NIEHS P30 Core Centers Assessment – 2010

September 1, 2010

Program Analysis Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences

NIEHS
National Institute of Environmental Health Sciences

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Contents

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Executive Summary

DERT conducted an assessment of the P30 Core Centers from March – September 2010. The purpose of the assessment was to:

- Assess the NIEHS P30 Core Centers in keeping with the five-year Funding Opportunity Announcement (FOA) cycle.
- Focus the assessment on programmatic and structural changes made for the Centers funded FY2007-FY2011.
- Recommend changes (as needed) to the next FOA (to be released in Fall 2010 for funding Centers in Spring FY2012).
- Identify questions/data that could be included in a broader assessment of the P30 program after more time elapses.

The primary intent for this assessment was to improve the Core Centers program and develop a sense of the collective experiences of grantees working under the new guidelines. We administered questionnaires to seven Principal Investigators (PIs) and five Community Outreach and Education Core (COEC) leaders funded under the new guidelines in 2007-2008. We also analyzed secondary data sources (i.e., publications, grant applications).

The key findings from our assessment an analysis are:

- Overall, the assessment leads us to believe that the guideline changes made in 2007 were positive, and that very few changes to the current set of guidelines are needed at this time.
- The facility cores within Centers seem to be more "translational" in their work, which was a key aim for the revised guidelines. Centers are providing a range of translational services, including expertise needed for clinical and epidemiological studies, biospecimen storage and processing, biomarkers and data management and analysis. PI's favored the expansion of flexibility within the facility core structure. The one recommended change to the guidelines is to further clarify the NIEHS definition of translation: specifically, the NIEHS translational research paradigm needs to explicitly include public health prevention and intervention activities.
- The Director's Fund was seen by PI's as very positive in that it gives the Directors considerable discretion to respond quickly to emerging situations, and to fund activities (often at a fairly small scale) that could result in important research advances at critical moments. A key highlight of the program was the ability to respond to the Gulf Oil Spill during the Spring and Summer of 2010.
- Pilot projects remain a core component of the program.
    - The assessment data are good validation that pilot projects support the mission of NIEHS.
    - PI responses indicate that pilot projects contribute strongly to translation and career development.
    - A return on investment (ROI) analysis of the pilot projects was not possible with the time and data available for the study. A full ROI study would likely be a useful component to future P30 Core Center evaluations. Tables collecting pilot project data could be improved to support ROI calculations.

- Career development is a key focus of the program, and it appears that the Centers are taking the opportunity to provide meaningful training experiences for junior faculty and students. Career development opportunities generally include salary/grant support, workshops, mentoring and training. These activities result in grant applications and awards, new collaborations, promotions and new positions. Efforts to recruit new investigators to the Center have been reasonably successful.
- Scoring – The assessment did not provide compelling evidence for changes to the scoring system. However, a broad assessment of the scoring/review process was outside the scope of this assessment because it would require input from funded and unfunded applicants, as well as reviewers.
- Community Outreach and Education Cores (COECs) indicate a continuing focus on meaningful dialogue and genuine partnerships with the community. It is important that this work continues. There were no major objections to the formal Community Advisory Board (CAB) requirement. In fact, a range of creative strategies have been employed to establish the CABs.
- The assessment has been a helpful sign post to indicate the program is basically on track, but the Core Centers program should continue to be evaluated periodically. Several recommendations for questions and analyses that could be useful in the future are noted in the main body of the report.

Introduction

In October 2005, for grantees funded in 2007, the guidelines for the P30 Core Centers program changed significantly. Major structural changes were made to facility core requirements, the director's fund, career development opportunities and the Community Outreach and Education Cores. A full list of changes is provided in Appendix 1.

An assessment of the program was undertaken between March – August 2010 to:

- Assess the NIEHS P30 Core Centers in keeping with the five-year Funding Opportunity Announcement (FOA) cycle.
- Focus the assessment on programmatic and structural changes made for the Centers funded FY2007-FY2011.
- Recommend changes (as needed) to the next FOA (to be released in Fall 2010 for funding Centers in Spring FY2012).
- Identify questions/data that could be included in a broader assessment of the P30 program after more time elapses.

Our primary intent for this assessment is to improve the Core Centers program and develop a sense of the collective experiences of grantees working under the new guidelines. We sought feedback from Principal Investigators (PIs) about ways to improve the structural elements of the program. We assured PIs that information collected would be aggregated for presentation.

Data Sources:

We made every attempt to minimize the data collection burden for this effort by selecting only the most important questions to address at this time. We asked that responses be brief. Surveys were distributed to seven PIs that have been operating under the revised guidelines for more than 2 years (Cohorts 1-2, Table 1). All but one replied. The five Community Outreach and Education Core leaders in Cohorts 1-2 (noted by an * in Table 1) were surveyed with a separate instrument.

Table 1: NIEHS P30 Core Center Grants Awarded in "Cohorts 1-3"

Cohort	PI Name	Institution	Grant #	Review Year	Funding Year
1	Beckman	Oregon State University*	P30ES000210-39A1	2006	2007
1	MacLeod	UT - MD Anderson*	P30ES007784-11A1	2006	2007
1	Ramos	University of Louisville*	P30ES014443-01A1	2006	2007
1	Thorne	University of Iowa	P30ES005605-17	2006	2007
2	Groopman	Johns Hopkins University*	P30ES003819-21	2007	2008
2	Ho	University of Cincinnati	P30ES006096-16A1	2007	2008
2	Santella	Columbia Univ Health Sciences*	P30ES009089-10	2007	2008
3	Dockery	Harvard University (Pub Hlth)	P30ES000002-46	2008	2009
3	Petering	Univ of Wisconsin Milwaukee	P30ES004184-22A1	2008	2009
3	Zarbl	UMDNJ-R W J Med School	P30ES005022-21	2008	2009

**Indicates that a Community Outreach and Education Core at this Center and that they participated in the COEC Director Survey*

In addition to the surveys, we gathered information from grant applications, progress reports, and publication data (as identified in the e-SPA tool). Some of the analyses below (mainly those using existing data sources such as the applications or publication data) include Cohort 3 as well. An outline of the assessment task schedule is provided in Appendix 2.

The subsequent sections focus on the major changes that were made to the Centers funded in 2007 and after, which included: Facility Cores, Pilot Projects, the Director's Fund, Personnel, Scoring/Review and Community Outreach and Education Cores. PIs and COEC directors were surveyed using separate instruments.

Facility Cores

Facility Cores are shared facilities that serve to enhance or make more cost effective the services, techniques, or instrumentation used by investigators within the EHS Core Center. Cores extend, support, and contribute to the work of the Center members. Centers have a minimum of two facility cores including an Integrative Health Sciences Facility Core. Providing facility Cores are a major function of the EHS Core Center. Facility Cores are designed to furnish groups of Center investigators with techniques, services, or instrumentation that will enhance the research in progress, consolidate manpower effort, and contribute to cost effectiveness. (Excerpted from the RFA: http://grants.nih.gov/grants/guide/rfa-files/RFA-ES-05-008.html)

A major change to facility cores in the new guidelines was the new requirement for an Integrated Health Sciences Facility Core (IHSFC). The IHSFC was a critical piece of the strategy used to increase the translational research focus of the program. We are interested in understanding the effects these new structural requirements are having on the Centers. The main assessment questions for this section were:

- What changes have there been to the facility cores with the introduction of the IHSFC?
- Are the science areas more translational than they were previously?
- Are the Centers more translational?
- How do the facility cores leverage funds, and how do other groups leverage the resources of facility cores?
- What are the overall benefits and challenges of the new structure?

Scientific Focus of the Facility Cores

We reviewed applications across the three cohorts to assess the current make up of facility cores (Table 2). Definitions for the facility core areas are provided in Appendix 3.

Table 2: Facility Core Areas in Cohorts 1-3

Facility Core Areas	2007	2008	2009	Total
Biostatistics/Bioinformatics	1	2	2	5
Analytical	1	1	1	3
Animal Models	2		1	3
Exposure Assessment	1	1	1	3
Imaging	2			2
Molecular Biology	1		1	2
Cell Biology	1			1
MISC.		1		1
Proteomics	1			1
Shared Instrumentation		1		1
Microarray				0
Molecular Structures				0
Toxicogenomics				0

Translational nature of Facility Cores

We used the NIEHS Division of Extramural Research and Training (DERT) draft Translational Research Paradigm (Fig 1) as one way to help us think about the translational nature of the facility core components for the Centers. The paradigm (unpublished) is comprised of five different major areas of research: emerging technology (ET), mechanistic understanding (MU), phenotypic validation (PV), clinical assessment (CA), and application and intervention (AI). A project or facility core is considered translational if it bridges more than one major area of the paradigm.

Due to time limitations, we analyzed the facility cores of Cohort 1 only. We examined the facility core descriptions from the three Center applications, recording the names of each facility core from both before and after the new guidelines came into effect. Then each core listed was analyzed for the its major research type (Fig 2).

Overall, the Facility Core makeup appears to be more translational. Fewer cores are focusing on enabling technology, perhaps suggesting that these technologies are now core elements of scientific research. Additionally, it appears that more work is being done in the more clinical/human population categories of the framework (CA, AI), and that the cores are more likely to include more areas of research and are thus more translational. One of the goals in 2007 was to expand the clinical focus of the Centers. These three Centers appear more oriented to clinical applications than in their previous formations.

Alignment of Center translational research with the NIEHS definition

In the Core Centers RFA, NIEHS defines translational research as: "*efforts along the spectrum of steps that transform scientific discoveries arising from laboratory, clinical, or population studies into clinical or population-based applications to reduce disease incidence, morbidity, and mortality.*" There appears to be fairly strong correlation between the Centers' definition of translational and the NIEHS definition.

All survey respondents reported that their Centers were fully engaged in multiple activities across the translational research paradigm. The Centers in the survey direct their focus to various environmental health topic areas (epigenetics, biomarkers, aging, etc), but are all combining a broad spectrum of scientific approaches and disciplines, including mechanistic work, animal models, novel methodologies, clinical studies and interventions, population studies and outreach. Interactions occur at multiple events, such as retreats, meetings, seminars, etc. In the words of one investigator, "Our ideal is a circular, positive-feedback loop between the bench- based and community-based scientists." Several also mentioned, however, the lack of prevention and public health in the NIEHS definition of translational work, noting that their focus was on bridging basic research to communities and public health, in addition to clinical applications.

Figure 1: Draft DERT Translational Research Paradigm

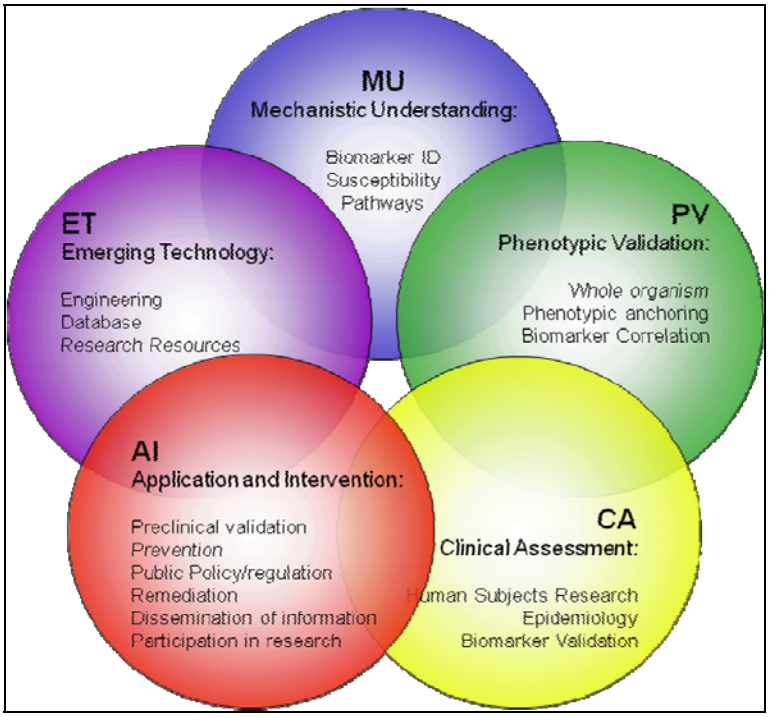


Figure 2: Translational Codes for Cohort 1 Facility Cores Before and After Changes to the FOA

Before Changes to FOA						After Changes to FOA					
	ET	MU	PV	CA	AI		ET	MU	PV	CA	AI
Aquatic Tox Facility and Service Core	x		x			IHSFC				x	x
Cell Culture	x	x				Aquatics Models Facility Core	x	x	x		
Cell Tissue Analysis		x	x			Cell Imaging and Analysis		x	x		
Mass Spectrometry		x				Mass Spectrometry		x	x		
Nucleic Acids and Proteins	x	x				COEC				x	x
COEP					x						
Statistics											
Molecular Biology		x	x			Molecular Biology		x	x		
Transgenic Animals	x	x	x			Analytical Instrumentation		x	x		
Histology & Tissue Processing		x	x			Cell & Tissue Analysis		x	x		
Cell and Tissue Analysis		x	x			Histology and Tissue Processing		x	x		
Analytical Instrumentation		x	x			IHSFC			x	x	
Biostatistics and informatics		x	x								
Pulmonary Health Outcomes			x	x		IHSFC			x	x	x
Oxidative Stress and Metabolism		x	x			Pulmonary toxicology		x	x		
Inflammation and innate immunity		x	x			Env modeling and expos asmnt				x	x
Inhalation toxicology		x	x			COEC				x	x
Clinical exposure facility			x	x							
Exposure modeling and assessment facility				x							
COEP				x	x						
Facility Core Count	4	13	13	4	2	Facility Core Count	1	8	10	6	5
% of all Facility Cores (n=19)	21%	68%	68%	21%	11%	% of all Facility Cores (n=14)	7%	57%	71%	43%	36%

Translational Role of the IHSFC

On the survey, PI's discussed a wide range of activities the IHSFC engages in to increase the translational role of the Center. These activities fall roughly into seven areas: epidemiology/clinical/IRB/ethics; biospecimens, biomarkers, analysis, data management and other services.

Epidemiology/Clinical/IRB/Ethics

- Provided Epidemiology research design
- Providing advice and assistance in designing and conducting human clinical studies
- Providing clinical services
- Created a clinical research infrastructure that has transformed the ability to conduct translational research
- Helped faculty to understand potential clinical applications of their work and to overcome the barriers to entering the translational research arena
- Found clinical partners (e.g., CTSA)
- Established clinical research center
- Assisted with IRB issues; Streamlined IRB submissions
- Held "Forth and Back" seminars, with a focus translating the findings of both laboratory, clinical and population studies into clinical practice (e.g. one Forth and Back conference focused on lead exposure in children)
- Conducted workshops on ethics and translational research
- Initiated broad range of integrative and translational studies (9 examples provided)

Biospecimens

- Provided information about and access to biorepositories and biomedical data
- Acquisition of clinical biospecimens
- Centralized biological specimen storage
- Provided centralized biospecimen processing facility that has greatly enhanced human studies
- Offered pre-submission consultations with applicants to the Pilot Project Program, during which applicants are made aware of additional measures of exposure and populations available to use for their study

Biomarkers

- Provided expertise about identifying and measuring biomarkers
- Facilitated early discovery processes geared toward development of biomarkers of environmental disease
- Identified key milestones for biomarker development and application that could be targeted for Center support
- Provided methodological approaches for biomarker development

Analysis

- Providing statistical support
- Made certain laboratory assays available within the IHSFC (oxidative stress and methylation)

Data management

- Developed resources such as electronic medical records to assure that these new resources can be used for research as well as patient care
- Data manager has dramatically increased the awareness of investigators of the importance of early discussions on questionnaire design and database development to the success of an epidemiologic study.

Other Scientific Expertise and Services

- Epigenetic research expertise
- Technology transfer information and advice
- Provided Leadership for implementation of the Director's Initiatives

Translational Outputs of the Centers

In addition to the survey results, we reviewed Center publications as a way to further explore the nature of the translational changes in the Centers. We analyzed publications from the first few years of all three cohorts and compared them to a similar period five years before. Publication data were identified using the NIH's e-SPA (electronic scientific portfolio assistant) tool. All publications citing the center grant as identified by the eSPA program were included in the analysis. We selected different analysis years for each grant based on its cohort start date (Table 3).

Table 3: Publication years selected for analysis by cohort

Cohort	Center Institution	Before Range (inclusive)	After Range (inclusive)
Cohort 1*	Oregon State University MD Anderson Canc Ctr University of Iowa	4/1/2002 – 4/1/2005	4/1/2007 – 4/1/2010
Cohort 2	Johns Hopkins Univ University of Cincinnati Columbia Univ Health Sci	4/1/2003 – 4/1/2005	4/1/2008-4/1/2010
Cohort 3	Harvard University (Pub Hlth) Univ Wisconsin Milwaukee UMDNJ-R.W.J. Med School	4/1/2004 – 4/1/2005	4/1/2009-4/1/2010

**Publications from the University of Louisville were not included in Cohort 1 as it was a new Center in 2007.*

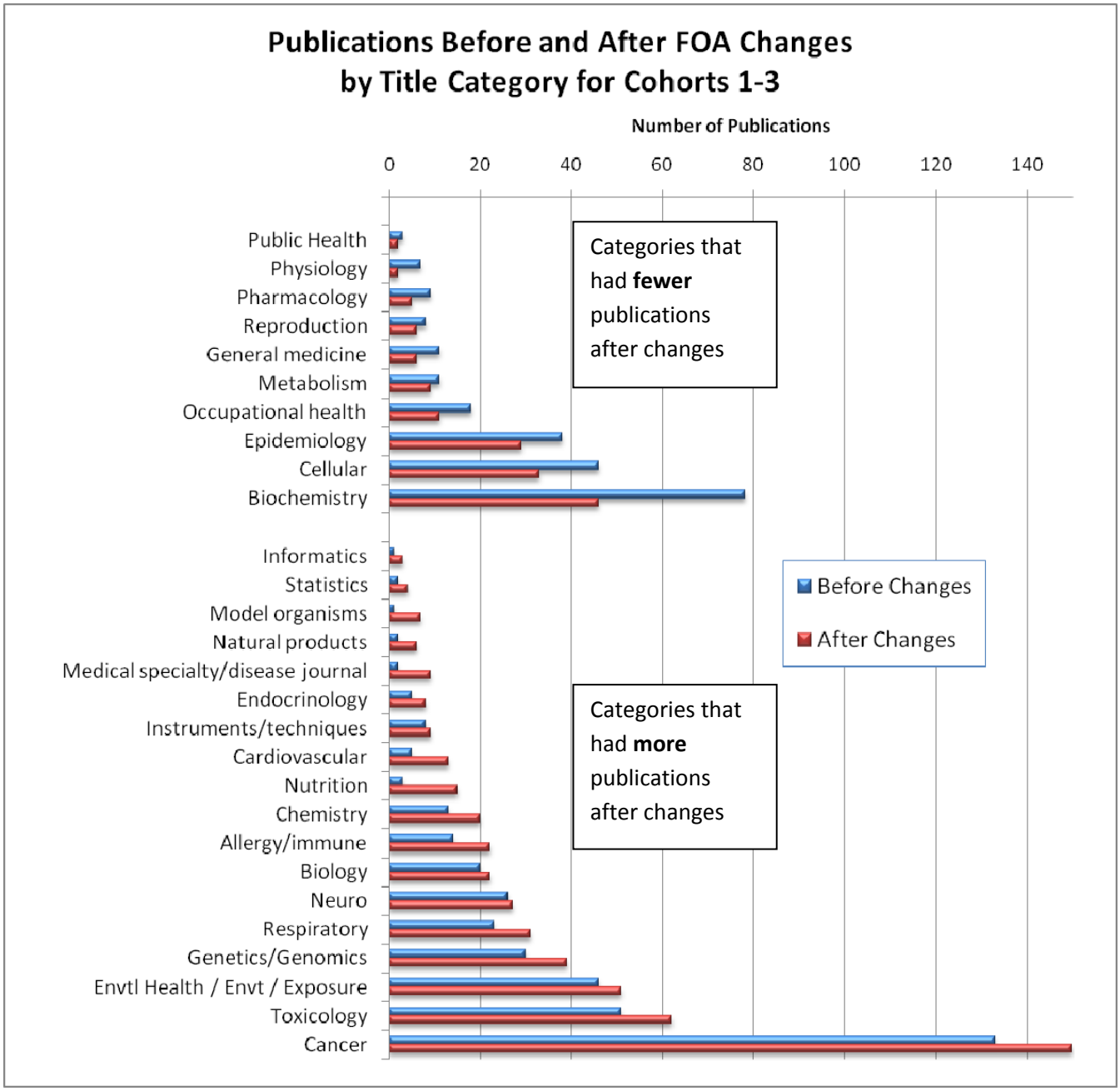
A total of 1,269 publications were identified from these nine grants, with 618 being published in the "before" range and 651 in the "after" range (Table 4). The impact factors of the publications did not change significantly from the "before" to the "after" period.

Table 4: Publication Count and Average Impact Factor Before and After Changes

	Publication Count			Average Impact Factor		
Cohort	Before Range	After Range	Grand Total	Before Range	After Range	Grand Total
1	285	345	630	4.7	4.4	4.5
2	202	215	417	5.0	4.7	4.9
3	131	91	222	3.7	3.8	3.8
Total	618	651	1269	4.6	4.4	4.5

Finally, using an inductive approach, i.e. applying codes that reflect the data, each journal title was given a broad category description. Results were compared before and after the FOA changes (Fig 3). Categories that had fewer publications in the "after" range are shown in the top portion of the graph, and categories that had more publications in the "after" range are shown in the bottom portion of the graph.

Figure 3: Publication Categories Before and after FOA Changes were Implemented in 2007



These data suggest that the nature of technologies in facility cores has evolved under the new guidelines. After the changes in the RFA, topics with greater numbers of publications appear to be more clinical in nature. Although the category "epidemiology" went down after the changes, many new medical specialty/disease journals were identified in the "after" set of publications and other disease based categories expanded (CVD, Respiratory, Neuro). Also, we find it significant that more categories increased than decreased, suggesting a more diverse and translational suite of research papers. Finally it should be noted that Cancer related publications have been a significant component of the program and remain so after the guidelines.

This preliminary analysis does have several limitations. First, the evolving nature of the codes (resulting from the inductive approach) and their application likely resulted in some inconsistencies. Moreover, each publication may have a mix of the different categories, so using the journal as a surrogate topic area could also introduce some error.

The length of each cohort was also different and the time to publication for Cohort 3 was small. Finally, not all Core Center publications may be accessed via e-SPA – if the grant number is not cited in the paper, it was not included. Time did not permit an in depth assessment of the gaps between publications presented in progress reports compared to those found in eSPA. However, despite these limitations, given the number of publications and the breadth of the portfolio, we believe it is reasonably representative of the program's output. Future assessment or evaluation efforts could likely include a more robust bibliometric analysis.

Leveraging

A key goal for the Core Centers is to provide infrastructure and expertise in environmental health sciences that can be leveraged by center members. We asked PI's about leveraging on the survey. All respondents (6) reported several specific examples of how facility cores allow Centers to leverage resources.

Examples of leveraging funds/grants:

- Two specifically mentioned links to CTSAs and other cores within the institution.
- Cores are independently competitive for extramural funding from NIH, from private foundations and for NCRR major equipment grants.
- Millions of dollars of support from the University administration have been used to build the core facilities.
- Pilot Project monies are awarded to provide access to the Core Facilities.
- The "Director's Fund and any fees collected by the facilities are directed towards expanding" the core facilities.
- The core facilities help secure matching funds for pilot project programs.
- Institutional investment in deep sequencing technology for biomarker development is anticipated.
- We continue to urge our higher Administration to find new ways to support these extremely important, laboratory-based Cores.

Examples of leveraging space/equipment:

- Physical space from other population health and travel health clinics
- Laboratory space for processing samples
- Core's work lead to the construction of a 1000 sq ft freezer farm for the Center about 3 years ago
- Cores provide a justification to ask for support that makes major facility upgrades possible
- Have allowed Center to acquire new instrumentation
- Tracking the use of the Core facilities, provides a strong edge in the competition for major equipment grants

Examples of leveraging positions

- The facility cores provide salary support for skilled technical people who make complex technologies accessible and provide maintenance of complex machines
- Staff are shared with clinical partners
- The University's Office of Technology Transfer (OTT) helps facilitate translation efforts in terms of intellectual property (for potentially relevant biomarkers) 2) assist with educational programs for center members to provide information on intellectual property protection, commercialization, and funding opportunities

Examples of leveraging ideas/expertise

- The competitiveness of our faculty has enabled us to leverage other resources
- Partnership with several other centers and institutes
- Outreach Core leverages IHSFC knowledge
- FC's leverage has expanded outreach programs
- Sample collection and storage is centralized making it easier for epidemiologists to propose human biomarker studies
- The IHSFC has simplified the writing of grants doing population studies

Benefits of the IHSFC

Survey respondents reported that the benefits of developing/implementing IHSFC include the following.

Funded Grants

- An NCI PPG award examining the epigenetics of cancer chemoprevention made extensive use of the IHSFC
- Superfund Research Program grant award
- ARRA-funded project on white blood cell methylation
- Funded grant in environmental cardiology based on an environmentally impacted population identified through a screening program
- Instrumental in the development of translational programs as part of a CTSA application to the NIH
- Supported pilot research projects that have led to acquisition of new R01 grants which have significantly expanded the research base and the portfolio of environmental health research programs at the Center
- ARRA grant on epigenetics was successful because of the availability of the new service of determining global methylation levels
- Collaborative NIH-funded project on ALS that also was supported by a pilot project
- 2 R01 grants received
- Several multi-investigator project applications submitted

New faculty and collaborations

- 3 true collaborations between basic and population scientists
- Two new faculty members joined the Center because of the availability of the methylation assays and Epigenetics Working Group

Additional benefits of the new structure

- Permits greater flexibility in responding to investigator needs
- Permits inclusion of new facilities if they are needed by Center members
- If each IHSFC component had been established as a separate facility core it would have been necessary to know in advance what the usage of each core would be, in order to set up budgets
- This new format facilitates the development of educational activities by bringing management of activities under one domain
- IHSFC has become a “one-stop shop” for advice and structure for the translational research in the center
- ISHFC was the best change – it brought new clinical resources and capabilities to a university with no Medical School, and in doing so has facilitated IRB approvals, launched multiple studies, linkages with the CTSA and improved coordination of studies between different institutions
- It is easier to organize human studies.

