Frequently Asked Questions

Financial Administration Questions about Cancer Clinical Trials with CancerControl Alberta Oversight
Frequently Asked Questions (FAQs)

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1. What is the purpose of this FAQ document

This document is meant to be a guide for Principal Investigators (PI) in understanding the myriad processes at the Cross Cancer Institute (CCI) and the Tom Baker Cancer Centre (TBCC) for clinical trials research (Industry, Cooperative Group, and Investigator Initiated Trials (IIT).)

Each center has slightly different administrative processes to take the PI from initiation of a clinical trial through to the termination of a clinical trial.

Each center has a Finance Team which supports the PI on the financial aspects of a clinical trial.

To learn more about cancer clinical trials please see the following websites:

• Alberta Cancer Clinical Trials
• Participating in a Cancer Clinical Trial
• Canadian Cancer Society Clinical Trials Information

For Administrative Approval for doing Research with Alberta Health Services, please see Health System Access for Research on the Alberta Health Services Webpage under https://www.albertahealthservices.ca/research/page8579.aspx. This webpage outlines AHS policies, procedures and best practice guidelines to assist researchers in Patient Recruitment, obtaining Operational Approval, Ethics Approval Resources, requesting AHS Data Resources, Purchased Services, etc.

For definitions, abbreviations and their explanations, please see the appendix to this FAQ.

Policies and Forms

2. What are the AHS policies relevant to the financial administration of research funds and where can I find these policies?

The AHS policies relevant to the financial management of research funds along with the objective(s) of each of these policies are as follows:

<table>
<thead>
<tr>
<th>Policy Name</th>
<th>Objective(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Grants and Clinical Trial Funding</td>
<td>• Sets out the requirements and responsibilities for the administration of research clinical trial funding and research grants funded by external entities.</td>
</tr>
<tr>
<td>Research Special Purpose Fund Account Deficit Management</td>
<td>• Ensures that restricted research accounts are effectively managed for cost overruns through effective monitoring and reporting of deficit balances on a regular basis, and consistent processes to address research accounts with persistent deficits.</td>
</tr>
<tr>
<td>Travel, Hospitality, and Working Session Expenses – Approval, Reimbursement, and Disclosure</td>
<td>• Provides guidance on the effective oversight of public resources for the approval, reimbursement and disclosure of travel, hospitality and working session expenses.</td>
</tr>
</tbody>
</table>
To view the policy documents, please click on the above links.

3. Where can I find the Finance forms commonly used for research accounts?

The Finance forms that are commonly used for research accounts are as follows:

- Research Account Terms of Reference Form
- Research Account Update Form
- Research Account Closure Form
- Payment Requisition Form
- Travel, Hospitality & Working Session Expense Claim Form
- Invoice Request Form – Non Patient (Provincial)

For cancer clinical trials at CCI and TBCC, the Grant Administrators complete the Research Account Terms of Reference, Account Update, Account Closure, Payment Requisition and Invoice Request Forms.

It is the PI’s responsibility to authorize (if required) the completed forms and return them to the Grant Administrators. The Grant Administrators will ensure that these forms are forwarded to the appropriate department for processing.

The instructions for submission and required supporting documentation are provided in each form.

**Initiation of a Cancer Clinical Trial**

4. How is a cancer clinical trial initiated?

CCI:
a. The sponsor approaches the PI/Site to determine if there is an interest in and a feasibility of running the trial. If the PI agrees, he/she is presented with a Confidentiality Disclosure Agreement (CDA) that is sent to the CTU Launch Team. The CDA is reviewed, negotiated, and finalized by a unit legal counsel (NACTRC legal personnel), and then returned to the PI for the signature.

b. Upon full execution of the CDA, the sponsor releases the protocols synopsis to the site running the trial.

c. PI reviews the trial proposal with the applicable Tumor Group (e.g., Breast, Phase I, Hematology, etc.) to determine the feasibility of the study in consideration of various factors such as patient population, competing studies, and resource availability.

d. PI and/or staff from Clinical Trials Unit (CTU) complete and submit the feasibility survey to the sponsor.

**TBCC:**

(Steps a to d are the same as for CCI)

e. PI submits the Trial Launch Form for Investigators to the Trial Launch Team via the email address ACB.TBCCTrialLaunchTeam@ahs.ca. For the blank form, contact Trial Launch Team.

f. Trial Launch Team gathers and disseminates required information to the Rapid Trial Review team, and works with TBCC service departments and the sponsor to ensure that the trial is operationally feasible. The Rapid Trial Review team is a team of designated individuals who work for each of the departments that are involved in a clinical trial. They are expected to read the protocol and other related trial documents and to comment on the operational feasibility of each trial. These departmental representatives complete and sign off the departmental approvals.

