

ALK Positive/LUNGeVity Foundation 2018 Request for Application

ALK-Positive Lung Cancer Transformational Research Program

IMPORTANT NOTES TO READ BEFORE PROCEEDING:

ALK Positive is partnering with LUNGeVity Foundation (“LUNGeVity”) to fund **research into ALK-positive non-small cell lung cancer**.

This award program is separate from, and in addition to, LUNGeVity’s Career Development, Early Detection, and Targeted Therapeutics award programs.

Applicants employed at U.S. and international institutions are eligible to apply.

An applicant with an existing LUNGeVity award that would be concurrent with the 2018 ALK-Positive Lung Cancer Transformational Research Award may apply.

An applicant may submit no more than two applications for this award.

LUNGeVity Foundation 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 ALK-Positive Lung Cancer Transformational Research Program uses a **two-step application process**. An applicant must first submit a letter of intent (LOI). Because there is only one award, only a subset of applicants will be invited to submit a full application after the LOIs are reviewed.

Detailed instructions for submitting the ALK-Positive Lung Cancer Transformational Research Award application, including critical dates, begin on page 10.

This grant application process will be managed through proposalCENTRAL.

ALK POSITIVE

ALK Positive, an international group of 700+ highly motivated, passionate, and dedicated ALK-positive patients and their caregivers, wants to drive change in the ALK lung cancer space. ALK Positive members are committed to raising funds for research to increase ALK-positive lung cancer patients’ survivorship. Their specific goal is to fund research proposals that will transform ALK-positive lung cancer into a chronic or curable condition for all patients living with this disease. ALK Positive is partnering with LUNGeVity to raise these funds for ALK research. This is the first group of ALK-positive patients who will influence the direction of research that will, one day, save their lives. For more information about ALK Positive, please visit www.alkpositive.org.

LUNGEVITY FOUNDATION

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

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ALK-POSITIVE LUNG CANCER TRANSFORMATIONAL RESEARCH FUNDING OPPORTUNITY DESCRIPTION

Goal of the program:

To fund high-impact research that seeks to transform the future for patients affected by ALK-positive non-small cell lung cancer by transforming ALK-positive lung cancer into a chronic or curable condition.

Overview:

ALK Positive is partnering with LUNGeVity Foundation to support ALK-positive non-small cell lung cancer research. ALK Positive will leverage LUNGeVity's scientific review process as well as fund their research through the Foundation. This research will address unanswered questions in the ALK space. This award program is separate from, and in addition to, LUNGeVity's Career Development, Early Detection, and Targeted Therapeutics award programs. It aligns well with the Foundation's mission of funding high-impact science.

This is a first-of-its-kind award in lung cancer, in that ALK-positive patients are expediting the research process themselves both by fundraising and crowdsourcing. In addition to fundraising, ALK Positive members are also committed to facilitating research by offering up their available histories, opinions, tissues, bodily fluids (blood, urine, etc.), and/or any other aspects of their condition to the funded investigators.

ALK-Positive Lung Cancer Transformational Research Program requirements:

The transformational research project that will be funded is expected to have a direct impact on the outcomes of patients with ALK-positive lung cancer, but innovative proposals that address other unmet needs in the ALK-positive lung cancer space are also invited for submission. Applicants are encouraged to propose projects that utilize the resources of the ALK Positive members.

Successful applicants are required to share their research progress with the ALK Positive members and the LUNGeVity team (Scientific Advisory Board, other reviewers, and other awardees) annually at the LUNGeVity science meeting.

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 post-doctoral 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.

Citizenship: Applicants are not required to be U.S. citizens or to be employed by a U.S. institution.

At the time of application, an applicant who is employed by a U.S. institution 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). This applicant/awardee must be employed by a U.S.

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institution throughout the duration of the award term.

At the time of application, an applicant who is not employed by a U.S. institution and either is or is not a United States citizen must name a co-investigator who 1) is employed by a U.S. institution and stays so throughout the duration of the award term and 2) is either a U.S. citizen or a foreign national with one of the immigration statuses outlined in the preceding paragraph. Disbursement of funds for the award must be made through a U.S. institution.

Award information:

Award Structure and Allocation:

Investigators may receive up to \$200,000 over two years (\$50,000 per six-month period). No more than 25% of the requested budget may be used for an investigator's salary and/or fringe benefits and no more than 10% 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 cannot be obtained from another source.

Duration: The ALK-Positive Lung Cancer Transformational Research Award is subject to six-month reviews and may be granted for up to two years. For highly successful projects, there is a possibility of follow-on funding upon successful completion of the original award (contingent on availability of funds). The goal of the follow-on funding is NOT to be a no-cost extension of the research proposed in the original grant, but rather to build upon the findings of the original research (take it to the next step).

Factors considered in evaluating applications:

Some of the factors considered when reviewing applications include:

- Scientific merit, innovation, and feasibility of the research plan
- How quickly the findings from the project will be moved to the clinic and impact patients
- Research environment
- Appropriateness of the requested budget to complete the proposed research project

OTHER TERMS AND CONDITIONS:

Following are the other terms and conditions that apply to the **ALK-Positive Lung Cancer Transformational Research Award**:

Animal Use

The ALK-Positive Lung Cancer Transformational Research Award 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 the ALK Positive/LUNGeVity-funded research project, applicants must provide ALK Positive/LUNGeVity with institutional endorsements that the research facility, its research, and its employees adhere to the:

- Animal Welfare Act
- USDA rules

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- 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 Animal Care and Use Committee (IACUC).

