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Novel Radiopharma Cancer Therapies: Enabling Technology Platforms and Drug Discovery Projects

Grant Guidelines and Policies

We are pleased to announce a new opportunity with the Lineberger Comprehensive Cancer Center (<https://unclineberger.org>) focused on advancing innovative therapeutics projects targeted at cancer indications with high unmet need. The *Novel Radiopharma Cancer Therapies: Enabling Technology Platforms and Drug Discovery Projects* Request for Proposals (RFP) is a funding opportunity that will provide translational grants to university researchers dedicated to driving forward translational science in radiopharmaceutical cancer therapies.

Eshelman Innovation is an emerging innovation engine that moves groundbreaking healthcare therapeutics and digital health ideas to reality. Since 2016, Eshelman Innovation has sought to fuel major impact at UNC through our funding, infrastructure, and partnerships. UNC's Lineberger Comprehensive Cancer Center (LCCC) houses state of the art capabilities and cutting-edge research dedicated toward understanding the causes of cancer at the genetic and environmental levels with the goal to translate findings into innovative clinical trials. Through a more comprehensive partnership, Eshelman Innovation and LCCC can advance oncology assets from discovery to preclinical and early development studies. Applying strategic investment and translational strategy will set a direction that meets the needs of key funders, ensuring that investments have the greatest potential of being both transformative and sustainable.

We encourage faculty and staff to submit proposals for innovative projects that create or further develop intellectual property or provide commercial opportunities that could support the sustainability of Eshelman Innovation. Proposals are encouraged to include a broad spectrum of scientific engagement through meaningful collaborations across a variety of diverse disciplines, departments, schools, and institutions. Please consider working with collaborators who provide broad scientific or commercial engagement to your idea.

— The way to better life has always been through innovation.

Please note that the information below is only for our *Novel Radiopharma Cancer Therapies: Enabling Technology Platforms and Drug Discovery Projects* grant process. An opportunistic proposal is available for novel ideas that do not fit with the current RFP. Please reach out to the Eshelman Innovation team at EshelmanInnovation@unc.edu to learn more. If you are interested in working with the Eshelman Innovation Digital Health Venture Studio, please find more information on our [website](#).

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Important Dates

Outlined below are important dates regarding our 2024 *Novel Radiopharma Cancer Therapies: Enabling Technology Platforms and Drug Discovery Projects* grant cycle.

- **July 15, 2024:** [Open form](#) to submit a full proposal
- **July 26, 2024:** Deadline to contact Office of Research Administration on your budget
- **August 2, 2024:** Deadline to submit aims and milestones to the Eshelman Innovation Project Manager via our online form
- **August 15, 2024:** Grant submission deadline
- **September 16, 2024:** PIs notified of pitch selection
- **September 30, 2024:** Pitch Day – virtual
- **October 16, 2024:** Notice of Award sent to selected grant recipients
- **November 1, 2024:** Funding begins
- **November 1, 2024:** Deadline to return signed Notice of Award, Photo, and Project Description
- **November 1 – November 29, 2024:** Funded project orientation/kick off with Eshelman Innovation and LCCC teams

Eligibility

Innovators with a faculty affiliation at a [UNC system school](#) or a collaborator with a faculty affiliation at a UNC system school are encouraged to apply for Lineberger Comprehensive Cancer Center (LCCC) and Eshelman Innovation's *Novel Radiopharma Cancer Therapies: Enabling Technology Platforms and Drug Discovery Projects* RFP. Full proposals will be reviewed by the LCCC and Eshelman Innovation Therapeutics Accelerator teams with the assistance of a scientific and commercial advisory panel. A selection of reviewed full proposals by the expert panel will be invited to present their work at a Pitch Day. All proposals must have a UNC system faculty or staff member on the proposal as either a Lead or co-Principal Investigator (PI). If an external innovator serves as Lead-PI on the proposal, please note that the UNC faculty or staff member will be the fund manager and oversee the UNC chart field string (CFS).

Grant Categories

The Radiopharma Cancer Therapies RFA offers grants within two categories.