Additional benefits of Core Centers

- The Center supplies guidance and assistance with procurement and management of biospecimens for researchers. The facility use table (sent separately) illustrates that several research programs have been supported by this effort
- A searchable database that contains information about laboratories capable of measuring exposure biomarkers was developed as a resource to the community of environmental scientists.
- A cohort study was transferred to the center from another organization that lost funding. The Center stepped in to assume stewardship of the program instead of letting it expire, which would have resulted in data loss.
- The Core Centers provide a coordinating force that keeps investigators focused on difficult problems that take longer to solve… these issues would be much more difficult to tackle without Core Center support.
- The Center has influenced the medical school, the School of Public Health, and the community.
- The Center provides formidable technical capabilities aimed at solving long-standing problems in environmental health science.

IHSFC Challenges faced and addressed

In the survey, PIs described several challenges and mitigation strategies that were used to address those challenges (Table 5).

Table 5. Challenges and mitigation strategies.

Challenge	Mitigation Strategy
Investigators do not always understand: • the resources that are available • the role of the IRB • how to connect with communities, discuss needs, or report findings to the community members	Providing opportunities for education as well as resources and expertise. Building on experiences of new projects within the Center (e.g. Fernald Community Cohort) to develop other "connections with communities."
No major challenges	The new structure has helped us to address the issues of underutilized facilities and the phasing out of some areas of support in order to use these resources for other translational initiatives
• Needed to create the core with in a very short time frame (4 months) • Keep Core Operating during "gap" year of funding • Perception that without a medical school the Center could not be translational • Essentially a new enterprise	• Added excellent staff for the IHSFC • Invested State reserve funds during the gap year • Found outside support to build a clinical laboratory • Invested heavily in pilot projects with University provided resources which allow us to move much faster than possible with reviews of pilot projects
Need to implement a culture shift among environmental health science investigators, who are not familiar with: • human translational research efforts and • the mechanisms required to directly interface with the clinical research enterprise of a large medical center	IHSFC addressed the educational needs of investigators and helped reduce the barriers to human investigation associated with the IRB process, the creation of biorepositories, access to existing biological samples and collaborations.
• Data management • Freezer space for human samples – a storage fee system was implemented recently and is resulting in an unanticipated expenses for projects	Considerable funding was allocated to data management but it never seems to be enough. Made targeted strategic investments using pilot projects called "Center Development Projects". These efforts to coordinate faculty expertise with Core advancement are expected pay off in the next five years in some exciting new technologies and other advances for EHS.
In the past, the Center was a "major force in faculty recruitment by providing the infrastructure needed to get assistant professors off the ground." The rising cost of recruitments now far outstrips the resources of the Center.	The Center has used the translational pilot grants and the core facilities to provide the initial data sets that should lead to further funding in the future. I think that we do the best we can with the capped budgets but a smaller and smaller fraction of the portfolio is supported by the Center.
The imposition of the IHSFC structure has a tendency to encourage members to attempt collaborations even when the scientific basis is not as it should be.	Our current plans are to drastically alter the way the IHSFC is structured to allow it to enhance the best science
The major challenge was in understanding what NIEHS wanted from the RFA, and in predicting what would be seen as outstanding by the first set of reviewers to look at the IHSFCs, and who also may not have known exactly what was required.	I think that because of these uncertainties, we over-reacted and dedicated an unrealistically high portion of our budget to the IHSFC. We are currently revamping our approach in order to make this resource more efficient, more productive, and more conducive to truly important translational research

PI recommendations for improving the requirements for Facility Cores

The survey asked PI's for their recommendations to improve the FOA requirements for facility cores. Their responses focused on a few key themes.

First, all six respondents noted that **flexibility** is essential for interactions. They were generally positive about the level of flexibility they currently have within the facility core feature, but also noted they didn't want to lose any of it. This flexibility is essential to ensure that EHS investigators can easily adapt to changing needs and to new opportunities as they become available. Flexibility for the Centers is important so that they can concentrate efforts on their strengths.

Three centers commented on the IHSFC requirement – noting the benefit of basic research and questioning the **need for all Centers to have population based/clinical studies**. One frankly recommended dropping the IHSFC requirement to allow Centers to find their own ways to promote translational collaborations.

One noted that the new structure allowed the Center to phase out facilities no longer being extensively used (such as some of the animal inhalation labs) and **refocus resources** on the mission of the IHSFC, such as epigenetics research cores. On the other hand, another noted that redirection of the budget into pilot projects, career development, director's fund, inflation, partnerships and a capped budget leaves little money to fund Cores, even as the costs have sky-rocketed.

Conclusions and recommendations

The Assessment Team found fairly strong evidence to indicate that the Centers have become more translational since the guidelines were revised. Centers are providing a range of translational services, including expertise needed for clinical and epidemiological studies, biospecimen storage and processing, biomarkers and data management and analysis. PI's favored the expansion of flexibility within the facility core structure. The one recommended change to the guidelines is to further clarify the NIEHS definition of translation: specifically, the NIEHS translational research paradigm needs to explicitly include public health prevention and intervention activities.

Director's Fund

The Director's fund is intended to provide a way for Core Center Directors to respond rapidly to new and emerging opportunities in environmental health sciences.

The Director's fund was expanded under the new guidelines to provide PIs more flexibility and discretion in program funding. The intent was to allow Directors to respond more nimbly to time sensitive issues or to those requiring a rapid response. Up to $100,000 may now be set aside each year, with up to $200,000 carried over to a subsequent year. Since this is a new requirement, we were interested in understanding more about how the funds are used, and how much is carried over. Assessment questions for the director's fund included:

- How much is allocated to the directors fund?
- How much of the directors' fund is used annually or carried over each year?
- To what purposes is the director's fund used?

Summary of Director's Fund Expenditures

Of the six survey respondents, one Center (in Cohort 1) reported no expenditures to date; they are carrying over $200,000. Reports from the other five centers are provided in Table 6.

Table 6. Fiscal year expenditures reported in dollars (n=5)

Fiscal Year	Center 1 Cohort 1	Center 2 Cohort 1	Center 4 Cohort 2	Center 5 Cohort 2	Center 6 Cohort 2	Grand Total
2008	50,000 (1)*		101,000 (5)	64,000 (4)		211,500 (10)
2009	50,000 (1)		111,000 (5)	51,000 (7)		212,000 (13)
2010			33,000 (2)		100,000 (1)	133,000 (3)
Year not reported	200,000 (7)	300,000 (5)				260,000 (12)
Grand Total	**300,000** (9)	**300,000 (5)**	**245,000** (12)	**115,000** (11)	**100,000** (1)	**760,000** (33)

*****Number of projects funded are shown in parentheses.*

Director's fund purposes

Respondents reported several types of expenditures for the director's fund:

Response to time sensitive issues

- Community Outreach and Education
- Summer Undergraduate Research program
- Supported new investigator

Time sensitive plus environmental situation

- Air quality samples were collected in Beijing immediately before and during the Olympics. The opportunity arose with just a few weeks to prepare. Director's funds supported foreign travel. Investigators measured particulate matter pollution in Beijing before, during, and after the 2008 Olympic Games. The Integrative Health Sciences Facility Core provided invaluable assistance in securing IRB approvals in China.
- Currently sending analytical teams to the Gulf of Mexico to collect air and water quality samples before oil from the recent spill started reaching the shores in Louisiana, Mississippi, Alabama and Florida. Funded travel to

sample within 5 days of spill. Analyzed about 800 common persistent environmental agents within two weeks. Data were provided to NIEHS as they held some of their initial meetings to consider how to respond to the Gulf spill. We will be using most of the Director's funds this year to continue this work to continue developing the response.

New Project Areas

- Director's Biomarker Initiative supported 5 large projects in the amount of $60,000 which were further matched with $20,000 by the institution.
- In 2010-11 began partnership with the University's Institute for NanoBiotechnology to fund pilot projects on the toxicology of nonmaterials ($100,000). This represents a major initiative for leverage with another major center at the university. All of the money that is used to support this project comes from the Director's fund since we have used our pilot project money for the $25,000 standard grants.

Equipment

- Replaced an essential piece of shared equipment that broke down.
- Supported travel Ghana to conduct pilot project for the Biomass Working Group.
- Purchased 24 well instruments using director's funds and matching funds from the Dean to established pyrosequencing methods for analysis of gene-specific and global DNA methylation.
- Purchased small pieces of equipment, such as a -80 freezer and partial support of service contracts not covered in Facility budgets.
- Purchased materials and supplies critical for laboratory experiments

Future plans

- We plan to use our Director's Fund to provide support for "demonstration projects" in our effort to refocus our IHSFC to more consistently encourage collaboration between basic and population scientists. We expect to use these initial experiences to fine-tune our plans for the upcoming competitive renewal.

Table 7: List of Director's Fund Titles, Realized/Anticipated Outcomes, and Amount (n=5)

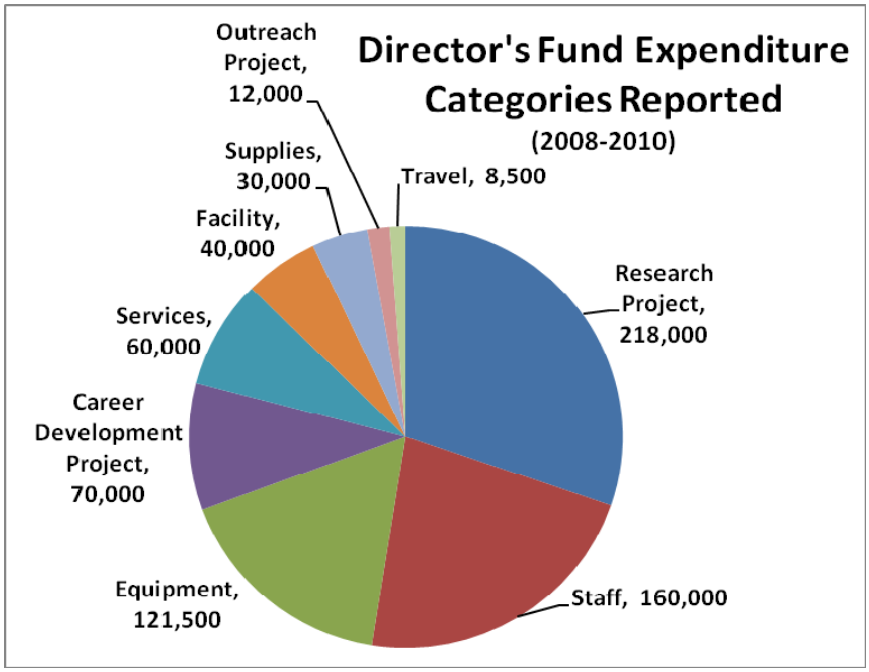
FY	Category	Director's Fund Project Title	Realized/Anticipated Outcomes	Amount
2008	Career Dev	Supplement to Career Development Core. Phenotype of Gene Expression Profiles in Response to Treatment in Nasal Epithelium of Children Hospitalized with Asthma Exacerbation	Funded gene expression profiles for clinical fellow in the Division of Allergy & Immunology. Received a Pilot Project award in 2009 using this preliminary data.	5,000
2008	Career Dev	Nitrosative protein modifications as an etiology of environmental diseases: targeting specific gene network.	Mass spectrometry evaluation possible for early career investigator. Grant application: Department of Defense Idea Award, (Direct Cost $375,000) Not funded.	25,000
2009	Career Dev	Nitrosative protein modifications as an etiology of environmental diseases: targeting specific gene network. Continuation of 2008 project	NIH/NCI, 1R21 (Direct Cost $275,000) Not funded NIH/NCI R21 (Direct Cost $275,000) Not funded	25,000
NR	Career Dev	"New Investigator" pilot projects	NR	15,000
2008	Equipment	Purchase gamma counter-partial support	Quick replacement of broken, old instrument	13,500
2008	Equipment	Purchase pyrosequencer- partial support	Allowed establishment of new assays for methylation. Lead to successful grant application and several papers	40,000
2008	Equipment	Purchase spectrophotometer for Trace Metals Facility Core to replace an old instrument	Allowed more rapid analysis of samples in the Core	7,000
2008	Equipment	The Endocrine Disruptor Bisphenol A Confers Chemoresistance in Breast	Preliminary data used in R21 Supplement ($113,868). A NIEHS T32 predoctoral fellow used	20,000

