Welcome to the CLU-IN Internet Seminar
Superfund Research Program P42 RFA Briefing (RFA ES 18-002)
Sponsored by:
National Institute of Environmental Health Sciences, Superfund Research Program

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Webinar Logistics:
Sara Amolegbe, MDB Inc., (samolegbe@michaeldbaker.com)

July 23, 2018 1:00 – 2:30 p.m. EST

Link to RFA: https://grants.nih.gov/grants/guide/rfa-files/RFA-ES-18-002.html
Link to RFA Information Page:
https://www.niehs.nih.gov/research/supported/centers/srp/funding/rfa/index.cfm

NIH
National Institute of Environmental Health Sciences
Superfund Research Program

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Funding Opportunity Webinar – P42 Center RFA ES-18-002

Agenda

- Welcome and Overview of P42 funding mechanism: William Suk (SRP Director)

- P42 RFA

  - General Information: Heather Henry, Danielle Carlin and Michelle Heacock, and Brittany Trottier

  - Review Criteria: Janice Allen (Scientific Review Officer)

  - Budget: Lisa Archer-Edwards (Grants Management Officer)

- Question / Answer

SRP Mandates under SARA

University-based basic research program established in 1986 under Superfund Amendments Reauthorization Act (SARA)

Development of:

Health Effects

- Advanced techniques for the detection, assessment, and evaluation of the human health effects of hazardous substances

Assessing Risks

- Methods to assess the risks to human health presented by hazardous substances

Detection

- Methods and technologies to detect hazardous substances in the environment

Remediation

- Basic biological, chemical, and physical methods to reduce the amount and toxicity of hazardous substances

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SRP Mandates: https://www.niehs.nih.gov/research/supported/centers/srp/about/program/index.cfm

SRP Strategic Plan

- Relevance
  - Interaction with stakeholders
  - Problem-based, solution-oriented research
  - Critical research areas
- Impact
- Innovation

SRP Stakeholders

- US Environmental Protection Agency (USEPA)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- National Oceanic and Atmospheric Administration
- U.S. Geological Survey
- U.S. Department of Defense
- U.S. Department of Energy
- Other federal agencies, state, local, and tribal entities responsible for sites
- Individuals and communities living near hazardous waste sites

SRP Strategic Plan: https://www.niehs.nih.gov/research/supported/centers/srp/about/register/index.cfm
SRP Website: https://www.niehs.nih.gov/research/supported/centers/srp/index.cfm

P42 Multi-Project Centers

RFA-ES-18-002

SUPERFUND HAZARDOUS SUBSTANCE RESEARCH AND TRAINING PROGRAM (P42)

Improve public health by supporting integrative, multi-disciplinary research.

Provide sound science, data, information, and knowledge to inform the risk assessment and remediation management processes.
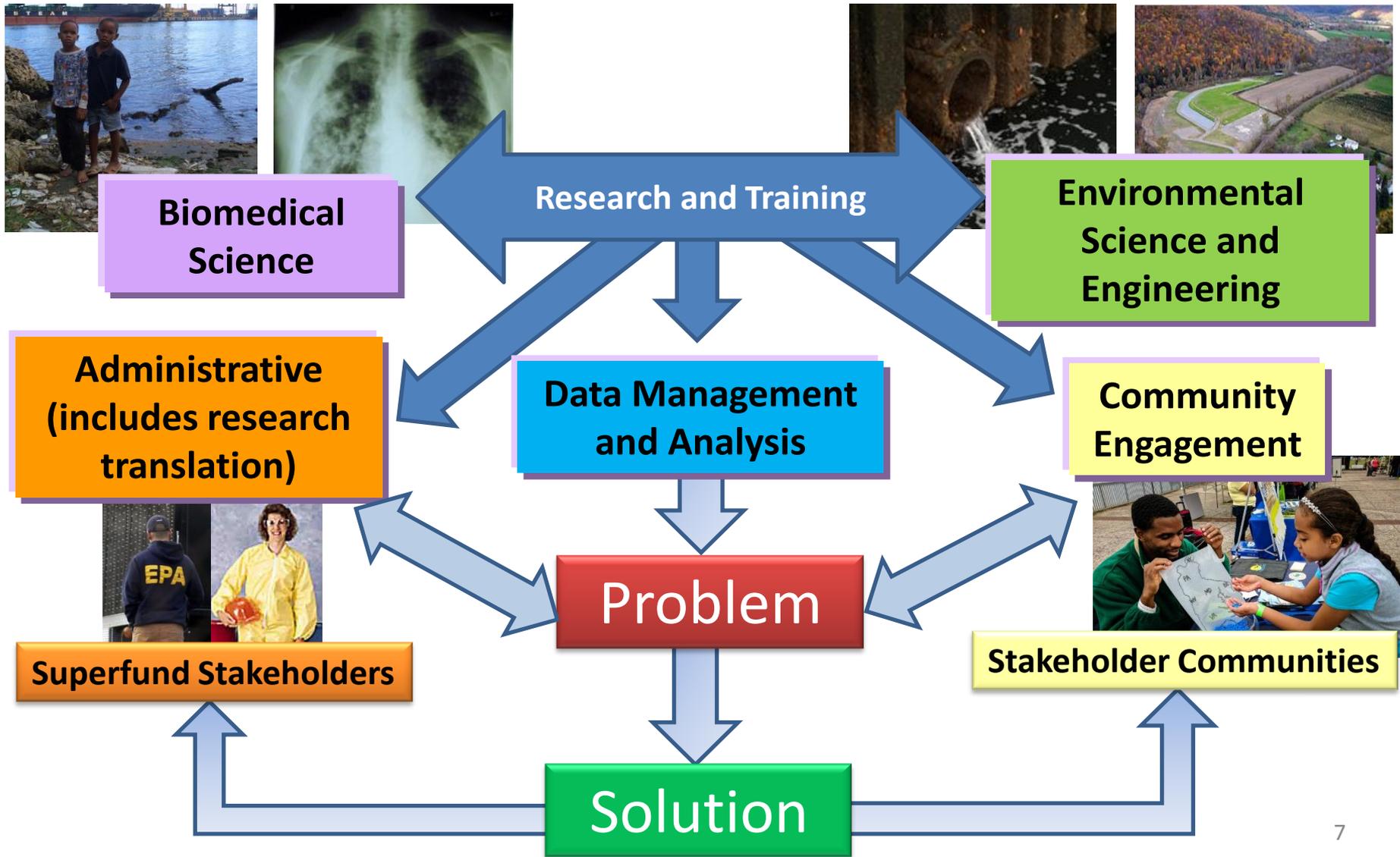
Bring expertise of multiple biomedical and environmental science and engineering disciplines to address scientific uncertainties facing the National Superfund Program.

- P42 RFA Website: https://www.niehs.nih.gov/research/supported/centers/srp/funding/rfa/index.cfm
- RFA-ES-18-002: https://grants.nih.gov/grants/guide/rfa-files/RFA-ES-18-002.html
- Suggested Research and Activities Document: https://www.niehs.nih.gov/research/supported/centers/srp/assets/docs/srp_funding_opps_suggested_research_and_activities_508.pdf
- Tips for Applicants: https://www.niehs.nih.gov/research/supported/centers/srp/funding/rfa/rfa_tips/index.cfm
- Additional Resources: https://www.niehs.nih.gov/research/supported/centers/srp/funding/rfa/rfa_resources/index.cfm

Key Dates

- Open Date (Earliest Submission Date): November 19, 2018

- Letter of Intent Due Date(s): November 19, 2018

- Application Due Date(s): December 19, 2018, by 5:00 PM Eastern Time

- Scientific Merit Review: May 2019

- Advisory Council Review: October 2019

- Earliest Start Date: December 1, 2019

P42 Multi-Project Centers

Biomedical Science

Research and Training

Environmental Science and Engineering

Administrative (includes research translation)

Data Management and Analysis

Community Engagement

Superfund Stakeholders

Problem

Stakeholder Communities

Solution

P42 Multi-Project Centers
Scope of the SRP Center Grant

SRP Mandates
- Advanced techniques for the detection, assessment, and evaluation of the effect of hazardous substances on **human health**
- Methods to assess the **risks** to human health presented by hazardous substances
- Methods and technologies to **detect** hazardous substances in the environment
- Basic biological, chemical, and physical methods to **reduce the amount and toxicity** of hazardous substances

SRP's Strategic Plan
- **Relevance:** to Superfund
- **Impact:** to Stakeholders
- **Innovation:** Trans-disciplinary/Paradigm-shifting

