



Limited Competition: Superfund Research and Training Program (P42 Clinical Trial Optional) (RFA ES 23-001)

Sponsored by:

National Institute of Environmental Health Sciences, Superfund Research Program

Presenters:

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Jean Balent, EPA (balent.jean@epa.gov)

May 15, 2023 12:00 – 1:00 pm Presentations / QA 1:00 – 1:30 pm EST

Link to NOFO: <https://grants.nih.gov/grants/guide/rfa-files/RFA-ES-23-001.html>

Link to NOFO Information Page:

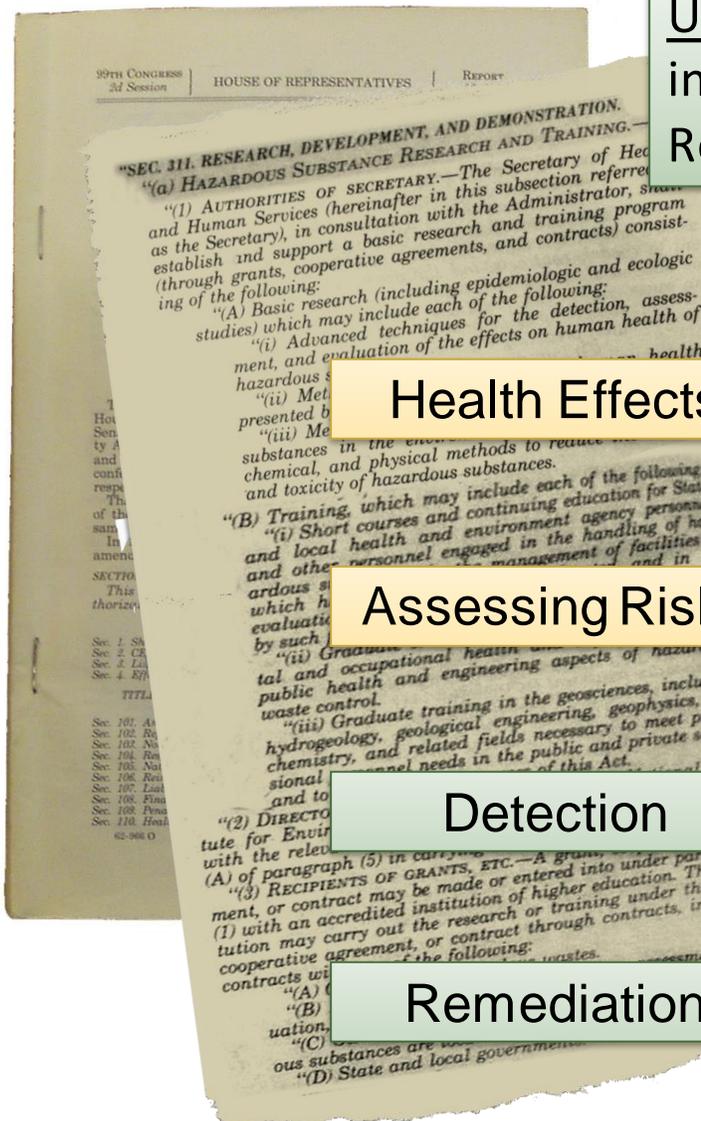
<https://www.niehs.nih.gov/research/supported/centers/srp/funding/rfa/index.cfm>

Funding Opportunity Webinar – P42 Center RFA ES-23-001

Agenda

- Welcome and Overview of P42 funding mechanism: Michelle Heacock (Acting SRP Director)
- P42 RFA
 - General Information: Heather Henry, Danielle Carlin, Michelle Heacock
 - Review Criteria: Varsha Shukla (Scientific Review Officer)
 - Budget: Jenny Greer (Chief, Grants Management Branch)
- Question / Answer

SRP Mandates under SARA



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

Development of:

Health Effects

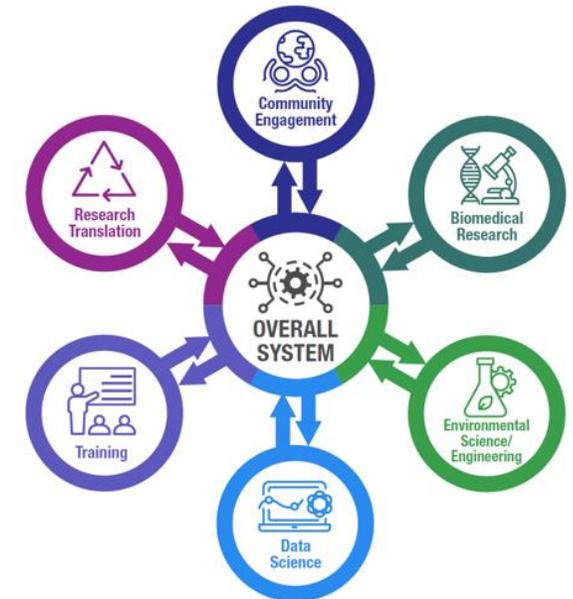
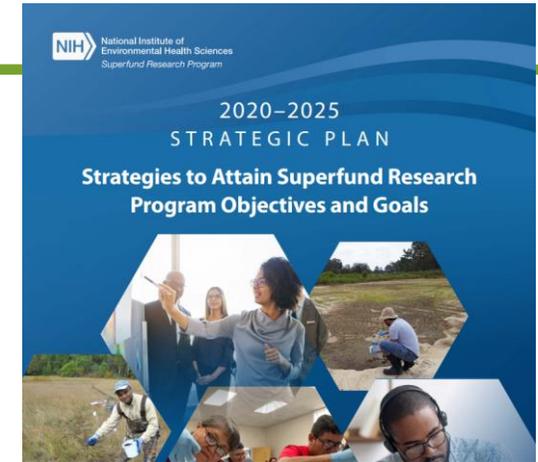
Assessing Risks

Detection

Remediation

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

- The **2020-2025 SRP Strategic Plan** provides direction to both SRP grantees and program staff to:
 - Address issues of high relevance
 - Maximize the impact of program investments
 - Foster innovations
- Adapts a **systems approach** to promote interdisciplinary research and advance SRP science in order to reduce exposures and the resulting burden of disease.
- Emphasizes the importance of broadening potential partners or end users.



SRP Stakeholders

- US Environmental Protection Agency (USEPA)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Other Federal agencies, such as NOAA, USGS, DOD, DOE
- State and local agencies and tribal entities responsible for sites
- Individuals and communities living near hazardous waste sites

RFA-ES-23-001

LIMITED COMPETITION: SUPERFUND HAZARDOUS SUBSTANCE RESEARCH AND TRAINING PROGRAM (P42) (P42 CLINICAL TRIAL OPTIONAL)

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

Bring expertise of multiple biomedical and environmental science and engineering disciplines to address scientific uncertainties facing the National Superfund Program.