FY	Category	Director's Fund Project Title	Realized/Anticipated Outcomes	Amount
		Cancer 1) to determine which receptor(s) mediate the actions of BPA, and 2) to examine the role of survival signaling pathways and activation of pro-apoptotic proteins for BPA.	this funding for dissertation research. Completed 2 publications	
2009	Equipment	Purchase image capture system	Enhanced research activities of several Center members	7,000
2009	Equipment	Purchase -80 freezer	Quick replacement of down freezer that was not worth repair	10,000
2009	Equipment	Purchase graphite rods for atomic absorption spectrophotometer	Dramatic increase in analyses by Trace Metals Core increased need for these parts	6,000
2009	Equipment	Purchase UV spectrophotometer	Enhance activities of Trace Metals Core	7,000
2009	Equipment	Purchase audio equipment and laptop for community partner	Enhanced their ability to translate research results to the community	3,000
2009	Equipment	Detector for Exposure Assessment Facility Core to allow determinations in the UV range of air samples	Expanded Core capabilities	8,000
NR	Facility	Mass Spec Assays	NR	10,000
NR	Facility	Develop world's first specific-pathogen-free facility	NR	30,000
2010	Outreach Project	Outreach Pilot Project Summer Undergraduate Research as a potential Outreach and Education Core activity	$2000 stipend support per investigator (maximum of 6 stipends) to provide summer undergraduate EHS and GxE research opportunities to students.	12,000
2008	Research Project	Bisphenol A and Epigenetic Regulation of Gene Expression	Supported NIEHS K99 with insufficient funds. Research was reported in the NIEHS newsletter in February and April 2009. Publication	21,000
2009	Research Project	Bisphenol A and Epigenetic Regulation of Gene Expression	Supported NIEHS K99 with insufficient funds. Research was reported in the NIEHS newsletter in February and April 2009. Publication	21,000
2009	Research Project	Biological response to nanomaterials in pulmonary exposure	RC2 application, not funded. R01 in preparation.	20,000
2009	Research Project	Maternal Epigenetic Programming in Metabolic Syndrome. Microarray costs for comparing global histone acetylation in adipose, liver and placenta from Fe/Cm vs. Ce/Cm mice that have been fed either a standard diet or a high fat diet.	This support is in line with the Epigenetics and Transgenerational health effects of the Center. R01 in preparation.	15,000
2010	Research Project	CCAAPS methylation project. Testing the utility of salivary DNA methylation as biomarkers of diesel exhaust particle (DEP) exposure and to determine if the methylation status relates to allergic disease and asthma.	Student using this data for her PhD dissertation project. This is the first epigenetic project using the CCAAPS cohort.	21,000
NR	Research Project	Building capabilities to work with zebrafish	NR	60,000
NR*	Research Project	BioMarker Initiative Projects	NR	60,000
2009	Services	Partial support for Allergen Lab service contracts	Supported work by several Center members	10,000
NR	Services	Service Contract	NR	50,000
2008	Staff	Hiring New Investigators	NR	50,000
2008	Staff	Salary support for early career investigator to study epigenetic modifications to chromatin due to	ESI will become a valuable EHS investigator. Submitted an R01 pending review. 2 publications	30,000

FY	Category	Director's Fund Project Title	Realized/Anticipated Outcomes	Amount
		arsenic exposure		
2009	Staff	Hiring New Investigators	NR	50,000
2009	Staff	Salary support for early career investigator to study epigenetic modifications to chromatin due to arsenic exposure	ESI will become a valuable EHS investigator. Submitted an R01 pending review. 2 publications	30,000
NR	Supplies	Charcoal and trout food supplies	NR	30,000
2008-2009	Travel	Airfare for doctoral student and faculty member to fly to Ghana for Biomass Working Group	Pilot data collected for submission of grant application on biomass fuels	3,500
NR	Travel	Travel to China to collect air pollution samples	NR	5,000

**NR=Not Reported*

Figure 4: Summary of Reported Director's Fund Expenditure Categories, 2008-2010, in dollars



Additional comments from PIs regarding the director's fund (e.g. benefits or challenges).

There was clear support by respondents for the DF program:

- The DF has primarily supported early career faculty, to launch their careers in EHS because they struggle to find support to develop enough preliminary data for their first independent research grant.
- Each of the funded projects is in line with important Center initiatives such as epigenetic remodeling and health outcomes or proteomics. The DF is a very useful mechanism for growing our research in these directions.
- This has been quite flexible and as described below we have initially focused use of these funds to create larger translational pilot grant initiatives
- I felt it was unusually bold to give the Centers this flexibility and it is the key opportunity for the Director to change in the direction of the Center. It is very easy for the Center budgets to be so firmly committed to what passed peer review that there is no flexibility to initiate new directions. This was a clear limitation in the previous incarnation of the Center Program.
- It has been very useful since our Grants and Contracts office have been extremely reluctant in the past to allow changes in spending from what was in the original proposal.

Challenges and concerns were also raised:

- The challenge of applying the DF is prioritizing projects, because there are always more meritorious proposals than there is funding available. The Center supports projects that most closely align with the mission and initiatives of the Center.
- I also felt that Center Director's were being given the rope to hang ourselves in the future. It would be very easy to second guess how the funds were used and state that they were wasted or misused in some way. Therefore, I did notify NIEHS about commitments that I felt might be controversial (foreign travel or construction costs for a facility core). I made the commitments before approval (as in the Gulf response), knowing I had State Fund Reserves that could be committed to re-budget the expenses if NIEHS did not approve. Before making any commitment using the Director's fund, I think in my mind about how I would answer an irate congressman why Federal dollars were spent on the project. How was this money a good investment of the taxpayers money?
- Since the availability of these funds, as well as the Dean's funds committed to the Center, is discussed at every Center meeting, requests frequently exceed the available funds.

Conclusions and recommendations

Overall, PI's view the Director's Fund as very positive, giving them considerable discretion to respond quickly to emerging situations, and to fund activities (often at a fairly small scale) that could result in important research advances at a key moment. A wide range of activities were reported to us, including research project, staff, equipment, career development, services, facilities, supplies, outreach projects and travel. However, a clear highlight of this new flexibility is the ability of Centers to respond to the Gulf Oil Spill rapidly during the Late Spring/Summer of 2010.

The Assessment Team had no recommendations for changes in this area.

Pilot Projects

Pilot projects are a cornerstone of the P30 program. No major changes were made in 2007, except to increase the overall cost that could be allotted to the pilot projects. The total was raised to up to $250,000/year. As part of the questionnaire, we asked PIs for a comprehensive list of pilot projects, and a sense of how these may be contributing to the overall translational and career development goals of the new guidelines. Assessment questions included:

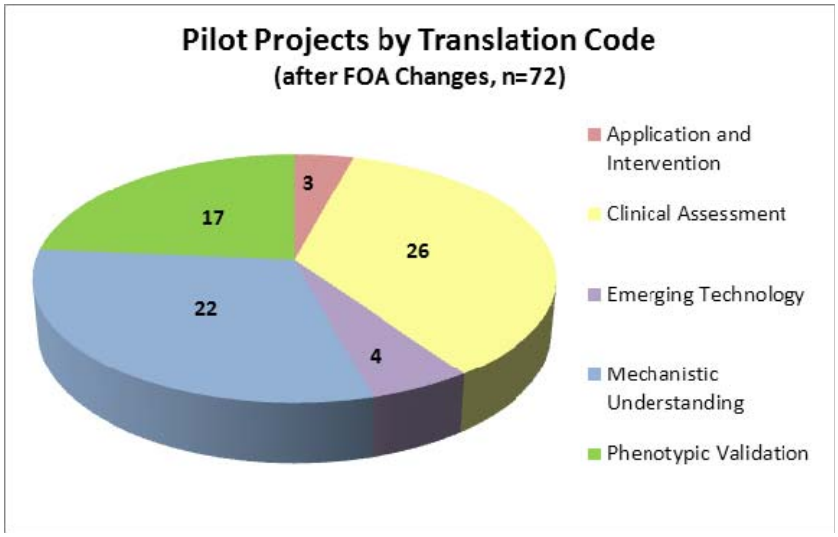
- What do the pilot projects address?
- How do pilots contribute to the revised center goals?
- How many pilot projects result in subsequent grant applications and awards funded by NIEHS/NIH?

As part of the questionnaire, we requested that Center Directors submit pilot project data in two standardized tables that Core Center Director's have used for several years in their progress reports. Table E1 includes information about the year a pilot project was funded, the name of the project leader, cost, title, resulting funding and resulting publications. Table E2 focuses on detailed outcomes, including columns for the Pilot Project title, PI, new grant funding institution, new grant number, new grant funding level, new grant title, project period, publications and other outcomes.

Pilot project topic areas

All six respondents provided a wealth of pilot project data (though not all in the same format for every question). According to data submitted on Table E1, the respondents funded a total of 54 pilot projects in the two years prior to the changes, and 72 pilot projects were funded after the guideline changes. We coded pilot project titles into the various translation categories described in Figure 1 above. About a quarter each were classified as clinical assessment, mechanistic understanding, or phenotypic validation (Figure 5).

Figure 5. Number of Pilot Projects in each Translational Research Category



Translational research categories are described above – see Figure 1.

Pilot Projects Contribution to Translational Focus

Several of the Centers reported that they have specific pilot project programs that deal with translation:

- Investigators compete for a $50,000 pilot project in translational research; requiring collaboration of two or more investigators. We have funded one of these in each of the last two years and this year we received 4 applications.

- In 2010 a partnership was formed with the University Institute to fund pilot projects on the toxicology of nanomaterials. This represents a major initiative for leverage with another major center at the university. All of the money that is used to support this project comes from the Director's fund.
- The Director's Biomarker Pilot Project Initiative is a program funded partly using institutional resources with the goal of identification or development of biomarkers for environmental disease. Proposals aim to identify or develop an environmentally relevant disease biomarker.

Examples of Translational Pilot Projects

- The Breast Implants, Environmental Carcinogens and the Risk of Breast Cancer pilot project has been funded for two years. The goal of the project is to more rigorously test the inverse relationship between breast cancer and implants. This study is also building connections with a CTSA. More than 20 epidemiological studies have specifically examined breast cancer risk and, contrary to expectations, have consistently reported 30-50% decreased risk of breast cancer in women receiving breast implants compared to women with no implant history. Our Research Coordinator in the IHSFC helped work through the IRBs and made contacts to eventually receive implants. It took 18 months to get everything aligned to receive the first explants. In addition, we recruited a newly hired epidemiologist that the Center helped hire.
- A pilot project funded in 2006 led to an R03, R01, and two ARRA supplements, producing an interactive project with journalists and a community based participatory research project to study the impact of manganese exposure on an Appalachian American population. The research program, built on the seed money from the Center, is now a training ground for students who want to learn how to work with communities in a bi-directional manner.
- Several projects on Bisphenol A are illustrating the impact that this chemical may have on human health at environmentally relevant doses. The preliminary data for several investigators were supported by pilots.
- Our most successful Pilot Project utilized advanced transgenic techniques to model the well-known p53 R72P polymorphism in mice, and directly linked a basic scientist with a population scientist through their shared interests in this polymorphism. This collaborative effort resulted in the funding of a new NIEHS grant.

Pilot Projects Contribution to Career Development

All 6 respondents reported using the pilot project program to help advance the careers of young investigators

- Pilot projects have supported 5 young investigators, 5 early stage investigators and are expecting to support 2 junior faculty; resulting in 1 new NIH R01, 3 new full Center Members and 1 new Associate Center Member

Examples of audiences targeted by the pilot project program

- New to EHS
- Innovator
- Affinity Group
- Mentee-Mentor Partnership
- Junior Faculty

Examples of Career Development Opportunities

- Career Development Core supports two programs for career development: Next Generation Biomedical Investigators are early career faculty, and New Investigator Scholars are graduate students or postdocs.
- Pilot proposals give early career investigators, post-doctoral fellows, and graduate students the opportunity to be co-investigators and practice grant writing skills.
    - Not every project can or should be funded, the centers take risks; use the process to help investigators understand weaknesses in their proposals early and to provide advice and hopefully new insights and collaborations that will aid them even if not funded.

- Center began using the DF to make small ($5K) investments rapidly that could be very strategic for new investigators at critical junctures of their careers.

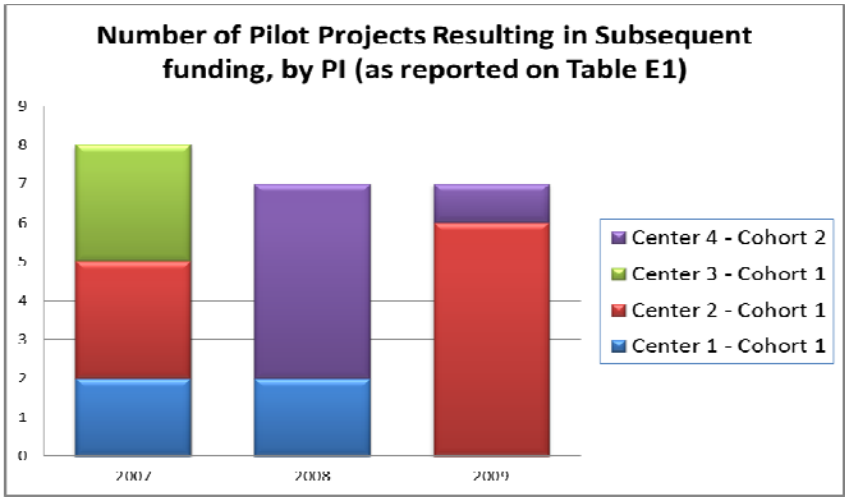
Examples of pilot projects by young investigators

- One highly successful pilot is that from a PI who applied to carry out pilot studies of oxidative stress in ALS; taking advantage of the IHS Core to process and store bloods and analyze urine and plasma for oxidative stress markers. Based on positive data in this pilot, he has obtained Muscular Dystrophy Association funding and a large multicenter NIH grant to study oxidative stress in ALS prognosis and has been asked by NIH to submit a supplement to expand to PLS (primary lateral sclerosis).
- DF investment made to a new cancer biologist, interested in the AhR receptor, needed funds to rent software to do homology modeling. The PI was paired with a network engineer that provided access to a large engineering cluster to run the simulations. This homology modeling expertise led to three publications involving five different Center members. They built a 3D homology model of AhR that successfully predicted novel binding partners.
- Pilot funds supported the efforts of an investigator to get the arsenic in urine analysis done in an epidemiology study of the relation of arsenic and hypertension. The lack of these data were cited in the initial review of her R01 application and by providing these resources she was able to rapidly respond to the reviewers' concerns and the application was funded as a revised application.
- Another pilot project allowed the collection of pilot data on biomass fuel air pollution and respiratory health; the pilot data was essential for the submission of a recent grant application.
- A pilot to an investigator in OBGYN allowed the collection of samples from pregnant women undergoing routine clinical care at the Medical Center. CDC is in the process of analyzing several biomarkers but the investigators were recently successful in obtaining R21 funding for an expanded study. This is a success of the Reproductive Working Group that is seeking to take advantage of the large number of pregnant women seen at the University as part of the Fetal Medicine Network. With additional funding, environmental exposures can be measured and linked to the large amount of pregnancy and birth outcome data normally collected.

