Frequently Asked Questions for RFA-ES-23-001
Limited Competition: Superfund Hazardous Substance Research and Training Program (P42 Clinical Trial Optional)

The following list of Frequently Asked Questions (FAQs) pertains to RFA-ES-23-001 and includes responses to questions asked during the May 15, 2023 P42 Funding Opportunity Webinar as well as frequent inquiries that have been received by NIEHS Staff pertaining to this Notice of Funding Opportunity (NOFO). Questions have been divided based on the components listed in the NOFO. Please contact an SRP staff member (contact information is also available in the NOFO) if you have a question that you would like answered and is not on this list. Note: If there are any discreprancies between responses In this document and the NIH Grants Policy Statement, the NIH Grants Policy Statement supersedes this document.

General and Overall Component Questions

1. **Q:** ***Who do we contact with questions on Center content?***
   A: You may contact any staff listed at the end of the NOFO for questions regarding your Center content:

   Danielle Carlin, Ph.D., DABT
   National Institute of Environmental Health Sciences (NIEHS)
   Telephone: 984-287-3244
   Email: danielle.carlin@nih.gov

   Michelle Heacock, Ph.D.
   National Institute of Environmental Health Sciences (NIEHS)
   Telephone: 984-287-3267
   Email: HeacockM@niehs.nih.gov

   Heather Henry, Ph.D.
   National Institute of Environmental Health Sciences (NIEHS)
   Telephone: 984-287-3268
   Email: henryh@niehs.nih.gov

   Brittany Trottier, MPH
   National Institute of Environmental Health Sciences (NIEHS)
   Telephone: 984-287-3331
   Email: brittany.trottier@nih.gov

2. **Q:** ***Is the Principal Investigator (PI) also the Center Director? Could you comment on the leadership of the Center (e.g., area of expertise, experience in managing centers or large research groups/collaborations, etc).***
   A: Yes, the PI of the application is considered the Center Director. The proposed Center Director should have the necessary experience/expertise to demonstrate effective and responsible leadership of the Center.

3. **Q:** ***Is there a specific number of new Centers that SRP will support/fund from this NOFO? Do new applications compete with the same review criteria and panels as the renewals or resubmissions?***
   A: The NOFO is open to new Center applications as well as renewals applications, and there is no set number of new, renewal, or resubmission applications that will be supported/funded by this NOFO. New, renewal, and resubmission applications are reviewed using the same criteria and review panels, with the exception that there are additional review criteria specific to renewal (progress of the prior period) and resubmission (responsiveness to prior review) applications.

4. **Q:** ***When does ASSIST open to begin uploading application documents?***
   A: As per the NOFO, the open date (i.e., earliest submission date) September 2, 2023.

5. **Q:** ***Does the $2M direct cost include consortium F&A or is the limit $2M direct cost less consortium F&A?***
   A: F&A for consortium is excluded from the Direct Cost cap, but when developing your budget, it will be part of your total direct cost.

6. **Q:** ***Do indirect costs on subcontracts count toward the cap on allowable direct costs for the program?***
   A: Indirect costs (F&A) for consortium is excluded from the direct cost cap of $2M, but please note that when putting the budget together it will be part of your total direct cost. Total Direct Cost will be over $2M by the amount of indirect cost for the consortiums.

7. **Q:** ***The NOFO states, under the Research Strategy section of Overall Component, the following subsections are recommended: Significance and Relevance to SRP Mandates and Superfund; Research Team; Innovation; Approach; Environment; and Center Integration. Do these subsections together need to be within the 12-page limit set for the Research Strategy section (which normally contains only Significance, Innovation and Approach subsections)?***
   A: Yes, the recommended subsections should be included in the 12-page limit.

8. **Q:** ***Under Research Strategy for the Overall Component and Research Projects, the following subsections exist: Center Integration and Relation to Overall Center, respectively. Are they the same?***
   A: No, they are not the same, but they are complementary. In addition, they are needed for overall evaluation of the proposed Center, and not a specific Project or vice-versa. Specifically, this Component includes a section titled "Center Integration". This section should describe/define aspects that demonstrate both multidisciplinary and interdisciplinary nature of the Center; the interactions between the projects and cores; how each project and core contributes to the Center's theme; and how the Center will facilitate the integration and interaction(s) among the biomedical and environmental science and engineering research. The Research Projects are required to have a section titled "Relation to Overall Center". This section should include a description that states the individual project relevance to the goals of the overall Center, how this project integrates with other projects and cores, and how the findings/activities of this project assist in addressing the goals of the Center. Coordination and or shared specific aims should be cross-referenced between projects/cores. Interactions with the Administrative Core's research translation functions and Data Management and Analysis Core should also be included. For projects, applicants may refer to their "*Table of Integration*

with Center" attachment (see Overall Section "Other Attachments").

