



A Guide for Industry Sponsors

Information for industry sponsors on conducting clinical trials at the University of Calgary.

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Abbreviations

The following abbreviations are used throughout this document:

ACH - Alberta Children's Hospital
AHS - Alberta Health Services
APL - Alberta Precision Laboratories
CCCR - Calgary Centre for Clinical Research
CDA - Confidential Disclosure Agreement
CHREB - Conjoint Health Research Ethics Board
CITI - Collaborative Institutional Training Initiative
CTA - Clinical trial agreement
CTMS - Clinical Trial Management System
CSM LEGAL - Cumming School of Medicine, Legal, Research Services
EMR - Electronic medical record
FMC - Foothills Medical Centre
HDL - High Density Library
HMRC - Heritage Medical Research Clinic
HREBA-CC - Health Research Ethics Board – Cancer Committee
IB - Investigator Brochure
ICF - Informed Consent Form
ICH-GCP - International Council for Harmonisation – Good Clinical Practice
ICU - Intensive care unit
IRISS - Institutional Research Information Services Solution
N2 - Network of Networks
NOL - No Objection Letter
PLC - Peter Lougheed Center
PSSV - Pre-site Selection Visit
REB - Research Ethics Board
RGH - Rockyview General Hospital
SHC - South Health Campus
SOP - Standard Operating Procedures
TBCC - Tom Baker Cancer Centre
UCalgary - University of Calgary

Introduction



The University of Calgary, located in Southern Alberta, is one of Canada's fastest growing research Universities. With a strategic focus on enabling research and innovation, our clinical trial ecosystem allows industry partners to tap into broad expertise that can provide a competitive edge in phase I-IV trials and life sciences research.

Our longstanding commitment to working with industry partners is reinforced by the programs, services and knowledge we provide--all meant to help enable and enhance clinical trials across a range of therapeutic areas. Whether you're developing a drug therapy for Alzheimer's Disease or a medical device to help monitor diabetes, our integrated research site can provide the infrastructure and resources you need to drive your discoveries forward.

This guide is designed to help clinical trial sponsors navigate the processes relevant to clinical trial start-up, conduct and closure at the University of Calgary.

If you have questions about this guide, or would like to learn more about how we can support your clinical trials, visit our website at:

<https://research.ucalgary.ca/clinical-trials> or reach out to our industry concierge at clinicaltrials@ucalgary.ca.



General Overview for Industry-sponsored trials

Industry-sponsored clinical trials typically commence as follows:

Initial Contact

- To reach out to the University of Calgary Clinical Trial Concierge about a clinical trial opportunity, please contact clinicaltrials@ucalgary.ca. To learn more about the clinical trial capabilities at the University, please visit <https://research.ucalgary.ca/clinical-trials>

Concierge Service

- The Clinical Trial Concierge acts as the primary point of contact for industry sponsors and CROs wishing to explore the feasibility of placing a clinical trial at the University of Calgary.
- The Concierge identifies UCalgary researchers interested in the clinical trial opportunity and facilitates introduction to the researchers and their study team.

Start-up Services

- The Calgary Centre for Clinical Research (CCCR) can assist with start-up services if the researcher wishes to use these free services.
- Services include submission of the Confidential Disclosure Agreement (CDA), completion of the feasibility questionnaire and organization and conduct of the pre site selection visit.



Once site selection is confirmed, the following start-up activities take place:

Submissions

- CTA, protocol and budget are uploaded to the UCalgary contract management system.
- The ethics application is completed online via IRISS. Through the research ethics application, our health system partner Alberta Health Services (AHS) receives a notification of the researcher's request to access its resources. Other clinical services would be contacted as needed for the conduct of studies.

Processing & Approvals

- Target timeline for processing to approvals: 6-12 weeks from receipt of the regulatory package to full approval.



Clinical Trial Support Services



At the University of Calgary our mission is to enable high-quality, efficiently conducted clinical trials.

Our central research service teams support the start-up, execution and closure of clinical trials through:

- Industry liaison services
- Study start-up services
- Contract and budget review and negotiations services
- Clinical Trials Management System
- Regulatory compliance services
- Research ethics review services

Industry liaison services

The Clinical Trial Concierge provides liaison services to trial sponsors as they engage in discussions with industry sponsors:

- Acting as the first point of contact for internal and external stakeholders who have inquiries pertaining to clinical trial conduct at the University of Calgary.
- Communicating with industry sponsors and CROs about upcoming clinical



trial opportunities.

