Lung Cancer Early Detection Award (EDA) Program
2023 Request for Application

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 will not be reviewed.

A two-step application process will be used. An applicant 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.

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 10.

LUNGEVITY FOUNDATION

LUNGevity Foundation is a 501(c)(3) philanthropy specifically focused on funding research for the early detection and successful 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 therapies and immunotherapy. LUNGevity focuses on translational science. For more information about LUNGevity Foundation, please visit www.LUNGevity.org.

FUNDING OPPORTUNITY DESCRIPTION

Overview

LUNGevity 2023 Early Detection Award grant funds will be awarded to support translational research projects directed at new approaches to improve clinical methods for the detection and diagnosis of primary tumors.

Applicants may apply as individuals or in teams. It is strongly encouraged that teams be composed of principal investigators (PIs) from different institutions. All PIs on the team share authority for scientific leadership.

Regardless of the number of PIs, the total amount to be awarded is $200,000-$300,000 per year over an award term of two-three years. The total award amount will not exceed $600,000.

Goal
Direct impact on early detection and/or diagnosis of lung cancer or a clear conceptual or experimental foundation for the future development of methods for early detection and/or diagnosis.

AWARD PROGRAM REQUIREMENTS

Studies must include investigations using human tissue specimens and preference will be given to studies that are likely to result in patient benefit in the foreseeable future.

The Foundation is particularly interested in, but projects are not limited to, one or more of the following:

- Biomarker discovery and/or validation for risk assessment, early detection, and prediction of recurrence after curative-intent therapy for localized disease
- Biomarkers to guide management of indeterminate pulmonary nodules
- Imaging biomarkers including novel molecular and functional imaging strategies that can refine LDCT
- Utility of multi-cancer early detection tests for lung cancer screening
- Minimally invasive early detection tools (for example, blood, sputum, or nasal swab-based approaches)
- Early detection strategies within populations who do not meet the current USPSTF screening guidelines

The following studies will **not** be considered:

- Pre-clinical drug development studies, such as toxicology or chemical compound screening
  Projects focused purely on animal or in vitro models
- Projects focused on the implementation of lung cancer screening

If you have any questions about the RFA scope, please email: Dr. Upal Basu Roy at ubasuroy@LUNGevity.org.

The use of existing resources is encouraged, including molecular tools, tissue or biospecimen repositories, and other existing collections of tissues, blood, or images. It is also strongly encouraged that those applying have direct and immediate access to the biospecimens necessary to complete the research.

High-risk, high-return proposals will receive equal consideration.

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 on an annual basis.

During the duration of the award term, awardees are required to attend LUNGevity's annual Fall Science Meeting (whether in-person or virtual) to report on their progress.

Eligibility

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

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.

Citizenship: At the time of application, 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. At the time of application and throughout the duration of the award, an applicant/awardee must be employed by a U.S. institution.

AWARD INFORMATION

Award Structure

The total amount awarded over an award period of two-three years is a maximum of $200,000-$300,000 per year, regardless of the number of PIs.

No more than 25% 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. Fringe benefit costs may only be expended upon the stipulation that they not be obtained from another source.

LUNGevity Early Detection 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 (if applicable) 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.

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:

- Project's relevance to the early detection and/or diagnosis of lung cancer
- Scientific and technical merit, innovation, and feasibility of the research plan
- Research environment
- Qualifications of the principal investigator(s) and team
- Appropriateness of the requested budget and timeline to complete the proposed research project

OTHER TERMS AND CONDITIONS

Following are the other terms and conditions that apply to the LUNGevity Early Detection 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) 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 grants research awards only to individuals; 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 awarded 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 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 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. 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. 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 amount of funds expendable for travel is $1,500 per year per investigator. Travel to LUNGevity meetings is paid directly by the Foundation and is not included in the allowable $1,500.

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 describing the clinical context in which the early detection strategy will be used
- Brief statement of the quantitative/performance that the biomarker/approach should achieve to show clinical utility
- 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. 0923-0001 and 0925-0002) of the applicant(s): PI(s) only. Biosketches should be limited to five pages. Note that in the section on research support, you must include the dollar value of all awards. 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 on page 3 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 more 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 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.***
- **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**, including the references.

• NIH **biosketches** (OMB No. 0925-0001 and 0925-0002) of the PI(s) and key personnel, per the biosketch instructions in the LOI section.

• **Budget information** by year, along with a justification.

• 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.

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.

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
jroosevelt@LUNGevity.org
847-525-2075

For help with proposalCENTRAL, please contact:

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