9. **Q:** ***Are subawards to foreign universities/organizations allowed? How do you add a foreign component?***
   A: Yes, subawards to foreign institutes/organizations are allowable. Subawards to foreign universities/organization may be added to either Projects or Cores. However, a foreign institute/organization cannot be supported directly (i.e., Project/Core Leaders cannot be from a foreign institute/organization, but they may include Co-Leaders from foreign universities/organizations).

10. **Q:** ***Is an annual increase in budget allowed, such as 2% increase per annum?***
    A: Although an applicant may request escalation, it will be removed if an application is selected for funding because NIH does not allow escalation.

11. **Q:** ***If submitting a Resubmission of a Renewal, should an applicant follow both Resubmission and Renewal instructions in the NOFO?***
    A: Yes, if submitting a Resubmission of a Renewal, an applicant should follow both Resubmission and Renewal instructions described in the NOFO.

12. **Q:** ***Should salary for individuals above the salary cap be budgeted at the actual salary or salary cap?***
    A: It is recommended that an applicant request the actual salary amount at the time of the award. (There are instances when the salary is increased after an application has been selected for funding.). SRP Grants Management Staff cannot increase what is asked for but can decrease it if an applicant has asked for more than what was allowed.

13. **Q:** ***Is there an order to the Cores that they should be entered into ASSIST?***
    A: There is no set order; however, it is encouraged to use the order of Cores as described in the RFA. Applicants should follow up with eRA commons about how to upload Cores to ensure they appear in the order desired.

14. **Q:** ***What are the page limits for Projects' and Cores' Research Strategies and how should each project/core establish an outline to follow when writing an application? Further, is the timeline, abstract/summary, narrative, and attachments separate from the research strategy?***
    A: The NOFO indicates the Research Strategy is limited to 12 pages for each Project and Core. There is no prescribed outline for Projects and Cores. The Project Research Strategy is recommended to have the following subsections: Significance and Relevance to SRP Mandates and Superfund; Investigators; Innovation; Approach; Environment; and Center Integration. The Cores do not have specific recommended subsections but should be written clearly and logically. Applicants should carefully read the review criteria specific to each project/core and ensure that the review elements are addressed and clearly marked in the research strategy section. The Project/Core abstract/summary, narrative, and any allowable attachments are separate from the Research Strategy section. Please see SF424 Application Guide for text/page limitations for the abstract/summary, narrative, and any allowable attachments.

15. **Q:** ***What kind of attachments can be included in the Cores?***
    A: Attachments are not allowed for the Cores, except for the RETCC which requires a "Trainee List" attachment for renewal applications.

16. **Q:** ***What materials are allowable in the Appendix?***
A: Very limited items are allowed in the Appendix. Multi-Project (M) Instructions in the SF424 (R&R) Application Guide cite the following: NIH Guide Notice on Allowable Appendix Materials for more information.

17. **Q (see revised response below, corrected 8/24/23):** ***The NOFO states that funds for travel by appropriate staff (i.e., Center Director, Center Administrator, Research Translation Coordinator, Research Experience and Training Coordination leader, Data Management and Analysis Core leader, Community Engagement Core leader, and four trainees) should be included in the Administrative Core budget. Could the costs for travelling these individuals be added to the budgets of their respective cores/projects?***
A (original response): In general, this is acceptable. However, the Administrative Core is responsible for ensuring that the required attendees have funds to travel to the meeting. For example, one would expect the Center Administrator's travel support to be in the Administrative Core's budget, but travel of the Director, and other travelers could be added to the budgets of the project/cores with which those individuals are associated. Any SRP Annual Meeting travel costs that are covered under other project/cores should be noted in the Administrative Core budget justification.
A (revised response): Please see response to question #10 in the Administrative Core section which specifically refers the budgeting for travel for Center members attending the SRP Annual Meeting. However, other travel not related to SRP Annual Meeting attendance should be included in the respective project or core budget.

