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Superfund Research Program

Best Practices for SRP Grantees

The following guidelines are intended for existing, awarded SRP grantees (P42, R01, R25, R13, SBIR/STTR) regarding best practices related to events or issues that may arise throughout the duration of a grant cycle. These guidelines are meant to complement, but not supersede, rules and guidelines emanating from the National Institutes of Health (NIH) and the U.S. Department of Health and Human Services (DHHS). Grantees are encouraged to refer to the NIH Grants Policy Statement (GPS)

http://grants.nih.gov/grants/policy/policy.htm for further details.

The information contained in this document can be found on the <u>Materials for Grantees</u> webpage. Please check the webpage to be sure you have the most up-to-date copy.

For specific issues, questions, and discussion, please contact your assigned Program Officer (PO) listed in the "NIEHS Staff Contacts" on this page.

A. Prior **Approval** Requests

Circumstances may change throughout the period of a grant award. Many changes do not need to be reported to NIEHS; however, there are several situations when official notification is needed to authorize changes to an award. This is referred to as "**Prior Approval**."

A Prior Approval request should be provided to NIH 30 days prior to any anticipated changes to the grant. Please refer to the NIH Grants Policy Statement for circumstances under which prior approval may be required. An official prior approval request must be submitted by your Institute's Authorized Organization Representative (AOR) through eRA Commons (preferred) or via email to the SRP Grants Management Officer (GMO) (cc: SRP PO) assigned to your grant. The request should include an explanation for the post award change. The NIEHS GMO and PO will review the request and the GMO will provide a response to the AOR regarding final disposition of the request. In addition, please contact your AOR for institutional guidelines. All email requests and correspondence must include the grant number and PI name in the subject line of the email and in the body of the cover letter and the request.

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Web: http://grants.nih.gov/support Email: commons@od.nih.gov Hours: Mon-Fri, 7am to 8pm Eastern Below are some of the most common prior approval requests that occur throughout the duration of a grant:

1). Changes in Key Personnel and Other Personnel

NIH has a specific policy for individuals who are named as "Key Personnel" on the "Notice of Award" (NOA). For P42 Center grants, Key Personnel tend to be each Project and Core leader as well as the Research Translation Coordinator and Center Director. For all other grants (i.e., SRP R01, R25, R13, SBIR/STTR), "Key Personnel" are usually only the Principal Investigator (PI).

Prior approval is required when Key Personnel effort is reduced by 25% or more, an individual listed as Key Personnel withdraws from the project entirely, or if Key Personnel will be absent for a continuous 3 months or more.

The request should include: a cover letter with the reason for the change, a timeline for the change, a justification for selection of the individual who will replace the key personnel (if applicable), an NIH biosketch of the proposed new individual, level of effort/other support for the new person, any budgetary implications of the change, and any other related materials (e.g. changes in staff contact details).

Please note that reporting that staff changed in section D.1 of the Research Performance Progress Report (RPPR) does not constitute an official prior approval request. However, answering yes to question D.2. (a 25% or more reduction in key personnel Level of effort) and listing the changes that will occur in the next budget period does constitute a prior approval request and our approval of the RPPR constitutes approval of the change. If you anticipate a change at a time that is outside of RPPR reporting, the prior approval request must come through the electronic submission process.

For other personnel who are not listed on the NOA, official prior approval is not required; however, we ask that you notify your SRP PO and provide updated contact information to ensure that new personnel are included in appropriate programmatic listservs and website information. As a courtesy, it is highly recommended that you notify your PO of any personnel changes associated with your grant,

Note: Changes in P42 Center Director are rare and require early communication with SRP staff to ensure that an appropriate transition process will be followed. Therefore, it is imperative that your SRP PO be notified about the possibility of a change in Center Director 6 to 12 months prior to any effective change.

2). Change of Institution

A change of institution is when a Center Director (P42) or the PI of anR01, R25, or SBIR/STTR plans to change institutes (move to another university) and your institution plans to relinquish the grant to allow it to transfer with the PI, your organization must submit a relinquishing statement through eRA Commons. The new organization that the PI is moving to must then submit a change of institution application at least 3 months before the move or before the anniversary date of the budget period (budget period start date).

Prior approval is not required when other key personnel listed on the NOA (i.e., other than the Center Director or PI) transfers institutes **unless** the activity constitutes a

change in scope or there is transfer of work to a foreign component. Unless prior approval is required, these changes should be listed in the next RPPR; please notify your SRP PO with updated contact information to ensure personnel are added to appropriate programmatic listservs and website information.