- **Therapeutic** – A project whose ultimate goal is to develop a drug
- **Technology Platform** – A project developing novel tool(s) with the potential to accelerate drug discovery/development

Grants are generally awarded from one to two years with various funding ranges. All funding asks will be thoroughly reviewed by LCCC and Eshelman Innovation, so funding asks should be concise to what is needed to complete the project. All funding will be disbursed to PIs based on the completion of their aims and milestones identified in their application.

Proposals that have the potential to generate novel, protectable intellectual property that is differentiated from existing solutions are encouraged to apply. All proposals must include a UNC system faculty or staff member as the Lead or co-PI. We encourage proposals that include a broad spectrum of scientific engagement through meaningful collaborations across a variety of disciplines, departments, schools, and institutions. Please consider including collaborators that provide broad scientific or commercial engagement. If you have questions about project role assignments on your proposal, please review our [Overview of Budget and Funding Guidelines](#).

PIs external to UNC-CH will be required to submit two letters of support with their application to be considered for funding. Please see the [Overview of Grant Policies](#) for more information on requirements for external PIs and collaborators. If you are interested in a possible internal/external collaboration and need support from Eshelman Innovation, please contact EshelmanInnovation@unc.edu.

While identifying team members for your project, please keep in mind the below clarification of common role assignments on projects:

- **Lead Principal Investigator (Lead PI):** The lead individual designated on the project to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. A project is allowed one Lead PI. External innovators to the UNC system may serve as the Lead PI, however, a UNC system faculty member or staff must serve as a Co-PI.
- **Co-Principal Investigator (Co-PI):** A Co-PI shares equal authority and responsibility as the Lead PI for all intellectual, administrative, and fiscal aspects of the award, consistent with

applicable laws and regulations and the terms and conditions of the award or agreement. A project may have more than one Co-PI. Eshelman Innovation allows innovators external to the UNC system to serve as a Co-PI, however, a UNC system faculty member or staff must serve as the Lead PI or a fellow Co-PI.

- **Co-Investigator (Co-I):** An individual involved with the PI in the scientific development or execution of a project. The Co-I (collaborator) may be employed by, or be affiliated with, the applicant/recipient organization or another organization participating in the project under a consortium agreement. A Co-I typically devotes a specified percentage of time to the project and is considered senior/key personnel.
- **Consultant:** An individual who provides professional advice or services for a fee, but normally is not engaged as an employee of the recipient institution.

How to Apply

Please note, all submissions must be submitted online through our [grant application form](#). Emailed submissions will not be accepted. To view the full list of questions on the full proposal form, please review the [Guideline Appendix](#).

The full proposal forms cannot be saved and returned to at a later date. If you plan to answer the forms in more than one sitting, please do not close out of the browser window and do not refresh the browser window. It is recommended to save your answers periodically in a separate document for backup purposes using the questions listed below. Additionally, as you complete the form, 'logic' questions will appear given your answers.

The **deadline for all proposal submissions is 5:00pm on August 15, 2024**. Applications received after this deadline will not be reviewed or considered for funding.

Full Proposal Guidelines

The full proposal consists of the following:

- **Proposal form** (online only; see [Guideline Appendix](#) for list of questions)
- File Upload (as separate documents):
 - **Proposal Summary File.** The below areas **MUST** be included in your proposal summary:

- **Executive summary:** Provide a 200-250 word overview of your proposal. The executive summary along with your proposal, budget, and aims will be sent to the Eshelman Innovation Steering Board.
- **Problem and/or Need:** Describe the problem and/or unmet need that motivates your unique solution and/or idea.
- **Evidence and Prior Art:** Outline the evidence and prior work in the area by others and/or the evidence or previous studies by the innovator. Enough evidence should be included in the application to demonstrate that the project is feasible, and that the innovator is likely to complete the project successfully within the duration of the award.
- **Innovative Solution:** Describe the proposed idea and/or solution. How is it different from other ideas and/or solutions? How will it substantially transform science, medicine, health care delivery, education, outcomes, or patient health? Be sure to include information outlining competition in the market and in development of the proposed idea.
- **Anticipated Challenges (Scientific and Commercial):** Describe any scientific and/or commercial challenges you anticipate for your proposed idea.
- **Aims and Approach:** State the specific aims and approach for executing your proposed idea and/or solution.
- **Next Steps:** Describe the plan or path for sustaining this work and/or program beyond initial funding through follow-on funding, commercialization, implementation, etc.
- **Budget and Budget Justification File**
 - A member of the UNC Eshelman School of Pharmacy's Office of Research Administration (ORA) team must approve each budget before applications may be submitted. If your budget is submitted without ORA approval, it will be considered ineligible.
 - For more information, please review our [Overview of Budget and Funding Guidelines](#).
 - If applicable, include signed documentation from the authorized institutional grants office at the collaborating institution that contains the following statement: *"The attached budget is consistent with the institutional policies and budgeting guidelines of [insert institution name] and has been reviewed and approved by our authorized institutional official."*
- **Aims and Milestones File**
 - PIs must work with Eshelman Innovation's Project Management (PM) team to craft the project's aims and milestones. *The PM team deals with a high volume of requests, so please do not delay getting in touch with them about your project's aims/milestones. PIs that do not meet with PM team about their aims and milestones will be considered ineligible.*
 - As a first step in the process, PIs must complete an aims and milestones [form](#).
 - The PM will meet with PIs to streamline aims and milestones and Gantt chart project objectives.
 - Please have your budget finalized before meeting with the PM team, so they can identify the proper tranche schedule for each aim with you.
 - The final aims, milestones, and Gantt chart that will be provided by the PM to the Lead PI must be uploaded in the proposal application.
- **IP Strategic Plan (if applicable)**

- If your project includes or relates to any collaborator IP, you will need to meet with an UNC OTC Commercialization Manager to craft your IP strategic plan during the full proposal process. OTC will work with the PIs to tie the aims and milestones into an IP strategic plan that considers both existing IP and proposed outcomes. If you have questions regarding the UNC OTC strategic plan, please contact otc@unc.edu.
- If applicable, a letter from collaborator's technology transfer office if the use of the existing IP of collaborator is essential to the IP strategic plan.
 - **Two (2) letters of support for any PI external to UNC**
 - **Lead PI CV, resume, or bio-sketch**
 - **Co-PI CV, resume, or bio-sketch (if applicable)**

Formatting of Full Proposal:

Proposal summaries should abide by the following formatting guidelines:

- **Length:** A minimum of 2 pages and maximum of 5 pages and may include up to 2 pages of pivotal references; no other required document has a limit.
- **Margins:** At least half-inch
- **Font:** No smaller than 11-point Times New Roman or its equivalent
- **Spacing:** Single or exactly 12-point line spacing
- **Header:** Please include your name and project title in the header of each page of the proposal summary
- **File Type:** PDF format only

All proposal submissions will be reviewed by a panel of scientific and commercial experts with subject matter expertise in the proposal's area of focus. Proposals and reviewer feedback will be reviewed by the LCCC and Eshelman Innovation Therapeutics Accelerator teams and select projects will be invited to pitch to an expert panel at a Pitch Day. Specifics around Pitch Day will be sent to PIs who are advancing in the process.

Overview of Budget and Funding Guidelines

This grant does not cap the funding request of the innovator. However, please keep funding asks concise to what is needed to complete the project. If an innovator's funding ask is beyond what is needed to complete the work, Eshelman Innovation and LCCC may fund only a portion of the request. All funding awarded to PIs will be tranching based on completion of their aims and milestones. Projects will be issued funding starting November 1, 2024, and may not exceed 24 months. All grants should fit within a one to two year timeline with the funding ranges reflecting the scope of the work.

Each innovator must work with the UNC Eshelman School of Pharmacy Office of Research Administration (ORA) to finalize their grant budget. To start, please contact the ORA (fiscelli@email.unc.edu or rajcash@email.unc.edu) to schedule a time to complete your budget. **A member of the ORA must sign off and approve each budget before applications may be submitted to Eshelman Innovation, or the application will be considered ineligible.**

If an external innovator is serving as Lead PI on the proposal, please note the Co-PI from UNC system school will be the fund manager and have oversight of the chart field string (CFS). PIs will be notified of their project start and end dates in their award letter. If the expenditures in a single budget category fluctuate by more than 25 percent from the original budget, PIs must submit a request to re-budget.