### 5. When does the site selection visit occur?

A site selection visit (SSV) is the process of interviewing and selecting a potential investigator for a clinical trial study and discussing the aims of the study and the number of participants that the investigator is expected to recruit. Another purpose of the SSV is to ensure that the site has the capability and capacity to conduct the trial.

a. The SSV is initiated by the sponsor or Clinical Research Organization (CRO) either remotely by phone or an on-site visit.

b. CCI/TBCC Launch Teams facilitate the visit and schedule a time for the PI, nurse, coordinator, and service department representatives.

### 6. What happens after a site is selected?

a. The sponsor or CRO sends a confirmation that the site has been selected.

b. Start-up package is prepared by the sponsor or CRO and sent to the site. This package normally includes the clinical trial agreement, budget, protocol, pharmacy manual, laboratory manual, and/or other documents pertinent to trial.
7. What are the start-up activities?

All start-up documents must be received prior to the initiation of any of the processes listed below (i.e., regulatory, contract, budget and ethics processes commence in unison).

i. Launch team prepares and submits the requirements for the ethics board.

ii. Legal teams prepare or review the contract.

iii. Nurse submits operational approval (summarizes the impact of the clinical trial to the AHS departments like Pharmacy, Diagnostic Imaging, and Laboratory.)
   - CCI nurses enter data from protocol into the NACTRC Operational Approval database.
   - TBCC nurses send the relevant forms to the service departments.

iv. Budget is prepared by CTU/CRU Finance team and negotiations with the sponsor or CRO start.

8. What happens upon completion of the start-up activities?

   a. How do I request a new research account to be created at AHS?
      i. The Grant Administrators are notified by the Launch team that all approvals are in place, and the trial is ready to start. The Grant Administrators then proceed with completing the Research Account Term of Reference (TOR) form. The completed form is sent to the PI for review, decision on signing authority and signatures (refer to section 8.b for explanation on signing authorities). The Manager of clinical unit signs off on section K “Approval to Establish Research Accounts” of the TOR form.
      ii. The TOR is submitted to the relevant department.
         - For CCI, it is NACTRC.
         - For TBCC, it is AHS Revenue Department.
         Each trial must have a unique research study account number which is assigned by the AHS Revenue Department.
      iii. The Grant Administrators send an email to Laboratory, Diagnostic Imaging and Pharmacy with the account and ethics number. The clinical trial nurse and coordinator are copied on this email.
      iv. The approved TOR is distributed as follows:
         - At CCI, a copy of the approved TOR is sent to the Launch Team which will forward the administration approval and the study account number to the PI.
         - At TBCC, the approved TOR is kept in the TBCC Grant Administrator’s office and a copy of TOR is sent to the PI.

   b. What is the difference between single signing authority and dual signing authority protocols on the Research Account TOR form?

      The authorities who should have the ability to approve and sign research expenses should be accurately documented in the Research Account TOR form. Signing authority protocol on the TOR form can either be single or dual.
i. Single authority protocol means that there must be at least two individuals with signing authority on the account where primary signing authority is the PI. The “Single (any one)” option means that any signing authority from the list of signing authorities (section J of the TOR form) can approve and sign research expenses. The “Single (one must be Primary or Secondary)” option means that only Primary or Secondary signing authority can approve and sign the research expenses. Under both options, no signing authority can approve their own expenses.

ii. Dual authority protocol means that there must be at least three individuals with signing authority on the account where primary signing authority is the PI. The “Dual (any two)” option means that any two signing authorities from the list of signing authorities (section J of the TOR form) can approve and sign research expenses. The “Dual (one must be Primary or Secondary)” option means that minimum two signatures are needed and one of the signatures is either primary or secondary signing authority. Under both options, no signing authority can approve their own expenses.

9. When can site initiation visits occur?

After administration approval from CRU/CTU Manager and sponsor has given approval to proceed, the site initiation visit (SIV) can be booked.