- Assisting with feasibility assessments.
- Providing information and addressing questions about the university research ecosystem.

Study start-up services

Study start-up services encompass all required steps from site selection to study initiation. Services include:

- Coordinating and planning site selection visits.
- Coordinating start-up activities including CDAs/CTAs, budget submissions, feasibility questionnaires, regulatory documents, REB submission etc.
- Advising on available research support services and facilitating connections as necessary.

Clinical trial contract and budget review and negotiations

- The CSM Legal team is highly experienced in reviewing and negotiating legal terms. All legal activities are tracked through a contract management system to ensure timely responses and fast turnaround times.
- The CCCR Finance Team provides central budget review and approval services. The team supports investigators throughout the budget negotiation process and works closely with the CSM Legal team to ensure that the budget and legal negotiations are wrapped up at the same time.

Clinical Trials Management System

The University of Calgary has adopted the OnCore Clinical Trial Management System (CTMS). This system enables increased capacity for studies, standardization and adoption of best practices, and improved study quality, budget management, and regulatory compliance.

OnCore is Advarra Inc.'s state-of-the-art enterprise solution in use at leading research institutions in the USA, including Yale University, Duke University, and Dana-Farber Cancer Institute/Harvard University. The OnCore CTMS is a cloud-based solution hosted in a Canadian Data Centre.

Sponsors benefit from our use of OnCore through standard and efficient clinical trial workflows and well documented studies. We are able to share comprehensive reports for your protocols, accruals, and financials.



Regulatory compliance services

[The University Quality Assurance Program](#) helps foster and maintain our reputation as a world-class site for clinical trials through:

- Providing training resources to research teams.
- Guiding trial investigators through the regulations and guidelines governing clinical trials (e.g.: university policies, TCPS2, ICH-GCP, Health Canada/FDA regulations, etc.).
- Assisting research teams to prepare for inspections from regulatory bodies, such as Health Canada and the FDA.
- Implementing and maintaining N2 Standard Operating Procedures for clinical trials conducted at the university.

Please note: SOPs are available for viewing at the site but we are unable to provide or send photocopies.

Ethics services

The University of Calgary maintains two research ethics boards, the Conjoint Faculties REB and the Conjoint Health REB. The CHREB is the Board that reviews clinical trial ethics applications. The exception to this is cancer-focused research; for such studies the University has delegated research ethics review to the provincial Health Research Ethics Board of Alberta, Cancer Committee (HREBA-CC).

- The CHREB administration fee applies to research that receives its funding from an industry sponsor (i.e. pharmaceutical/medical devices company) or other for-profit organization. The administration fee for ethics review at the CHREB is Can \$5,000. The fee covers the initial ethics review of a new project and all subsequent REB activities such as amendments, annual renewals, and ongoing monitoring. As such, it is a service fee that is unrelated to the speed of review.
- Where the application is for a study falling under the provincial reciprocity agreement and the University of Calgary is a secondary site (i.e., the primary ethics review has been undertaken at another REB in Alberta) the fee is Can \$2,000 if the study is submitted via the REB Exchange (rebexchange.ca). This covers all post approval monitoring and review activities. For a participating site that is submitted separately (without REB Exchange), the review fee will be \$5,000.00 Canadian.
- For industry sponsored projects with a budget of Can \$10,000 or less, a reduced ethics fee of Can \$2,500 applies.
- The fee is payable regardless of the outcome of the ethics review.



The REB Exchange (REBX)

The REB Exchange (REBX) streamlines the ethics application process for multi-site health research in Alberta. It's a simple, easy-to-use tool, built into the ethics application platform available at the University of Calgary and the University of Alberta. Once a trial receives ethics approval, Participating Sites (pSites) can be added with a truncated site-specific application.



Clinical Trial Facilities



Heritage Medical Research Clinic (HMRC)

Located at the Foothills Campus, The HMRC is a dedicated research clinic offering a unique blend of facilities and services. The clinic provides access to expert services and over 7000 square feet of state-of-the-art facilities and equipment, including outpatient research facilities and nursing services to laboratory equipment and an on-site Alberta Health Services research pharmacy. Facilities can support a wide range of clinical research studies and can accommodate both adult and pediatric participants (including those with disabilities).