Note: Change of institution for a P42 Center Director is rare and requires early communication with SRP staff. Therefore, it is imperative that your SRP PO be notified about the possibility of a change of institution for the Center Director 6 to 12 months prior to any effective change.

3). Sabbatical Leave

When a PI or key personnel listed on the NOA is absent from the institute for a continuous period of 3 months or more, prior approval is required even if the PI intends to continue grant-related work at the sabbatical location. Your SRP PO will need to determine whether an interim PI should be identified due to the PI's absence. Hence, if you anticipate sabbatical leave greater than 3 months, please notify your SRP PO immediately and initiate the prior approval process.

4). Significant Changes to Center Structure or Scope

Any significant change in scope to a project or core requires prior approval. Contact your SRP PO at least 4-6 months prior to making modifications to the scope of a project or core to determine whether the proposed changes necessitate a prior approval request. Examples of changes in scope include the addition or deletion of a specific aim or the addition of human subjects and/or vertebrate animals if they were not proposed in the initial review of the grant application (please review the NIH Grants Policy Statement for more examples). If your PO determines the changes are a change in change in scope, please submit a prior approval request.

5). No Cost Extensions

First No Cost Extension (1st NCE): If at the end of the project end date, more time is needed to complete tasks, you may request a "No Cost Extension" (NCE). Use the eRA Commons No-Cost Extension feature to electronically notify NIH that you are exercising your one-time authority to extend (without funds) the expiration date of your award. The No-Cost Extension feature is available 90 days prior to the end of the project end date. This extension may be up to 12 months beyond the final budget period end date. In the eRA Commons, this notification can be made up to the last day of the current project end date. Upon receipt of this notification, the budget and project period end dates are automatically extended in eRA Commons and an e-mail notification will be automatically sent to the NIEHS GMO. No further action is required by the grantee. A revised NOA will **not** be provided. Your Institution should receive an email notification that the NCE was accepted; however, the best way to confirm acceptance is to check eRA Commons to see if the end date has been extended.

Second No Cost Extension (2nd NCE): A 2nd NCE can be requested if a grantee currently on a 1st NCE anticipates more time will be needed to complete grant activities. A prior approval request is required for a 2nd NCE. The prior approval request should be submitted no less than 30 days prior to the last day of the project end date through the eRA Commons (preferred). The request should include a description of the project activities that require support during the extension and a statement about the funds

available to support the extension. The applicant may wish to include reasons/special circumstances for the delay in completing the remaining activities. The letter should clearly state the desired new end date (we recommend asking for a full 12 months). (Note: if a large unobligated balance is associated with the 2nd NCE, contact your PO in advance, as additional information may be requested.)

6). Foreign Projects or Studies

Any foreign studies, collaborations, or sub-contracts not approved in the competitive application require <u>prior</u> approval from NIEHS. You must submit a prior approval request at least 30 days before the proposed change. The request should include a detailed description of the foreign involvement and a justification for why the work must be performed outside the US or in partnership with a foreign collaborator. Please be aware that foreign involvement requires complete and compelling justification. Examples of foreign involvement justification include access to a population exposed to a chemical or level of a chemical agent that does not occur in the US; a collaborator with a singular piece of equipment or resource that is not available in the US; or a population with a unique set of polymorphisms (such as in a unique and identified, large family) and exposure history. See the NIH Grants Policy Statement (Section <u>8.1.2.10</u>) for more information.

B. Carryover Requests - for Center Grants (P42) Only

If you have unobligated funds remaining at the end of the grant's budget period, <u>and if</u> there is a bona fide need for additional funds, you may request a Carryover of Unobligated Funds from prior budget periods into your current budget period.

To do that efficiently, the following items are needed to facilitate the process:

- 1). Submit Your Federal Financial Report (FFR): The FFR is due from your institutional business office to NIH (via eRA Commons) 90 days after the end of the calendar quarter in which your budget period ends (e.g. for grants ending on January 31, February 28 or March 31st, the FFR is due by June 30). The FFR should be received and accepted by the NIH Office of Financial Management before you send a request for Carryover (see "B. Carryover Request to NIEHS" below). Any delay in the FFR may result in a delay in processing a carryover request.
- **2). Carryover Request to NIEHS:** After your FFR has been accepted by NIH, your university's AOR should submit a carryover request that includes the following information:
- Grant number and name of PI
- Cover Letter that includes:
 - Reason for the unobligated balance (e.g., projects and cores contributing to the carryover balance, details about other delays contributing to the balance).
 - The amount of funds to be carried over: direct, facilities and administrative (F&A), and total costs.
 - Explanation of why the work cannot be accomplished through rebudgeting
 of current budget period funds. Be sure to emphasize your <u>immediate</u>
 need. Carryover will not be approved if there is no immediate need.