Subsequent funding

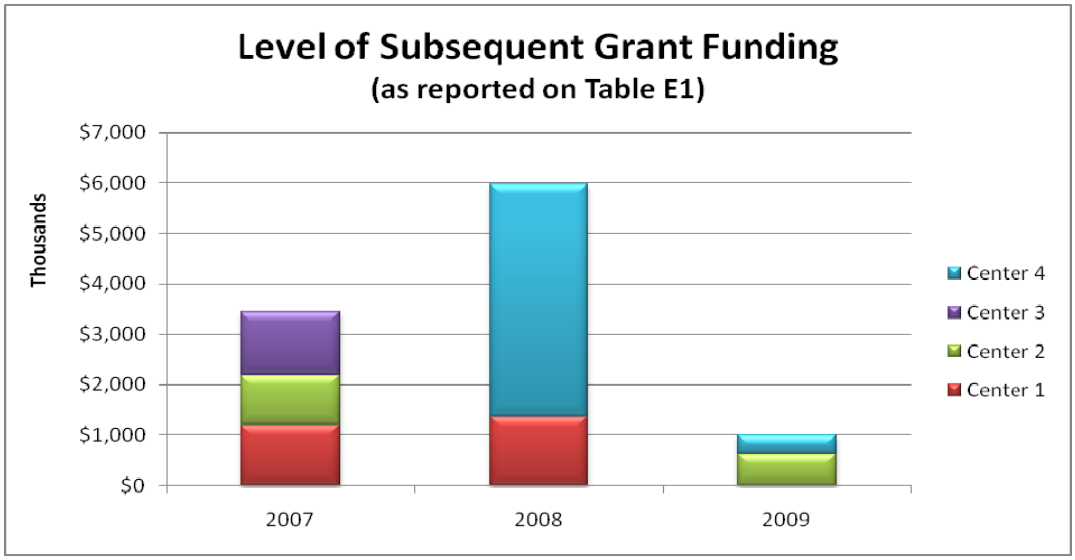
Subsequent funding resulting from pilot projects is an important indicator for pilot projects. Data submitted on Table E1 indicates that the four Centers reporting data in this format have a total of 27 pilot projects that have been linked to subsequent grant funding (Figure 6).

Figure 6: Pilot Projects Resulting in Grants by Year



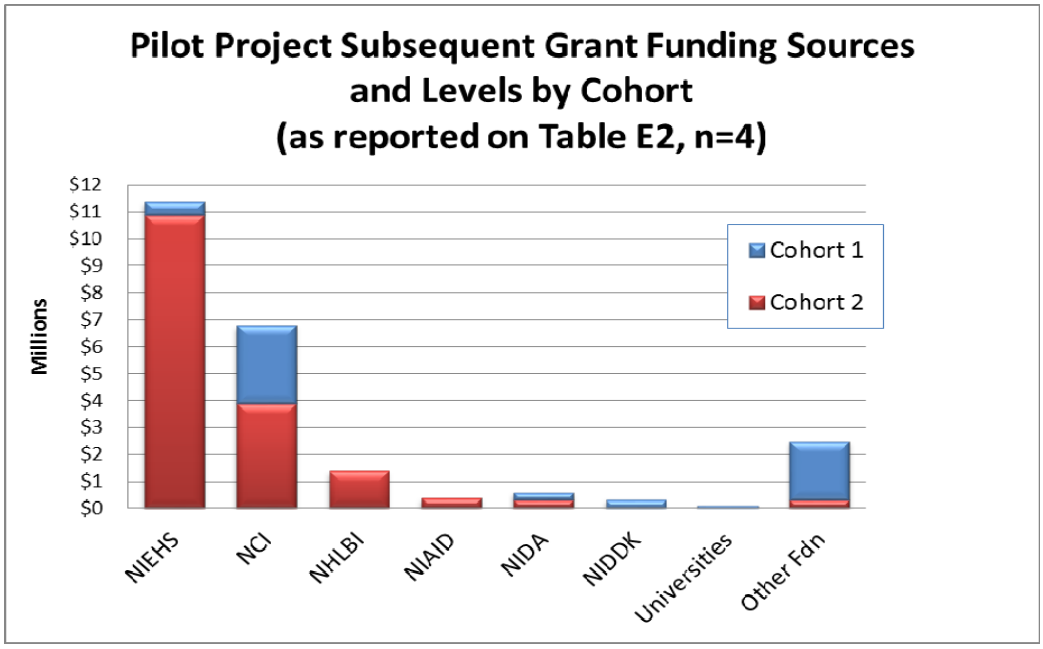
These 27 projects resulted in approximately $11 million in subsequent grant support (Figure 7).

Figure 7. Subsequent Grant Funding Reported by Center Directors, After Changes to the Guidelines



Respondents reported a total of about $18 million in subsequent grants on Table E2, which also contains more detailed information about the subsequent grant funding sources. Sources of the funds included NIEHS, other Institutes, Private foundations and University support (Figure 8).

Figure 8: Sources for Pilot Project subsequent grant funding



Return on Investment for Pilot Projects

The Assessment Team was interested in the concept of Return on Investment (ROI). In the financial world, ROI is a measure that calculates the relative performance of investments, and is derived by dividing profits by investments

during a particular period. In this context, ROI could be defined as Profit/Investment (where profit = new grant funding building on that pilot project, and investment = initial pilot project costs.) ROI was not calculated on the data submitted for several reasons. First, not enough time has passed for the increased investment in pilot projects to result in subsequent funding. It takes time for pilot project data to work its way into a funded grant proposal. Additionally, some subsequent grant dollars were provided as totals, i.e., a 5 year project at $100K each year was entered as $500K, while others provided only single year grant dollars. Moreover, during the analysis, we discovered that the data reported in Tables E1 and E2 do not always match for a given Center. There is no common identifier that allows us to join the tables together, which hinders our understanding of pilot project outcomes. A robust ROI analysis requires better information, and thus the committee recommends evaluating the data in Tables E1 and E2 to ensure the data we collect support future ROI analyses. A combined table that includes Pilot project costs linked to subsequent funding and other outcomes could be useful. This consolidated table might include the following data fields:

- Year(s) Funded
- Pilot Project Awardee Name
- Pilot Project Title
- Pilot Project Amount (Total Costs, including multiple years)
- Subsequent Grant Funding Institution
- Subsequent Grant Number
- Subsequent Grant Title
- Subsequent Grant Amount (Total Costs)
- Subsequent Grant Period
- Number of Resulting Publications
- Other Outcomes

Conclusions and recommendations

Pilot projects remain a core component of the program. These assessment data provide validation that pilot projects support the mission of NIEHS. It is clear from the responses received that the pilot projects contribute strongly to translation and career development, and result in subsequent funding for Center members.

A full return on investment analysis was not possible in the time available for the study, but would be a useful component to future P30 Core Center evaluations. It could be useful to partner with PIs to see how they keep track of the return on investments in pilot projects.

The Assessment Team recommends updating the structural elements of tables E1 and E2 on the progress reports to better clarify pilot project time frames, and calculate return on investment.

Personnel/Career Development

The revised guidelines formalized career development requirements. In this section we summarize questionnaire responses from PI's relating to early stage investigators, new investigators to the centers, and other career development opportunities. Specific assessment questions included:

- What career development activities have been undertaken?
- What results have these career development activities begun to have?
- What new recruits, disciplines and investigators have been added to the Center?

Career development activities

Development opportunities for graduate students and early career investigators reported by PIs generally fall within four categories: salary/grant support, workshops, mentoring and training.

Salary/grant support

- Support for junior investigators with $50k for each of two years.
- Funds for career development activities including workshop and meeting costs, research supplies, and salary support.
- Salary support for new assistant professors with a particular EHS focus area.
- Start up funds for 9 new investigators.
- Supported a junior faculty member in biostatistics and one in medicine (respiratory disease).
- Eligibility for a Pilot Project award under a limited competition
- Access to all of our facility cores and receive preferential priority for the pilot funds.

Workshops/seminars

- Workshops that focus on scientific career development (e.g., grant submission process, internal steps required to submit grants, and how to find funding opportunities.) Slides available online.
- Outlines for standard grant formats are available.
- ASTM Certification course aims to provide a standardized set of skills and knowledge on the environmental health and safety of nanomaterials and nanotechnology.
- Workshops to increase Mentees' awareness of opportunities within the Center, in particular with respect to the Facility Cores
- A very successful Seminar, sponsored and arranged by the Career Development Program, was given by Dr. Jerry Heindel of the NIEHS on the general topic of grantsmanship
- Facility cores presented workshops (molecular biology, histology, and flow cytometry) providing investigators with valuable information that may diversify the experiments in which they engage.
- Annual Pilot Project Symposium: Center members gather to hear the progress of the Pilot Projects. The question and answer sessions produce interesting discussions on cross-disciplinary research opportunities.
- Works with the Department of Environmental Health to bring invited speakers to the weekly seminar. Core leaders use this forum to present opportunities for research with leading-edge technologies.
- 2009 Environmental Health Scientist Student Showcase: Collaborated with local and regional NIEHS T32 programs to celebrate EHS work and provide networking opportunities. Students from different disciplines across EHS projects met both formally and informally to learn about research in the region.
- Most impressive are the unexpected collaborations that have developed from our center retreats and the informal discussions between people in five different colleges. So much has happened because people asked -- oh -- would this work with my problem?
- Several workshops have been developed under the auspices of the Centers, addressing Biomarkers, DNA, and single nucleotide polymorphisms (SNPs).

Mentoring

- Mentoring for junior investigators. 3 person committee, incl Center Director. Jr Investigators speak once a year at Center meetings and receive services from the Facility Cores either free or at a reduced cost.
- Several Center members serve as mentors on the K awards of junior faculty."
- 1:1 mentoring of young investigators by center Members

Training and Cross-training

- Facility Cores continue to train postdocs and graduate students on various methods carried out in the Cores.
- Supported six Summer Undergraduate Research Fellowships with EHS scientists in the Center.
- Engaging Scientists and Journalists: Worked with Department of English to team Environmental Journalism students with Center members for experiential training in communicating to each other.
- Developing new collaborations and interactions using new technologies, including a number of new studies initiated in the field of epigenetics. Have yielded a series of grant submissions.
- Several students and postdocs have learned specific assays in the Facility Cores, e.g., a doctoral student learned the assay for nitrotyrosine in plasma; another doctoral student spent a summer in abroad learning how to use air monitoring devices designed by our Exposure Assessment Core.
- The Epigenetics Working Group members have provided education on various aspects of methylation assays and epigenetic alterations to other Center members who are not laboratory oriented but want to use the assays in population studies.
- The pilot project program provides young investigators the financial support to generate data that can be used to garner extramural support, subsequently furthering their careers.
- The pilot project program provides established investigators the opportunity to foster collaborative relationships.
- The Center itself provides investigators from a variety of disciplines the opportunity to interact, which may have lead to cross training opportunities that not would otherwise been realized.

Results of career development activities

PI's reported that career development activities result in grant applications and awards, new collaborations, promotions and new positions.

Grant applications/awards

- K07 application to NCI that has received a very promising score.
- K99 from NIEHS to investigate estrogens/xenoestrogens and epigenetic regulation of gene expression.
- $31,000 Dean's funding.
- Collaboration with Pediatric Environmental Health Specialty Unit (PEHSU) to translate knowledge about environmental health to practitioners.
- Publications and grant awards accrued by the awardees.
- Some have been competitive in the NIEHS ONES grant program
- Mentees have received a Fulbright Scholarship and research grants from the American Cancer Society and NIH.

New collaborations:

- We have identified junior faculty members who will also link the Center translational research programs, as well as the other Core Facilities of our Center.
- New collaborations with several Center members and has been written into several grant proposals.

Promotions and new positions

- Promotion in their career ladders; one of these has moved to an independent position as Program Director in the Intramural Research of the NCI.
- One of our current Mentees was successful this year in being awarded one of our Pilot Projects.
- Our other initial career development awardee was so successful he was recruited away!"

