ALK Positive/LUNGevity Foundation 2022 Request for Application

ALK Positive/LUNGevity ALK-positive Lung Cancer Research Award Program

IMPORTANT NOTES TO READ BEFORE PROCEEDING:

ALK Positive Inc. ("ALK Positive") is partnering with LUNGevity Foundation ("LUNGevity") to issue an RFA specific to the study of ALK-positive lung cancer.

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/LUNGevity ALK-positive Lung Cancer Research Award Program uses a **two-step application process**. 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.

Detailed instructions for submitting an ALK-positive Lung Cancer Research Award Program application, including critical dates, begin on page 11.

This award application process will be managed through proposalCENTRAL.

ALK POSITIVE

ALK Positive is a 501(c)(3) organization committed to raising funds for research to improve the life expectancy and quality of life for ALK-positive lung cancer patients worldwide. 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. ALK Positive partners with the world's largest group of ALK-positive patients. ALK Positive is influencing the direction of research that will improve the life expectancy and quality of life for ALK-positive lung cancer patients worldwide. 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.

ALK-POSITIVE LUNG CANCER RESEARCH AWARD PROGRAM 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 advanced ALK-positive lung cancer into a chronic or curable condition.

ALK Positive/LUNGevity Foundation 2022 Request for Application

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..

With this award, 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 Research Award Program requirements

The research project(s) that will be funded is expected to have a direct impact on the outcomes of patients with advanced 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. **Awards totaling up to $1,500,000 will be funded, with individual awards up to $750,000.**

- 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 and at the ALK Positive annual summit.

Scientific scope of projects

The goal of the award is to fund impactful proposals in the ALK-positive lung cancer space.

Projects may be either;

- pre-clinical studies, providing they can reasonably be expected to lead to a clinical trial within 4 years of starting the project, or

- a clinical trial study

Suggested areas of investigation may include, but are not limited to, the following:

1. Projects that aim to understand novel treatment options. A novel treatment option may be a **new** monotherapy option or a rationally designed combination approach.
2. Projects that aim to identify existing biomarkers that predict both sensitivity to specific therapies and timing of relapse on therapy. Such biomarkers could be tissue-based or blood-based biomarkers.
3. Projects that add an ALK lung cancer arm to existing/proposed clinical studies. If studies are proposed in this category, proof of IRB approval of protocol at the time of grant activation will be required.
4. Retrospective chart reviews or "data mining" projects that have the potential to change standard treatment before clinical trial results are available. If such studies are proposed, the connection between the chart review and potential change in practice must be clearly identified.
5. Projects that aim to understand the clinical and genomic features of ALK TKI "**short responders**" and suggest how to improve their treatment and monitoring. For purposes of this RFA, short responders are defined as those who progress within one year of commencing their first-line TKI therapy. Similarly, proposals geared towards studying **exceptional responders** will be considered.

6. Projects that aim to eliminate persister cells.
7. Projects that are directed toward the post-lorlatinib or post-TKI treatment space. These may include novel TKIs that address ALK point mutations that occur post-lorlatinib; or novel drugs or combinations that target ALK-independent bypass mechanisms.

The research questions listed above are meant to serve as examples and are by no means restrictive. Projects that are out of scope include projects studying the lived experience of patients with ALK-positive NSCLC and infrastructure studies related to building registries.

Projects are to include at least one aim that is translational and has the potential to lead directly to improved outcomes for patients or lead directly to a clinical trial. Applicants will be asked to estimate the time frame for their research to result in a clinical trial: within how many years.

Based on progress, the ALK Positive team may consider providing follow-on funding, especially for projects that demonstrate high potential for translation into the clinic within 6 months of completion of the project.

Final selection will be contingent on scientific review and availability of funds.

Award eligibility:

Education and Experience: At the time of the award 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 postdoctoral training fellowship. An applicant may be at any level of research experience.

An applicant must be an independent, self-directed researcher for whom their 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. An applicant with an existing LUNGevity award that would be concurrent with a 2022 ALK-positive Lung Cancer Research Award is not precluded from applying. Applicants are encouraged to form multi-institutional teams and apply for this grant.

Geographical Restriction: **The Award Program does not have any geographical restrictions**. At the time of application, it is recommended that an international collaborator (who is not employed by a U.S. institution and either is or is not a United States citizen) 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 following paragraph. In case a U.S. institution is named, disbursement of funds for the award will be made through the U.S. institution to allow timely commencement of the project.

