Health Research Webinar Series

UNIVERSITY OF CALGARY

- Please ensure that your **mic is muted** & that your **camera is turned off**
- This session is being recorded and will be available on the CCCR website along with previous Lunch & Learn presentations.
- Comments & questions are welcome in the chat box throughout the presentation and will be answered at the end.

November 4th, 2024

The University of Calgary, located in the heart of Southern Alberta, both acknowledges and pays tribute to the traditional territories of the peoples of Treaty 7, which include the Blackfoot Confederacy (comprised of the Siksika, the Piikani, and the Kainai First Nations), the Tsuut'ina First Nation, and the Stoney Nakoda (including Chiniki, Bearspaw, and Goodstoney First Nations). The City of Calgary is also home to the Métis Nation of Alberta (Districts 5 and 6).

Researcher's Guide to Clinical Trials

at the University of Calgary

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November 4, 2024

Acknowledgments

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- CCCR Team
- Cello Tonelli & Stephen Freedman + their research teams
- System & Process Owners:
  - IRISS
  - Ethics
  - CRU
  - CSM Legal
  - Central Finance Operations
  - Research Trust Accounting
- Coordinator's Community of Practice attendees

Learning Objectives

- Know where to access the new **Researcher's Guide to Clinical Trials at the University of Calgary**
- Be able to explain the purpose and scope of the new guide
- ~~Have a general understanding of the systems, teams, and processes for clinical trial workflows at the UC~~
- Have a general understanding of the contents of the new guide

Print copies will be available soon:

- Monthly (OnCore) Coordinator Community of Practice in the CCCR offices
  - CWPH Suite 400
- Lobby of Cal Wenzel Precision Health Building

Always note the date of last update!

Researcher's Guide to Clinical Trials

Information and guidance for study teams and researchers conducting clinical trials at the University of Calgary.

