NIH prior approval for grants not subject to expanded authorities (see "Expanded Authorities" below).

Once approval is obtained, transferring the same work to a different third party does not require NIH approval.

- ◆ Change in key personnel whose expertise is critical to the approved project.
- ◆ Significant rebudgeting, whether or not the particular expenditure(s) require prior approval under rules governing budget changes. Significant rebudgeting occurs when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established at the time of the competing award by more than 25 percent of the total costs awarded. For example, if the award budget for total costs is \$200,000, NIH prior approval is required for any rebudgeting that would result in an increase or decrease of more than \$50,000 in a budget category. The baseline used for determining significant rebudgeting excludes the effects of prior year carryover balances but includes competing and noncompeting supplements. When the applicable threshold is reached, the grantee must consult with the GMO for a decision as to whether the rebudgeting constitutes a change of scope. If the GMO determines that the significant rebudgeting constitutes a change of scope, NIH prior approval is required.
- ◆ Incurrence of patient care costs if not previously approved by NIH or if a grantee desires to rebudget additional funds into or rebudget funds out of the patient care category. NOTE: These types of actions always require NIH prior approval for grants not subject to expanded authorities (see "Expanded Authorities" below).

Preaward Costs: See "Cost Considerations—

Allowability of Costs/Activities—Selected Items of Cost—Preaward (Preagreement) Costs."

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

The grantee is required to notify NIH if the PI or other key personnel 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 his or her time devoted to the project by 25 or more percent 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). NIH must approve any alternate arrangement, including any replacement PI or other key personnel proposed by the grantee.

The request for approval of a substitute PI/key person should include a justification for the change, the curriculum vitae 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 NIH, the grant may be suspended and/or terminated. If the grantee wishes to terminate the project because it cannot make suitable alternate arrangements, it must notify the awarding office GMO, in writing, of its wish to terminate, and NIH will forward closeout instructions.

Change of Grantee Organization: NIH prior approval is required for the transfer of the legal and administrative responsibility for a grant-supported project or activity from one legal entity to another before the expiration date of the approved project period. Such a change of grantee organization may be accomplished under most NIH grants, including construction grants, if:

- ◆ The grant to be transferred has been terminated in accordance with 45 CFR 74.61 or 92.43;
- ◆ A noncompeting continuation award that is within an approved project period has been withheld because of the