Alberta Health Services

POLICY

TITLE
RESEARCH GRANTS AND CLINICAL TRIAL FUNDING

SCOPE
Provincial: Research, Innovation & Analytics; Finance

DOCUMENT #
1150

APPROVAL AUTHORITY
Vice President Research, Innovation & Analytics; Vice President Corporate Services & CFO

INITIAL EFFECTIVE DATE
June 21, 2013

SPONSOR
Research, Innovation & Analytics / Finance

REVISION EFFECTIVE DATE
February 14, 2018

PARENT DOCUMENT TITLE, TYPE AND NUMBER
Not applicable

SCHEDULED REVIEW DATE
February 14, 2021

NOTE: The first appearance of terms in bold in the body of this document (except titles) are defined terms – please refer to the Definitions section.

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OBJECTIVE

- To set out the requirements and responsibilities for the administration of **clinical trial funding** and **research grants** ("research funding" or "research funds") funded by external entities other than the **Government of Alberta**.

PRINCIPLES

AHS is committed to the sound financial administration of research funding in its control through transparent processes. **Funding recipients** are required to effectively manage research funding awarded to or administered by AHS by pursuing each funding opportunity with care, ensuring compliance with all funding stipulations**, and defining expectations from all parties involved**.

APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staffs, Students, Volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary).

Compliance with this Policy is also required by all individuals accessing research funds under administration by AHS.

As outlined in the Collaborative Clinical Research Procedures Agreement (CCRPA) between AHS and the University of Alberta, the two institutions work collaboratively to develop and apply policies that govern the research activities administered by the Northern Alberta Clinical Trials and Research Centre (NACTRC). NACTRC works with the two institutions to identify inconsistent policies and procedures, and develop procedures that support the achievement of better patient outcomes through research.

ELEMENTS

1. Research Grant Applications

1.1 Researchers are encouraged to obtain approval from the appropriate **program authority** prior to submitting a research funding application to a **funding agency**.

1.2 When the funding agency requires sign-off from a program area, research funding applications shall be approved and signed in accordance with *Appendix A* by the appropriate program authority.

1.3 In addition to Section 1.2, when the funding agency has requested additional sign-off by Finance, the research funding applications shall be approved and signed in accordance with *Appendix A* by the appropriate authority within Finance.

2. Research Funding Agreements

2.1 The review and approval process for research funding agreements is undertaken in coordination among stakeholders including but not limited to:

a) the funding recipient;

b) **Research Administration**, Finance, and Legal & Privacy divisions;

c) the applicable university's research services office; and

d) the applicable AHS operational leader, as necessary.

2.2 Budgets are required for all research funding agreements. Finance reviews research funding agreements for reasonability of finance-related stipulations and accuracy of provided financial information.

2.3 Research funding agreements wherein a **government of another jurisdiction** is a signatory shall be approved by the Minister of Health. Contracting, Procurement & Supply Management coordinates the review process for these agreements with Alberta Health's Legal department, and AHS Legal & Privacy, as needed. The Office of the President and Chief Executive Officer facilitates the process for obtaining Ministerial approval.

2.4 To come into effect, all research funding agreements shall be approved and signed in accordance with *Appendix A* by the appropriate program and Finance authorities.

3. Research Accounts

3.1 Based on a fully signed research funding agreement, funding recipients shall complete the *Terms of Reference* ("TOR") Form which specifies the:

a) title and description of the study;

b) source of funds;

c) allowable expenditures, in accordance with the agreement;

d) the **primary authority** and designated signing authorities; and

e) instructions pertaining to residual funds upon study completion.

3.2 Completed TORs shall be approved by the applicable **Research Administrative Lead**, and then by the Manager, Treasury or higher. Upon approval of the TOR, Finance, Revenue ("Revenue") initiates, coordinates, and completes the required internal forms to set up a restricted functional centre for a research study or clinical trial ("study account").

3.3 All research funding agreements with a total funding amount in excess of $10,000, or with external financial reporting or surplus repayment requirements shall have a unique study account. Multiple study accounts may be set up for a funding agreement only if the funding is intended for multiple projects or **principal investigators**, or for a combination of operating and capital projects.