18. **Q:** ***Do we include a letter from our EAC in the application?***
A: Letters of support from the EAC are allowable in the application.

19. **Q:** ***Does the PI receive feedback after they submit the letter of intent?***
A: The Scientific Review Officer - will respond to applicants to let them know that the LOI was received and if it is missing any information, the SRO will request that information. As to content of the science described in the LOI, the applicant will not receive any feedback on that. This is why it is important for applicants to reach out to Program Officers early and often for feedback on – for example - relevancy of content.

20. **Q:** ***Are cross Center collaborations between Centers encouraged for specific projects and how should these be treated in the application?***
A: As part of the Research Translation component of the Administrative Core includes "Cross-Center communication: communicating with research translation coordinators from other SRP Centers. For example, the RT Coordinator should participate in regular SRP-hosted conference calls/webinars on research translation, and community engagement." In addition, coordinating with other SRP Centers could be a good opportunity for Investigator Initiated Research Translation. In addition, there are opportunities to collaborate with other Centers (e.g. the KC Donnelly Externship) that applicants should explore. These are just some ideas and a conversation with PO is advised.

21. **Q:** ***Does the 1.8 mo effort need to be funded through the SRP budget if there is institutional support to incorporate that will provide part of that 1.8 mo effort committed to SRP?***
A: The institution can provide the funding to support the 1.8 mo; however, applicants should

make sure that it is very clear in the budget justification that the Director is allocating 1.8 mo level of effort since this is a requirement of the NOFO.

22. **Q:** ***Is matching by the Institution, although not needed, advantageous to highlight the Commitment of the Institution?***
A: Yes, it is advantageous to highlight matching funds provided by the institutions to show the commitment of the institution.

23. **Q:** ***If an institution has no doctoral programs in biomedical areas and small programs in environmental and engineering sciences, it would probably be most desirable to partner with a larger and more biomedically active institution. Any suggestions for how to find such campuses?***
A: Yes it would be advantageous to seek out partners at institutions with graduate programs in both biomedical and environmental science and engineering. Please speak with your PO or any of the contact POs listed in the NOFO.

24. **Q:** ***The NOFO does not mention the Facilities and Other Resources and Major Equipment which we can upload in the projects and cores (i.e., Other Components section), we would also be able to upload these files in Overall?***
A: You should consult the SF424 (Multi-Project Instructions) and use the Facilities & Other Resources attachment and the Equipment attachment. As is written in the SF424 on p. 49: "**Unless specific instructions are provided in the NOFO, applicants have the option of including the "Equipment" attachment in the Overall Component, Other Components, or both (whichever is most appropriate for your application).** User defined bookmarks provided in the Equipment attachment will be included with the bookmarks of the assembled application image in eRA Commons. If you include the "Equipment" attachment only in the Overall Component, you may want to use bookmarks to organize equipment by component." SRP staff recommends that it might be best to include in both places, being careful to cross reference. In this way it will be clearer to reviewers.

25. **Q:** ***Are we allowed to have multiple-PIs listed as contacts/key personnel for projects and cores in our P42 application?***
A: While we understand that varying expertise if needed to accomplish the goals of a project/core, we highly recommend that you only have one Project/Core Leader assigned to each project/core. This will help reviewers in the evaluation of the appropriate leadership and expertise for each project/core, as each project/core are reviewed separately. In addition, after an award is made, your assigned Program Officer will determine which Project/Core Leaders are considered essential to the success of a project/core, and those project/core leaders will listed as Key Personnel on the Notice of Award (NOA).

26. **Q:** ***Would an institution be eligible to apply if they don't have a current center?***
A: Yes, provided the other eligibility criteria are met.

27. **Q:** ***Are Center applications allowed to include currently funded SRP Project and Core Leaders as Key Personnel in new and renewal P42 applications?***
A: There is no limitation to including currently funded SRP Project and Core Leaders as Key Personnel in new and renewal applications. However, the project research/core activity(ies) can not be within scope of the currently funded P42 work, and the current project/core leaders

must have sufficient effort available to participate in a new or renewal application. In addition, it should be clear in the new/renewal application why the expertise of the currently funded project/core leader is necessary, rather than seeking out other non-currently funded project/core leaders.

