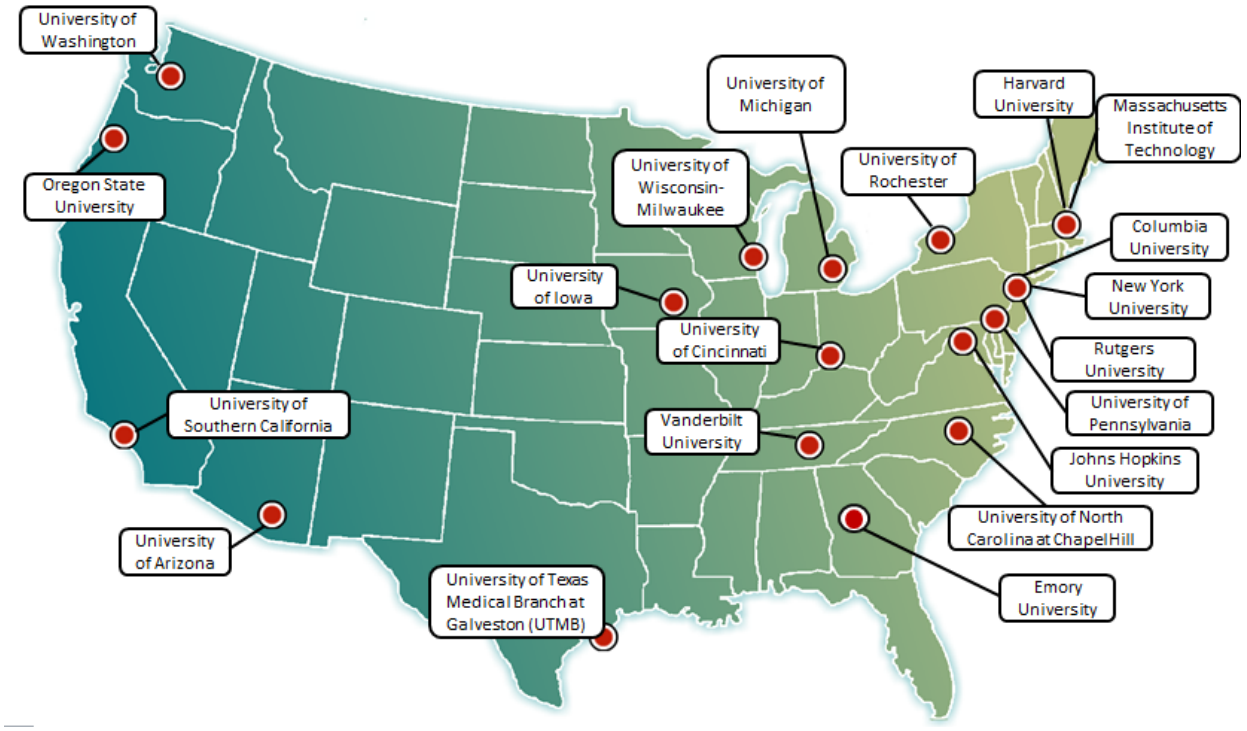
NIEHS Core Centers Evaluation
Evaluation Advisory Subcommittee Final Report

Executive Summary

The National Institute of Environmental Health Sciences has used the NIH P30 Center Core Grant mechanism to support shared resources and facilities for environmental health research for more than 50 years. The aim of the Environmental Health Sciences Core Centers (Centers) is to guide and support environmental health research at institutions throughout the United States, provide intellectual leadership in environmental health research, foster innovation and support new ideas and collaborations among investigators. The Centers also provide career development for future leaders in environmental health science by their provision of centralized scientific resources and facilities that are shared by investigators working on existing research projects funded by other mechanisms. The Centers strive to translate research into public health outcomes and to foster community-academic partnerships through engaging communities in multi-directional communication with researchers (See Appendix A for an overview of the Core Centers program.)

The following map shows the current Centers. The essential structure of each Center includes an administrative core, an overall strategic vision or theme, an Integrated Health Sciences Facility Core (IHSFC), Community Outreach and Engagement Core (COEC), other optional facility cores, a Pilot Project Program and a Career Development Core.