3.4 Affiliated studies or principal investigators can have a separate restricted functional centre for shared costs that cannot be immediately attributed to individual study accounts ("indirect cost account"). A primary authority shall be appointed to oversee the management of this account. Expenses charged to an indirect cost account shall be subsequently allocated to affiliated study or contingency accounts except when separate funding for shared costs of affiliated studies is obtained from an external source.

3.5 Funding recipients may request a restricted functional centre for contingency items ("contingency account") to be set up to hold:

a) funding for a specific research study not exceeding $10,000 and without stipulations for external financial reporting or repayment of surplus funds;

b) residual funding from completed studies that are not affiliated with an indirect cost account; or

c) when applicable, overhead rebates as outlined in the Collaborative Clinical Research Procedures Agreement administered by NACTRC.

3.6 Any request to set up a new contingency account shall be supported by a contingency account agreement signed by the funding recipient and the applicable Research Administrative Lead, and a TOR signed in accordance with Section 3.2.

3.7 A contingency account is only to be used for research-related purposes, such as clearing shortfalls in study accounts, or payment of research expenses not

covered by a particular research funding agreement, including travel and educational activities of the funding recipient or research staff.

3.8 AHS only holds research funds that provide a direct benefit to AHS.

4. Monitoring of Accounts

4.1 Finance shall:

a) review research expenses in excess of $250 to confirm availability of funds, validate expenditure signing authorities, and verify the appropriateness of expenses against the TOR;

b) investigate research accounts that are in overdraft and coordinate with Research Administration and researchers, as needed, to ensure resolution of the issue; and

c) review study accounts with surplus funds in excess of a predefined threshold to reasonably ensure that all eligible expenses are charged against the research funding prior to its termination.

4.2 Primary authorities are responsible for any deficit incurred by the research study upon research funding termination, or any deficit balance in a research contingency or indirect cost account. In the absence of a primary authority, designated signing authorities may be responsible for the deficit.

4.3 The monitoring, management and resolution of research deficits shall comply with the *Research Special Purpose Fund Account Deficit Management* Procedure (#1150-01).

5. Payment of Grant and Contract Funds and Cash Flow

5.1 Funding recipients shall notify Finance of the receipt of the research funding.

5.2 Finance shall immediately notify the funding recipient when Finance receives research funding directly from a funding agency.

5.3 Research funding shall be sent through either electronic funds transfer to an AHS bank account, or by a cheque made payable to AHS.

5.4 The total amount of research funding received shall be deposited into a study account, or into a contingency account if the criteria per Section 3.5 (a) are met.

5.5 The funding recipient shall follow up with the funding agency to ensure that the receivable portion of the total funding amount is received in accordance with the research funding agreement.

5.6 If the total research funding or a portion of it is still outstanding, Finance shall set up a receivable for the outstanding current year funding amount provided:

a) the research funding amount for the current fiscal year has been authorized by the funding agency and communicated to AHS;

b) the eligibility criteria, if any, for the research funding have been met;

c) the stipulations, if any, for the research funding have been met; and

d) the research funding amount's ultimate collection is reasonably assured.

5.7 Unspent research funds are reported in AHS financial statements as deferred revenue for future use.

6. Overhead

6.1 Overhead fees are charged against research funding to recover the **indirect costs of research** except when:

a) the funding agency is a not-for-profit organization (e.g., a foundation or an academic institution) with formally established policies or regulations expressly prohibiting the use of research funding for indirect costs; or

b) funding relates to a **principal investigator initiated study or clinical trial with funding from a peer reviewed funding agency**.

6.2 Research overhead fees, when applicable, shall be charged at the following standard rates:

a) 30% of the research funding for start-up fees and direct costs of an **industry sponsored study or clinical trial**;

b) 15% of the research funding for start-up fees and direct costs of a **principal investigator initiated study or clinical trial with funding from industry**.

6.3 In exceptional circumstances, overhead fees applicable to a specific research study or clinical trial with oversight from NACTRC can be reduced or waived if approved by the NACTRC Board in accordance with the Collaborative Clinical Research Procedures Agreement between the University of Alberta and AHS. A reduction or waiver of overhead fees applicable to a research study or clinical trial without oversight from NACTRC requires approval of the Vice President, Research, Innovation & Analytics or designate. Revenue shall be informed of any approved reduction or waiver of overhead fees.