- A fully equipped laboratory, electrocardiograms, patient reception and parking facilitation, consultation rooms, examination rooms, as well as an area for monitoring visits and storage of study specific equipment.
- Qualified research staff, including nurse clinicians, phlebotomists and lab technicians.
- Specialized rooms to support pediatric trials and patients with special needs.

For more information please visit the HMRC website: <https://cumming.ucalgary.ca/research/hmrc/home>



Phase 1 overnight facilities

The Phase I overnight facility is located at the Foothills Medical Campus. Being located in the Intensive Care Unit, it offers standard hospital care or ICU level care depended on the care requirement of the clinical trial protocol.



Research pharmacy facilities

Located onsite at the HMRC, the AHS research pharmacy provides investigational drug receipt, storage and distribution for trials conducted at the university. The facility is fully staffed by GCP trained pharmacists. Equipment includes:

- Centrally alarmed refrigerators and freezers
- A -80C non-cycling freezer
- A class 7 sterile and ante room, Class 2, type B2 biosafety cabinet

Diagnostic imaging facilities

Trial sponsors have access to an array of advanced imaging resources with capabilities including CT scans, Dual-Energy X-ray Absorptiometry or Bone Densitometry (DXA Scan), Fluoroscopy, MRI, MR Angiography (MRA), MR Spectroscopy (MRS), X-ray, Mammography, Nuclear medicine (e.g., Bone scan, thyroid scan, thallium cardiac stress test), Positron Emission Tomography (PET) Scan. Most facilities are located onsite at the university.

Research laboratory facilities

University of Calgary investigators can access Alberta Precision Laboratory services, staff and facilities. Equipment available includes refrigerators (2 to 8 Degrees C) and freezers (-20 to -80 Degrees C) located at different AHS facilities. Temperatures are taken daily and recorded on in house temperature logs which can be shared upon request. We have an "in control range" of +/- 5C for the -20C and -80C freezers and +/- 3C for the fridge. Anything outside of this range would be investigated. Temperatures are monitored manually and checked once per day Monday through Friday. The fridge, -20C and -80C freezers are all plugged in to emergency power. The -80C freezer is centrally alarmed (set to alarm in our 24/7 acute care lab on the 7th floor McCaig tower if the temperature warms above -60C).



AHS facilities

AHS is a provincial health authority. Clinical trials at university of Calgary for various therapeutic areas is also conducted in collaboration with AHS at various AHS locations, including

- Foothills Hospital
- South Health Campus
- Tom Baker Cancer Centre
- Alberta Children's Hospital
- Rockyview Hospital
- Peter Lougheed Center

Major clinical research projects are conducted across numerous therapeutic areas including GI, Cardiac, Neurology, Pediatrics, Respiratory, Nephrology, psychiatry, and Oncology.

Long term storage facilities

Upon study closure all records are sent to a storage facility (the High Density Library located at the Spy Hill campus).

High Density Library
University of Calgary
Spy Hill Campus
11711, 85 Street NW
Calgary, AB
T3R 1J3

Medical records

Currently:

- Both electronic and paper medical records
- EMR system: Sunrise Clinical Manager
- CRAs have limited access to EMRs
- Research staff have experience utilizing Electronic Data Capture systems such as InForm, Medidata Rave

In process of implementation:

- One EMR (EPIC)
- Direct EMR access for monitors



Frequently Asked Questions



Contracts and budget

What types of contracts are required for review and signature at the University of Calgary?

A 3-way contract is required. Example: Sponsor – Institution – Principal Investigator.

What legal entity information must be included within the CTA?

Our legal team can provide all required legal entity information to trial sponsors. To initiate this process, please contact us.

Does the University of Calgary accept and sign CTA in English?

Yes, only in English.



To enable the study to be performed at the University of Calgary Investigational Site in accordance with the Protocol, will the participation of pharmacy, radiology or other separate medical departments or services be required?

Yes. The site coordinator requests these services as needed. Agreements with these services are internal and do not require a sign off from the trial sponsor.

Ethics

Does the UCalgary Investigational site utilize a local or central REB?

The University of Calgary investigational sites utilize the institutional REB called Conjoint Health Research Ethics Board (CHREB).

