Research Special Purpose Fund (SPF) Account Deficit Management Policy (#1150-01) Frequently Asked Questions (FAQs)

Background

AHS acknowledges the value of research and is committed to supporting researchers in the important work they do to improve patient health outcomes and care delivery (AHS Strategy for Clinical Health Research, Innovation and Analytics 2015-2020).

AHS ensures sound financial stewardship of research funding received from external sources by utilizing these funds in accordance with their intended purposes. Research studies or clinical trials are not funded through the general operating funding received by AHS from Alberta Health, and is instead paid for by a funding agency, typically either an industry sponsor or a government agency. Therefore, any deficits incurred for research studies or clinical trials need to be covered as well through external funding rather than funded through AHS operating dollars.

As a steward of external research funding, AHS ensures that expenditures related to clinical and health research projects are held to the same standards as expenditures for AHS operations. Ensuring that research expenses incurred are recoverable and research funding balances are closely monitored is essential to the sound financial administration of research funding received by AHS.
FAQs

1. Why did AHS develop the new policy on Research SPF Account Deficit Management?

2. As a Principal Investigator (PI) / Account Holder, why am I personally accountable for any research account deficits?

3. If I inherit an account from another PI who is no longer affiliated with AHS or its academic partners, would I be accountable for the deficit in the account?

4. As a PI, I’m part of a CancerControl Cooperative Clinical Trial group (CTU), am I responsible for the deficit in the associated amalgamated group account?

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6. What are the implications for patient care if the study account for a clinical trial is halted, as well as the implications for AHS contractual obligations if the clinical trial is halted?

7. If the cost-recovery and/or repayment plan fails to clear the deficit, could there be a plan put in place that includes the collection of outstanding receivables and re-deployment of employees?

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12. As a PI interested in being proactive about deficits, will I be provided with resources to negotiate better budgets, payment terms and payment schedule with the Sponsor in the contract review and negotiation process?

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18. Will the deficit resolution process apply to billing accounts used to cost-recover salaries of staff supporting different groups/PIs from various research accounts administered through the University?

19. Are there more efficient mechanisms to avoid temporary deficits due to delays in processing journal entries and account reconciliation?

20. Why is the resolution process not aligned with that of University of Alberta, where the Research Services Office will inactivate the account in a timely manner and where the “department chair” can use a departmental operating account to address the deficit?

21. How can I prevent the salaries of AHS research employees that have transitioned to clinical duties from being continually charged to my research accounts?

22. Is there a list of the Finance contacts supporting researchers?
PURPOSE OF THE NEW POLICY

1. Why did AHS develop the new policy on Research SPF Account Deficit Management?

AHS developed the new policy on Research SPF Account Deficit Management to ensure that restricted research accounts housing external research funding administered by AHS are effectively managed for cost overruns through the effective monitoring and reporting of deficit balances on a regular basis, through consistent processes for addressing persistent deficits, and by clearly defining accountabilities of various stakeholders.

ACCOUNTABILITY FOR RESEARCH DEFICITS

2. As a Principal Investigator (PI) / Account Holder, why am I personally accountable for any research account deficits?

Research studies / clinical trials are funded through external funding sources (e.g., industry sponsor, or government agency), rather than through AHS. As a result, any deficits incurred must also be resolved with external funds.

AHS Research Administration and AHS Finance have committed to jointly increase their efforts to ensure that PIs are truly aware of their obligations relating to deficits. On the front end, this responsibility for assuming deficits of research studies is outlined in the Research Grants and Clinical Trial Funding Policy (#1150), and is noted in the Terms of Reference (TOR) that is signed by the PI when setting up a restricted research account. By signing the TOR, PIs assume the responsibility for any deficits incurred by the associated research account.

3. If I inherit an account from another PI who is no longer affiliated with AHS or its academic partners, would I be accountable for the deficit in the account?

When a PI is no longer affiliated with AHS or its academic partner, the PI is to work with AHS Finance and AHS Research Administration to resolve outstanding expenditures and close out their accounts prior to leaving AHS as per Policy #1150. The balance of a PI’s contingency account will be applied against deficits, if any, in research study accounts, and the remaining balance will be transferred to another contingency account, or another institution for research purposes.

If another PI assumes the active study and corresponding study account through an amendment to the research funding agreement and TOR, AHS Research Administration and AHS Finance will flag this scenario going forward and work with both the incoming and outgoing PIs to resolve any outstanding issues, including having the updated ethics approval in place that reflects the change in PI. These discussions should also include resolution of deficits in the research account prior to the change in account ownership.