Produced by the Calgary Centre for Clinical Research – October 2024

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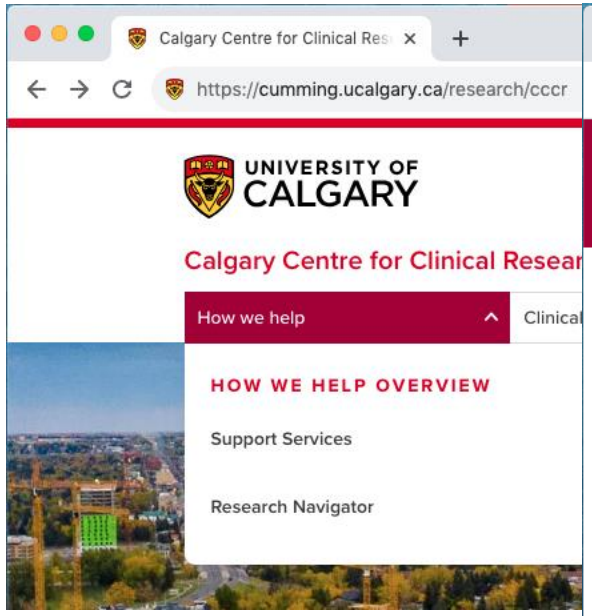
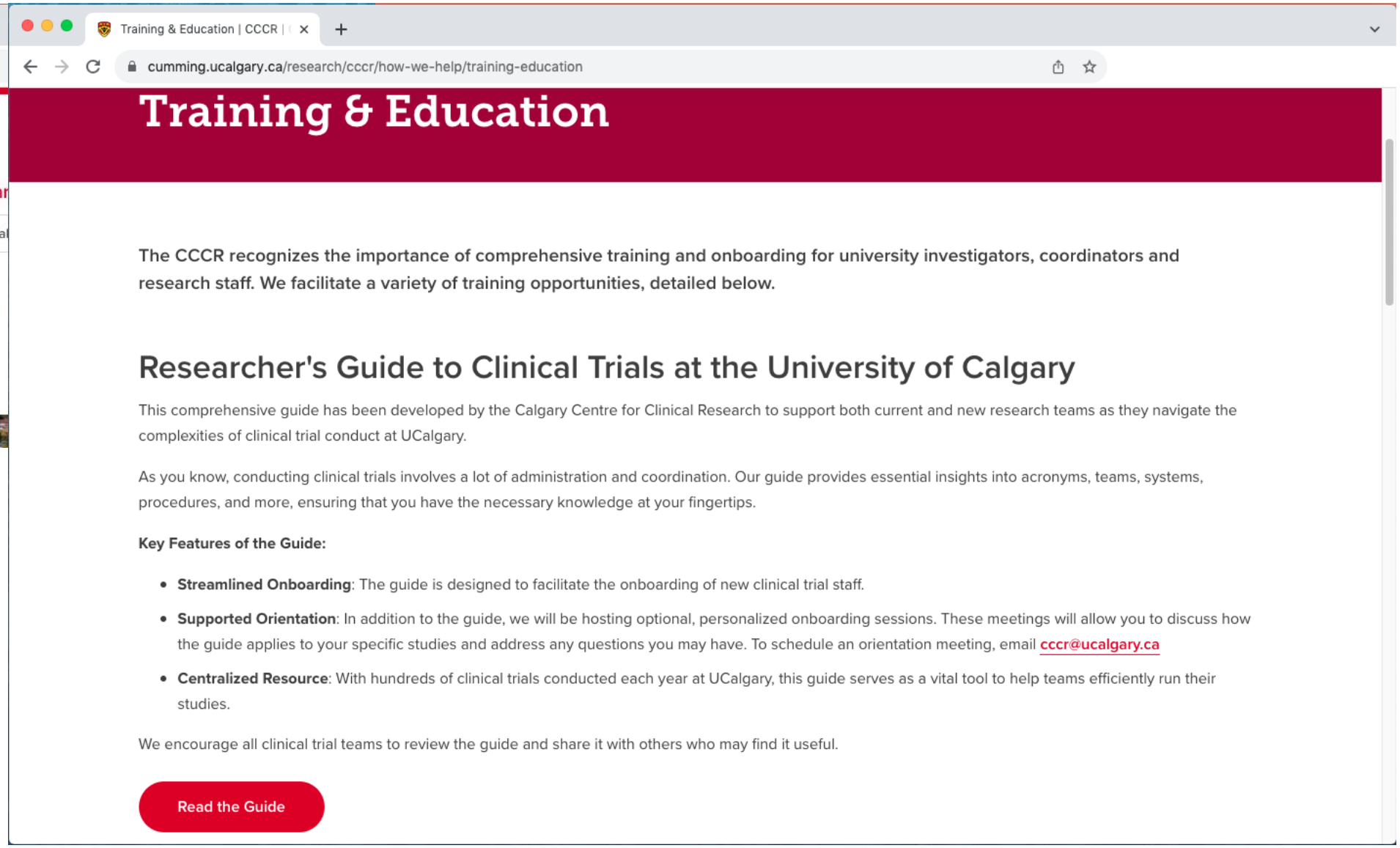
Where to Access: CCCR Website





The Need for a Guide

- Clinical trials require a lot of administrative activity
- Many teams/people involved in the setup of a new study
- University of Calgary is a big institution
- Increasing number of systems and training used/available
- Some parts are mandatory, others are optional
- Old processes have been retired and links are often broken
- Onboarding is overwhelming
- Learning on the job can perpetuate mistakes

Purpose

- Ease the onboarding process for clinical trial staff that are new to UC and/or new to clinical trials

- Establish an easy-to-reference source of truth for clinical trial processes at the UC

