Start-Up Fee Recovery of Studies That Terminate Prior to Site Activation	CR-207
Clinical Research Standard Practices	**Effective Date:** February 2025

SCOPE AND PURPOSE The document is applicable to the following roles within Penn State College of Medicine and Penn State Health entities engaged in clinical research:

Roles:

X	Principal Investigators	X	Regulatory Specialists
X	Sub-Investigators	X	Key Study Ancillary Personnel
X	Study Coordinators/Associates	X	Financial Analyst/Research Accountants
	Data Specialists	X	Central Research Office Personnel

This standard operating procedure (SOP) describes the process by which start-up fees are recovered for studies that Sponsor/CRO terminate prior to this investigative site being activated.

This SOP is not intended to be shared externally. Contact the Clinical Trials Office if Sponsor/CRO require documentation of investigative site's policy/procedure.

POLICY AND PROCEDURE STATEMENTS

1. When Sponsor/CRO terminates a study prior to this investigative site being activated, the study team will notify the Clinical Trials Office (CTO) Budget Analyst (BA), Office of Research Affairs (ORA), and central post-award research accountant (Research Accountant).
    a. The study team will provide the following information:
        - PI Name
        - Study Title
        - IRB Number
        - OSP Number
    b. Study team should set the study to "On Hold" status in clinical research management system STAR.

2. The BA will provide the study team and Research Accountant with the full amount of the start-up fees that would have been charged if the contract were fully-executed and the study was activated at the investigative site.
    a. BA will update the Master Study List to indicate the study was canceled/abandoned.
    b. BA will provide the Research Accountant the internal distribution of start-up fees

3. The study team will request Sponsor/CRO to pay for start-up fees. This request will include the descriptions and amounts of the fees being requested. The BA and Research Accountant should be included on the correspondence with Sponsor/CRO for the request. BA will provide study team with template language that can be used for their request.

a. If Sponsor/CRO refuses to pay for start-up fees, the BA will record Sponsor/CRO's refusal in the Master Study List and update STAR.
b. If Sponsor/CRO counteroffers with a reduced start-fee, the BA will provide a pro-rated amount, including justifications.
c. If Sponsor/CRO counteroffers a second time, then the CTO Director or Assistant Director will work with the study team to allocate the funds.

4. The study team will confirm with Sponsor/CRO if they require a contract or if the correspondence is sufficient for an invoice to be issued.
    a. If Sponsor/CRO requires a contract, ORA will be notified to negotiate contract.
    b. If Sponsor/CRO does not require a contract, the correspondence will serve as documentation of Sponsor/CRO's intention to pay for the invoiced amount of start-up fees.

5. ORA will award the study in SIMS for the total amount of fees for which Sponsor/CRO is being invoiced. The correspondence from Sponsor/CRO or executed contract will be used as the agreement by which the study can be activated in SIMS and a SIMBA Internal Order (IO) number can be generated.
    a. If the IAF was marked as 'Unfunded' it will need to be re-activated by ORA Administrative Support Coordinator or ORA Business Process Analyst.
    b. Since the IAF is in proposal stage the information (i.e. dates, funding, etc.) does not have to match with the actual award.
        i. If the IAF has been successfully routed through all proposal stage approvals including ORA, then no changes are needed.
        ii. If the IAF has not been successfully routed through all proposal stage approvals, then any questions which require compliance approvals (Human Subjects, Biosafety, IACUC, etc.) should be changed to 'No'.
    c. If the SIMS Log status was previously changed to 'Hold' or "Dead Document" status ORA Administrative Support Coordinator or ORA Business Process Analyst will need to revise the status to 'Active'.
    d. Upon reactivation the SIMS Log will be returned to the ORA Contractor Negotiator's Work Queue in SIMS and Negotiator will need to write up the Award Summary Sheet.
    e. On the Award Summary Sheet, there is no need to break out the individual start-up fees. All funding should be placed into the 'Pass Thru Fees' field.
    f. Add a note to the Award Summary Sheet indicating that sponsor is paying for start-up fees only and the study is not moving forward.
    g. The overhead rate for the project will be set to ***ZERO***, as all start-up fees have the applicable current Clinical Trials overhead rate built-in.
    h. In the SIMS Final folder, you will need to include one of the following:
        i. The fully executed letter or agreement required by the CRO/Sponsor to obtain reimbursement.
        ii. If no letter or agreement was required, a copy of the email from the CRO/Sponsor indicating that they will pay us for start-up fees including the amount of the reimbursement.
        iii. The respective ORA director should be consulted if it is unclear if the documentation is sufficient.

6. Upon confirmation that Sponsor/CRO will pay for start-up fees), the Research Accountant will invoice for the start-up fees as outlined by CTO.
    a. The following information is be obtained as to where the invoice is to be sent:
        i. Sponsor/CRO name
        ii. Sponsor/CRO address
        iii. Sponsor/CRO email address
    b. The BA will provide the Research Accountant with the allocations for the funds to be distributed to the study team, CTO, the IRB, and any other applicable department/office.
    c. The Research Accountant will record the allocation in the "IRB Billing Spreadsheet".
    d. The BA can be dropped off further correspondence once Sponsor/CRO has agreed to the amount of fees to be invoiced; however, the CTO can be re-engaged as needed should questions or concerns arise.

7. Once the invoice has been sent, the Research Accountant will record the fees owed on the billing spreadsheet used to track and allocate start-up and IRB fees to the central offices.

8. The Research Accountant will notify the study team and/or department financial analyst when payment has been received and will ensure that the funds are deposited into the IO number created for the study.

9. The Controller's Office will distribute funds according to the "IRB Billing Spreadsheet".

10. BA will update STAR to reflect the study being canceled.

11. In the event that no response is received from Sponsor/CRO, the Research Accountant will invoice for start-up fees.
    a. If no correspondence is received but the invoice is paid, then remittance will be submitted to the Office of Research Affairs to serve as documentation of Sponsor/CRO's intention to pay and as the agreement by which the study can be activated in SIMS and a SIMBA Internal Order number can be generated.
    b. If no correspondence or payment is received:
        i. And a CRO is involved, the Research Accountant will attempt to invoice Sponsor directly using the process outlined above.
        ii. And Sponsor is invoiced directly (either due to no CRO involvement or the CRO is non-responsive), then the invoice will be reversed. The Research Accountant will notify the CTO. The CTO will record in the Master Study List that Sponsor and/or CRO did not provide remuneration for start-up activities of the study.

12. If study team decides to terminate start-up activities, the process outlines above should be followed. However, it is not encouraged that study teams terminate start-up activities and seek remuneration for start-up activities without seeking guidance from the CTO Director or Assistant Director.

RELATED POLICIES AND REFERENCES

Penn State F&A Rate Summary Sheet (https://researchsupport.psu.edu/osp/prepare-proposals/develop-budget/fringe-benefits-and-fa-costs/)

APPROVALS

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HISTORY OF REVIEWS AND REVISIONS

March 2024	
Scope and Purpose	Entities removed as all research at Penn State Health facilities are required to follow the policies and SOPs of College of Medicine.
Policy and Procedure Statements	Steps 5 and 6 re-ordered to match Research Accountant's workflow. The Director of Contracts, Office of Research Affairs should be consulted if it is unclear if the documentation provided by Sponsor/CRO sufficient.
History of Reviews and Revisions	Section added.
January 2025	
Policy and Procedure Statements	"CPARA" reference removed to align new titles. BA will update STAR to indicate the study's cancellation, as Research Accountant lacks the access privileges to perform this task.
Related Polices and Procedures	Updated URL for F&A Summary Page