In 2014, NIEHS formed an evaluation advisory subcommittee to evaluate its Environmental Health Sciences Core Centers Program (See Appendix B for a list of the subcommittee members). This was the third programmatic evaluation of the Core Centers since their inception. The first evaluation focused on outcomes of the Core Centers program from 1993 to 2003, including key highlights of the Centers, the outcomes of the pilot funding within Centers, and supplements to the

Core Centers funding. The evaluation lasted more than 18 months and included substantial data collection, publication analysis, and exemplars of successful activities. The results of the evaluation resulted in changes to the funding opportunity announcement (FOA). Following these changes in FOA, a second evaluation was conducted in 2010 that focused on the process that Centers used to fulfill their goals and specifically to assess the effectiveness of the programmatic and structural changes that were made in the October 2005 FOA. The evaluation lasted approximately 8 months and included grantee surveys (with PI and COEC leaders), publications, and analyses of facility cores (See Appendix C for a summary of previous Core Center Evaluations).

The current evaluation goals included both process and outcomes of the Core Centers and focused on the extent to which the Centers foster and produce complex, emerging and translational environmental health research, including examples of the complex, emerging and translational research they support, the strategies they use to facilitate this research, and the impacts of the research. The evaluation also addressed the strategies by which the Centers support career development and the NIEHS strategic plan (See Appendix D for an overview of the evaluation).

The committee was convened in September 2014, when the purpose and goals of the review were presented by NIEHS staff and the evaluative questions were reviewed. This meeting was followed by three conference calls in early 2015 to review data assembled from the Centers by NIEHS staff. In June 2015 a face-to-face meeting was held to discuss the summative evaluation questions and to plan the final products of the evaluation (See Appendix E for the evaluation timeline). The committee reviewed the substantial evidence that had been compiled by NIEHS staff and answered the following summative questions:

1. How does the EHSCC Program bring value, (i.e., lead the EHS field) in relation to complex, emerging and translational research?
2. What can the Centers do that can't be done with other research mechanisms?
3. What promising processes and strategies emerge from the Centers as critical for the program and the EHS field (defined broadly and including public health)?
4. How can the Centers help inform NIEHS about emerging fields and scientific opportunities?
5. How should the Centers be involved with identifying and implementing the next set of strategic plan goals?

In this report, we summarize our responses to each of these questions. Key messages that arose during the review process follow:

P30 centers serve as critical hubs for environmental health research.

Numerous examples were provided by the Center directors of ways in which the Centers foster interactions, collaborations, training, mentoring, innovation and application of leading edge inter-disciplinary approaches. The intellectual interactions may not have occurred in the absence of the environment created by the Center. The resources that are provided within the cores to both junior and more accomplished investigators are significant and provide valuable assistance to investigators pursuing new areas of scientific inquiry. An important aspect of the Centers is that they introduce many individuals to the area of environmental health science and offers opportunities for individuals to interact with NIEHS who might not if the Center did not exist. Many of the current Centers are long-standing, which highlights the importance of leadership succession and sustainability planning.

Core Centers are a source of collaboration and sharing for Environmental Health Science

Examples provided by the Centers point to the ability of the centers to connect across the university with other research centers that may or may not be funded by NIH, or specifically NIEHS. This collaboration among centers was viewed by the committee to be highly positive. The potential for Centers to connect both with other centers in their own institutions or across institutions has not been fully realized. The committee recommends that NIEHS do more to enhance cross collaboration. These collaborations could occur at the investigator level, as well as with the core facilities and with other institutions or agencies.

COECs are a critical and integral component of the EHSCCs

With their strong emphasis on community outreach and engagement, Centers have a finger on the pulse of the public; thus, the Community Outreach and Engagement Cores are viewed as critical to the Centers. The definition of community is broadly defined as anything "beyond academia," and includes a variety of entities including neighborhoods, populations, and other stakeholders. The COECs are viewed as a critical component for the translation of Center work and environmental health to the public. If the work of the Centers does not reach the American people, its value is not fully realized. The COECs should not only be viewed as the mechanism for translating the work of the scientific community, but also the body that insures that Center members can engage in translation. The COECs also play a critical role in assuring that the scientific community hears and responds to the priorities and research needs of the community. Community engagement should be explicitly and thoughtfully considered for all aspects of the Center (pilot projects, cores, research project users of facilities) and community engagement should be an expectation of all Center members and encouraged to be a part of all projects and cores.

