FAQs from CEHC Technical Assistance Webinars
October 20, 2014 and November 4, 2014

This document is a compilation of questions that were asked in both Technical Assistance Webinars. For clarity, questions were simplified and redundant questions were removed. An attempt was made to categorize questions into related topics. Please search the document for the answer to your questions, before contacting staff.

Letters of intent (LOI)

1. *When are letters of intent due?*
   Letters of Intent are due on November 22, 2014

2. *What is needed in the LOI?*
   The letter of intent should include a descriptive title of proposed activity; the name(s), address(es), and telephone number(s) of the PD(s)/PI(s); names of other key personnel; participating institution(s);
   and the number and title of this funding opportunity.
   The letter of intent should be sent to:

   Linda Bass, Ph.D.
   National Institute of Environmental Health Sciences
   Telephone: 919-541-1307
   Email: bass@niehs.nih.gov

Supplemental Materials

3. What supplemental application materials are allowed and when are they due to be submitted?
   Supplemental Information (e.g. new publications, new funding) will be accepted by the Scientific Review Officer with a **due date of no later than 5:00 p.m. (EST) on February 24, 2015**. Supplemental Information **must** be contained in 3-pages and **must** conform to NIH guidelines for supplemental materials. No information will be accepted after this date.

   The list of acceptable post-submission materials in includes:
   - Revised budget page(s) (e.g., change in budget request due to new funding or institutional acquisition of equipment).
   - Biographical sketches (e.g., change in senior/key personnel due to the hiring, replacement, or loss of an investigator).
   - Letters of support or collaboration resulting from a change in senior/key personnel due to the hiring, replacement, or loss of an investigator.
   - Adjustments resulting from natural disasters (e.g., loss of an animal colony).
   - Adjustments resulting from change of institution (e.g., PD/PI moves to another university).
   - News of an article accepted for publication (a copy of the article should not be sent)

Foreign components

4. *Can non-U.S. entities be collaborators on projects if the lead applicant is U.S. based and the research is conducted in the U.S?*

   Yes, a non-US entity may be a collaborator. If recommended for funding, there are additional steps required, post review, that these applications will have to go through for Fogarty clearance. For EPA, while the applicant must be a U.S. entity, foreign components are allowed but require approval post review if recommended for funding from EPA's Office of International and Tribal Affairs (OITA) on a case-by-case basis.

Page Limits

5. *Regarding page limits for the 'Research Project' section, is it 12 pages per research project, or is it a total of 12 pages for all 3 projects.*

   Each Research Project has a 12 page limit. For example; Research Project 1 gets 12 pages, Research Project 2 gets 12 pages, and so forth.

6. *Do the 12 page and 6 page limits for the Projects and Cores include the specific aims single page?*

   No. There is one page for Specific Aims, which is separate and, therefore, not counted in the in the 12 or 6 pages allotted for the corresponding section.

7. *Are more than 3 research projects allowed?*

   Yes, but remember that all projects proposed will be reviewed and scored and be part of the overall score.

Human Subjects / Animals

8. *Should an overall description of Human Subjects Protections, Inclusion of Women & Minorities, Inclusion of Children, and Vertebrate Animal Use be included in the Overall component of the application? Or should these descriptions be provided only within the Project or Core components to which they are relevant?*

   Applicants MUST include a detailed description in each Project/Core that proposes the use of human subjects (or animals). Please refer to the RFA for all the required components / information for this section. Description in the Overall is not needed.

9. *Is the 6 pages of EPA Human Subjects Research Statement (HSRS) included within the Human Subjects Protections attachment?*

   Yes. The EPA HSRS should be included within each human subject's protection attachment.

New / Renewal Applications / Progress Reports

10. *Because our application is for renewal of funding, we are assuming that the progress report for our Center's first funding cycle is to be complied as a single summary, encompassing progress for all our Center's current Projects and Cores. Is this correct? If so, where should the progress report be included in the application? (e.g. Should it go in the Overall Component's "Research Strategy" document, at the end of the Research Strategy section?) If not, how should the progress report be configured and where should it be located in the application? Additionally, can you please tell us if there is a page limit for the progress report? Can you also*

confirm that the progress report does not count toward the page limit of the Research Strategy?

Progress Reports for Renewal Applications pertain to the progress of the Overall Center. The Progress Report should include comments on the Research Projects and Cores as well the Center as a whole since the previous review. Applicants should also briefly discuss any major changes (updates) in the Projects and Cores in their separate sections (within the stated page limits). The Progress Report must be included in the 12 page limit for the Overall Section (no additional pages for Progress Reports). How much of the 12 pages the Principal Investigator wants to devote to the Progress Report is their decision.