Authorized Award Holders:

The ALK-Positive Lung Cancer Transformational Research Awards are granted only to an individual; awards are not awarded to institutions. No award may be held by or transferred to another individual.

Award Payment Schedule:

ALK Positive/LUNGeVity will issue the initial \$50,000 award payment in late spring 2018. Assuming award renewals, contingent on meeting milestones, ALK Positive/LUNGeVity will issue the subsequent payments in approximately 6-month intervals thereafter. Timing will depend in part on an unexpended funding balance of under \$25,000.

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 third six-month funding period requires prior approval by ALK Positive/LUNGeVity. All requests must be in writing and received by ALK Positive/LUNGeVity 60 days prior to the end of the second six-month funding period. 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, all items must be itemized.

Change in Budget:

Requests for changes in budget require prior approval by ALK Positive/LUNGeVity. All requests must be in writing and received by ALK Positive/LUNGeVity 60 days prior to the end of the second six-month funding period. 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, all items must be itemized.

Change of Institution:

Transfer of the ALK Positive/LUNGeVity award from one institution to another requires prior approval by ALK Positive/LUNGeVity. All requests must be in writing. All unexpended funds must be returned to ALK

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Positive/LUNGeVity within 45 days of transfer approval. Once ALK Positive/LUNGeVity receives the unexpended funds, they will be reissued to the new institution after an agreement document with the new institution has been fully executed.

Equal Employment Opportunity:

ALK Positive/LUNGeVity awards will be awarded to individuals working in institutions identified as Equal Opportunity Employers.

Equipment Purchase:

None (0%) of the award budget may be used for the purchase of permanent equipment.

Equipment Repair & Service Contracts:

None (0%) of the award budget may 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, ALK Positive/LUNGeVity requires a complete financial disbursement report covering the entire award period. The disbursement report must reflect the award expenditures as approved by ALK Positive/LUNGeVity. Any funds used for unauthorized expenditures or unexpended funds must be returned to ALK Positives, with the disbursement report, within 60 days of the award termination date.

Human Subjects:

Whenever human subjects are a part of the ALK Positive/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 ALK Positive/LUNGeVity before award funds will be disbursed.

Malpractice Liability:

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

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Other Funding:

ALK Positive/LUNGeVity research funds will not be awarded to duplicate any work that is being supported by other funding agencies. Details about additional funding sought for the same project should be provided in the full application.

Overhead/Indirect Costs:

Overhead or indirect costs are permitted up to 10% of the award and 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 the ALK Positive/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.

Progress Reports:

Interim written progress reports are due every six months. Interim reports are the basis for the decision to award the next round of funding. A final written report is also required 45 days after the conclusion of the project. These reports are in addition to the progress presentations that will be made annually at the LUNGeVity science meeting.

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, payment for 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 the ALK Positive/LUNGeVity grant must be made available in the PubMed Central online archive. The LUNGeVity public access policy is described in full on page 9

Publication Expenditures:

The maximum amount of funds expendable for publication costs is \$1,000 per year. All publication costs must directly relate to the ALK Positive/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 ALK Positive/LUNGeVity as a supporting entity as follows: "This study was supported by a grant from ALK Positive/LUNGeVity Foundation." Reprints of abstracts, manuscripts, or other articles that reflect research done after award acceptance must be submitted to ALK Positive/LUNGeVity.

Student Tuition:

ALK Positive/LUNGeVity will not pay tuition for awardees or any key personnel.

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Supply Purchases:

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

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 should not be included in the \$1,000.

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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 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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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 six 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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ALK-POSITIVE LUNG CANCER TRANSFORMATIONAL RESEARCH AWARD APPLICATION INSTRUCTIONS AND TIMELINE

Applicants will be allowed to submit their letter of intent (LOI) beginning Wednesday, November 15, 2017.

Letter of Intent (LOI)

The letter of intent must include:

- A **narrative** that includes:
 1. **Rationale** for the project with details on how the project will impact clinical care of ALK-positive lung cancer patients
 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 therapeutic strategy will be used
 5. Brief statement of the **quantitative metrics/performance** that the approach should achieve to show clinical utility
 6. 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** of the applicant(s): principal investigator only if at a U.S. institution; principal investigator *and* co-principal investigator who is at a U.S. institution if principal investigator is not at a U.S. institution

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 Tuesday, January 16, 2018 (11:59pm EST)**, via proposalCENTRAL: <https://proposalCENTRAL.altum.com>. 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 **Wednesday, February 21, 2018**, 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 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. Specific details on how the project will have a near-term impact on the clinical outcome of ALK-positive lung cancer patients should be included.
 2. **Scientific Abstract** that would be appropriate for a reviewer of a peer-review journal
 3. **Background**: Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe previous experience most pertinent to this application.
 4. **Hypothesis or Objective**: State the hypothesis to be tested or the objective to be reached.

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5. **Specific Aims:** Concisely explain the project's specific aims. Please include a description on how you propose to include biospecimens from the the ALK Postive patients in your proposed experiments.
6. **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.
7. **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** of all PIs and Key Personnel (both current and pending support). The sketches should be limited to four pages each. Include education/training; positions and honors; a list of presentations at national/international meetings; and a list of peer-reviewed publications.

- **Budget information** by six-month period, along with a justification

- If relevant, the **following documents**:

- a copy of the documents listed on page 4 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 **Friday, March 23, 2018 (11:59pm 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 no earlier than **April 2018** whether they will receive an award. LUNGeVity will also provide results of the peer review process for full applications.

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 with **original signatures** 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 Marketing 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