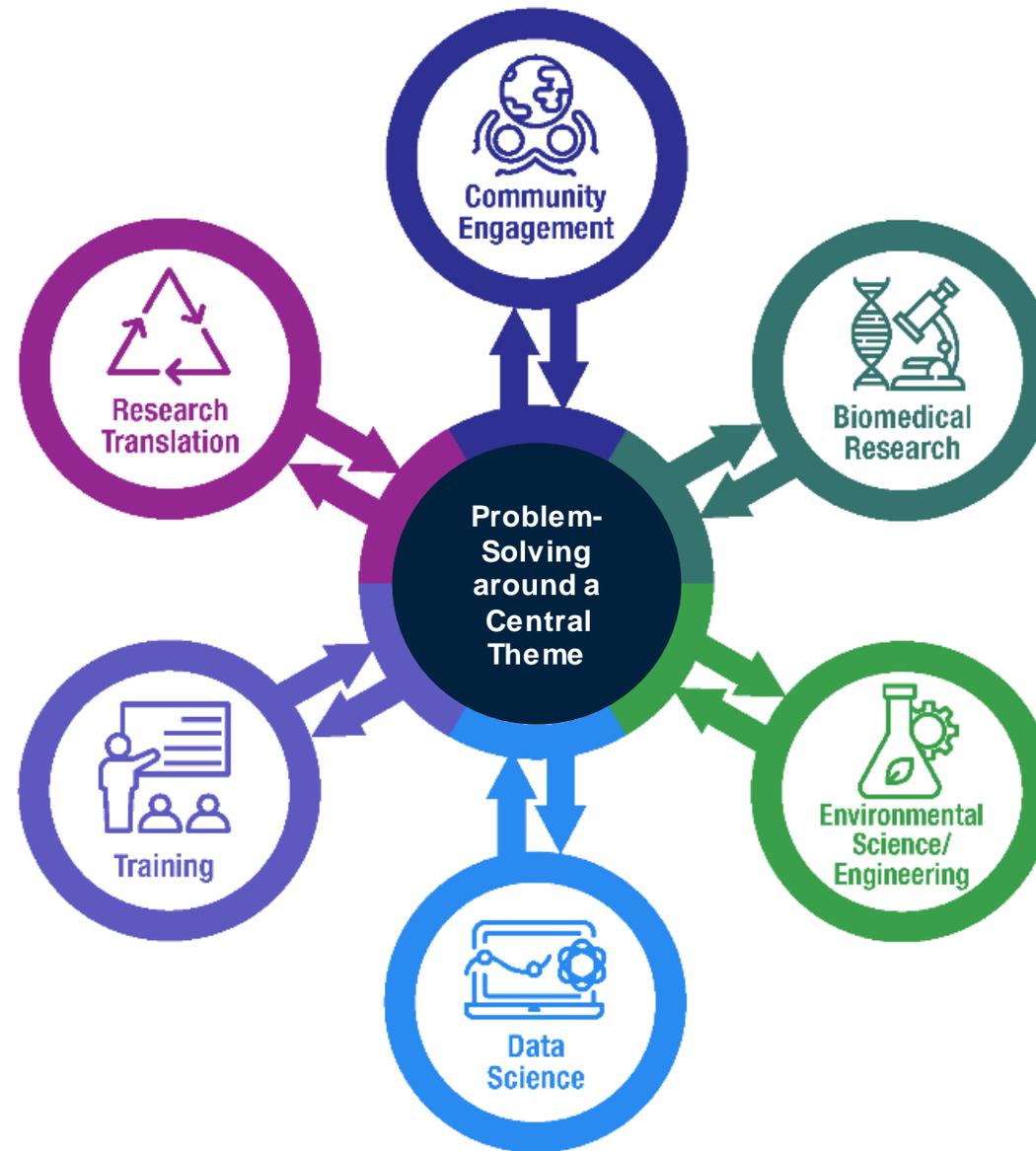
Provide sound science, data, information, and knowledge to inform the risk assessment and remediation management processes.

- P42 NOFO Website: <https://www.niehs.nih.gov/research/supported/centers/srp/funding/rfa/index.cfm>
- RFA-ES-23-001: <https://grants.nih.gov/grants/guide/rfa-files/RFA-ES-23-001.html>
- Suggested Research and Activities Document: https://www.niehs.nih.gov/research/supported/centers/srp/assets/docs/srp_funding_rfa_suggested_research_2023_rfa_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): September 2, 2023
- Letter of Intent Due Date: September 2, 2023
- Application Due Date: **October 2, 2023**, by 5PM local time of applicant organization
- Scientific Merit Review: April 2024
- Advisory Council Review: October 2024
- Earliest Start Date: February 2025

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

Programmatic Balance

- **See Current Grant Recipients:**
<https://tools.niehs.nih.gov/srp/programs/index267.cfm>

SRP's Strategic Plan

- **Relevance:** to Superfund
- **Impact:** to End-users
- **Innovation:** Multi-disciplinary/Paradigm-shifting

Not Required: Superfund Site

CERCLA Substances/Hazardous Substances:

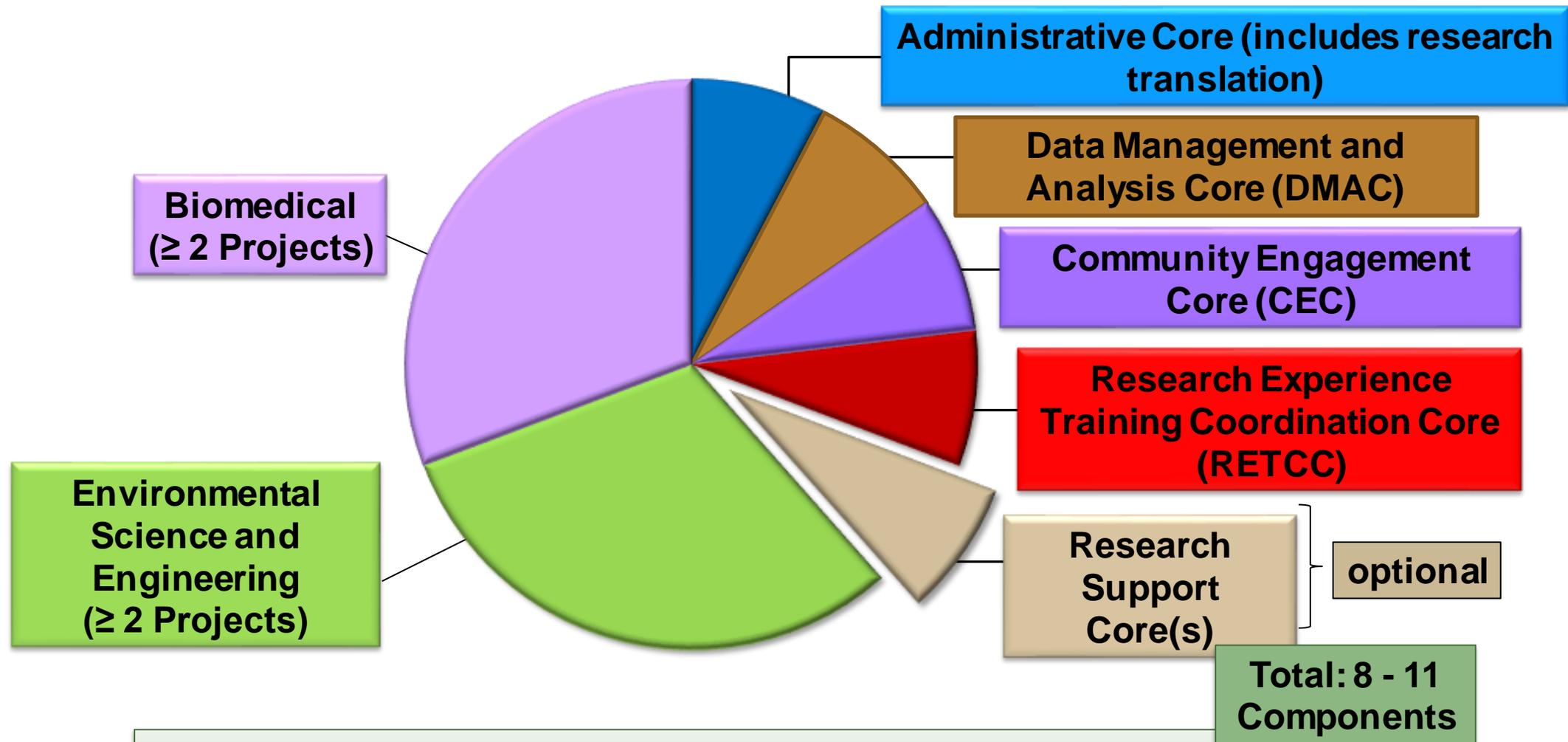
<https://www.atsdr.cdc.gov/SPL/index.html>
https://www.niehs.nih.gov/research/supported/centers/srp/funding/rfa/rfa_resources/index.cfm

Suggested Research Topics and Activities

- High priority areas for SRP End-users
https://www.niehs.nih.gov/research/supported/centers/srp/assets/docs/srp_funding_rfa_suggested_research_2023_rfa_5_08.pdf