11. *Should progress reports be submitted on the 2590?*
    No. See above.

12. *How do we incorporate all the publications in the progress report? Does this count towards the Overall page total?*
    If there is a separate place within ASSIST to list all publications, you may use it. If there is no separate section for publications, any publications listed in the Overall component must be contained within the 12 pages allotted.

13. *Can a funded P01 apply as a new P50 or should it always be a renewal application?*
    Yes. An existing P01 Children Centers may apply as a new P50.

14. *Are there specific guidelines for a Center at an institution that already has one, i.e., a second Center at an institution that has one?*
    No. However, each Center must be scientifically distinct and NIEHS and EPA will have a joint post review to look at program balance and agency mission and priorities.

15. *For competing renewal Centers, should we include progress from our last Center grant that is no longer relevant to our competing renewal application?*
    If the application is not an extension of the research from the previous center program, then the application would be considered new.

Publications

16. *We are assuming that we should provide separate bibliographies for each Project's and Core's research plan (where applicable); but that a bibliography for the Overall component will not be needed, unless references are cited in the Overall component's research plan. Is this correct?*
    Yes, a separate Bibliography section is needed for each Project and Core. A Bibliography section associated with the Overall is at the discretion of the Principal Investigator as to whether to include or not as it counts towards the allowed 12 pages.

Scoring

17. *Can you explain how animal/human subjects' research will be factored into overall impact score?*
    NIH requires applicants to address specific criteria for the use of human subjects in research. Any issues or concerns with the use of human subjects can impact the priority score as well as bar the possibility of funding. The same applies for animal research.

Awards

18. *How many centers are funded now and will go up for renewal this year? About how many new centers will be funded this year? How many awards go to renewals?*
NIEHS and EPA funded 8 Centers under the FOA 12-001 and 6 Centers under FOA 08-002. There are 6 eligible Centers for competing renewal. Funds have been allocated to fund 4 – 5 Centers based on the overall center score (peer review) and programmatic priorities of each agency (second level of review), and total costs. There is no set-aside for competing renewals versus new applications.

19. *Will you be seeking balance in terms of exposures? That is are you trying to involve Centers focusing on different environmental exposures?*
Program always seeks balance yet is cognizant that more scientific discovery may be warranted and complementary by incorporating new technologies and approaches and underserved populations.

20. *Will you be seeking geographic balance in terms of parts of the country?*
NIEHS and EPA have a post review program priority meeting and we do consider scientific balance and agency priorities, which includes under-served populations.

Intervention/Exposures

21. *Would an intervention study aimed at mitigating the harmful health effects of a given exposure be aligned with the RFA and NIEHS/EPA goals?*
A goal for NIEHS is to promote health through prevention of exposure, reduce exposure, as well as the development of strategies to mitigate the harmful effects of environmental threats. EPA goals are to improve the health of our families and protect the environment. Proposed research projects may not intentionally expose (increase, decrease, or otherwise change the exposure of) children, pregnant or nursing women. If you are proposing an intervention study, please contact NIEHS and EPA program to assure it fits within both agencies missions.

22. *Would secondhand tobacco smoke be considered a relevant chemical stressor?*
Secondhand smoke is not a priority compound of interest. Please contact Program staff for more information about the approach being used to determine responsiveness.

Center Staffing

23. *Is it acceptable to have Co-Leadership of our Center's Projects (i.e. May we have 2 key personnel serving as Co-Leaders of a single project)?*
The ASSIST system should allow multiple individuals to be assigned the "Project Lead" role on a project. RFA-ES-14-002 does not specifically exclude co-Leaders on projects, but does indicate that any Center's proposed administrative and organizational structure must be well thought out and scientifically justified.

24. *May cores also have co-leads?*
No. Cores should have a single lead.

25. *Should the Project (Center) Director also be a PI on one of the 3 projects?*
It is not necessary for the Center Direct to be a PI on one of the projects.

26. The instructions state the "Program Director" should provide a letter of recommendation for the Career Development Investigator (CDI). Is the "Program Director" the same as the director of the Center (i.e. the PD/PI)? Or is the "Program Director" the Director of the CDI's current program?
The Program Director is synonymous with Center Director (PD/PI).

27. Is the CDI plan a separate document or is it included in the Admin Core? Is there a recommended page length or limit for the actual career development plan, i.e., not the description of how a Center will go about finding and selecting a candidate?
The Career Development Plan is part of the Administrative Core. There are 12 pages set-aside for the Admin Core (this is an increase of 6 pages) to allow for the additional information. The Core has other functions and roles so I would estimate about 2-3 pages for the career development plan. If a candidate is known, their biosketch could be used to describe their interest.

