



LUNGeVity Foundation 2016 Request for Application Career Development Award Program

IMPORTANT NOTES TO READ BEFORE PROCEEDING:

The LUNGeVity Foundation (“LUNGeVity”) 2016 Career Development Award is for translational research in early detection or targeted therapeutics in a career development context.

An applicant may submit only one application for this award.

LUNGeVity Foundation advises applicants to read the entire Request for Application, 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.

LUNGeVity will grant only one Career Development Award per institution.

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 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 targeted therapeutics, including immuno-oncology. 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 will be part of the required submission. CDAs 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 immuno-oncology.

High-risk, high-return proposals will receive equal consideration. Translational research includes epidemiology studies, and we especially encourage clinical correlative studies.

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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 bio-specimen repositories, and other existing sets of tissue, blood, or images. It is strongly encouraged that those applying have direct and immediate access to the bio-specimens necessary to complete their research.

Successful applicants will attend annual Scientific Advisory Board meetings and participate as *ex officio* members of our Scientific Advisory Board for the duration of the award. Awardees will be required to share their research progress with the LUNgevity team (Scientific Advisory Board, other reviewers, and other grantees) on an annual basis.

Award eligibility

- 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.

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.

- Support: 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, or K23.
- Citizenship: 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. At the time of submission of the LOI and throughout the duration of the award, an applicant/awardee must be employed by a U.S. institution.

Award information

- Award Structure and Allocation: 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

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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 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:

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



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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 up to two annual Scientific Advisory Board meetings. Awardees are required to attend these meetings.

Authorized Award Holders

LUNgevity grants research awards only to individuals; awards are not made to institutions. No award may be held by or transferred to another individual.

Award Payment Schedule

LUNgevity will issue the first-year award payment upon receipt of the fully executed agreement documents. LUNgevity will issue the second- and third-year payments following award renewal.

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 or Extensions

Carryover and/or award extensions require prior approval by LUNgevity. All requests must be in writing. The written requests for carryover and/or extensions must be received by LUNgevity 30 days prior to the award's official termination date. When making the request, the awardee must indicate the amount and from what budget-line and to what budget-line the monies are being applied. In the case of supplies or equipment, all items must be itemized. Awardees may only request a carryover or extension once per award.

Change in Budget

Requests for changes in budget require prior approval by LUNgevity. All requests must be in writing. 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 requires prior approval by LUNgevity. All requests must be in writing. All unexpended funds must be returned to LUNgevity within 45 days of transfer approval. Once LUNgevity receives the unexpended funds, they 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. Any departure from this requires prior written approval from LUNgevity.

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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 disbursement report must reflect the award expenditures as approved by LUNgevity. Any funds used for unauthorized expenditures or unexpended funds must be returned to LUNgevity, with the disbursement 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.

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 7.

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Progress Reports and Renewal of Funding

Annual interim written progress reports (as well as presentations at a LUNGeVity science meeting) are required along with the interim financial reports. Interim reports are the basis for the decision to award subsequent years of funding. A final report is also required 45 days after the conclusion of the project.

Project Support Expenditures

No award shall be used for the purchase of furniture or computers, the construction or renovation of facilities, payment of honoraria or membership dues, tuition, the purchase of textbooks or periodicals, or payment for secretarial support.

Public Access Policy

All peer-reviewed articles supported in whole or in part by LUNGeVity grants must be made available in the PubMed Central online archive. The LUNGeVity policy is described in full on page 8.

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.

Student Tuition

LUNGeVity will not pay tuition for CDA awardees.

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 travel are \$1,000 per year per investigator. Travel to LUNGeVity SAB meetings is paid directly by the Foundation and should not be included.

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LUNGEVITY FOUNDATION 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 LUNGeVity Research and Program Services. 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 e).