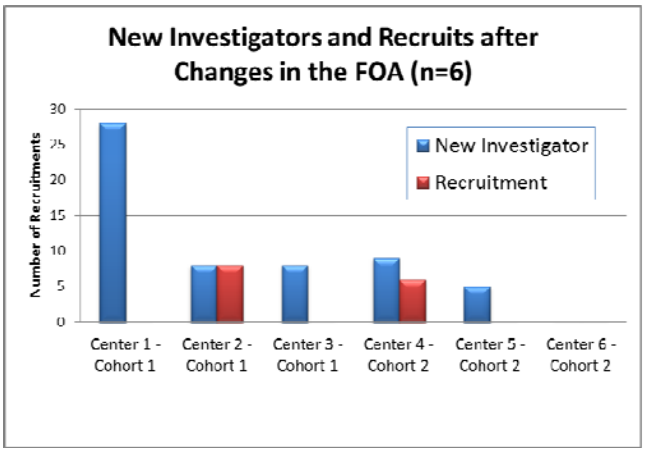
Challenge:

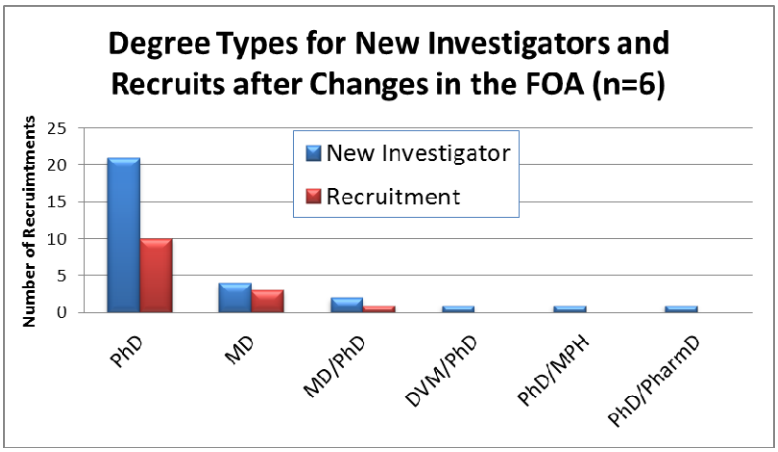
- A challenge for the future will be to track the success of trainees who leave the University for faculty positions elsewhere.

New recruits and investigators

A total of 58 new investigators and 14 new recruitments were reported by investigators. Once center accounts for nearly half of these; and one Center reported none. The other four centers reported between five and ten new investigators and 0-8 recruitments. These individuals mainly hold Ph.D.s, some are M.D.s and some hold joint degrees (Figure 9).

*Figure 9: New Investigators and Recruits / Degree Types**





***Recruited center investigators** are independent investigators newly recruited from outside the Center. This mechanism is intended to infuse Center research with novel technologies and approaches by supporting independent investigators, ideally, who are at the beginning stages of their research careers, and will add needed expertise to the Center structure. The recruit would be expected to bring new technologies or novel scientific areas of expertise into the environmental health sciences arena that enhance the Center's research capabilities. Former graduate students and postdoctoral fellows of Center members should not be considered for support unless, in exceptional cases, it can be demonstrated that they have established independent research careers and will provide critical expertise.*

*A **Named New Investigator** in a specified area of research can work in the basic sciences, clinical research, or public health disciplines relevant to environmental health. Former post-doctoral assistants and fellows are eligible for this position.* http://grants.nih.gov/grants/guide/rfa-files/RFA-ES-10-001.html

Conclusions and recommendations

Career development is a key focus of the program, and it appears that the Centers are taking the opportunity to provide meaningful training experiences for junior faculty and students. Development opportunities generally include salary/grant support, workshops, mentoring and training. These activities result in grant applications and awards, new collaborations, promotions and new positions. Efforts to recruit new investigators to the Center have been reasonably successful. Tracking trainees associated with the core centers is not systematic.

The Assessment Team does not recommend any changes to the Career Development components at this time.

Scoring/Review

Several scoring changes were made in 2007 that have affected P30 cohorts 1-3 (Table 8). Additionally, the NIH Center for Scientific Review changed to an entirely new 9 point scoring system in 2009, affecting the way all NIH grants are scored. These changes have been applied to cohort 4 and beyond. For more details on the new CSR scoring system, see: http://enhancing-peer-review.nih.gov/

The primary reason for changing the scoring system in 2007 was to improve the rating scale so that it realistically reflects the range of quality of applications, thereby encouraging the routine use of the entire rating scale. In the new scoring system, the scores were designed to 1) encourage use of the full scoring range; and 2) provide additional feedback to applicants and program staff of the rating for each review component. Applicants see the preliminary scores for each of the review criteria as additional feedback on their summary statement.

Table 3: SRB Scoring System Structure Pre and Post Changes

Prior to Cohort 1 (2007)	Cohort 1 - and Beyond
Essential Characteristics (each scored separately) • Interdisciplinary coordination • Overall organization and facilities • Research focus in EHS • Center Director • Institutional Commitment	Essential Characteristics (each scored separately) • Strategic Vision • Career Development • EH Identity and Impact on Research base • Center Director • Institutional Commitment
Each facility core got a separate score	Facility core scores combined
COEP scored	COEC scored
Administrative Core scored	Admin. Core (includes Director's fund) scored
Each Science Research Core scored separately	Integrated Health Sciences Facility Score
Pilot Projects scored	Pilot Projects scored
Overall Summary Score	Overall Summary Score

Assessment questions

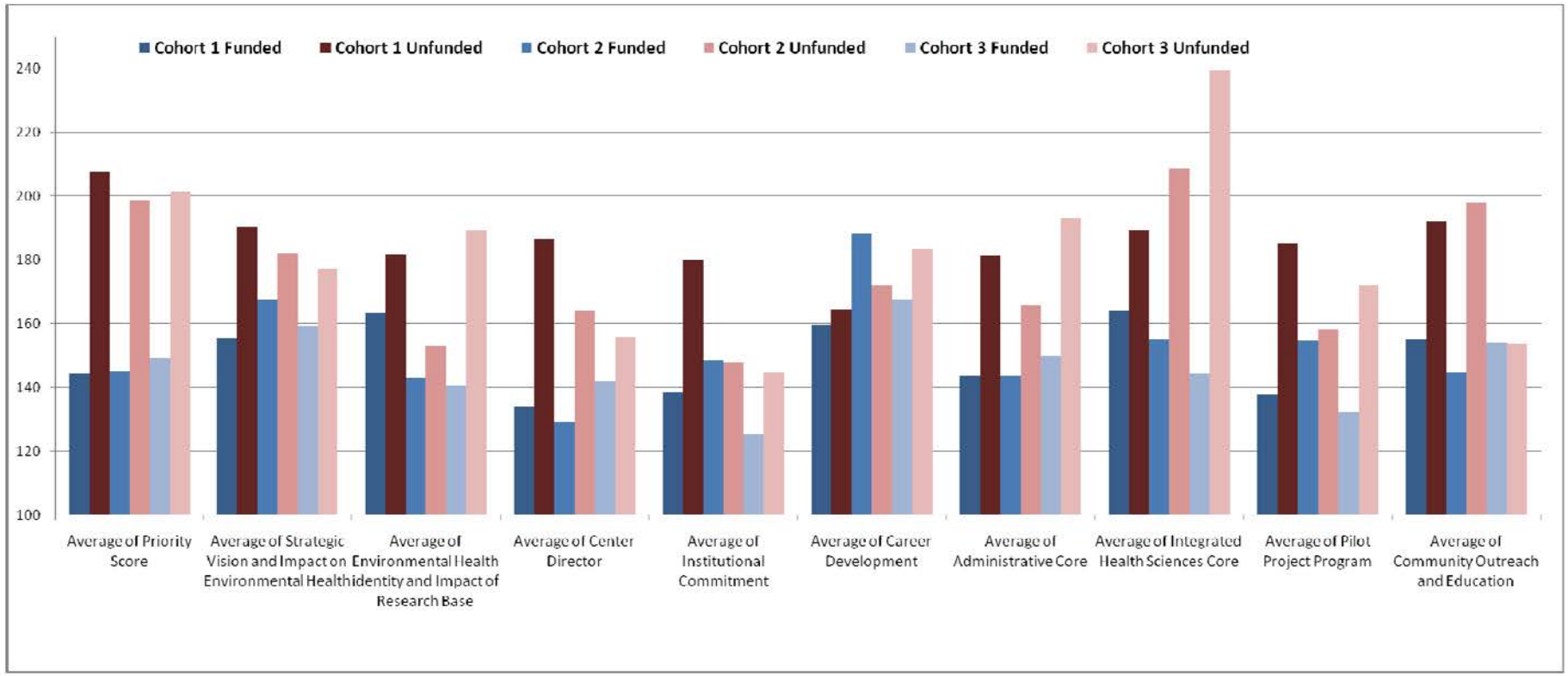
The Assessment Team narrowed the relevant questions for this analysis because to fully understand the impacts of these changes, we would need to survey both reviewers as well as all applicants (both funded and unfunded). These were beyond our capacity in 2010, though we have added them to the list of potential questions for a future Core Centers assessments and evaluations. Questions for this assessment were limited to the following:

1. Did changes to the scoring process encourage use of the full scoring range?
2. How did the new strategic vision score compare to the overall score

Scoring Range

We briefly looked at the average scores for funded and unfunded applications in Cohorts 1-3 (Figure 10). In most categories the scores for the funded applications (blue tints) are better than (i.e., lower than) those for the unfunded applications (reddish tints).

Figure 10: Priority Scores of Funded and Unfunded Applications in Cohorts 1-3 (2007-2009 P30 Core Centers)



Strategic vision

We also reviewed the strategic vision scores compared to the overall score (figure 10-11). For most applications three is good correlation between these two scores (Figure 11). However, two grants with good strategic vision scores were not, apparently, able to convince the reviewers that they could execute the vision (Figure 12).

Figure11: Strategic Vision Score vs Overall Score – Cohorts 1-3

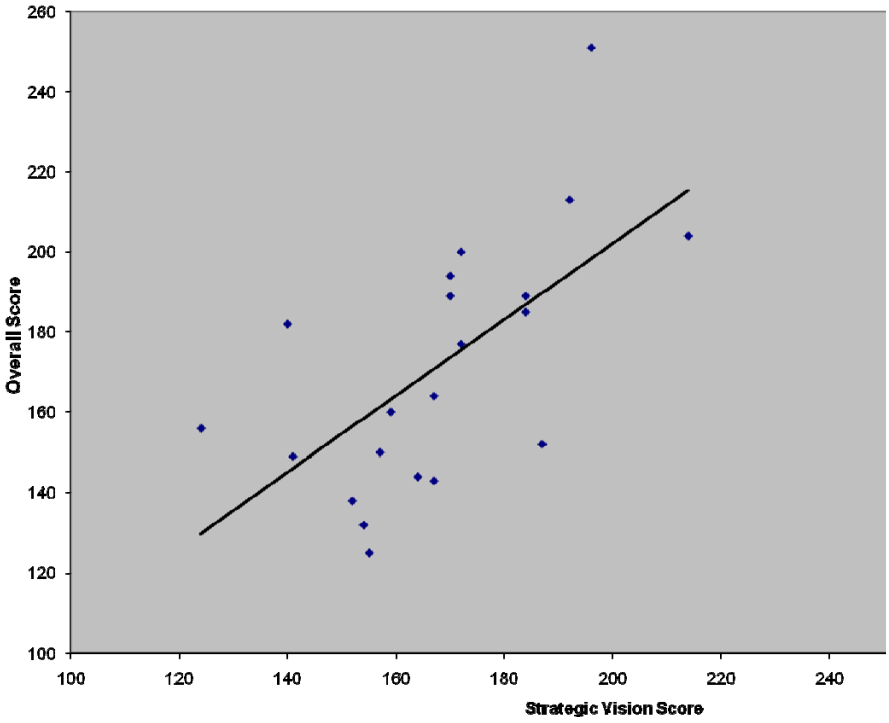
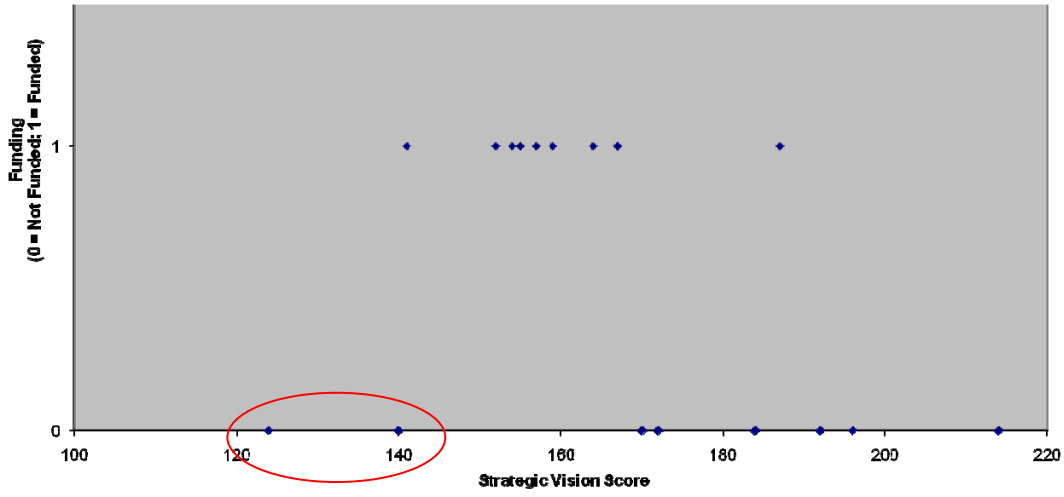


Figure 12: Strategic Vision Score compared to Funding Decision – Cohorts 1-3



Scoring Comments

No explicit questions about scoring were included in our questionnaires, but several comments were received.