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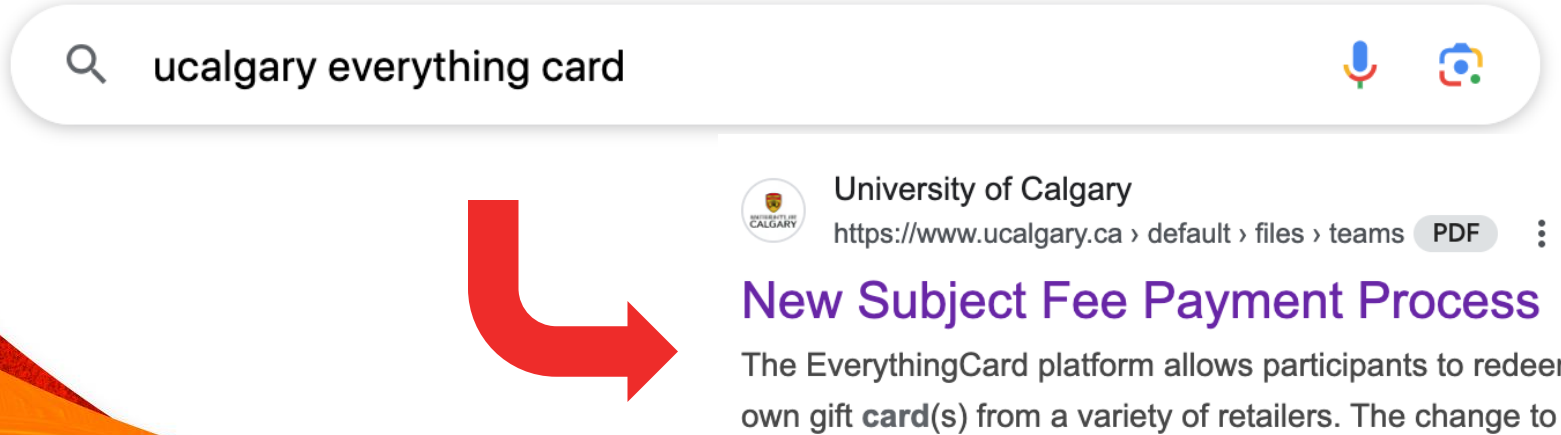
Scope of the Guide

High-level summary of:

- Training you'll complete
- Teams you'll interact with
- Systems you'll use
- Processes you'll follow (mandatory)
- Services you may access (optional)

Enough info for you to be able to google the right words

Not enough info that you can skip other training & resources



CCCR is here to help …

- As the administrative office for clinical research at UC, we exist to help you through these processes!

- Schedule a personalized orientation to the Researcher's Guide to Clinical Trials
  - We can go through the guide together – with you, your new hire, or your whole team
  - Discuss how it applies to your specific study/situation/setup
  - Introduce you to the right people
  - Listen to your pain points so they can get addressed

Email us to schedule a meeting: cccr@ucalgary.ca

Researcher's Guide to Clinical Trials

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Abbreviations

The following abbreviations are used throughout this document:

AHS	Alberta Health Services
ACH	Alberta Children's Hospital
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
CRU	Clinical Research Unit (EDC support, including REDCap)
CRF	Clinical Research Fund
CSM Legal	Cumming School of Medicine - Legal, Research Services
CTA	Clinical Trial Agreement (legal contract)
CTA	Clinical Trial Application (Health Canada submission)
CTMS	Clinical Trial Management System
EDC	Electronic Data Capture
EMR	Electronic Medical Record
FMC	Foothills Medical Centre
HIA	Health Information Act
HMRC	Heritage Medical Research Clinic
HREBA-CC	Health Research Ethics Board – Cancer Committee
HSA	Health Systems Access (Alberta Health Services Research Administration)
ICH-GCP	International Council for Harmonization – Good Clinical Practice
ISO14155-GCP	International Organization for Standards: Clinical Investigation of Medical Devices
IRISS	Institutional Research Information Services Solution (ethics, AHS & legal submission software)
ITA	Investigational Testing Authorization
MDR	Medical Device Regulation
N2	Network of Networks
NOL	No Objection Letter
POST	Provincial OnCore Support Team
REB	Research Ethics Board
REBX	Research Ethics Board Exchange
REDCap	Research Electronic Data Capture
RMS	Research Management System
RSO	Research Services Office
SOP	Standard Operating Procedures
TCPS 2	Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)
W21C	Ward of the 21st Century Research and Innovation Centre

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My other favourite resource for clinical research terminology & acronyms:

https://www.acrc.albertainnovates.ca/glossary

Teams

Distinguish between offices that serve:

- the entire University
- all types of research
- *clinical* research (within the CSM)

For each team:

- what they do in ~2 sentences
- what systems they use

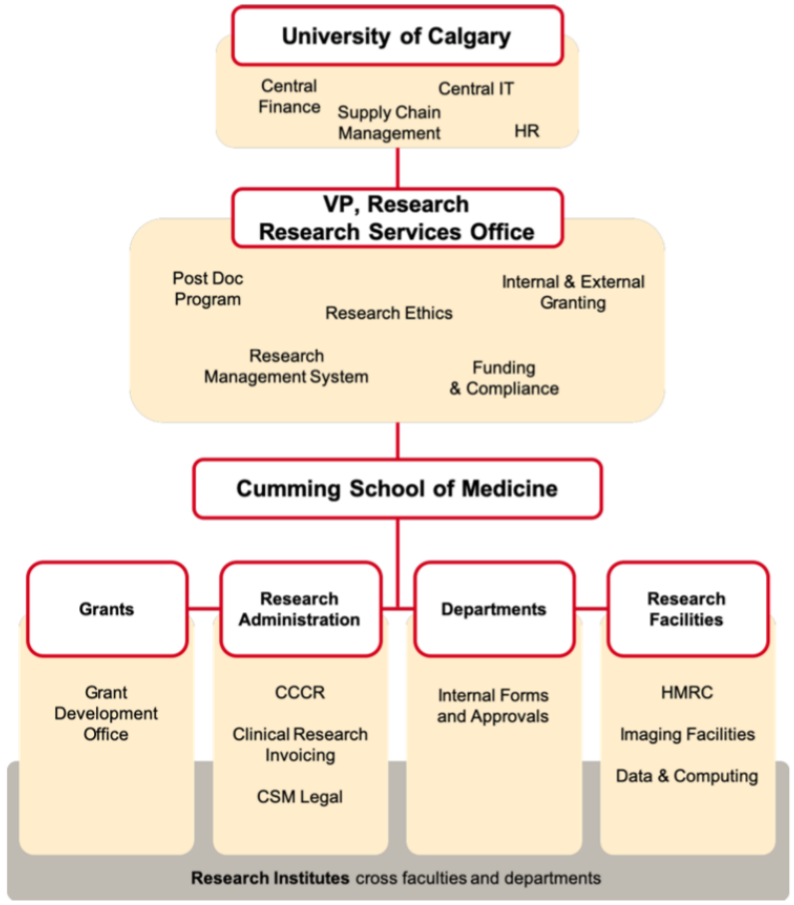

Figure 1 - Teams providing research support across the University of Calgary

Research Services Office (RSO)

The RSO supports all types of research across all University of Calgary faculties, including clinical health research in the Cumming School of Medicine. Their role is to increase research revenue and manage compliance with funding terms, ethics, policies and regulations. The RSO is made up of teams to facilitate external grant applications, support internal grants & trainee funding, manage the postdoctoral program, administer the research management system (RMS), manage ethics applications, and more.

Cumming School of Medicine (CSM)

The Cumming School of Medicine (CSM) oversees clinical health research done by its faculty members through the offices of the Senior Associate Dean of Research and the Associate Dean of Clinical Trials. The CSM Grant Development Office is the first point of contact for faculty submitting external research grant applications.

Systems

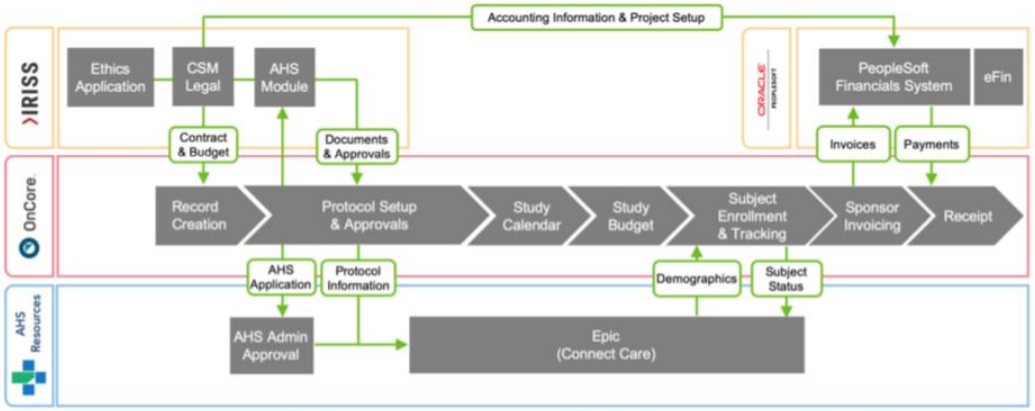

Figure 2 – Information flow between systems. Clinical trial agreement submission to CSM Legal initiates protocol record creation in the OnCore Clinical Trial Management System (CTMS) and project account creation in PeopleSoft. Requests for AHS resources in the IRISS AHS Module initiate the OnCore-Epic Protocol and Subject Integrations where applicable. The OnCore-Ethics integration maintains ethics approved information in OnCore. The Epic-OnCore Demographics Integration allows OnCore to search and retrieve demographic information from Epic. The OnCore-PeopleSoft invoicing interface allows invoices created in OnCore to be transferred to PeopleSoft for approval and email to sponsors. Financial transactions are displayed by project account in eFin.