PIs may request a no-cost extension (NCE) if the work will not be completed in the allotted time. NCEs must be requested between 90 to 15 days before the end of the project. To merit an extension, projects must provide detailed information on the project's success to date. All projects are allowed one NCE request for six months. NCE requests will be thoroughly reviewed by Eshelman Innovation prior to a final decision. If an NCE is not approved, the remaining balance will be returned to Eshelman Innovation.

If the Lead PI leaves their institution (the UNC system or external) during the funding period, unspent funds will be returned to LCCC and Eshelman Innovation. The opportunity may also be available to request a transfer of funds to a co-PI or collaborator within the UNC system upon the discretion of the innovator's Division Chair, the LCCC Director, and the Eshelman Innovation's Director.

Following the conclusion of a project, unspent funds will be returned to Eshelman Innovation and LCCC within 60 days unless a NCE has been approved. All budget requests may be submitted by contacting us at EshelmanInnovation@unc.edu.

For PIs working with collaborators at institutions outside of UNC-CH, Eshelman Innovation requires signed documentation that contains the following statement from the authorized institutional grants office at the collaborating institution: "*The attached budget is consistent with the institutional policies and budgeting guidelines of (insert institution name) and has been reviewed and approved by our authorized institutional official.*" This documentation can be combined with the UNC budget and uploaded as a single attachment.

Personnel Funding for All Grants:

Please note, the below funding policies are applicable to all applicants.

Eshelman Innovation/LCCC will fund:

- Salaries and fringe benefits of students, postdocs, and research support staff such as technicians/associates, software engineers, etc.
- Salaries of research track faculty
- Travel – Requests for travel support should be limited to funds directly related to project performance. Travel to conferences and meetings will be permitted. International travel is also permitted.
- Equipment – Requests for equipment should be limited to funds directly related to project performance. For example, a laptop for a research assistant to use in clinic to collect data would be appropriate.

Eshelman Innovation/LCCC will not fund:*

- Salaries of tenure track or clinical track faculty, whether new or existing.

Please note: Eshelman Innovation and LCCC will NOT fund overhead, indirect, or F&A costs from UNC or from any external collaborating partners or institutions.

Unused funds will revert to the supporting funding source. All proposed expenses must conform to the general policies of the University. Projects that use the UNC Lineberger Biostatistics Core, the Tissue Procurement Core, and/or other core resources are encouraged to consult with those cores prior to submission.

Building A Budget

When building your budget, please consider project expenses in the following areas:

- **Personnel:**
 - Personnel's percent effort should be determined by that person's annual contribution to the project.
 - Please indicate a reasonable percent effort for faculty consistent with the scope of work. This percent effort will be reflected on additional faculty support documents sent to other sponsors.
 - Based on salary and percent effort, calculate the cost for each team member, and then calculate and insert a total personnel cost into your budget.

- If you have questions about salary for 'to be named' personnel, please contact your department's HR consultant or contact Blair Dodson (EshelmanInnovation@unc.edu).
- **Consultants:** Purchased services and contract costs.
- **Travel:** Costs associated with traveling to conferences, etc.
- **Other Direct Costs:** Costs that can be identified specifically with your project, an instructional activity, or any other institutional activity, or that can be directly assigned to such activities relatively easily with a high degree of accuracy.
- **Equipment:** An article of tangible nonexpendable personal property that has a useful life of more than one year and an acquisition cost per unit that equals or exceeds \$5,000. Eshelman Innovation will fund equipment only when it's truly novel, unique, opportunistic, and necessary. Once a project is completed, all equipment purchased with Eshelman Innovation's funding is subject to return.
- **Other:** Include any miscellaneous expenses and explain the need in detail.
- **Subcontracts:** If you are working with collaborators at institutions outside of UNC-CH, Eshelman Innovation requires signed documentation that contains the following statement from the authorized institutional grants office at the collaborating institution: *"The attached budget is consistent with the institutional policies and budgeting guidelines of [insert institution name] and has been reviewed and approved by our authorized institutional official."*

UNC Eshelman School of Pharmacy Support Services and UNC Offices

It is vital to work with all UNC-CH support services and offices and follow all policies and procedures.