4. As a PI, I’m part of a CancerControl Cooperative Clinical Trial group (CTU), am I responsible for the deficit in the associated amalgamated group account?

The day-to-day operations of Cooperative Group trials are managed centrally through the site CTU. As such, the program area responsible for the CTU operational mandate (i.e.,
CancerControl Alberta (CCA) leadership group) is in a better position to address the accountability requirements of the indirect cost accounts.

As a whole, the program area can make strategic decisions to shift resource allocation and the use of other funds to respond to emerging issues. In consultation with CCA and AHS Finance, the current requirements for TOR approval have been amended to allow a generic program area or unit to be listed as the Primary Authority. The assignment of the program area as the Primary Authority does not negate the responsibility of the Cooperative Group investigators to manage the resources allocated in a fiscally responsible manner.

SUSPENSION OF RESEARCH ACCOUNTS

5. What is the process for suspending a clinical trial?

If the clinical trial is to be suspended with the suspension of the account, the Account Holder will initiate the trial suspension in coordination with AHS Research Administration and other appropriate parties. The process will be guided by AHS Research Administration and will include, at minimum:

- Written notification to the Funding Agency/Sponsor of the pending suspension, outlining rationale and steps to be taken to address the safety, rights and welfare of enrolled participants. The Account Holder and AHS will respond to any terms and conditions outlined by the Funding Agency/Sponsor around the pending suspension.
- If the suspension proceeds, the Account Holder or the designated PI will notify all applicable regulatory authorities, including the applicable Research Ethics Board (REB), with the reason for the suspension and steps to be taken to address the safety, rights and welfare of enrolled participants. The PI will respond to any terms and conditions outlined by the REB around the pending suspension.
- Plan to transition current study participants from research to clinical care, if applicable.
- Notification of all current and past participants of the study suspension.
- Completion of the plan to transition out impacted study staff initiated upon study account suspension.

6. What are the implications for patient care if the study account for a clinical trial is halted, as well as the implications for AHS contractual obligations if the clinical trial is halted?

The suspension of the study account is not equivalent to the suspension of the clinical trial. Upon notification of account suspension, the Account Holder, in coordination with Research Administration and other parties as appropriate, will identify an appropriate restricted research or operating account(s), starting with the appropriate contingency account(s), towards which the outstanding deficits and continuing commitments of the project can be redirected.

To prevent compromising patient care and safety and to meet contractual obligations, AHS’ deficit resolution process is less restrictive compared to the processes used by AHS’ University partners which do not have a direct mandate for patient care. Generally, AHS will not suspend a study even if steps are taken to suspend the study account. When signing off
on a Clinical Trials Agreement (CTA), AHS is also signing off on an agreed study budget. Unless there is a specific termination clause that allows AHS to terminate the CTA for any reason with written notice, the risk of cost overruns is not a basis for suspending patient accrual, or for study termination.

7. **If the cost-recovery and/or repayment plan fails to clear the deficit, could there be a plan put in place that includes the collection of outstanding receivables and redeployment of employees?**

   Outstanding receivables alone are unlikely to be the sole reason for suspending an account. The collection of outstanding receivables would be a critical and default step in all recovery/repayment plans approved. The redeployment of employees would also be a key step of the deficit management plan. Please see Question 8 regarding the transfer of positions from a suspended account.

8. **What is the impact on staff if the research account is no longer active?**

   As per section 3.13 (a) of the Research SPF Account Deficit Management Policy (#1150-01), another account needs to be identified to clear the outstanding deficits and to address the continuing commitments, including compensation expenses, of the clinical trial or research study upon suspension of the associated research account. Any positions impacted are expected to be transferred out of the suspended account to the alternate account with adequate funding. Employee termination will not occur as a result of the suspension of an account.

**MONITORING AND RESOLUTION OF DEFICITS**

9. **As a Principal Investigator / Account Holder, how will I monitor my research account? How will deficits be recovered?**

   During the study, AHS Research Administration and AHS Finance monitor deficit account balances and work with the PIs to develop a recovery plan for clearing the deficits. PIs opening up a new research account will normally also open up a contingency account, if not yet in place, to hold overhead rebates, or residual funding from completed studies that do not have to be repaid to the research sponsor. These contingency accounts can be one option for eliminating the deficit. In the event that other funding cannot be obtained, the PI will be required to cover the funding shortfall.

