

Calgary Centre for Clinical Research (CCCR)



UNIVERSITY OF
CALGARY

Building A Clinical Trial Budget

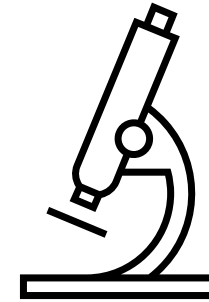
Investigator Initiated vs Sponsored Clinical Trials

Investigator Initiated Clinical Trials

- ▶ Build from Scratch
- ▶ Typically funded through Grants or Industry
- ▶ Budget is limited

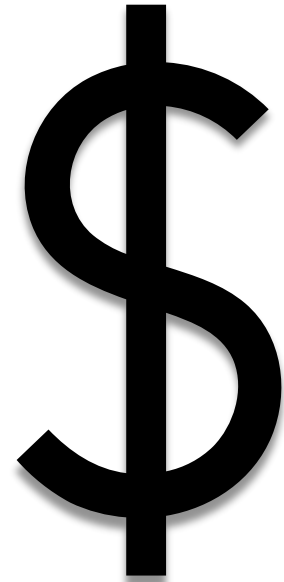
Sponsored Clinical Trials

- ▶ Budget template provided by the sponsor
- ▶ Industry Sponsors (Complex Budgets)
- ▶ Non-Profit Sponsors (Simple Budgets)



GET COST ESTIMATES

- Ascertain Essential Services Based on Clinical Trial Protocol
- Early Outreach to Service Providers for Cost Estimates
- Key Service Providers:
 - AHS Research Pharmacy
 - Alberta Precision Health Laboratories
 - MOJO Diagnostic Imaging
 - Heritage Medical Research Clinic
 - Other Third-Party Services



Sample Budget Template

[Download Template](#)

BUDGET SUMMARY				
If your study has costs associated with it (e.g., personnel, services/procedures, supplies, etc.), you must complete this budget summary page.				
1. Funding Source(s)				
A. Non-Industry Funding				
Source of Funding (Agency's name)	Total Amount of Funding	Funding Status		
		<input type="checkbox"/> Pending	<input type="checkbox"/> Awarded/Funded	
		<input type="checkbox"/> Pending	<input type="checkbox"/> Awarded/Funded	
		<input type="checkbox"/> Pending	<input type="checkbox"/> Awarded/Funded	
		<input type="checkbox"/> Pending	<input type="checkbox"/> Awarded/Funded	
Note: Your ethics application will not be reviewed unless funding is confirmed. If you have indicated above that you have applied for funding, but it is not confirmed (e.g. pending), please confirm the research will be undertaken using alternative resources in the event the grant application is unsuccessful.				
<input type="checkbox"/> Yes, this research will continue regardless of whether funding is received <input type="checkbox"/> No, this research will not continue				
B. Industry/For-Profit Funding				
Source of Funding (Company Name)	Contact Name/Phone/Email	Projected Number of Participants	Per Participant Funding	Total Budget
a. Institutional Overhead included (e.g. 30% for Industry Sponsored Clinical Trials (Refer to Overhead Policy for more info)): <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable Percent overhead Appliedn to Budget:				Research Overhead Policy CHREB Administration Fee for Industry Sponsored Research
b. Is the Investigator/Instituion receiving any honoraria or additional funding beyond per-participant funding for this trial? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, what amount:				
c. For Industry/For-Profit Company funding, has the invoice request form for the REB fee been included? <input type="checkbox"/> Yes <input type="checkbox"/> No If No, explain:				
2. Study Budget				
Below are examples only and budget requirements are not limited to these. Please include ALL research related services/procedures				
A. Research Procedure Costs				
Service/Procedures	Quantity	Cost Per Item	Projected Number of Participants	Total Costs
Informed consent				
Initial medical history only				
Hematology/Chemistry/Urinalysis				
Audio recording and transcription services				
Focus group				
Interview sessions				
Sub-Total				0
B. Personnel Costs				
Personnel	cost per Visit	Total Visits	Projected Number of Participants	Total Costs
Study Coordinator				
Physician (reimbursement for service)				
Research Assistant				
Sub-Total				0
C. Non-Procedure Costs				
Service/Cost	Quantity	Cost per Item	Projected Number of Participants	Total Costs
Participant reimbursement (e.g. parking)				
Participant payment (e.g. \$50/visit)				
Sub-total				0
Total Study Cost				0
D. Additional Costs				
Item				Total Costs
Hematology/Chemistry/Urinalysis: Lab handling and/or shipping				
REB Admin Review Fee				
Long-term record retention				
Equipment (e.g. camera, computer, audio recorder)				
Printing costs (e.g. posters, brochures, questionnaires)				
Total Additional Costs				0
CHREB Template: Feb 2021				

KNOW WHERE TO GET HELP

▶ **CCCR Finance Team (finanlgl@ucalgary.ca)**

- ▶ Can help in determining the items typically form part of a clinical trial budget.
- ▶ Applicable Overhead Policy.