IRISS Ethics Module

The IRISS ethics system is where you manage all of your ethics submissions, modifications, reportable events, annual renewals, and other ethics-related study activities.

OnCore-IRISS Ethics Integration: This integration transfers ethics approved staff and review information to OnCore.

IRISS CSM Legal Module

The CSM Legal module in IRISS is used to submit legal documents, such as a non-disclosure agreement, clinical trial agreement, or amendment, for negotiation and execution by CSM Legal.

IRISS AHS Module

The AHS module in IRISS allows you to apply to conduct research in AHS facilities, and/or access AHS resources. The AHS application menu will become available in IRISS when the use of AHS services or facilities is indicated in the ethics application and submitted through IRISS. These applications are supported by the AHS Health Systems Access team.

Research Ethics Board Exchange (REBX)

REBX is integrated functionality within IRISS that allows for ethics applications, documents, and reviews to be transferred between universities, allowing for a single Board of Record (BoR) for a study. As a lead site of a clinical trial, you may invite participating sites to join your ethics application. As a participating site in a clinical trial, you may leverage lead site approvals and documents to expedite your own ethics application. This functionality is offered between the University of Calgary, University of Alberta, and University of British Columbia.

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For each system:

- the purpose of the system
- the integrations that exist between systems

Example: PeopleSoft vs eFin

Training required by study type

- Short description of the content
- Where to access courses
- Noting which certificates need to be uploaded to IRISS when you're done

Training Requirements

The following training requirements are applicable to all studies conducted at the University of Calgary. This summary does not include study-specific requirements such as training on the protocol, investigator brochure, lab manuals, informed consent, etc.

Research Type	SOPs	Privacy (HIA)	Cyber-Security & Privacy	TCPS 2 CORE	Good Clinical Practice	Health Canada	OnCore CTMS	Epic (Connect Care)
Retrospective Chart Review	X	X	X	X				If Using
Observational Research	X	X	X	X			If Using	If Using
Interventional Research	X	X	X	X	ICH		X	If Using
Phase I – IV Regulated Research	X	X	X	X	ICH	Div 5	X	If Using
Medical Device Research	X	X	X	X	ISO14155	MDR	X	If Using

Table 1 – Training requirements by type of research. SOP = Standard Operating Procedures, HIA = Health Information Act, TCPS-2 CORE = Tri-Council Policy Statement 2 Course on Research Ethics, GCP = Good Clinical Practice, ICH = International Council for Harmonization, ISO = International Organization for Standardization, Div 5 = Division 5, MDR = Medical Device Regulation, CTMS = Clinical Trial Management System.

	Industry-Sponsored Trials	Investigator-Initiated Trials
Initiate Design the research study, write the protocol, submit to Health Canada	Industry Sponsor (i.e., Corporation) *Industry approaches UC as a study site, optionally supported by CCCR*	Investigator *Health Canada application (when required) supported by CCCR*
Budget & Funding Budget for study conduct, obtain funding, pay for the conduct of the study	Industry Contract, 30% overhead *Budget negotiation with sponsor optionally supported by CCCR* *Final budget is reviewed by CCCR*	Investigator Grant, overhead assessed at a lower rate *Self-Funded (Departmental Funds), Grant Funded (Foundation, Agency, Industry Grant)* *Final budget is reviewed by CCCR*
Contract Review and execution by CSM Legal	Clinical Trial Agreement	Sub-site Agreement *If coordinating a multi-site study*
Start Up Apply for ethics and approvals	Investigator & Study Staff	Investigator & Study Staff
Manage Manage the study and comply with regulations	Industry Sponsor in collaboration with investigator & study staff *OnCore CTMS supported by CCCR*	Investigator & Study Staff *OnCore CTMS supported by CCCR*
Conduct Responsible for the conduct of the study at the University of Calgary	Investigator & Study Staff *Monitoring conducted by the industry sponsor*	Investigator & Study Staff *Monitoring services optionally provided by CCCR*
Bill for Services Issue invoices for research activities	Investigator & Study Staff *OnCore-PeopleSoft interface, supported by CCCR*	Investigator & Study Staff *Invoicing supported by CCCR when required, often not needed for grant funded studies*
Closure Close accounts and archive study records	Investigator & Study Staff *Archiving and project closure supported by CCCR*	Investigator & Study Staff *Archiving and project closure supported by CCCR*