As part of the full proposal, PIs are required to identify and indicate which FAO team from the Eshelman School of Pharmacy each project will need to utilize for support services. There is a place on the application to indicate which support services are needed. That list can be found [here](#).

All budget tracking will occur within the UNC Eshelman School of Pharmacy. Pam Morrison is the contact for Eshelman Innovation's budget tracking. The CFS provided upon funding must be utilized for all invoices. PIs may contact Pam Morrison at pamm@email.unc.edu or 919-843-2499 for all information pertaining to finances.

All appropriate IRB and IACUC approvals must be in place prior to the use of funding. Information on the IRB and the Office of Human Research Ethics can be found [here](#). Information on the IACUC can be found at [here](#).

All subcontracts must be submitted on the UNC ALICE system, the administrative utility application for managing clinical trial agreements at UNC-Chapel Hill. These agreements are processed through the UNC Office of Industry Contracting before executing any work. If funded, PIs must work with Eshelman Innovation's Scientific Program Manager, to submit their request. PIs will need to provide the contract, scope of work, budget for contractor, and payment schedule. PIs will be asked to provide the contact information for the appropriate personnel that can negotiate and sign contracts on behalf of the contracting institution.

Guideline Appendix

Please note questions listed below are subject to change.

Therapeutic Full Proposal Questions

- Innovator Information:
 - Lead PI Name
 - Did you attend the Radiopharmaceutical Summit at the NC Biotech Center?
 - Lead PI Institution
 - Lead PI School/Department
 - Lead PI Title
 - Lead PI Email
 - Lead PI Phone Number
 - UNC System PI Supervisor/Chair Email
 - Is there a Co-PI on this project?
 - Co-PI Name
 - Co-PI Email
 - Co-PI School/Department
 - Co-PI Title
 - Does the Co-PI have an appointment at an UNC system school?
 - If yes:
 - Co-PI Institution
 - UNC system Co-PI Supervisor/Chair Email
 - If no:
 - What institution/organization is the Co-PI affiliated with?
 - Co-PI Letters of Support – External collaborators are required to upload two letters of support (please add to the appendix of the proposal).
- Project Outline
 - Project Title
 - Projected length of project
 - Estimated Funding Ask
 - Please select a grant category (therapeutic, technology platform)
 - If therapeutic, What is the primary therapeutic area of this project?
 - Please select your project's focus area
 - Basic Pharmaceutical Science
 - Target Validation and Drug Discovery
 - Drug Delivery
 - Existing Drug Optimization and Repurposing
 - Other
 - If other, please describe.
- Subcontract Information
 - Will your project require a subcontract to an external institution? If yes:
 - Briefly outline the intent of the subcontract
 - Will the subcontract agreement involve human subject research?

- Will the subcontract agreement involve clinical trials?
 - Will the subcontract agreement consider clinical trials?
 - Will the subcontract agreement involve laboratory animal research?
- Additional Funding
 - Have either the Lead or Co-PI had other projects funded by the Eshelman Innovation?
 - Have you received any additional funding related to the topic outlined in this proposal?
 - If yes, Have you previously submitted and/or received Eshelman Innovation Funding for work related to the topic in this proposal?
 - If yes, please provide details
- Additional Resources Needed
 - Please list any departments that you will require additional support for
 - Please explain what kind of support you may need from these departments
- Intellectual Property
 - Please read the [UNC Patent and Invention Policy](#) and agree to the terms and conditions.
 - What type of IP will this project generate (e.g. composition of matter, methods of manufacture, software, etc.)?
 - Who will be listed as inventors on any IP generated?
 - Is there any existing intellectual property to or related to or required for this project? If yes:
 - Identify an existing UNC, external, or third party IP related to or required for this project?
 - Will you be using materials obtained from other institutions that cannot be obtained from commercial or other unrestricted sources? (i.e. cell lines, transgenic animals, other reagents)
 - If not listed in your approved budget or list of team members, please list all potential inventors or authors of any IP that will be generated from this project.
- Compliance Questions
 - Does this project involve animals?
 - Does this project involve human subjects?
 - Does the project involve hazardous materials?
- Conflict of Interest
 - Please read the [UNC Conflict of Interest Policy](#)
 - Do you expect to have any conflicts of interest or commitments that have the potential to directly and significantly affect the University's interests, compromise objectivity in carrying out University responsibilities, or otherwise compromise performance of University responsibilities? If yes, please explain.
 - Are you launching a software or services startup company during this project? If yes, have you started the COI application process?
- File Upload (as separate documents):
 - **Proposal Summary File.** The below areas **MUST** be included in your proposal summary:
 - **Executive summary:** Provide a 200-250 word overview of your proposal. The executive summary along with your proposal, budget, and aims will be send to the Eshelman Innovation Steering Board.
 - **Problem and/or Need:** Describe the problem and/or unmet need that motivates your unique solution and/or idea.