- Detailed budget, including personnel names and calendar months of effort. NIH will
 generally not consider "to be named" personnel. The budget should cover only
 whatever months remain in the current budget period. For example, if you ask for
 carryover with only 2 months remaining in the current budget period, you cannot
 request funds for 3 months of effort.
- F&A costs for the grantee and subawardees, using the F&A rates used to award the year to which the funds are being carried over
- Checklist page reflecting the requested F&A rate and F&A costs
- Budgetary and scientific justifications. <u>Note: please confirm in writing that the proposed</u> use of the carryover funds is within scope of the grant.
- Description of how you will pay for any recurring expenses (such as supplies and personnel) in the future, after the carryover funds are expended.
- If new personnel will be added, include appropriate required personnel information, e.g., human subjects' education certification, biosketch, other support, etc.

Submission: The carryover request should be submitted via the eRA Commons through the electronic Carryover submission process in the "Prior Approval" module. This YouTube walks you through the process: https://www.youtube.com/watch?v=-wm6D94 mXY&feature=youtu.be.

3). Additional Carryover information:

- Justification for the use of carryover funds in the next budget period must be within the approved scope of the grant (see section above "Significant Changes to Center Structure or Scope" for what constitutes a change in scope, which may require prior approval).
- For more information about policy, please see Grants Policy Statement for Carryover of Unobligated Balances (http://grants.nih.gov/grants/policy/policy.htm)
- If you have questions about what to include in the letter or detailed budgets, please contact your Grants Management Officer before submitting your Carryover request.

C. Administrative Supplements

Grantees may request additional funds, in the form of Administrative Supplements, for emergency needs or other unanticipated situations that result in unforeseen costs. Administrative Supplements may also be used to follow up on unanticipated results or to enhance components of research that have been unexpectedly productive. In addition, SRP provides supplements for other opportunities in environmental health sciences. Details about Administrative Supplements and the process for submitting may be found on the Materials for Grantees main page. Note: it is important that you contact your SRP PO before applying for a supplement to ensure that the request is within the scope of the parent grant and to determine whether a supplement is the most appropriate mechanism given timing and budgetary constraints. Please note: grantees in a No Cost Extension are not eligible for Administrative Supplements.

D. Reporting

1). Progress Reports

For multi-year awards, a Research Performance Progress Report (RPPR) is due and must be approved before funds will be released for the next non-competing year. The progress report must be submitted to eRA commons by the following due dates:

- For P42 Center Grants: The progress report is due 60 days (for non-SNAP) prior to the next budget start date (Due date varies per awardee see your Notice of Award).
- For R01s and R25s: The progress report is due 45 days (for SNAP) prior to the next budget start date (Due date varies per awardee see your Notice of Award).
- For SBIR/STTRs: The progress report is due 45 days (for SNAP) prior to the next budget start date (Due date varies per awardee see your Notice of Award).

If this is your first time submitting an RPPRto NIH, please contact your AOR to become familiar with your institute's submission procedures and internal deadlines.

NIH RPPR instructions are available on the following website: http://grants.nih.gov/grants/rppr/index.htm. Because the RPPR process is constantly evolving, SRP staff will provide specific details of what to include in your progress report closer to its due date. These details are provided on the Materials for Grantees webpage in a separate document.

2). Trainee Tracking through CareerTrac

The SRP defines "trainees" as graduate students and post-doctoral researchers supported directly by the Center and/or performing research/activities that are supported by a P42, R01, R21, R25 or SBIR grant. Generally, one is considered a trainee if they spend at least 1 calendar month/year performing research/activities on the grant.

CareerTrac is an NIH/NIEHS-funded system to enable evaluation of the training program for SRP trainees specializing in the environmental health sciences. CareerTrac is accessible through the NIEHS Research Partners website.

Note – eCommons ID is also required for any new trainees to be added to CareerTrac. Please only add graduate and postdoctoral trainees to CareerTrac. Please work with your trainees as soon as they join the grant to obtain their eCommons ID.

Please contact Brittany Trottier (<u>brittany.trottier@nih.gov</u>) for specific instructions for adding trainees to eRA Commons and CareerTrac and the pertinent trainee information that should be added to the system.

