

Health Research Office (HRO) Frequently Asked Questions (FAQ)

Grant FAQ's

When will CURE or other Health Research Office (HRO) issued grants be posted and open for applications?

Response: HRO appropriations are not finalized until well into the respective State Fiscal Year (SFY): As a result, grants for the appropriate State Fiscal Year won't post before August of that SFY at the earliest while grants have posted as late as April. Due to these unique circumstances with Commonwealth Universal Research Enhancement (CURE) grants, the goal is to minimally have fully executed documents in place by the end of June of the respective SFY. Efforts are underway to assure grantees receive the maximum term to execute grant research activities in the future.

If grants aren't fully executed until June of the respective SFY, how are we to responsibly spend down that year's budget?

Response: Because HRO CURE grants typically are not fully executed until May or June of the respective SFY, one-year grants or the first year of a multi-year grant will run from the date of full execution through June 30th of the following SFY. Therefore, grantees are responsible for demonstrating good faith efforts on monthly work toward grant goals and expenditures and will have a full 12 months minimally to conduct their research.

Can we begin work on a grant knowing that we may not receive fully executed documents until the last month of a SFY and apply expenditures retroactively during the term of the entire SFY?

Response: Expenditures incurred against a grant must fall within the grant execution and termination date. Expenses outside that time frame are not eligible for reimbursement with grant funds. For that reason, work may not begin on grant research projects until documents are fully executed. If an entity is okay funding a project with its own funds and recognizes that it **will not** be reimbursed for those expenses, work can begin before a grant's full execution. Again, expenses incurred prior to grant full execution are not eligible for reimbursement with grant funds.

Receiving fully executed documents by the end of the last month in any SFY isn't as big a problem for multi-year grants. What if the grant is only a one-year grant? Can we request a no cost extension (NCE)?

Response: Because HRO CURE grants typically are not fully executed until May or June of the respective SFY, one-year grants will run from the date of full execution through June 30th of the following SFY. Therefore, grantees will have a full year to spend grant funds and are responsible for demonstrating good faith efforts on monthly work toward grant goals and expenditures. No cost extensions will not be granted in the absence of extenuating circumstances necessitating the extension.

What exactly is a no cost extension?

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Response: A no cost extension is the ability to allow a grant to continue beyond its original termination date for a set length of time for the purpose of finishing research with the original funding. For the purposes of HRO, no cost extensions are considered on a case-by-case basis when extenuating circumstances are identified that prohibited the timely and efficient use of grant funds during the original grant term. Entities requesting no cost extensions must be able to demonstrate good faith effort to complete research and expend grant funds during the original grant term. According to Act 77 of 2001, HRO grants **cannot extend beyond four years**.

Can we request a no cost extension on any grant?

Response: For the purposes of HRO, no cost extensions are considered on a case-by-case basis only when extenuating circumstances are identified that prohibited the timely and efficient use of grant funds.

How many times can we request a no cost extension on a grant?

Response: No cost extensions may be granted for any reasonable term consistent with the approved research project and/or aim up to the maximum four-year term allowable by Act 77 of 2001. As stated previously, grantees must be able to demonstrate good faith effort to complete research and expend grant funds during the original grant term.

Where is my payment:

Response: Questions about grant payments should be directed to RA-healthresearch@pa.gov. In the future, a self-service lookup tool will be available at <https://www.budget.pa.gov/Services/ForVendors/Pages/Self-Service-Payment-Lookup.aspx> ; however, it is still in beta testing currently.

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Where is my grant:

Response: We are unable to provide a specific timetable as grant applications are reviewed and eventually signed by several state entities after leaving the Health Research Office including minimally the Office of Procurement, the Office of Legal Counsel, the Office of the Comptroller, the Office of General Counsel, and the Office of the Attorney General. When the grant does become fully executed, you will receive the fully executed grant agreement via email at the same time it is sent to our office.

Why are we required to submit annual reports?

Response: Annual reports are tools to help validate that the research is occurring and expenses incurred are consistent with the approved project. They also assist in the evaluation of research progress and projection of project completion by comparison of milestone achievement against strategic plans.

What is the purpose of a grant final report?