Not Required: Superfund Site

CERCLA Substances/Hazardous Substances:
https://www.atsdr.cdc.gov/SPL/index.html;
https://www.niehs.nih.gov/research/supported/centers/srp/funding/rfa/rfa_resources/index.cfm
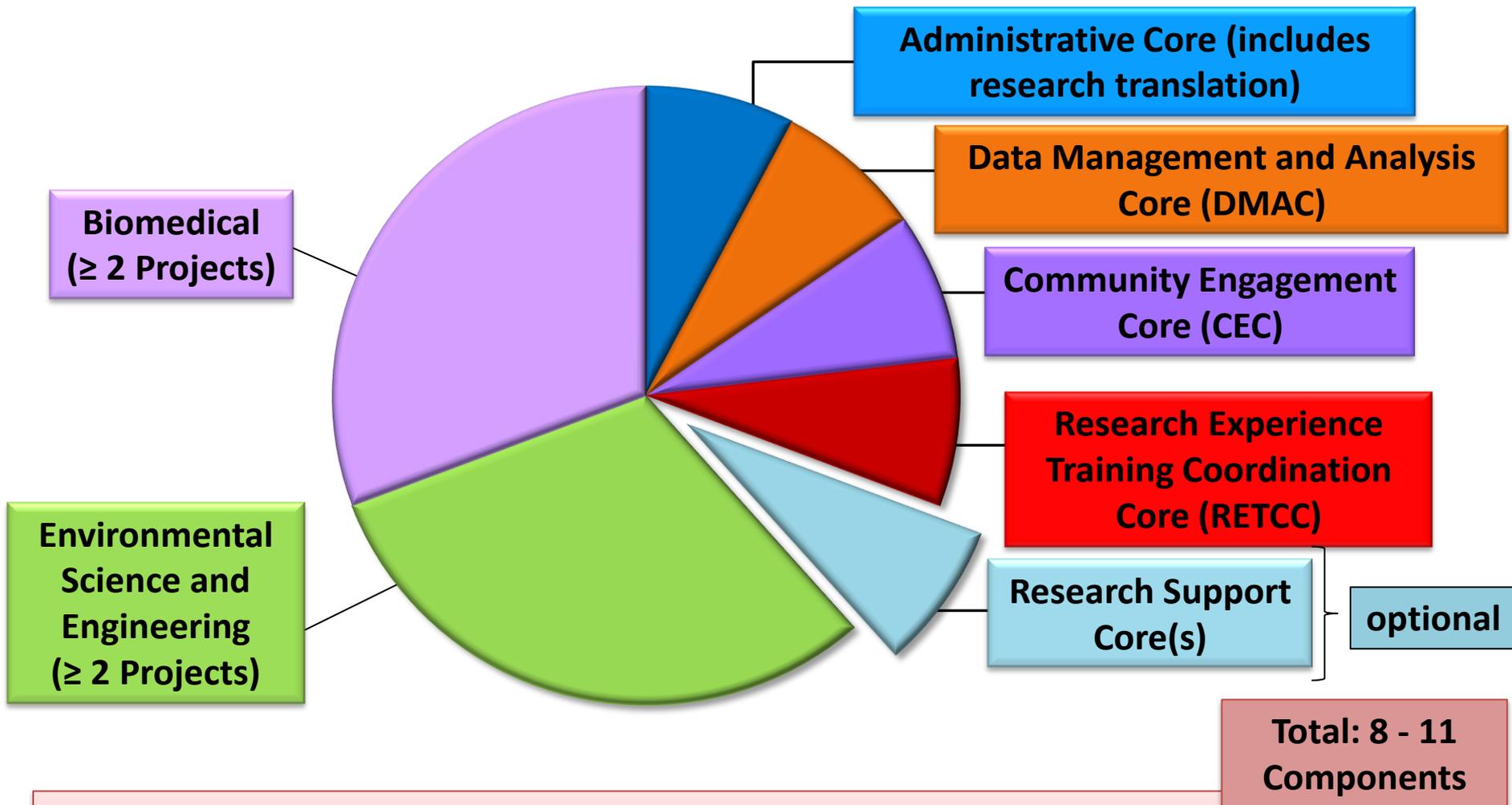
Suggested Research Topics and Activities
- High priority areas for SRP Stakeholders
https://www.niehs.nih.gov/research/supported/centers/srp/assets/docs/srp_funding_opps_suggested_research_and_activities_508.pdf

Programmatic Balance
- **See Current Grantees:**
http://tools.niehs.nih.gov/srp/programs/index267.cfm

**Broad Scope –
Ultimately should be a clear link to Superfund.**

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P42 Multi-Project Centers
All Components Interacting, Addressing Problem

Administrative Core (includes research translation)

Data Management and Analysis Core (DMAC)

Community Engagement Core (CEC)

Research Experience Training Coordination Core (RETCC)

Research Support Core(s)

optional

Biomedical (≥ 2 Projects)

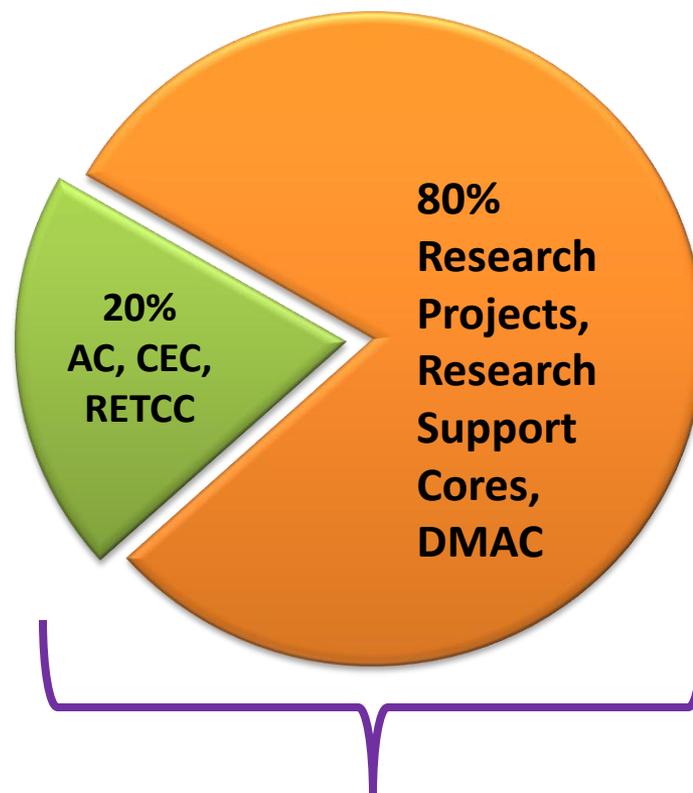Environmental Science and Engineering (≥ 2 Projects)

Total: 8 - 11 Components

New, Renewal Proposals, and Resubmissions: up to $1.75M/year direct costs for 5 years

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Cost Limitations (Direct)

Cores Sum ≤ 20% Total Center
Administrative
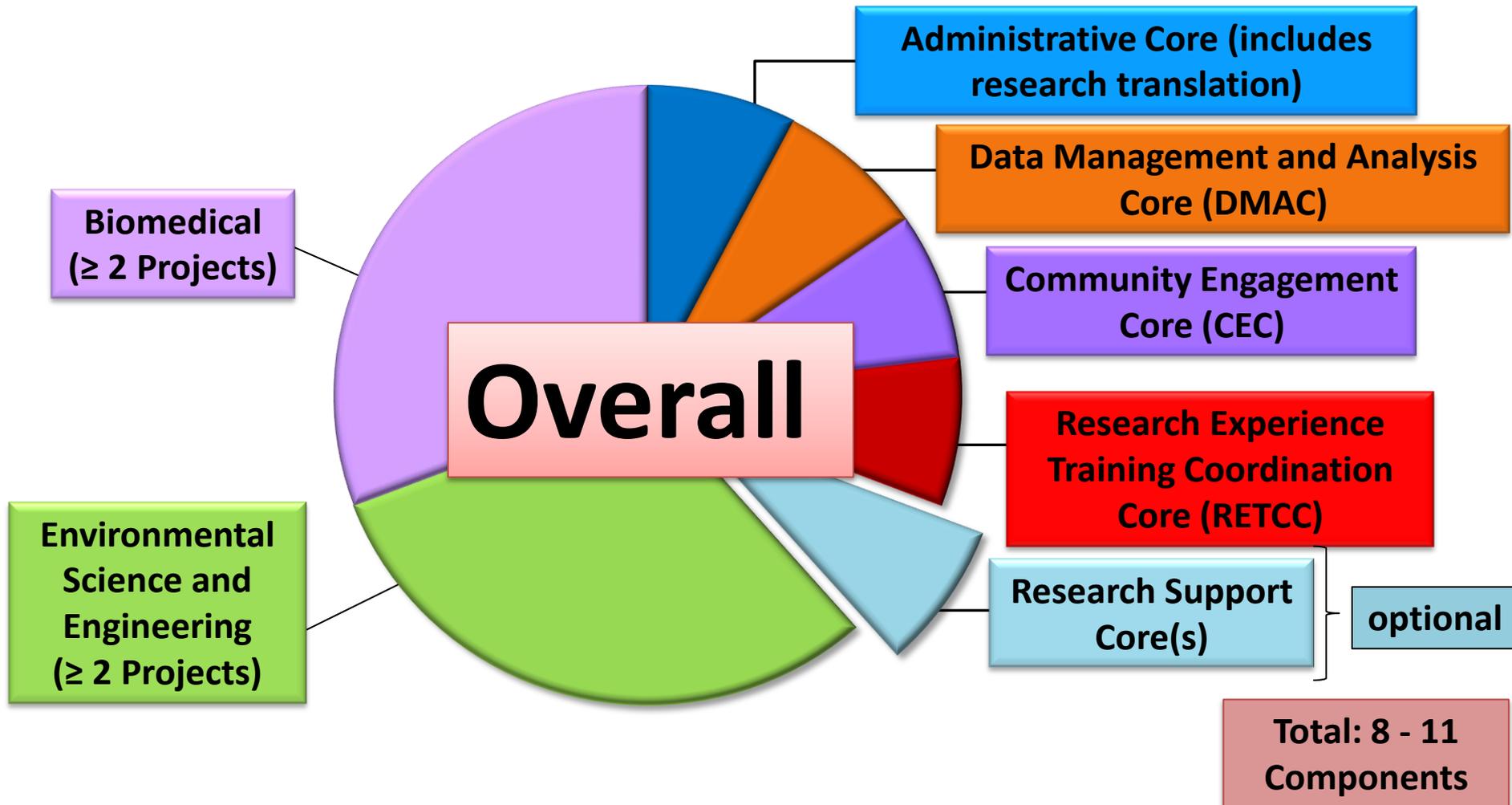**Community Engagement**
Research Experience and Training
Coordination

