



LUNGevity Foundation 2021 Request for Application (RFA) Lung Cancer Early Detection Award (EDA) Program

IMPORTANT NOTES TO READ BEFORE PROCEEDING:

An applicant may submit only one application for a 2021 LUNGevity award.

An applicant with an existing LUNGevity award that would be concurrent with a 2021 award may not apply.

LUNGevity advises applicants to read the entire RFA, including eligibility requirements and other terms and conditions, before starting an application. 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.

The Lung Cancer Early Detection Program 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.

LUNGevity manages its grant process within proposalCENTRAL.

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

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 lung cancer research to make findings from basic science useful in the clinic.

LUNG CANCER EARLY DETECTION AWARD PROGRAM FUNDING OPPORTUNITY DESCRIPTION

Overview

LUNGevity 2021 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 years.

Awardees are required to share their research progress with the LUNGevity team (the LUNGevity Scientific Advisory Board members, non-LUNGevity experts who are participating in the review process, and other awardees) on an annual basis.



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Early Detection Project Requirements

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.

- Studies must include investigations using human tissue specimens.
- Preference is for 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, validation, and implementation (including combinations of multiple biomarkers and assay development). Biomarker categories include risk assessment, early detection, and prediction of recurrence after curative-intent therapy for localized disease
- Biomarkers to guide management of lung lesions
- Imaging, including novel molecular and functional imaging strategies
- Minimally invasive strategies for early detection
- Identification of mechanisms leading to development of various types of lung cancer, with a plan for how to translate these findings to novel early detection strategies
- Implementation of lung cancer screening or early detection strategies, including research within groups outside of current 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,

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.

Award 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.



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institution.

Award information

- **Award Structure and Allocation:**

The total amount awarded over an award period of two 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.

- **Duration:** LUNGEvity Early Detection Awards are subject to annual review and may be granted for two years.

Factors considered in evaluating applications

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**:

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.



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- Institutional Animal Care and Use of Committee (IACUC) approval.

A researcher is **not** eligible to apply 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).

Annual Meetings

LUNGevity hosts an annual science meeting in the fall. Awardees are required to attend the meeting (whether in-person or virtual) to report on their progress.

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.

Award Payment Schedule

LUNGevity will issue the year-one award payment no earlier than November 2021, following receipt of the fully executed agreement documents. LUNGevity will issue the year-two payment following an award renewal after year one, which is based on satisfactory progress. The second-year payment will be made only after the awardee's funding balance has decreased to \$25,000 or less.

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 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.



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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 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 the interim progress report. 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 and any funds used for unauthorized expenditures must be returned to LUNGevity, with the final financial report, within 60 days of the award termination date.

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



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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

An interim written progress report (as well as presentations at the annual science meeting) is required along with the interim financial report. The Interim progress report is the basis for the decision to award the second year 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.



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



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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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LUNG CANCER EARLY DETECTION AWARD APPLICATION INSTRUCTIONS AND TIMELINE

Letter of Intent (LOI)

The letter of intent must include:

- A **narrative** that includes:
 1. **Rationale** for the project
 2. Planned **specific aims** (may be modified slightly in the full application)
 3. Brief statement of the **overall experimental approach**
 4. Brief statement describing the **clinical context** in which the early detection strategy will be used
 5. Brief statement of the **quantitative/performance** that the biomarker/approach should achieve to show clinical utility
 6. 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 2 under "Award Eligibility." Attach this to the end of the biosketch.

No budget information or other supporting materials should be included.

Templates and more detailed instructions can be found at <https://proposalCENTRAL.com>.

Applicants are required to electronically submit the LOI by **Wednesday, February 24 (11:59pm EST)**, via proposalCENTRAL. Extensions will not be given. Once an LOI has been submitted electronically via proposalCENTRAL, it cannot be changed.

A sponsoring institution signature is not required.

Applicants will be notified by email no earlier than **Thursday, April 1**, 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.



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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 seven components:
 1. **Lay Abstract** that explains your project completely in lay terms that will be clear to individuals who do not have a scientific background.
 2. **Scientific Abstract** that would be appropriate for a reviewer of a peer-review journal
Background: Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe previous experience most pertinent to this application.
 3. **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
 4. **Specific Aims:** Concisely explain the project's specific aims.
 5. **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.
 6. **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 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 on page 3 in the "Animal Use" section
- a copy of the biohazard document named on page 4 in the "Biohazards" section

- 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>.

Applicants are required to electronically submit the full application by **Monday, May 10 (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 2021** whether they will receive an award.

LUNGEvity will provide results of the peer review process for full applications at that time.

Awardees will receive formal agreement documents at the time of or soon after award notification. These must be signed by both the awardee and an authorized representative of the sponsoring institution and then returned to LUNGEvity before any funds will be released. Funds will be released no earlier than November 1, 2021, the start date of the grant term.



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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
312-407-6109

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