Response: The final report serves to summarize the outcome of approved projects and highlights findings, delimitations, barriers, redirections and suggestions for future research, as well as other significant information resulting from the research.

Who uses grant final reports?

Response: Once approved, final reports are loaded onto the PA's public CURE website and serve a variety of purposes. Initially, the final report is used by the Department to evaluate research outcomes and contributions to the overall body of research. It is also accessed and used by others planning or conducting research, as well as State and Federal officials responsible for allocating research funding and/or advocates and lobbyists interested in impacting the direction of research or amount of funds being provided for such work.

Budget FAQ's

We've always been allowed to move money around before. Why are there suddenly so many rules and restrictions governing the budget process?

Response: Regardless of grant type, the fully executed grant agreement drives what is allowable. Although we've discovered some inconsistency in what was allowed over the years, there are some general rules grantees need to be aware of when setting up a budget or requesting changes.

- The first is it is always easier to move money out of personnel than it is to move money into personnel. In general, the only way a grantee is allowed to move money into personnel is if there is additional work resulting from a

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Supplemental Available Funds action or a pay increase resulting from Union contract negotiations that resulted in a ratified contract after full execution of the grant. In the event of the latter, supporting contractual documents are required as is a full budget revision;

- Hourly salary rates may not exceed the maximum salary assigned to the Executive Level II salary level noted in the respective grant document for the appropriate time period and corresponding to P.L. 116-260, Sec. 202 - for maximum hourly rate (40hrs/week, 52 weeks/year).
- Next, indirect rates may not be modified for the life of the grant. The Federally qualified indirect rate at the time of contract execution remains consistent throughout the life of the grant;
- The total amount on any budget line cannot exceed the total amount budgeted for that line;
- And, the total overall budget cannot exceed the total amount allocated to an entity for the research, infrastructure or other funded project.

“Why can’t I move money into personnel?”

Response: The Personnel category is one of several areas monitored closely by multiple oversight bodies. For example, Personnel includes hourly rate restrictions linked to Federal reimbursement schedules and calculations are required by multiple agencies to verify expenditures for work done over time. Once approved, this line category is locked unless additional work is assigned or Union contract changes are implemented after full execution of grant documents requiring adjustment. Under either situation, back-up documentation is required supporting the changes.

“When do I need to notify HRO of budget revisions?”

Response: Your Project Officer should always be kept informed of changes to your budget to avoid misunderstanding. However, if nothing in the fully executed grant agreement instructs differently, the Project Officer should be notified or consulted on budget revisions as soon as reasonable possible after identifying the need to move funds but no later than 30 business days before exceeding any budget line.

Most grant agreements going forward will include language that permits grantees to move up to 20% of their total grant funds between lines except where disallowed. For example grantees are not allowed to move money into Personnel; however, they will be permitted to move money out of personnel if needed.

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“When do I need approval for a budget revision?”

Response: If your grant does not specifically allow the movement of up to 20% of your total grant between lines (with the exception of Personnel), you should notify your Project Officer and seek formal approval. Additionally, if your grant allows the movement of up to 20% of your total grant between lines (with the exception of Personnel) and your desired revision exceeds 20%, you will be required to have formal approval from your Project Officer and proceed with a formal budget revision.

“As long as we’re not over budget, can’t I move money around where I want?”

Response: You may not move money into Personnel arbitrarily and must comply with the guidance above with respect to increasing Personnel allocations. You are also restricted from changing Indirect rates. With the exception of the restrictions identified here and in the grant instructions, you have wide latitude to move funds between categories. You may not completely zero out a line item without formal approval.

Institutional Review Board (IRB) FAQ’s

What is an Institutional Review Board (IRB)?

Response: The IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted or financially supported by the Pennsylvania DOH. Members of this board evaluate the potential risks and benefits to human subjects, as well as methods of informed consent and safeguards put in place for human subjects. It has the authority to approve, require modifications, or disapprove all research activities that fall within its jurisdiction.

When do I need to submit information to the IRB?

