

Changes in Scope

A change in scope is defined as a change in the direction, aims, objectives, purposes or type of research training identified in the approved project.

The following process is required for changes in Scope:

Changes in Scope are determined by the PD/PI in collaboration OSP and the Program Officer if applicable.

Steps for processing a change in Scope

Submit a request with the following information at least 30 days prior to the proposed change:

- PI's name
- Grant Number
- Grant Title
- Project period
- Explanation of what the changes are in the scope
- Revised budget if applicable

Upon receipt, the Pre-Award person will submit to the funding agency. The PD/PI and the Department Administrator will be informed when a decision is made by the sponsor.

Examples of Changes in Scope:

Potential indicators of a change in scope include, but are not limited to, the following:

- Change from the approved use of live vertebrate animals.
- Change from the approved involvement of human subjects that would result in an increased risk. This includes:
 - An addition or change that would result in changing the overall human subjects or clinical trial designation of the award from No to Yes;
 - The new inclusion of subject populations that are covered by additional regulatory protections under 45 CFR 46;
 - Any change to the study protocol that would increase the risk level for subjects;
- Shift of the research emphasis from one disease area to another.
- Application of a new technology, e.g., changing assays from those approved to a different type of assay.
- Transfer of the performance of substantive programmatic work to a third party through a consortium agreement, by contract, or any other means. If the third party is a foreign component, prior approval is always required.
- Change in other senior/key personnel not specifically named in the NoA.
- Significant rebudgeting, whether or not the particular expenditure(s) require prior approval. Significant rebudgeting occurs when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by 25 percent or more of the total costs awarded. For example, if the award budget for total costs is \$200,000, any rebudgeting that would result in an increase or decrease of more than \$50,000 in a budget category is considered significant rebudgeting. The base used for determining significant rebudgeting excludes the effects of prior-year carryover balances but includes competing and non-competing supplements. Significant rebudgeting does not apply to modular grants.
- Purchase of a unit of equipment exceeding \$25,000.

Change in PI

A change in PI is defined as a change in status, including absence of Principal Investigator and Other Key Personnel, reduction in effort of 25% or more than what was initially approved or the relinquishment of active direction of the project.

Steps for processing a change in PI

Submit to the Pre-Award person the following information at least 30 days prior to the change if possible:

- Name of Current PI
- Grant Number
- Grant Title
- Justification of the change and a revised budget if necessary. If a substitute PI is being named, include their biosketch and Other Support.

Upon receipt, the Pre-Award Person will submit the information to the funding agency and inform the PD/PI and Department Administrator when a decision is made by the sponsor.

Examples of change in Status, Including Absence, of Principal Investigator and Other Key Personnel:

- The grantee is required to notify the sponsor in writing if the PI or key personnel specifically named in the NGA will withdraw from the project entirely, be absent from the project during any continuous period of 3 months or more, or reduce time devoted to the project by 25 percent or more from the level that was approved at the time of award (for example, a proposed change from 40 percent effort to 30 percent or less effort). The sponsor must approve any alternate arrangement proposed by the grantee, including any replacement of the PI or key personnel named in the NGA.
- The request for approval of a substitute PI/key person should include a justification for the change, the biographical sketch of the individual proposed, other sources of support, and any budget changes resulting from the proposed change. If the arrangements proposed by the grantee, including the qualifications of any proposed replacement, are not acceptable to the sponsor, the grant may be suspended or terminated. If the grantee wishes to terminate the project because it cannot make suitable alternate arrangements, it must notify the sponsor, in writing, of its wish to terminate.
- The requirement to obtain prior approval for a change in status pertains only to the PI and those key personnel named.