Research Expenses

10. How are research expenses or invoices managed by the Clinical Trial/Research Units?

Expenses and invoices for research accounts are managed differently from AHS operational accounts. Below is a summary of how various types of research expenses are handled in AHS.

a. All payment requests, external invoices, and transfer requests from internal service providers (e.g., Pharmacy, Diagnostic Imaging, and Laboratory) should be forwarded to the Grant Administrators.
   i. The Grant Administrators will prepare a payment requisition form for the external service providers, and have the PI authorize the payment. The Senior Financial Analyst will verify the authorizing signature and that funds are available to cover the expense. This form is submitted to AHS Accounts Payable for the cheque to be issued.
   ii. For internal service providers, the transfer request with backup is forwarded by the Grant Administrators to the PI for authorization. Once PI authorization is obtained, the transfer request is sent back to the service department which initiated the inter-fund transfer.
   iii. Research expenses need to be approved in accordance with the applicable Research Account TOR signing authority protocol.

b. Expense claims do not use iExpense and require a travel, hospitality & working
   session expense claim form to be manually completed. The PI is responsible for the
completion of the travel, hospitality & working session expense claim and for its submission with receipts.

11. Who do I contact for any payment inquiries?

For invoice payments via the payment requisitions or payments to internal service providers please contact the Grant Administrators via the following email addresses:

CCI:
ACB.CCITrial.Payments@ahs.ca

TBCC:
Darlene.Wyles@ahs.ca or Asim.Nadeem2@ahs.ca

Any expense claims not directly related to clinical studies (e.g., education, conferences, travel, or hospitality) can be directed to the following email addresses:

Primary email: researchexpenses@ahs.ca

Secondary email: AHS.APHelpDesk@ahs.ca

If you are experiencing issues related expense claims, please contact the Grant Administrator(s) at each site for assistance.

12. Can unbudgeted research study expenses be paid out of an AHS research account?

Unbudgeted expenses related to a research study including reimbursements to a PI can be paid out of an AHS research study account if a written approval for such expenses was obtained from the research sponsor.

In the absence of a written approval from the research sponsor, the unbudgeted expenses can be paid out of the PI's contingency account provided that such account has sufficient funding to cover the unbudgeted expenses and the unbudgeted expenses qualify as eligible expenses per the Research Contingency Account Agreement between AHS and the PI, and applicable AHS policies.

13. Can I hire employees for my cancer clinical trial research study?

No, all personnel costs associated with a cancer clinical trial are managed by the AHS Cancer Clinical Trial operations team under CancerControl Alberta. AHS Clinical Trial personnel resources that are used are allocated to the trial based on the agreed upon rate and hours required for the trial. Please contact the Clinical Trial or Research Unit to assign resources to your cancer clinical trial.

Collection of Research Funds
14. Who looks after collecting patient visit fees and other revenue from Sponsor?

The Grant Administrators are responsible for collecting the patient visit fees, invoicing for other procedures, and depositing the funds into the research account.

15. What happens with the financial balance of the study account after trial is terminated?

Once, the trial is terminated and the final invoices from the service departments and the final deposit from the sponsor are received, the trial deficit or surplus is to be transferred to the following:

- **CCI**: Either the PI’s personal research contingency account, or the Tumor Group’s Indirect Cost account as determined by the PI.
- **TBCC**: Tumor Group’s Indirect Cost account (amalgamated account.)

Generally speaking, the PI or the associated research teams are directly responsible for the cost overruns.

16. How do I set up my study for EFT payment from sponsors?

In most cases, setting up the EFT payment is part of the start-up activities which is completed by the Clinical Trial/Research Unit staff. If there is a request from a sponsor to setup an EFT payment for the research account, please forward the request to the Grant Administrators who will work with the AHS Cash Handling team to provide the sponsor with the necessary banking information.

**Internal Financial Reports**

17. Where can I get information regarding my account balance and transaction details?

The Senior Financial Analyst sends out the CCI Tumor Group reports or TBCC Trial Financial Portfolio reports each quarter in an excel spreadsheet. The first tab on the spreadsheet is a high level summary of the whole tumor group or portfolio. The second tab contains the specific details as it relates to the particular research study account.