Response: The following research projects involving human subjects require the review of the DOH IRB:

- Research involving grants for which a program at DOH is applying;
- Research involving grants awarded by the DOH to grantees;
- Research conducted by the DOH;
- Entities using DOH biological specimens and/or data;
- Entities using DOH protected health information; and
- Research that is going to be conducted at a DOH licensed/approved nursing home or long-term care facility.

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What information do I need to submit to the IRB?

Response: Required documentation includes, but is not limited to:

- [Completed Applications](#) to the Pennsylvania Department of Health's Institutional Review Board for Approval of Research Project under the Federal Policy for the Protection of Human Subjects;
- Full research protocol;
- Proposed informed consent documents;
- Relevant grant applications ;
- Relevant data request applications ;
- Investigator's brochure (if available); and
- Subject recruitment materials.

How do I submit material to the IRB?

Response: A completed [IRB Application](#) and any other requested documents should be submitted via email to RA-HealthResearch@pa.gov.

How often do I need to submit material to the IRB?

Response: Projects must be reviewed at least once per year following initial approval. At the discretion of the IRB, projects may need to undergo more frequent continuing reviews.

If my project requires a continuing review, what should I do?

Response: Please submit the continuing review document linked below via e-mail to ra-healthresearch@pa.gov. Fill out the document in its entirety and submit any required attachments as stipulated in the document.

How long does it take to get a decision from the IRB?

Response: Barring no complications, a decision from the IRB should be available in about 21 calendar days; however, extremely long or complex projects may take longer.

How does the IRB review my research application?

Response: If you apply for the IRB and submit a reason for exemption, a Primary Review Team (PRT) composed of the chief of the IRB, a Department attorney and one other member will review your application for exemption. Upon reviewing the application, the PRT will notify the researcher whether the research was approved as exempt or if a full application needs to be submitted.

If you apply for the IRB and request expedited review, they will review your application. After reviewing the entire application, the PRT will then make one of three decisions:

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- They may notify the researcher that the project has been approved;
- They may request minor protocol modifications by the researcher prior to approving; or
- They may determine that the application must undergo full review by the entire IRB rather than expedited review.

If your application is undergoing a full review, all members of the IRB (consisting of at least five members) will review the application. The IRB may make one of several decisions regarding the application:

- The IRB may approve the research;
- The IRB may disapprove of the research;
- The IRB may request certain modifications to the proposal prior to approval; or
- The IRB may state that approval will be given if the research project complies with certain conditions determined by the IRB.

If we use a local IRB, do we also have to submit material to the State IRB?

Response: If the research project has been approved by another institutional review board, the Primary Investigator can request that the DOH IRB accept the approval of the other institution's IRB by completing an [Application to the Pennsylvania Department of Health's Institutional Review Board for Approval](#) of Research Project under the Federal Policy for the Protection of Human Subjects form, which can be obtained on DOH's website (www.health.pa.gov), and any other documents submitted by the PI should be sent to the IRB administrator via email to RA-DHIRB@pa.gov or mail to Department of Health, Health Research Office, Health and Welfare Building, Room 833, 625 Forster St., Harrisburg, PA 17120-0701. The PRT will review the request.

If the State IRB rejects a project or project protocols but our local IRB approved them, is there an appeal process?

Response: Yes. The Secretary of Health (SOH) is the ultimate authority and a request for appeal may be submitted to the IRB for the SOH's consideration.

I need to change my already approved protocol. What should I do?

Response: Please submit the protocol change request form linked below via e-mail to ra-healthresearch@pa.gov. Fill out the document in its entirety and submit any required attachments as stipulated in the document.

What should I do if there are any risks to the subject that were not anticipated in the initial IRB review?

Response: The IRB needs to be notified of any unanticipated risks to the subjects. Please write a description of the risks in a word document and submit the document to the DOH IRB administrator via email to ra-healthresearch@pa.gov.

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What should I do if I find that part of my experiment is out of compliance?

Response: The IRB needs to be notified of any noncompliance. Please write a description of the noncompliance in a word document and submit the document to the DOH IRB administrator via e-mail to ra-healthresearch@pa.gov.

I have a question that is not listed here. Who should I contact to answer my question?

Response: Please email your question to the DOH IRB administrator using the email ra-healthresearch@pa.gov.