



IMPORTANT NOTES TO READ BEFORE PROCEEDING

Potential applicants are encouraged to read this RFA in its entirety, including all eligibility requirements and other terms and conditions, before starting an application. 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.

The grant will be funded at a maximum of \$25,000 for one year. Only one grant will be awarded, unless additional funds become available at ASTRO and LUNGevity's discretion. One no-cost extension (NCE) may be considered by ASTRO and LUNGevity at their full discretion. However, the total project period may not exceed 2 years.

At the time of submission and throughout the duration of the award term, an applicant/awardee must be employed by a U.S. institution.

The application process will be managed through proposalCENTRAL.

Important Dates:

- March 24, 2023: Application deadline
- Early Summer 2023: Award notifications made
- July 1, 2023: Earliest award start date

Detailed instructions for applying for this award begin on page 4.

ASTRO

ASTRO is the premier radiation oncology society in the world. ASTRO's mission is to advance the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly evolving health care environment. For more information about ASTRO, please visit https://www.astro.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

The ASTRO-LUNGevity Residents/Fellows in Radiation Oncology Seed Grant is intended to foster and develop the research careers of residents and fellows interested in radiation-oncology related basic, translational and/or clinical research to benefit patients with lung cancer. The grant will be funded at a maximum of \$25,000 for one year. Only one grant will be awarded, unless additional funds become available at ASTRO and LUNGevity's discretion.

ELIGIBILITY

The general eligibility criteria are listed below. ASTRO has full discretion in any funding decision and is not obligated nor liable to issue any award to any eligible or ineligible applicants at any time.

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are encouraged to apply as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

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Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

Foreign Institutions

- Non-domestic (non-U.S.) Entities (Foreign Institutions) are **not** eligible to apply.
- Non-domestic (non-U.S.) components of U.S. Organizations are not eligible to apply.

<u>Eligible Individuals (Residents/Fellows):</u> Any candidate with the skills, knowledge, and resources necessary to carry out the proposed research as the Principal Investigator (PI) is invited to work with his/her mentor and organization to develop an application for support.

Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are especially encouraged to apply for ASTRO support. Multiple PIs are not allowed.

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<u>Degree Requirements and Employment Status:</u> Applicants must hold a doctorate degree such as Ph.D., M.D./Ph.D., M.D., D.O., or other equivalent degrees) and must be enrolled in a U.S. residency or fellowship at the time of application.

<u>Level of effort:</u> Pls are required to commit at least 75% of their full-time professional effort to research. The remainder may be devoted to clinical or other pursuits consistent with the objectives of the grant.

<u>ASTRO Membership:</u> The applicant **must** be a current and active ASTRO member, or have submitted an application for ASTRO membership, as of the due date of the application. If selected, the PI will be required to maintain his/her membership throughout the duration of the grant.

COMMITMENT FROM THE APPLICANT

The applicant must designate a mentor at his/her Institution who will provide guidance and support for the research project. Mentors should be senior investigators with a minimum of R01 or equivalent level funding and provide a letter of support detailing their oversight and support.

- <u>Meetings</u>: If awarded, the PI is encouraged to attend at least one ASTRO Annual Meeting and one LUNGevity Annual meeting, and present his/her research findings.
- <u>LUNGevity Meeting</u>: If awarded, the PI is required to attend the LUNGevity Fall Science Meeting and present their research findings.

COMMITMENT FROM THE APPLICANT'S MENTOR

- The mentor should be an accomplished investigator in the proposed research area and have a track record of success in training independent investigators.
- The mentor should have sufficient independent research support to cover the costs of the proposed research project in excess of the allowable costs of this award.
- The mentor must demonstrate, in writing, a commitment to the development of the applicant as a productive, independent investigator. It is expected that the mentor will meet with the PI at least weekly.
- Applicants may also nominate co-mentors as appropriate to the goals of the program.
- At least one mentor must be an active member of ASTRO.