28. ***New Q (added 8/16/23): Is the Organizational Structure Attachment part of the Overall Component's 12 page limit?***
    A: The applicant should include the organizational structure diagram under "other attachments" attached to the Overall Center, and it will not count towards the 12 pg limit for the Overall Center page limit. (Note: none of the Other Attachments count toward the Overall Component's 12 page limit.)

29. ***New Q (added 8/16/23): Is an additional description or caption (i.e., text) of the organizational structure allowed in the Organizational Structure attachment? Or does the text need to be included in the 12 page description of the Overall Center?***
    A: ASSIST provides a finite amount of space for each attachment. Please consider using this space wisely as you put together each attachment.

30. ***New Q (added 8/16/23): Can expenses related to the EAC members allowable in the budget?***
    A: Expenses related to travel of EAC members to EAC meetings may be added to the budget, but salary for EAC members is unallowable. Note: If this is a new application, EAC members are not to be named in the application.

31. **New Q (added 8/16/23):** ***If a government employee (e.g., USEPA) provides significant input on an application or is designated a co-investigator on a Project or Core, can salary be provided to that employee?***
    A: There is a limit to what costs can be covered for federal employees. They are outlined in the NIH Grants Policy statement section [17.6](): ***Federal (U.S. Government) Employees.*** Whether or not costs will be charged to the grant, when a Federal employee will be involved in an NIH grant-supported activity in any capacity other than as an employee working on a grant to a Federal institution, or a study subject, specified conditions apply as provided in this subsection. The limitations in this subsection do not apply to individuals that are classified as special government employees because of service on advisory groups or as a result of a formal consulting arrangement with a Federal agency. (See the HHS Standards of Conduct at [45 CFR Part 73, Subpart J]() for additional guidance.) The Federal employee should consult with their agency ethics officials to determine whether outside activity approval is required by their employing agency. Only four types of costs-consultant fees, subject costs, salary or fringe benefits, and travel costs-can be charged to NIH grants on behalf of Federal employees, whether by a recipient or a consortium participant, and under the conditions specified only. Applicants/recipients should advise any Federal employee with whom these types of arrangements may be made to consult with their employing agency concerning their ability to participate and to meet the required conditions for payment. The applicant organization must submit, as part of the grant application, any letters or documentation specified below, and that documentation must be deemed acceptable by the GMO before the Federal employee's involvement in the project.

<u>Research Projects</u>

1. **Q:** ***Should a single environmental science and engineering (ESE) project be solely dedicated to SRP's Mandate 4? Can Mandate 4 be supported with individual aims from the ESE projects?***
   A: SRP requires that at least one ESE project supports Mandate 4 "basic biological, chemical, and physical methods to reduce the amount and toxicity of hazardous substances." A single project is not required to be solely dedicated to Mandate 4. Having an aim with a good connection to Mandate 4 is acceptable, but the applicant should be sure to emphasize (i.e., be specific) how the aim supports Mandate 4. If a poor connection is made to Mandate 4, the application may be returned as unresponsive, or it could raise concern by reviewers. In addition, the applicant should carefully review the RFA Sections titled "Environmental Science and Engineering (ESE) Projects"; and Mandate #4 *"*Basic biological, chemical, and physical methods to reduce the amount and toxicity of hazardous substances". The application should also review the Suggested Research and Activities Document which provided examples of ESE research that supports Mandate 4.

2. **Q:** ***What is the definition of "delayed onset" for human subjects' research?***
   A: The NIH definition of delayed onset can be found here:
   https://nexus.od.nih.gov/all/2017/12/28/what-is-delayed-onset/

3. **Q:** ***The NOFO states, under the Research Strategy section of research projects, the following subsections are recommended: Significance and Relevance to SRP Mandates and Superfund; Investigators; Innovation; Approach; Environment; and Center Integration. Do these subsections together need to be within the 12-page limit for the Research Strategy section (which normally contains only Significance, Innovation and Approach subsections)?***
   A: Yes, the subsections recommended are included in the 12-page limit.

4. **Q:** ***Investigator expertise is typically derived from the biosketch. It appears that an applicant is being asked to add a section to the Research strategy section on investigators. Is that correct?***
   A: An applicant may include, in the Research Strategy, the group's expertise to accomplish the overall goals of the Project, but without duplicating information in biosketches.