Importance of the Core Centers embracing the Strategic Plan

One of the most challenging areas of the evaluation was the determination of the extent to which the Centers embrace the NIEHS strategic plan. To date the Centers have not been asked to address or provide examples of how they align with the strategic plan but ample examples arose regarding the potential for the Centers to play a more important role in this area. Specifically the strong outreach and engagement cores within the Centers could provide a platform for helping to educate the public about the overall goals and strategic plan of NIEHS. Pilot project programs and other initiatives, especially in translational work, could provide a resource for NIEHS to grow under-represented areas of the strategic plan. Cross collaboration among the centers could allow the development of communities of interest around special topics aligning with the strategic plan such as the current inter-Center workgroup on fracking.

Reporting

The review committee appreciated the large volume of data that the Centers produce and that was distilled by the NIEHS staff. Yet there was the overarching sense that a lot of the data have been collected historically and may not adequately reflect the parameters currently of most interest. Specifically, new metrics are needed to capture translational research, innovative science, community engagement, and collaboration/sharing across and within Centers. Measures are needed to accurately determine the extent to which the Centers enhance the institutional infrastructure for environmental health sciences research. Core use is routinely measured, but the data suggest that most research projects were found to use only one core. Broad use of cores by investigative teams is encouraged. It wasn't clear that the current system captures all that we need to see about core use, given their critical role in the Center infrastructure. Methods are needed to measure the extent to which the Center cores are derived from infrastructure already present in the university, and what is the specific additive value that the Center funding brings. It is important to track the outcomes of core usage and the extent to which trainees are able to use core facilities and how

these costs are recovered. In general, the committee found that the formal metrics did not capture much of the exciting work of the Centers. Rather, narrative accounts of Center activities provided a more thorough and in-depth database that the committee drew upon.

A translational framework in EHS research is needed

In the October 2005, the Core Centers FOA was modified to stipulate that Centers were required to include an Integrated Health Sciences Facility Core (IHSFC) to facilitate translational and clinical investigations, either patient-oriented or population-based research, that enhance translation of basic research findings into practical applications for patients and communities. This addition was in direct alignment with the NIEHS strategic plan that aims to understand individual susceptibility across the life span to chronic, complex diseases resulting from environmental factors, in basic and population-based studies, to facilitate prevention and decrease public health burden.

All 20 Centers indicated in their applications that they use the IHSFC to help promote translational research; however, the way in which this is accomplished varied. Examples include support for global population research studies; assistance with studies involving human participants; and encouraging investigators to include environmental measures in their funded cohort studies. There was much flexibility in the design of the IHSFCs with some cores providing opportunities for center members to obtain clinical samples and patient data needed for their research and/or other cores supporting studies of the etiology, pathogenesis, and course of disease in patient populations. NIH supports bench-to-bedside translational research within the Clinical and Translational Science Award (CTSA) program or other translational programs from various Institutes and Centers. NIEHS Centers provided examples of partnerships with CTSA programs that take advantage of the resources offered by the CTSAs such as pilot program funding, training for students and junior investigators, access to biorepositories and other data, access to clinical and community populations, and biostatistics training and services.

The wide array of examples of translational research was so great that the evaluation committee spent considerable time exploring models that capture the translational process within the EHS domain. Historically EHS has focused on the health of broad populations and not necessarily the health of groups of patients. While the committee believes that the link between environmental exposures and diseases seen in clinical practice is critically important, requiring Centers to conduct studies of clinical populations may not be desirable.

The major components that appear to be offered by the IHSFCs include:

1) Helping educate investigators on the meaning of translational research and ways to increase its presence in the research portfolio,
2) Service provision including assistance in recruitment, IRB assistance, transport of biological samples, translation of discovery into innovation and/or practice as a few examples, and
3) Collaboration with existing CTSAs to broaden and expand research beyond the patient population and the traditional clinical trial model.