**CCI**

Note that on the internal CCI reports below, a bracket around a dollar amount or a dollar amount in red font indicates a funding deficit or a decrease in revenue which both have a negative effect on the account. The absence of brackets or a dollar amount in black font, on the other hand, indicates either a funding surplus, funding receivable, an increase in revenue, or a receipt of funds which all have a positive effect on the account.
Illustration 1: First Tab of the CCI Tumor Group Report

(NAME) of Tumor Group @ December 31, 2018

<table>
<thead>
<tr>
<th>General Ledger Account Balance</th>
<th>IIT Funding</th>
<th>Funds for Other Sites</th>
<th>Accounts Receivable</th>
<th>Total Available Funds</th>
<th>Monthly Payroll</th>
<th># Months Payroll Costs Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>$1,575,265</td>
<td>($125,000)</td>
<td></td>
<td>$203,869</td>
<td>$1,654,134</td>
<td>$60,327</td>
<td>21</td>
</tr>
</tbody>
</table>

Illustration 2: Second Tab of the CCI Tumor Group Report

In the example below, many of the columns are hidden for ease of viewing.

Tumor Group Account Balances

<table>
<thead>
<tr>
<th>Ethics# CTC</th>
<th>AHS Account #</th>
<th>Sponsor / Title / Description of trial</th>
<th>PI</th>
<th>Current Account Balance (includes outstanding invoices)</th>
<th>Outstanding Invoices (included in Closing Balance)</th>
<th>Accounts Receivable (Patient Visits)</th>
<th>Cheques not yet posted</th>
<th>Holdback</th>
</tr>
</thead>
<tbody>
<tr>
<td>2549x</td>
<td>103.0729.7176 xxxxxxx</td>
<td>Sponsor/Title /Description of trial</td>
<td>Dr. XXXX</td>
<td>$37,146</td>
<td>$13,500</td>
<td>$156,000</td>
<td>$15,000</td>
<td>$15,600</td>
</tr>
<tr>
<td>268xx</td>
<td>103.0729.7176 xxxxxxx</td>
<td>Sponsor/Title /Description of trial</td>
<td>Dr. YYYY</td>
<td>$42,345</td>
<td>$0</td>
<td>$18,767</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15x25</td>
<td>103.0729.7176 xxxxxxx</td>
<td>Sponsor/Title /Description of trial</td>
<td>Dr. ZZZZ</td>
<td>$1,156</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TBCC

Note that on the internal TBCC reports below, a black font or negative amount indicates a funding surplus, whereas a red font or positive amount indicates a funding deficit.

Illustration 1: First Tab of the TBCC Tumor Group Trial Financial Portfolio Report

<table>
<thead>
<tr>
<th>Account Number</th>
<th>PI and Study Identification</th>
<th>Balance as of April 1st of Current Fiscal Year</th>
<th>Year to Date Balance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumor Group Indirect Cost Account (Amalgamated)</td>
<td>PI, Protocol Name, Sponsor Name, Project ID</td>
<td>$0</td>
<td>$-457,000</td>
</tr>
<tr>
<td>Total Amalgamated Trial Accounts</td>
<td></td>
<td>$0</td>
<td>$-457,000</td>
</tr>
</tbody>
</table>

Illustration 2: Second Tab of the TBCC Tumor Group Trial Financial Portfolio Report

<table>
<thead>
<tr>
<th>Individual Trial Accounts</th>
<th>Balance</th>
</tr>
</thead>
<tbody>
<tr>
<td>103.0713.7176000XXXX, PI, Trial Name, Sponsor, and TBCC Project Number</td>
<td>$125,000 deficit</td>
</tr>
</tbody>
</table>
18. Where can I find the current balance of my account on the AHS monthly financial reports that I may receive?

The current funding balance of a research account is provided under the “Fiscal YTD Amount” column, and the closing balance rows on the last page of the SPF summary report.

Below is an illustration of the SPF summary report which a PI or researcher in CCI or TBCC may receive. This sample report shows a surplus of $47,541.66. Please ignore the far right column as it is not applicable for your monthly account review.

<table>
<thead>
<tr>
<th>Account Number</th>
<th>Account Description</th>
<th>Current Period SEP-18</th>
<th>Fiscal YTD Amount (As at end SEP-18)</th>
<th>Cumulative Fund To Date Amount (As at end SEP-18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>69500000</td>
<td>Sundry Expenses Not Elsewhere Classified</td>
<td>0.00</td>
<td>0.00</td>
<td>1,522.62</td>
</tr>
<tr>
<td>69998000</td>
<td>Shared Service Interfunctional Other</td>
<td>0.00</td>
<td>0.00</td>
<td>23,958.00</td>
</tr>
<tr>
<td>69738001</td>
<td>Shared Serv Clinical Support Research</td>
<td>0.00</td>
<td>0.00</td>
<td>150.00</td>
</tr>
<tr>
<td>Expenses Total</td>
<td></td>
<td>3,000.00</td>
<td>7,798.36</td>
<td>309,725.07</td>
</tr>
<tr>
<td>Closing Balance</td>
<td></td>
<td>3,000.00</td>
<td>47,541.66</td>
<td>(47,541.66)</td>
</tr>
<tr>
<td>Closing Balance Total</td>
<td></td>
<td>3,000.00</td>
<td>47,541.66</td>
<td>(47,541.66)</td>
</tr>
</tbody>
</table>

External Financial Reporting

19. How do I know if a financial report is required to be submitted to the funding agency?

The research funding agreement should indicate whether a financial report is required. This would include the frequency, due date, and the report recipient. Industry sponsors for the clinical trials usually do not require a financial report.

Alberta Cancer Foundation (ACF) and some other organizations granting research funding do request financial reporting mainly on Investigator Initiated Trials. The financial reports for these trials are prepared by the Senior Financial Analyst in the Clinical Trial/Research Unit. The reports are sent to External Financial Reporting (EFR) for review and approval prior to being submitted to ACF or the other organization providing funding and requesting financial reports.
20. Who do I contact for inquiries related to the preparation of a financial report required by the funding agency?

Any inquiries related to the preparation of financial reports can be directed to the Senior Financial Analyst of the Clinical Trial/Research Unit via the email addresses as follows:

- **CCI:**
  ACB.CCITrialLaunch.Budgets@ahs.ca

- **TBCC:**
  Margaret.Mac@ahs.ca

21. How do I know if the report has been submitted?

The PI or funding recipient will be included in the distribution list when the signed report is submitted to the funding agency.

22. How do I complete financial forms sent to me by the sponsor, such as the W-8BEN, state tax withholding, and audit confirmation forms?

For W-8BEN, state tax withholding, audit confirmation, and other financial forms pertaining to research studies and clinical trials, please contact:

- **CCI:**
  Clinical Trial Unit Launch Team at ACB.CCITrialLaunchEthics@ahs.ca

- **TBCC:**
  Darlene.Wyles@ahs.ca or Asim.Nadeem2@ahs.ca

Contacts

23. Who should I contact if I have an inquiry that needs to be directed to the Clinical Trial/Research Units?

Inquiries related to new studies, amendments, status of contract, operational approval or administrative approval, and W-8BEN can be directed to the trial launch team. The email address of the trial launch team, and the contacts for other types of inquiries are provided below.

- **CCI:**
  Trial Launch Team - ACB.CCITrialLaunchEthics@ahs.ca
  Budget and account balance inquiries - ACB.CCITrialLaunch.Budgets@ahs.ca
  Payments, expenses, TOR questions - ACB.CCITrial.Payments@ahs.ca

- **TBCC:**
  Trial Launch Team - ACB.TBCCTrialLaunch@ahs.ca
Budget and account balance inquiries – Margaret.Mac@ahs.ca
Payments, expenses, TOR questions – Asim.Nadeem2@ahs.ca or Darlene.Wyles@ahs.ca
Acronyms

ACF – Alberta Cancer Foundation
CCI – Cross Cancer Institute
CDA – Confidentiality Disclosure Agreement
CT – Clinical Trial
CRO – Clinical Research Organization
CRU – Clinical Research Unit (relevant for TBCC)
CTU – Clinical Trial Unit (relevant for CCI)
EFR – External Financial Reporting
EFT – Electronic Funds Transfer
GA – Grant Administrator
IIT – Investigator Initiated Trial
NACTRC – Northern Alberta Clinical Trials Research
PI – Principal Investigator
SFA - Senior Financial Analyst
TBCC – Tom Baker Cancer Center
TLT – Trial Launch Team
TOR – Research Account Terms Of Reference Form
SIV – Site Initiation Visit
SPF – Special Purpose Fund
SSV – Site Selection Visit
Definitions

NACTRC (Northern Alberta Clinical Trials Research) is a joint venture between the University of Alberta and Alberta Health Services. NACTRC helps investigators who work with these organizations to conduct clinical research, develop new treatments, and bring them to the market for human use. (https://nactrc.ca)

HSA (Health System Access for Research) is a team in Alberta Health Services which works with Alberta’s academic institutions, affiliated research institutes and centres to support health research. (https://www.albertahealthservices.ca/research/page8579.aspx)