etc.) should also be included. Ideally, the applicant will collaborate with a biostatistician on their grant proposal, including this analysis plan. In the event that methods from other quantitative sciences are planned (for example, bioinformatics or computational biology), it is recommended that the applicant also collaborate with experts from those respective fields to develop their application and analysis plan. It is recommended that candidates use a full page of the application for their statistical analysis plan.
 - Career and Mentoring Plan: Describe your career and mentoring plan in detail, based on the specifications below. We suggest using 1 full page of the application for the mentorship plan.
 - Show a logical progression from prior research and training experiences to the research and career development experiences that will occur during the award period and then to independent investigator status.
 - Describe clearly pertinent research and educational resources of your institution, including the research environment and the availability and quality of needed research facilities and research resources (e.g., equipment, laboratory space,

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computer time, available research support, etc.). This should include items such as classes, seminars, and opportunities for interaction with other groups and scientists in thoracic oncology research, as well as training in career skills, e.g., grant-writing, manuscript reviewing, mentoring, and making effective presentations.

- Describe the mentor's research qualifications, why they are well-suited for the role as mentor on the project.
- Includes a brief description of other faculty involved in mentorship besides the primary mentor.
- Addresses the value of the proposed fellowship experience and research training program for the candidate's preparation for a career as an independent scientist in thoracic oncology research.

References

The narrative should be typed in Arial 11-point type, single-spaced, with .5" margins. The narrative should not exceed a total of 11 pages (10 pages for the narrative plus 1 page for the mentoring plan), including the references.

- NIH biosketches (OMB No. 0925-0001 and 0925-0002) of the applicant and key personnel, including mentors. *Mentors must include a list of previous mentees and the mentees' current institutions.*
- Budget information by year, along with a justification
- Other Support: For the applicant only: Be sure to include the dollar amount of each award.
- If relevant, the following documents:
- a copy of the documents listed in the "Animal Use" section
- a copy of the biohazard document named in the "Biohazards" section
- a copy of proof of visa immigrant status as described in the "Award Eligibility" section of the RFA (this may be attached at the end of the applicant's biosketch)
- Do **not** include reprints of your previous publications.
- Include **letters of reference** from the mentors (ideally, both a clinician and a scientist from the translational lab) as well as from the chair of the department of the applicant's institution.

Templates and more detailed instructions for all of the above materials and any other materials that must be included can be found at https://proposalCENTRAL.com.

Full applications must be submitted via proposalCENTRAL by May 8, 2023 at 11:59pm EST. Extensions will not be granted. Once a full application has been submitted, it cannot be changed.

Applicants will be notified of award decisions by email in **Late Summer 2023**. Review comments will be provided for full applications only.

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Awardees will receive a formal agreement document at the time of or soon after award notification. This must be signed by both the awardee and an authorized representative of the sponsoring institution and then returned before any funds will be released. Funds will be released no earlier than **November 1, 2023.**

APPLICATION ASSISTANCE

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

Jody Roosevelt Research Program Coordinator <u>jroosevelt@LUNGevity.org</u> 847-525-2075

For help with proposalCENTRAL, please contact:

proposalCENTRAL Help Desk pcsupport@altum.com 800-875-2562

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