10. **Will PIs receive additional resources and staff to support compliance with this policy, including access to adequate financial systems that provide real-time data?**

    This policy expands on existing processes for research deficit management and formalizes an approach that has largely been implemented in practice. In regards to monitoring of research accounts, AHS Research Administration and AHS Finance will continue efforts to identify adequate support and tools for site research administration teams and the PIs to jointly respond to emerging deficit account situations in a timely fashion. AHS Finance, in coordination with AHS IT, is currently exploring options for improving the financial reporting provided to account holders. Any changes to the current process for receiving information will be supported with additional training to account holders.
11. Which groups within AHS are responsible for supporting the deficit monitoring and resolution processes?

AHS Research Administration and AHS Finance jointly developed the deficit monitoring and resolution process, and will both be providing ongoing support. Please contact Sheila Lamano at Sheila.Lamano@ahs.ca or Jan Javorcik at Jan.Javorcik@ahs.ca (Finance) or Huey Chong at Huey.Chong@ahs.ca (RIA) if you have any specific process questions. Process flowcharts can be made available on request.

12. As a PI interested in being proactive about deficits, will I be provided with resources to negotiate better budgets, payment terms and payment schedule with the Sponsor in the contract review and negotiation process?

As per the Research Grants & Clinical Trial Funding Policy (#1150), AHS Finance reviews research grant applications and research funding agreements for reasonability of finance-related stipulations and accuracy of provided financial information. AHS Finance is one of the signatories on all approved research funding agreements. It’s important for research teams to connect with operational areas impacted by the research study to assess costs and when applicable, adhere to their service fee schedule when budgeting. Regarding the payment term/schedule, the temporary deficits resulting from study initiation and start-up are acknowledged and the policy accommodates deficits due to short-term timing differences by up to 9 months.

13. Will the policy accommodate artificial deficits resulting from the delays between billing and receipt of payments from Sponsors?

Research Administration will only proceed with the deficit resolution process if all of these four conditions exist:

1. Deficit is likely the result of over-expenditures rather than short-term timing differences (resulting from delays in the receipt of funds or allocation of shared expenses by up to 9 months);
2. Deficit exceeds $25,000;
3. Deficit has been outstanding for at least 90 days; and
4. There is no approved recovery or repayment plan already in place.

As part of the monitoring process, AHS Finance will work with the PIs and the study teams to resolve short-term deficits through regular allocation of shared expenses, timely recording of funding receipts, and timely adjustments of revenue and expenses.

14. Is there any flexibility to extend the allowable window for outstanding deficits (90 days) and deficits resulting from short-term timing differences (9 months)?

If the outstanding deficits are proven to be the result of short-term timing differences with supportable evidence (i.e., copy of invoice sent to sponsor for cost reimbursements and contract section indicating the timing of invoice payments from sponsors), then the 90 days window extends to 9 months. If the temporary deficit exceeds 9 months but the funding is
shown to be forthcoming, AHS Finance will note the exception in their deficit tracking system and AHS Research Administration will not initiate the deficit resolution process.

15. If applicable, can overhead revenue for a CancerControl Cooperative Group trials be used to address deficits in individual accounts?

CCA leadership group has indicated that Cooperative Group trial expenses that are not completely covered by direct funding alone will be coordinated with other revenue streams, which may nominally include overhead revenue from industry clinical trials. However, as per the draft “Eligibility of Research Overhead Expenses” policy, salaries and benefits of staff and other costs associated with affiliated studies must be applied first against funding held in the relevant individual study, PI contingency, and indirect cost accounts prior to utilizing overhead funding held in a restricted research overhead account.

16. How will AHS pursue cost-recovery from PIs who are non-AHS employees?

The majority of research accounts administered by AHS stem from research funding agreements that are executed jointly with the University Partner where the PI is primarily and concurrently appointed. As per policy, deficit resolution will involve all relevant parties, including AHS’ University Partner as required.

17. For divisions that operate as a single clinical trials group, is there a more efficient mechanism for transferring research funds from specific research accounts into contingency accounts which have been set up to pay salaries of research staff?

If the contingency account is the PI’s personal contingency account, please contact AHS Finance to set up an indirect cost account for the entire division. Per Policy #1150, affiliated studies or PIs can have a separate restricted functional centre for shared costs (“indirect cost account”). A primary authority must be appointed to oversee the management of the account. Salaries and benefits of staff and other costs associated with affiliated studies that cannot be immediately charged to study accounts will be charged to the appropriate indirect cost account. Costs held in the indirect cost accounts should be eventually allocated to the affiliated study accounts unless funding for indirect costs of affiliated studies is received from an external source.