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

All Components Interacting, Addressing Problem

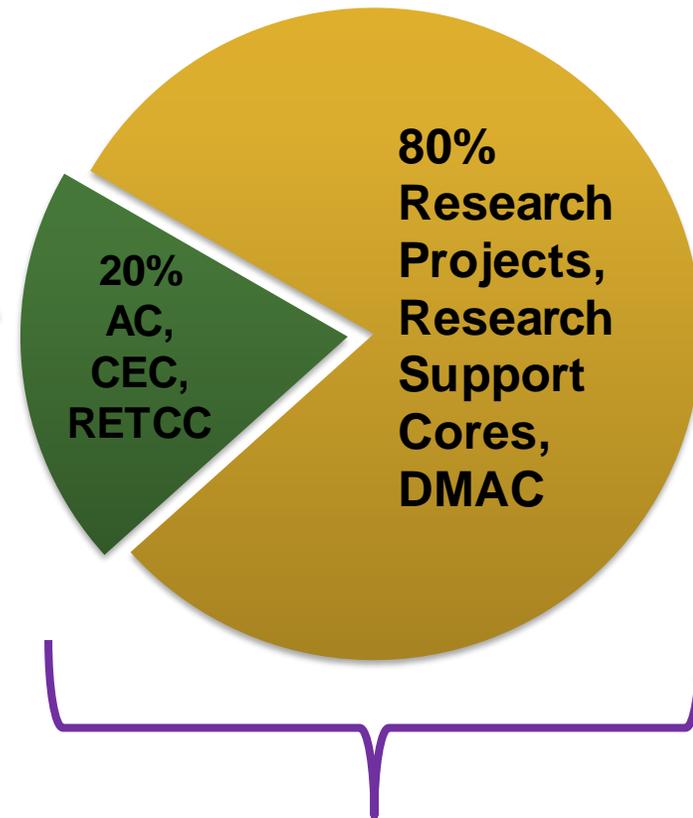


New, Renewal Proposals, and Resubmissions: up to \$2 M/year direct costs for 5 years

Cost Limitations (Direct)

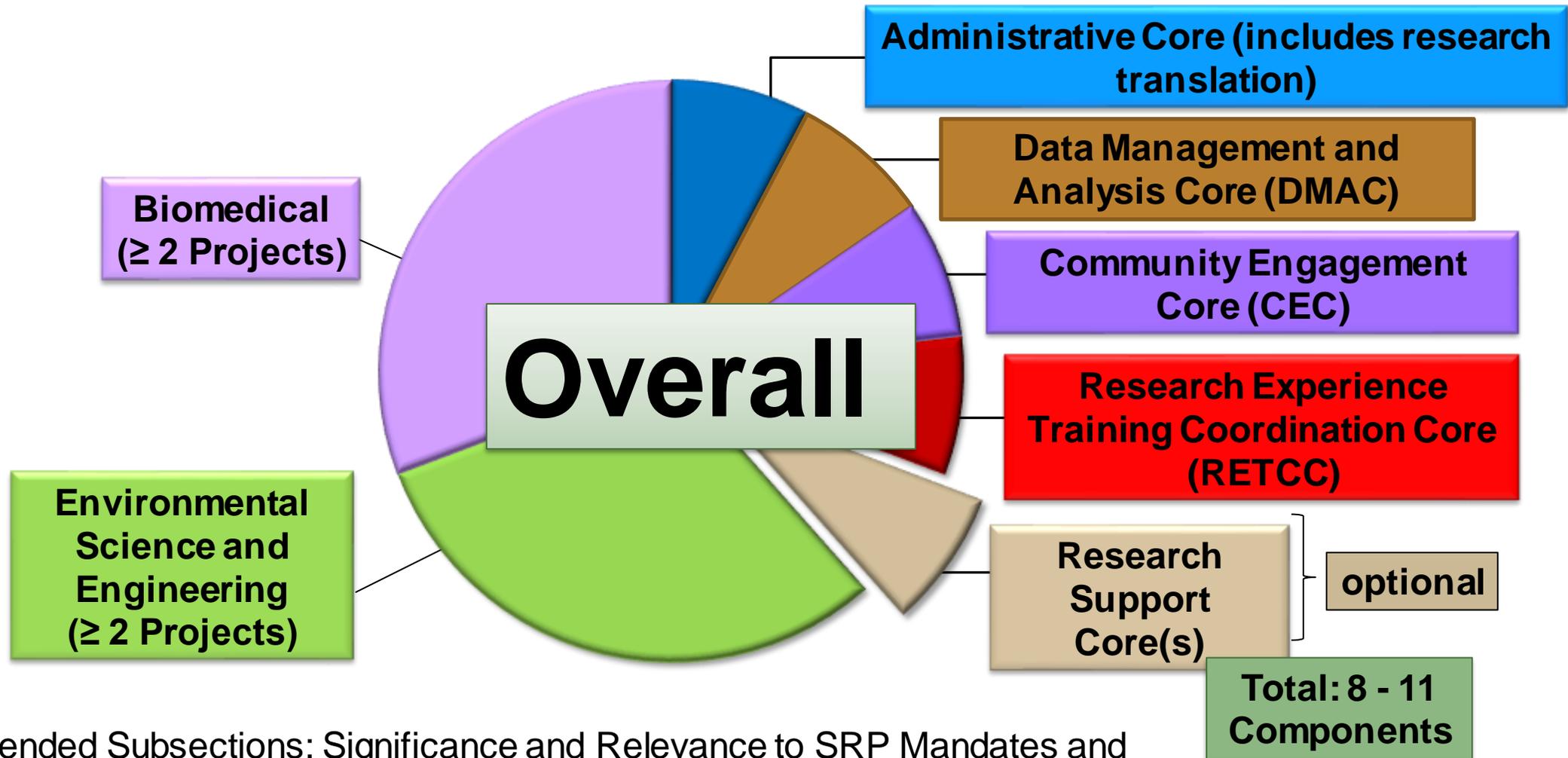
Cores Sum ≤ 20% Total Center
Administrative
Community Engagement
Research Experience and Training
Coordination

- Core Limitations (Direct):**
- **Administrative - \$170K**
 - **Community Engagement - \$120K**
 - **Research Experience and Training Coordination- \$120K**
 - **Data Management and Analysis – no set budget**
 - **Research Support Core (Optional) – no set budget**



Center:
New and Renewal Applicants:
up to \$2 M/year direct costs for 5 years

All Components Interacting, Addressing Problem



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

UPDATE

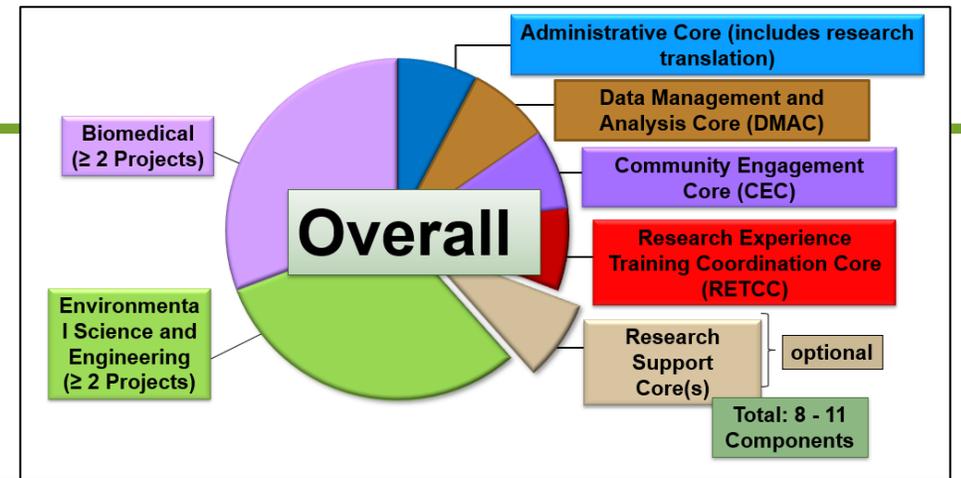
Overall Component

Other Attachments

- Center Organizational Structure
- Table of Integration with Center
- Table of End-users and Field Sites
- Table of Research Support Core and DMAC Utilization
- Table of Changes to Projects and Cores (renewal/resubmission applications)
- Table of Research Approaches

Tips for Applicants:

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



Resource Sharing Plan -follow SF424

UPDATE: NEW!