Core Limitations (Direct):

- **Administrative - $150K**

- **Community Engagement - $100K**

- **Research Experience and Training Coordination- $100K**

- **Data Management and Analysis – no set budget**

- **Research Support Core (Optional) – no set budget**

20% AC, CEC, RETCC

80% Research Projects, Research Support Cores, DMAC

Center:
New and Renewal Applicants: up to $1.75M/year direct costs for 5 years

Overall Component

Administrative Core (includes research translation)

Data Management and Analysis Core (DMAC)

Community Engagement Core (CEC)

Research Experience Training Coordination Core (RETCC)

Research Support Core(s)

optional

Biomedical (≥ 2 Projects)

Environmental Science and Engineering (≥ 2 Projects)
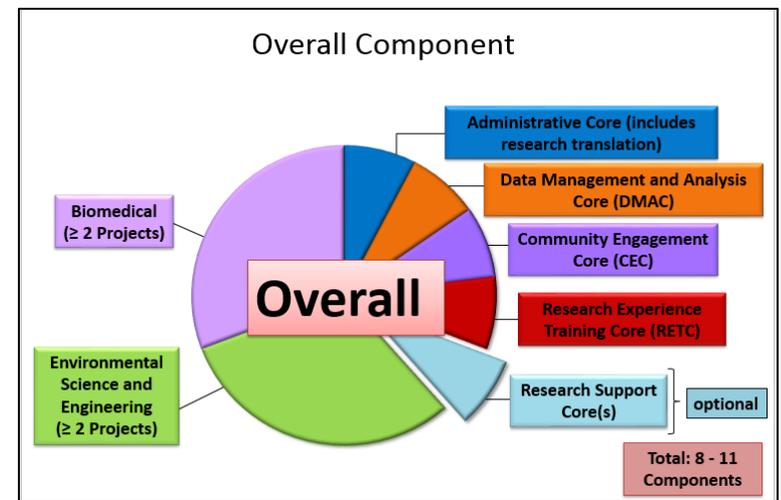
Overall

Total: 8 - 11 Components

Recommended Subsections: Significance and Relevance to SRP Mandates and Superfund; Research Team; Innovation, Approach; Environment; and Center Integration

Overall Component

Overall Component

Other Attachments

- *Center Organizational Structure*

- *Table of Research Support and Data Management and Analysis Core Utilization*

- *Table of Changes to Projects and Cores* (renewal/resubmission applications)

- *Table of Research Approaches*

- *Table of Integration with Center* **NEW!**

Resource Sharing Plan

- *Summary of Center Data Management and Analysis* **NEW!**

Tips for Applicants:
https://www.niehs.nih.gov/research/supported/centers/srp/funding/rfa/rfa_tips/index.cfm

Table Examples for Overall Section

Tips for Applicants

Superfund Research Program

The following links provide information for Superfund Research Program Center (P42) applicants to assist in putting together a P42 application. In addition to the information below, please visit the P42 Funding Opportunities Webpage, which contains links to Suggested Research and Activities 📄(485KB), Additional Resources, and Frequently Asked Questions (Coming Soon) for assisting P42 applicants in developing robust and relevant research projects and core activities.

Electronic Appl

Table of RSC and DMAC Utilization

Research Projects	Data Management and Analysis Core	Research Support Core A: Analytical Core	Research Support Core B: Statistics
Research Project 1	20%	50%	0
Research Project 2	20%	0	0
Research Project 3	20%	50%	30%
Research Project 4	20%	0	70%
Admin Core	5%	0	0
Research Experience and Training Coordination Core	5%	0	0
Community Engagement Core	5%	0	0
Research Support Core A	2.5%	N/A	0
Research Support Core B	2.5%	0	N/A

Table of Changes

Current Project Number/Core Name	Project/Core Status*	Project Core Leader	Title of Project/Core	Biomedical (BMR) or Environmental Science and Engineering (ESE)**	Previous Project Number/Core Name
Project 1	C	Georgia Matisse	Markers of Exposures to Mixtures	BMR	Project 1
Project 2	N	Pablo Braque	Individual Susceptibility to Disease Risk	BMR	New
Project 3	C	Ansel Modigliani	Redistribution of PAHs	ESE	Project 3
Project 4	M	Georges Picasso	PAH Remediation	ESE Mandate 4	Project 5
Administrative Core	C	Georgia Matisse	Administrative Core	-	Administrative Core
Data Management and Analysis Core	C	Juan Monet	Data Management and Analysis Core	-	Data and Biostatistics Core
Community Engagement Core	M	Claude Kolliwitz	Community Engagement Core	-	Community Engagement Core
Research Experience and Training Coordination Core	N	Georges Picasso	Research Experience and Training Coordination Core	-	Training Core
Core A	C	Kathe Pollack	Biomarker Core	-	Core A
Discontinued	F	Claude Pollock	Molecular Effects of Low Level Exposures	BMR	Project 2

* Please label in the following format: new = N; continuing = C; substantially modified = M; finished/completed = F; or discontinued = D.
** For research projects only

Table of Research Approaches

Illustration 3: Table of Research Approaches. To facilitate the identification of projects and cores, a table should be included indicating the use of human subjects, clinical research, vertebrate animals, international collaborations, and stem cells. Please list all research projects and cores. This table should be loaded as a pdf file titled "Table of Research Approaches" under the "SF424 (R&R) Research & Related Other Project Information" under "Other Attachments" in the Overall section.

Project Number or Core Letter	Human Subjects*	Clinical Trial	Vertebrate Animals	International Collaborations	Stem Cell Research**	NIH-Required Sharing***
Project 1	Yes	Yes	Yes	Yes	No	No
Project 2	Delayed Onset	No	No	No	non-hESC	Yes - GWAS
Project 3	No	No	Yes	Yes	Yes	Yes - Omics
Project 4	No	No	No	No	No	No
Core A	Yes	No	Yes	Yes	No	Unique Model Organism
Community Engagement Core	Delayed Onset (Survey)	No	No	Yes	No	No

Tips for Applicants:
https://www.niehs.nih.gov/research/supported/centers/srp/funding/rfa/rfa_tips/index.cfm

Table Examples for Overall Section

New: Table of Integration with Center **NEW!**

Illustration 4. Table of Integration with Center. To assist the reviewers in determining the relationship between components, a table should be provided showing interactions between projects and cores for the achievement of the Center's overall objectives. Applicants may want to include a key for the full project titles. All projects This table should be provided as a pdf file titled "Table of Integration with Center".

Integrated Research Goals	Project 1 (BMR)	Project 2 (BMR)	Project 3 (BMR)	Project 4 (ESE)	Project 5 (ESE)	Core A	Core B	Explanation of Integration
Finding targets and endpoints of X exposure	x		x			x		Results from Project 1 will determine the dose ranges for Project 3. Core A will determine gene networks activated for early biomarker of exposure in Projects 1 and 3.
Pathways of exposure prevention		x	x					Project 2 will identify gene targets for potential interventions (Project 3).
Targets for remediation	x			x	x		x	Project 1 and Core B will screen and identify the most toxic metabolites to inform Project 4 and 5 of which metabolites to monitor and remediate.
Fate and transport of X				x	x			Projects 4 and 5 will share sediment samples from the contaminated and control sites and will determine sensor technology predicts bioavailability.
Remediation effectiveness	x				x			Project 1 will run toxicity tests of byproducts of remediation technology (Project 4).
Analytical Support		x	x	x	x		x	Core B analysis of compound X for Projects 2-5.
	x	x			x		x	Core B analysis of compound Y for Projects 1-2, 5.
Biomarker monitoring			x	x				Project 4 will develop protocols to test sensor for external dose as well as biomonitoring for Project 3.

