ESHELMAN SCHOOL OF PHARMACY
Eshelman Institute for Innovation

Opioid Abatement Research Program 2022

Basic and Early Translational Research Towards Novel Pain Therapeutics

Request for Proposals

Pre-Proposal Deadline: October 20, 2022, at 5:00pm

The Eshelman Institute for Innovation (EII), headquartered at the University of North Carolina at Chapel Hill (UNC-Chapel Hill), is partnering with the North Carolina Collaboratory to request research and development proposals that can advance the discovery and translation of therapeutics for opioid use disorder.

Opportunity Overview

- **Eligible applicants:** Academic institutions located in North Carolina
- **Award project period:** Projects will be issued funding starting April 1, 2023, and may not exceed 36 months
- **Funding source:** State appropriation via the North Carolina Collaboratory.
- **Funding requirements:** All funds distributed via this program must be used in accordance with State regulations found in Title 09, Subchapter 03M of the North Carolina Administrative Code.
- **Spending restrictions:** No indirect (F&A) costs are permitted, as per Article 31A of North Carolina General Statute (NCGS) Chapter 116-255 Subsection (c)(2) and Section 8.12(a) of Session Law 2021-180.

All applicants should read these instructions thoroughly before preparing an application. Questions regarding this Request for Proposals (RFP) are welcome and may be sent to the Eshelman Institute for Innovation at EshelmanInstitute@unc.edu.

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Important Dates

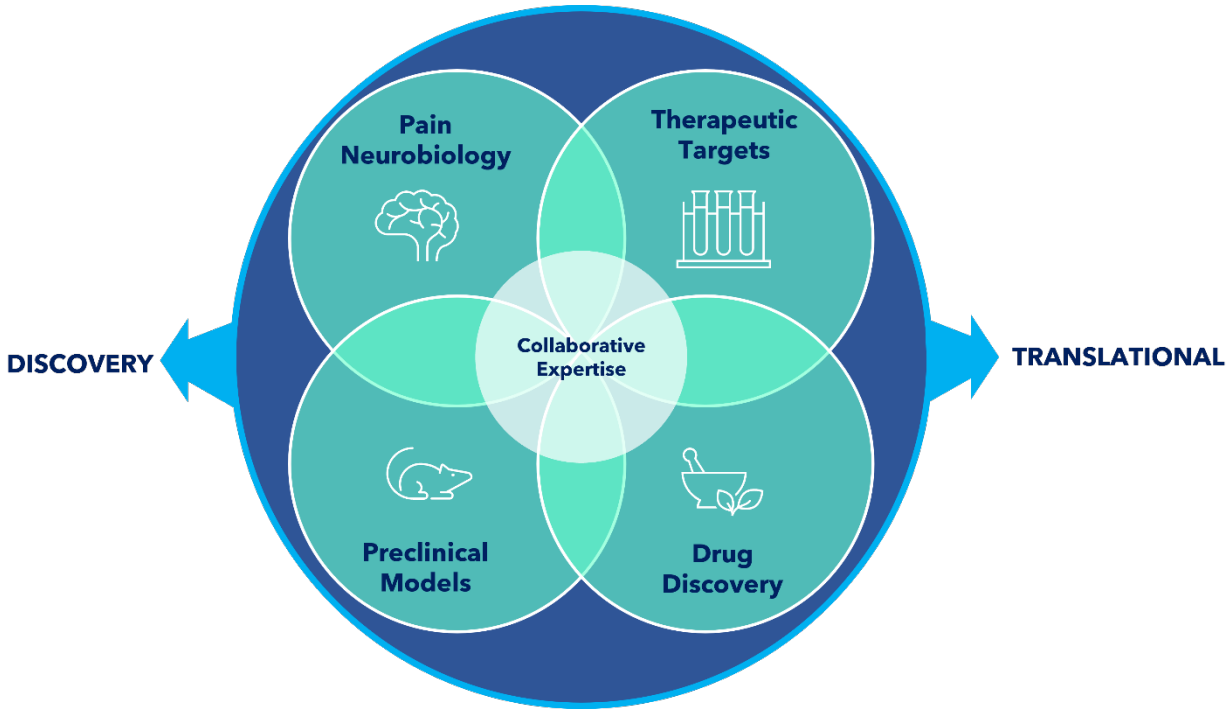
- **Pre-Proposal open:** September 26, 2022
- **Pre-Proposal deadline:** October 20, 2022
- **Full Proposal open**: November 14, 2022 *(only applicants selected through our pre-proposal process are authorized to submit a full proposal)*
- **Full Proposal deadline:** December 13, 2022
- **Pitch Day:** February 2023 (date to be announced)
- **Award announcements:** on or before March 7, 2023
- **Earliest project start date:** April 1, 2023