The committee concluded that generating a common definition of translational research is also something NIEHS should consider and communicate. It may be difficult for some Centers to self-categorize or present their own research as translational if a shared understanding is not developed on what this term means. The committee discussed translational science as a research process, product, data set, or technology that contributes to the health of the

American people. Information dissemination is communication or science translation, but not translational research. The importance of educating environmental health researchers on translational research compelled the committee to propose a model that could encompass the science within the Centers and educate others for how environmental health science community can contribute to the body of knowledge on translational research. The importance of describing translational research in environmental health led the committee to draft a separate document that is being submitted to NIEHS as a starting point for this important discussion that needs to be held in the EHS community.

The body of the following report is organized by the summative evaluation questions that were posed to the evaluation committee and provides more detailed examples of the main issues and highlights in this summary. In summary, the key recommendations described in the report are:

1. NIEHS should develop additional ways to capture the important work emerging out of Centers particularly in regard to emerging and translational research, and to determine the most useful reporting method. Metrics are needed to capture collaborations within an institution and across the other Core Centers.
2. Templates and standard reporting tools need to be developed to capture and quantify Center activities that align with the NIEHS Strategic Plan. Also mechanisms are recommended to increase the engagement of the Directors in evaluating progress on goals of the Strategic Plan and future strategic planning activities.
3. The role of the Center Director is critically important to the outcomes of a Center. Strategies are needed to assure sustainability of strong Center leadership. Development of impactful EHS leaders of the future should be a goal of the program.
4. The COECs are critical to the Center structure and function, but their scope and function vary across Centers. Opportunities exist to optimize the role of the COEC particularly in increasing the capacity of all environmental health scientists to understand and engage in translational work.
5. A common definition of translational research in environmental health science is needed. The Committee is developing a separate document, proposing a first step in beginning the dialogue on a common framework that could be used across all Centers, and which would improve our ability to measure engagement in translational research.

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List of Appendices

Appendix A.
NIEHS Environmental Health Sciences Core Centers Program Overview

Program Description

The EHS Core Centers Program provides funding for institutional infrastructure to support scientific equipment, facilities, and other resources shared among researchers tackling related environmental health questions. The centers foster interactions among researchers to allow them to take advantage of innovations and approaches beyond what individual scientists would be likely to attain by working independently.

The EHS Core Centers Program is intended to provide the intellectual leadership and foster innovation to accelerate and deepen the insights gained from environmental health research conducted along the spectrum from basic science to population and public health and dissemination. The NIEHS approach is for this mechanism to 1) foster integration, coordination, and **translational** cooperation among investigators conducting high-quality research clearly related to the effects of environmental factors on human health; 2) integrate and build upon existing programs in order to answer **complex questions** leading to improved strategies towards preventing environmentally-induced disorders; and 3) interact bi-directionally with affected communities. While the Program clearly sets the expectation that Centers will address issues of complex, translational and emerging research, it leaves the interpretation of these concepts open and offers some flexibility for the Centers to identify their specific research areas.

For FY 2014, we have 21 active EHS Core Center grants. Many of these grants have a long history of support through the EHS Core Centers Program. Nine programs have been existence for more than 35 years and five programs have been in existence for more than 10 years.
In order to provide increased flexibility in organization and structure, the Centers can create dynamic features which meet the on-going intellectual needs of their members. These features can change as the intellectual needs change in order to accommodate new opportunities for research and collaboration, but the Centers are required to have six specific components as part their programs.

Required Components of the Core Centers include:

- Administrative Core
- Integrated Health Sciences Facility Core
- Facility Cores
- Community Outreach and Engagement Cores
- Pilot Projects
- Career Development

Administrative Core

This component oversees organizational, budgeting and reporting aspects and provides the leadership for scientific and programmatic activities of the EHS CC. The administrative core is intended to:

- Coordinate and integrate EHS CC components and activities.
- Assess productivity, effectiveness, and appropriateness of EHS CC activities and identify scientific opportunities and areas for collaboration among EHS CC members.
- Organize EHS CC activities, such as retreats, invitation of consultants, meetings, and focus groups.
- Organize the Internal and External Advisory Groups.
- Keep track of meeting minutes and measures of success including: use of EHS CC facilities, publications, pilot project awards, and new grant applications resulting from preliminary data enabled by the EHS CC.
- Interact with other EHS CCs, the NIEHS, and other appropriate individuals, groups, or organizations.