6.4 Where funding is awarded pursuant to an application process, the request and approval of a reduction or waiver of overhead fees shall be completed prior to the submission of the research funding application. An overhead fee reduction or waiver shall not be considered after an application has been made or after an award has been received.

6.5 Overhead rates shall be reviewed as needed to ensure that research overhead fees are reasonable relative to industry standards, fees charged by other institutions, and actual indirect costs incurred. Any changes to the standard overhead rates resulting from such review process require approval of the Vice President, Research, Innovation & Analytics, and the Vice President, Corporate Services & Chief Financial Officer in consultation with NACTRC and appropriate leadership.

6.6 Upon receipt of research funding, overhead fees shall be recorded as research revenue and then deducted as an overhead expense in the study account.

6.7 Overhead revenues collected from research funding shall be held in a deferred revenue account until eligible overhead expenses are incurred.

6.8 Finance shall manage the collection and distribution of overhead revenues.

7. Uses of Funding

7.1 Research funding shall be used only for the purposes set out in the TOR and in accordance with the research funding agreement, applicable legislation, regulations, and this policy. Use of research funding for any purpose other than those set out in the research funding agreement requires the prior written consent of the funding agency.

7.2 Funding agencies may reserve the right to disallow and recover from the research funding recipient the amount of any expenditure that is contrary to the terms and conditions of the research funding agreement.

7.3 Travel-related eligible expenses and approvals shall comply with the AHS *Travel, Hospitality and Working Session Expenses – Approval, Reimbursement and Disclosure* (#1122) Policy, the *Management and Oversight of Research Expenses for Travel, Hospitality and Working Sessions* (#RESEARCH-001) Standard, other applicable AHS policies and procedures, and other applicable governance documents.

7.4 Salaries and benefits of research staff and other direct costs shall be charged to a study account, or to a contingency account, if associated with funds referred to in Section 3.5.

7.5 Salaries and benefits of staff and other costs associated with affiliated studies that cannot be immediately attributed to individual study accounts or contingency accounts shall be charged to the appropriate indirect cost account.

7.6 Subject to Section 3.4, shared costs charged to an indirect cost account shall be allocated to affiliated study accounts or contingency accounts at least on a quarterly basis.

7.7 Research study or clinical trial spending in excess of the associated research funding received or receivable from an external funding agency is not permitted unless other valid sources of funds exist.

8. Reporting

8.1 Funding recipients, Business Advisory Services, or External Financial Reporting ("EFR") shall prepare interim and final financial reports, if any, required by a funding agency. These financial reports shall be reviewed and approved by the principal investigator, and then by EFR.

8.2 Financial reports shall be submitted to external funding agencies only after EFR has approved their distribution.

8.3 Funding recipients shall provide the funding agencies with activity, progress, or status reports, as required in the research funding agreement. Approval from EFR is not required for the distribution of these reports.

9. Return, Retention, and Uses of Surplus Funds

9.1 When surplus funds are available at the conclusion of the project, funding recipients shall:

a) Ask the funding agency whether the surplus funds may be retained or repurposed if repayment of surplus funds is required by the research funding agreement and the funding recipient has identified a valid alternate use of the funds within the area of research;

b) return the surplus funds to the funding agency if repayment of surplus funds is required by the research funding agreement and a valid alternate use of the funds within the area of research does not exist; or

c) transfer the surplus funds to a contingency account or indirect cost account if repayment of surplus funds is not required by the research funding agreement.

9.2 The amount of surplus funds to be returned to a funding agency must reconcile with the funding balance on the final financial report approved in accordance with Section 8.1.

9.3 The payment requisition for the return of surplus funds is approved in accordance with Appendix A by the appropriate program authority and submitted to Revenue together with a copy of the signed final financial report.

9.4 Revenue shall review the payment requisition for accuracy and completeness, and then submit the payment requisition to Accounts Payable for processing.

9.5 To transfer surplus funds to a contingency account or indirect cost account, the funding recipient shall ensure:

a) study termination has been confirmed by the funding agency in writing to Research Administration;

b) study termination has been confirmed by the Research Ethics Board in writing to Research Administration, as applicable;

c) all study-related expenses have been paid;

d) there is no funding agency restriction on the use of the surplus funds other than using these funds for research or educational purposes; and

e) notification is sent to Revenue.