▶ **ONCORE CTMS (oncoresupport@ucalgary.ca)**

- ▶ A great tool to help with planning and conducting your trial
- ▶ OnCore Charge Master includes pricing for over 400 protocol- and subject-related items to create an accurate clinical trial budget

▶ **Grant Development Office**

- ▶ Grant Development Team knows the grant competition requirements and can do a final budget review to ensure your clinical trial budget complies fully.



Calgary Centre for Clinical Research (CCCR)



UNIVERSITY OF
CALGARY

CCCR Finance



Our Team



Asim Nadeem ,
Manager, Clinical
Research Business
Services



Min Seong Park, Sr.
Business Advisor,
Clinical Research



Sarvjeet Sodhi, Sr.
Business Advisor,
Clinical Research



Faizan Ahmed, Jr.
Business Advisor,
Clinical Research



Sanica Abbott,
Business
Administrator, Clinical
Research



Our Objective



SUPPORT



PROFESSIONALISM



EFFECTIVE
COMMUNICATION



ACCURACY

Overview: What We Do

Budget
Approvals

Budget
Negotiations

Invoicing

OnCore Budget
Negotiated
Signoff

Clinical
Research Grants

Assist Research
Teams with
Other Financial
Inquiries – Ex. EFT

Project Closures

OnCore
PeopleSoft
Integration
Reports

Budgets

01

Review and Analyze Budgets

Assess and evaluate budget proposals and provide recommendations to the study team

02

Budget Negotiation

Negotiate the study budgets with sponsor on behalf of Study team and make sure that fair market price is achieved for the study related activities.

03

Budget Approvals

Process the final budget approval in IRISS Legal with CCCR stamp ensuring the correct budget is included in the contract.

Invoicing

PeopleSoft invoicing

Handle invoicing requests for Clinical Trials
/Research Projects



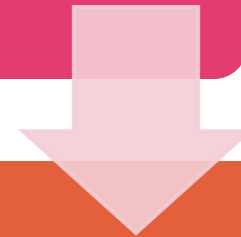
Pharmacy Invoices

Process and ensure accuracy of
HMRC Pharmacy invoices.

Oncore >> PeopleSoft Integration and Budget Sign-Off

Negotiated Sign-off

Review and check final negotiated rates are entered in Oncore.



Integration Reports

Review OnCore PeopleSoft integration report on daily basis to ensure accuracy.

Clinical Research Funds

SEED Grants

Coordinate the biannual Seed Grant competition, assisting researchers in applying for and establishing new projects.

Pre-Submission Grant

Oversee Pre-Submission grant application process throughout the year

Provide guidance and support to applicants to enhance the quality and success of their submissions.

**Seed and Pre-Submission grants are currently discontinued and will be replaced with a new grant expected to be launched in May-2025*

Other Services We Offer

- ▶ Helping researchers in development of trial budgets for investigator-initiated trials (IITs)
- ▶ Providing guidance on overhead policy
- ▶ Coordination of trial closure activities
- ▶ Project Account Closures and archiving of study documents
- ▶ Process Interdepartmental billing, payment requisitions and purchase orders



Our Collaborative Partners



CSM LEGAL



UNIVERSITY OF
CALGARY'S CENTRAL
FINANCE



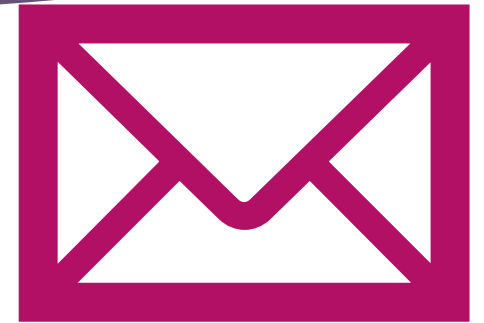
PROVINCIAL ONCORE
SUPPORT TEAM (POST)



PRINCIPAL
INVESTIGATORS AND
STUDY TEAMS

Contact CCCR Finance

- ▶ Budget Support / General Inquires:
finanlgl@ucalgary.ca
- ▶ Invoicing Support:
cccrinvoicing@ucalgary.ca
- ▶ CRF Grants:
crf@ucalgary.ca
- ▶ Project Closures:
cccr@ucalgary.ca



Thank You

Questions?

