EGFR Resisters/LUNGevity Research Award Program for EGFR-positive Lung Cancer 2023 Request for Application (RFA)

IMPORTANT NOTES TO READ BEFORE PROCEEDING

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

LUNGevity Foundation advises potential applicants to read this RFA in its entirety, including eligibility requirements and other terms and conditions, before starting an application. The application process will be managed through proposalCENTRAL.

A two-step application process will be used. Applicants 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.

An applicant may submit no more than two applications for this award. Award(s) will be funded at a maximum of $100,000 per year for two years ($200,000 total).

Any applicant who is deemed ineligible for this award or does not follow the instructions for preparing the application will be disqualified and the application not reviewed.

Important Dates:

- February 27, 2023: Letter of Intent (LOI) deadline
- May 8, 2023: Full applications due from invited applicants
- Late Summer 2023: Award notifications made
- November 1, 2023: Awards begin

Detailed instructions for applying for this award begin on page 12.

EGFR RESISTERS

EGFR Resisters is a grassroots community of close to 4,000 EGFR-positive lung cancer patients and caregivers from 90+ countries, dedicated exclusively to improving outcomes for people with EGFR-positive lung cancer by changing EGFR-positive lung cancer into a manageable, chronic disease. The group uses the strength of its collaborations to drive important research questions and fund novel re-search and clinical trials. For more information about EGFR Resisters, please visit www.egfrcancer.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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FUNDING OPPORTUNITY DESCRIPTION

Overview

EGFR Resisters is partnering with **LUNGevity Foundation** to support EGFR-positive non-small cell lung cancer research. EGFR Resisters will leverage LUNGevity's scientific review process as well as fund its research through the Foundation. This research will address the critical unanswered questions in the EGFR 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.

Goal of the Award Program

To fund high-impact research that seeks to transform the future for patients diagnosed with EGFR-positive lung cancer by changing EGFR-positive lung cancer into a chronic or curable condition.

With this award, EGFR-positive patients are expediting the research process themselves both by fundraising and crowdsourcing. In addition to fundraising, members of EGFR Resisters are also committed to facilitating research by offering up their available histories, opinions, tissues, bodily fluids (blood, urine, etc.), and/or any other specimens or information about their condition to the funded investigators.

AWARD PROGRAM REQUIREMENTS

The research funded through this award is expected to have a direct impact on the outcomes of patients with advanced EGFR-positive lung cancer, but innovative proposals that address other unmet needs in the EGFR-positive lung cancer space are also invited for submission. Please note that we are not accepting psychosocial research proposals as part of this RFA. Applicants are encouraged to propose projects that utilize the resources of the members of EGFR Resisters.

Successful applicants are required during the duration of the award term to share their research progress with the members of EGFR Resisters and LUNGevity, including Scientific Advisory Board members, study section reviewers, and other awardees) every six months virtually as well as annually at the LUNGevity Fall Science Meeting.

Scientific scope

Proposed projects **must** include at least one translational aim that is directly related to improvement of patient outcomes and/or leads to a clinical trial. Potential areas of exploration include, but are not limited to, the following types of projects:

- CNS metastases and leptomeningeal disease – why cancer spreads here in some, how cancer in the CNS differs from systemic disease and what are the best treatments

