CENTER OF EXCELLENCE IN ENVIRONMENTAL TOXICOLOGY (CEET)

Environmental Health Science Rapid Response Pilot Project Grants

Grants up to $10,000 available per project

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 two (2) types of Rapid Response** pilot project opportunities.

1. **Request to Obtain Needed Preliminary Data** - Provides up to $10,000 to obtain needed preliminary data to support a revised grant application to the NIH or other agency
2. **Community Engagement Rapid Pilot Project** - Provide up to $10,000 for a CEET member to work with a community partner on community engaged research

Applications are due by **Monday, December 21, 2020** and will be reviewed **within two weeks of submission**.

Applicants can request up to $10,000 for one year. No salary support for the faculty member is allowable. Any member of the standing or research faculty from any University of Pennsylvania School may apply.

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 Review	Award Notification	Award Start Date
By Monday December 21, 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 Rapid Response Pilot Project Grant Application

Eligibility Requirements

1. Any member of the standing or research faculty from any University of Pennsylvania School may apply
2. Preference will be given to applications that seek to revise a grant application submitted to the National Institute of Environmental Health Sciences (NIEHS) OR to applicants that seek to conduct community engaged research
3. 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
4. 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 an annual progress report within 3 months of the end of the funding period - The progress report should follow the same format as that required for an NIH R01 RPPR-progress report
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@pennmedicine.upenn.edu. Applications should include the following, **in this order**:

Note that in addition to the '*general application requirements*', each application type has additional requirements as noted below.

Request to Obtain Needed Preliminary Data

1. Applicant must provide a copy of their Summary Statement to indicate why these data are required
2. Abstract (0.5 page)
3. Description of Needed Experiments (0.5 page)
4. Justification of Why the Needed Experiments will make a difference (0.5 page)

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Community Engagement Rapid Pilot Project

1. Applicant must include a letter of sponsorship from Director of Community Engagement Core
2. Applicant must include a letter of support from the community partner
3. Description of Study Describing the role of the CEET member (1.0 page)
4. Description of Study Describing the role of the community partner (1.0 page)
5. Outcome metrics: impact on policy /regulatory science or primer for larger study

General Application Requirements

1. Application Form (**see attached below**)
2. New Format NIH Biosketch for P.I. and other co-investigators (limit 5 pages)
3. Follow instructions above for each type of award
4. Separate List of Current and Pending Grant Support using NIH formatting guidelines (**NOTE: this should be a separate document in addition to the Biosketch**)
5. References
6. Budget – an NIH-style budget table of personnel, equipment, supplies, and other estimated costs to perform the proposed project. Travel is only allowable if this involves visits to a community.
7. Budget Justification – a detailed explanation and justification of the funding request. *Non-allowable expenses include:*
    - Salaries for Associate and Full Professors
    - Tuition for graduate students
8. 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 Rapid Response Pilot Project Grant Application

Application Form (Please Type)

Name		
Position/Title		
Department		
Please select applicable Rapid Pilot Project	___Request to Obtain Needed Preliminary Data ___Community Engagement Rapid Pilot Project	
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?	___ Yes	___ No
If CEET Member, please list your Thematic Area(s)		
Are you an Early State Investigator?	___ Yes	___ No
Do you plan to use a CEET Facility Core?	___ Yes	___ No
If so, please indicate which Core(s) you plan to use?	_____ Integrative Health Sciences Facility Core (IHSFC) _____ Translational Biomarker Core _____ The Exposure Biology Informatics Core _____ Community Engagement Core	
Have you met with a Core Director?	___Yes ___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?	___Yes ___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?	____ Yes ____ No	
Are humans Subjects included in this study?	____ Yes ____ No	

Center of Excellence in Environmental Toxicology (CEET)

Environmental Health Science Rapid Response 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**

5. Recruitment and Retention Plan – not required if Exempt #4	**Attach as additional document**
6. Recruitment Status (Please Select One):	**____Not yet recruiting** **____Recruiting** **____Enrolling by invitation** **____Active** **____Not Recruiting** **____Completed** **____Suspended** **____Terminated (Halted prematurely)** **____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?	**____ Yes ____ 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	**____ Yes ____ No**
9. Overall structure of the study team - required for Clinical Trial, optional for all other Human Subjects research	**Attach as additional document**

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 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@pennmedicine.upenn.edu