Integrated Health Sciences Facility Core (IHSFC)

The IHSFC supports collaborative efforts among basic scientists, clinical researchers, community engagement experts, and/or public health practitioners by:

- Providing services and access to instrumentation and technologies that foster integration of basic science, public health research including epidemiology and intervention studies, and patient-oriented clinical research.
- Supporting research to improve early detection, prevention, and/or therapeutic strategies for environmentally–related disorders.
- Enhancing partnerships between researchers and community-based organizations that impact on conduct of clinical and public health research.

Among its functions, the IHSFC provides services that capitalize on access to well-characterized patient groups and control subjects for research projects, including study subject recruitment and retention activities, and follow-up by mail, phone or in-person to gather needed data for research projects. Clinical services include clinical laboratory or other assessments, pathology services, collection, processing and long-term storage of human tissue samples, blood, urine or other biospecimens, and preparation of questionnaires or other assessment tools. The IHSFC also facilitates and supports partnerships between study investigators and human populations, communities, or health care providers.

Facility Cores

Facility cores draw on EHS CC research needs, including, but not limited to: animal use and transgenic, imaging, tissue culture, pathology support, biostatistics and statistical support, oligonucleotide synthesis, analytical chemistry, proteomics, bioinformatics, exposure assessment, and handling of human tissue specimens. Although Facility Cores provide services for Center members, they also play an

important role in developing new methodologies, adapting instrumentation for Center needs, and educating Center members of the value and utility of services and methods.

Community Outreach and Engagement Core (COEC)

COECs are responsible for translating and disseminating EHS CC research results into environmental public health knowledge for identified audience(s). COECs develop and implement appropriate outreach and engagement programs to increase awareness and understanding of environmental health research being conducted at the EHS CC. COECs also serve to advance the field of community engagement by evaluating outreach models, disseminating results at local and national levels, and promoting models for national implementation. COECs are also encouraged to collaborate with each other.

COECs are not expected to conduct community-based participatory research (CBPR), as it is not their intended goal. In addition, COECs are not allowed to develop K-12 curricula.

Pilot Projects

A Pilot Project Program is an integral part of the EHS CCs and should be designed to support pilot studies for basic or clinical biomedical, epidemiological, educational, or behavioral research. The Pilot Project Program should support short-term projects to explore the feasibility of new areas of study which leads to collection of sufficient data to pursue support through other funding mechanisms. Pilot Projects are intended to:

- Provide initial support for new investigators to establish new lines of research;
- Allow exploration of possible innovative new directions representing a significant departure from ongoing funded research for established investigators in environmental health sciences;
- Stimulate investigators from other areas of endeavor to apply their expertise to environmental health research and environmental medicine; and
- Foster opportunities that meet goals set out in the EHS CC Plan. Pilot projects should strive to fill in gaps in research areas relevant to the scientific focus of the EHS CC.

Career Development

The EHS CC Program encourages clinical and basic scientists with a broad range of skills to work together on a unified theme presenting a rich environment for young investigators to be exposed to and develop skills. By creating mentor/mentee teams that pair center investigators having strong mentorship credentials with junior investigators, this component of the EHS Core Centers Program is intended to:

- Support new investigators in progressing to more senior status and eventual NIEHS funding by enhancing their research skills and knowledge in translational and clinical research, and

- Assist new investigators in attaining independent status or established investigators in developing new promising areas of expertise should be an objective of the Core activities.

The component requires a career development plan that outlines the investigators who will participate, a description of cross-training, mentoring or other opportunities and activities, approaches to measure progress and attention to underrepresented minorities. Centers typically provide salary support for junior investigators or new center members.

