NCSU Center for Human Health and the Environment 2018 Pilot Award Guidelines

I. Purpose

The overarching objective of the Center for Human Health and the Environment's Pilot Project Program (PPP) is to expand environmental health science research at NC State, ECU and NCCU. Pilot project funding to Center members and other NC State, ECU and NCCU investigators is awarded to collect preliminary data that will <u>support applications for external funding from the</u> <u>National Institute of Environmental Health Sciences (NIEHS</u>), other NIH Institutes and Federal agencies. Consequently, the major emphasis of the PPP is on research into the effects, potential consequences and prevention of environmental exposures on human health. The PPP will support high quality basic, applied, clinical and public health research. The PPP will provide funding for individual, collaborative and multidisciplinary research aimed at understanding the adverse impacts of environmental factors on human health and disease. Multidisciplinary collaborations and use of CHHE's core facilities are strongly encouraged but not required.

II. Funding

Individual awards will range upwards to \$25,000 (direct cost) for one year. The CHHE expects to fund up to 11 proposals. The final number and amount of awards will depend upon 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 enter grant information into PINS (or your respective grants management office) and all pilot project applicants must include both direct (≤25K) and indirect costs in their budgets. Expenditures will begin at specified start times but all appropriate animal and human subject approvals must be in place before spending can begin. Funds must be expended within the time limits set by the award notice. Final reporting on progress, significance, and impact is required (details to be provided upon award notification).

III. Eligibility

All CHHE members are eligible to apply. All NC State, ECU and NCCU faculty and research scientists eligible to be principal investigators on NIH grants are also eligible to apply. This includes individuals with tenure-track and fixed term appointments.

An investigator (acting as principal investigator) may submit only one proposal per round. Investigators can be co-investigators on multiple projects or principal investigator on one project and co-investigator on one or more other projects.

For review and reporting purposes, each award will have only one PI of record. Functionally, projects may have co-PIs.

IV. Application

Applications for the Spring 2018 PPP are due at 5 pm EDT on January 15, 2018. Grant information must be entered in PINS for NC State investigators and complete applications should be submitted electronically as a single pdf file to Jackie Broughton (jackie_broughton@ncsu.edu). 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) A specific aims page

4) Research plan limited to three pages which include a) significance, b) innovation, and c) approach (approach should be 1.5-2 pages).

5) 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.

6) Human and/or vertebrate animal sections following NIH guidelines (not required for submission but will be required if project is funded).

7) Budget using NIH Form Page 4: Detailed Budget for Initial Period http://grants.nih.gov/grants/funding/phs398/phs398.html

8) NIH biosketches for all key personnel (must use new format) http://grants.nih.gov/grants/funding/phs398/phs398.html

9) Letters of support if applicable.

Applications missing one or more of the required components will be considered incomplete and will not be reviewed. Applicants will be encouraged to consult with the CHHE Bioinformatician, Dereje Jima (ddjima@ncsu.edu) prior to submission to ensure the studies are sufficiently powered for the desired results.

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 or line spacing; and no smaller than 11 pt Times Roman or Arial font or its equivalent. 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 upon the goals and mission of the CHHE to expand EHS research, completeness of the application, justification of budget and how the project will be used to 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 Deputy Director. Applications deemed responsive in the initial review stage will be sent for expert peer review.

Each application will be independently reviewed by three 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 remaining two will be external reviewers 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 three expert reviewers will evaluate the

scientific and technical merit of each project, and 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, <u>particularly from NIEHS</u>. 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 around mid to late March 2018.

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 April 1, 2018 with 12 months to expend awarded dollars. No-cost extensions across fiscal years will need to be requested. Contact <u>Jackie Broughton</u> for assistance.

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) Salary. Faculty/PI salaries will not be supported.

2) Travel. Requests for support should be limited to travel that is essential for carrying out the proposed work and should not include expenses related to conferences.

3) Equipment. Requests for equipment should also be limited to funds directly related to project performance and will be scrutinized for need.

Unused funds will revert to the CHHE. All proposed expenses must conform to the general policies of NC State.

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. Reviews and approvals may be "Just in Time" and are not required for application. 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 shall be submitted within three months after the end date of support. 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 end of the funding.

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 in part by NIEHS under award number P30ES025128.

For more information contact Pilot Project Program Leader; James Bonner <u>jcbonner@ncsu.edu</u> 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? 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, instrumentation, or interventions proposed?

Approach Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented?

Impact 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 Major Weakness: A weakness that severely limits impact | | |