- Optimizing first-line treatment to better eradicate persister cells that remain on treatment – is combo therapy best, what combos, should we risk/adapt treatments plans
- Investigating the differences in locations of metastatic disease seen in EGFR-positive lung cancer (brain metastasis, bone, other metastases, etc.) and new treatment strategies
- Novel applications of liquid and tissue biopsies (and/or other methodologies) to improve under-standing of TKI resistance and/or tailor therapy
- Uncommon EGFR mutations – how are these different than EGFR L858R/ex19del, how to best treat
- Novel combination therapies for common subsets of EGFR-positive lung cancer (for example, drug repurposing of FDA-approved agents)
- Oligometastatic disease and oligoprogression- what does this mean biology-wise and how to best treat
- Treatment of progressive disease in the absence of traditional oncogenic drivers driving resistance
- Biology of co-occurring mutations in the diagnosis and prognosis of EGFR-positive lung cancer – How can this information be used for treatment decision and prognostication?
- Studying biomarkers of treatment response in EGFR-mutant lung cancer and how they can be used to optimize patient treatment.
- Histologic transformation of EGFR+ NSCLC into SCLC/squamous cell lung carcinoma/other types – Biology and treatment approaches
- Studying how the biology of the disease — mutations, resistance mechanisms, efficacy of treatments, etc. — varies across diverse populations

Eligibility

If an applicant does not meet an eligibility requirement at the time of application, but will meet it prior to the award start date OR has special circumstances that prevent an eligibility requirement from being met, the applicant must notify LUNGevity at the time of LOI submission. This information should be attached to the applicant's biosketch and should be no more than one page.

Education and Experience: This award program is open to all faculty members. At the time of the start of the award term, the applicant, who must be a principal investigator for the proposed research, must:

1) hold a doctoral degree
2) have completed a postdoctoral training fellowship
3) have a faculty appointment with a university-based academic institution or a research institution that is not formally associated with a university. An applicant may be at any level

of research experience. If the applicant is within five years of their faculty appointment, a mentor **must** be identified who will vouch for the successful completion of the proposed project or be able to provide justification for any special circumstances for which a mentor would not be needed.

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.

Current LUNGevity funding: An applicant with a current LUNGevity award that would be concurrent with a 2023 EGFR-positive Lung Cancer Research Award is not precluded from applying.

Geographical Restriction: The Award Program is open to applications that include an international collaborator. At the time of application, an international collaborator (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 following paragraph.

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.

Disbursement of funds for the award will **only** be made to a U.S. institution to allow timely commencement of project**.**

AWARD INFORMATION

Award Structure

The project will be awarded up to $100,000 per year for 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.

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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. The award may be used to assist with operational costs, **however, drug costs will not be covered.** The applicant must provide a letter of commitment of support for the project from the pharmaceutical partner, including that they will provide the drug.

Award Payment Schedule
The first award payment will be disbursed no earlier than November. Subsequent payments will be issued Assuming award renewals, contingent on meeting milestones, EGFR Resisters/LUNGeity will issue the second payment following award renewal. The second payment will be made only after the awardee's funding balance has decreased to $25,000 or less.

Award Selection
Final selection of the project(s) to be funded will be contingent on scientific review and availability of funds.

Some of the factors considered when reviewing applications include:

- **Innovation** – Does the project address a previously uninvestigated area of EGFR-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 3-4 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

Animal Use
The EGFR-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.

If animals will be used in the proposed research projectg, applicants must provide institutional endorsements that the research facility, its research, and its employees adhere to the appropriate animal welfare regulations in their country. In the U.S., these include:

- Animal Welfare Act
- USDA rules
- National Research Council *Guide for the Care and Use of Laboratory Animals*
- Public Health Service Policy on Humane Care and Use of Laboratory Animals

In addition to the above, applications must also include the following documents:

- Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) accreditation.
- Institutional Animal Care and Use of Committee (IACUC) approval.

A project is **not** eligible for an award if the research proposal involves animals and the institution does not have accreditation from the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC), **or** does not hold a current Public Health Service (PHS) Animal Welfare Assurance, **or** does not have accreditation from the United States Department of Agriculture or does not have accreditation from the Institutional Animal Care and Use Committee (IACUC).

Authorized Award Holders
The EGFR-positive Lung Cancer 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.

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 second funding period requires prior approval by EGFR Resisters /LUNGevity. All requests must be in writing and received by EGFR Resisters/LUNGevity 60 days prior to the end of the first 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 EGFR Resisters/LUNGevity. All requests must be in writing and received by EGFR Resisters/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 to be transferred, the budget line the funds are currently included in and to where they would be transferred. In the case of supplies, all items must be itemized.