Other Plan(s): Data Management and Sharing Plan (Forms-H)

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html>,

<https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.300-r&r-budget-form.htm#F>

Please visit the NIH Data Sharing Website for more information, <https://sharing.nih.gov>

Table of Integration with Center

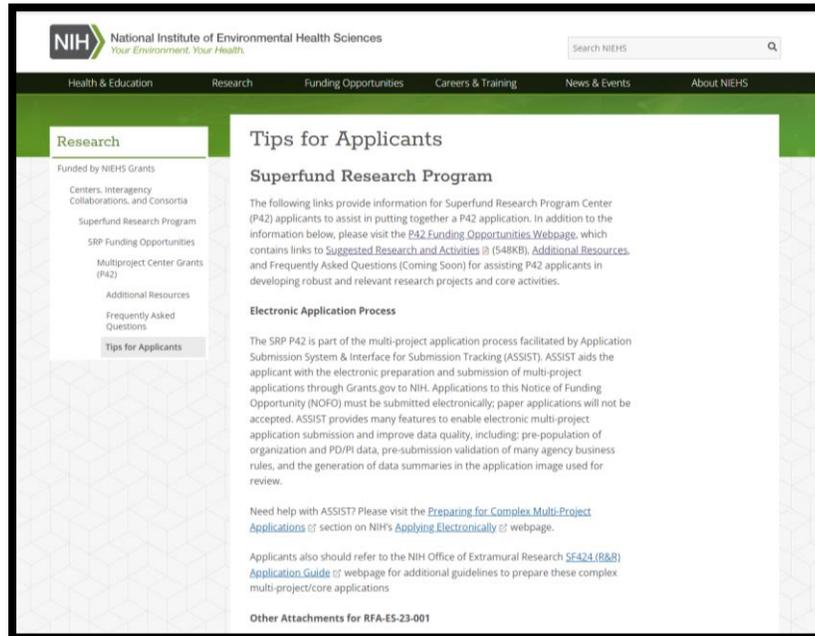


Illustration 1. Table of Integration with Center. To assist the reviewers in determining the relationship between components, a table should be provided showing interactions between projects and cores (by project title and project/core leader) and the purpose of the interaction for the achievement of the Center's overall objectives. Applicants are encouraged to use a systems approach to identify problem-solving leverage points the Center will address. 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

Examples of Tables for RFA-ES-23-001:

https://www.niehs.nih.gov/research/supported/centers/srp/assets/docs/srp_rfaes23001_examples_of_tables_doc.pdf

The Data Management and Sharing Plan should address the following:

- Element 1: Data Type
- Element 2: Related Tools, Software and/or Code
- Element 3: Standards
- Element 4: Data Preservation, Access, and Associated Timelines
- Element 5: Access, Distribution, or Reuse Considerations
- Element 6: Oversight of Data Management and Sharing

The Data Management and Sharing Plan must be provided in the Overall component, attached in Other Plan(s) attachment in FORMS-H application forms package)

CORRECTION: Include budget information for *Data Management and Sharing Costs* for each respective Component as a line item in section F. Other Direct Costs, <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.300-r&r-budget-form.htm#F>

Supplemental Information to the NIH Policy for Data Management and Sharing: Elements of an NIH Data Management and Sharing Plan, [NOT-OD-21-014](#)

NIH Data Management and Sharing Policy, [NOT-OD-21-013](#)

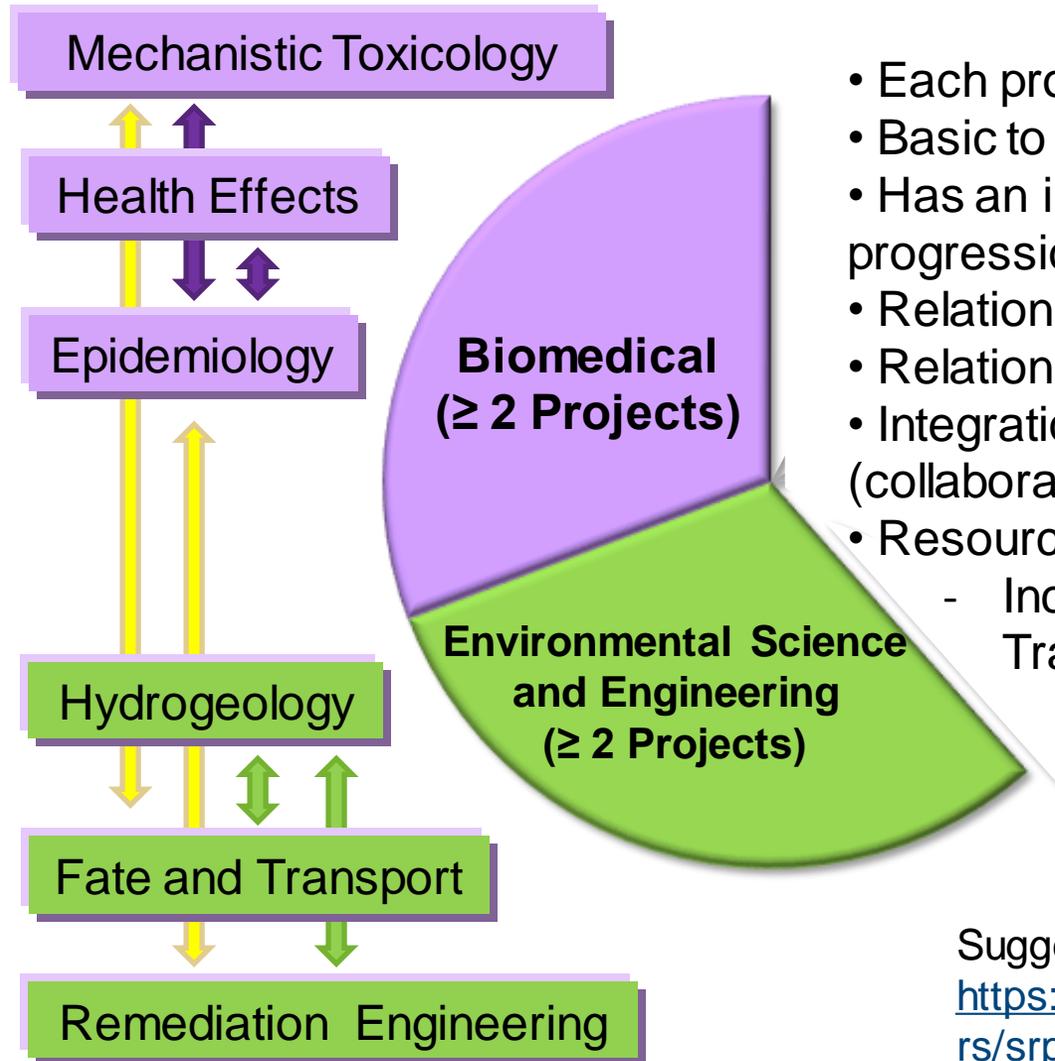
<https://www.niehs.nih.gov/research/scientific-data/plan/index.cfm>

Please visit the NIH Data Sharing Website for more information, <https://sharing.nih.gov>

Additional Resources Regarding Data Management and Sharing Plans

- Example data sharing plans: <https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/writing-a-data-management-and-sharing-plan#sample-plans>
- Further Budget justification information: <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.300-r&r-budget-form.htm#F>