COMMITMENT FROM THE APPLICANT'S AFFILIATED ELIGIBLE ORGANIZATION(S)

• If awarded, the host department will act as the fiscal intermediary. The Institution will administer the funds to the PI and be responsible for satisfying tax withholding, deposit and/or reporting requirements applicable to the payment of the award. The PI will be responsible for individual income taxes. The Institution will be required to

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provide sufficient additional funds to supplement salaries or supplies as needed for the research project.

- Any change in Institution, mentor, and chair or in the applicant's position that might affect their ability to successfully complete their training should be communicated as soon as possible to ASTRO so that appropriate action can be taken.
- When a mentor at the grantee's Institution is to be replaced, the Institution must submit a letter from the proposed mentor documenting 1) the need for substitution 2) the new mentor's qualifications for supervising the project and 3) the level of support for the applicant's career development.
- Only 1 grant can support the proposed research project. If independent funding is obtained for the same scope of work selected by ASTRO for this award the recipient must refuse either this or the competing award(s).

APPLICATION GUIDELINES

<u>Submission:</u> Applicants must submit a proposal to only one of the 2022 ASTRO Seed Grant funding opportunities. All applications are due by 11:59 pm Eastern time on March 24, 2023. Proposals will not be considered after the deadline. Applications must be submitted online using the application tool at proposalCENTRAL and the document templates and requirements therein.

<u>Application Content:</u> It is critical that applicants follow the instructions. Conformance to the requirements in this PA are required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

All materials must be prepared in English, single spaced, using a font size of 11 or 12 points. Smaller text in figures and charts is acceptable, once it is legible when the page is viewed at 100%. Arial or Times New Roman fonts are recommended. A minimum of one-half inch margins must be used on all page borders.

- 1. **Title Page**: Enter the Project Title, Discipline of Research, and indicate whether you have other research funding.
- 2. **Templates and Instructions**: Download PA and templates.
- 3. **Enable Other Users to Access this Proposal**: Allow others (e.g. Institutional administrators or collaborators) to view, edit, or submit the proposal.
- 4. **Applicant**: Complete all required fields that include PI's name and contact information, and level of effort (%) that will be allocated to the proposed research project.
- 5. **PI Demographics**: Providing this information is optional and is not part of the review process.
- 6. **Institution and Contacts**: Provide the Institution name, address and type of organization and requested contact information of the mentor and signing official.
- 7. **Key Personnel**: List and provide contact information for key persons.

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- 8. Scientific Abstracts, Impact Statement, Modalities and Common Scientific Outline (CSO) Codes:
 - Provide a general audience abstract (non-technical) (2,000 characters including spaces max) and a technical abstract (3,000 characters including spaces max) that concisely describe the background, rationale, specific aims, experimental approach including model system and statistical approach, anticipated outcomes and impact of the project. Note the general audience abstract will become public if the proposal is selected for funding, therefore, it should not include any proprietary information.
 - Impact Statement: Statement of Proposal's Benefit to lung cancer and radiation oncology research (1,000 characters including spaces max).
 - Select all relevant Modalities and CSO Codes that best represent the proposed research
- 9. **Other Support**: List any additional research support that the PI currently holds. Include Project Title, Funding Source, Project Status, Award Number, Start and End Dates, Person Months, and Overlap.
- 10. **Research Assurances**: Indicate status of IRB/IACUC approvals as applicable, use of recombinant DNA, biohazardous materials, genetically engineered organisms, or fetal tissue
- 11. **Application Documents**: Upload the below required application documents.
 - **Research Plan (6-page limit):** Project description to fit within the 1-year project period and should include:
 - o Background
 - o Preliminary data and figures (if applicable, but not required)
 - o Specific aims
 - o Experimental design/methods
 - o Statistical analysis plan
 - o Anticipated outcomes
 - o Potential pitfalls and alternatives
 - o Significance
 - o Future directions

References must be included but will not count toward the 6-page limit.