Change of Institution
Transfer of the EGFR Resisters/LUNGevity award from one institution to another requires prior approval by EGFR Resisters/LUNGevity. All requests must be in writing. All unexpended funds must be returned to EGFR Resisters/LUNGevity within 45 days of transfer approval. Once EGFR Resisters/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
EGFR Resisters/LUNGevity awards will be awarded to individuals working in institutions identified as Equal Opportunity Employers.

Equipment Purchase, Repair & Service Contracts
No portion of the award budget may be used for the purchase, repair, or service contract costs for institutional equipment.

Human Subjects
Whenever human participants are a part of the EGFR Resisters/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.
- A copy of the appropriate institutional committee approval for research involving human adult stem cells or use of human fetal tissue.

If the proposed research project involves human subjects, the population sampled shall be inclusive of the general population of relevance to the scientific question posed, without restriction in regard to gender, race, age, and socioeconomic status. Proposals that intentionally restrict the population sampled must include a compelling scientific rationale for such design.

LUNGevity encourages applicants to submit their projects to the appropriate human subjects Institutional Review Board at the time of application.

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Malpractice Liability
EGFR Resisters/LUNGevity will not assume responsibility for, and the institution will indemnify and hold EGFR Resisters/LUNGevity harmless from any lawsuit, claim, judgment, damages, awards, or malpractice arising from research or investigations related to an award.

Other Funding
EGFR Resisters/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 and discoveries from research performed during the term of the EGFR Resisters/LUNGevity award will be subject to the current EGFR Resisters/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 9.

Progress and Financial Reports
Interim written progress and financial reports are due every six months and six-month virtual reviews will also take place with representatives from EGFR Resisters/ LUNGevity. Interim reports should be submitted by the deadline provided, as they will provide the basis for the decision to disburse the next period of funding. In addition to written interim reports, progress presentations at the annual LUNGevity Fall Science Meeting are expected during the award term.

Final progress and financial reports are also required after the conclusion of the project. At the conclusion of the award period, EGFR Resisters/LUNGevity requires a complete financial disbursement report covering the entire award period. The disbursement report must reflect the award expenditures as approved by EGFR Resisters/LUNGevity. Any funds used for unauthorized expenditures or unexpended funds must be returned to EGFR Resisters/LUNGevity, with the disbursement report, within 60 days of the award termination date.

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 EGFR Resisters/LUNGevity grant must be made available in the PubMed Central online archive. The EGFR Resisters/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. All publication costs must directly relate to the EGFR Resisters/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 EGFR Resisters/LUNGevity as a supporting entity as follows: "This study was supported by a grant from EGFR Resisters/LUNGevity Foundation." Reprints of abstracts, manuscripts, or other articles that reflect research done after award acceptance must be submitted to EGFR Resisters/LUNGevity.

Student Tuition
EGFR Resisters/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
EGFR Resisters/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 $1,500 per year per investigator. These travel funds can only be used if the work related to this grant is being presented in poster/oral presentation/abstract form. Travel to LUNGevity meetings is paid directly by the Foundation and should not be included in the $1,500.

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EGFR RESISTERS/LUNGEVITY FOUNDATION PATENT AND INTELLECTUAL PROPERTY POLICY

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).

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.

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.

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.

LUNGEVITY and EGFR Resisters reserve the right to public acknowledgment for inventions or intellectual property resulting from support by LUNGEVITY and EGFR Resisters; however, LUNGEVITY and EGFR Resisters name and logo may not be used in association with an invention or intellectual property without prior approval of LUNGEVITY and EGFR Resisters.

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EGFR RESISTERS/LUNGEVITY FOUNDATION PUBLIC ACCESS POLICY

LUNGevity, in partnership with EGFR Resisters, 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 EGFR Resisters 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 EGFR Resisters, 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 EGFR Resisters/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.