- **Evidence and Prior Art:** Outline the evidence and prior work in the area by others and/or the evidence or previous studies by the innovator. Enough evidence should be included in the application to demonstrate that the project is feasible, and that the innovator is likely to complete the project successfully within the duration of the award.
- **Innovative Solution:** Describe the proposed idea and/or solution. How is it different from other ideas and/or solutions? How will it substantially transform science, medicine, health care delivery, education, outcomes, or patient health? Be sure to include information outlining competition in the market and in development of the proposed idea.
- **Anticipated Challenges (Scientific and Commercial):** Describe any scientific and/or commercial challenges you anticipate for your proposed idea.
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 - As a first step in the process, PIs must complete an aims and milestones form that will be sent to the Lead/Co-PIs by the PM.
 - The PM will meet with PIs to streamline aims and milestones and Gantt chart project objectives.
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- **IP Strategic Plan (if applicable)**
 - If your project includes or relates to any collaborator IP, you will need to meet with an UNC OTC Commercialization Manager to craft your IP strategic plan during the full proposal process. OTC will work with the PIs to tie the aims and milestones into an IP strategic plan that considers both existing IP and proposed

outcomes. If you have questions regarding the UNC OTC strategic plan, please contact otc@unc.edu.

- If applicable, a letter from collaborator's technology transfer office if the use of the existing IP of collaborator is essential to the IP strategic plan.
- **Two (2) letters of support for any PI external to UNC**
- **Lead PI CV, resume, or bio-sketch**
- **Co-PI CV, resume, or bio-sketch (if applicable)**

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- **Spacing:** Single or exactly 12-point line spacing
- **Header:** Please include your name and project title in the header of each page of the proposal summary
- **Type:** PDF format only

All proposal submissions will be reviewed by a panel of scientific and commercial experts with subject matter expertise in the proposal's area of focus. Proposals and reviewer feedback will be reviewed by the LCCC and Eshelman Innovation Therapeutics Accelerator teams and select projects will be invited to pitch to an expert panel at a Pitch Day. Specifics around Pitch Day will be sent to PIs who are advancing in the process.

Review Criteria Appendix

Proposal submissions will be reviewed using the following criteria by a panel of scientific and commercial experts with subject matter expertise in the proposal's area of focus. Reviewer feedback scores will be compiled by the LCCC and Eshelman Innovation Therapeutics Accelerator teams. Based upon reviewer feedback select projects will be invited to pitch to an expert panel.

Eshelman Innovation Review Criteria

SCORING

Problem or Need: Is the problem or need truly significant, and, if funded, will the proposed idea or solution make a meaningful contribution to understanding and solving it?

Innovative Solution: Is the proposed idea, solution, or technology truly unique or disruptive?

Impact: Does the proposed idea or solution have potential commercial impact in a competitive landscape?

Commercial Value: How would you rank the proposed idea's commercial value (if successful)?

Commercial Success: How would you assess the proposed solution's probability of commercial success given current market dynamics?

Aims and Approach: Is the proposed approach feasible in terms of budget, timeline, and personnel?

Next Steps: Are the next steps post-award well-articulated, and is there a path to sustainability for this program that may ultimately lead to the desired outcome?

Milestones, Results, & Outcomes: Please refer to the aims, milestones, anticipated results, and/or outcomes document. Are the aims and milestones well-structured and likely to lead to the anticipated results and/or outcomes?