- A combined Facility Core score sends a message that Cores are not important to the Center because the overall impact to the score is only about 10%. Moreover, counting how many times a Facility Core is used and cited tends to reinforce the use of standard technologies rather than moving towards the cutting edge. Facility cores can drive new science, and as such overlap with the former Research Cores – but this does not get rewarded by the scoring system.
- The scoring for Career Development activities should be reconsidered because the diversity in the culture across public and private universities with regard to career development prevents a "level playing field."

Conclusions and recommendations

The Assessment Team concluded that these analyses did not warrant any additional changes to the scoring system at this time. Future assessments may want to include different data collection efforts to assess the scoring system more fully.

Community Outreach and Education Cores

The goal of the Community Outreach and Education Core (COEC) is to develop the field of environmental health outreach by promoting the widespread dissemination and institutionalization of outreach and education projects that are effective in translating environmental health science to target audiences. COECs translate research information into tools and resources for various professional and public stakeholders. This is done in part by encouraging open dialog and peer review of these strategies, approaches, and models. COEC activities should be based in sound outreach and evaluation theory and research, as it relates to the field of environmental health, in order to improve clinical and public health.

Changes to the guidelines in 2005 (for Centers funded in 2007) made the COEC an optional element. In 2009, however, (for 2011 funding) the COEC again became a required element. In June 2010, NIEHS invited awarded (P30) Environmental Health Sciences Core Centers that do not currently support a Community Outreach and Education Core (COEC) to compete for funds for this activity (NOT-ES-10-009).

Additionally, in 2005, COEC is required to establish a Stakeholder/Community Advisory Board (CAB) to strengthen the bi-directional interaction between the EHS Core Center and its partners. The purpose of this advisory group is to ensure EHS Core Center understanding of community and other stakeholder needs, as well as to insure more effective dissemination of EHS Core Center research in appropriate venues.

Assessment questions for the COECs are:

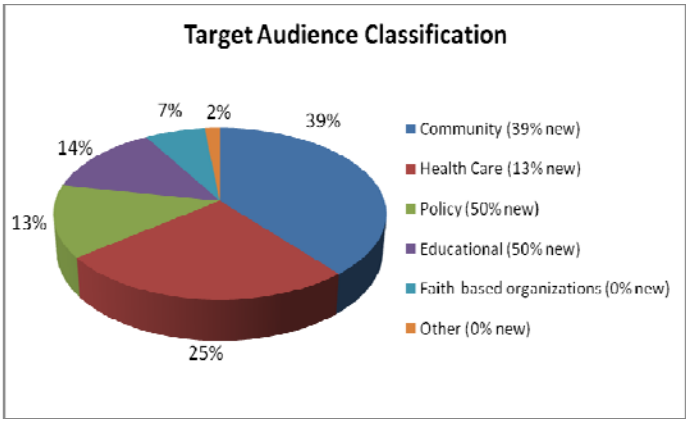
1. Who are the target audiences of the COECS?
2. What is the impact of requiring a Community Advisory Board?
    a. Is there more evidence of community involvement? More bi-directional communication?
    b. Do COEC's lead to other partnerships?
    c. What evidence shows the CAB's impact research questions either within the P30 or for other RPGs?

All data in this section of the report were generated from a questionnaire submitted to COEC directors. All five current directors provided responses.

Target Audiences

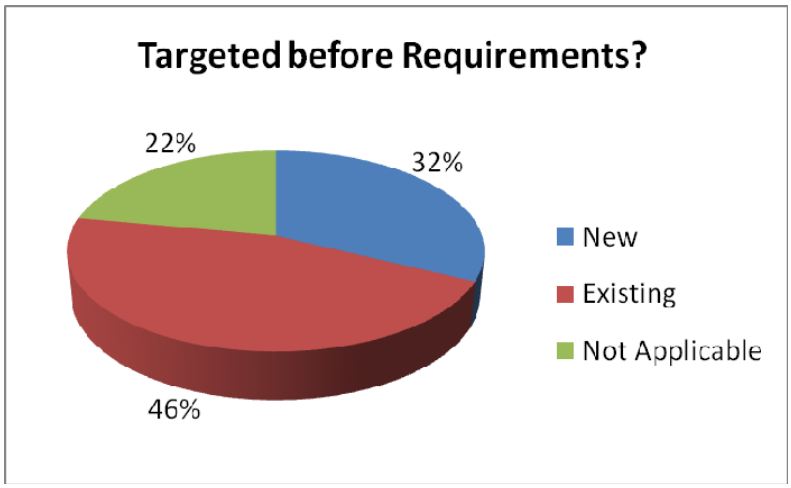
Respondents were asked to list up to 15 target audiences, classify them into broad groups, and note if they were new

Figure 13: Target Audience Classification reported by COEC directors, June 2010.



targets or existing prior to the Center (Figure 13, Figure 14, and Table 9). Fifty nine target audiences were listed by respondents. Approximately 19 of these (32%) were reported as being new targets since the changes in the Core Center's requirements. Over three quarters of the target audiences fall within the Community, Health/Health Care or Policy categories.

Figure 14: Proportion of new target audiences



Additional Partnerships

All respondents noted that CAB activities have led to development of additional partnerships. Examples reported include.

- Community Leaders
  - Faith-based organizations
  - Environmental Justice groups
  - Drug Abuse and Alcohol Coalition
  - Collaborative groups (who engage large numbers of community groups via town meetings)
  - Women-Infant-Children Program
  - Healthy Homes Programs
  - Health Clinics
- City, County & State Organizations
  - Health, Environmental Health, Environment and Agriculture Departments/Offices
  - Mayor's office
  - County organizations
  - Fire Department
  - State Environmental Council
- Educational
  - Other departments in the University
  - Other Research Institutes/Universities
  - University Extension Service
  - A medical television show
- National Organizations
  - National Pesticide Information Center
  - American Lung Association
- Grants
  - Received EPA CARES grant
  - Environmental Public Health Tracking Grant

Table 9: Target audiences by category

Community

- Alianza Dominicana
- American Lung Association
- Americana Community Health Center
- Broadway Housing Communities
- Corvallis Sustainability Coalition
- East Baltimore Development Inc.
- El Centro Latino
- Environmental Justice Partnership
- Friends of Macombs Bridge Branch Library
- Grant Houses Tenant Assoc.
- Harlem Business Alliance
- Harlem Children's Zone
- Hopkins Home Safety Community Canvasing Campaign
- Lower Wash. Hts Neighborhood Assoc.
- MH/WH Sanitation Coalition
- Mother Clara Hale Bus Depot Taskforce
- Neighborhood Places
- Northern Man. Improvement Corp
- Oregon Environmental Council
- Residents of and grass roots organizations in small rural towns around our center, this includes local civic orgaizations such as the Lion's Club, educational support groups, etc.
- WIC Programs
- Johns Hopkins Center for Childhood Asthma in the Urban Environment

Educational

- Carter G. Woodson Elementary/Middle
- Community Colleges
- Curtis Bay Elementary/Middle
- Independent School Districts and the state educational Agency, national organiza.tions such as National teachers Association, local Colleges of Education
- Northeast Middle School
- Northwestern High School
- OSU Extension Service
- School Districts

Faith-based organizations

- Church of Annunciation
- Holy Name Catholic Church
- Little Sisters of the Assumption
- St. Joseph Catholic Church

Other

- National Pesticide Information Center

Policy

- Coalition to End Childhood Lead Poisoning
- Greater Baltimore Asthma Alliance
- Harris Creek Watershed 246 Project
- Local Community Boards 9-12
- National Capitol Regional Asthma Partnership
- Oregon DEQ
- Public Health Assoc of New York
- State legislature, especially committees/subcommittees focused on environment and education; county and city leaders, ie mayors, city managers

Health/Health Care

- Baltimore City Health Dept.
- Baltimore Medical System
- Emergency Medical Personnel
- Family Health Clinic
- Health Department
- Local, regional hospitals and health care providers, schools of Public Health
- Men's and Family Center
- N Man Perinatal Partnership
- NYC Dept of Health
- Oregon County Health Departments
- Oregon Department of Human Services
- Oregon Public Health Association
- Promotores Network
- School of Public Health

NB: Some of the categories submitted were edited slightly to match the categories requested in the survey.

Educational Outreach Strategies

Three of the four continuing Centers reported little change in their educational outreach strategies with the new changes to the RFA.

One reported these specific changes:

- Targeted new partners
- Shifted to broader based internet projects
- Developed a Train-the-Trainer model to reach schools and students

Specific outreach strategies mentioned in the responses include:

- Focusing on responsibility to be a service component for the Core Center
- Making stronger connections with community
- Building strong [outreach/communication] infrastructure
- Train the trainer model for outreach and education

Existence of a formal CAB prior to the changes

Three of the four continuing Centers reported that they formulated a new CAB. One had a CAB prior to the requirement, and one Center was new, so the question is not applicable.

Two comments about the CAB requirement were submitted as part of an open ended question – indicating a somewhat mixed response on the part of the Core Leaders about the requirement.

- We support a requirement that a CAB is required; interactions the COEC has had with the board have been invaluable.
- The requirement for a formal CAB needs to be re- considered. A formal CAB is needed in focused research center projects like the Children's Centers, but it is not necessarily a good fit for Core Centers because the COECs are not conducting research per se. If the COEC is not serving our targeted audiences properly, the target audiences will let COEC know.

General Composition of CAB

Respondents reported a wide mix of structures for their CABs. One group sends out ~100 invitations for each CAB meeting, which typically results in ~35 participants. Different people may attend each time, but the COEC leader feels the approach assures "good representation and lots of feedback". At the other extreme, one of the centers has just 3 members on their CAB. Close relationships with these partners result in the ability to "interact with many people and organizations we could not otherwise reach." All COECs reported that they strive for a range and balance of partners who represent important local interests and concerns. Examples include:

- Local groups with environmental health interests (Asthma, lead, solid waste management, pesticides, etc)
- Environmental justice organizations
- Faith based organizations
- Tribal communities
- Public/environmental health educators
- Health departments
- News media
- Educators (some with a focus on minorities)

CAB's influence on community involvement

Four of the five centers described a range of ways that their CABs have increased community involvement. One noted that CAB has not significantly contributed to increased involvement. Examples of the activities CAB members participate in reported by respondents included:

- Provide feedback on appropriateness and impact of activities

- Provide advice about process
- Help devise what to communicate, best ways to communicate and market activities
- Communicates messages from the Center to the target audiences
- Bring researchers and community members together to develop data and information needed to address community concerns
- Engages other Facility Cores from the Center in community dialogue
- Facilitate connections for researchers to engage community members and groups for research projects
- Work with researchers to identify community members for CAB
- Develop questions used to develop educational programs
- Speak to students in the Center's Environmental Health Community Outreach (the course provides community residents and groups a forum to present their concerns to the class)
- Develop programs to educate new CAB members
- Prioritize strategies for educational interventions
- Create list of community resources and potential partners
- Form coalitions and networks with other groups around specific issues
- Create a task force of community groups to work to monitor the renovation of a Bus Depot to reduce air and water pollution
- Engage more than 40 community organizations, agencies, and businesses in a process to assess community concerns about environmental health, and in particular, adequate disposal of solid waste
- Hold community forums in response to specific issues

Influence of CAB on Research Questions

Four of the five respondents reported that their CABs are influencing research questions. The CABs provide input on research questions for additional grant applications, pilot projects and other activities and projects going on within the Centers. For example, CABs have:

- Influenced grant applications on community exposure and risk assessment related to a specific location and the neighborhood bus depot
- Helped shape research on demolition practices in _____ City
- Contributed to pilot projects addressing Environmental Justice Partnership and a regular outreach activity
- Guided development and implementation of COEC programs that were closely integrated with Center programs
- Influenced a research project that gave "Tribal community members the opportunity to identify the ways in which cultural practices have been affected by environmental contaminates and to play a key role in identifying ways to … simultaneously reduce exposure and preserve cultural traditions."

COEC Challenges

COEC directors described several challenges and their responses to those challenges (Table 8).

Table 10: COEC Challenges and potential responses

Challenges	Responses
How to best formalize a CAB for overall Core Center activities. It is easier to organize advice around specific issues, and more difficult for broad, diffuse issues.	None provided
Getting broad representation on the CAB was an initial challenge.	Developed the floating membership model. They invite 100+ individuals and approximately 35 participate in each meeting.
Establishing contacts with key leaders and building trust among them.	Holding regular meetings to help overcome this
Managing the shift from K-12 to community education (with the added challenge of a staffing transition)	Working to gain information from other COEC's with established CABs.
Community needs and research do not always align	o Need to determine needs and interests beyond basic or applied research conducted o Focused on outreach, workshops, and original material on indoor air quality issues and pesticides
Budget constraints are a challenge	When immediate short term needs have arisen, COEC Director has gone to the Center Director with specific financial requests for these activities.