Conjoint Health Research Ethics Board (CHREB)
2500 University Drive NW
Calgary AB T2N 1N4
chreb@ucalgary.ca
403-220-2297

For cancer studies, the Health Research Ethics Board of Alberta Cancer Committee (HREBA-CC) is utilized.

Health Research Ethics Board of Alberta Cancer Committee
1500- 10104 103 Ave NW
Edmonton AB T5J 0H8
1-877-423-5727
cancer@hreba.ca

Who can benefit from the REB Exchange program?

Alberta multisite research studies can take advantage of the REB Exchange program. Please visit the [REB Exchange](#) website for more information.

If the UCalgary Investigational site uses a local REB, what are your submission timelines?

The CHREB meets on the 1st and 3rd Thursday of each month. There are no submission deadlines for CHREB. Submissions can be made at any time through the electronic submission system IRISS. All applications undergo an administrative check prior to being placed in the review queue. Once the study file has been received, feedback will be logged and sent back via IRISS.

Is an NOL required for CHREB approval?

No, CHREB does not require an NOL to issue the initial approval. Prior to opening the study for accrual an NOL must be submitted to the CHREB.



How long does it take for an application to be reviewed and approved by CHREB?

The length of review depends on the completeness and accuracy of the application and supporting documents as well as whether or not it requires Full Board or Delegated review based on risk levels.

What documents are required for REB submission?

Required documents include the study protocol, ICF (including assent forms if applicable), IB, all patient facing documents, departmental approval, budget summary, recruitment materials and data collection instruments.

Does CHREB require payment prior to release of final approval?

CHREB requires payment at the time of the REB submission review, regardless of the outcome of the review.

Do contract/budget negotiations run concurrently with the REB submission/ review?

Yes, contract/budget review and negotiations run concurrently with the REB submission/review.

AHS

Do clinical trials conducted at the University of Calgary require approval from a separate review committee?

Studies making use of AHS resources will require approval from AHS.

How many weeks does the additional AHS review take?

On average, the additional AHS approval is received 2-4 weeks after REB approval.

Does the additional AHS review occur in parallel with the REB review?

AHS review occurs after the REB approval; however, clinical trials are prioritized in the AHS review process.

Investigational product

Is the Investigational Product storage room secured with controlled access?

Yes, the IP is stored within the research pharmacy, which is only accessible by pharmacy staff.



Can you generate a temperature monitoring log for the Investigational Product storage room?

Yes, all temperatures are recorded daily (excluding weekends and statutory holidays) on site specific temperature logs, using digital temperature recording devices located in each of our refrigerators and freezers. Please note: the AHS research pharmacy cannot use trial specific temperature logs or recording devices.

Does the Investigational Product storage room provide min/max temperature monitoring?

Yes, room temperature monitoring is conducted using a min/max thermometer. Fridge and freezer graphs provide continuous monitoring.

Does the Investigational Product storage room have back-up power?

Yes.

Does the Investigational Product storage room have a temperature alarm?

Yes, both the fridge and freezer are alarmed.

Do you have an SOP which supports calibration of the temperature monitoring equipment?

Fridge and freezer temperature thermometers are calibrated annually and room temperature thermometers are replaced upon their expiry. We do not have a specific SOP regarding calibration.

Can your facility manage on-site or off-site destruction of Investigational Products?

We collect IP onsite for destruction (incinerated off-site). Destruction certificates are available upon request.

Does your facility have a written SOP for the destruction of Investigational Products?

Yes, this SOP can be provided on request.



Do you provide your satellite site(s) with a dedicated inventory of study Investigational Product?

For multisite studies, each site must receive, maintain and dispense their own IP inventory.

Does your facility have a written SOP to ensure that investigational products are appropriately maintained during transportation to satellite site(s)?

We do not transport IP between sites.

Does your site have experience receiving Investigational Products in liquid Nitrogen?

Yes, the Heritage Medical Research Clinical s able to receive IPs in liquid Nitrogen.

What is the IP drug shipping address at Foothill Medical Centre?

Research Pharmacy
Attn: Candice Cameron, Pharmacist
TRW Building, 5th floor
3280 Hospital Dr. NW
Calgary AB T2N 4Z6
Tel: 403-944-1187 Fax: 403-944-1266
Email: pharmacy.research@albertahealthservices.ca

Research staff and consent

Are there dedicated research staff available to support clinical trials?