Appendix B.
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Appendix C.
Summary of Previous Core Center Evaluations

	2004	2010
Timeframe	1993-2003	2007-2010
Focus	Outcomes	Process
Data	Key highlights Pilot projects Supplements	Programmatic and structural changes that were made in the 2005 FOA
Methods	Substantial data collection, site visits, publication analysis, "snapshots" of successful activities	Surveys from several cohorts (PI and COECs), publications; translational analysis of facility cores
Duration	>18 months	<8 months
Outcome	Major changes to FOA	No structural changes to FOA
Advisory Panel	Yes	No

2004 Evaluation

26 Center Directors were asked to provide NIEHS with up to 5 key highlights, information on supplement outcomes, and data on pilot programs. The evaluation also included analyses of data from IMPAC II. The data focused from 1993-2003.

Key Evaluation Questions and Findings:

1. **How does the NIEHS P30 program compare to P30 programs at other ICs?**

   NIEHS, like other ICs, uses a variety of mechanisms to support center research, although from 1993-2003, NIEHS used the P30 mechanisms exclusively. Because scoring across ICs is so varied, it was not feasible to compare scores among P30 grantees.

2. **How has the scientific content of the NIEHS P30 program shifted from 1993-2003?**

   Centers demonstrated a trend toward less use of analytical and exposure assessment cores and increase in the use of toxicogenomic and proteomic cores. Also less molecular biology and more microarray and novel-omics tehcnologies. Still large numbers of animal model cores and biostatistical and bioinformatics cores. Increased use of imaging. Gaps in research include risk and/or economic analysis of environmental questions.

3. **How has the NIEHS P30 program helped to build research capacity in environmental sciences?**

   Core Center investigators tend to have slightly higher success rates (36.7% vs. 31.5%) from 1999 to 2004. Available data do not indicate that the Core Centers program has helped build institutional research capacity. Core Centers tend to have an increase in the number of applications and awards submitted in the 3 years after a center is established but success rates do not change. Many pilot projects were able to secure mainstream sources of funding. The supplements were used effectively, but evaluations focused on process and outputs, rather than impacts (number of school systems

adopting a curriculum, number of residents whose behavior regarding drinking water changed, number of teachers who applied their new skill in the classroom, community actions that occurred as a results of the project.)

4. **How has the P30 program contributed significantly to the achievements of the field of environmental health sciences? And given the level of funding for this program, are the products commensurate with NIEHS' investment?**

   Research is generally exposure specific or discipline specific. The quality of the research as judged by the "snapshots" was variable. Publications were not in high profile or general interest journals, but rather in toxicological or cancer focused journals. Collaboration among COEPs was widely varied. Some COEPs took on meaningful interaction with their partners/communities. Others did presentations, lectures, consulting, etc. that seemed to be unlikely to result in either capacity building or positive environmental impacts.

2010 ASSESSMENT

Focus on assessment of programmatic and structural changes that were made in the 2007 FOA.
Data collection included questionnaires completed by 7 PIs and 5 COEC leaders; analysis of publications and applications. Only able to look at the first 2-3 cohorts (depending on the question) because not enough time had gone by to fully assess. Key program elements assessed: Integrated Health Sciences Facility Core (IHSFC), pilot projects, director's fund, Community Outreach and Education Cores (COEC), scientific review criteria and career development.

Key Evaluation Questions and Findings:

- What changes resulted from the new IHSFC?
  - The IHSFCs funded new grants, facilitated new faculty and collaborations and developed clinical expertise among researchers
- Are the centers more translational?
  - The facility cores expanded their clinical and epidemiological studies, provided IRB expertise to researchers, provided access to biospecimen storage and processing, biomarker development and data management and analysis services
- What is the benefit of the pilot projects?
  - Pilot projects address a wide range of topics and approaches and contribute strongly to the translation and career development aims of the program. Pilot projects also result in subsequent funding from multiple sources.
- What is the benefit of the COECs?
  - COECs are generating meaningful community partnerships and no centers had any objections to the community advisory board requirements.
- What career development activities are supported/what results?
  - Career development activities include salary/grant support, workshops, mentoring and training. These activities lead to new grants, collaborations, promotions and new positions.