28. The RFA instructions say that the Career Development plan should be included as part of the Administrative Core. Does this mean that the Career Development Investigator (CDI) should be supported, at least in part, in the Administrative Core budget? Or may that investigator be supported through other project/core budgets within the Center, but not on the Admin Core budget?
If the CDI candidate is actively involved in one or more projects, their salaried effort may be budgeted to those projects. Salaried effort that specifically addresses career development activities described in the career development plan, which are not specific to any one research project, may be attributed to the Administrative Core budget.

29. Can you name more than one individual for career development? If you have more than one CDI, do they both need to be on for 3 months?
Yes. You may name more than one CDI. However, one CDI must be on the grant for 3 months per year for the entire grant period. You may bring on other staff for shorter periods of time. Additional staff may be at any level: undergraduate student, graduate students, early stage investigator, etc. Note that NIH offers a variety of supplement programs to provide support for various stages of career development.

30. Will this P50 RFA encourage established experts who may not have previous environmental health related research to start join work on or lead new related projects under this RFA?
Absolutely! We are looking at this Centers program to recruit scientific expertise from all disciplines related to the theme of the Center to enhance the science under discovery.

31. Are we required to name the Career Development Investigator (CDI) as a "Key Personnel" position, or may that position be non-key?
Per the SF424 (R&R) instructions, "senior/key personnel are defined as all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are requested." If the identified CDI meets that definition, they should be treated as key personnel on the application. If the CDI does not meet the definition – for example, if the CDI is to be recruited, and thus their specific role within the

center is still undefined – then that position does not need to be identified as key personnel on the application.

32. *Can the CDI have concurrent K award and still contribute effort / take salary?*

Having K award support would not disqualify an individual from meeting the definition of a "New Investigator", which is a requirement in the RFA. However, the support/effort on the Children's Center award cannot have commitment, budgetary, or scientific overlap with the K award. For example, if an individual is required to commit 9 months of effort to the K award, the 3 months of effort required for the CDI position would be in addition to, and not a component of, the 9 months for the K award. If the individual cannot meet the effort requirements for the K award, the Children's Center award, and any other support commitments, without exceeding 12 calendar months, there are specific circumstances in which the awarding IC may negotiate a reduction of effort on the K award (see NIH Grants Policy Statement section 12.3.6.2 - http://grants.nih.gov/grants/policy/nihgps_2013/nihgps_ch12.htm#_Toc271265198). Please n0ote that the specific circumstances in which concurrent effort can be negotiated depends on the type of K award, so applicants should be cautious.

33. *Can the Pediatric Health Specialist also be a Program Director?*

The Pediatric Health Specialist cannot be the Program Director also referred to as the Center Director. However, they can be a PI of a research project.

Data / Resource Sharing Plans

34. *We are assuming that we should provide a separate Resource Sharing Plan within each Project and Core component (where applicable), that addresses sharing of the resources generated by that Core/Project. Should we also provide an overall Resource Sharing Plan, within the Overall component? If so, what content should be provided the Overall component's Resource Sharing Plan? Additionally, can you confirm that each resource sharing plan is limited to 2 pages?*

A separate Data Sharing Plan MUST be included in each Project/Core if applicable to that Project's/Core's activities. There should not be a Data Sharing Plan in the Overview Section. There will be a field for that data in each section in ASSIST. You MUST insert something in that field every place you see it. Where appropriate add a description of how you will share data/resources. If a section does not have a need for data/resource sharing, please insert that in the corresponding data/resource sharing field. The data sharing plan is in a separate field so does not affect 12 or 6 page limits.

35. *Where can we find an example of a short data sharing plan appropriate for Center applications?*

There isn't a template since all data is collected differently and all Institutions operationalize this policy differently and there is not a universal IRB or template. It is our hope that applicants will be more creative in finding solutions to data sharing and facilitate sharing data with the broader community.

Budgets/Consortia/Subcontracts

36. *Is the $1.25 million per year total costs for new applications inclusive of the indirect costs? Or does the $1.25 million per year only include directs costs?*

The $1.25 million/year is a total cost cap, which means that includes indirect costs; likewise for the $1.5 million total costs.

37. Within each Project and Core component, we will be providing a description of the Consortium/ Contractual arrangements relevant to that Project/Core. Should we also include, in the Overall component, an overall description of the all the Consortium/Contractual arrangements across Center's Projects and Cores? (Note that this would be a duplication of information found in each of the Projects and Cores).