5. **Q:** ***Is it allowed to have a National Lab collaborator (e.g., PNNL to work with us on a project/core) and if so, could some amount of money for SRP project go there?***
   A: Yes, it is fine to have National Lab collaborators. If the National Lab employee's contract is such that it allows federal grant money, then NIEHS has authorization to cover expenses for their efforts, in accordance to the employee's contract.

6. **Q:** ***Would "biohazards" need to be a separate section, or can it be part of the Authentication of Key Biological and/or Chemical Resources section?***
   A: The SF424 guidelines refer to the "Facility Section" as a place to mention biohazard handling/management. As applicable, biohazard handling information may also be included in the vertebrate animals section and should be consistent with IACUC policy for handling, storage and disposal of any hazardous materials. In the interest of establishing rigor and reproducibility of your biological strains, one may also include information in the "Authentication of Key Biological and Chemical Resources" Section.

7. **Q:** ***Do grantees need full IRB approval, or just a date of approval?***
   A: NIEHS does not ask you to include the copy of the entire IRB approval, just the date of

approval. Please make sure that date is associated with an IRB approval that matches what is in the grant policy statement and meets those criteria. It can't be conditional meaning the IRB cannot be just or for one portion of the project – but the applicant must have an IRB approval that covers all the human subject activities that will be conducted under the project. **Note:** IRB approval date is requested as part of "Just In Time."

8. **Q:** ***If a subcontractor is component lead, but a member of the prime institution plays a paid role in the component, how is that presented in the budget?***
   A: Applicant should do a budget for the prime institution including any staff from the prime institution and should also do a subcontract for the component lead. Even if an organization is a lead on a component, they will still be a sub-awardee to the grantee institution.

9. **Q:** ***Could you please clarify what was said about subawardee indirect costs not counting toward overall direct cost cap?***
   A: When an applicant has entered in all of the budget information, they will be able to see a total amount of direct cost for the applicant organization. In that number it will include all of the subaward costs (subaward direct and subaward indirect costs); however, when we are calculating the cap, we will only count the subaward direct cost – we will exclude the subaward indirect costs.

10. **Q:** ***Would individuals owning or who are near the hazardous sites allow access to the PI/Co-PI and other researchers to their sites?***
    A: The NOFO webpage lists several resources for contacts at EPA/ATSDR that may be helpful. Applicants should refer to the following language from the NOFO under "Activities on Hazardous Waste Sites". "Whether through project research or core activity, Centers are strongly encouraged to seek opportunities for interactions at Superfund and other managed hazardous waste sites. Superfund sites serve as a good conceptual model for research focusing on hazardous substances. If on-site activities will be conducted, researchers must coordinate with appropriate Federal or State site officials and must observe best safety practices. When applicable, applicants must: propose a procedure for coordinating and documenting site activities including record of the research conducted, sample collected, or translation/ engagement activities; and delineate procedures for bi-directional communication and outcome reporting to appropriate site officials, site managers, and SRP staff at NIEHS. In addition, engagement of site officials in the early stages of project development and throughout the process is recommended, as this greatly increases the positive impact of SRP research and its utility to stakeholders. Links to stakeholder points of contact and suggestions for Hazardous Waste Site access are included on the "Additional Resources" webpage accessible from the following website: (https://www.niehs.nih.gov/research/supported/centers/srp/funding#multiproject_center). **NOTE:** The SRP is not a site-specific program. Applicants are not required to work on Superfund or hazardous waste sites."

<u>**Administrative Core**</u>

1. **Q:** ***Is the research translation (within the Administrative Core) goal to mainly focus on projects that are linked to project-specific research translation rather than projects that span the overall theme of the program?***
   A: The NOFO lists four objectives for research translation (within the Administrative Core): 1) Communicating within SRP and to SRP staff; 2) Partnerships with Government Agencies; 3)

Technology Transfer, 4) Information Dissemination to Other End-Users. One is not emphasized over the other. “Communicating within SRP and to SRP Staff” includes working with projects on their project-specific research translation activities.

2. **Q:** ***If an applicant had member on the External Advisory Committee (EAC) from a previous application, does that member need to be listed if they will stay on the EAC?***
   A: If the applicant is a renewal (Type 2), then they should include EAC members who are staying on for the renewal period. If the applicant is new (Type 1), the applicant should not list members of the EAC.