Project 1: (Title, PI Name); Project 2: (Title, PI Name); etc.

Tips for Applicants:
https://www.niehs.nih.gov/research/supported/centers/srp/funding/rfa/rfa_tips/index.cfm

Overall Resource Sharing Plan

- Current RFA: include a *"Summary of Center Data Management and Analysis"*
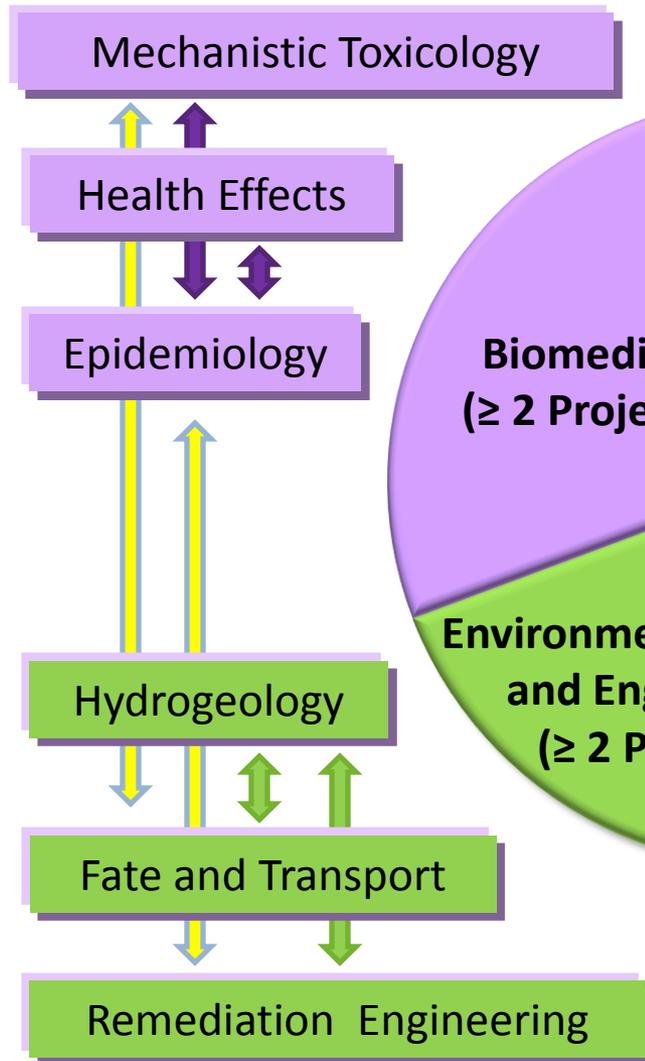
Resource Sharing Plan
- *Summary of Center Data Management and Analysis* **NEW!**

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide, with the following modification:

For the Overall Resource Sharing Plan, Centers should summarize data-sharing activities and the sharing of other resources (e.g., sharing model organisms, genomic data sharing, reagents, etc.) within and beyond the SRP Center in a "Summary of Center Data Management and Analysis".

Summary of Center Data Management and Analysis: The applicant should provide a Summary of Center Data Management and Analysis. This summary should include a general description of the types of data expected to be generated from the Center, a synopsis of proposed data management/sharing activities. Applicants may wish to highlight anticipated integration opportunities between projects and cores. Information included in this section should briefly summarize, but not duplicate, data management plans from the component sections of the application; however, applicants are encouraged to cross-reference DMAC component and project/core Resource Sharing Plans for additional details about data management and analysis.

P42 Projects

Mechanistic Toxicology

Health Effects

Epidemiology

Hydrogeology

Fate and Transport

Remediation Engineering

Biomedical (≥ 2 Projects)

Environmental Science and Engineering (≥ 2 Projects)

Maximum of 6 projects

- Each project is reviewed as stand-alone
- Basic to application oriented
- Has an independent testable hypothesis or a logical progression of tasks
- Relation to SRP mandate(s)
- Relation to Overall Center
- Integration with other projects and Cores
- Resource Sharing Plan
  - Sharing: data, specimens, technology
  - Data Management Plan (1 paragraph) **NEW!**
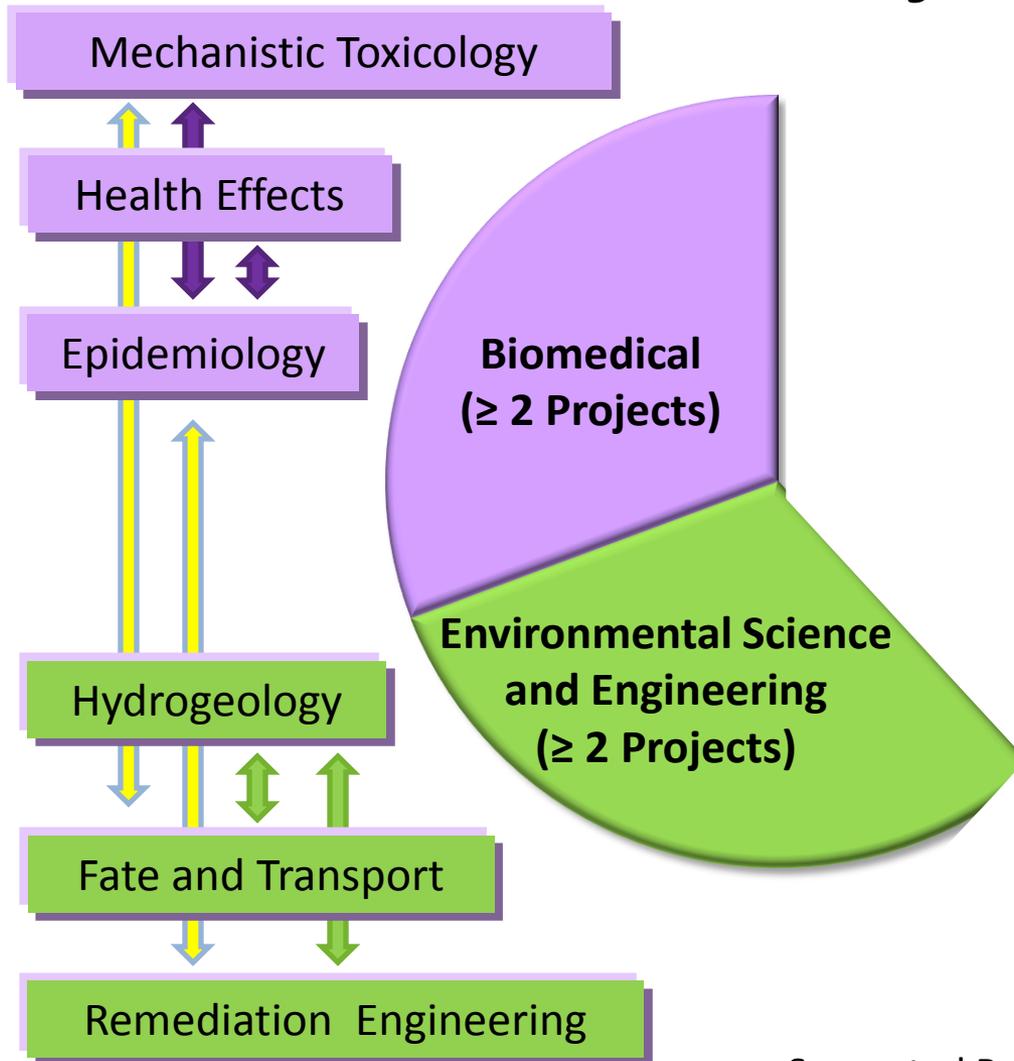 - Investigator-initiated research translation (1 paragraph)

Suggested Research and Activities:
https://www.niehs.nih.gov/research/supported/centers/srp/assets/docs/srp_funding_opps_suggested_research_and_activities_508.pdf

P42 Projects

NEW to ESE Projects!

Mechanistic Toxicology

Health Effects

Epidemiology

Hydrogeology

Fate and Transport

Remediation Engineering

Biomedical (≥ 2 Projects)

Environmental Science and Engineering (≥ 2 Projects)

• Applications should include at least one ESE project that supports SRP's fourth mandate "basic biological, chemical, and physical methods to reduce the amount and toxicity of hazardous substances"

• Review RFA section titled "Scope of the SRP Center Grant"

• Questions if a Project qualifies? Please contact SRP staff.

