Frequently Asked Questions

1. How is this new NIH effort different from the NCS? This sounds like just another version of the NCS.
    a. *NIH has learned much from the NCS. The FY16 program, which we currently are calling ECHO, will differ from the NCS in several important ways – it is structured to be more n efficient by taking advantage of existing programs. At least initially, we propose to utilize extant cohorts – those that are already established or have begun recruiting. This is one way in which we are attempting to address a major hurdle faced by the NCS. Additionally, we also have limited the focus of the potential studies – the four Focus Areas – and considered how best to integrate them (Core Elements). We will take maximal advantage of existing and developing advances in data science as well. A Steering Committee made up of the studies' PIs and external and internal experts also will help to guide and direct the effort.*
    b. *Further, we are proposing to launch an IDeA States National Pediatric Clinical Research Network to create a rural pediatric clinical research network to increase racial/ethnic/SES diversity by establishing a team of pediatric clinical researchers embedded at IDeA locations. It will allow NIH to leverage an existing infrastructure at IDeA locations, provide additional expertise, and address access gaps for rural and underserved children.*
    c. *To summarize, the goal of ECHO is to more efficiently and effectively utilize and leverage our current resources to address a hugely important area of research.*

2. How will the FY15 projects feed into this new effort?
    a. *The FY15 projects will absolutely be applicable going forward. At least initially, some of the FY15 studies may be a bit premature to leverage, but there is still tremendous opportunity with the others for FY16. For example, the Children's Health Exposure Analysis Resource (CHEAR) program will develop a network of laboratory Hubs, supporting comprehensive analytical services to extend or complement the objectives of children's health studies to measure environmental exposures. Awards will be made soon, and we anticipate it being functional, although not to capacity, by mid-FY16. This means that those studies supported as part of the ECHO program will be able to utilize this resource. In fact, we strongly encourage them to do so and expect that some of the ECHO analytics will be done through CHEAR.*

3. Why limit to extant cohorts? Extant cohorts may lack important samples/metadata/etc. There should be the capability of proposing novel cohorts.
    a. *Initially, we are limiting the applications to extant cohorts. While we recognize there may be some limitations to this approach, we are confident that this is the best option at this time to make the most efficient use of funds, as we can leverage investments already made and extend resources further. For FY 16, we hope that leveraging extant cohorts will allow the program to begin to take shape and advance knowledge. We also will employ the latest methods in data science to address any concerns about combining and analyzing data from different studies. However, we are open to the possibility of including novel cohorts in future years.*

4. What is the definition of "extant cohort"? (e.g., If there's an existing resource of identified pregnant women from which participants could be recruited efficiently, is that an "extant cohort"? Perhaps I'm perseverating here, but I did not understand that the case was closed for including only existing research cohorts.) What extant cohorts will be eligible? Will birth cohorts whose participants are adults be eligible to apply?
    a. *By extant cohorts, we are referring to projects that have already been set up to recruit participants – that they have the infrastructure in place to recruit additional participants to the study or a new component of the study, those that can leverage their current participants, those that are currently recruiting, those that are just about to recruit, and those that have samples from previous studies that have yet to be analyzed.*
    b. *Eligible cohorts include:*

i. *Those which are still actively collecting longitudinal follow up data*
ii. *Those which enrolled mothers before or during pregnancy that have the potential of collecting data on offspring*
iii. *Those which enrolled children at birth or in the first year of life*
iv. *Those with success in retention and data collection*

5. Can international investigators and cohorts participate?
   a. *While this is certainly a possibility, the questions in the proposal have to be unique and compelling, and able to provide data that currently is not possible using cohorts in the US*.

6. Can cohorts that have already completed pregnancy / postnatal data collection participate? Extant cohorts may not able to add exposure measures or outcomes from earlier time points and may not be able to address all of the elements in the plan.
   a. *Yes, we are open to participation for cohorts that have already begun data collection. In the proposal, the investigator would need to describe the questions and measurements that would be feasible with the existing cohort. The proposals would be of interest if they are able to answer interesting and compelling questions. Extant cohorts should incorporate the Core Elements into their study and address (at least) one of the four Focus Areas. We are, however, open to including additional cohorts in the future.*

7. What are the roles of the coordinating center vs. individual projects (e.g., data management, quality control, data distribution inside and outside ECHO)?
   a. *The Coordinating Center will manage all of the studies and serve as the hub for communication, collaboration, and interaction amongst the studies. An analytical or data science component will be incorporated either into the Coordinating Center or be set up independently, albeit connected. It will be overseen by a Steering Committee with NIH staff, the heads of the Coordinating Center, and the PIs of the studies.*
   b. *The individual projects will investigate the key questions of import to their study, but also include measurements of the Core Elements. Further, all studies within each area will coordinate collection of standard disease-specific questions, as identified by the community, in addition to the study-specific questions and Core Elements.*

8. Will data already collected need to be harmonized? How will future data be harmonized and will NIH measurement tools, like PROMIS, be required?
   a. *No, data collected in the past are not expected to conform to the data standards that will be developed for this program. However, advances in analytical tools can allow for comparison of data that were collected differentially. Prospective data will be harmonized through the Coordinating Center, which will identify the standardized research measures, or Core Elements. Focus Area common measurements will be identified by the appropriate research communities. Using NIH-developed measurement tools will not be a requirement.*

9. Can investigators and cohorts collaborate in their proposals? Do you prefer single site or multi-site proposals?
   a. *Yes, we absolutely would welcome and encourage collaboration. In fact, some investigators have suggested that they may create a synthetic cohort, combining several existing studies that focus on a particular disease area. In terms of sites, the ideas will be investigator-initiated, and we have no preference for single or multi-site proposals. The number of sites will depend on the questions in the study, and the most appropriate means of addressing them.*

10. How does the IDeA state network fit with the overall program?
   a. *The IDeA States National Pediatric Clinical Research Network will be an additional related, but separate, opportunity. This network will be encouraged to make the four focus areas a priority, and to utilize the same standardized research measures, or the Core Elements, as the broader program.*