

Center for Human Health and the Environment (CHHE) Pilot Project Program Guidelines

Letter of Intent (LOI) and Pilot Project Full proposal submission is now online. You will receive a submission link for the full proposal once your LOI is approved. You can find the form to submit the LOI on the PPP website.

I. Purpose

The CHHE Pilot Project Program (PPP) fosters collaborations, increases interdisciplinary research and aids in the career development of early-stage investigators to *advance environmental health research*. The overarching goal of CHHE's PPP is to provide support for innovative individual, collaborative, and multidisciplinary research aimed at understanding the adverse impacts of environmental factors on human health and disease. Such goals can be accomplished through a system-based approach employing a range of models used in varied cell and animal model systems. The CHHE PPP encourages multidisciplinary/collaborative approaches and the use of CHHE's cores and resources.

Pilot project funding is awarded to collect preliminary data that: 1) advances the mission of CHHE and the National Institute of Environmental Health Sciences (NIEHS) Strategic Plan and 2) supports EHS applications for external funding from the NIH/NIEHS and other Federal agencies. The PPP supports high quality basic, applied, clinical and public health research, especially in areas relevant to the five CHHE research interest groups which are: 1) Water and Emerging Challenges, 2) Genes, Environmental and Precision Health, 3) Health and Airborne Contaminants, 4) Behavior and Neuroscience, and 5) Environmental Health Disparities. CHHE PPP also supports high-quality environmental health research outside of its thematic areas as well as high-risk/high-gain research addressing environmental health concerns. CHHE's PPP encourages applications from CHHE members as well as non-member faculty from NC State University, ECU and NCCU.

The PPP also accepts applications originating between CHHE members and community partners that address community issues that align with the Center's thematic research interest areas. Our Community Engagement Core (CEC) Co-Directors will work with all investigators to identify and connect stakeholders with mutual interests in specific environmental problems and vice versa. This mechanism will provide opportunities for partnerships and aid in the development of community engaged projects with the PPP.

II. Funding

Individual PI awards are up to \$25,000 (direct costs) and CHHE expects to fund four proposals. We may also fund one dual-investigator, multi-disciplinary collaborative \$50,000 (direct costs) project. The pilot project project/budget period is 1 year. A separate budget is required for each investigator on a multi-PI proposal. Multi-institution and multi-departmental proposals are encouraged. The total number of awards will depend on the quality of the proposals received, their relevance to the CHHE mission centered around environmental health, and available funding.

A budget and budget justification appropriate for the ideas and work proposed will be part of the review criterion. NC State investigators must submit their proposals via the Research Enterprise Data (RED) System (PKA Project Information and Navigation System (PINS)). External applicants must follow their university's pre-award requirements. All pilot project applicants must include

both direct (<\$25K) and indirect costs (your institution's approved F&A rate) in their budgets. Expenditures will begin at specified start times, but all the required animal and human subject approvals must be completed before awards are distributed. The total project budget must be fully expended within the project budget period of one year set by the award notice. Final reporting on progress, significance, and impact is **required** (details to be provided upon award notification).

Under the CHHE Voucher Program and given available funds, CHHE may pay 50% of the costs for up to \$30K of core or program services for projects with EHS relevance for CHHE full members. CHHE full members can use the Voucher Program Funds for Systems Technology Core (STC), pathology, or other services that are part of a CHHE program project. For example, if a Full member is planning to use \$10K for STC services in their pilot project then they would only need to include \$5K in their budget and indicate the other \$5K is being covered by the Voucher Program. This is a bonus for CHHE full members.

Pilot projects are being funded for one year but if funded across NIEHS grant years, the project will be automatically extended into the next funding cycle (starting in June) and that will be initiated by MJ (mpjames@ncsu.edu). A one-time no-cost extension (NCE) on projects may be allowed under exceptional circumstances. Fall projects will have automatic NCE when funds become available in the new budget year (>June 1). Please submit your NCE request via an online portal using this [link](https://chhe.research.ncsu.edu/ppp-no-cost-extension-request/) (<https://chhe.research.ncsu.edu/ppp-no-cost-extension-request/>).

III. Eligibility

All NC State, ECU, and NCCU faculty that are eligible to apply for federal grants are eligible to apply for this funding. An investigator, as principal investigator (PI) or Co-PI, may apply more than one proposal per round, but only one of the high-scoring proposals will be funded. An investigator can be a co-investigator on multiple projects or a principal investigator on one project and a co-investigator on one or more projects. For review and reporting purposes, each \$25K award will have only one PI of record. The \$50K collaborative awards will have two co-PIs who are funded separately.

IV. Application.

Applications are due by 11:59 pm EDT on the dates shown here:

Cycle	Announcement	Letter of Intent due	Full application due	Final Decisions
Fall	August 1	September 1	September 15	November 1
Spring	February 1	March 1	March 15	May 1

If the indicated date falls on a weekend or a federal holiday, these deadlines will be automatically extended to the next business day.

Applicants must submit a brief Letter of Intent (LOI) along with a pre-proposal abstract or concept paragraph via an [online portal](#), according to the above schedule to ensure that the topic is relevant to the mission of CHHE. LOI are reviewed as received.