- Biosketches (5-page limit): The applicant and lead mentor must each submit a biosketch including a list of relevant publications and currently funded research projects. DoD and NIH formats will be accepted. Biosketches for collaborators and research support staff are not required.
- Budget and Budget Justification: Submit a detailed budget (can be prepared using the NIH budget form e.g. PHS 398) and Budget Justification with a breakdown and description of the estimated costs. ASTRO will cover only direct costs. Funding cannot go towards supporting salaries of mentors or collaborators.

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- Mentoring plan (1-page limit): A detailed mentoring plan from the applicant's mentor that outlines courses, lectures, meetings, and other ways to support the applicant and help increase likelihood of success must be included.
- Letters of support (2): Upload 2 letters of support. One must be from your mentor. The other can be from a collaborator. Letters of support from additional collaborators can be appended but are not required.
- Institutional letter of support: Upload one letter of support from the Institution or Department. This letter must indicate the level of commitment through matching funds or in-kind contribution from the Institution to this award. This letter should include a guarantee that the applicant will be afforded at least 75 percent protected time to perform research.
- 12. **Validate:** Review entire proposal for missing required information.
- 13. **Signature Page:** Before submitting the application, complete all fields within the signature page. A signature is required from both the Applicant/PI and a Signing Official from the applicant's Institution. **Applications will not be considered for review if required signatures are missing.**

APPLICATION REVIEW

All proposals will undergo a rigorous peer review by the ASTRO Grant Review Panel. Reviewers are members of the ASTRO Research Grants Evaluation Committee. A study section consisting of researchers with expertise in the areas and topics of each grant will review the application for scientific merit and appropriateness for funding. Final decisions will be subject to the approval of the ASTRO Board of Directors. If no suitable candidates are found, no awards may be issued.

Review Criteria: In general, reviewers should evaluate the candidate's potential for developing an independent research career that will make important contributions to advance lung cancer and radiation oncology research, taking into consideration the likely value of the proposed research project to lead to submissions for larger grant applications. Selected proposals will have strong scientific merit and impact, and possess an innovative and transformative approach, and demonstrate potential for progression to the clinic.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the Lung cancer and radiation oncology research fields. In addition, Reviewers should provide their assessment of the likelihood that the proposed mentorship and research plan will enhance the candidate's potential for a productive, independent scientific research career, taking into consideration the criteria below in determining the overall impact score.

Scored Review Criteria

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Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

If the proposed research includes clinical study, the reviewers will consider that any clinical study may include study design, methods, and intervention that are not by themselves innovative, but address important questions or unmet needs. Reviewers should also consider the scope of the clinical study relative to the available resources.

Significance

- Does the project address an important problem or a critical barrier to progress in the field?
- If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
- How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Candidate

- Are the PI, collaborators/mentors well suited to the project?
- Does the candidate have the potential to develop as an independent and productive researcher?
- Are the candidate's prior training and research experience appropriate for this award?
- Is the candidate's academic, clinical (if relevant), and research record of high quality?
- Is there evidence of the candidate's commitment to meeting the program objectives to become an independent investigator in research?
- Do the reference letters address the above review criteria, and do they provide evidence that the candidate has a high potential for becoming an independent investigator?
- Does the candidate have the potential to organize, manage, and implement the proposed research?
- Does the candidate have training (or plans to receive training) in data management and statistics relevant to the proposed research?

Mentoring Plan/Career Goals and Objectives

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate and lead to scientific independence?
- Are the candidate's prior training and research experience appropriate for this award?
- Are the content, scope, phasing, and duration of the mentoring plan appropriate when considered in the context of prior training/research experience and the stated training and research objectives for achieving research independence?
- Are there adequate plans for monitoring and evaluating the candidate's research and career development progress?