3. **Q:** ***If the SRP application is a multiple PI application, can the 1.8 months of effort be split between two Pis (i.e., two Administrative Core Leaders)?***
   A: Multi-PI applications are allowed; however, Program staff discourage this arrangement unless there is a strong justification. If you are considering submitting a multiple PI application, please discuss with SRP Program Staff. They can also provide guidance about how the level of effort should be applied.

4. **Q:** ***When an application includes multiple institutions, must there be an Administrative Core Leader (PI) and Center Administrator at each institution?***
   A: The Administrative Core Leader (i.e., PI) should be from the institution submitting the application. In addition, there would be one Center Administrator, preferably from the applicant university.

5. **Q:** ***Is there a conflict of having a PI from a P42 Center (currently in competition) named as an EAC member for a different university that is also currently in competition?***
   A: There is no conflict.

6. **Q:** ***Is a resubmission application included in the following statement from the NOFO: “New applicants should not list names of anticipated EAC members, unless they provide input into the design of the application?”***
   A: If it is a resubmission of a new application (Type 1) from the last NOFO, then names for EAC members should not be provided. If it is a resubmission of a renewal application (Type 2), then it would be appropriate to add the names of the EAC members.

7. **Q:** ***Are the Core limits (i.e. $175k direct costs for Admin Core) a yearly limit?***
   A: Yes

8. **Q:** ***Are honoraria funds allowed for External Advisory Board members in the Administrative Core budget?***
   A: Per Section 7.9.1 of the NIH Grants Policy Statement (GPS), honoraria are *unallowable when the primary intent is to confer distinction on, or to symbolize respect, esteem, or admiration for, the recipient of the honorarium. A payment for services rendered, such as a speaker’s fee under a conference grant, is allowable*.

9. **New Q (added 8/16/23):** ***Are biosketches required for IAC and EAC members?***
   A: If your EAC and IAC members are significantly contributing to the development of the grant application, biosketches are required for those individuals. NIH defines “Other Significant Contributors” as “Individuals who have committed to contribute to the scientific development

or execution of the project, but are not committing any specified measurable effort (i.e., person months) to the project. The names are required for the EAC members for competitive renewals.

10. **New Q (added 8/16/23):** ***The instructions for the P42 competing renewal say to include travel funds to the annual meeting for 10 people (listed below) in the Admin budget. The Admin budget is limited so we usually only put the travel of the Admin team in the Admin budget. However, we do always make sure to include the annual meeting travel for the rest of the required people in each Project and Core and have not had a problem before since they are all attending the annual meeting. My question is, for the competing renewal, if travel funds for each required person listed below are in the budgets for their related Project or Core, is that OK? Or must it all really go in the Admin budget?***
    A: Travel for those individuals must be included in the Administrative Core, as the RFA specifies.

<u>**Data Management and Analysis Core (DMAC)**</u>

1. **Q:** ***Is the budget for the DMAC part of the 20% limit of the overall direct costs budget? And what is the total allowable budget for the DMAC?***
   A: No, the budget for the DMAC is not part of the 20% limit of the overall direct costs budget, and there is no budget cap for the DMAC.

2. **Q:** ***Can bioinformatics be included in the budget for the DMAC?***
   A: As appropriate for the research goals of the DMAC, bioinformatics can be included in the DMAC. For example, if one of the projects requires a bioinformatics approach, the Center should budget accordingly for the respective research project and its role in the DMAC, if applicable. Keep in mind these additional functionalities (i.e., bioinformatics) are optional and should not detract from the data management and analysis responsibilities of the DMAC.

3. **Q:** ***Is the expectation that the DMAC facilitate integration of data across projects mean that there is an expectation that there be cross-project analyses performed?***
   A: There is no requirement that there will be cross-project analyses, but an applicant would include cross-project analyses if it meets the scientific goals of the Center.

4. **Q:** ***Is there an expectation for a DMAC to develop data standards and ontologies?***
   A: The DMAC should work with the projects and cores to determine the most appropriate associated scientific discipline-endorsed standards and associated metadata. The DMAC is not required to develop ontologies, rather it should leverage existing ontologies to facilitate data sharing and integration. It may describe how metadata (e.g., data descriptors) and ontologies (or semantic relationships) will be used to harmonize data across and outside the Center to enable interoperability and compatibility and to identify the relationships between data.

5. **Q:** ***Is the DMAC required to establish and maintain a data repository?***
   A: No, the DMAC is not expected to create a repository for the Center's data, the core should be familiar with databases that can be used to deposit the data (https://fairsharing.org/), recommending domain specific repositories (NIH encourages researchers to select data repositories that exemplify the desired characteristics, https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/selecting-a-data-repository) and the

tools needed to share and analyze this data.