Applicants are **not** required to be U.S. citizens or to be employed by a U.S. institution. **At the time of application, if an applicant is employed by a U.S. institution**, they 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. institution throughout the duration of the award term.

Award information:

Award Structure and Allocation:
Investigators may receive **up to** $750,000 per project, over two years. 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.

Allowable costs for clinical trials include: expenses related to subject recruitment (such as participation incentives, subject remuneration, phlebotomy charges, etc.), clinical laboratory analyses of human subjects or their samples (such as clinical laboratory assays, imaging charges, etc.), and correlative studies. While the award may be used to help with operational costs, the investigator is encouraged to obtain partial support from the drug company donating their drug to the trial. **Drug costs will not be covered**.

Duration: The ALK-positive Lung Cancer 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:

- **Innovation** – Does the project address a previously uninvestigated area of ALK-positive lung cancer?
- **Scientific merit and feasibility of the research plan**, including partnerships
- **Impact** – How will the research findings from the project move to the clinic within 1-2 years and impact patients? What plans does/do the applicant(s) have for the clinical application of the findings of the project?
- **Study design and its burden on patient participation,** i.e., how difficult is it for patients to participate in the proposed study?
- **Research environment –** Does the applicant have access to institutional resources required for the successful completion of the proposed project?
- **Appropriateness of the requested budget** to complete the proposed research project/Other sources of funding, including potential overlap with proposed project

OTHER TERMS AND CONDITIONS:

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

Animal Use

The ALK-positive Lung Cancer Research Award Program 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 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, 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).

Award Payment Schedule:

ALK Positive/LUNGevity will issue the initial award payment no earlier than November 1, 2022. 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 $50,000.

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 Awardee or Institution:

An award may not be transferred from the awardee to another individual. 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 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 Positive/LUNGevity, 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 (or non-U.S. equivalent) 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 (or the non-U.S. equivalent) 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.

Other Funding:

ALK Positive/LUNGevity research funds will not be awarded to duplicate any work that is being supported by other funding agencies. Partial funding from a pharmaceutical company for a phase 1 trial is encouraged. 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, discoveries, and other intellectual property rights from research performed during the term of the ALK Positive/LUNGevity award will be subject to the current ALK Positive/LUNGevity patent policy as well as to the patent policies of the institution where the work is performed. The ALK Positive / LUNGevity policy is described in full on page 9.

Press Releases:

See page 10 for information about press releases and non-scientific dissemination of research results.

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 ALK Positive/LUNGevity public access policy is described in full on page 10.

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 and Conference Presentations:

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.

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 applicants who have received direct funding or funding from agencies of the tobacco industry.

Travel Expenditures:
The maximum amount of funds expendable for travel is $3,000 per year per investigator. Travel to LUNGevity meetings is paid directly by the Foundation and should not be included in the $3,000.

ALK POSITIVE PATENT AND INTELLECTUAL PROPERTY POLICY

a. All intellectual property made with support in whole or in part by research or training grants or awards from LUNGEVITY ("Research IP") 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 file provisional patent applications, full patent applications, or for any other form of legal protection for intellectual property encompassing Research IP, and to incorporate all reasonable comments or objections LUNGEVITY may have concerning such Intellectual Property filings. 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 and such grantee institution shall sign assignments, obtain inventor assignments, and cooperate as needed for LUNGEVITY or a third party selected by LUNGEVITY to seek and obtain intellectual property protection for Research IP.

c. No patent, patent application, or other type of intellectual property protection for Research IP shall be abandoned without first notifying the Research and Program Services Division at least 90 days before such abandonment. At the time of such notice, the grantee institution shall give LUNGEVITY the opportunity to take title to the patent, patent application, or other type of intellectual property and grantee institution shall sign assignments, obtain inventor assignments, and cooperate as needed for LUNGEVITY or a third party selected by LUNGEVITY to seek, obtain and/or own such intellectual property

d. When licensing any intellectual property right in Research IP, the grantee institution shall obligate the licensee as follows: (1) 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; (2)in the event that the licensee fails 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 or , 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 has an ongoing and active manufacturing, marketing or licensing program providing the production, sale, or access to patients of treatments encompassing the Research IP, this would be deemed sufficient evidence that the licensee has commercialized the invention or intellectual property. Upon commercialization of the Research IP, a portion of royalties shall be paid to LUNGEVITY and ALK Positive.

e. LUNGEVITY and ALK Positive reserves the right to make public acknowledgments for inventions or intellectual property resulting from support by LUNGEVITY and ALK Positive; however, LUNGEVITY and ALK Positive name and logo may not be used in association with an invention or intellectual property without prior written approval of LUNGEVITY and ALK Positive.