Additional COEC Comments

COEC directors also provided overall comments in an open ended question.

- One size does not fit all; it is essential that each COEC develop strategies and approaches that work best for their individual needs.
- Much of the research at NIEHS does not address the real world concerns of State Departments of Public Health and Environmental Quality or of the EPA.
- COECs should be allowed to do what their community wants/needs and should be evaluated on the effectiveness and impact.
- COECs cannot dictate to partners what we can /should do, it has to be a mutual collaboration based on their [the partner's] needs and goals. Outreach and Education programs should work with their target audiences to determine needs and then identify the best ways to meet those needs. Getting time with students/teachers requires that we "provide" something that assists them in achieving their goals.
- Programs that stimulate student interest in science/health careers will not be successful if they focus exclusively on high school and undergraduate students. Activities/programs that focus on younger and mid-level students are also needed.
- The redirection of COEC to Partnerships in Environmental Health presents many positive opportunities for COEC, but may also lead down a narrow focus of issues driven by community activists that do not necessarily represent the larger community or tackle actual risk (rather issues of risk perception or advocacy positions may be put forward that distract from pressing environmental health issues).
- NIEHS should consider increasing COEC budget
- It is difficult to determine what activities are allowed and which ones are not allowed under the new guidelines. The narrow focus of the review panels of the newest vision of COEC is constraining

Conclusions and recommendations

Responses to the Community Outreach and Education Cores (COECs) questionnaire indicate a positive trend of meaningful dialogue and genuine partnerships with the community. It is important that this work continue. The COEC's are reaching a broad range of target audiences, a good portion of which are newly added since the guidelines were initiated. CABs appear to have influenced community involvement as well as research questions. The formal addition of a Community Advisory Board (CAB) does not appear to be an undue burden, in fact, a range of creative strategies have been employed to establish the CABs.

Questions for Future Assessments

During our discussions throughout the P30 Core Center's Assessment, the Assessment Team kept track of potential questions for future analyses and evaluations for the Core Centers. Overall, there is great interest in understanding the general scientific impact of the Core Centers, but this was well beyond the scope of our current assessment.

Other, more detailed analyses that came up during various discussions included:

- Assess "cutting edge" technologies that are being used in the Facility Cores, how has this changed over time?
- Evaluate the P30 Core Centers program components in relation to other large programs, such as the Superfund Research Program (P42) or multiprogram project grant programs (P01).
- Fully evaluate the return on investment for the Pilot Projects.
- Conduct future bibliometric analyses.
    - Look at Center outputs to evaluate center impacts more fully.
    - Assess publication reporting gaps: i.e., how do publications reported on progress reports differ from what is available in SPIRES/Pubmed.
- Expand data collection for assessment of review/scoring changes.
    - Survey the reviewers themselves.
    - Survey all applicants (both funded and unfunded).
- Explore possibility/interest of Core Center Directors in tracking trainees through a system in development at NIEHS (CareerTrac)
- Look at CAB Recruitment procedures to determine strengths and weaknesses of each.

Appendix 1: List of Changes to the EHS Core Center Guidelines: Cohorts funded FY 2007-2011

This following changes were made to the EHS Core Center Guidelines for the time frames appropriate to the assessment.

FY2007 Funding

The following changes were implemented September 1, 2005 for new and competing applications to the Environmental Health Sciences Core Centers:

1. NIEHS merged the NIEHS Core Centers and Marine Freshwater Biology Centers programs into a single program entitled, "The Environmental Health Sciences Core Centers Program" (EHS Core Centers).

2. Site visits are no longer conducted as part of the review process. Program staff may decide to visit selected applicants to gain further information on which to base funding decisions.

3. The program endeavors to focus investigators to a greater extent on clinical applications, translation, and interdisciplinary research that will have a greater impact on human disease and public health.

4. In order to provide increased flexibility in organization and structure of the EHS Core Center, the Director may develop a dynamic structure which meets the on-going intellectual needs of the Center. This structure can change as the intellectual needs change to accommodate new opportunities for collaboration. Research Cores are no longer required as organizational units in the Center. The proposed Center organization must include the required components outlined above, but, beyond those, no additional structure is imposed by NIEHS.

5. An Integrative Health Sciences Facilities Core is required as one of the Center Facility Cores.

6. Greater emphasis on career development for environmental health scientists is encouraged. The application needs to address plans that will promote training of new investigators and bring new expertise into the area of environmental health sciences. Specify the plans to cross-train researchers in current techniques that are absent from the EHS Core center or individual research programs. Training and cross-training may include collaborations that will introduce a focus on human subjects and tissues into laboratory-based studies.

7. Community Outreach and Education programs which focus on partnering with stakeholders in order to disseminate EHS Center research results are important to the Core Centers program, but in our solicitations we consider them optional. This is to allow Centers who excel at Community Outreach and Education to incorporate them into their centers. Those Centers who chose not to have a Community Outreach Program are not penalized. Centers that choose to apply for a Community Outreach and Education Core are eligible for additional $100,000 direct costs. Kindergarten-Grade12 curriculum development and implementation is no longer allowed as a COEC activity.

8. Instituted a new set of Essential Characteristics for the competing renewal:

    - Strategic Vision and Impact on Environmental Health
    - Environmental Health Sciences Identity – the Center's capacity, breadth, and size of research related to environmental health sciences
    - Center Director

- Career Development for Environmental Health Investigators
- Institutional Commitment

9. Organizational Elements of the Center
    - Administrative Core
    - Facility/Service Cores
    - Integrative Health Sciences Facility Core
    - Pilot Project Program
    - Community Outreach and Education Core (COEC) – optional, but if included can receive up to $100,000 direct costs per year

10. Page limits apply to the application (see Section IV, Part 6 "Other Submission Requirements" of this RFA). Applicants can download preformatted tables to facilitate completion of the application from the NIEHS website at http://www.niehs.nih.gov/centers/appguide.htm

FY 2008 Funding

The following change was implemented in October 2006:

Applications may include up to 10% of the budget dedicated to a Director's Fund to be used for rapid responses to new and emerging opportunities in environmental health sciences. [In October 2007, the caps were applied to the Director's fund: Applications may include up to 10% of the budget - up to $100,000.00 in any one budget period –to the Director's Fund. A direct cost cap of $200,000 is imposed at all times and, with NIEHS approval, EHS Core Centers may carry forward a maximum of $200,000 within the Director's Fund.]

FY 2009 Funding

The following change was implemented in October, 2007:

Changes in Tables A, C, D, and E – Simplifications have been made to these tables that are provided to applicants to assist in completion of the application. Applicants are encouraged to download the updated tables from the EHS Core Center Program web page at: http://www.niehs.nih.gov/centers/appguide.htm.

FY2010 Funding

The following changes were implemented in October, 2008:

1. Page Limit changes (not shown here because superseded by changes for 2011 funding).

2. Community Outreach and Education Cores are required. Maximum $100,000 direct costs for the COEC (bringing the total cost for the Core Center to $1.1 million).

FY 2011 Funding

As of October 2009, the COEC became a required element of the EHS Core Center and must be an integrated component of the program. The Center is expected to provide a minimum of $100,000 annual direct costs to the COEC (RFA-ES-10-001).

In concert with NIH Requirements, new page limits were also implemented in October 2009:

PAGE LIMITS

1. Strategic Vision and Impact on Environmental Health – 12 pages
2. Environmental Health Identity and Impact of Research Base – 12 pages
3. Center Director - 5 pages
4. Career Development – 10 pages
5. Institutional Commitment – 5 pages
6. Administrative Core – 12 pages
7. Each Facility Core – 12 pages
8. Pilot Projects – 12 pages
9. COEC (optional)– 12 pages

FY 2012 Funding

A supplemental funding opportunity was offered to grantees without a COEC in June 2010 (RFA-ES-10-009).

Appendix 2: Assessment Timeline

Plans for conducting the NIEHS P30 Core Centers Assessment were announced at the February 2010 Council. The Assessment Team was chaired by Dr. Christie Drew, Chief Program Analysis Branch. Division of Extramural Research and Training Team members included: Dr. Linda Bass, Ms. Pam Clarke, Ms. Helena Davis, Dr. Jerry Heindel, Mr. Liam O'Fallon, Mr. Aaron Nicholas, Mr. Jerry Phelps, and Dr. Les Reinlib, Dr. Claudia Thompson. Two Council Liaisons were recruited, Dr. Stephen Lloyd, Oregon Health & Science University, and Dr. Palmer Taylor, University of California, San Diego.

The schedule for the Assessment was as follows:

Feb 17, 2010	Overview Presentation to NAEHS Council.
Mar, 2010	DERT Team members began planning the assessment and compiling secondary data sources.
Apr 1, 2010	Initial kick off meeting (teleconference). A background document was prepared for discussion. We reviewed the major assessment topic areas, changes to the guidelines in each of those areas, and assessment questions and approaches for those areas.
May 13, 2010	Meeting to discuss progress and review draft questionnaires (face-to-face). The team created 2 surveys for primary data collection that was sent to PIs and COEC directors of cohorts one and two after the changes were implemented in 2006.
May-Jun 2010	DERT Assessment Team conducted analysis of secondary data: grant applications, publication data, scoring.
May 18, 2010	Survey's sent to seven PI's and five COEC Center Directors.
Jun 4, 2010	Survey responses due.
Jun 6, 2010	Follow up email sent to non respondents by COEC Program Director (Reinlib).
Jun 17, 2010	Final follow up email sent to non respondents.
Jun 23, 2010	Final PI survey submitted accepted for inclusion in the analysis.
Jul 2, 2010	Initial assessment results distributed to committee.
Jul 26, 2010	Final Assessment Team meeting held to discuss results and formulate conclusions.
Sep 1, 2010	Report completed, presented to NAEHS Council.

Appendix 3. Definitions for Facility Core Areas

(These definitions, created for the 2004 NIEHS Core Centers Assessment, were also used in the Facility Core analysis for the current assessment.)

Area	Common Tools Used/Services Provided	Purpose
Analytical	High Performance Liquid Chromatography (HPLC) stations, gas chromatography/mass spectrometer (CG/MS), Atomic Absorption	Provide analytical support including sample preparation, extraction and standard analytical measurements to Center investigators. For some it is to measure and detect organic/inorganic metabolites, peptides and proteins.
Animal Models	Microinjections (DNA & Blastocyst), hatcheries (trout, zebrafish, etc.), primates, mice	Provide resources for the development and manipulation of model systems. They primarily help develop and utilize transgenic animal models.
Biostatistics Bioinformatics	Databases, statistical software (SAS, SPSS), SUN Stations, spatial analysis, gene-expression array analysis.	Provide direction on experimental design, data collection and management; they are available for consultation on data analysis; and develop innovative biostatistical methods for the analysis of environmental data.
Cell Biology	Cell culture, microinjection, histopathology, Coulter counter, tissue preparation	Enhance the experimentation and interpretation of research at the cellular level. Provide assistance in the development of cell culture models.
Exposure Assessment	Human & animal exposure chambers, HPLC, Sampling devices, Air monitors, Mass Spec.	Provide one or more of the following 1) Research Planning; 2) Instrumentation; 3) Equipment Maintenance and Calibration; 4) Laboratory Analysis; and 5) Field Support.
Imaging	microscopy (confocal laser, fluorescent, video) flow cytometry, cell sorter, digital analysis, tissue preparation, immunohistochemical staining	Provide state of the art microscopic imaging instrumentation and technology to further Center member research.
Microarray	Affymetrix microarray, PCR, Affymetrix genechip system, bioinformatics resource -- Sun V880 dual processor server	Provide state of the art technologies for analysis of gene expression and protein production. Access to instrumentation, instruction and help in methods and training in data analysis.
Miscellaneous	Microscopes, Databases, HPLC, cell cultures, culture systems.	These are unique facilities that didn't fit into a larger group.
Molecular Biology	DNA sequencer, RT-PCR, DNA Analyzer, DNA Synthesizer	Provide both routine and specialized molecular biology services to Center investigators. Help identify, introduce/develop, and implement new technologies to meet needs of Center members.
Molecular Structures	Nuclear Magnetic Resonance Spectrometers and Ancillary Equipment, X-ray crystallography, Silicon Graphics	Provide advanced instrumentation, training, and expertise necessary for accurate determination of the molecular structure of organic compounds. Produce vivid 3-D pictures and models.
Proteomics	MALDI TOF Mass Spec, protein sequencing, LCQ electrospray ion-trap mass spectrometer, gels, HPLC	Provide for the systematic analysis of proteins for their identity, quantity and function via state-of-the-art modern mass spectrometry. Also provide for structural analysis of biological molecules and for qualitative and quantitative assays of xenobiotic agents and metabolites in tissues
Shared Instrumentation	DNA sequencers, molecular biology stocks, Electron Microscope Imaging Core,	Provide Center members with access to state-of-the-art research facilities and approaches that would not be possible to develop or maintain using Center resources alone.
Toxicogenomics	Automated Capillary DNA sequencers, Affymetrix GeneChip System, protein sequencing, Mass Spectrometers, RT/PCR	Provide rapid, accurate, and state of the art sequencing and microarray capabilities by expert technical personnel.