6. **Q**: ***Is there an expectation for the DMAC to have a web-based platform for sharing data with other SRP grantees?***
   A: While we do not require a web-based platform to share data outward with other SRP grantees, the DMAC research strategy should address plans for sharing data within and outside the Center, including which data repositories will be used.

7. **Q:** ***Can the authentication of key biological and/or chemical resources section for DMAC simply cross reference information provided in the research project component? Or is more information needed in this section, the DMAC, and/or Admin Core section?***
   A: It depends on the focus of that core. If the authentication of biological or chemical resources is central to some aspect of what a core does, then the applicant would be advised to include details within the component. However, if the core is not leading efforts with the supplied resources or reagents, requiring authentication then it would be reasonable to cross reference the section/component of the application where the experimental design is executed.

8. **Q:** ***What expertise should the Core Leader of the DMAC have? Is it acceptable to have a DMAC Leader with expertise in data management, but no experience leading a core or vice versa (a DMAC Leader with experience leading a core, but limited expertise in data management)?***
   A: The DMAC leader should have relevant experience to lead the core. The core key personnel should have expertise in data management; and, as applicable, may wish to include other expertise relevant to the DMAC's objectives (e.g., biostatistics and/or bioinformatics, data visualization, information and knowledge management, software development, semantic engineering, etc.).

9. **Q:** ***For data management and sharing costs, it was indicated on the funding opportunities webinar to include these costs in "the Overall Component as a line item in section F. Other Direct Costs."***
   A: The information provided in the funding opportunities webinar was incorrect and has been updated. Budget information for the Data Management and Sharing Costs should be included in each respective component in Section F. Other Direct Costs as a line item entitled, Data Management and Sharing Costs. Please see the NIH data sharing page (Budgeting for Data Management & Sharing | Data Sharing (nih.gov) for more information and follow the application instructions (https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.300-r&r-budget-form.htm#F).

10. **Q:** ***Does the DMS Plan still have a 2-page limit, given the overall size of the P42?***
    A: DMS Plans are not limited to 2 pages, they are recommended to be two pages or less. They should be submitted as attached in the Other Plan(s) attachment in FORMS-H application forms packages. The Data Management and Sharing (DMS) Plan must be provided in the Overall component.

Community Engagement Core (CEC)

1. **Q:** ***Are Significance and Innovation sections required in the CEC Research Strategy section?***
   A: No, please refer to the NOFO for guidance on what to include in the Research Strategy section. In addition, please ensure that you are responsive to the review criteria for the CEC.

2. **Q:** ***How many total pages are allowed for the CEC?***
   A: Summary/Abstract is 30 lines total, Project Narrative is three sentences, Specific Aims are 1 page, and the Research Strategy is a total of 12 pages. Applicants should also review SF424 for further guidelines regarding text and page limitations.

3. **Q:** ***For the CEC, is there a page limit for the Progress Report (for renewal applications) which is to be included in the Research Strategy section (whose overall page limit is 12 pages)?***
   A: There is no page limit for the Progress Report, but it does have to be within the 12 page Research Strategy. Note: The Progress Report only applies to renewal (Type 2) applications.

4. **Q:** ***Are collaborative aims allowed for CEC or only between projects?***
   A: Yes, collaborative aims are allowed for CECs and are encouraged.

5. **Q:** ***Where should the timeline be placed in the CEC? Can it be a table? Is there a page limit?***
   A: The timeline is part of the 12 pages in the CEC Research Strategy. It can be a table or can be text.

<u>**Research Experience and Training Coordination Core (RETCC)**</u>

1. **Q:** ***For the KC Donnelly externship component of the RETCC, how do you plan a specific externship without having certainty what the potential sites are for the externship (not knowing which centers will be awarded)?***
   A: The NOFO states applicants may include in their RETCC budget funds for 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 (https://www.niehs.nih.gov/research/supported/centers/srp/training/donnelly/index.cfm) 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.” Applicants should provide budget details to the best of their ability, estimating budget needs for the allowable categories. Note that once awarded, grantees would need to be in discussions with the PO about the details of their KC Donnelly extern applicants, per NOFO “The PD/PI is also strongly encouraged to contact their Program Administrator to discuss their proposed externship plans to ensure that it fulfills the description and goals of the KC Donnelly Externship Program).”