P42 Projects



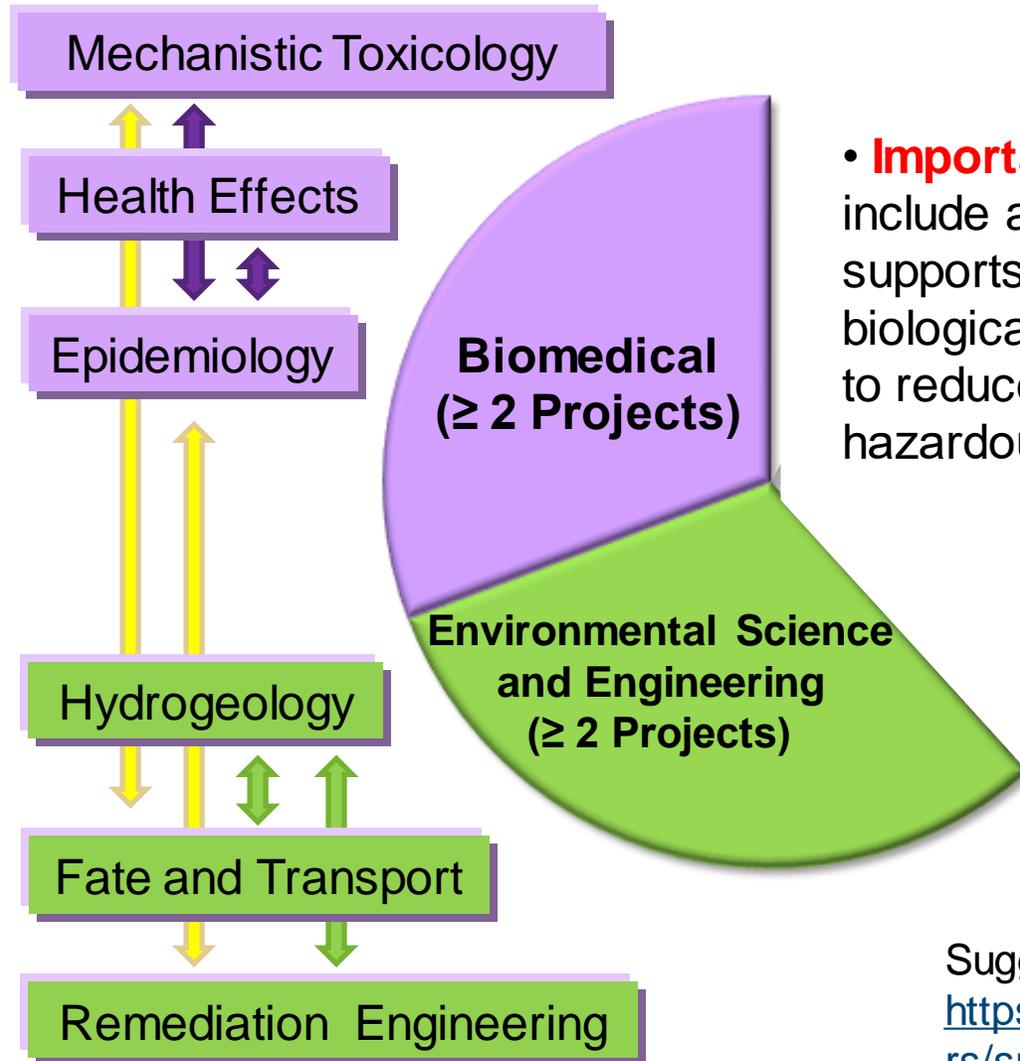
- Each project is reviewed as stand-alone
- Basic to application oriented
- Has an independent testable hypothesis or a logical progression of tasks
- Relation to SRP mandate(s)
- Relation to Overall Center
- Integration with other Projects and Cores (collaborative aims are allowed, not required)
- Resource Sharing Plan
 - Includes a "Project-Specific Research Translation Plan" (PSRT)

Suggested Research and Activities:

https://www.niehs.nih.gov/research/supported/centers/srp/assets/docs/srp_funding_rfa_suggested_research_2023_rfa_508.pdf

Maximum of 6 projects

P42 Projects



Maximum of 6 projects

- **Important Note:** 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"
 - Questions if a Project qualifies? Please contact SRP staff.

Suggested Research and Activities:
https://www.niehs.nih.gov/research/supported/centers/srp/assets/docs/srp_funding_rfa_suggested_research_2023_rfa_508.pdf

FOCUS!!!!

- Centers should be VERY judicious in assembling research projects. Keep a clear focus and do not try to do too much!!
- Include projects with most solid connection to the Center's problem-solving theme.
- Justify model organisms, study numbers (e.g., animals; human subjects), dose, exposure relevance, etc.
- 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.
- Collaborative aims – if applicable, point them out!
- Refer to "*Table of Integration with Center*" (*Overall Section*)

Avoid Jargon!

P42 Reviewers have broad expertise

- Write abstracts/titles for a general audience (Plain Language: http://grants.nih.gov/grants/plain_language.htm)
- Write Specific Aims for technical experts
- Define Abbreviations

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

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 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_rfa_suggested_research_2023_rfa_508.pdf

SRP Data Collection Tool: <https://tools.niehs.nih.gov/srp/rtc/index.cfm>

NIH CareerTrac database: <https://careertrac.niehs.nih.gov/public/home>

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 (Type 1): include expertise of potential EAC members, **do not include names of any individuals*

Administrative Core not to exceed \$170,000 Direct Costs;
Center Director must commit a minimum of 1.8 person months

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

Serving a resource for facilitating and supporting effective data management :

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

Provides Points of Contact (in Relation to Overall Center)

- Data Collection Tool
- SRP-hosted webinars on data management and analysis

- 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

DMAC does not have set budget

Data sharing policies: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html>;
<https://sharing.nih.gov/>; <https://fairsharing.org/>

SRP Data Collection Tool: <https://tools.niehs.nih.gov/srp/rtc/index.cfm>

CEC addresses prevention/intervention defined by SRP's fourth mandate as “basic biological, chemical, and physical methods to reduce the amount and toxicity of hazardous substances”

Functions:

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

Target communities

- Communities impacted by hazardous substances (e.g., local government groups, Tribal councils/communities, community service groups, etc.)
- Emphasis: environmental justice communities (i.e., economically disadvantaged, underserved or vulnerable populations, minority populations, and Tribal communities)

Include descriptions of:

- Intervention and prevention activities
- How CEC fits into Center theme
- Timeline with milestones
- Plan to measure and verify outcomes
- Approach/methodology for surveys and/or sample collection (may be considered HS)
- Process to ensure effective bi-directional exchange of needs, recommendations, and results
- Recommended to include letters of support from community

**Core not to exceed \$120,000
Direct Costs**

Please Note: Prevention/Intervention activities involving human subjects may be classed as a clinical trial. For more information see, <https://grants.nih.gov/ct-decision/index.htm>

Provide Point of Contact for SRP-hosted webinars on community engagement

Suggested Research and Activities:

https://www.niehs.nih.gov/research/supported/centers/srp/assets/docs/srp_fundin_g_rfa_suggested_research_2023_rfa_508.pdf

P42 Research Support Core (Optional)

Purpose:

- Provides centralized services
- Shared by at least 2 projects

Can include 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

Include information on:

- How Core is a resource to the Center as a whole. Does it help integrate projects? How does it coordinate with DMAC?
- 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.

Graduate and Post-doctoral level cross-disciplinary training

Functions

- Promote interactions between biomedical and environmental science & 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
- Identify ways to enhance inclusion of trainees from diverse backgrounds

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, mentoring (esp. diverse backgrounds) etc.

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

Not to exceed \$120,000
Direct Costs

NIH CareerTrac database:

<https://careertrac.niehs.nih.gov/public/home>

SPAN Leadership Committee:

<https://www.niehs.nih.gov/research/supported/centers/srp/training/spa/committee/index.cfm>

Trainee List (for renewals only)

Illustration 6: Trainee List. In order to assist the review, a "Trainee List" is required in the Research Experience and Training Coordination Core Progress Report attachment for competitive renewal applications. In the "Trainee List," it is important that the application identify graduate student and postdoctoral researchers who participated in the "Training Core" during the previous funding cycle. (The SRP considers "trainees" as graduate students and post-doctoral researchers that perform research/activities that are supported by the Center.) This list should be in tabular form and include the names of the trainees, their SRP Center-associated mentor name, and project/core. Also, please indicate in the application that the trainee information has been entered into the [NIH CareerTrac database](#) (Note: All trainees should be entered into the NIH CareerTrac database)

Name of Trainee	Position Title (i.e., Graduate Student or Post-Doc)	Project Number/ Core Name	Mentor Name*	Current Status**
Dr. Esperanza Jones	Post-Doc	Project 1	Dr. Ella Davis	In Training
Ms. Diana Coltrane	Master's student	Project 2	Dr. Louis Holiday	In Training
Dr. Winslow Spalding	Post-Doc	Project 3	Dr. Dean Armstrong	Complete
Dr. Nora	Post-Doc	Project 3	Dr. Miles	Other

Tips for Applicants:

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

Examples of Tables for RFA-ES-23-001

https://www.niehs.nih.gov/research/supported/centers/srp/assets/docs/srp_rfaes23001_examples_of_tables_doc.pdf

SRP KC Donnelly Externship Program

- **New to RFA-ES-23-001 and the RETCC!**
- In honor of KC Donnelly, the SRP has established this program to provide current SRP-funded graduate students and postdoctoral researchers with translational/multi- disciplinary opportunities and experiences within other SRP-funded centers, government laboratories (EPA, ATSDR, NIEHS), or other agencies (state, local, Tribal).
- Budgets may include up to 2 KC Donnelly externships.
- KC Donnelly externships should be listed as a separate line item under "Other" in the budget section. Each KC Donnelly externship is limited to \$10,000 direct costs for support up to three (3) months, consisting of supplies, travel to externship site(s), housing costs, and travel to the SRP Annual Meeting to present the externship experience.
- In the budget justification, the KC Donnelly expenses must be clearly detailed. Provide details on level of effort and salary of core leader/staff, description of other expenses, etc. in the justification section.
- For more information about the SRP KC Donnelly Program, see <https://www.niehs.nih.gov/research/supported/centers/srp/training/donnelly/index.cfm>

Laura Dine
Laura Dine, Ph.D., is a postdoctoral research scholar with the University of North Carolina at Chapel Hill. She received her Ph.D. from the University of North Carolina at Chapel Hill in 2018. Her research interests include environmental toxicology and the role of epigenetics in disease pathogenesis. She is currently working on a project that aims to identify novel biomarkers for early detection of cancer.

Rebecca Dickinson
Rebecca Dickinson is a postdoctoral research scholar at the University of North Carolina at Chapel Hill. She received her Ph.D. from the University of North Carolina at Chapel Hill in 2018. Her research interests include environmental toxicology and the role of epigenetics in disease pathogenesis. She is currently working on a project that aims to identify novel biomarkers for early detection of cancer.

Arishah Estroff
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Pravleen Sahni
Pravleen Sahni, Ph.D., is a postdoctoral research scholar with the University of North Carolina at Chapel Hill. She received her Ph.D. from the University of North Carolina at Chapel Hill in 2018. Her research interests include environmental toxicology and the role of epigenetics in disease pathogenesis. She is currently working on a project that aims to identify novel biomarkers for early detection of cancer.

Martina Matthews
Martina Matthews is a postdoctoral research scholar at the University of North Carolina at Chapel Hill. She received her Ph.D. from the University of North Carolina at Chapel Hill in 2018. Her research interests include environmental toxicology and the role of epigenetics in disease pathogenesis. She is currently working on a project that aims to identify novel biomarkers for early detection of cancer.

Christina Wirth
Christina Wirth is a postdoctoral research scholar at the University of North Carolina at Chapel Hill. She received her Ph.D. from the University of North Carolina at Chapel Hill in 2018. Her research interests include environmental toxicology and the role of epigenetics in disease pathogenesis. She is currently working on a project that aims to identify novel biomarkers for early detection of cancer.

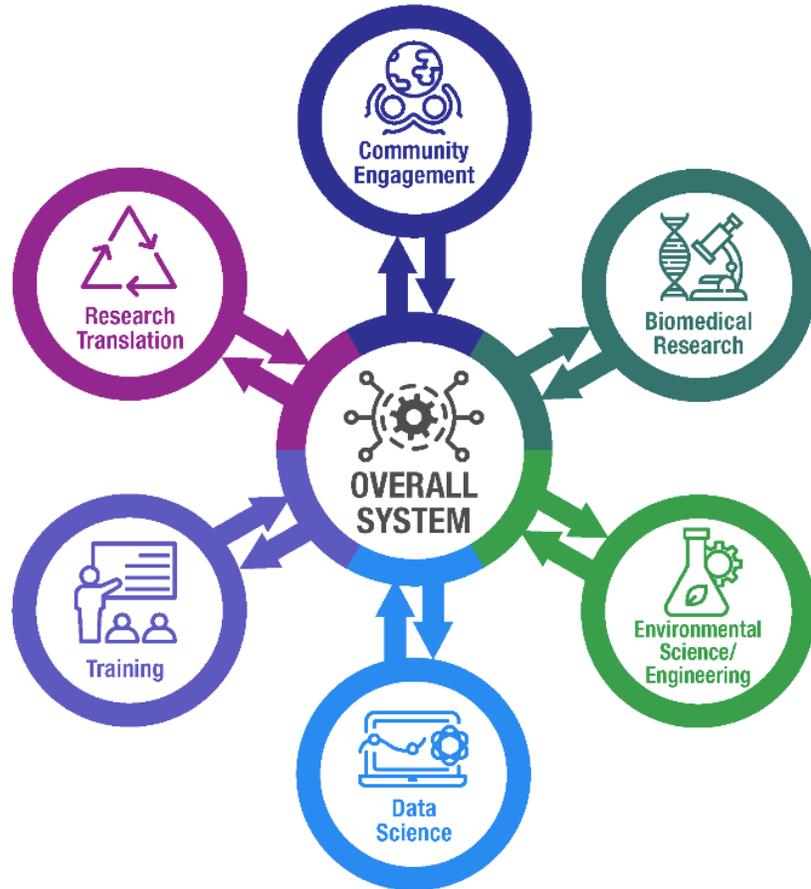
Melissa Woodward
Melissa Woodward is a postdoctoral research scholar at the University of North Carolina at Chapel Hill. She received her Ph.D. from the University of North Carolina at Chapel Hill in 2018. Her research interests include environmental toxicology and the role of epigenetics in disease pathogenesis. She is currently working on a project that aims to identify novel biomarkers for early detection of cancer.

Other Tips for Projects & Cores:

- **Authentication of Key Biological and/or Chemical Resources:** Please read NOFO for full text
- **Biohazards:** As applicable, procedures for proper handling and disposal should be included for biological materials, hazardous chemicals/materials, etc. This section should be included for any projects working with hazardous substances.
- **Appendix:** Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.
- **UPDATE:** Include budget information for *Data Management and Sharing Costs* for each respective Component as a line item in section F. Other Direct Costs

Please Note: Prevention/Intervention activities involving human subjects may be classed as a clinical trial. Need help determining whether you are doing a clinical trial? See, <https://grants.nih.gov/ct-decision/index.htm>

And finally.....



Projects and Cores Uniformly Meritorious

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

Addressing Important Problem

Aids End-users in Effective Decision-Making

Want to learn more about currently funded Centers? Check out the "Progress in Research" webinar series happening on Clu-In April/May 2023: https://www.niehs.nih.gov/research/supported/centers/srp/events/inprogresswebinar/multiproject_2023/index.cfm



Scientific Review



NIEHS P42 Superfund Program: Scientific Review Section

Scientific Review Officers:

Varsha Shukla, Ph.D.

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984-287-3288

Leroy Worth Jr., Ph.D

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984-287-3340

Scientific Review Branch
Division of Extramural Research & Training
National Institute of Environmental Health Sciences

May 15, 2023
12:00-1:30 pm ET

Schedule and Deadline

- **New RFA: [RFA-ES-23-001](#): Superfund Hazardous Substance Research and Training Program (P42 Clinical Trial Optional)**

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date
October 02, 2023	October 02, 2023	Not Applicable	April 2024	October 2024	February 2025

- **Priority Scores: Expect within ~48 hours after Review Meeting ends.**
- **SS Released in IMPAC: No later than August 2024**

Letter of intent (LOI)

- **Letter of Intent:** Not mandatory but helps in planning/recruiting purposes.
- 30 days prior to Application Receipt date (sent to the SRO of Note: Varsha.Shukla@nih.gov).
- Preference is by September 05, 2023 COB.

Include in the LOI:

- Descriptive title of the Overall Center
 - Brief description of the research proposed in the Center.
 - **Include 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.

Electronic Submission

All applications would be submitted electronically via Grants.gov using ASSIST (Application Submission System & Interface for Submission Tracking)

The screenshot shows the ASSIST login interface. At the top left, the ASSIST logo is circled in red. On the right side, the 'APPLICATION GUIDE' and 'ASSIST USER GUIDE' links are also circled in red. In the center, a red box highlights a notice: 'Active Grants.gov and eRA Commons credentials are required to prepare and submit applications using ASSIST.' The page includes login options for Login.gov, eRA Credentials, and Federated Accounts, along with a central section for submitting applications and a warning notice at the bottom.

<https://public.era.nih.gov/assist/public/login.era?TARGET=https%3A%2F%2Fpublic.era.nih.gov>

ASSIST

https://www.era.nih.gov/erahelp/ASSIST/default.htm#About_Help_System_ASSIST.htm?TocPath=___1

Welcome to the ASSIST Online Help

Revised 4/5/2023

Welcome to the ASSIST Online Help

This collection of help topics provides online information about the ASSIST functionality. You can access the online help by selecting the Help icon from any of the screens within ASSIST.

Use the following options to navigate the online help:

Contents Tab

The **Contents** tab displays books and pages that represent the categories of information in the online help. Click a closed book to open it and display sub-books and pages. Click an open book to close it. Click on a page to view it in the right pane.

Print Button

The **Print** button enables you to print the topic located in the right pane. Any collapsed information within the topic will not be included in the print-out. To include all information, make sure to use the **Expand All** button before printing.

