

CENTER OF EXCELLENCE IN ENVIRONMENTAL TOXICOLOGY (CEET)

Environmental Health Science Mentored Scientist Transition Award

Grants up to \$50,000 available per year for up to two years

Supported by the National Institute of Environmental Health Sciences (NIEHS) Grant #2 P30 ES013508

Application Packet

Background

The [Center of Excellence in Environmental Toxicology](#) (CEET) announces the following Mentored Scientist Transition pilot project opportunity. This award provides up to \$50,000 per year in salary support to allow a senior postdoctoral researcher or clinical fellow establish independence in environmental health sciences.

Applications are due by **Tuesday, December 1, 2020**.

Applicants can request up to \$50,000 per year for up to two years. The second year is contingent on peer-reviewed progress. This award is for salary support only to provide protected time to establish independence. The award must have a faculty mentor from the standing faculty. The senior postdoctoral researcher or clinical fellow must be mentored by a member of the standing faculty from any School at the University of Pennsylvania.

Applicants who submitted in a previous cycle and were unfunded and encouraged in their decision letter may submit a revised application.

Deadlines and Notifications

All applications will be sent out for peer-review to experts in the field, the CEET Executive Committee will then meet to select the awardees. Each application will be scored using the NIH scoring system (refer to '[application review criteria](#)' section). Below are the application deadlines and timeline.

Application Deadline	CEET Executive Committee Meeting	Award Notification	Award Start Date
By Tuesday December 1, 2020	By Monday January 4, 2021	By Friday January 15, 2021	Monday February 1, 2021

Center of Excellence in Environmental Toxicology (CEET)
Environmental Health Science Mentored Scientist Transition Pilot Project Grant Application

Eligibility Requirements

1. Any senior postdoctoral researcher or clinical fellow conducting mentored environmental health research at any University of Pennsylvania School may apply
2. They must be mentored by a member of the standing faculty.
3. Preference will be given to first-time applicants
4. Preference will be given to applicants that seek a R00/K99, K-award, ONES Award, or other career development award from the National Institute of Environmental Health Sciences (NIEHS)
5. Preference will be given for research projects that will utilize one or more of the [CEET Facility Cores](#)
 - Integrative Health Sciences Facility Core
 - Translational Biomarker Core
 - Exposure Biology Informatics Core
 - Community Engagement Core
6. The research being proposed cannot be funded by an external funding agency

Funding/Reporting Requirements

The anticipated period of funded project performance will be for 12 months following the project start date.

Funded applications **must** meet the following compliance guidelines.

1. All IRB and IACUC protocols must be in place before the funding can be awarded. A copy of the approved protocols should be submitted to the CEET before an award notice can be issued. For more information, see 'IRB and IACUC' in the [Full Application Instructions](#) section below.
2. Submit a progress report by the end of the first year - The progress report should follow the same format as that required for an NIH R01 RPPR-progress report. At that time the applicant may request an additional year of support with justification as to why an additional year of support is required. This additional year is contingent on satisfactory progress towards independence and must be accompanied by a mentor letter.
3. Present your findings at a CEET Pilot-Project Progress Seminar within 6 months of the end of the funding cycle
4. Acknowledge the parent P30 grant on all publications with the following language: "This publication was made possible by P30 ES013508 from the National Institute of Environmental Health Sciences, NIH. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of NIEHS, NIH." It is the responsibility of the P.I to ensure that all papers resulting from the pilot project are submitted to PubMed Central and assigned a PMCID number

Full Application Instructions:

Applications must be submitted in **a single PDF** for internal review to paula.williams@pennterapeutics.upenn.edu. Applications should include the following, **in this order**:

1. Application Form (**see attached below**)
2. Applicant Must Provide a Letter of Support from their Mentor /Chairperson with a plan towards independence.
3. Mentor must provide a copy of their Other Support page to verify that the project is not duplicative of their funded research
4. Applicant must provide a plan for a K-ward or career development award application.
5. New Format NIH Biosketch (limit 5 pages)
6. An abstract – a brief summary of the project (no more than 300 words)
7. Introduction-**Revised Applications Only**. These must include a one-page response to the previous critique; and then follow the instructions below.