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Research Plan

- Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
- Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?
- Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
- Are the proposed research questions, design, and methodology of significant scientific and technical merit?
- Has the candidate included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project?
- Has the candidate presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- If relevant, has the candidate presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?
- Is the research plan relevant to the candidate's research career objectives?
- Is the research plan appropriate to the candidate's stage of research development and as a vehicle for developing the research skills described in the mentoring plan?
- If relevant, are the scientific rationale and need for a clinical, feasibility or ancillary study well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms?
- If proposing a small feasibility study, is the study warranted and will it contribute to planning and preliminary data needed for design of future larger scale clinical trials?
- If relevant, is the clinical or ancillary study necessary for testing the safety, efficacy or effectiveness of an intervention, or in the case of a feasibility study necessary to establish feasibility of a future clinical trial?
- Is the study design justified and relevant to the clinical, biological, and statistical hypothesis(es) being tested?
- Are the plans to standardize, assure quality of, and monitor adherence to, the protocol and data collection or distribution guidelines appropriate?
- Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions, if interventions are delivered?

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)

- Are the qualifications of the mentor(s) in the area of the proposed research appropriate?
- Does the mentor(s) adequately address the candidate's potential and their strengths and areas needing improvement?
- Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate?

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- Is the mentor's description of the elements of the research career development activities, including formal course work adequate?
- Is there evidence of the mentor's, consultant's, and/or collaborator's previous experience in fostering the development of independent investigators?
- Is there evidence of the mentor's current research productivity and peer-reviewed support?
- Is active/pending support for the proposed research project appropriate and adequate?
- Are there adequate plans for monitoring and evaluating the career development of the candidate's progress toward independence through a detailed mentoring plan?
- Does the mentor or mentoring team have the expertise, experience, and ability to guide the applicant in the organization, management and implementation of the proposed research and help them to meet timelines?

Environment & Institutional Commitment to the Candidate

- Is there clear commitment of the sponsoring Institution to ensure that the required minimum of the candidate's effort will be devoted directly to the research described in the application, with the remaining percent effort being devoted to an appropriate balance of applicable research, teaching, administrative, and clinical responsibilities?
- Is the Institutional commitment to the career development of the candidate appropriately strong?
- Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate?
- Is the environment for scientific and professional development of the candidate of high quality?
- If applicable, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?
- Does the application adequately address the capability and ability to conduct the proposed research at the proposed site(s) or centers? If applicable, are there plans to add or drop enrollment centers, as needed, appropriate?
- If international site(s) is/are proposed, does the application adequately address the complexity of executing the proposed research?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories
of research that are exempt under 45 CFR Part 46, the committee will evaluate the
justification for involvement of human subjects and the proposed protections from
research risk relating to their participation according to the following five review

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- criteria: (1) risk to subjects, (2) adequacy of protection against risks, (3) potential benefits to the subjects and others, (4) importance of the knowledge to be gained, and (5) data and safety monitoring for clinical trials.
- For research that involves human subjects and meets the criteria for one or more of
 the categories of research that are exempt under 45 CFR Part 46, the committee will
 evaluate: (1) the justification for the exemption, (2) human subjects involvement and
 characteristics, and (3) sources of materials. For additional information on review of
 the Human Subjects section, please refer to the NIH <u>Guidelines for the Review of
 Human Subjects</u>.

Inclusion of Women, Minorities, and Individuals Across the Lifespan

• When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals across the lifespan (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the NIH <u>Guidelines for the Review of Inclusion in Clinical Research.</u>

Vertebrate Animals

• The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the NIH Worksheet for Review of the Vertebrate Animal Section.

Biohazards: Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Authentication of Key Biological and/or Chemical Resources: For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget: Reviewers will consider whether the budget is fully justified and reasonable in relation to the proposed research within the project period.

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PROGRAM CONTACT

Email questions about this RFA to the Research Department at LUNGevity Foundation Jody Roosevelt iroosevelt@lungevity.org

Technical questions about the ProposalCentral submission system should be directed to their customer support at 1-800-875-2562 (Toll-free U.S. and Canada) or by email pcsupport@altum.com. Support is available during normal business hours: 8:30 am - 5:00 pm Eastern Time (Monday through Friday).

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