ALK POSITIVE/LUNGEVITY FOUNDATION PUBLIC ACCESS POLICY

LUNGevity, in partnership with ALK Positive, is funding 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 and the ALK Positive expect its researchers to disseminate their findings, including publishing in peer-reviewed journals.

In addition, it is a condition of this award 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 the ALK Positive, as well as patients, clinicians, educators, students, and others.

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 ALK Positive/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.

ALK Positive/LUNGevity award recipients must acknowledge ALK Positive/LUNGevity grant support in every article arising from such funding. The acknowledgment statement must include the applicable grant number. The award recipients must notify ALK Positive (by emailing info@alkpositive.org) and LUNGevity Foundation (by emailing Margery Jacobson at mjacobson@LUNGevity.org) of any articles arising from such funding. This will enable the ALK Positive and LUNGevity to link the published outputs of research to the support that has been provided.

LUNGevity and ALK Positive also encourage 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.

PRESS RELEASES AND OTHER NON-SCIENTIFIC DISSEMINATION

A mutually accepted joint press release announcing the RFA including quotes from both LUNGevity and ALK Positive leadership will be issued as appropriate. LUNGevity and ALK Positive will also issue a mutually acceptable joint press release upon selection of the awardees and again upon completion of the research projects and will disseminate results via multiple channels. Both LUNGevity and ALK Positive have the right to publicly present non-scientific results of the research project, but scientific publications must be managed pursuant to LUNGevity Policy. Notwithstanding, this does not remove any obligations of LUNGevity and ALK Positive to seek approvals from any awardee regarding the dissemination of scientific or nonscientific publications.

ALK Positive/LUNGevity Foundation 2022 Request for Application

ALK-POSITIVE LUNG CANCER RESEARCH AWARD PROGRAM
APPLICATION INSTRUCTIONS AND TIMELINE

Applicants will be allowed to submit their letter of intent (LOI) beginning January 26, 2022.

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 Arial 11-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 and co-principal investigators only.

N**o** budget information or other supporting materials should be included.

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

Applicants are required to electronically submit the LOI **by Wednesday, February 23, 2022 (11:59 pm EST)**, via proposalCENTRAL: https://proposalCENTRAL.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 April 1 whether they may proceed with the full application. ALK Positive/LUNGevity will not provide results of the peer review process.

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 the following::
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.
5. **Specific Aims:** Concisely explain the project's specific aims. Please include a description on whether and 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.
   If proposing a clinical trial, please include a detailed sample size justification and any statistical analysis you propose to use. Also, clearly describe impact on patient participation (for example, number and frequency of blood draws and biopsies, number of clinical visits, etc.)
7. **Patient impact statement** – How will the research findings from the project move to the clinic within 1-2 years and impact patients? What plans does/do the applicant(s) have for the clinical application of the findings of the project?
8. **Other funds available to support the proposed project**, such as funds provided by drug companies for part of a clinical trial (as applicable)
9. **Statistical analysis plan:** A detailed statistical analysis plan is required for all applications and is limited to 1 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.
10. **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 11 pages, including one page for the statistical analysis plan. The references should also be included within the 11 pages.

• NIH **biosketches** of all PIs and Key Personnel (both current and pending support). The sketches should be limited to four pages each.

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

• **Other support**, including current and pending, is only required for the PI and any co-Pis. The value of the support should be included.

• If relevant, the **following documents**:
- a copy of the documents listed in the "Animal Use" section
- a copy of the biohazard document named in the "Biohazards" section

• Do **not** include reprints of your previous publications.

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 9 (11:59 pm 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 no earlier than **late summer 2022** whether they will receive an award. ALK Positive/LUNGevity will 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 to LUNGevity 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
Senior Research and Education Services Manager
mjacobson@LUNGevity.org

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