Yes, the CCCR and W21C both have access to a pool of research coordinators to support studies.

Does your facility have a training program for research staff?

Staff have the opportunity to participate in continuing education through monthly training sessions.

Does your facility use an external program to conduct research training?

Yes, the CITI training program is available to all staff.

Does the course content include GCP?

Yes, and all research staff are required to renew GCP certification every 3 years.



Do you have a process or program in place to retrain research staff when a protocol is amended?

Yes, all relevant study staff are retrained on updates before the implementation of a protocol amendment.

Does your facility have a written SOP for Informed Consent?

Yes, the University of Calgary utilizes the N2 SOP for Informed Consent.

Does your facility require language translations for consents?

No, only English.

Can your facility support patient visits on weekends?

Yes, the Heritage Medical Research Clinic can accommodate both evening and weekend visits.

Can your facility support in-patient admissions for research studies?

Yes, UCalgary researchers have access to four major adult hospitals and one pediatric hospital.

Does your facility have access to translators and translation support for study conduct (e.g., consent, study specific instruction)?

All study related communications occur in English (including ICF). However, language assistance can be offered by phone.

Does the facility have storage space for study-related materials (e.g., lab kits, patient materials, etc.)?

Yes, the Heritage Medical Research Clinic provides storage space for study related materials.

Do the staff that prepare or transport dangerous goods have training that meets the IATA International Air Transport Association (US) standards?

Yes, the IATA certificates are available upon request.



Source documentation

What capabilities do you have at your site to support EDC and monitoring visits?

Dedicated Space and high-speed internet access.

What kinds of source documents are used at your site?

Both electronic and paper.

What is the name of the EMR system you use?

Sunrise Clinical Manager, Netcare (NOTE: Calgary sites are transitioning to EPIC in 2022).

Do staff have experience utilizing Electronic Data Capture systems?

Yes, staff are well versed in a variety of data capture systems including InForm and Medidata Rave.

Equipment

Does the University have access to overnight beds for research purposes?

Yes, the University of Calgary has access to two ICU beds specifically allocated to clinical research (located within the Foothills Medical Centre).

Does your site have access to a freezer (-70 C), refrigerated centrifuge, and dry ice?

Yes, in the Heritage Medical Research Clinic.

Does your facility have the ability to collect and store PK/PD specimens?

Yes, both the Heritage Medical Research Clinic and Alberta Precision Laboratories have the ability to collect and store PK/ PD specimens.



Does your Facility have the ability to collect PK/PD samples beyond normal business hours?

Yes, arrangements can be made to collect PK/PD samples beyond normal business hours.

Does your Facility have an SOP or process that ensures routine calibration and maintenance of general equipment?

Yes, there is an SOP in place and routine calibration and maintenance of general equipment is documented.

Does your Facility have the necessary equipment to treat medical emergencies?

Yes, the Heritage Medical Research Clinic has a defibrillator, Oxygen and suction apparatus and an anaphylaxis kit on site to respond to medical emergencies.

Does the Facility have access to local IT support?

Yes, UCalgary IT support is available during normal business hours.



Key Contacts

The following list includes information on the key research support teams and contacts at the University of Calgary.

Cumming School of Medicine (CSM) Legal, Research Services Team

CSM Legal, Research Services Team	When to contact:	csmlgl@ucalgary.ca
	Status inquiries for contracts/ agreements currently in execution, request for copies of a fully executed contract general inquires and request about execution.	

The CCCR (Calgary Centre for Clinical Research)

Finance Team	When to contact:	finanlgl@ucalgary.ca
	Final budget review/ negotiations	

Industry Concierge	When to contact:	clinicaltrials@ucalgary.ca
	Upcoming clinical trial opportunities / site selection phase / clinical trial start-up activities	



Research Ethics Board (CHREB)

**Ethics Administrator /
Ethics Office**

When to contact:

chreb@ucalgary.ca

Questions relating to Ethics
submissions, review timelines,
CHREB administrative fee

Research Pharmacy at AHS

**Pharmacy Research
Service**

When to contact:

pharmacy.research@ahs.ca

Alberta Health Services –
Calgary Zone

Research Laboratory (Alberta Precision Laboratories)

**Laboratory Research
Service**

When to contact:

research@cls.ab.ca

Alberta Precision Laboratories -
Calgary Zone