Maximum of 6 projects

Suggested Research and Activities:
https://www.niehs.nih.gov/research/supported/centers/srp/assets/docs/srp_funding_opps_suggested_research_and_activities_508.pdf

P42 Projects

FOCUS!!!!
- Centers should be VERY judicious in assembling research projects. Center should, with projects, keep a clear focus and not try to do too much!!
- Include projects with most solid connection to the Center's problem-solving theme.
- Lean Times: Not too big! Consider coming in under budget and well under 11-component limit.

Interactions:
- Cross-reference interactions between projects and cores. Should be consistent throughout.
- Refer to "*Table of Integration with Center*" (*Overall Section*)

Avoid Jargon!

P42 Reviewers have broad expertise
- Write abstracts/titles for a general audience
- Write Specific Aims for technical experts
- Define Abbreviations
- Use Plain Language: http://grants.nih.gov/grants/plain_language.htm

P42 Administrative Core (Required)

Consists (at minimum) of Center Director, **Research Translation Coordinator, and Center Administrator**

Functions

— Planning and coordination

— Promote cross-discipline interaction among projects and cores

— Oversee fiscal and quality management

— Ensures research translation

NEW to Admin Core!

Research Translation
1. Communication within SRP and to SRP staff
2. Partnerships with Government Agencies
3. Technology Transfer
4. Information Dissemination to Other End-Users

Administrative Core identifies Points of Contact (on behalf of the whole Center):
- Data Collection Tool
- NIH/NIEHS CareerTrac
- SRP-hosted conference calls/webinars on research translation, community engagement, and data management

Suggested Research and Activities:
https://www.niehs.nih.gov/research/supported/centers/srp/assets/docs/srp_funding_opps_suggested_research_and_activities_508.pdf
SRP Data Collection Tool: https://tools.niehs.nih.gov/srp/rtc/index.cfm
NIH CareerTrac database: https://careertrac.niehs.nih.gov/auth/login

P42 Administrative Core (Required)

External Advisory Committee (EAC)

- Provides Guidance to Director
  - Scientific Merit
  - Relevance, sharing of data, integration
  - Effectiveness of research translation, community engagement, training activities
  - Discussion of projects that should be continued, modified, or discontinued

Anticipated EAC Members*
Academics *(biomedical AND environmental science and engineering)*, Stakeholders, EPA/ATSDR, Industry, Community

*New Applicants: include expertise of potential EAC members, **not names***

Administrative Core not to exceed $150,000 Direct Costs; Center Director must commit a minimum of 1.8 person months

P42 Research Experience and Training Coordination Core (Required)

Graduate and Post-doctoral level cross-disciplinary training

NEW title BUT similar functions!

Functions
- Promote interactions between biomedical and environmental science and engineering trainees
- Professional development
- Promote involvement in Community Engagement and research translation, etc. (not mandatory but encouraged)
- Promote interaction with Data Management and Analysis Core
- Provide information about trainees and their activities to the SRP

NIH CareerTrac database:
https://careertrac.niehs.nih.gov/auth/login
SPAN Leadership Committee:
https://www.niehs.nih.gov/research/supported/centers/srp/training/spa/committee/index.cfm

Activities: tailored curricula development, selected coursework, cross-disciplinary lab experiences, seminar series, journal clubs, workshops/conferences related to professional development, and travel to scientific meetings, etc.

For renewals, inquiring Reviewers want to know about past trainee successes (i.e., Trainee List)

Not to exceed $100,000 Direct Costs

P42 Research Support Core (Optional)

- Provides centralized services
- Shared by at least 2 projects

Laboratory facilities, analytical chemistry, '-omics' support, or analytical equipment and services; does not typically include research

- Pros and Cons of RSC
  - Pros:
    - Excellent Interactions/Integration
    - Opportunities for Training
    - Assurance of Quality
  - Cons:
    - May not be critical (if facilities already available)
    - 11 component limit

- How Core is a resource to the Center as a whole.
- How the Core's centralized services will produce an economy of effort and/or savings in overall costs compared to their inclusion as part of each project in the Center.
- Research Support Cores that provide analytical and quantitative services to the applicant's Center should include a Quality Assurance Section (https://www.epa.gov/quality)

Reference "Table of Research Support and Data Management and Analysis Core Utilization," described in the Overall component

RSCs do not have a set budget.

P42 Community Engagement Core (Required)

Functions:
- Ensure bidirectional communication between the CEC and the community
- Direct best practices and activities in community engagement for prevention and/or intervention
- Provide potential solutions to communities to reduce or mitigate the impact of hazardous substance exposure (SRP Mandate #4)

Include:
- **Description of the proposed intervention and prevention activities with communities**
- Description of how CEC fits into Center theme
- Timeline with milestones
- Plan to measure and verify outcomes (e.g., a logic model)
- **Approach/methodology for surveys and/or sample collection**
- Process to guarantee effective bi-directional exchange of needs, recommendations, and results

Target communities
- SRP defines target communities as those impacted by hazardous substances
- Examples: local government groups, Tribal councils/communities, community service groups, non-governmental organizations working closely with a community, economically disadvantaged, and environmental justice communities

Provide Point of Contact
SRP-hosted conference calls/webinars on community engagement

Core not to exceed $100,000 Direct Costs

Suggested Research and Activities:
https://www.niehs.nih.gov/research/supported/centers/srp/assets/docs/srp_funding_opps_suggested_research_and_activities_508.pdf

NEW CORE!
P42 Data Management and Analysis Core (Required)

Purposes
- Support the management and integration of data assets across the Center, irrespective of dataset size
- Establish, coordinate, and monitor processes for data analysis
- Work with project/core leaders to ensure high data quality through lifecycle of data
- Identify opportunities for integrating project/core-generated data with other existing datasets
- Foster and enable interoperability of data between BMR and ESE projects to accelerate impact of Center's research

Comprehensive data management plan
1) coordination with projects and cores
2) fostering data sharing and interoperability
3) data quality assurance and quality control.

- May also include additional functionalities of biostatistics, bioinformatics, geographical information systems, and computational modeling, etc.
- Note: Not required to create a repository for the Center's data

Provides Points of Contact (in Relation to Overall Center)
- Data Collection Tool
- SRP-hosted conference calls/webinars data management and analysis

DMAC does not have set budget

Data sharing policies: https://grants.nih.gov/policy/sharing.htm; https://fairsharing.org/
SRP Data Collection Tool: https://tools.niehs.nih.gov/srp/rtc/index.cfm

P42 Multi-Project Centers

* Projects and Cores Uniformly Meritorious

Biomedical Science

Research and Training

Environmental Science and Engineering

* Integration, Interaction, Synergy:
- **Biomedical and Environmental Science & Engineering**
- **Projects and Cores**

Administration (includes research translation)

Community Engagement

* Addressing Important Problem

Superfund Stakeholder

Problem

Stakeholder Communities

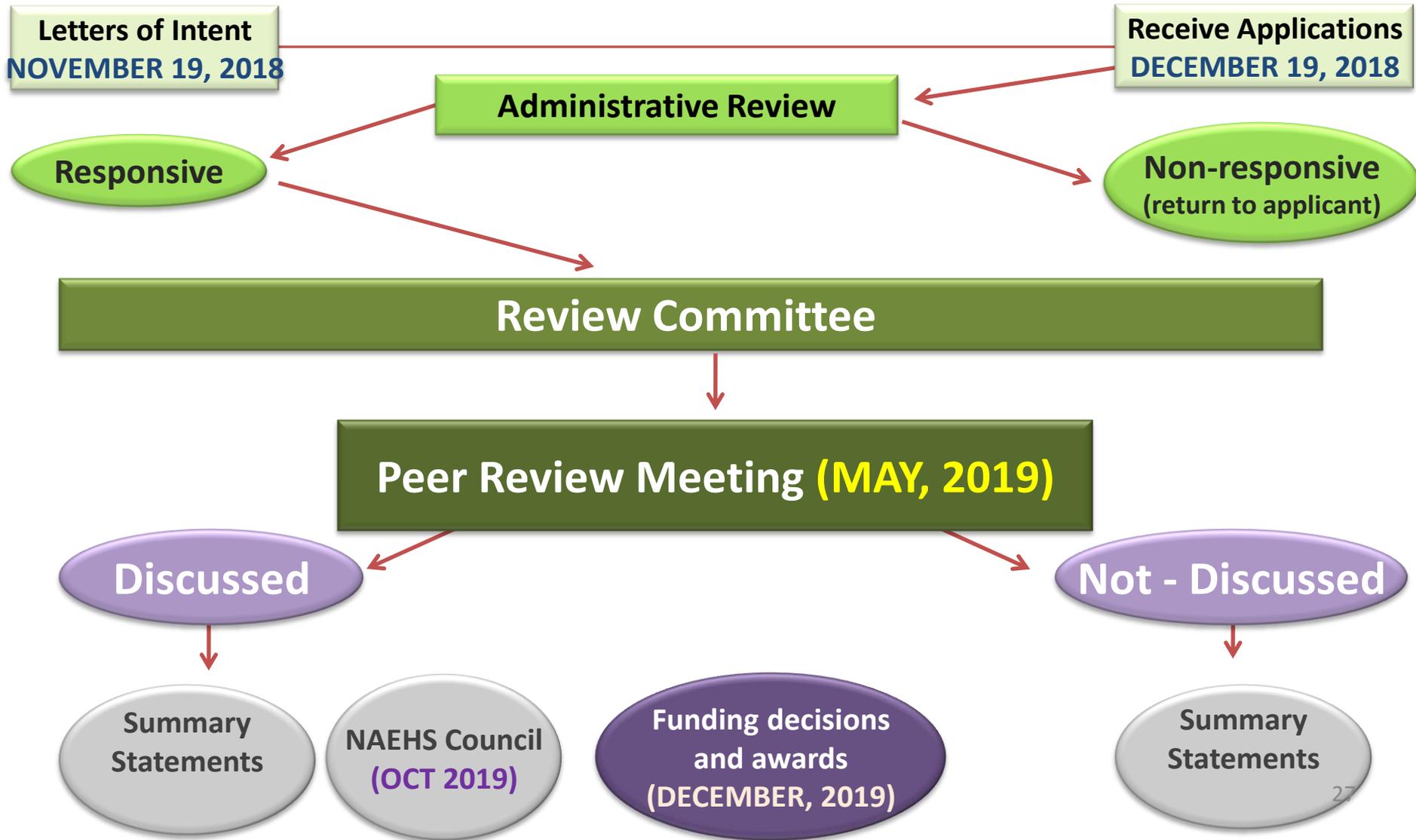*** Aids Stakeholders in Effective Decision-Making**

Solution

"NIEHS SCIENTIFIC PEER REVIEW"

JANICE ALLEN, PHD – SRO (984-287-3232)
LAURA THOMAS, PHD – SRO (984-287-3328)
DEBORAH JONES – ESA (984-287-3275)

2019 P42 REVIEW

The Peer Review Process

Letters of Intent
NOVEMBER 19, 2018

Receive Applications
DECEMBER 19, 2018

Administrative Review

Responsive

Non-responsive
(return to applicant)

Review Committee

Peer Review Meeting (MAY, 2019)

Discussed

Not - Discussed

Summary Statements

NAEHS Council (OCT 2019)

Funding decisions and awards (DECEMBER, 2019)

Summary Statements

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Pre-Submission of P42 Application

- **Submission of Letter of Intent (LOI):**
  - Assists in review planning
  - Email to **Dr. Janice Allen** at allen9@niehs.nih.gov **Requested by NOVEMBER 19, 2018 (not required, but HIGHLY recommended)**
- **Include in the LOI:**
  - Descriptive title of the Overall Center
    - Brief description of the research proposed in the Center
    - Include the title of each Research Project and Core
  - Name, address, and telephone number of the PD(s)/PI(s)
  - Names of key personnel (Project and Core Leaders)
  - Names of any participating institutions

P42 Peer Review Process

- **Review Criteria are in the solicitation:**
  http://grants.nih.gov/grants/guide/rfa-files/RFA-ES-15-019.html

- **Review of the Individual Research Projects, Cores**

- **Review the Overall Center**

Research Projects

Significance

Investigator(s)

Innovation

Approach

Environment

NIH's Five Review Criteria
(criterion scores 10-90)

Contribution to SRP Center

Other Specific Criteria*

Impact Score (10-90)

Each Project is reviewed. Each Receives Criterion Scores and written critiques. Note- Applications not discussed will NOT receive an overall impact score (e.g Center , individual Projects, and Cores).

***Note: Human Subjects, Animal Care, and Biohazards can be considered in the overall score. Budget Concerns are not considered in score.**

Cores

- **Contribution to SRP Center**
- **Other Criteria Specific to Each Core**
  - **Administrative**
  - Data Management and Analysis
  - Community Engagement
  - Research Experience and Training Coordination
  - Research Support
  (see RFA for specific criteria)

Impact Score (10-90)

Overall Center

Addresses a critical problem relevant to the SRP

Relevance/Merit of Projects and Cores (scientific gain)

Collaboration/Integration/Synergy

Leadership

Final Score (Range: 10-90)

Helpful Hints

- **Read and understand the Funding Announcement**
- **Contact <u>Program Staff</u> for clarification of scientific matters and <u>Grants Management Staff</u> for budget issues.**
- **Follow the guidelines: page limits, font size, and so forth**
- **Start early………because:**
  - ✓ **Any mistakes made with electronic submission (i.e., ASSIST) may cause your application to be returned without further deliberation by NIEHS Review staff.**

Grantsmanship Issues

- **Be clear and concise….don't expect reviewers to "know what you mean."**

- **All the components are important. One weak research project will impact the overall score. Extraneous or unnecessary cores will reduce cohesiveness of the center.**

- **Too many projects…application sinks under its own weight.**

- **Inadequate time allowed to prepare application.**

P42 Resources

- **RFA Webpage**
  - **Suggested Research and Activities - Numerous areas of general interest as well as specific needs identified by stakeholders**
  - **Tips for Applicants – electronic submission, what to include, etc.**
  - **Additional Resources – Links to EPA, ATSDR, information to aid in community engagement activities, and other helpful websites**
  - **Program Contacts**

RFA Webpage:
http://www.niehs.nih.gov/research/supported/srp/funding/rfa/index.cfm

Also see "Current P42 Grantees:"
http://tools.niehs.nih.gov/srp/programs/index267.cfm

RPG Application and Review

Element of Rigor and Transparency	Section of Application	Criterion Score	Additional Review Consideration	Contribute to Overall Impact?
Scientific Premise	Research Strategy	Significance	NA	Yes
Scientific Rigor	Research Strategy	Approach	NA	Yes
Consideration of Relevant Biological Variables, Such as Sex	Research Strategy	Approach	NA	Yes
Authentication of Key Biological and/or Chemical Resources	New Attachment	NA	Acceptable or unacceptable	No

Updated Application Instructions: Scientific Premise

By GrindtXX (Own work) [CC BY-SA 3.0 (http://creativecommons.org/licenses/by-sa/3.0)], via Wikimedia Commons

5.5.3 Research Strategy.... Significance

• Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.

• Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.

• Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

• Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

http://grants.nih.gov/reproducibility/index.htm

Updated Review Language: Scientific Premise

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Review Criterion: Significance

- Does the project address an important problem or a critical barrier to progress in the field?

- **Is there a strong scientific premise for the project?**

- If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?

- How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

http://grants.nih.gov/reproducibility/index.htm

Updated Application Instructions: Scientific Rigor

5.5.3 Research Strategy….
Approach

• Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in the Resource Sharing Plan, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.

• Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.

• Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.

• If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work…

Credit: National Eye Institute (NEI), NIH. https://www.flickr.com/photos/nihgov/20656342263/in/album-72157656890787872/

http://grants.nih.gov/reproducibility/index.htm

Updated Review Language: Scientific Rigor

Review Criterion: Approach

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?

- **Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?**

- Are potential problems, alternative strategies, and benchmarks for success presented?

- If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

- If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Credit: National Eye Institute (NEI), NIH. https://www.flickr.com/photos/nihgov/20656342263/in/album-72157656890787872/

http://grants.nih.gov/reproducibility/index.htm

What should I include in my application to ensure that it is rigorous?

The features of rigorous experimental design that are most important will depend upon the research proposed. Here are some examples…

- Statistical procedures used to determine appropriate group sizes
- Plans for data analysis
- Methods to reduce bias
  - Procedures to ensure independent, blinded measurements
  - Procedures to improve precision and minimize variability
- Subject inclusion and exclusion criteria
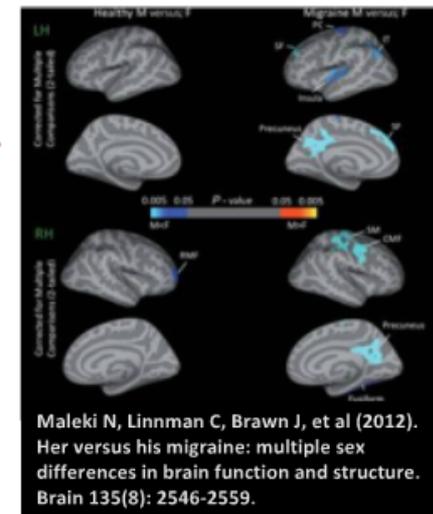- Plans to address loss to follow-up and missing data

FAQs: http://grants.nih.gov/reproducibility/faqs.htm

Resource Guide: https://nih-extramural-intranet.od.nih.gov/d/sites/default/files/RigorTrainingResourceGuide.pdf

Updated Review Language:
Relevant Biological Variables

Review Criterion: Approach

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
- Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- Are potential problems, alternative strategies, and benchmarks for success presented?
- If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?
- **Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?**
- If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Maleki N, Linnman C, Brawn J, et al (2012). Her versus his migraine: multiple sex differences in brain function and structure. Brain 135(8): 2546-2559.

http://grants.nih.gov/reproducibility/index.htm

What does it mean to consider sex as a biological variable?