10. Amendments

10.1 Reviews of amendments to research funding agreements are undertaken in coordination among stakeholders including but not limited to:

a) the funding recipient;

b) Research Administration, Finance, and Legal & Privacy divisions;

c) the applicable university's research services office; and

d) the applicable AHS operational leader, as necessary.

10.2 All amendments of research funding agreements must be approved and signed in accordance with Appendix A by the appropriate program and Finance authorities.

10.3 Principal investigators may amend research account information in a TOR such as signatories, recipients of financial information, signing protocols, and expected expiry date via a Research Account Updates Form. All other amendments to research account information require a revised TOR. Amendments via a Research Account Updates Form require approval of:

a) the primary signing authority except when the amendment pertains to a change in such authority; and

b) the applicable Research Administrative Lead, and Revenue if the amendment pertains to a change in the primary signing authority.

10.4 In the event of a change in the principal investigator of a research study or clinical trial, the principal investigators or parties involved, in consultation with Research Administration, shall determine and agree in writing who shall assume responsibility for the deficit, if any, as at the effective date of such change.

11. Renewals

11.1 Funding recipients shall obtain a written commitment from the funding agency to renew the research funding for another term if the agreement has a defined end date and additional time and funding are required to complete the research study. The written commitment shall be obtained before the expiry of the current term.

11.2 Where written commitment to renew the research funding is not received, the funding recipient shall conclude the project and notify both the Research Ethics Board and Research Administration.

12. Closure of Research Accounts

12.1 Upon termination of the research study or clinical trial, a Research Account Closure Request form approved by the primary signing authority and the appropriate Research Administrative Lead shall be submitted to Revenue along with supporting documentation such as written confirmation of study termination from the Research Ethics Board, or sponsor close-out letter. If the funding balance of a research account associated with a terminated study or clinical trial is nil, a final financial report may be provided in lieu of the supporting documentation referred to above.

12.2 Notwithstanding Section 12.1, Revenue may initiate the account closure process, in coordination with Research Administration, if it obtains a copy of the written confirmation of study termination from the Research Ethics Board, or a copy of the sponsor close-out letter.

12.3 Funding balance in a research account requested for closure shall be:

a) cleared in accordance with Section 9, if closure request relates to a study account with a surplus balance;

b) transferred to another institution for research purposes, as appropriate, if closure request relates to a contingency account with a surplus balance; or

c) cleared in accordance with the *Research Special Purpose Fund Account Deficit Management* Policy *(#1150-01)*, if closure request relates to an account with a deficit balance.

12.4 Revenue shall complete the research account closure form, and then submit the form to Chart of Accounts – Data Governance after:

a) the research account balance has been cleared;

b) positions, purchase orders, and capital assets have been removed from the research account, or transferred to another research account, as appropriate; and

c) system budgets have been cleared.

13. Responsibilities

13.1 Funding recipients:

a) manage the funding in accordance with the terms of the research funding agreement;

b) provide the funding agency with activity, progress, or status reports;

c) assume responsibility for research deficits of concluded studies, and/or deficits of research contingency or indirect cost accounts; and

d) dispose of contingency funds prior to leaving AHS.

13.2 Finance:

a) provides Finance support to the funding recipient to properly account for, record, and report on restricted funding usage in accordance with the Canadian Public Sector Accounting Standards and applicable regulations;

b) provides a funding recipient with monthly financial reports detailing revenue and expense transactions, as well as the surplus or deficit balance of each account;

c) reviews and approves any financial reports required by funding agencies;

d) monitors receipts and expenditures for compliance with the research funding agreement and the related TOR;

e) reviews surplus and deficit balances on a regular basis and resolves underlying issues with the researchers; and

f) monitors and reports on compliance with this policy.

DEFINITIONS

Board means the governance body of AHS appointed by the Minister of Health in accordance with the applicable statute(s).

Clinical trial funding means funding awarded by an external funding agency to eligible individual(s) to support an investigator-initiated or a sponsored clinical trial project. This includes revenue for research-related travel and other allowable research-related expenses.

