

University of Pennsylvania Perelman School of Medicine
Policy and Procedure Manual
Clinical Trials

Distribution of Residual Funding from Clinical Trials

RESEARCH ADMINISTRATION
Policy Number: RA-CLIN-001
Date Written: DEC-02-99
Reviewed/Revised: April 25, 2023

I. PURPOSE

To establish a procedure for the distribution and use of industry sponsored clinical trial residual balances.

II. POLICY STATEMENT

On the recommendation of the Department Chair, the PSOM’s Finance Office will establish an unrestricted fund, consistent with the terms of the clinical trial agreement, to receive residual balances distributed at the discretion of the Chair as either:

- 1) Special purpose fund(s) for the department, used to support the department’s mission, and/or
- 2) Special purpose fund (s) assigned to the Investigator(s) of record to be used to support the Investigator’s research at the University of Pennsylvania.

Disbursement of these funds is at the discretion of the Chair subject to oversight by and accountability to the administration of the PSOM. The funds shall be used to support the mission of the PSOM and shall never be used as a source of personal inurement for any individual.

In order for a Center or Institute to transfer a residual balance on a clinical trial that is managed by that Center/Institute, the Center/Institute will need to work through the PI’s home department. Where a Center or Institute manages the clinical trial, the Investigator’s Department Chair retains the discretionary authority over the use of the residual funds with the caveat that the residuals must first be used to reimburse any outstanding grant or contract over-expenditures (if applicable).

III. REASON FOR POLICY

The performance of industry sponsored clinical trials may result in residual funds that can be retained by the PSOM. It should be noted that it is not the intention of the PSOM to generate residual balances from the performance of clinical trials as all necessary expenditures should be expensed to the clinical trial account. However, if residual funds remain they may be used as a source of funds to support the research of the faculty of the PSOM.

SUPERSEDES: NONE – New Policy	ISSUED BY: _____ Dean, Perelman School of Medicine & Date EVP of the University of PA for UPHS
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The policies of the PSOM should be designed to assure that appropriate indirect costs are recovered from both the direct clinical trial funding and from any potential residual funds while preserving the incentive for faculty to attract clinical trials funding by maximizing the benefit to the Principal Investigator. When residual balances are transferred in accordance with this policy, the PSOM department/division will be required to transfer the balance net of indirect costs, at the negotiated rate and subject to change.

Good business practices dictate that once a clinical trial has been completed, the funds should be closed out within ninety (90) days and the residual balances (if applicable) transferred to an unrestricted fund for utilization as described above. It is important that clinical trial accounts are charged in accordance with their approved budgets. It is equally important that all costs are recorded against the clinical trial prior to requesting the closing of the fund and transfer of residuals. In instances where zero costs were recorded, it is recommended that any residual balance be designated departmental residuals rather than individual PI residuals to offset any departmental costs that may have been borne such as PI time and effort and nurse coordinator time and effort as well as any other costs that should have been recorded to the clinical trial fund. It is also important that the department closeout the clinical trial account on a timely basis (within ninety (90) days after the end date of the fund) and transfer the balance to an unrestricted departmental fund, net of appropriate overhead and indirect costs, before using the residuals to fund activities unrelated to the performance of the clinical trial. The procedures below will detail the requirements for transferring the clinical trial balance. It should be noted that the Department would be responsible for paying, out of departmental funds, any expenses related to the closed clinical trial (such as expenses related to an FDA audit or documentation storage fee). If the department does not initiate the residual transfer and fund closeout within one hundred twenty (120) days after the end date of the fund or has not requested an extension of the fund as appropriate, the Office of Clinical Research (OCR) will initiate the closeout and transfer process on behalf of the department and provide copies for the department.

IV. WHO SHOULD KNOW THIS POLICY?

- School of Medicine Administration
- Department Chairs
- Departmental Business Administrators
- Clinical Trial Coordinators
- Principal Investigators
- Office of Clinical Research
- Office of Research Support Services
- Office of Audit, Compliance and Privacy
- Office of Research Services

V. PROCEDURES

RESPONSIBLE PERSON / DEPT	PROCEDURE
DEPARTMENT CHAIR, CENTER AND INSTITUTE	Determine the appropriate use of the transferred funds as either Department funds and/or funds identified to the investigator(s) of record for the industry sponsored clinical trial.

**DIRECTOR
BUSINESS
ADMINISTRATOR**

To transfer the cash balances within ninety (90) days after the end date of a clinical trial the following journal entry should be made, and forwarded to OCR. OCR will forward to the appropriate Research Accountant in Research Services along with supporting documentation (Attachment A of this policy – as described below).