Expand/Collapse All Button

eRA Help Desk:

Monday-Friday, 7 a.m.-8 p.m. EST

301-402-7469; Toll Free: 866-504-9552

<http://grants.nih.gov/support/index>

NIH Resources for electronic Submission

<https://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/submit-track-view.htm>

GRANTS & FUNDING
NIH Central Resource for Grants and Funding Information

HOME ABOUT GRANTS FUNDING POLICY & COMPLIANCE NEWS & EVENTS ABOUT OER

Home > About Grants > How to Apply - Application Guide > Submission Process > How To Submit, Track and View Your Application

ABOUT GRANTS

- Grants Process Overview
- Get Started
- How to Apply
- Application Referral and Review
- Pre-Award and Post-Award Processes
- Forms Library
- Information For

How to Submit, Track and View Your Application

You must login to eRA Commons[®] and use the **Status** feature to access your submitted applications and grants.

This page is an informational overview of the process used to submit, track and view your application.

At this point in the application process, your application preparation team should have already...

- Verified all required registrations are in place and your System for Award Management (SAM) registration is active
- Identified your funding opportunity and due date
- Chosen your submission method (ASSIST, your own system-to-system solution, Grants.gov Workspace)
- Prepared your application forms per the announcement and application guide instructions
- Checked the related notices section of your announcement for any late breaking changes
- Completed any internal reviews and sign-offs required by your office of sponsored research
- Routed your application to the person authorized by your organization to submit (i.e. Grants.gov user with the Authorized Organization Representative (AOR) role)

...and you, the AOR, are ready to submit. You're almost there; you just have a few steps to go.

- Submit your application to Grants.gov by 5 p.m. local time on your due date using your chosen submission method
- Track your submission in Grants.gov and eRA Commons and address any identified errors
- View your assembled application image in eRA Commons to verify we got it and that it correctly reflects your submitted application information. *If you can't VIEW it, we can't REVIEW it!*

Submission Process Overview

Once you submit your application to Grants.gov, they perform some basic application checks. If a problem is found, Grants.gov rejects your application with a "Rejected with Errors" status. You must address all errors and submit again. If no problem is found, Grants.gov places your application in a queue for agency retrieval.

Our eRA systems are constantly checking Grants.gov to see if they have any applications ready for us. When we retrieve your application, we check it against our own agency business rules and place the results in eRA Commons. We refer to these business rule checks as "validations".

You must check the status of your application in eRA Commons. If we identify problems with your application, we provide a list of errors and warnings. Errors are showstoppers and must be addressed. Warnings will not stop your application from progressing through NIH systems and on to NIH staff for further processing. Do not simply ignore warnings. Warnings alert you to potential problems that could lead to NIH staff withdrawing your application. Consider each warning carefully in the context of your situation and address any that apply.

Once we receive your error-free application, we create a consolidated document of all your submitted forms and attachments in a consistent format. We add headers, footers, a table of contents, and bookmarks and place the assembled application image in eRA Commons Status for you to view.

You have a 2-business day application viewing window to check your assembled application image and notify the eRA Service Desk[®] of any assembly issues (e.g., missing attachment, garbled text). The day of submission is not counted towards the application viewing window. Your application automatically moves forward to our receipt and referral staff for further processing at midnight Eastern Time on the second day of the viewing window unless you explicitly reject[®] the application in eRA Commons.

Submit

- We recommend you submit early - at least 2 days before the due date. Submitting early provides time to track your application, correct any errors and view your application by the due date.
- The specific actions you take to submit your application will vary by submission method (ASSIST, Grants.gov workspace, your organization's system-to-system solution).
 - Steps to submit to Grants.gov using ASSIST[®]
- Regardless of how you submit, your application will be assigned a Grants.gov tracking number (e.g., GRANT12345678).
 - Save this number. You will need it to track your submission and receive support.
- You will also receive a Grants.gov timestamp that we will use to determine if you submitted on-time.
- Your error-free application must be submitted by 5 p.m. local time for your organization.
 - We determine "local time" using the address in the Applicant Information section (item #5) of your SF424 (R&R) application form.
 - Grants.gov displays their timestamp in Eastern Time. Don't worry; we'll do the conversion to your local time before determining if you are on-time.
- Check out our Submission Policies page for guidance on due dates that fall on holidays/weekends, late applications, how to handle system issues impacting your on time submission and more.

Track

- You are responsible for tracking your application through Grants.gov to a visible application image in eRA Commons.
- You will receive a series of Grants.gov and eRA Commons email notifications throughout the submission process. Email can be unreliable, so it is good practice to proactively track your application status in Grants.gov and eRA Commons.
 - Track submission status in Grants.gov[®]
 - Steps for PI to track submission status in eRA Commons
 - Steps for Signing Officials (SOs) to track submission status in eRA Commons
- You must address any errors identified in Grants.gov and eRA Commons before the submission deadline. Warnings do not stop application processing. Read all warnings carefully and use your discretion to determine which, if any, you will address.
 - Learn How We Check Your Application for Completeness
 - Submit a Changed/Corrected Application

Note that PIs can check status information in eRA Commons on the go, using Commons Mobile (see info).

Application Preparation and Submission

Pre-Submission Checklist- carefully read and following the Guidelines (Key Personnel, font size, page limits, etc.). **Importantly,** understand the instructions outlined in the RFA.