Disestablished Authority means Aspen Regional Health Authority, Calgary Health Region, Capital Health, Chinook Regional Health Authority, David Thompson Regional Health Authority, East Central Health, Northern Lights Health Region, Palliser Health Region, Peace Country

Health, Alberta Cancer Board, Alberta Mental Health Board, and Alberta Alcohol and Drug Abuse Commission.

Funding agency means an individual or entity providing the grant funding.

Funding recipient means any individual acting on behalf of AHS who applies for a grant and/or receives a grant or clinical trial funding.

Government of Alberta means the ministries of the Government of Alberta and excludes organizations that it controls such as provincial agencies (e.g., Alberta Innovates Health Solutions), non-commercial Crown-controlled corporations, school jurisdictions and charter schools, universities, colleges, technical institutes, and health entities (e.g., Alberta Cancer Foundation, Calgary Health Trust, and Health Quality Council of Alberta).

Government of another jurisdiction means the Government of Canada or a minister, department, agency or official of it, the government of another province or territory of Canada or any minister, department, agency or official of if, or the government of a foreign country or any state, minister, agency or official of it.

Indirect costs of research mean expenditures incurred in the conduct of research that are not directly attributable or effectively traceable to a specific research study or clinical trial. Such costs include but are not limited to research facility maintenance, services provided by corporate and clinical support service departments, and research reinvestments.

Industry sponsored study or clinical trial means a clinical trial where the protocol is designed, initiated and funded by industry.

Primary authority means a funding recipient, a principal investigator, or an AHS program authority.

Principal investigator means an individual who is primarily responsible for conducting a research study or clinical trial.

Principal investigator initiated study or clinical trial with funding from industry means a study or clinical trial where the principal investigator designs and writes the protocol and obtains funding from a pharmaceutical company or another industry sponsor.

Principal investigator initiated study or clinical trial with funding from a peer reviewed funding agency means a study or clinical trial where the principal investigator designs and writes the protocol and obtains funding from a non-industry sponsor.

Program authority means a manager or higher in Research, Innovation & Analytics, or another program area the signing authority of the Vice President, Research, Innovation & Analytics has been delegated to.

Research Administration means the teams, such as NACTRC, AHS Cancer Clinical Trial Unit, or AHS Research Administration, as delegated by the Vice President, Research, Innovation & Analytics.

Research Administrative Lead means the individual delegated by the Vice President, Research, Innovation & Analytics as accountable for research administration, such as the NACTRC Director, the AHS Cancer Clinical Trial Unit Manager, or the AHS Research Administration Director.

Research grant means funding awarded by an external funding agency to eligible individual(s) to support a health research project. This includes revenue for research-related travel and other allowable research-related expenses.

REFERENCES

- Appendix A – *Approval and Contract Signing Limits for Research Grants and Clinical Trial Funding*
- AHS Policies and Procedures:
  - *Delegation of Authority and Establishment of Controls for Commitments* Policy (#1100)
  - *Corporate Contracting* Policy (#1152)
  - *Delegation of Authority for Financial Commitments "Financial Authorization" Matrix*
  - *Travel, Hospitality and Working Session Expenses – Approval, Reimbursement and Disclosure* Policy (#1122)
  - *Research Overhead Revenue Administration* Policy (#1176)
  - *Restricted Grants* Policy (#1136)
  - *Management and Oversight of Research Expenses for Travel, Hospitality and Working Sessions* Policy (#RESEARCH-001)
  - *Research Special Purpose Fund Account Deficit Managemen*t Policy (#1150-01)
- AHS Forms:
  - *Research Account Terms of Reference* Form (#18986)
  - *Research Account Updates* Form (#18985)
  - *Research Account Closure Request* Form (#20634)
  - *Contingency Account Agreement* Form
- Other Documents:
  - *Regional Health Authorities Act* (Alberta)
  - *Financial Administration Act* (Alberta)
  - *Health and Wellness Grants Regulation* (Alberta)

VERSION HISTORY

Date	Action Taken
February 14, 2018	Revised (posted March 22, 2018)

APPENDIX A

Approval and Contract Signing Limits for Research Grants and Clinical Trial Funding