3). Data Collection Tool

The SRP Data Collection Tool is a research translation tool that allows grantees to inform SRP staff of grantee activities such as webinars/meetings, interactions with stakeholders, trainee/investigator awards, news articles and publications. While not required, grantees are encouraged to utilize this tool. The tool can be assessed through this link http://tools.niehs.nih.gov/srp/resources/rtc.cfm. Please contact Michelle Heacock (heacockm@niehs.nih.gov) if you have any questions.

E. Grant Closeout

Closeout requirements can be found in section 8.6 of Grants Policy Statement as well as in the Terms for your Notice of Award. SRP and NIEHS urge you to submit your closeout documents in a timely fashion. Please review NIH Closeout Policy (NOT-OD-18-107) and note that there are new requirements for Interim- and Final-RPPRs.

When a grant comes to an end, grantees must submit the following closeout reports whether or not the grant is renewed:

- Final Federal Financial Report
- Final Invention Statement and Certification
- Final Research Performance Progress Report (F-RPPR) or Interim Research Performance Progress Report (I-RPPR)

All reports required for closeout must be submitted no later than 120 days after the project end date (if a no cost extension is requested, the project end date is the end of the no cost extension period). The Final Federal Financial Report *must* be submitted through the eRA Commons at https://commons.era.nih.gov/commons. (Also see eRA Commons User Guide.) The Final/Interim-RPPR and the Final Invention Statement (if applicable) are also submitted through eRA Commons.

If your project is in competition status at the time of your closeout (e.g., P42s in re-competition or SBIR Phase I submitting a Phase II) you will submit an I-RPPR. If your project is no longer competing, you will submit an F-RPPR. The forms are exactly the same – the only difference is that NIH converts your I-RPPR to an F-RPPR in the event that the new application is not funded.

The following webpages provide guidance for the F-RPPR and I-RPPR; however, please see (below) specific guidance tailored to your grant's mechanism. Contact your Grants Management Officer or SRP PO if you have any questions.

- Final Research Performance Progress Report (F-RPPR) or Interim Research Performance Progress Report (I-RPPR): https://grants.nih.gov/grants/rppr/index.htm
- Overview of I-RPPR (and F-RPPR): https://era.nih.gov/erahelp/commons/Commons/rppr/Interim RPPR/interim RPPR overview.htm#Overview
- NIH Guidance on Interim and Final RPPRs: https://www.niehs.nih.gov/funding/grants/instructions/guidance/nih-guidance/index.cfm
- What to include in the FRPPR / IRPPR: https://era.nih.gov/erahelp/commons/Commons/status/closeout/Final RPPR.htm
- RPPR, Frequently Asked Questions: https://grants.nih.gov/faqs#/research-performance-progress-report.htm?anchor=header11513

1) Closeout for Multi-Component (P42) I-RPPR / F-RPPR:

For Multi-Component grants, the I-RPPR / F-RPPR process is a simplified version of the regular RPPR process in that all reporting is submitted through the "Overall" component. Hence, progress from the projects and cores must be combined for this submission. In eRA Commons, you will be asked to fill in the Sections A, B, C, D, E, G, I for the I-RPPR / F-RPPR. We suggest the following approach:

Section A. Cover Page: Follow instructions.

