

NC STATE/NIEHS Center for Human Health and the Environment 2021 Pilot Project Award Guidelines

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. 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 applications for external funding from the NIEHS, other NIH Institutes and Federal agencies. The PPP supports high quality basic, applied, clinical and public health research, especially in areas relevant to the four CHHE research interest groups which are: 1) Emerging Contaminants, 2) Environmental Epigenetics and Genetics (GxE, ExE interactions), 3) Pulmonary Health and 4) Behavioral and Neuroscience. 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 PPP encourages applications from CHHE members as well as non-member faculty from NC State University, ECU and NCCU. Abstract pre-submission is encouraged but not required to determine if proposal topics are consistent with the mission of the CHHE; send pre-submission abstracts to Jamie Bonner, Pilot Project Program Leader, at jbbonner@ncsu.edu.

The PPP also accepts applications between CHHE members and community partners that address community issues that align with the Center's thematic research interest areas. CEC Co-Directors will work with PPP and CHHE 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 awards are up to \$25,000 (direct costs) for one year and CHHE expects to fund up to five proposals. This year CHHE will also award up to \$50,000 (direct costs) for one year for dual-investigator, multi-disciplinary collaborative research, which requires additional funding and separate budgets. The CHHE expects to fund up to two of these proposals. The total number of awards will depend on the quality of the proposals received, their relevance to the CHHE mission, and the available funding.

A budget appropriate for the ideas and work proposed will be part of the review criterion. NC State investigators must submit their proposals via PINS (or comparable proposal tracking systems) and all pilot project applicants must include both direct ($\leq 25K$) and indirect costs (your institutions 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 spending can begin. 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 STC Voucher Program, CHHE pays 50% of the costs for up to \$30K of STC services for projects with EHS relevance for Full CHHE members. CHHE full members can now use the STC Voucher Program Funds for STC services that are part of a CHHE PP. 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 STC Voucher Program. This is a bonus for CHHE full members.

III. Eligibility

All NC State, ECU and NCCU faculty are eligible to apply.

An investigator (acting as principal investigator) may submit only one proposal per round. 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.

IV. Application

Applications for the Fall 2021 PPP are due at 5 pm EDT on September 15, 2021. Grant information must be submitted via PINS for NC State investigators and comparable proposal tracking systems for ECU and NCCU. Complete applications must be submitted by PI electronically as a single pdf file to Michico James, Program Manager, at mpjames@ncsu.edu.

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 may 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. Otherwise, the details of the application are the same as those for single investigator proposals listed below.

To be eligible for review, each application must consist of:

1. Cover page with project title, investigator(s), degrees and academic ranks, department and college affiliations, and email addresses.
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 an 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 project is funded).
8. Budget using NIH Form Page 4: Detailed Budget for Initial Period
<http://grants.nih.gov/grants/funding/phs398/phs398.html>
9. NIH biosketches for all key personnel (must use new format)
<https://grants.nih.gov/grants/forms/biosketch.htm>
10. Letters of support if applicable.

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. Funding must be requested for a project that can be completed in the designated period of award. No-cost extensions will be rare exceptions. Funds may be budgeted for any of the standard categories and for purposes deemed necessary for the successful execution of the proposed project. Additionally, all proposed expenses must conform to the general policies of NC State. 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 to the project and to avoid duplicating resources within the CHHE.

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 may apply.

Applicants must consult with facility cores for cost estimates and we strongly encourage applicants to

consult with Dereje Jima, CHHE's Environmental Data Science Bioinformatician/Statistician, at ddjima@ncsu.edu, prior to submission to ensure that the studies are sufficiently powered for the desired results. 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) will provide assistance in the preparation of the IRB application and the PI must consult IHSFC 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 for relevance, completeness, and eligibility and a second stage for expert peer review. The initial assessment of relevance for each application will be based on the goals and mission of the CHHE to expand EHS research, completeness of the application, the budget justification, how the project will support an extramural grant application, and eligibility of the PI. Each application will be marked as acceptable for review or not by a subcommittee composed of the PPP Director, CHHE Director, and the Deputy Director. Applications deemed responsive in the initial review stage will be sent for expert peer review.

Each application will be independently reviewed by two expert peer reviewers. In most cases, one reviewer will be an internal reviewer drawn from the CHHE membership, IAC Committee, or others at NC State with relevant expertise. The external reviewer will be identified by the PPP director with input from the PPP Advisory Committee and the use of PubMed to search for 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 RFP
- Evidence of collaborative and multidisciplinary research
- Effect on career development of early-stage investigators
- Use of core facilities and CHHE resources
- Likelihood the project will lead to external funding from the NIEHS, other NIH Institutes or 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. Applicants (with exception of triaged applications) will receive a final score/ranking and a brief critique. Final decisions will be announced by mid to late November 2021.

VI. Requirements

Funding must be used for a project that can be completed in the designated period of award. The earliest start date will be mid to late November 2021 with twelve months to expend the total project budget. Our P30 CHHE

grant is on a 4/1-3/31 fiscal year, therefore if an award period crosses P30's fiscal year the PI must request a no cost extension to extend the PP award period. Contact Michico James, Program Manager, at mpjames@ncsu.edu for assistance.

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 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 may be asked to provide a summary progress report update for up to two years after the project period end date.

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 National Institute of Environmental Health Sciences of the National Institutes of Health under 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.

For more information contact Jamie Bonner, Pilot Project Program Leader, at jcbonner@ncsu.edu or 919-515-8615.

Review Criteria

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 4 CHHE research interest themes which are: 1) Emerging Contaminants, 2) Environmental Epigenetics and Genetics (GxE, ExE interactions), 3) Pulmonary Health and 4) Behavior and Neuroscience? 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, 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?

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?

Impact includes the potential for future grants, particularly at the R01 level, as well as the potential to increase collaborations and 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: An easily addressable weakness that does not substantially lessen impact

Moderate Weakness: A weakness that lessens impact