Background and Scope

Established in the summer of 2016 by the North Carolina General Assembly (NCGA), the North Carolina Collaboratory facilitates the dissemination of expertise within the UNC System and other institutions of higher education for practical use by State and local governments and the communities they serve. In July 2022, the NCGA appropriated funds to the Collaboratory to establish a partnership with the UNC Eshelman Institute for Innovation (EII) for the purpose of supporting opioid abatement research and development activities in North Carolina.

This appropriation of State funds is part of a $26 billion national opioid agreement with major drug distributors. Over the next 18 years, payments to State and local governments in North Carolina will total $750 million, with the overall goal of addressing the opioid crisis through treatment recovery, harm reduction and other strategies.

To this end, EII and the Collaboratory are soliciting research proposals focused on the early steps in the drug discovery process in the topic areas outlined below, with the ultimate objective of developing novel and non-addictive analgesics.



EII anticipates that this will be the first of multiple Requests for Proposals (RFPs) aimed at achieving this objective. To maximize the distribution of available funds this year, we are prioritizing proposals that target the earlier, relatively less expensive phases of novel therapeutic development. Specifically, this RFP will focus on projects encompassing activities prior to and including efficacy proof-of-concept in animal models.

Priority Areas

This RFP seeks to help academic researchers generate critical research knowledge in neurobiology, discovery of novel drug targets, and therapeutic approaches for chronic pain as the underlying driver of opioid addiction according to the following four priority areas:

Priority Area I: Neurobiology of pain and opioid use disorder.

Applications that investigate either fundamental mechanisms underlying pain perception or elucidate the mechanisms of action of opioids:

- Studies designed to elucidate novel non-opioid pain pathways
- Identification and validation of novel molecular mechanisms and pathways for opioid action, with the goal of dissociating desired analgesic effects from unwanted side effects
- Investigation of the molecular and physiological basis of chronic pain
- Elucidating the basic mechanisms of psychedelic-like compounds and their therapeutic impact on addiction

Priority Area II: Discovery, validation, and optimization of novel therapeutic targets for chronic pain or opioid use disorder.

Research aimed at identifying and validating novel molecular targets for the treatment of pain or modulation of undesirable side effects of opioid treatment, including:

- Genomic analyses, RNA-seq or proteomics studies, or genome-wide genetic screens (CRISPR, RNAi, etc), designed to identify novel therapeutic targets for pain
- Identification of novel therapeutic targets for the modulation of opioid reward, craving and withdrawal
- Studies designed to further validate existing potential pain targets

Priority Area III: Preclinical models and imaging.

Research aimed at improving the armamentarium of preclinical animal models for pain research, including:

- Platform technologies enabling the study of neurobiological targets and receptors
- Development of imaging agents for use in opioid and non-opioid pain research
- Generation of genetically engineered preclinical animal models for pain research

Priority Area IV: Early therapeutics development.