Clinical Trial Fund:

Where \$Z = Total Residual Balance

Special Purpose fund for Dept and /or Investigator⁽¹⁾

Where “\$Y” = Imputed Direct Cost($Y = [Z / (1 + \text{negotiated rate})]$)
 $(1 + \text{negotiated rate}) \times Y = Z$; $Y = (Z / (1 + \text{negotiated rate}))$

If the Chair determines that a Special Purpose Fund will be established for the Investigator the Department will manage the Investigator Special Purpose Fund (i.e. the Responsible ORG for the fund).

School Indirect Cost Recovery:

$Z - Y$

Example:

The remaining residual balance per Ben Financials \$100 (Clinical trial not managed by Center / Institute)

- Debit Clinical Trial \$100 to transfer balance
- Credit Imputed Direct Cost: $\$100 / 1.350 = \$ 74.07$ to transfer to department or investigator unrestricted fund.
- Credit Imputed Indirect Cost and Allocated Cost Tax: $\$100 - 74.07 = \25.93 to School Indirect Cost Recovery

In no case will the indirect cost rate applied to the residual funds be less than the approved negotiated indirect cost rate effective at the time of the CTA.

The use of the transferred residual balance must be consistent with the mission of the PSOM.

VI. DEFINITIONS

Residual Funds: Residual funds are those funds remaining after all costs incurred in conducting the study, including indirect costs, have been paid for grants that do not have a return of funds requirement. Clinical trial funds cannot be designated as residual funds until the full indirect costs (Negotiated Rate on Industry Sponsored Clinical Trials) have been paid on the award. It should be noted that it is not the

intention of the PSOM to generate residual balances from the performance of clinical trials. However, it is recognized that methods of contracting with industry sponsors may result in a residual balance.

Personal Inurement: No part of the clinical trial residual balance may be used to benefit a private individual, rather the funds should be used to further the mission of the Perelman School of Medicine and should be considered institutional funds. Residual balances from clinical trials should not be used to pay for private (i.e., not in support of the tripartite mission of the PSOM and University) expenses of an individual. The use of the clinical trial residual balances must be in accordance with the University and School policies on the proper use of institutional funds.

VII. CONTACTS

PSOM Office of Clinical Research

Phone: (215) 746-8334

PSOM Office of Research Support Services

Phone: (215) 573-8798

VIII. ATTACHMENTS

Attachment 1: Clinical Trial Residual Balance Memorandum

Attachment 2: Clinical Trial Residual Balance Worksheet

ATTACHMENT 1:

INTEROFFICE MEMORANDUM

TO: PSOM – OFFICE OF CLINICAL RESEARCH
FROM:
SUBJECT: REQUEST FOR TRANSFER OF CLINICAL TRIAL RESIDUAL BALANCE
DATE:

Grant Fund No.: _____ PI Name: _____

Sponsor: _____

(a) Total Budget (\$) : _____ } Residual % (b) / (a): _____

(b) Residual Balance (\$)¹: _____ } ***if residual balance is greater than 50%,
further explanation from Principal Investigator is required. (see item (b) below)**

The signatures below certify the following: appropriate University indirect costs have been withheld from the requested transfer at the negotiated rate; all costs expended in support of the clinical trial have been charged to the clinical trial and the Department BA or designee has reconciled the account to ensure that **all** costs have been recorded on the account; If costs have not been recorded, a detailed explanation stating why costs have not been recorded, is included in the request for transfer of the residual. The Department recognizes that the Department is required to pay any additional costs applicable to this clinical trial that may arise after the transfer (such as cost associated with an FDA audit or document storage costs) out of Departmental funds; the Department also recognizes that the residual funds, even if assigned to a particular investigator, remain University of Pennsylvania funds, and therefore may not be reassigned to another institution should that investigator leave this institution; the use of the residual funds will be limited to supporting the mission of the School of Medicine and may not be used to directly and personally benefit any individual²; Work on the project is complete, and no future payments are expected from the sponsor. Study end date will be changed to the date Research Services transfers the residual balance and disables the fund.

¹ Gross residual balance before application of indirect costs.

²Residual balances may be used (at the Chair’s discretion) to support the PI’s activities (e.g. unfunded research, or other scholarly activity) including the salary & benefits of the PI or other lab personnel. Also, the residual balance once transferred, may be used to offset the cost of salary, bonus or incentive plans as long as the PI’s salary / bonus/ incentive plan is not contingent on (or increased by) by the magnitude or existence of clinical trial residual balances.

Business Administrator Signature:

Principal Investigator Signature:

Department Chair Signature:

School of Medicine Approval:
