CDC Prior Approvals for Research Awards

Office of Financial Resources, Office of Grants Services

CDC anticipates that recipients may need to make post-award changes to budget and programmatic plans during the period of performance to accomplish award objectives. This guidance provides CDC recipients with an overview of prior approval requests for post-award changes, and also describes documentation recipients must submit for these requests. Additionally, the document provides links to other prior approval resources and tools to assist recipients with prior approval request submissions.

Types of Activities Requiring Prior Approval

When recipients propose certain types of budget-related and programmatic-related changes from pre-award plans, prior approval may be required. See below for a description of typical activities which require prior approval. Recipients should review their terms and conditions of the Notice of Award (NoA) for a full listing of activities that require CDC prior approval for their specific award.

• Budget Revision

- Significant rebudgeting occurs when cumulative redirections among direct cost budget categories deviate (increase or decrease) by more than the rebudgeting threshold identified in the NoA.
 Typically, the rebudgeting threshold for CDC awards is 25 percent of the total approved budget in the budget period.
- Budget revisions made by a recipient with a high-risk condition noted in the NoA these changes require a prior approval, regardless of amount.
- Implementation of a new activity or entering into a sub-award that is not specified in the approved budget.
- Change in indirect cost rate costs incurred by a recipient for common or joint objectives and cannot be identified specifically with a particular project or program.
- Changes related to cost sharing or matching occur in instances such as the addition of funding from a supplemental award, which results in CDC recalculating cost sharing or matching amounts.
- Transfer of substantive programmatic work required for a recipient to transfer substantive programmatic work to a subaward.
- Change in scope an activity whereby the objectives or specific aims identified in the approved application are significantly changed by the recipient after award.
- **Carryover of Funds** the process by which unobligated federal funds remaining at the end of a budget period may be carried forward to another budget period within the period of performance to cover allowable costs of that budget period (whether as an offset or additional authorization). Recipients with <u>expanded authority for carryover</u> do not require prior approval to use unobligated funds for approved activities/costs that fall within the scope and objectives of the project.
- **No-Cost Extension** a limited period of time beyond the end of the period of performance needed to complete project activities.
- Change of Principal Investigator (PI) or Other Key Personnel when key personnel specified on the NoA change.
- Successor of Interest (Change of Institution) a process whereby the rights to, and obligations of, an awarding agency award are acquired incidental to the transfer of all or part of the assets of the recipient involved in the performance of the award (e.g., transfer of an award).

Submission

Recipients should submit prior approval requests at least **30 days** before the date of the proposed change to allow for an adequate and timely review, and to ensure continuity of projects. Additionally, recipients should submit requests at least **120 days** prior to the end of budget period, to ensure timely GMO approval. The requests must be submitted to the assigned Grants Management Specialist/Officer (GMS/GMO) through the eRA Commons/<u>ASSIST</u> amendment process. The request can be initiated by clicking the "Status" button in the system for the applicable award. Prior approval must be granted by the GMS/GMO before a recipient undertakes any of the activities contained in their request.

Any request for prior approval must be submitted and certified by the assigned Authorized Organizational Representative (AOR), designated as a Signatory Official (SO) role in eRA Commons AOR in eRA Commons/ASSIST. The Principal Investigator/Project Director (PI/PD) may initiate a request for prior approval in eRA Commons/ASSIST. The request must then be routed to the AOR/SO, who certifies and submits the request.

Recipients can locate more information on eRA Commons at <u>https://www.era.nih.gov/</u>. If a recipient has challenges submitting the prior approval request in eRA Commons/ASSIST, they may submit a request to the eRA Help Desk and self-identify as a "CDC research recipient." If the eRA help desk is unable to resolve the issue, please contact assigned GMS/GMO.

All prior approval requests require a cover letter on official letterhead, and should include the following:

- Date
- Recipient name and award number
- Point of contact name, phone number, and email address
- A brief description of the request

If an amendment involves a budget worksheet (i.e., Budget Revision or Carryover) it should be submitted individually (not combined with other prior approval requests).

Required Documentation

CDC requires recipients submit information in specific sections within eRA Commons for certain prior approval or amendment actions. The GMS/GMO may also require additional supporting documentation or information be uploaded in eRA Commons to make a determination. Recipients should upload the eRA Commons required information and the required supporting documentation at the same time.

The required information and documentation must be entered/uploaded in the following eRA Commons sections:

- SF424 Research & Related (R&R) Cover Form Application for Federal Assistance
- Senior/Key Person Profile (if applicable)
- R&R Budget (this section is required for the non-competitive supplement action only; for all other amendments requiring budget information, include a completed PDF of an SF424A with supporting documentation to the Research Plan section)
- Research Plan
 - Within this section, the cover letter and additional supporting documentation outlined in the table below should be uploaded under number "3. Research Strategy."

The most common prior approval amendments are listed in the table below, along with required information and documentation. The third column provides links to additional resources or instructions, such as templates to use for the cover letter. Recipients are encouraged to contact the GMO/GMS of record on their most recent Notice of Award (NoA) for specific questions concerning a prior approval request.