Center of Excellence in Environmental Toxicology (CEET)

Environmental Health Science Mentored Scientist Transition Pilot Project Grant Application

8. Specific Aims (not more than 1 page) – concise goals of the proposed research and a summary of expected outcomes, including specific objectives
9. Research Strategy (not more than 6 pages)
 - **Significance** – describe the importance of the problem or critical barrier that the project addresses in Environmental Health Sciences, and explain how the project will improve scientific knowledge, technical capability, or clinical practice if the proposed aims are achieved
 - **Innovation** – describe how the proposed research seeks to shift research practice paradigms and how any methodologies or theoretical concepts that are being developed or used in the project may have an advantage over existing practices
 - **Approach** – describe the overall strategy, methodology, and analyses to be used to accomplish specific aims, including how data will be collected. Discuss potential problems, alternative strategies, and benchmarks of success
 - **Statistical Plan and Plan for Scientific Rigor & Reproducibility**
10. Project Timeline (1 page) – a proposed timeline of study performance should be included, identifying specific tasks and milestones in project progress for the 12-month period of performance
11. A brief outline of how the results from the pilot study will enable the submission of a subsequent NIEHS/NIH grant and a detailed plan for this subsequent grant submission (not more than 1 page)
12. Separate List of Current and Pending Grant Support using NIH formatting guidelines (**NOTE: this should be a separate document in addition to the Biosketch**)
13. References
14. Budget – an NIH-style budget table should be enclosed. The budget is restricted to salary only. No supplies, equipment or travel are allowable.
15. Budget Justification – a detailed explanation and justification of the salary funding request
16. Facility Core Usage and Correspondence – The CEET Facility Cores offer technical and research support to Center investigators and Pilot Project awardees. A wide range of capabilities, including biostatistical support, analytical sample preparation/processing, and biological sample measurements are available. Early discussion with Core Directors is strongly encouraged. For information on The CEET’s cores and their directors, please [click here](#). CEET Facility Core Directors should be contacted to provide a letter of support as a part of this application. **NOTE: If CEET Facility Cores are NOT proposed to support Pilot Project performance, a written justification must be provided as a part of the application.**

IRB and IACUC

Applications using Vertebrate Animals or Human Subjects must also submit the corresponding sections required in an NIH grant (**see below**). Failure to do so will lead to the application being not considered for funding.

Vertebrate Animals:

1. Proposed Use of Animals
2. Justification for the Use of Animals
3. Veterinary Care
4. Procedures
5. Method of Euthanasia

Protection of Human Subjects

Please complete the Human Subjects Questionnaire including all attachments. (**see attached below**)

Center of Excellence in Environmental Toxicology (CEET)

Environmental Health Science Mentored Scientist Transition Pilot Project Grant Application

Application Form (Please Type)

Name			
Position/Title			
Department			
Preferred Phone Number		Preferred Email	
Preferred Mailing Address			
Application/Research Title			
Total Funding Amount Being Requested			
Name and Contact Information of Business or Grant Administrator			
Questionnaire			
Are you a CEET Member?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
If CEET Member, please list your Thematic Area(s)			
Are you an Early State Investigator?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Do you plan to use a CEET Facility Core?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
If so, please indicate which Core(s) you plan to use?	<input type="checkbox"/> Integrative Health Sciences Facility Core (IHSFC) <input type="checkbox"/> Translational Biomarker Core <input type="checkbox"/> The Exposure Biology Informatics Core <input type="checkbox"/> Community Engagement Core		
Have you met with a Core Director?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
If yes, please list of names of the individuals that you have met with?			
Is a letter of support from a Core Director included with this packet?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
If you do not plan on using a CEET Facility Core, please provide a written justification here.			
Are there animals included in this study?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Are humans Subjects included in this study?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Application Check List			
Please provide a 'check' or 'x' next to every item that is included in this application packet.			
Application Form <input type="checkbox"/>	Biosketch <input type="checkbox"/>	Abstract <input type="checkbox"/>	Specific Aims <input type="checkbox"/>
Preliminary Studies <input type="checkbox"/>	Methods <input type="checkbox"/>	Research Strategy <input type="checkbox"/>	Project Timeline <input type="checkbox"/>
Future Funding Statement <input type="checkbox"/>	Grant Support List <input type="checkbox"/>	References <input type="checkbox"/>	Budget/Budget Justification <input type="checkbox"/>
Facility Core Letter of Support <input type="checkbox"/>	Applicable IRB <input type="checkbox"/>	Applicable IACUC <input type="checkbox"/>	Letter of Support from their Mentor /Chairperson <input type="checkbox"/>
Mentor Other Support <input type="checkbox"/>	K-ward or Career Development award Plan <input type="checkbox"/>		

Center of Excellence in Environmental Toxicology (CEET)

Environmental Health Science Mentored Scientist Transition Pilot Project Grant Application

Human Subjects Questionnaire

Please answer all questions below. Note that some questions require attachments. Please use additional paper as needed to answer questions. NOTE: If your study does not include human subjects, please answer 'no' to question number one. There is no need to answer other questions.