EGFR Resisters/LUNGevity award recipients must acknowledge EGFR Resisters/LUNGevity grant support in every article arising from such funding. The acknowledgment statement must include the applicable grant number. The award recipients must notify EGFR Resisters (by emailing egfrresisters@gmail.com and LUNGevity Foundation (by emailing Jody Roosevelt at jroosevelt@LUNGevity.org) of any articles arising from such funding. This will enable the EGFR Resisters and LUNGevity to link the published outputs of research to the support that has been provided. LUNGevity and EGFR Resisters 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.

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APPLICATION INSTRUCTIONS AND TIMELINE

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

Applicants will be allowed to submit their letter of intent (LOI) beginning January 25, 2023.

Letter of Intent (LOI)

The letter of intent **must** include a narrative that contains:

- Rationale for the project with details on how the project will impact clinical care of EGFR-positive lung cancer patients
- Planned specific aims (these may be modified slightly if invited to submit a full application)
- Brief statement of the overall experimental approach
- Brief statement describing the clinical context in which the therapeutic strategy will be used
- Brief statement of the quantitative metrics/performance that the approach should achieve to show clinical utility, and
- References

The narrative should be typed in Arial 11-point type, single-spaced, with .5" margins and **should not exceed a total of two pages**, excluding references.

The following items should be included as part of the LOI:

- An NIH **biosketch** for the PI and any co-PIs. Note that "other support" should include the value of past, current, and pending support.

No budget information or other supporting materials should be included with the LOI. A sponsoring institution signature is not required.

Letters of Intent are due **by February 27, 2023 (11:59pm EST)** via proposalCENTRAL. Extensions will not be given. Once an LOI has been submitted it cannot be changed.

Applicants will be notified by email no earlier than **March 31, 2023,** whether they will be invited to submit full application. EGFR Resisters/LUNGevity will **not** provide feedback regarding results of the review of any Letter of Intent submitted.

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Full Application

Only invited applicants may prepare and submit a full application. Instructions for how to proceed will accompany the invitation. Among other materials, the full application must include:

-A narrative containing the following sections in this order:

- **Scientific Abstract**: this should be appropriate for a reviewer of a peer-review journal
- **Lay Abstract:** explain 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 EGFR-positive lung cancer patients should be included.
- **Background**: Present the ideas and reasoning behind the proposed research; 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. Please include a description on whether and how you propose to include biospecimens from EGFR-positive lung cancer patients in your proposed experiments.
- **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.)
- **Patient impact statement**: How will the research findings from the project move to the clinic within 3-4 years and impact patients? What plans does/do the applicant(s) have for the clinical application of the findings of the project?
- **Other funds available to support the proposed project**, such as funds provided by drug
companies for part of a clinical trial (as applicable)
- **References**

-NIH **Biosketches** for PI/co-PI and Key Personnel

-If the proposed project is a clinical trial: a **letter of support** from the pharmaceutical partner that includes confirmation that the partners will provide the drug.

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

-If applicable, institutional documentation regarding the use of animals and biohazards in the proposed research

Templates and more detailed instructions for all of the above materials and any other materials that must be included can be found at https://proposalCENTRAL.com.

Full applications must be submitted via proposalCENTRAL **by May 8, 2023 at 11:59pm EST.** Extensions will not be granted. Once a full application has been submitted, it cannot be changed.

Applicants will be notified of award decisions by email in **Late Summer 2023**. Review comments will be provided for full applications only.

Awardees will receive 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 returned to LUNGevity before any funds will be released.

APPLICATION ASSISTANCE

For questions regarding programs, eligibility, policies, terms and conditions, or instructions for the letter of intent or full application, please contact:

Jody Roosevelt
Research Program Coordinator
jroosevelt@LUNGevity.org
847-525-2075

For help with proposalCENTRAL, please contact:

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