Here are some possibilities, but you'll have to decide what's appropriate:

What is known about males and females in relation to the disease, condition, or question?

If little is known, application should include both sexes:
- Sufficient numbers to inform the presence of sex differences
- Report separately by sex in progress reports and publications
- Specific hypotheses about sex differences may not be possible
- Statistically powered comparisons between sexes may not be justified
- *Inclusion of both sexes and analysis/reporting of results for each sex is a big step forward!*

http://orwh.od.nih.gov/sexinscience/overview/pdf/NOT-OD-15-102_Guidance.pdf

Updated Application Instructions: Resource Authentication

Other Research Plan Attachment:

Authentication of Key Biological and/or Chemical Resources

Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies.

Key biological and/or chemical resources may or may not be generated with NIH funds and:

1) may differ from laboratory to laboratory or over time;

2) may have qualities and/or qualifications that could influence the research data; and

3) are integral to the proposed research.

These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.

Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.

Reviewers will assess the information provided in this Section. Any reviewer questions associated with key biological and/or chemical resource authentication will need to be addressed prior to award.

Information in this section must focus only on authentication and/or validation of key resources to be used in the study; all other methods and preliminary data must be included within the page limits of the research strategy. Applications identified as non-compliant with this limitation will be withdrawn from the review process (see NOT-OD-15-095).

http://grants.nih.gov/reproducibility/index.htm

Updated Review Language:
Resource Authentication

Additional Review Consideration:

Authentication of Key Biological and/or Chemical Resources

Credit: Dylan Burnette and Jennifer Lippincott-Schwartz, NICHD, NIH
https://www.flickr.com/photos/nihgov/204 95441928/in/album-72157656657569008/
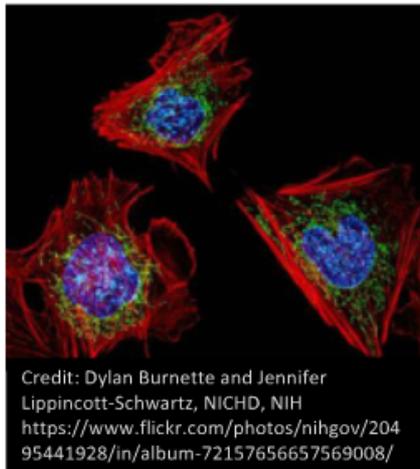
- For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

http://grants.nih.gov/reproducibility/index.htm

"QUESTIONS?"

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2019 P42 REVIEW

Budget

NIEHS GRANTS MANAGEMENT

LISA EDWARDS, MBA

Electronic Budget

- Prepare the Application using ASSIST:
  https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/submission-options/assist.htm

- Webinar for Applicants: Electronic Submission Process of Multi-Project Applications
  https://grants.nih.gov/grants/webinar_docs/webinar_20130813.htm

- SF424 (R&R) Detailed Budget forms

- Budget data <u>collected</u> at component and subaward levels only
  Component and subaward budget data used to auto-calculate "Cumulative" (Composite) budget

Budget pages required for parent site and all consortium sites

Budget Preparation

Form Pages, Approvals, Other Support, Notices

Forms (http://grants.nih.gov/grants/forms.htm)
   SF424 (R&R) electronic submission

Approvals
   IACUC Approval (Vertebrate Animals)
   IRB Approval (Human Subjects)
   Begin process at time of application, but final approval will be requested for Just In Time*

Other Support
   "0%", "Varies", "As Needed", etc., are not acceptable
   Total time commitment cannot exceed 12 calendar months

Important Notices

- Revised Grants Policy Statement: https://grants.nih.gov/policy/nihgps/index.htm

- Salary caps: NOT-OD-18-137 http://grants1.nih.gov/grants/policy/salcap_summary.htm.

*Just in Time: Request for information required prior to award.

Budget Preparation

Non-Modular

Provide detailed categorical budgets
• Each Project
• Each Core **(Note – RETCC (training core) uses a "Core" component budget, not the NRSA form used in the past)**
• Each Subaward/Consortium (Note: SF424 will not allow Subawards on Subawards)

Escalation
Budgets submitted in subsequent years may request an escalation on recurring direct costs. (Note: Currently NIH does provide an escalation in subsequent years)

Must be justified:
• Is the amount of escalation requested supported by institutional policies?
• Is the amount clearly stated?

Travel to Annual Meeting

Administrative Core Budget: Funds for travel by appropriate staff (i.e., Center Director, Center Administrator, and four trainees) to attend the Superfund Research Program three-day annual meeting shall be included in the Administrative Core's budget for each year.

Escalation in outyears will be removed at the time of award.

Budget Preparation

- Parent Grant Direct Costs
  - Consideration of *equipment* in the out-years will be based upon justification and availability of funds

- Subawards/Consortium
  - must follow same guidelines as parent; <u>budget pages required and should follow associated project or core</u>
  - Subawards/consortium direct costs are included in the parent grant Subtotal Direct Costs, which may be subject to budget caps
  - F&A of subawards/consortium is included in Total direct Costs of parent grant, but will not count against budget cap

- Budget Justifications (Be detailed and specific)
    - Are all costs itemized?
    - <u>Are all additions and changes in subsequent/future years fully justified and identified clearly; specifically changes in personnel effort?</u>

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

* ORGANIZATIONAL DUNS: [ ] ← Use DUNS of organization responsible for the component.

* Budget Type: [ ] Project   [ ] Subaward/Consortium

Enter name of Organization: [ ]

* Start Date: [ ]   * End Date: [ ]   Budget Period 1

Every Sr./Key listed must have measurable effort in either Calendar Months or a combination of Academic and Summer Months.

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.						Project Lead							
2.													
3.													
4.													
5.													
6.													
7.													
8.													

Role should reflect the Sr/Key persons role on the specific component.

Base Salary can be left blank for submission, but is required prior to award.

9. Total Funds requested for all Senior Key Persons in the attached file

Total Senior/Key Person [ ]

Additional Senior Key Persons: [ ]   [Add Attachment] [Delete Attachment] [View Attachment]

If more than 100 Sr./Key, use attachment and enter total funds requested for additional Sr./Key persons.

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						

Aggregate information should be provided in section B. More detailed information should be provided in Budget Justification.

| Total Number Other Personnel [ ] | | Total Other Personnel [ ] |

Total Salary, Wages and Fringe Benefits (A+B) [ ]

RESEARCH & RELATED Budget {A-B} (Funds Requested)

R&R Budget Sections A & B

Personnel separated into 2 sections:

- **A. Senior/Key Person**
  - First field must be completed, even if person on a component given role of "Project Leader" and not PD/PI

- **B. Other Personnel**
  - Postdocs, Grad Students, Undergrads: Only number of personnel required (not specific names)

*Include only personnel employed by (e.g., receiving salary from) your organization.

Close Form

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

* ORGANIZATIONAL DUNS:

* Budget Type: ☐ Project ☐ Subaward/Consortium

Enter name of Organization:

Delete Entry * Start Date: * End Date: Budget Period 1

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment item	* Funds Requested ($)
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11. Total funds requested for all equipment listed in the attached file	
Total Equipment	

Itemize up to 100 pieces of equipment. If more, include total dollars in line 11 and provide details in the Additional Equipment attachment

Additional Equipment: Add Attachment   Delete Attachment   View Attachment

D. Travel   Funds Requested ($)

1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)

2. Foreign Travel Costs

Total Travel Cost

E. Participant/Trainee Support Costs   Funds Requested ($)

1. Tuition/Fees/Health Insurance

2. Stipends

3. Travel

4. Subsistence

5. Other

Not required for P42

Number of Participants/Trainees   Total Participant/Trainee Support Costs

R&R Budget

Sections C - E

RESEARCH & RELATED Budget {C-E} (Funds Requested)

R&R Budget Sections C - E

- **Item D, Travel**
  - 424 form differentiates between foreign and domestic travel

Close Form

RESEARCH & RELATED BUDGET - SECTION F-K, BUDGET PERIOD 1   Next Period

* ORGANIZATIONAL DUNS: [_____]

* Budget Type: ☐ Project   ☐ Subaward/Consortium

Enter name of Organization: [_____]

Delete Entry   Start Date: [_____] * End Date: [_____]   Budget Period 1

F. Other Direct Costs   **Funds Requested ($)**

1. Materials and Supplies   [_____]
2. Publication Costs   [_____]
3. Consultant Services   [_____]
4. ADP/Computer Services   [_____]
5. Subawards/Consortium/Contractual Costs   [_____] ←
6. Equipment or Facility Rental/User Fees   [_____]
7. Alterations and Renovations   [_____]
8. [_____]   [_____]
9. [_____]   [_____]
10. [_____]   [_____]

                          Total Other Direct Costs [_____]

> **Subaward/Consortium/Contractual Cost not pre-populated. Include both Total Direct and Indirect cost**

G. Direct Costs   **Funds Requested ($)**

                    Total Direct Costs (A thru F) [_____]

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1.			
2.			
3.			
4.			