1. Program Approval and Contract Signing Limits

1.1 The program approval and/or contract signing limits for research grant applications, and research funding agreements, amendments, and surplus returns are:

Program Authority[2,3]	Funding Application, (Contract Value)[4]	Funding Agreement or Amendment (Contract Value)[5]	Surplus Return[5]
President and Chief Executive Officer[1]	$90,000,000	$90,000,000	$90,000,000
Vice President or equivalent	$60,000,000	$60,000,000	$1,800,000
Chief Operating Officer or equivalent	$22,500,000	$22,500,000	$675,000
Senior Operating Officer or equivalent	$15,000,000	$15,000,000	$450,000
Executive Director	$3,000,000	$3,000,000	$90,000
Director or equivalent	$2,250,000	$2,250,000	N/A
Manager or equivalent	$225,000	$225,000	N/A

Note 1: In addition to the above, the President and Chief Executive Officer must sign all research funding agreements wherein a government of another jurisdiction is a signatory.

Note 2: Authority equivalencies and delegation of authority for financial commitments for AHS Medical Leaders are defined in the Delegation of Authority for Financial Commitments "Financial Authorization" Matrix.

Note 3: A delegated authority per this table must be an AHS employee.

Note 4: Research funding applications shall be approved and signed by a delegated authority within the program requesting research funding. The Vice President, Research, Innovation & Analytics or designate shall approve and sign funding applications if requested by the funding agency.

Note 5: A delegated authority within Research, Innovation & Analytics shall approve and sign research funding agreements or amendments, and shall approve surplus returns. AHS staff within NACTRC are authorized to sign research funding agreements on behalf of AHS only when the University of Alberta is a party to the agreement.

1.2 Notwithstanding the approval limits as set out in the table above, amendments, renewals and extensions ("changes") to an existing research funding agreement shall be approved as follows. For this purpose the term "combined contract

value" means (a) the value of the underlying original research funding agreement, plus (b) the value of any prior approved changes, and (c) the value of the proposed change. Note that the value of a change represents the total value of such change, irrespective of whether it applies to a single year research funding agreement or a multi-year research funding agreement.

a) For any change to an existing research funding agreement that was originally approved by the President and Chief Executive Officer ("CEO"), or executed by a **Disestablished Authority,** the CEO shall be entitled to approve any change that will not result in a combined contract value exceeding the CEO's approved limits as set out in the table above. Where the change will result in a combined contract value which exceeds the CEO's approved limits as set out in the table above, the change shall be approved by the **Board**.

b) For any change to an existing research funding agreement that either:

(i) was originally approved by the current, or a previous Board or executed by a Disestablished Authority; or

(ii) underwent a change that was previously approved by the current, or a previous Board, or executed by a Disestablished Authority as per Section 1.2 (a) above,

the CEO shall be entitled to approve any changes to a cumulative value of $30 million. Where the cumulative value of these changes exceeds $30 million, the change to such research funding agreement shall be approved by the Board.

1.3 Research funding agreements that do not specify a contract value are approved and signed at minimum by a Director in Research Administration or another program area the signing authority of the Vice President, Research, Innovation & Analytics has been delegated to.

2. Finance Approval and Contract Signing Limits

2.1 Research funding applications are not required to be approved and signed by Finance except when Finance sign-off has been requested by the funding agency. If Finance sign-off has been requested, the research funding applications are approved and signed by Finance in accordance with Section 2.2 below.

2.2 All research funding agreements and amendments, and any research grant applications requiring Finance sign-off, are approved and signed by Finance as set out below.

Finance Authority	Funding Application, Agreement and Amendment (Contract Value)
Chief Program Officer, Finance or Senior Director, Financial Reporting & Treasury	No limit
Director[1]	$2,250,000
Manager[2]	$500,000

Note 1: Pertains to a Director within the Financial Reporting & Treasury group.
Note 2: Pertains to a Manager within the Financial Reporting & Treasury group, or Finance Lead in NACTRC.
Note 3: The Finance Lead in NACTRC is authorized to sign research funding agreements on behalf of AHS only when the University of Alberta is a party to the agreement.

2.3 Research funding agreements that do not specify a contract value are approved and signed by a Manager within the Financial Reporting & Treasury group, or higher as required.