

Q&A Session for Pre-Application Webinar for the Collaborative Centers in Children's Environmental Health Research and Translation

Date: Thursday, September 24, 2020

Starting time: 2:30 PM

QUESTION: To clarify: We need both an internal and external advisory board but the EAB is not named? For the IAB they can't be co-investigators I assume?

ANSWER: At this time, post aware, NIEHS Program will ask each Center to nominate an external advisory board member, yet each Center should develop an Internal Advisory Board to provide critical review of your Center's progress. Please don't provide names in application, just types of expertise.

QUESTION: Are the guidelines for amount of funds to provide to pilot projects?

ANSWER: There is just a guideline on funds to be set-aside, but Centers can manage size and scope pilot/catalyst projects. If human subjects, NIEHS will have to review and approve and additional information will be needed for approval.

QUESTION: If our center doesn't include a clinical trial, but a pilot project submitted/ funded through the development core is submitted later and includes a clinical trial, how will that be handled?

ANSWER: There is an internal approval process to submit to NIEHS for approval including human subject section to be added to Center grant with required tracking, enrollment forms and IRB approval.

QUESTION: Does the Deputy Director have to meet the CEH Active Scientist criteria? If this individual has translational expertise, it may not be in CEH--rather communication etc. Can you clarify? Thanks!

ANSWER: The DD does not have to meet the CEH active Scientist criteria. We recommend that someone in Center leadership whether Director or Deputy should be a CEH leader in the field though.

QUESTION: To what extent can funding for the Catalyst pilot studies and/or the PPP in the Translational Core come from the Admin Core?

ANSWER: For peer-review, the pilot project programs, and their budgets should be in the appropriate Core, however, you will have the flexibility ability to manage the funds accordingly. The role of AC is different than DC and TC. TC leads and DC leads should develop the topics to compete and AC support outward facing administration of a fare and transparent program.

QUESTION: And must the IAB members be a center member with FTE support? Or should they have no affiliation with the Center?

ANSWER: No affiliation with center and no FTE support required.

QUESTION: Are there any environmental threats/exposures that are of interest for the FOA?

ANSWER: NIEHS has not called any specific chemicals or exposures or health outcomes. Chemicals and or exposures of pollutants should be areas of research in CEH that NIEHS supports and that there is a body of knowledge to translate and or develop.

QUESTION: If the Translational Core uses new CEH research, does this imply initial research is done by the CEHRT, to establish the "science" (e.g. exposure and CEH outcomes), then followed pilot interventions? (in later years of center)

ANSWER: Some research can be done within the Cores and as needed. We see the developmental core purpose to keep the new science simmering and response to emerging issues, new tools and technologies, and pipeline of CEH investigators.

QUESTION: Does the Admin Core also be the center director?

ANSWER: No.

QUESTION: Can the Translation Core include for-profit private entities?

ANSWER: yes. But please discuss with your office of sponsored research the best approach to include them as certain items, services may not be allowable.

QUESTION: What are the requirements for a Center Member? Are they supposed to be internal or external to our institution? What are the members supposed to do? How will they be judged within the grant and how do they relate to the success of the Center?

ANSWER: Members should have a defined role in one of the Cores. This is research resource center, so their services need to be aligned with the vision and objective of children's environmental program.

QUESTION: Translational Core budget is \$250K minimum? Does the entire core budget need to go to pilot projects or can TC funds support staff to organize the pilot project RFA and administration?

ANSWER: The budget includes the pilot. The pilot funds are flexible.

QUESTION: Is there an expectation of collaboration between Translational Core and Development Core? Can their proposed work be interwoven and support each other?

ANSWER: They should be integrated as they move the existing CEH science into policy and practice and yet communicate gaps and science to development core in areas that may be needed to help accelerate the science.

QUESTION: Slides and the presentations are very informative. Would you please share the slides - that will be very helpful?

ANSWER: Slides are on site of meeting announcement.

QUESTION: Should individual centers focus on regional issues (i.e., involving vulnerable populations) or exclusively on national issues? Do we need to identify/name the pipeline of early career investigators in the application?

ANSWER: Focus is really what makes sense based on your Center membership. Do not need to name early career investigators just the source of pipeline and activities to recruit them.

QUESTION: How much is an activity of the Translational Core to translate the science versus supporting and funding pilot work that does this translation? Active development of tools vs. being a support and a resource to others. Thank you!

ANSWER: This depends on the Center vision and resources. If you have access to wealth of existing data, then more can be done with translation and use pilot funds later.

QUESTION: Does evaluation research assessing a translational tool fall within the scope of the Translation core, or would that have to occur under the auspices of one of the pilot project programs?

ANSWER: Could be either. If you start with an evaluation component nested within TC, then use TC funds. Pilots are small funds and thus you may need resources.

QUESTION: Do both pilot projects (in the development core and the translational core) need to include open solicitations for applicants? Or could we define the pilots within the translational core in the initial application (and not include an open solicitation)?

ANSWER: The Centers should be prepared for open competition from outside sources, yet I would think more of the funds for outside sources would be for development core. However, you may want to consider an opportunity where you would include an outside competition in future years in TC for testing theories/intervention/tools.

QUESTION: Can pilot program funds from the Translation Core be awarded to community organizations?

ANSWER: Yes.

QUESTION: Does research on environmental effects on clinical populations fall in the scope of research translation? I.e. how does say air pollution affect children with cystic fibrosis as an example. The clinical population is defined as a vulnerable population.

ANSWER: Yes. But again, this is a research resource grant mechanism. Thus, our justification for the program was the wealth of data that NIEHS has supported that remains “untranslated.” I am unaware of a vast amount published research on Environment and cystic fibrosis.

QUESTION: Is there an expectation of collaboration between Translational Core and Development Core? Can their proposed work be interwoven and support each other?

ANSWER: It would make for a good Center to be integrated but we could see a broad Center working on extant issues in CEH in the TC and emerging issues in DC.

QUESTION: How are you defining secondary institutions?

ANSWER: Institution of record for the Center will be the Center Director’s affiliation.

QUESTION: Is implementation science same as translational research?

ANSWER: This question has been answered verbally.

QUESTION: Kim may have just said this quickly, but I was hoping you could share some of those examples of translational products that are NOT communication materials.

ANSWER: Besides communication materials, following research areas that inform policy and practice could be testing of contextual factors that would influence success of dissemination and implementation efforts, ways to improve uptake, as well as understanding how effective interventions works to help inform CEH interventions can be adapted or delivered in various settings.

QUESTION: Would interactions between env hazard and social factors be allowable? For example, how social factors can exacerbate or ameliorate the effect of a traditional environmental stressor?

ANSWER: Yes.

QUESTION: In terms of tobacco smoke exposure as a focus, does this include vaping and other nicotine products?

ANSWER: Second-hand tobacco smoke and other products are in NIEHS mission.