                          Total Indirect Costs [_____]

Cognizant Federal Agency [_____]
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs   **Funds Requested ($)**

      Total Direct and Indirect Institutional Costs (G + H) [_____]

J. Fee   **Funds Requested ($)**
                                                             [_____]

K. * Budget Justification [_____]   Add Attachment   Delete Attachment   View Attachment
            (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

R&R Budget Sections F-K

- **Tuition remission**
  - Include in Item F, Other Direct Costs (boxes 8, 9 or 10)
- **Supplies**
  - Not a major line item on 424 budgets
  - Included as line F.1 (Other Direct Costs: Materials and Supplies)
- **Alteration and Renovations**
  - Not a major line item on 424 budgets
  - Included as line F.7 (Other Direct Costs: Alterations and Renovations)
- **Inpatient and Outpatient Care Costs**
  - 424 does not include as major / minor line item
  - Current instructions require inserting in fields F.8-F.10 (Other Direct Costs: Other Costs)

RESEARCH & RELATED BUDGET - Cumulative Budget

Totals ($)

Section A, Senior/Key Person	[ ]
Section B, Other Personnel	[ ]
Total Number Other Personnel	[ ]
Total Salary, Wages and Fringe Benefits (A+B)	[ ]
Section C, Equipment	[ ]
Section D, Travel	[ ]
1. Domestic	[ ]
2. Foreign	[ ]
Section E, Participant/Trainee Support Costs	[ ]
1. Tuition/Fees/Health Insurance	[ ]
2. Stipends	[ ]
3. Travel	[ ]
4. Subsistence	[ ]
5. Other	[ ]
6. Number of Participants/Trainees	[ ]
Section F, Other Direct Costs	[ ]
1. Materials and Supplies	[ ]
2. Publication Costs	[ ]
3. Consultant Services	[ ]
4. ADP/Computer Services	[ ]
5. Subawards/Consortium/Contractual Costs	[ ]
6. Equipment or Facility Rental/User Fees	[ ]
7. Alterations and Renovations	[ ]
8. Other 1	[ ]
9. Other 2	[ ]
10. Other 3	[ ]
Section G, Direct Costs (A thru F)	[ ]
Section H, Indirect Costs	[ ]
Section I, Total Direct and Indirect Costs (G + H)	[ ]
Section J, Fee	[ ]

R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

If submitting an application with >30 subaward budgets, budgets 31 and above should be converted to PDF and included as part of the Budget Justification of the parent budget in Section K of the R&R Budget form.

The sum of all subaward budgets (e.g., those attached separately on this form and those provided as part of the budget justification), must be included in Line F.5 Subawards/Consortium/Contractual Costs of the parent budget.

When submitting subaward budgets that are not active for all periods of the project, fill out the subaward R&R Budget form and include only the number of periods for which the subaward is active. The budget period start/end dates reflected in each period of the subaward should match the project budget period start/end dates that correspond to the active periods.

ASSIST provides the ability to add up to 30 subaward budgets per component using the SF424 RR budget form. ASSIST will automatically include the subawards with the application so there is no need to attach them as separate files.

Resources

- SF424 (R&R) Application and Electronic Submission Information" webpage:
  - http://grants.nih.gov/grants/funding/424/index.htm#inst
- Applying Electronically to Multi-project Applications:
  - http://grants.nih.gov/grants/ElectronicReceipt/com_index.htm
- Help with ASSIST
  - http://grants.nih.gov/grants/ElectronicReceipt/assist.htm
- "New" NIH Biographical Sketch Format:
  https://grants.nih.gov/grants/guide/notice-files/not-od-16-080.html
- NIH Guidance on Rigor and Reproducibility:
  http://grants.nih.gov/reproducibility/index.htm

eRA Commons - https://commons.era.nih.gov/commons/index.jsp
Registered PD/PIs can check assignment/contact information, review outcome, and other important information.

eRA Commons Help Desk:
Hours: Mon-Fri, 7AM-8PM EDT/EST; Web: http://grants.nih.gov/support/; Toll-free: 1-866-504-9552. Phone: 301-402-7469

P42 Multi-Project Centers

- **Submit Application EARLY!!!**

- **NIEHS Contacts on RFA**

  Program Officers (contacts for initial consultation):

  - *Danielle Carlin (danielle.carlin@nih.gov)*

  - *Michelle Heacock (HeacockM@niehs.nih.gov)*

  - *Heather Henry (henryh@niehs.nih.gov)*

  SRP Director William Suk (suk@niehs.nih.gov)

  SRP Health Specialist, Brittany Trottier (brittany.trottier@nih.gov)

  Scientific Review Officer, Janice Allen (allen9@niehs.nih.gov)

  Grants Management Officer, Lisa Archer-Edwards (archer3@niehs.nih.gov)

Link to RFA: https://grants.nih.gov/grants/guide/rfa-files/RFA-ES-18-002.html
Link to RFA Information Page:
https://www.niehs.nih.gov/research/supported/centers/srp/funding/rfa/index.cfm

National Institute of
Environmental Health Sciences
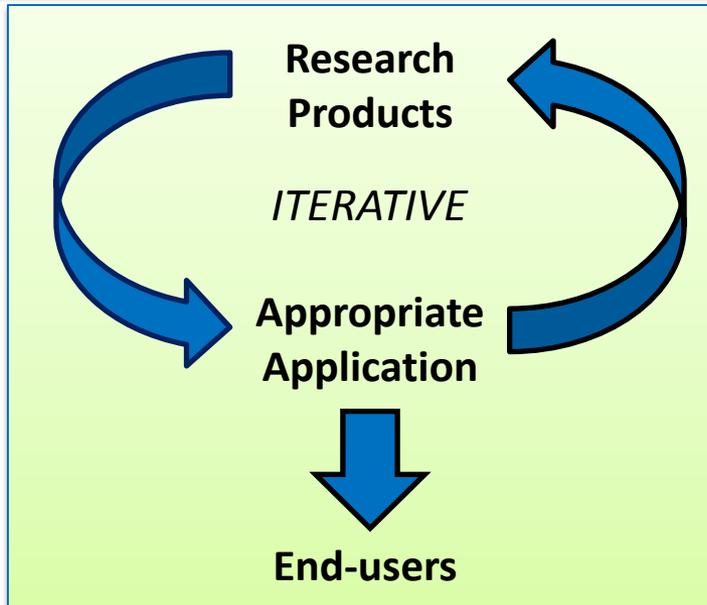*Superfund Research Program*

QUESTIONS??
Thank You!

Acknowledgements:
EPA's CLU-In.org
Jean Balent, EPA TIFSD
Sara Amolegbe, MDB Inc.

Questions not covered during seminar will be answered off-line and posted on P42 Funding Opportunity Webpage:
http://www.niehs.nih.gov/research/supported/dert/programs/srp/funding/rfa/index.cfm

Audio Archive will be available in approximately 4 weeks and are accessible from the above website.

Administrative Core's research translation function

Research
Products

ITERATIVE

Appropriate
Application

End-users

Community Engagement

Theme of Center

BIDIRECTIONAL

Impacted Community

- **Initiated by the research translation coordinator or Project Leader**
- **Based on research "product"**
- **Opportunistic and rapid response**
- **Critical role reporting successes**
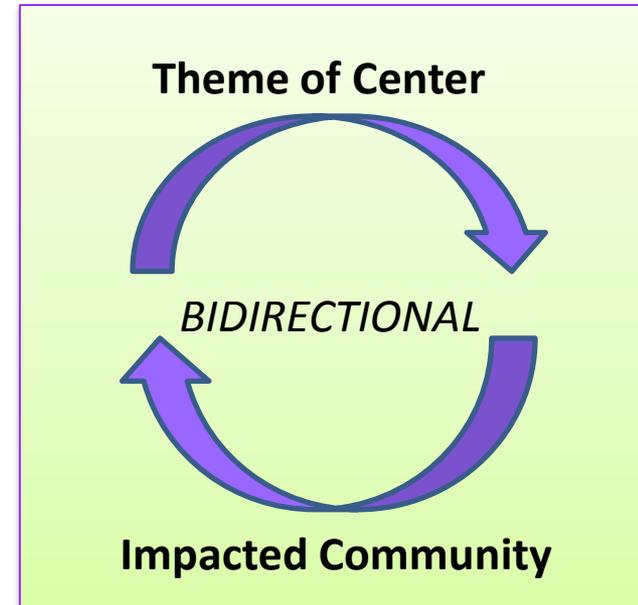
- **Partnership-driven**
- **Bidirectional with impacted community(ies)**
- **Finite/Defined Activities focuses on Prevention/Intervention**
- **Activities should have the goal of reducing exposures**