- Section B. Accomplishments: For each project and core, include a summary of advances since the last RPPR report i.e. the current reporting year plus all no cost extension years. Combine all projects/cores in one attachment. For content, refer to SRP's RPPR instructions for components section "B2 Studies and Results" which includes a "Progress Update for SRP Website" (250 words) and a "Full Progress Report" (up to 2 pages). Detailed supplement updates (1/4 to 1 page, depending on size of supplement) should also be included in the "Full Progress Report" referencing the supplement title and grant number. The entire attachment for I/FRPPR "B2 Studies and Results" should not exceed 30 pages. As applicable, list any supplements that were active since the last RPPR in Section B3 "Revision/Supplement" including a brief description of the supplement and referencing where additional details are found in the Full Progress Report.
- Section C. Products: List publications, patents, data citations, etc. for all projects/cores since the last RPPR report i.e. the current reporting year plus all no cost extension years. Similar to the RPPR, the "C2 Websites, "C3 Technologies and Techniques" and "C5 other products" section allows reporting for several categories (e.g. audio/video, educational aids, protocols, new business creation, other, etc). Please reference the respective Project/Core when reporting in C2, C3, C5.
- Section D. Participants: Include all participants for the current reporting year minus any approved no cost extensions. Follow RPPR guidelines for criteria for inclusion for the "Participants" section.
- Section E. Impact (optional): Generally, this section does not apply to P42s;
 however, other mechanisms use this section to describe ways in which the grant
 made an impact, or is likely to make an impact, on commercial technology or public
 use, including: transfer of results to entities in government or industry; instances
 where the research has led to the initiation of a start-up company; or adoption of new
 practices. You may report such items in section "E. Impacts," or you can mark this
 section as "Not Applicable" and include any of these items as part of "C. Products."
- Section G. Special Reporting Requirements: Include an attachment with the names of attendees at the SRP Annual Meeting(s). If the project period included more than one SRP Annual Meeting, please break it down by year.
- Section I. Project Outcomes (summary of Center for the NIH RePORTER website): Summarize, in plain language, the success of the whole Center from the most recent award period (that is, since your most recent competition, or, usually, 5 years). This section is limited to 8000 characters (approximately 2-3 pages) for the entire Center. We recommend including a succinct description of the major accomplishments of each Project and Core as well as any other overarching accomplishments of the Center. (Tip: Often, this would be included as part of the Overall section of the competitive renewal). Please note: the "Project Outcomes" will be posted on NIH RePORTER, so it is important to redact any proprietary information and write in lay language for the general public (NIH will not approve I-RPPR / F-RPPR if the "Project Outcomes" section is written in technical jargon). Please call eRA Commons help desk if this section is not allowing the full 8000 character limit (~ 2-3 pages). Please send your PO your draft Project Outcomes in advance of submission.
- Note: Sections F: Changes and Section H: Budget are not part of Interim/Final RPPR.
- **2).** Closeout for Other SRP Mechanisms (R01, R13, R25, SBIR/STTR) I-RPPR / F-RPPR: In eRA Commons, you will be asked to fill in the Sections A, B, C, D, E (required for SBIR/STTR), G, I for the I-RPPR / F-RPPR. For Sections A G, include relevant information **since the last**

RPPR report – i.e. the current reporting year plus all no cost extension years. For Section "I. Project Outcomes" summarize accomplishments over the entire grant (all years). "Project Outcomes" will be posted on the NIH RePORTER website. This section is limited to 8000 characters (approximately 2-3 pages). Because this section will be publicly available, please redact any proprietary information and write in lay language for the general public. NIH will not approve I-RPPR / F-RPPR if the "Project Outcomes" section is written in technical jargon. Follow instructions in the I-RPPR / F-RPPR guides (see links above) for general instructions. For specific instructions tailored to your grant mechanism, please see the tips below:

- **R01 Individual Research Grant F-RPPRs** Generally, R01s will include an F-RPPR since the SRP R01 RFAs are typically not renewed. Contact your PO Heather Henry for questions about specific instructions (henryh@niehs.nih.gov; 984-287-3268).
- R13 Conference Grant F-RPPRs Generally, R13s will include an F-RPPR since they are typically not renewed. Please include sections in the "B. Accomplishments" and "I. Outcomes": title, date (including year), location of the conference. Be sure to identify how the NIEHS funds were utilized (e.g. information about the people you traveled and their role in the conference). Include websites and information about potential outcomes, such as publications. If the conference resulted in a consensus decision/message, identification of new scientific opportunities, or identification of research gaps, describe these accomplishments in your F-RPPR. Contact your PO Brittany Trottier for questions about specific instructions (brittany.trottier@nih.gov; 984-287-3331).
- R25 Occupational Health Grants I-RPPRs / F-RPPRs Contact your PO Danielle Carlin for questions about specific instructions (danielle.carlin@nih.gov; 984-287-3244).
- R41-R44 (SBIR/STTR) I-RPPRs / F-RPPRs Contact your PO Heather Henry for questions about specific instructions (henryh@niehs.nih.gov; 984-287-3268).

F. Other Information

1) Requests for Conference Funding

The Superfund Research Program provides support of Conference and Scientific Meetings through the R13 grant mechanism. For more information about the R13 mechanism, please see the following website: http://www.niehs.nih.gov/funding/grants/mechanisms/r13u13/ or contact Brittany Trottier (brittany.trottier@nih.gov).

2) Lobbying Guidance for Grantee Activities

The NIH has provided guidance on the use of appropriated funds by NIH and its grantees for advocacy, lobbying, and related activities. For more information please see the <u>Lobbying</u> <u>Guidance for Grantee Activities</u> and the <u>Reminder of Lobbying Prohibition on Federal Funds for All NIH-Supported Institutions.</u>

3) Logos

If you would like to use the Superfund Research Program, NIEHS, or NIH logos on any electronic or printed materials, please contact Christine Bruske Flowers, Director of the NIEHS Office of Communications & Public Liaison, for guidance on proper use of the logos and to request the image files. Ms. Flowers can be reached at bruskec@niehs.nih.gov.