



NIH

Post Award: All Things Prior Approval at NIH

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LEARNING OBJECTIVES

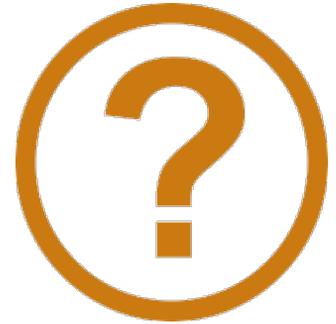
Research Administration Professionals will be able to:

1. Define what is a Prior Approval.
2. Learn the NIH General Policy requirements regarding prior approval requests and the submission process.
3. Identify what actions do and do not require NIH prior approval.

What is a Prior Approval?

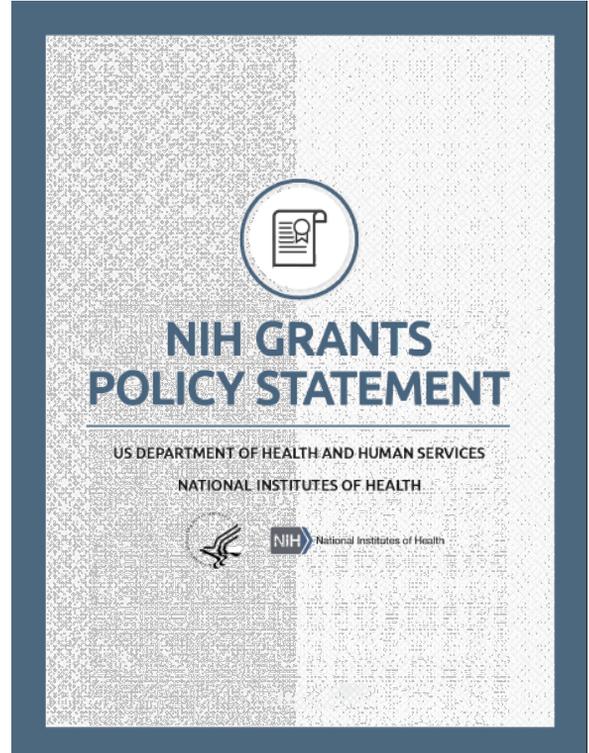
When a recipient institution wishes to undertake certain activities or incur specific costs not authorized/approved in the Notice of Award (NOA).

This would require the submission of a written prior approval to the cognizant awarding agency by the Authorized Organization Representative (AOR).



GENERAL POLICY REQUIREMENTS

All prior approval requests must be submitted via eRA Commons prior approval module no later than **30 days** prior to the proposed change or effective date by the AOR.



**When does an action
require NIH prior approval?**

Common Actions Requiring NIH Prior Approval

- Additional no-cost extension, extension greater than 12 months, or late notification of initial no-cost extension ([8.1.2.1](#))
- Carryover of unobligated balances ([8.1.2.4](#))
- Change in status of the PD/PI or senior/key personnel named in the NoA ([8.1.2.6](#))
- Change of recipient organization ([8.1.2.7](#))
- Foreign component added to a grant to a domestic or foreign organization ([8.1.2.10](#))
- Deviation from award terms and conditions ([8.1.2.9](#))
- Pre-Award costs over 90 days ([8.1.2.14](#))

Other Actions Requiring NIH Prior Approval

- Rebudgeting funds from trainee costs ([8.1.2.15](#))
- Alterations & Renovations ([8.1.2.2](#))
- Capital expenditures (construction, land, or building acquisition) ([8.1.2.3](#))
- Make subawards based on fixed amounts ([8.1.2.11](#))
- Retention of research grant funds when CDA (Career Development Award) is awarded ([8.1.2.17](#))
- Rebudgeting of funds between construction and non-construction work ([8.1.2.16](#))
- Need for additional NIH funding ([8.1.2.12](#) and [8.1.2.13](#))

SUBMISSION PROCESS

Once the need for a prior approval has been determined:

1. AOR submits prior approval request at least 30 days prior to the proposed change or effective date through the eRA Commons prior approval module.
2. Considerations may include but are not limited to:
 - Bona fide need for request
 - Detailed Justification
 - Timely submission

Things that will get you on the NIH “naughty list”

- Retroactive requests
- Incomplete requests
- Inconsistency within request



Questions



Test your knowledge



1. NIH prior approval is required when rebudgeting under the following circumstances? (choose all that apply)

- a. Never: the recipient has full authority to re-budget as they see fit under any circumstances
- b. If the rebudgeting represents a change in scope
- c. If the rebudgeting is less than 25% and is within scope
- d. If the rebudgeting is more than 25%