Early development of novel therapeutic agents for pain, up to efficacy proof-of-concept in animal models, including:

- High throughput screening of small molecule or antibody libraries against novel pain therapeutic targets

- Design or screening of novel antisense oligonucleotides, siRNAs, as well as mRNA- or cell-based therapeutics for pain
- Preclinical development of therapeutics, including medicinal chemistry, antibody optimization, etc., as well as initial DMPK and tox studies designed to achieve efficacy proof-of-concept in animal models
- Screening of non-hallucinogenic compounds, such as psychoplastogens, with therapeutic properties for substance use disorders
- Synthesis of psychedelic-like molecules for evaluation as new drug therapies

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Funding Guidelines

All funds distributed via this program constitute State appropriations from the NCGA and must be used in accordance with North Carolina State law, including State regulations found in Title 09, Subchapter 03M of the North Carolina Administrative Code**.** All budgets should reflect the actual needs of the proposed project and scope of work. No matching costs are required.

Funding Restrictions and Requirements

Allowable budget requests:

- Salaries and fringe benefits of students, postdocs, and research support staff such as technicians/associates, software engineers, etc.
- Salaries of research track faculty
- Consultants (e.g. community/government partners).
- Travel expenses.
- Equipment.
- Materials and supplies.
- Contracted services.
- Publication fees.
- IRB costs.

Budget restrictions:

- Salaries of tenure track or clinical track faculty, whether new or existing, are not permitted.
- Institutional overhead/indirect costs (F&A) are not permitted, as set forth in North Carolina General Statute (NCGS) 116-255(c)(2) and Section 8.12.(a) of Session Law 2021-180.

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Eligibility

Applicants

Applications will only be accepted from institutions of higher education in North Carolina. Any individual with the resource, skills, and knowledge required to carry out the proposed activities may serve as principal investigator (PI) in accordance with their institutional policies and procedures. Individuals from underrepresented racial and ethnic groups and individuals with disabilities are encouraged to apply for this funding opportunity.

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Application Instructions

All activities described in the application should accurately reflect the amount of funds requested for the project and be feasible within the proposed timeframe.

All applicants are required to submit a pre-proposal as the first step in the application process. Following a review, select applicants will be invited to submit a full proposal.

Pre-proposals must be submitted here:
https://app.smartsheet.com/b/form/7e1a81964e944bd98e38c0b20a5edcc2

During the full proposal submission process, applicants must work with the UNC Eshelman School of Pharmacy Office of Administration to approve their budget and EII to approve their project's aims and milestones. More information will be provided to applicants who advance in the process.

All full proposals will be reviewed by a panel of scientific and commercial experts who are experts in the proposal's area of focus. After reviewing submissions and soliciting review panel feedback, EII will invite specific applicants to pitch their idea to the EII Industry Advisory Board during a Pitch Day (details of which will be sent to selected applicants).

Pre-Proposal Instructions

All applicants are required to submit a pre-proposal as the first step in the application process. Following a review, select applicants will be invited to submit a full proposal. Pre-proposals are submitted online via our application form: https://app.smartsheet.com/b/form/7e1a81964e944bd98e38c0b20a5edcc2.

All full proposal submissions must be submitted online through our grant application. Emailed submissions will not be accepted.

Pre-proposals should:

- Include a PI from an institution of higher education in North Carolina.
- Indicate the relevant connection to opioid research as it relates to the research focus areas outlined in the RFP.
- Include a brief project summary and identify the type of innovation you are proposing and the expected mode of delivery to end users.
- Address the novelty and differentiation of the proposed technology, product, service, or asset.
- Include a preliminary list of existing intellectual property known to be required for commercialization of the proposed product.
- Provide an analysis of the competitive landscape.
- Identify three subject matter experts who would be ideal to review your full proposal.

Full Proposal Instructions

If invited to submit a full proposal, PIs will receive specific instructions on the application process and requirements. *All full proposal submissions must be submitted online through our grant application. Emailed submissions will not be accepted.*

Proposals must adhere to the following formatting requirements:

- **Proposal Summary Length:** Proposals summaries must be within 2-5 pages, and may include up to an additional 2 pages of pivotal references; no other required document has a limit.
- **Margins:** At least 0.5 inches.
- **Font:** No smaller than 11-point Times New Roman or its equivalent.
- **Spacing:** Single or exactly 12-point line spacing.
- **Header:** Include your name and project title in the header of each page of the proposal summary.
- **File Type:** PDF.