2. **Q:** ***Are the training efforts in the RETCC expected to be innovative?***
   A: While innovation is not explicitly mentioned in the description of the RETCC or the review criteria, it is encouraged to demonstrate some originality within the proposed Core.

3. **Q:** ***Trainee success stories (usually a table placed in the progress report section) can be moved to the list of current and former trainees (which is outside of the 12 page limit for the Research Strategy). Is this correct?***
   A: Renewal applications are encouraged to include examples of trainee success stories in the Progress Report in the RETCC Research Strategy Section. In their Progress Report, applicants

should also refer to the Trainee List (an allowable attachment) for a full list of current and past trainees.

4. **Q:** ***For travel to the SRP annual meeting for trainees, can travel be budgeted in the RETCC?***
   A: Yes, traveling trainees to the SRP annual meeting may be budgeted within the RETCC travel budget. However, please note there is a limit of one trip to a scientific meeting per trainee per year in the travel budget of the RETCC.

5. **Q:** ***For the RETCC, would trainee travel be considered a Participant Support Cost?***
   A: No, the cost should be listed under travel.

6. **Q:** ***Although the NOFO indicates the type of training activities they're looking for, there's no specific structure recommended. Am I correct in assuming we do not follow the traditional, "Significance, Approach, Innovation, Research Plan" format of an R01?***
   A: Yes

7. **Q:** ***It specifies to use "Component type 'Core'"- this automatically means the RTCC core proposal has a page limit of 12 pages +aims, correct?***
   A: Yes

8. **Q:** ***Are past trainee successes required for new submissions by old programs going back in (not a renewal)?***
   A: It would be in your best interest to recognize some of the successes that the team of investigators (e.g. the RETCC) has had in training efforts. Note: the "Trainee List", which is an attachment for the RETCC is for renewal applications only.

9. **New Q (added 8/16/23):** ***We would like to budget for two KC Donnelly externships for each year. If for some reason we don't have 2 trainees who can or who want to do externships, will we be allowed to re-budget these funds or would we lose them?***
   A: Likely there will be a term and condition in the Notice of Award, and rebudgeting will be addressed there. Program staff will also manage these kinds of issues on a case-by-case basis. The goal will be for grant recipients to do all that is possible to find trainees interested in participating in KC Donnelly externships.

10. **New Q (added 8/16/23):** ***If we (I.e, grant recipent) receive funds for KC Donnelly externships, will there still be a proposal and review process for SRP/NIEHS staff or will we just make arrangements and carry out the externship without involving the SRP?***
    A: The goal would be for grant recipients to reach out to their POs to ensure that the KCDs are within scope of the grant/overall program (provide link to program here). For example, SRP staff request that grant recipients ask their trainees to work with another SRP Center or fed/state/or local laboratory or agency. There will no longer be any SRP KC Donnelly supplement application process (I.e, NIEHS submission or review of KC Donnelly applications pertaining to the grant recipients responding to this RFA).

<u>Research Support Cores (optional)</u>

1. **Q:** ***Can new equipment requests be included in Research Support Cores?***
   A: Capital expenditures for **special purpose equipment** are allowable as **direct costs**. Please refer to the NIH Grants Policy Statement 7.9 & 1.2 for additional information.

2. **Q:** ***Does the analytical or service core need to be already existing in the university? Like an instrument center of a department?***
   A: No, research support cores (such as an analytical or service core) do not need to be already existing in the university.

3. **Q:** ***If a Research Support Core provides a service involving handling/housing animal models, should IACUC approval forms (for vertebrate) be provided for the core if they have been included in the Projects?***
   A: IACUC approval forms should be provided for each Project using vertebrate animals and should be referenced in the Research Support Core, as applicable.

4. **Q:** ***The NOFO states, under the Research Strategy section of research projects, "the following subsections are recommended: Significance and Relevance to SRP Mandates and Superfund; Investigators; Innovation; Approach; Environment; and Center Integration". How do the recommended subsections apply to the Research Strategy section of optional research support cores?***
   A: The recommended subsections do not necessarily apply to optional Research Support Cores, but the same subsections may be used, if applicable. Applicants should refer to the review criteria to ensure that the review elements are addressed and clearly marked in the research strategy section.