Prior Approval	Required Supporting Documentation	Additional Resources
Amendment		
Budget Revision (see page 1, under the bullet "Budget Revision" for a list of typical, budget-related activities for this amendment). A budget revision only occurs for funds awarded in the current active budget period.	 Cover letter (with AOR signature if request not initiated by AOR), which includes: A brief description of the request; include a statement that the budget revision remains within the scope of the Notice of Funding Opportunity (NOFO). Provide justification for any change in scope of approved activities, if applicable. A budget narrative outlining proposed changes, following the <u>CDC Budget Preparation Guidance</u> Summary table which displays columns for the Original Budget, Difference from Original Amount, and New Revised Budget Total SF-424A Budget Information Non-Construction (recipient should upload a completed <u>PDF form</u>) available on grants.gov Indirect Cost Rate Agreement (if applicable) 	Please use the <u>Prior</u> <u>Approval Budget Revision</u> <u>Cover Letter Template</u> to draft the cover letter.
Carryover of Funds (using funding from the prior budget period to conduct grant activities) Note: if approved for Expanded Authority, prior approval is only required for carryover if you plan to use unobligated funds for activities not supported by your approved workplan.	 Cover letter (with AOR signature if request not submitted by AOR) which includes: A brief description of the request; include a statement that the budget revision remains within the scope of the NOFO and will be used to support the ongoing activities A budget narrative outlining proposed changes, following the <u>CDC Budget Preparation Guidance</u> Summary table which displays columns for the Original Budget, Proposed Carryover, and New Revised Budget Total SF-424A Budget Information Non-Construction (recipient should upload a completed <u>PDF form</u>) Indirect Cost Rate Agreement (if applicable) Copy of Annual Federal Financial Report (FFR) from PMS 	Please use the <u>Prior</u> <u>Approval Carryover Cover</u> <u>Letter Template</u> to draft the cover letter.
Change in Project Director (PD)/Principal Investigator (PI) Note: a PD/PI change should be submitted separately from any other key personnel changes.	 Cover letter (with AOR signature if request not submitted by AOR) and description of request including new PD/PI effective date New PD/PI CV/resume and contact information Complete required Senior/Key Person Profile section 	Please use the <u>Prior</u> <u>Approval PD/PI Change</u> <u>Cover Letter Template</u> to draft the cover letter.

Prior Approval Amendment	Required Supporting Documentation	Additional Resources
Change in (other) Key Personnel Note: other key personnel changes should be submitted for all personnel changes that are not the PD/PI. Also, if a change in key personnel requires a budget change, the Budget Revision amendment is also required. Verify with the assigned GMS/GMO whether to submit the request in conjunction or separately.	 Cover letter with AOR signature (if request not submitted by AOR) with a description of the request including: Name and position title of the key personnel that is changing Name, address, phone, and email address for new key staff Proposed effective date of the change New key personnel resume or CV 	Please use the <u>Prior</u> <u>Approval Other Key</u> <u>Personnel Change Cover</u> <u>Letter Template</u> to draft the cover letter.
No-Cost Extension Note: if approved for expanded authority (in the terms and conditions of the award) allowing for extension of the project an additional 12 months, prior approval is not required; however, the assigned GMS must be notified via email and a revised NoA will be issued.	 Cover letter (with AOR signature if request not submitted by AOR) with a description of the request including: Specific recipient activities that will continue and why Timeline for completing the activities Reason recipient was unable to complete activities within the period of performance Budget revision(s) should be completed prior to submitting a No-Cost Extension 	Please use the <u>Prior</u> <u>Approval No-Cost</u> <u>Extension Cover Letter</u> <u>Template</u> to draft the cover letter.
Non-Competing Supplement	 Cover letter (with AOR signature if request not submitted by AOR) with a description of the request including: A budget narrative outlining proposed changes, following the <u>CDC Budget Preparation Guidance</u> Research plan 	Contact your assigned GMO/GMS for requirements for this action.
Notification of Contractor or Consultant	 Cover letter (with AOR signature if request not submitted by AOR) with a description of the request including the required elements for contractor or consultant approval in accordance with the <u>CDC Budget Preparation Guidance</u> 	Please use the <u>Prior</u> <u>Approval</u> <u>Contractor/Consultant</u> <u>Cover Letter Template</u> to draft the cover letter.
Remove Restrictions	 Cover letter (with AOR signature if request not submitted by AOR) with a description of the request including justification for release of funding restrictions, contractor restrictions, etc. Any supporting documentation requested in the Notice of Award (NoA) For human subject restrictions, include Federal 	Please use the <u>Prior</u> <u>Approval Restrictions</u> <u>Cover Letter Template</u> to draft the cover letter.

Prior Approval Amendment	Required Supporting Documentation	Additional Resources
	Wide Assurance (FWA) and/or Institutional Review Boards (IRB) approval	
Successor-In-Interest, or Transfer (Change of Institution)	 Cover letter with description of request (with AOR signature from current recipient if request not submitted by AOR) Relinquishing Statement/PHS 3734 from current recipient Final FFR and closeout documents from current recipient (refer to the <u>CDC General Terms and Conditions for Research Awards</u> for closeout requirements) 	Reach out to your GMS/GMO for assistance in submitting a Successor of Interest.
Termination	 Cover letter (with AOR signature if request not submitted by AOR) with a description of the request including: Relinquishing Statement/PHS 3734 Termination justification with the effective date If partial termination, portion to be terminated 	Reach out to your GMS/GMO for assistance in submitting a termination request.
Response to Terms and Conditions Note: use for actions not listed above and indicated in NoA as requiring a prior approval.	 Cover letter with description of request (with AOR signature if request not submitted by AOR) Any supporting documentation requested in NoA If rebudgeting funds, follow the documentation requirements for Budget Revision above 	Reach out to your GMS/GMO for assistance in responding to terms and conditions.