Title of Application	
Name	
Position	
Title	
Contact Information	
Study Title	
SECTION 1 - CLINICAL TRIAL QUESTIONNAIRE:	
1. Does this study involve human participants?	___ Yes ___ No (If no, stop here)
2. Are the participants prospectively assigned to an intervention?	___ Yes ___ No
3. Is the study a Delayed Onset study? Delayed onset means you can't fully define your plans for the human subjects study in your application. Typically, this means you need initial results from the first part of the grant before finalizing plans for the human subjects portion.	___ Yes ___ No
4. Is this study exempt from federal regulations?	___ Yes ___ No
If "Yes" to question 4 above, Circle the appropriate exemption number:	1 2 3 4 5 6 7 8
5. Is the study designed to evaluate the effect of the intervention on the participants?	___ Yes ___ No
6. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	___ Yes ___ No
SECTION 2 – STUDY POPULATION CHARACTERISTICS	
1. Conditions or Focus of the Study Identify the name(s) of the disease(s) or condition(s) you are studying, or the focus of the study. If available, use appropriate descriptors from NLM's Medical Subject Headings (MeSH)	
2. Eligibility Criteria	
3. Age Limits – if no limit, enter "N/A"	
4. Inclusion of Women, Minorities, and Children	Attach as additional document

Center of Excellence in Environmental Toxicology (CEET)

Environmental Health Science Mentored Scientist Transition Pilot Project Grant Application

5. Recruitment and Retention Plan – <u>not required if Exempt #4</u>	Attach as additional document
6. Recruitment Status (Please Select One):	<input type="checkbox"/> Not yet recruiting <input type="checkbox"/> Recruiting <input type="checkbox"/> Enrolling by invitation <input type="checkbox"/> Active <input type="checkbox"/> Not Recruiting <input type="checkbox"/> Completed <input type="checkbox"/> Suspended <input type="checkbox"/> Terminated (Halted prematurely) <input checked="" type="checkbox"/> Withdrawn (No Participants Enrolled)
7. Study Timeline	Attach as additional document
8. Enrollment of First Subject – Enter the date and if it is Anticipated or Actual	
9. Inclusion Enrollment Report – Use template to provide information for manual entry into Penn eRA	See attached form
SECTION 3 – PROTECTION AND MONITORING PLANS (ATTACH AS ONE SINGLE DOCUMENT)	
1. Protection of Human Subjects	Attach as additional document
2. Risks to Human Subjects a. Human Subjects Involvement, Characteristics, and Design b. Study Procedures, Materials, and Potential Risks	Attach as additional document
3. Adequacy of Protection Against Risks a. Informed Consent and Assent b. Protections Against Risk c. Vulnerable Subjects, if relevant to your study	Attach as additional document
4. Potential Benefits of the Proposed Research to Research Participants and Others	Attach as additional document
5. Importance of the Knowledge to be Gained	Attach as additional document
6. Is this multi-site?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes to the question above, describe the single IRB plan	Attach as additional document
7. Data and Safety Monitoring Plan – required for Clinical Trial, optional for all other Human Subjects research	Attach as additional document
8. Will a Data and Safety Monitoring Board be appointed for this study? – required for Clinical Trial, optional for all other Human Subjects research	<input type="checkbox"/> Yes <input type="checkbox"/> No
9. Overall structure of the study team - required for Clinical Trial, optional for all other Human Subjects research	Attach as additional document

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APPLICATION REVIEW CRITERIA:

Applications will be sent out for peer-review to experts in the field, the CEET Executive Committee will then meet to select the awardees.

The major review criteria are and will be scored using the NIH system

1. Significance
2. Approach
3. Innovation
4. Investigator
5. Resources & Environment
6. Budget/Budget Justification
7. Likelihood that the project will lead to NIEHS/NIH independent grant support

Funding will begin **February 1, 2021** and a Notification of award will be sent to the P.I. and their B.A. **by January 15, 2021.**

Each application will receive a decision letter and a copy of the critique and scores. If an applicant is encouraged to reapply they must provide a response to the critique (no more than one page).

For questions or more information, contact: Paula Williams
(215) 746-3031
paula.williams@penncmedicine.upenn.edu