



## Residual Funds in Corporate Sponsored Clinical Research Activities

### Policy

This policy addresses the practice of dealing with residual funds left in an account at the completion of a commercially sponsored clinical study. Residual funds may not be directed to an account under the control of the principal investigator (PI) on the study. All such funds shall be directed to the departmental Chair of the respective division chief. If the PI is a department Chief, guidance will be sought from the VP of Research Administration and Legal Counsel.

In addition, whenever the residual amount is greater than 25% of the original direct cost budget or \$5,000, whichever is greater, the Research Finance department will require the PI to provide a reasonable written explanation of how the unexpended balance occurred, before releasing the residual balance in these accounts.

### Purpose

The intent of this policy is to avoid the possible conflict of excessive financial remuneration for a study, to prevent a "financial recruitment incentive" that may override (or appear to override) the principal investigator's responsibility to provide the best care for a patient or research subject.

The hospital is also concerned that a large unexpended balance on these accounts indicates a possibility that activities supporting the commercially sponsored clinical research project may have been inappropriately charged to another sponsor's account or might have been inadvertently billed to a third party.

### Procedure

Upon completion of any commercially sponsored clinical research study, the Research Finance office will calculate the account balance. The account balance will be calculated as total sponsor payments less total study expenses (direct and indirect expenses). A residual balance will be determined whenever this calculation results in a surplus of sponsor payments over total expenses. The accountant will further calculate whether this residual balance amount is greater than 25% of the original direct cost budget.

Whenever a residual balance exists, the Research Finance office accountant will inform the principal investigator (in writing) that such a balance exists. The accountant will also provide the principal investigator with a copy of this policy statement. Whenever the residual balance amount is greater than 25% of the original direct cost budget or \$5,000, whichever is greater, the written notification will request that the principal investigator provide a reasonable written explanation of how the unexpended balance occurred. The notification will also inform the principal investigator to whom the funds will be released along with the amount that will be released. Only the direct cost portion of the residual balance amount will be released. The total residual balance will be separated into its direct

and indirect components, by dividing it by the overhead rate negotiated for the clinical study.

Once the principal investigator provides the Research Finance office with a reasonable written explanation of how the unexpended balance occurred, the accountant will process a journal entry to release the funds as described above. The clinical trial account will then be set to an inactive status.

## Related Content

## Document Attributes

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