

# **NIEHS and EPA Children's Environmental Health and Disease Prevention Research Centers**

**Technical Assistance Webinar**

**RFA-ES-14-002**

## Virtual Housekeeping

- **Submit Questions:** Use the Q&A Box at any time to send us your questions. We will collect them, read them aloud, and respond to them during the webinar.
- **Mute Phones:** Please mute your phone during the webinar. Due to the expected number of participants, questions will be taken by Q&A box only.
- **Recording:** We will be recording today's webinar.
- **FAQs:** We will develop an FAQ document from the questions we receive and the answers we provide today. It will be posted at <http://www.niehs.nih.gov/research/supported/dert/programs/prevention/index.cfm>.
- **Technical Difficulty:** Please use the Q&A Box. If that is not working, contact [ofallon@niehs.nih.gov](mailto:ofallon@niehs.nih.gov).

## Who We Are at NIEHS

### Program Directors:

Kimberly Gray and Liam O'Fallon

### Scientific Review Officer:

Linda Bass

### Grants Management Specialist:

Molly Puente



# Who We Are at EPA

## Project Officers

Rich Callan and Nica Louie

EPA National Center for Environmental Research (NCER)

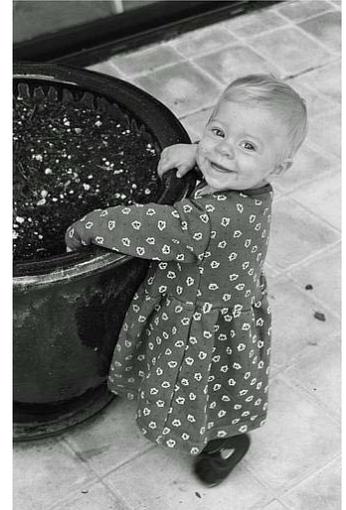
## Human Subjects Research Review Official

Toby Schonfeld

EPA Office of the Science Advisor

“...EPA’s responsibility to protect public health and the environment is driven in large part by our duty to protect our kids and future generations.”

– EPA Administrator Gina McCarthy (10/14/2014)



## Children's Environmental Health & Disease Prevention Research Centers



- Promote multidisciplinary interactions
- Turn research into real world interventions and solutions
- Establish a national network of Centers and researchers
- Engage with communities to address their concerns

# Funding Opportunity Reissue (now P50)

- Posted: September 30, 2014
- LOI: November 22, 2014  
*(Letter of Intent)*
- Due Date: December 22, 2014
- Review Date: May 2015
- Council Date: August 2015
- Start Date: September 1 2015



Joseph Tart/EHP

# Anticipated Funding and Potential Number of Awards

**\$7 million** – combined budget from NIEHS and EPA per year for four years

**4-5 awards** – potential number of Centers

**\$1.5 million** – total costs for renewal applications (former P01s in past two years)

**\$1.25 million** – total costs for new applications

## Program Objectives

- Leverage and build upon research findings and resources
- Enhance the application of novel findings and approaches
- Develop, validate, discover and apply new or improved lifestage-specific biomarkers of exposure and early effect
- Introduce new investigators to state-of-the-art tool and methodologies
- Ensure active participation of identified stakeholders and the broader community

# Types of Exposure

## Required

- Applicants must study one or more environmental agent(s)/chemical(s)/stressor(s) to which there is human exposure and or the potential for exposure.

## Encouraged

- Non-chemical stressors (e.g., nutrition, social, economic, stress, socioeconomic status, race/ethnicity, and cultural factors) cannot be considered alone, but applicants are encouraged to include them as secondary or modifying variables to the primary environmental stressor(s).

# Required Elements

- 3 Research projects (each similar to an R01)
- Community Engagement including a Community Outreach and Translation Core (COTC)
- Health Specialist
- Career Development Plan
- Administrative Core
- Data Sharing Plan

# Community Engagement

- Community Outreach Translation Core (COTC) required
  - Active participation of relevant stakeholders
  - Develop strategies to translate scientific findings to key audience for the protection of children's health.
- Additional approaches for community engagement
  - Community-engaged Research (CEnR) Plan
  - Community Advisory Board

# Health Specialist

- Qualified active researcher to assist with coordination and integration of scientific projects
- Ensure that the science under investigation will translate to clinical practice or improved public health
- Discipline that has direct contact with mothers and/or young children and relevant to the Center's scientific theme
- NOT the Center Director

# Career Development Plan

- Designed to foster the next generation of scientists in children's environmental health research
- New, junior faculty-level investigator, Career Development Investigator (CDI)
  - Fewer than 8 years postdoc experience
- At least 3 person-months and long-term commitment to research
- Application should include (1) Letter from candidate outlining goals and (2) Description of the career development proposed
- Or If candidate unknown, general plan to recruit CDI is required

# Administrative Core

- Provide details about how project objectives will be successfully achieved within the project period;
- External Advisory Committee (EAC)
  - Two-thirds of EAC membership from outside grantee institution
  - Provide only description of committee representation and expertise
- Provide a plan for tracking the impact of CEHC on investigator development should be described.
- Assist in coordinating and planning meeting of CEHC investigators.