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Highlight the differences between IITs and Industry Sponsored Studies:

- Different responsibilities
- Services available

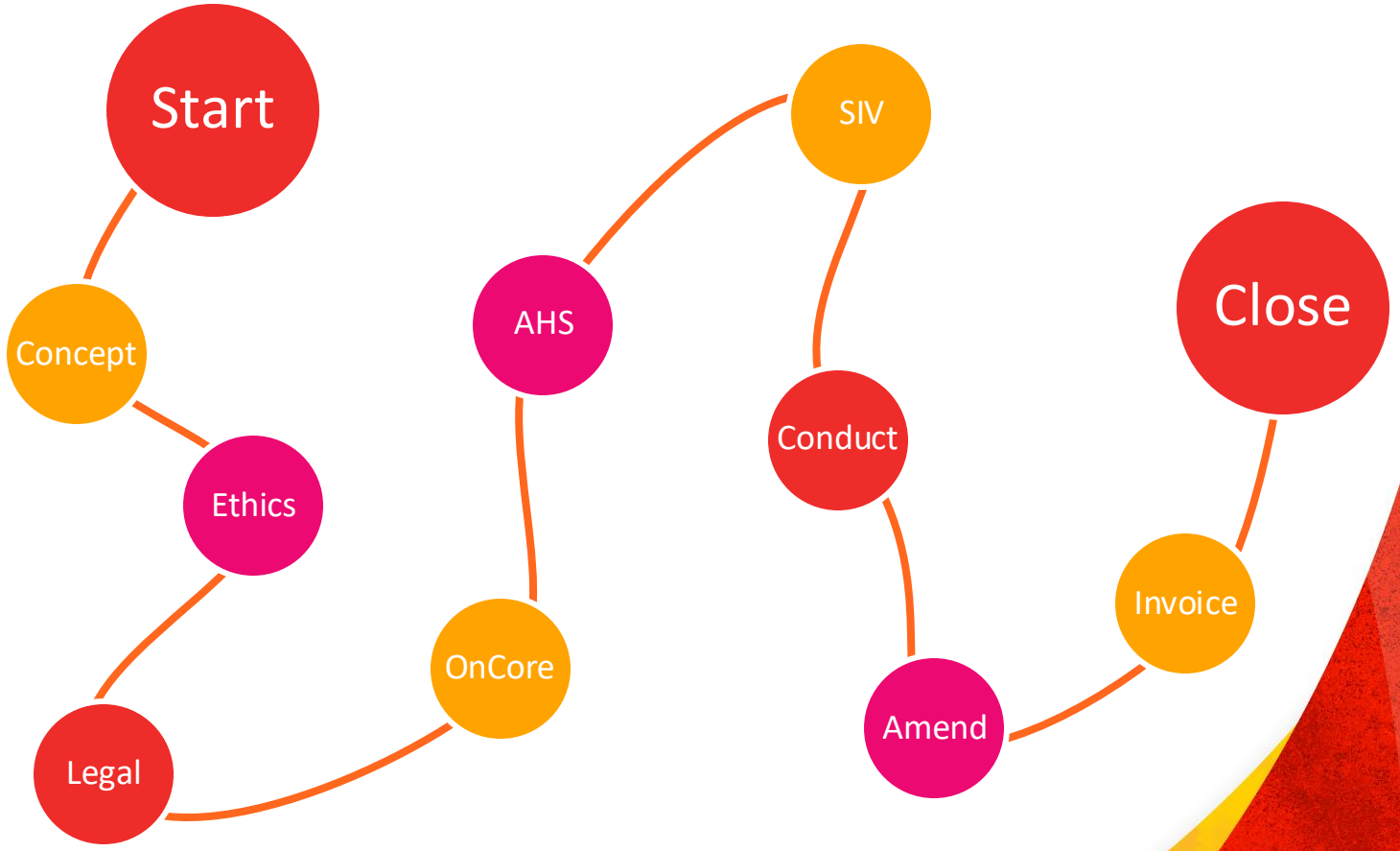
Example: Monitoring

Clinical Trial Happy Path

Clinical Trial Happy Path:

- “Ideal” order of operations
- Notes about which teams/systems you interact with at each step
- Mandatory processes
- Integration points

Example: When studies are linked between OnCore and Connect Care



CCCR Services by Team:

- Startup & Regulatory
- Finance
- Provincial OnCore Support

+ Health Systems Access Advisor

Clinical Trial Agreements:

- What parts do you *really* need to know?
- The important parts about compensation (that should be included if they're not already there!)

Appendix A

Clinical Trial Agreements

A clinical trial agreement (CTA) is a legal contract that the University of Calgary enters into with other parties for the conduct of a clinical trial. The CTA details the entirety of your agreement with the sponsor to be a site for their clinical trial. Because it contains important details about the conduct of the trial, including reporting provisions, deadlines, and consequences, it is important for anyone managing a clinical trial to read and understand the key requirements in a CTA.

Sections of the CTA that you should pay extra attention to:

- **Scope of Work / Conduct of the Study**
  This section states that the University is agreeing to conduct the study according to the protocol. The section may also include other tasks that the PI and study team are to perform.

- **Case Report Forms (CRFs) / Study Data Submission**
  This section usually specifies the amount of time allotted for the study team to complete and submit data from study visits.

- **Adverse Events**
  This section outlines the responsibilities for adverse event reporting.

- **Compensation / Payment Schedule**
  This section (often an Exhibit at the end of the contract) details the conditions of payment. Beyond the negotiated amounts for various procedures/visits, you should know:
  - Which items are automatically paid based on triggering events such as data submission or contract execution?
  - Does withholding apply to any payments and when do you receive that money?
  - What currency is your budget negotiated in?
  - Which items need to be invoiced for and what supporting documents do they require?
  - Where are you supposed to email or submit invoices?
  - What information is required to be on an invoice (example, PI name and site ID)?
  - What is your negotiated overhead rate? This rate must be in accordance with the University's overhead policy unless otherwise approved by the VP Research. Overhead applies to all incoming funds, including expense reimbursements. As such, invoiceable amounts should include overhead on all items. The only exception is an initial REB review.

Appendix B

Financial Procedures

Conducting a clinical trial often involves managing expenses, bills, and service providers in addition to invoicing an industry sponsor. It can take some time to familiarize yourself with the University of Calgary's policies and procedures for sending and receiving money. **Always refer to your clinical trial agreement for study-specific invoicing instructions, automatic payment conditions, and withheld amounts**.

Sponsor Invoicing is supported by CCCR (CCCRInvoicing@ucalgary.ca). All other financial processes are supported by Central Finance at the University of Calgary. Central finance can be contacted anytime through UService (finance@ucalgary.ca). Please use the following link to find the official guidelines, policies, and more detailed instructions on how to complete these transactions.

Forms, procedures, guidelines, and handbooks: https://www.ucalgary.ca/finance/finance-forms

Finance Admin Job Aids: https://www.ucalgary.ca/hr/learning-development/how-learning-resources/finance-admin-tasks

Accounts Payable (A/P):
Paying money to vendors/service providers ("suppliers") for goods & services they have provided for your study.

Example: you are paying a Diagnostic Imaging Clinic $600 for a CT Scan that they performed for your study

Expense Claim	The reimbursement process for employee-paid expenses.
P-Card	A University-issued credit card ("purchasing card") for direct payment of study-related expenses.
T&E Card	A University-issued credit card ("travel and expense card") for direct payment of travel-related expenses, including participant transportation and accommodation.
Supplier Setup/Update	To pay for goods & services **without** either of the above methods, you must set up the vendor (or patient) as a Supplier before you can issue payments to them.
Bill/Invoice Payment	The process for paying a Supplier in response to an invoice you received for goods & services.
Interdepartmental Billing	The process for paying an internal service unit within the University in response to an invoice you received for goods & services.

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Financial Procedures:

- Introduce terminology
- Central Finance procedures & forms in the context clinical trial activities

Example: visit milestone payments vs. pass through or "invoice" items

Learning Objectives

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Questions?

https://cumming.ucalgary.ca/research/cccr/

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