Submission- Start early

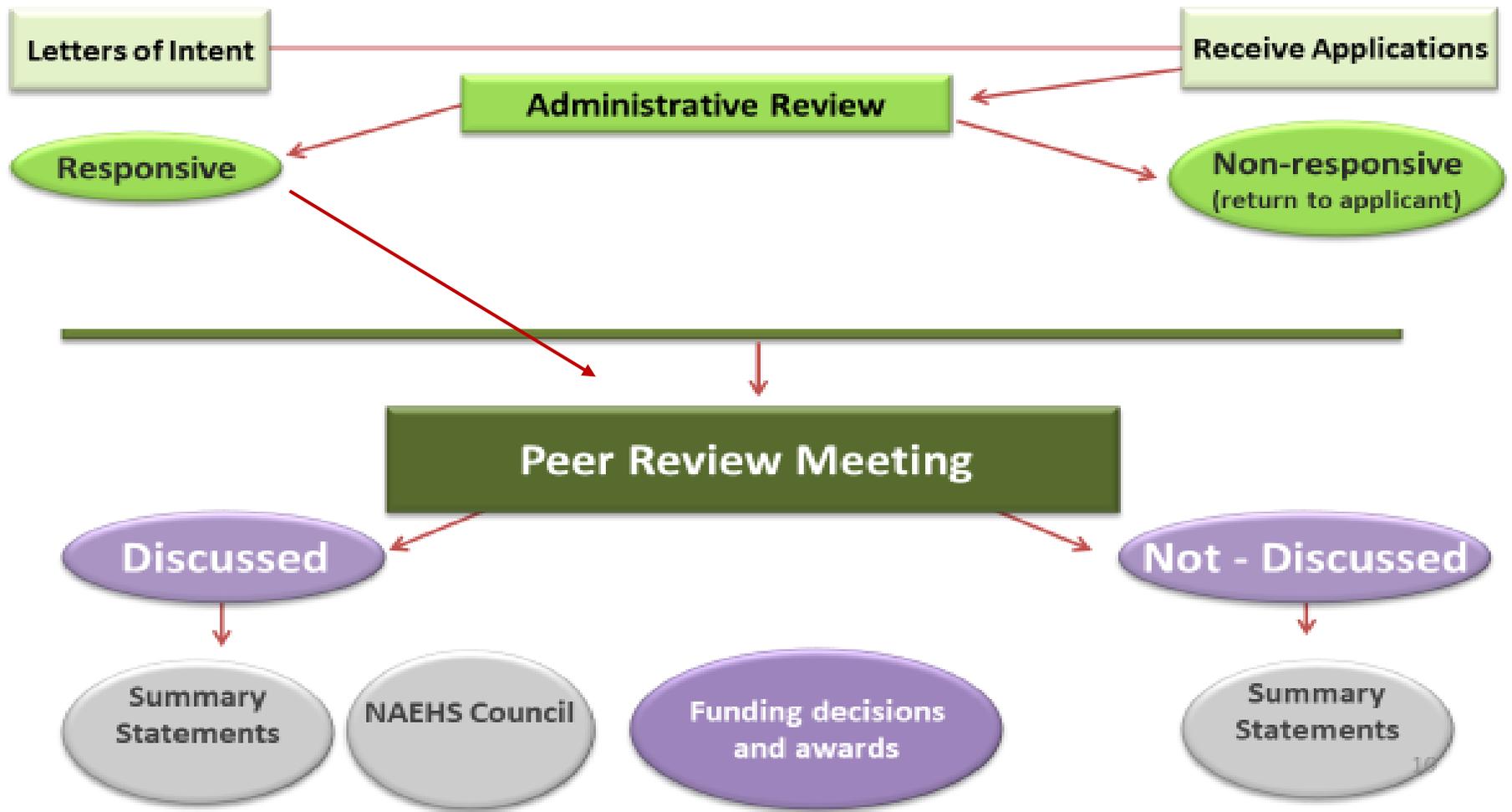


****Late Submissions-NIH Policy on Late Submissions ([NOT-OD-15-039](#))**

Electronic Submission

- **Grants.gov-** Due by **5:00 p.m.** local time of application's organization on the specified due date.
- **Must have eRA Commons account**
 - At least 5 Business Days prior to the Application Deadline.
 - Notification of Acceptance or Error (2-3 days).
- **Accepted by DHHS/NIH**
- **Assigned to an Institute/Center**
 - CSR: Receipt & Referral
 - Assigned an Application #
- **Accepted by the Institute/Center (NIEHS)**
 - Assigned to a Review Group

The Peer Review Process



Components and page limits

The application may consist of the following components:

All page limitations described in the SF424 Application Guide and the [Table of Page Limits](#) must be followed.

Component	Component Type for Submission	Page Limit	Required/Optional	Minimum	Maximum
Overall	Overall	12	Required	1	1
Research Project	Project	12	Required	4	6
Admin Core	Admin Core	12	Required	1	1
Data Management and Analysis Core - DMAC	DMAC	12	Required	1	1
Community Engagement Core - CEC	CEC	12	Required	1	1
Research Experience and Training Coordination Core - RETCC	RETCC	12	Required	1	1
Research Support Core - RSC	RSC	12	Optional	0	2

Components: Section V. Application Review Information

A. Scorable criteria:

Each section would receive a score:

- Overall
- Research Projects

- ✓ Significance
- ✓ Investigator
- ✓ Innovation
- ✓ Approach
- ✓ Environment

- Cores

- Administrative Core
- Data Management and Analysis Core (DMAC)
- Community Engagement Core (CEC)
- Research Experience and Training Coordination Core (RETCC)
- Research Support Core (RSC)

Components: Section V. Application Review Information

B. Additional Review Criteria:

Not individually scored but taken into consideration when providing overall score.

- Integration of the Center (only Overall)
- Study timeline (only Overall if involving Clinical Trials)
- Contribution to SRP Center (applies to all Projects and Cores)
- Protections for Human Subjects
- Inclusion of Women, Minorities, and Individuals Across the Lifespan
- Vertebrate Animals
- Biohazards
- Resubmissions
- Renewals

Components: Section V. Application Review Information

C. Post Scoring items:

Additional review considerations are not scored but are important part of the application.

- Select Agent Research
- Resource sharing Plans
- Authentication of Key Biological and/or Chemical Resources
- Budget and Period of Support

Reminder

- Please **go through the NOFO** ([RFA-ES-23-001](#)) before you begin your application preparation.
- Follow **SF424 (R&R) application guide** for instructions whether its use of Appendix, determination of Clinical Trial studies or Delayed onset.

Key Personnel List

- **Only** Center leadership, Project and Core leaders should be listed as Key Personnel.
- For new applications don't propose EAC members (just the expertise should be mentioned)

Post-submission Materials

- 30 days prior to the review date and sent to the SRO via AOR of your institution.
- SROs will follow-up with an email.
- It's a courtesy and not expectation to be read by the panel members.

Tips on Grantsmanship: Common Pitfalls

- ✓ Failure to carefully read and follow the instructions for completing the application.
- ✓ Biographical sketch not provided for applicable Center membership.
- ✓ Inconsistency fonts size throughout application.
- ✓ Inconsistency page numbering.
- ✓ Improperly prepared budgets.
- ✓ No formal letter of commitment for collaborative research.
- ✓ Checkpoints for Human Subjects & Animals.
- ✓ **Overall quality of application is poor-** (for example, typos, editing, organization, properly identified sections, & illegible figures or tables)....**carefully proof before submitting.**

Read the RFA and Submit Early!!



THANK YOU!

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Leroy Worth Jr., Ph.D

worth@niehs.nih.gov

984-287-3340



Budget Preparation

Budget Preparation

Provide detailed categorical budgets

- Each Project
- Each Core
- 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:

Annual SRP Grantee Meetings: Funds for travel by required staff (see RFA) to attend the Superfund Research Program three-day annual meeting shall be included in the Administrative Core's budget for each year.

Budget Justification

- Be detailed and specific
- Are all costs itemized?
- Are all additions and changes in subsequent/future years fully justified and identified clearly; specifically changes in personnel effort?
- Is there enough detail to allow grants management staff to determine if costs are reasonable and allowable?

Escalation/Inflation will be removed from out year budgets at the time of award.

Sub F&A will be included in the direct costs for the parent, but does not count against the direct cost cap

DO NOT USE

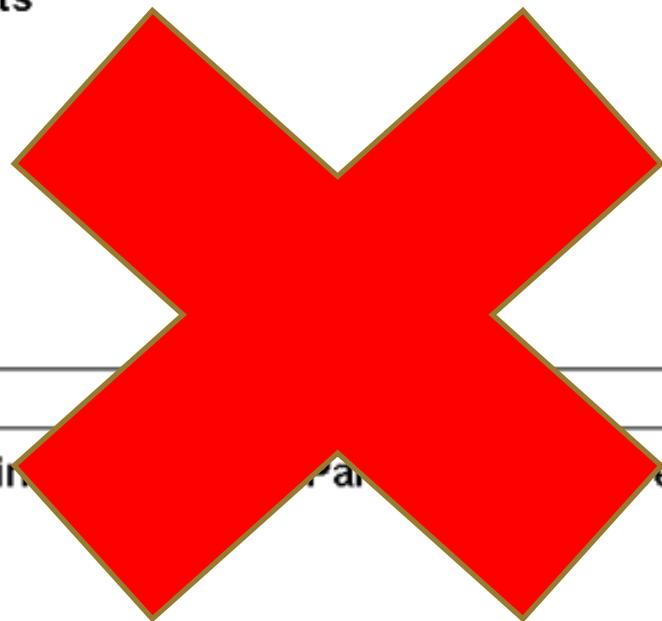
E. Participant/Trainee Support Costs

- 1. Tuition/Fees/Health Insurance
- 2. Stipends
- 3. Travel
- 4. Subsistence
- 5. Other

Funds Requested (\$)

<input type="text"/>

Number of Participants/Trainees **Per Participant Support Costs**



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

Common Budget Errors

- Exceeding the NOFO budget amount
- Costs in budget differ from the Budget Justification
- Salaries exceed the NIH salary cap
- Calendar months effort does not equate to the requested salary
- Miscalculation of F&A costs
- Waiting until the last minute to contact NIH on budget clarification questions
- Not asking questions

Helpful Resources

How to Apply - Application Guide: <http://grants.nih.gov/grants/how-to-apply-application-guide.htm>

Annotated SF424 (R&R) Application Forms: <https://grants.nih.gov/grants/how-to-apply-application-guide.html>

How we check for application completeness: <https://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/how-we-check-for-completeness.htm>

Help Resources page: <http://grants.nih.gov/support/index.html>

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

Scientific Review Officer, Varsha Shukla, NIEHS (varsha.shukla@nih.gov)

Chief, Grants Management Branch, Jenny Greer, NIEHS (jenny.greer@nih.gov)

Link to NOFO: <https://grants.nih.gov/grants/guide/rfa-files/RFA-ES-23-001.html>

Link to RFA Information Page:

<https://www.niehs.nih.gov/research/supported/centers/srp/funding/rfa/index.cfm>

Thank You!

Acknowledgements:
EPA's CLU-In.org,
Jean Balent, and MDB Inc.

Questions not covered during seminar will be answered off-line and posted on P42 Funding Opportunity Webpage:
<https://www.niehs.nih.gov/research/supported/centers/srp/funding/index.cfm>

Audio Archive will be available soon and accessible from the above website.