# Data Sharing Plan

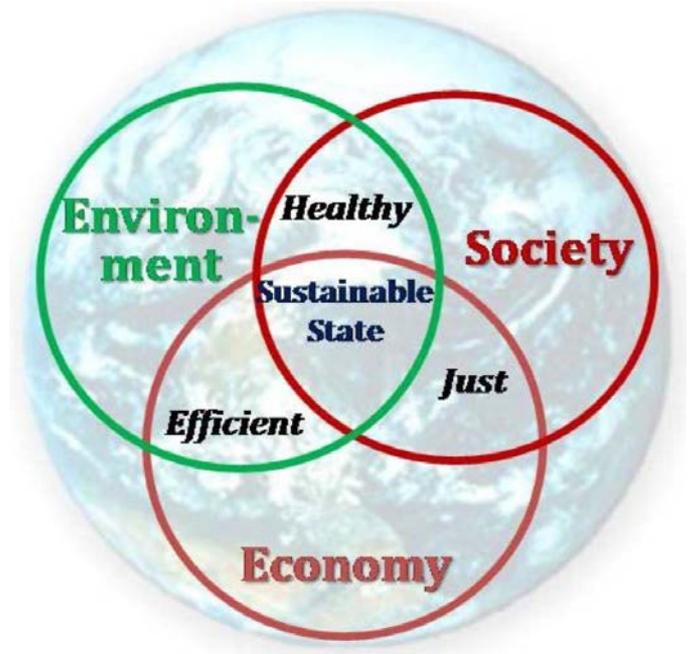
- Data sharing plan to facilitate data sharing with other Centers, federal researchers, the public and key stake holders.
- Provide a plan to make all data resulting from this FOA available in a format and with documentation/metadata such that they may be used by others in the scientific community.
- Databases containing proprietary or restricted information are expected to included a strategy to make the data widely available, while protecting privacy or property rights.
- Data sharing plan is part of the COTC.

## EPA Requirements

- Proposed research focus must consist of activities within the statutory terms of EPA's financial assistance authorities:
  - **Safe Drinking Water Act**, Section 1442, 42 U.S.C. 300j-1;
  - **Toxic Substances Control Act**, Section 10, 15 U.S.C. 2609;
  - **Federal Insecticide, Fungicide, and Rodenticide Act**, Section 20, 7 U.S.C. 136r;
  - **Clean Air Act**, Section 103, 42 U.S.C. 7403;
  - **Clean Water Act**, Section 104, 33 U.S.C. 1254;
  - **Solid Waste Disposal Act**, Section 8001, 42 U.S.C. 6981.
  - For research with an international aspect, the above statutes are supplemented, as appropriate, by the **National Environmental Policy Act**, Section 102(2)(F). - See more at: <http://grants.nih.gov/grants/guide/rfa-files/RFA-ES-14-002.html#sthash.DkLOXAZ7.yyOu4n6j.dpuf>

# EPA Requirements

- Generally, a project must address the causes, effects, extent, prevention, reduction, and elimination of air pollution, water pollution, solid/hazardous waste pollution, toxic substances control, or pesticide control
  - Non-chemical stressors, social and cultural factors, and settings cannot be considered alone, but may be included as modifier variables to the primary environmental stressor(s).



# EPA Requirements

- The relevance of the proposed science to EPA research priorities, including alignment with ORD's Sustainable and Healthy Communities Programs Research Priorities at <http://www2.epa.gov/epa-research/sustainable-and-health-communities-strategic-research-action-plan-2012-2016>
- Non-U.S. entities are not eligible to apply
- Foreign components are allowed but require approval from EPA's Office of International and Tribal Affairs (OITA) [http://grants.nih.gov/grants/policy/nihgps\\_2013/nihgps\\_ch1.htm#def\\_foreign\\_component](http://grants.nih.gov/grants/policy/nihgps_2013/nihgps_ch1.htm#def_foreign_component)



# Human Subjects Research (HSR) at EPA

Investigators may not intentionally expose (increase, decrease, or otherwise change the exposure) of the following groups of people:

- Children
- Pregnant Women
- Nursing Women

## 2-step approval for HSR:

- 1) Conditional approval: prior to decision meeting
- 2) Final approval: after award; after IRB approval

## For more information:

<http://www.epa.gov/osa/phre/index.htm>

<http://www.epa.gov/osa/phre/project.htm>

## Human Subjects Research – EPA requirements

- If the proposed research does not involve human subjects:  
Provide statement and clear justification
- If the proposed research involves human subjects, provide a Human subjects research statement (HSRS) that:
  - Addresses each applicable section listed in the RFA under the Sub-heading: *EPA Human Subjects Research Statement (HSRS) Requirements* (Section IV: Application and Submission Information; Subsection 2: Content and Form of Application Submission; Heading: PHS 398 Research Plan (Research Projects))
  - Items 1-8 for all studies involving human subjects
  - Items 9-15 for studies involving intentional exposures (may not include children, pregnant or nursing women)
  - For each research project - do not exceed 6 consecutively numbered, 8.5x11-inch pages of single-spaced, standard 12-point type with 1-inch margins

# What's new

- Changed from P01 to P50.
  - All previously awarded P01s will get new P50 number and will be considered competing renewals.
  - Overall program objective and format are the same
- Capped Total Costs.
  - 1.5 million total costs per year for competing renewals.
  - 1.25 million total costs per year for new applications.
- Limit to 4 years of funding.
- Career Development Investigator and Plan has replaced the term Faculty Development
- Required data sharing plan.
  - Reviewed element in proposal.
- Electronic Application.

# Electronic Application

- Paper submissions will not be accepted
- Please start the application process early!
- Recommend between **five to seven business days**
- Look for confirmation...
- Avoiding common errors:  
[http://grants.nih.gov/grants/ElectronicReceipt/avoiding\\_errors.htm](http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm)



# Page Limitations

<b>Component Types Available in ASSIST</b>	<b>Research Strategy/ Program Plan Page Limits</b>
Overall	12
Admin Core	12
COTC	6
Facility Cores (optional)	6
Project (use for Research Project)	12

# ASSIST

## (Application Submission System & Interface For Submission Tracking)

- Start early (follow instructions in the RFA)
- Entering components
- Human Subjects/Animal Welfare
- Budgets
- Resource Sharing Plans
- eRA Help Desk, Monday-Friday, 7am-8pm Eastern Time
- 301-402-7469; Toll Free: 866-504-9552
- <http://grants.nih.gov/support/index.html>

# Review Criteria

## Research Projects \*

- **Scored Review Criteria**

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

- **Additional Review Criteria**

- Protections for Human Subjects
- Incl. Women, Minorities and Children
- Vertebrate Animals
- Biohazards

- **Overall Impact Score**

- **Additional Review Considerations**

- Resource Sharing Plans
- Budget and Period of Support

## Criterion Scores

\* Each assigned reviewer provides scores (1-9) for each criterion. The Overall Impact Score is **NOT** an average of these Criterion Scores.

## Core Components

**Each Core will be reviewed and receive an Impact Score**

(no Criterion Scores)

# Overall Center Impact/Priority Score

**\*\*The Overall Impact Score is NOT an average of the different components, but the scientific merit of the Center as a whole. Whether the whole of the Center is greater than sum of components.\*\***

**Merit of Projects and Cores:** The coordination and interrelationships of all individual research projects and cores to the common theme of the Center. The interactive and collaborative research opportunities that exist within the program. The scientific gain of combining the components.

**Integration:** The overall quality of the synergy among the research projects and cores.

**Leadership:** The ability of the Program Director and their commitment to develop a well-defined central research focus for the Center.

**Translation:** The bidirectional flow and dissemination of information that involve scientists and public health professionals that can lead to public health action.

**Involvement** of a Health Specialist and the **Career Development** of new/junior investigators in EHS.

**Final Score  
(Range: 10-90)**

# 9-point Scoring Descriptions

Impact	Score	Descriptor	Strengths/Weaknesses
High Impact	1	Exceptional	
	2	Outstanding	
	3	Excellent	
Moderate Impact	4	Very Good	
	5	Good	
	6	Satisfactory	
Low Impact	7	Fair	
	8	Marginal	
	9	Poor	

**Non-numeric score options:** NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND=Not Discussed



# Questions?

**Please type questions into the Q&A box.**

**We will read out the questions we receive.**

**FAQ sheet will be available online at:**

**<http://www.niehs.nih.gov/research/supported/dert/programs/prevention/index.cfm>**