Applications that include documents that are illegible and/or do not conform to instructions within this RFP will be withdrawn from consideration and will not undergo review.

Full Proposal Content

Applicants who are invited to submit a full proposal must complete the EII online proposal form and upload additional information described below. Applicants who advance to the full proposal will receive full details on how to submit their application.

Document	Page Limit	Instructions
(1) Proposal Form	-	Complete the online submission form, which will be spent via email to selected applicants
(2) Proposal Summary *(attached as part of the online submission form)*	2-5 pages	▪ **Executive summary:** Provide a 200-250 word overview of your proposal. ▪ **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. ▪ **References:** Using your preferred reference style, provide full references for all information/literature cited in the Proposal Summary (references do not count towards your proposal length limit)
(3) Budget and Budget Justification	-	Applicants outside of UNC must work with their institution's grants office to finalize their budget and budget justification. Once budgets are approved, they must be sent to the UNC Eshelman School of Pharmacy's Office of Research Administration (ORA) to receive final approval. Applicants internal to UNC must work with the ORA to craft and finalize their budget and budget justification. A budget template will be provided to applicants advancing to the full proposal.
(4) Aims and Milestones	-	PIs must work with the EII Project Manager (PM) to craft the project's aims and milestones. 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 Institute. Please have your budget finalized before meeting with PM, 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.
(5) Letters of support	-	Two letters of support are required for the PI and Co-PIs (if applicable).
(6) Biosketches	-	CV, resume, or biosketch must be provided for the PI and Co-PIs (if applicable).

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Submission Process

The deadline for pre-proposal submissions is 5:00pm on October 20, 2022. Applications received after this deadline will not be reviewed or considered for funding.

Applicants who are invited to submit a full proposal will be notified by November 14, 2022. The deadline for full proposal submissions is 5:00pm on December 13, 2022.

Select applicants will be invited to pitch their idea in February during an EII Pitch Day event. If selected for funding, projects will receive funding by April 1, 2023, at the latest.

All pre-proposal and full proposals must be submitted online via emailed submissions will not be accepted.

This RFP is solely a request for expressions of interest and statements of qualification. It is not an offer to contract or an invitation capable of acceptance to create a contract. The EII may cancel or modify this RFP at any time without liability for any loss, cost, or expense as a result of that cancellation or modification. For more information about the Eshelman Institute and previously funded projects, please see UNCEII.org

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Review Process

All proposals will be evaluated by a review panel comprised of subject matter experts. **During the pre-proposal process, PIs must suggest three experts that they believe could provide valuable input on their proposal.**

EII will solicit detailed feedback from reviewers using a review rubric. All reviewers will be asked to complete a confidentiality agreement prior to receiving and reviewing your application materials.

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Award Process

EII anticipates notifying applicants of award decisions no later than March 7, 2023. Projects may last for up to 36 months, starting no earlier than April 1, 2023. Before funds are released, award recipient

institutions will be required to review and sign a Funding Agreement (shared after the notification of award).

Projects selected for funding must agree to work with the EII Project Manager to strategize and track the completion of the project's milestones and aims. This includes but is not limited to regular check-ins, lab visits, and team meetings with the Project Manager. Please note that disbursement of subsequent tranches of funding will be contingent on achieving the project's milestones.

In addition, you agree to formally report on your project's progress throughout the project period. This could include but is not limited to an annual progress report, yearly presentations for multi-year projects, and a final report. Failure to submit reports by the deadlines provided by EII may result in a hold on or retraction of remaining funds from the award.

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Contact

Questions regarding this funding opportunity and the application process are welcome and should be sent to the EII team via email to EshelmanInstitute@unc.edu.

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