A submission link for the full proposal will be sent to applicants, once their LOI is approved. Complete applications must be submitted online.

In addition, grant information must be submitted via PINS/RED for NC State investigators and comparable proposal tracking systems for ECU and NCCU.

Single Investigator Proposals:

These \$25,000 direct cost proposals may only have one principal investigator (PI) and one budget awarded directly to the PI, although other collaborators from the same or different institutions may be listed in the proposal to support the proposal.

Dual Investigator Proposals:

These \$50,000 direct cost proposals must have two co-principal investigators and a separate budget for each of the two co-PIs limited to \$25,000 each. Additional collaborators from the same or different institutions may also be listed to support the proposal but will not receive a budget. A key element of the dual investigator proposal is a section within the 3-page Research Plan that clearly states the complementary, but distinct, expertise of the two co-PIs that is required to accomplish the aims, as this will be an additional review criterion beyond that of the single investigator proposals. Budget justifications for each co-PI must support their individual and necessary effort within the project. Otherwise, the details of the application are the same as those for single investigator proposals listed below.

Once your LOI is approved, you will receive a link for submission of the full proposal, which should include the following information:

To be eligible for review, the pdf must contain:

1. Cover Page: Project Title, Investigator(s), Degrees and Academic Ranks, Department, PINS/RED Number, College Affiliations, and Email Addresses etc.
2. Project abstract of 250 words or less.
3. Specific aims page
4. Research plan is **limited to three pages** which include a) significance, b) innovation, and c) approach (approach should be 1.5-2 pages).
5. References - full bibliography citations, no page limit
6. Description of 250 words or less detailing how results from the pilot project will support a NIEHS grant application or an application to another environmental health agency.
7. Human and/or vertebrate animal sections following NIH guidelines (not required for submission but will be required if the project is funded).
8. [Budget using NIH Form Page 4: Detailed Budget for Initial Period](#)
9. NIH biosketches for all key personnel (must use new SciENcv format)
<https://grants.nih.gov/grants/forms/biosketch.htm>
10. Letters of support if applicable.
11. Lay summary, written in non-technical language, should explain the project's public health relevance (250 words). The Lay summary should include:
 - **Title:** explains the study in lay language [may be different from the proposal title]
 - **Background Info:**
 - Provide relevant context about what is known/not known on the topic
 - Explain how this study fits into that context/fills a research gap
 - **Methods**
 - Briefly describe how the work will be done, what you will measure and why
 - **Importance and Implications**
 - Why will this study matter?
 - What will you be able to do with the findings?
 - How will the new information advance the EHS field?
 - Why is this study important to the public?

Applications missing one or more of the required components will be considered incomplete and will not be reviewed. IACUC and IRB approvals are “Just in Time” and are not required at the time of application submission. When developing your budget, funding must be requested for a project that can be completed in the designated period of the award (1 year). Funds may be budgeted for any of the standard categories and for purposes deemed necessary for the successful execution of the proposed project. However, there are several cases where restrictions and additional scrutiny apply:

1. Faculty salary will not be supported.
2. Requests for travel support must be directly related to the project performance. Travel for conferences and meetings will not be supported; and
3. Requests for equipment must be directly related to the project performance and these costs will be scrutinized to confirm the need of the equipment for the project and to avoid duplicating resources within the CHHE.

Applicants must consult with facility cores for cost estimates prior to submission. We strongly encourage applicants to consult with Dereje Jima, CHHE’s Environmental Data Science Bioinformatician (ddjima@ncsu.edu) or Emily Griffith, Statistician (emily_griffith@ncsu.edu) prior to submission to ensure that the studies are sufficiently powered for the desired results. If consultants/collaborators are included from outside of NCSU, ECU or NCCU, letters of support are strongly encouraged. All required Institutional Animal Care and Use Committee (IACUC) and Institutional Review Board (IRB) approvals must be in place before pilot projects can be initiated. The Integrated Health Science Facility Core (IHSFC) can aid in the preparation of the IRB application and the PI must consult the Translational Research Support Core (TRSC) prior to submitting their proposal to ensure a complete understanding of the IRB requirements before the project is awarded.

Extensions of the deadline will not be granted. Supplementary or additional materials will not be accepted after the submission deadline.

Use at least 0.5-inch margins, single line spacing; and a minimum of 11 pt. Times New Roman, Arial, or an equivalent font. Use of NIH forms is not required (except for the budget and biosketches), for example, you do not need to submit an NIH face page.

V. Review

The review process will occur in two stages; an initial compliance check of the LOI for EHS relevance and a second stage based on invited full proposals that will undergo expert peer review. The initial assessment of relevance for each LOI will be based on the goals and mission of the CHHE to expand EHS research, potential for the project to support an extramural grant application, and eligibility of the PI. Each application will be deemed acceptable for invitation of full proposal or not by the PPP co-directors in consultation with the CHHE Director, and Deputy Director. Applications deemed responsive in the initial review stage will receive an email invitation from the PPP co-directors to submit a full proposal.