Inclusion of this information in the Overall component is at your discretion within the limits of the 12 pages allotted.

38. In the prior application, there were budget guidelines for various components. This does not appear to be the case with the current RFA. Are there any guidelines for various budget categories?

Due to the shortened time frame (4 years) and the cap on total costs, we wanted to give Centers as much flexibility as possible to allocate their budgets where it made the most sense for the science. Therefore, we have not included any specific budget guidelines for any of the components except for a reminder that the Administrative Core should include funds for an annual Centers Meeting.

39. We have 4-5 subcontracts that will be preparing different components for the proposal like project A, project B and so forth. I understand that I will create each component specific to their submission in ASSIST but how does NIH know that they are our subcontracts?

The first component for your application should be labelled "Overall". The DUNS number associated with the SF424 (R&R) Cover Page on the "Overall" component will signal to NIH which institution is the lead applicant organization. As you create additional components, if a subaward institution will have primary responsibility for a component (e.g. Project A), then entering their DUNS number on the SF424 (R&R) Cover Page for that component will signal to NIH that the subaward is taking the lead for that particular component.

Within each component, you can identify the participation of subawards/consortia through the budget forms. The SF424 R&R budget form includes a blank for DUNS number at the top of each form. ASSIST will match the DUNS numbers with your institutional DUNS number to verify whether the budget page is from the lead institution (marked "Project") or from a subaward institution (marked "subaward/consortium"). For more information see this NIH FAQ set on ASSIST, Section F "Multi-project Application Budgets": http://grants.nih.gov/grants/ElectronicReceipt/faq_full.htm#assist.

40. If I am creating components for each subcontract university to enter their information, then what is the Subaward form used for?

The designation of a component should be based on the scientific role of the component. You should follow the component organization scheme outlined in RFA-ES-14-002, Section IV.2, exactly; failure to follow that component organizational scheme may result in your application not being accepted. For example, RFA-ES-14-002 requests a single Community Outreach and Translation Core (COTC). If you have multiple organizations participating in the COTC, they should work together to create one COTC application component, and not submit a separate COTC component for each organization.

Subaward budget forms can be used to add subcontract organization budget information to your application.

41. *Can I add more than one institution per component in ASSIST e.g. can there be three different universities submitting project C? If yes, will I be creating project C under components three times because every university will have different PD/PI, different performance site and so forth?*

You may have multiple institutions working together on a single component (e.g. project C). For each component, a lead organization should be designated by entering that organization's DUNS number on the SF424 R&R Cover Page for that component. All other organizations working on that component should provide the lead organization with their information (performance sites, biosketches, budget pages) and the lead organization is in charge of entering the information for that component. For more information, refer to section G. "Managing Application Access" in the NIH ASSIST FAQs: http://grants.nih.gov/grants/ElectronicReceipt/faq_full.htm#assist. For the purposes of RFA-ES-14-002, note that the terminology "PD/PI" only refers to the individual(s) designated as Program Director over the entire Children's Center. For leaders of individual components, use the term "Project Leader" when identifying key personnel and establishing budgets.

42. *In regards to creating subaward - when all other organizations working on that component provide the lead organization with their information (performance sites, biosketches, budget pages) where does the lead organization in charge enter that information for that component? When uploading the subaward form in the particular component, will all other form be included with it (cover page, site performance, etc)?*

Unlike the old paper forms where subaward information was often submitted as a mini-application within the larger application, the electronic SF424 (R&R) forms incorporate subaward information throughout the application. For example, the key personnel section would include biosketches from both the applicant institution and all the subawards together in one place. The only specific subaward form is the consortium budget pages. For more information , you may want to refer to the step-by-step instructions in section 7.2 (Adding Other Components) of the ASSIST User Guide: http://era.nih.gov/files/ASSIST_user_guide.pdf.

43. *We have a situation where the subaward institution (University B) will be taking the primary lead on one of the projects (Project 1). The primary institution for the rest of the Center (University A) will also have a role on Project 1, but not the lead role. Does this scenario (with costs associated with the "non-lead' prime) force us to keep the prime institution as the Core Lead and push the actual Core Lead into the subaward budget?*

Per the FAQs (See section F at: http://grants.nih.gov/grants/ElectronicReceipt/faq_full.htm#assist), the ASSIST program will match DUNS numbers when creating the composite roll-up budget, so there is some flexibility in how you set up your subaward budgets within the individual components. If you try an approach and cannot get the correct budget calculations in your overall component, contact the eRA Helpdesk for additional guidance on using ASSIST. (http://grants.nih.gov/support/index.html).