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-g 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-f shall not apply.

c. Distribution of income derived from an invention or intellectual property that might include equity disposition shall be according to the policies of the grantee institution, although LUNGeVity would expect to participate in income derived from the invention or intellectual property to the extent and at a rate of remuneration determined by mutual agreement between the grantee institution and LUNGeVity no later than six months after first receipt of income. Such agreement shall be guided by the principle that LUNGeVity's proportion of sharing in the income shall be reasonably related to LUNGeVity's proportion of support for the invention or intellectual property.

d. If any invention or intellectual property is made with the joint support of LUNGeVity and other organizations, it is expected that income distribution shall be in accordance with the provisions of the policy. Should an exception be taken to this provision, the grantee institution, LUNGeVity, and other sponsoring agencies will confer to reach a mutually satisfactory disposition of invention or intellectual property rights.

e. No patent, patent application, or other type of protection shall be abandoned without first notifying LUNGeVity Research and Program Services. At such time, the grantee institution and individual awardee shall give LUNGeVity the opportunity to take title to the invention or other intellectual property.

f. 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.

g. LUNGeVity reserves the right to public acknowledgment for inventions or intellectual property resulting from support by LUNGeVity; however, the 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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LUNGevity FOUNDATION PUBLIC ACCESS POLICY

LUNGevity funds biomedical research in order to better understand the causes of lung cancer and to advance its prevention, diagnosis, and treatment. The main output of this research is new knowledge. To ensure this knowledge can be accessed, read, applied, and built upon in fulfillment of our goals, LUNGevity expects its researchers to disseminate their findings, including publishing in peer-reviewed journals.

In addition, it is a condition of LUNGevity funding that all peer-reviewed articles supported in whole or in part by its grants must be made available in the PubMed Central online archive. PubMed Central is a database of full-text biomedical journal articles available online without a fee, hosted by the National Library of Medicine in the National Institutes of Health. Once posted in PubMed Central, results of research become more accessible, prominent, and integrated, making it easier for scientists worldwide to pursue biomedical research. It also makes this information accessible to LUNGevity and its donors, as well as patients, clinicians, educators, students, and others.

LUNGevity award recipients are required to deposit an electronic copy of their final peer-reviewed manuscripts in PubMed Central immediately upon acceptance for journal publication and take the steps necessary to link that manuscript to the appropriate LUNGevity grant. The manuscript is to be made publicly available in PubMed Central no later than 12 months after the official date of journal publication.

LUNGevity award recipients must acknowledge LUNGevity support in every article arising from such funding. The acknowledgment statement must include the applicable LUNGevity grant number. This will enable LUNGevity to link the published outputs of research to the support it has provided.

LUNGevity also encourages award recipients to publish in peer-reviewed open access journals with a policy of immediate availability of the published version without restriction, and permits use of non-salary/stipend grant funds to pay associated publication fees.

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LUNG CANCER CAREER DEVELOPMENT AWARD APPLICATION INSTRUCTIONS AND TIMELINE

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 Times New Roman 12-point type, single-spaced, with .5" margins. It should not exceed a total of **three pages**, including the references.

- An NIH **biosketch** (Form SF424R-R) of the applicant only
- If a non-citizen, proof of visa immigration status, as described on page 2 under "Award Eligibility"

No budget information or other supporting materials should be included.

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

Applicants are required to electronically submit the LOI by **Wednesday, February 17, 2016 (9:00pm 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 Monday, January 4, 2016.

A sponsoring-institution signature is not required.

Applicants will be notified by email no earlier than **Wednesday, March 23, 2016**, whether they may proceed with the full application. LUNGEvity will provide results of the peer review process upon request.

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.

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- **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.
- **Career and Mentoring Plan:** Describe your career and mentoring plan in detail.
- **A few pertinent references.**

The narrative should be typed in Times New Roman 12-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 **ten pages**, including the references.

- **NIH biosketches** (Form SF424R-R) of the PI and Key Personnel, including mentors. Mentors should include a list of previous mentees and their current institutions.

- **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.altum.com>.

Applicants are required to electronically submit the full application by **Wednesday, May 4, 2016 (9:00pm EST)**, via proposalCENTRAL: <https://proposalCENTRAL.altum.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 **July 2016** whether they will receive an award.

LUNgevity will provide results of the peer review process for full applications in Summer 2016.

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 before any funds will be released.

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
Research and Project 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