Each full application will be evaluated for completeness of the application, inclusion of budget justification, and then independently peer-reviewed by two subject matter experts. In most cases, one reviewer will be an internal reviewer drawn from the CHHE membership, Internal Advisory Board, or others at NC State with relevant expertise. The external reviewer will be identified by the PPP co-directors with input from CHHE leadership, as needed, and the use of PubMed to search for

local relevant experts in the research domain. These reviewers will evaluate the scientific and technical merit of each project, and the likelihood that the successful completion of the project will support an extramural grant application. Expert reviewers will be asked to assess the assigned application(s) using the NIH 1-9 scale (see Review Criteria) and supporting information from NIH regarding the numerical values will be provided to reviewers.

Evaluation criteria are weighted to reward high-quality, top-notch science that has potential for extramural funding, particularly from NIEHS.

The primary review factors that will receive favorable consideration in funding priority are:

- High-quality research
- Research that is relevant to CHHE's thematic research interest areas (see Section I Purpose) and mission or special emphasis CHHE research calls
- Evidence of collaborative and multidisciplinary research, especially from multiple institutions or multiple departments within an institution
- Effect on career development of early-stage investigators (members and non-members)
- Use of core facilities and CHHE resources
- Likelihood the project will lead to external funding from the NIH/NIEHS and other Federal agencies
- Involvement of community stakeholders (when appropriate)
- For dual investigator proposals only, evidence of complementary, but distinct, expertise of each co-PI.

CHHE will use the NIH scoring system with some modifications. The five primary criteria are described below as is the NIH scoring system that will be used. The intent of the review process is to fund the best applications as identified, but other factors may also affect final award decisions. Other review factors may include but are not limited to; the multidisciplinary nature of the research project, the applicant PI's overall past productivity; potential balance across colleges; early-stage investigators in EHS and use of CHHE's core facilities. The contact PIs will be emailed final scores and review critiques, regardless of funding outcomes.

VI. Other Requirements

Funding must be used for a project that can be completed in the designated period of award. The project will have twelve months to expend the total project budget. Our P30 CHHE grant is on a 6/1-5/31 fiscal year, therefore if an award period crosses P30's fiscal year the PI must request a NCE to extend the PP award period.

Prior to actual funding, all awarded projects that involve animals, or human subjects must be reviewed and approved in accordance with the NCSU's general assurances and HIPAA. Projects involving human subjects must be approved by the Institutional Review Board (IRB). Projects involving animals must be approved by the Institutional Animal Care and Use Committee (IACUC).

A one-year summary progress report is due within three months after the project period end date. The summary progress report should assess the project's initial statement of innovation and impact. To assess the longer-term impact, principal investigators will be asked to provide a

summary progress report update for up to two years after the project period end date. The PI will be deemed ineligible for the future Pilot Project submissions if he/she does not submit the required progress report for a previously funded Pilot Project. The Letter of Intent from the PI who has not submitted the required Pilot Project progress report will be rejected.

Awardees will be expected to present their results at a CHHE event. All manuscripts, abstracts, posters, and presentations should acknowledge support from the CHHE as follows:

“Research reported in this publication was supported by the CHHE Pilot Project Program funded under National Institute of Environmental Health Sciences Award number P30ES025128. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health”.

Please e-mail chhepilotprogram@ncsu.edu for more information.

VII. Review Criteria

Reviewers will submit their review reports via an online [portal](#).

Overall Score:

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to lead to an extramurally funded grant that will exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria, and additional review criteria (as applicable for the project proposed).

Scored Review Criteria:

Reviewers will consider each of the review criteria below in the determination of scientific and technical 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. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance:

Does the project address an important problem or a critical barrier to progress in the field of environmental health especially in areas relevant to the 5 CHHE research interest themes which are: 1) Water and Emerging Challenges, 2) Genes, Environmental and Precision Health, 3) Climate Change and Airborne Contaminants, 4) Behavioral and Neuroscience, and 5) Environmental Health Disparities? If not, in these thematic areas, is the proposal of high scientific merit and/or a high risk/high gain proposal addressing environmental health concerns?

If the aims of the project are achieved, how will scientific knowledge, technical capability, community engagement 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?

Innovation. 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? Does the project build bridges with community partners or advance our ability to educate the public?

Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Does the project use CHHE core facilities and

resources? Have the PIs mentioned how they will translate their findings to concerned communities, if relevant?

Impact. Includes the potential for securing substantial EHS-relevant federal funding, as well as the potential to increase collaborations, engage with concerned audiences, advance the given field of expertise, or to bring new and junior investigators into environmental health research.

Feasibility. Given the facilities, budget, time, investigative team expertise and other resources, can the project's aims be accomplished in the time allotted?

Score	Descriptor	Additional Guidance on Strengths/Weaknesses
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
4	Very Good	Strong but with numerous minor weaknesses
5	Good	Strong but with at least one moderate weakness
6	Satisfactory	Some strengths but also some moderate weaknesses
7	Fair	Some strengths but with at least one major weakness
8	Marginal	A few strengths and a few major weaknesses
9	Poor	Very few strengths and numerous major weaknesses

Minor Weakness: Easily addressable weakness(es) that does not substantially lessen impact

Moderate Weakness: A weakness that is expected to lessen impact