The overall health of the affiliated accounts for the research group will be taken into consideration in both the monitoring and deficit resolution processes. Under section 2.1a(ii) of the Research SPF Account Deficit Management Policy (#1150-01), the Principal Investigator Report provides an overview of the revenue, expense and funding balances of all research accounts associated with each Account Holder. Under section 2.2 (c)(i), Account Holders or their designate should collaborate with AHS Finance to ensure that:

- Shared research expenses are allocated at minimum on a quarterly basis; and
- Funding receipts and revenue or expense adjustments are recorded in a timely manner.
18. Will the deficit resolution process apply to billing accounts used to cost-recover salaries of staff supporting different groups/PIs from various research accounts administered through the University?

All restricted research accounts have a TOR which would list a primary authority. As per section 2.5 of Policy #1150, “indirect cost accounts” set up for managing shared costs of affiliated studies or PIs must have a primary authority appointed to oversee the management of the account. As such, the Research SPF Account Deficit Management Policy (#1150-01) would apply to billing accounts referred to above.

19. Are there more efficient mechanisms to avoid temporary deficits due to delays in processing journal entries and account reconciliation?

Delays in the processing of journal entries can be avoided by ensuring that journal entry forms or requests for adjustments or corrections with required supporting documents are submitted to AHS Finance, Revenue by noon on Work Day 3 of each month. To prevent errors from re-occurring, AHS Finance, Revenue has started reviewing errors impacting research accounts to understand root causes and address underlying issues in coordination with AHS Research Administration and other relevant departments.

20. Why is the resolution process not aligned with that of University of Alberta, where the Research Services Office will inactivate the account in a timely manner and where the “department chair” can use a departmental operating account to address the deficit?

It should be noted that for the majority of sponsored clinical trial accounts in the Edmonton Zone, AHS and the University of Alberta (U of A) are jointly listed as the “Institutions” on these contracts but the accounts are established and maintained by AHS because sufficient expertise, resources and infrastructure for administering clinical research lies within AHS. The longer timeline to account suspension in the AHS context compared to the U of A is intended to address the temporary deficits encountered by most PIs during the start-up phase of the study. This is not the case for most studies managed through the U of A. In the case of AHS, the use of a program area’s unrestricted operating accounts or other restricted research accounts, including contingency accounts, to clear an outstanding deficit is also permissible (and key to the resolution process).

21. How can I prevent the salaries of AHS research employees that have transitioned to clinical duties from being continually charged to my research accounts?

The PIs can avoid this situation by setting up temporary positions to support research studies while working with the research HR advisor to ensure compliance with HR policies and procedures when addressing staffing on a temporary basis. To resolve the issue of research coordinators still being charged to the clinical trials that have been completed, AHS Finance and AHS Research Administration are working to determine the transfer of these positions to the relevant clinical operating accounts.
22. Is there a list of Finance contacts supporting researchers?

Please see table below for list of contacts:

<table>
<thead>
<tr>
<th>Finance Member</th>
<th>Duties</th>
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<tbody>
<tr>
<td>Wayne King via <a href="mailto:Research.expenses@ahs.ca">Research.expenses@ahs.ca</a></td>
<td>Research account related expense claims. *</td>
</tr>
<tr>
<td></td>
<td>*Claims from Special Purpose Funds (SPF) Research accounts will continue to be paper-based and are exempted from the iExpense expense claim process.</td>
</tr>
<tr>
<td>Filoza Bandali</td>
<td>Terms of reference, account set-up**, coding of cheques, HR and capital equipment requests. **NACTRC – Account set-up requests and TORs for Edmonton Zone Researchers (excluding adult oncology) will continue to be processed via <a href="mailto:NACTRC.Contracts@ahs.ca">NACTRC.Contracts@ahs.ca</a>.</td>
</tr>
<tr>
<td>Adrian Sava</td>
<td>Account closures, monthly SPF and PI reports, GL journal entry requests.</td>
</tr>
<tr>
<td>Shuming Heilesen</td>
<td>Review of research funding proposals if Finance sign-off is required by funders</td>
</tr>
<tr>
<td>Grants Reporting Group via <a href="mailto:Fin.GrantReporting@ahs.ca">Fin.GrantReporting@ahs.ca</a></td>
<td>Review of financial reports to funders</td>
</tr>
<tr>
<td>Diane Kinnear (CCI); Margaret Maclsaac (TBCC)</td>
<td>CTU research budgets and management of CCI/TBCC adult oncology clinical trial research accounts; will continue to manage the account set-up, financial transactions, reporting and closing functions.</td>
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