UNIVERSITY OF CALGARY
CUMMING SCHOOL OF MEDICINE

Calgary Centre for Clinical Research (CCCR)
Clinical Trials Office (CTO)

# Study Monitoring Services

## Overview

The sponsors/sponsor-investigator of a clinical trial is responsible for ensuring trials are properly monitored. Monitoring is an essential element of study conduct designed to ensure ethical conduct, proper collection and documentation of study results, appropriate records of study procedures and subject interactions, and compliance with the approved protocol. Monitoring ensures the protection of subjects' rights and safety, as well as the integrity and quality of the resultant data.

## What Monitoring Approach Will Be Used?

The extent of monitoring is determined by a risk-based approach. Per ICH E6, "the aim of monitoring is to ensure the participants' rights, safety and well-being and the reliability of trial results as the trial progresses."

## Who Can Use This Service?

Monitoring services are available to all researchers conducting investigator-initiated drug or device trials sponsored by the University of Calgary.

## How Much Does This Service Cost?

CTO monitoring services are offered on a cost-recovery basis. Cost estimates for specific studies are provided after finalizing the monitoring plan.

## What is the Monitoring Process?

### Risk Assessment

Responsibility for determining the risk level of the trial lies with the Sponsor of the trial. For University of Calgary investigator-initiated trials, this will be completed by Quality Assurance (QA) personnel at the CCCR. QA personnel evaluate the frequency and extent of monitoring required and propose a budget for the service based on the known risk factors.

cumming.ucalgary.ca/research/cccr/clinical-trials-office/monitoring-services-0

### Monitoring Plan

Monitoring services for investigator-initiated trials ensure the safety and integrity of the trial participants from the initial design to the final review. The monitoring plan outlines the monitoring scope and process, such as timing and frequency, monitor qualifications, extent of source data verification, communication and closeout procedures. QA personnel prepare this plan for approval by the study team upon acceptance of the proposed budget.

### Initial Visit

An Initial Monitoring Visit takes place after the site has obtained all approvals. This includes review of essential documents and record management, eligibility criteria and review process, lab and pharmacy manuals (if applicable), delegate training on the protocol, Tri-Council Policy Statement, GCP, SOPs, and Health Canada Regulations (if applicable), informed consent requirements, REB obligations, adverse event reporting, safety reporting, case report forms, and the data management plan.

### Interim Monitoring Visits

Interim monitoring visits evaluate study conduct according to the regulations and allow for source document verification.

The monitoring plan determines the duration and frequency of the visits. During these visits, the study monitor evaluates and reviews all necessary CRFs, Serious Adverse events (SAEs), study file documents, consent forms and reviews findings with the PI and study team.

### Closeout Visit

The closeout visit is conducted when the study has been completed. It includes a final review of the study file documents, completion of any queries or outstanding case report forms, review of outstanding payments or reporting to ensure all the necessary aspects of the study have been addressed prior to closeout and archiving.

Contact **cccrmonitoring@ucalgary.ca** preferably in the early development of the project to receive advice on risk management strategies and budget development.