Appendix D.
NIEHS Environmental Health Sciences Core Centers Evaluation Evaluation Overview

Evaluation PURPOSE

To assess the ability of the Core Centers Program to produce complex, emerging and translational environmental health research.

Intended Evaluation USE

1. Characterize what the Environmental Health Sciences Core Centers (Centers) do, how they do it, and to what effect. (The evaluation is not intended to be an inventory of all Center activities and accomplishments.)
2. Identify opportunities for program improvement
3. Identify and promote best practices that we can leverage among the Centers and EHS researchers
4. Understand how Centers can be used to implement the NIEHS Strategic plan
5. Inform understanding of the state of the program and communicate the successes of the program

Evaluation GOALS

1. Assess what kind complex and emerging translational problems the centers are addressing (Q 1)
2. Assess how the structural changes made in 2006 to the FOA contribute to the evolution of the Centers and their ability to do translational research (Q 2)
3. Assess how scientific collaborations, community partnerships, pilot projects, and facility cores contribute to the success of Centers (Q 3)
4. Assess career development outcomes within the Centers (Q 4)
5. Assess how the Centers can help implement the NIEHS strategic plan (Q 5)

Evaluation QUESTIONS

We translated the goals above into the following specific evaluation questions, organized into three broad areas: Supporting Complex, Emerging & Translational Research; Providing Opportunities for Career Development, and Supporting the NIEHS Strategic Plan.

1. What complex, emerging and translational research are the Centers doing?
2. How do the Centers conduct complex, emerging, and translational research?
3. What are the complex, emerging, and translational achievements, successes and impacts of the Centers?
4. What are the career development achievements of these Centers? *(Not limited to complex, emerging and translational research)*

5. How can Centers help implement the NIEHS strategic plan? *(Not limited to complex, emerging and translational research)*

Data Sources

We will develop a plan to compile and analyze data to answer the evaluation questions (above) and present it to the evaluation advisory subcommittee. The evaluation will include both primary and secondary (documents/data that have previously been submitted by grantees) data sources. Prior to asking grantees for any information directly we will review secondary data sources to ensure that we have obtained as much information as possible from these sources in an effort to minimize the response burden on the grantees. Data we plan to review or collect include:

- Progress reports, including appendix tables
- QVR/IMPACII
- Data submitted/discussed during previous grantee meetings (COEC history wall/2013; CTE discussion/2014)
- Publication list
- Data submitted to program staff (biographical information on newly recruited investigators)
- NIEHS/DERT Portfolio Coding Database
- Interviews with principal investigators (PIs) and other Center staff
- Group interviews with center staff

Summative Questions for the Evaluation Advisory Subcommittee

Taking the findings into consideration, the Evaluation Advisory Subcommittee will be asked to answer the following summative evaluation questions:

1. How does the EHSCC Program bring value, (i.e., lead the EHS field) in relation to complex, emerging and translational research?
2. What can the Centers do that can't be done with other research mechanisms?
3. What best practices emerge from the Centers as critical for the program and the EHS field (defined broadly and including public health)?
4. How can the Centers help inform NIEHS about emerging fields and scientific opportunities?
5. How should the Centers be involved with identifying and implementing the next set of strategic plan goals?

Appendix E.
EHS Core Centers Evaluation Timeline

2014	
September 15	Provide EAS with materials for Kick-Off Meeting
September 30	EAS Web Kick-Off Meeting
October - December	Data collection and analysis (progress reports, appendix tables, interviews)
December 15	Provide EAS with data for Questions 1, 4 & 5
2015	
January 7	EAS Web Meeting – Questions 1, 4, 5
January – February	Coding and Data Analysis of Interview Data; Incorporation of all Data Analysis
February - March	Internal NIEHS discussions of findings Additional data collection if needed
February 20	Provide EAS with data for Questions 2 & 3
March 19	EAS Web Meeting – Questions 2,3
April	Grantee meeting – final data collection opportunity
April	Planning meeting for in-person meeting
May 15	Provide EAS with data for June in-person meeting
June	EAS Meeting in conjunction with Council
June – August	Prep for Council presentation
September	Council Presentation