

IMPORTANT NOTES TO READ BEFORE PROCEEDING:

LUNGevity Foundation advises applicants to read the entire Request for Application, including all eligibility requirements and other terms and conditions, before starting an application.

The LUNGevity Foundation ("LUNGevity") 2022 Career Development Award is for biomarkerdirected translational research in early detection or treatment in a career development context.

The start date of the 2022 Career Development Award's grant term will be November 1, 2022.

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.

An applicant may submit only one application for a 2022 LUNGevity award.

An applicant who is deemed ineligible for this award and/or does not follow the instructions for preparing the application will be disqualified and the application not reviewed.

LUNGevity will grant only one Career Development Award per institution, although more than one applicant from an institution may apply.

The Career Development Award uses a **two-step application process**. An applicant must first submit a letter of intent (LOI). Because there are a limited number of awards, only a subset of applicants will be invited to submit a full application after the LOIs are reviewed.

Detailed instructions for submitting the Career Development Award application, including critical dates, begin on page 9.

LUNGevity manages its grant process within proposalCENTRAL.

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.

CAREER DEVELOPMENT AWARDS FOR TRANSLATIONAL RESEARCH 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.



Translational Research Project Requirements

The translational research projects that will be funded 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 we especially encourage clinical correlative studies. 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.

Successful applicants are required during the duration of their award to attend the annual LUNGevity Science Meeting (whether virtual or in-person), where they must present their research progress to the LUNGevity Scientific Advisory Board, LUNGevity staff, other reviewers, other awardees, and invited guests, as well as participate as *ex officio* members of the Scientific Advisory Board.

Award eligibility

If an applicant does not currently meet an eligibility requirement, but either will meet it soon or has special circumstances that prevent it from being met, the applicant must let us know at the time the LOI is submitted. A page with the information should be attached to the back of the biosketch.

• Education and Experience: At the beginning of the grant term, an applicant (who must be the principal investigator for the proposed research) must 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, and have completed a training fellowship. An applicant may be at any level of research experience. Because the award term for the 2022 Career Development Award begins on November 1, 2022, an applicant's first faculty appointment must have begun no earlier than the start of the 2017 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 his/her 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 the November 1, 2022, start date of the grant term, 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 (and full application, if the application movies forward.)

- <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 \$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

• <u>Award Structure and Allocation</u>: 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.

• <u>Duration</u>: LUNGevity Career Development Awards are subject to annual review and may be granted for up to three years. The second and third years of support are based on demonstrating satisfactory progress.

Factors considered in evaluating applications

Some of the factors considered when reviewing applications include:

- 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.

Whenever animal use is a part of a LUNGevity-funded research project, applicants must provide LUNGevity with institutional endorsements that the research facility, its research, and its employees adhere to the:

- 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, those applicants who are invited to submit a full application must include in their materials 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) Animal Welfare Assurance, **or** does not have accreditation from the United States Department of Agriculture, **or** does not have accreditation from the Institutional Care and Use Committee (IACUC).

Award Payment Schedule

LUNGevity will issue the first-year award payment no earlier than November 2022, 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.

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 and from what budget-line and to what budget-line the monies are being transferred. In the case of supplies or equipment, all items must be itemized.

Change of Awardee or Institution

No award may be transferred from the awardee to another individual. 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.

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 award shall be used for repair or service contract costs for institutional equipment.

Financial Reports

An interim financial report is required at the same time as each of the interim progress reports. In addition, at the conclusion of the award period, LUNGevity requires 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. LUNGevity.



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

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 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 8.

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 interim written progress reports (as well as presentations at the annual LUNGevity Science Meeting) are required along with the interim financial reports. 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.

Project Support Expenditures

No award shall be used for the purchase of furniture or computers, repair or service contracts, institutional equipment, 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. LUNGEVITY has 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.

Publication Expenditures

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

Publications

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 \$1,000 per year. Travel to LUNGevity meetings is paid directly by the Foundation and is not included in the allowable \$1,000.



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 commercial 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.



LUNG CANCER CAREER DEVELOPMENT AWARD 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 with these components:
 - Rationale for the project
- Planned **specific aims** (may be modified slightly in the 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.**

• 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." Attach this to the end of the biosketch.

No budget information or other supporting materials should be included.

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

Applicants are required to electronically submit the LOI by **Wednesday**, **February 23**, **2022** (11:59pm EST), via proposalCENTRAL. Extensions will not be given. Once an LOI has been submitted electronically via proposalCENTRAL, it cannot be changed. proposalCENTRAL will be open to submit letters of intent beginning on Wednesday, January 26, 2022.

A sponsoring-institution signature is not required.

Applicants will be notified by email no earlier than **Friday**, **April 1**, **2022**, whether they may proceed with the full application.

FEEDBACK WILL NOT BE PROVIDED FOR THE LOIS. LUNGevity will provide results of the peer review process upon request for full applications only.



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 eight 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 journal.
- **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.
- A few pertinent references.

The narrative should be typed in Arial 11-point type, single-spaced, with .5" margins. Clarity and brevity are highly desirable qualities in an application. The narrative should not exceed a total of **10 pages**, 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: 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
- 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.

Applicants are required to electronically submit the full application by **Monday, May 9, 2022** (11:59pm EST), via proposalCENTRAL: https://proposalcentral.com. Extensions will not be given. Once a full application has been submitted electronically, it cannot be changed.

Applicants will be notified by email in late summer 2022 whether they will receive an award.

LUNGevity will provide results of the peer review process upon request for full applications at that time.

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 the **November 1, 2022, start date of the grant term.**

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:

Margery Jacobson Senior Research and Education Services Manager mjacobson@LUNGevity.org

For help with the proposalCENTRAL electronic application process, please contact: Help Desk at proposalCENTRAL <u>pcsupport@altum.com</u> 1-800-875-2562