Answer: B and D

- a. Never: the recipient has full authority to re-budget as they see fit under any circumstances
- b. If the rebudgeting represents a change in scope
- c. If the rebudgeting is less than 25% and is within scope
- d. If the rebudgeting is more than 25%

2. Which of the following situations require NIH prior approval? (choose all that apply)

- a. Adding or removing key personnel to the grant
- b. Adding or removing graduate students to the grant
- c. Adding a domestic consortium
- d. Adding a foreign consortium

Answer: A and D

- a. Adding or removing key personnel to the grant
- b. Adding or removing graduate students to the grant
- c. Adding a domestic consortium
- d. Adding a foreign consortium

3. Which of the following may indicate a possible change of scope? (choose all that apply)

- a. Substitution of one animal model for another
- b. Significant rebudgeting
- c. Shift of the research emphasis from one disease area to another
- d. Change of key personnel

Answer: A,B,C and D

- a. Substitution of one animal model for another
- b. Significant rebudgeting
- c. Shift of the research emphasis from one disease area to another
- d. Change of key personnel

4. Which of the following are true about Change of Recipient Organization requests?
(choose all that apply)

- a. The grant belongs to the PI so the request to transfer comes from the PI
- b. If the grant is relinquished by the old institution, NIH approval of the transfer is automatically approved
- c. Peer review is required for a grant to be transferred mid project period
- d. The original recipient must agree to relinquish responsibility for an active project before the completion date of the approved project period

Answer: D

- a. The grant belongs to the PI so the request to transfer comes from the PI
- b. If the grant is relinquished by the old institution, NIH approval of the transfer is automatically approved
- c. Peer review is required for a grant to be transferred mid project period
- d. **The original recipient must agree to relinquish responsibility for an active project before the completion date of the approved project period**

5. Can a subrecipient request prior approval?

a. Yes

b. No

Answer: No

- **Prior Approval Requirements for Subawards:** Because NIH's legal relationship is with the prime recipient, subrecipients should contact the prime to request any prior approvals. If a recipient (or consortium participant) proposes the transfer of work to a foreign site, NIH prior approval is required.

6. Is a first no cost extension a prior approval?

a. Yes

b. No

c. It Depends

Answer: It Depends

- NIH Standard Terms of Award include the provision for grantees to extend the final budget period of a previously approved project period one time for a period of up to 12 months without additional NIH funds, and without prior approval.

Recipients will need prior approval if any of the following situations apply:

- They miss a deadline for a first extension. Request must be submitted via eRA Commons (Prior Approval Module).
- The award is Multi- Year -funded (MYF).
- There has been a mid project extension.
- The need for a second or third extension.

7. Is prior approval required when changing a subaward from the original subaward that was listed in the competing application?

a. Yes

b. No

Answer: It Depends

In general, prior approval is not needed to change a domestic subaward to a domestic grant. However, prior approval IS needed to change from a domestic subaward to a foreign subaward. Prior approval is also required to change both domestic and foreign subawards for SBIRs and STTRs.

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-149.html>

8. Is prior approval required for pre-award cost more than 90 days before the effective date of the initial budget period of a competing award?

- a. True
- b. False

Answer: True

NIH **prior approval** is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or competing continuation award.

A recipient may, at its own risk and without NIH **prior approval**, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new or renewal award if such costs:

- are necessary to conduct the project, and
- would be allowable under the grant, if awarded, without NIH **prior approval**.

9. Is NIH approval required for a change in the Data Management Sharing Plan (DMSP)?

a. Yes

b. No

Answer: Yes

- Prior approval is required when a change of DMSP for a funded award is necessary. Documents needed may include a justification for the change, budget documents if the revised DMSP impacts the budget, and a Revised DMSP. In most cases, prior approval for a change of DMSP on an NIH grant can be requested via the eRA Commons Prior Approval Module. A completed **NIH Prior Approval for Change of DMSP**



CASE STUDY

Scenario:

A grant without Carryover Authority such as a P50 (specialized center grant) or U01 (cooperative agreement) consistently has a large unobligated balance and by the 4th year of a 5-year project period, a pattern has emerged of repeated large carryover requests. Each year the carryover request gets larger, and it does not appear that the funds are being consistently spent.

- What do you think is going on with the progress of the grant?
- What could be possible reasons for the large unobligated balance?
- What are the possible solutions ?

Possible Solutions:

There are several ways to look at this situation.

- It is suggested to the recipient that a mid-project extension can help them to get back on track. If the recipient agrees, milestones are re-negotiated, and a mid-project extension would be considered.
- An offset may be considered for the upcoming non-competing year if it's determined that the grant is overfunded.

Questions

