CCCR

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To: clinical-coordinators-l@mailman.ucalgary.ca; clinical-trials-teams-L@mailman.ucalgary.ca; clinical-researcher-L@mailman.ucalgary.ca; hmrc-L@mailman.ucalgary.ca
Subject: Clinical Trial Monitoring Now Available!

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UNIVERSITY OF CALGARY

Calgary Centre for Clinical Research

Clinical Trial Monitoring Now Available!

The Clinical Trials Office (CTO) under the Calgary Centre for Clinical Research (CCCR) is pleased to announce the addition of clinical trial monitoring services as of March 1st, 2023. The service will be available for investigator initiated clinical trials sponsored by the University of Calgary.

The service includes assistance with developing risk-based monitoring plans and the conduct of monitoring visits for a fee. A reduced welcome fee will be available for the first studies signing-up to use the new service. More info can be found here.

To discuss your study's monitoring needs, please reach out to cccrmonitoring@ucalgary.ca.

CALGARY CENTRE FOR CLINICAL RESEARCH
CUMMING SCHOOL OF MEDICINE, UNIVERSITY OF CALGARY

STUDY MONITORING SERVICES

THE CLINICAL TRIALS OFFICE (CTO) UNDER THE CALGARY CENTRE FOR CLINICAL RESEARCH (CCCR) IS PLEASED TO OFFER CLINICAL TRIAL MONITORING SERVICES.

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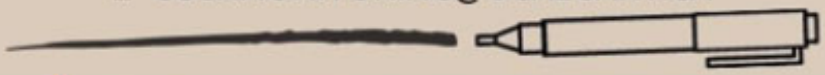

OVERVIEW

The Sponsors/Sponsor-Investigator of a clinical trial is responsible to ensure that 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 resulting data.

WHAT MONITORING APPROACH WILL BE USED?

The extent of monitoring is determined by a risk-based approach. Per ICH E6[SM1] , "the purposes of trial monitoring are to verify:

- The rights and well-being of human subjects are protected.
- The reported trial data are accurate, complete, and verifiable from source documents.
- The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).

WHO CAN USE THIS SERVICE?

The monitoring service is 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

CALGARY CENTRE FOR CLINICAL RESEARCH
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STUDY MONITORING SERVICES

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WHAT IS THE MONITORING PROCESS?

1

RISK ASSESSMENT

The responsibility of 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 Calgary Centre for Clinical Research. The QA personnel will evaluate the frequency and extent of monitoring that will be required and propose a budget for the service based on the known risk factors

MONITORING PLAN

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

2

3

INITIATION VISIT

A Study Initiation Visit will take place after the site has completed all regulatory requirements and has obtained all approvals. The Initiation is the last step before the study site will be activated for recruitment by the sponsor. The visit will include review of the essential document and record management, including eligibility criteria and review process, lab and pharmacy manuals (if applicable), delegates awareness and training on the protocol, , Tri-Council Policy Statement, Good Clinical Practice (GCP) guidelines, Standard Operating Procedures, and Health Canada Regulations (if applicable), informed consent requirements, REB obligations, adverse event reporting, safety reporting, data forms review (CRFs), and data management plan.

INTERIM MONITORING VISITS

The interim monitoring visit will be done to evaluate the study being conducted according to set regulations and to perform source document verification. The duration and frequency of the visits will be according to the set Sponsor monitoring plan. During these visits the study monitor will evaluate and review all necessary CRF's, Serious Adverse events (SAE's), Study file

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University of Calgary Foothills Campus
Health Sciences Centre, G370
3330 Hospital Dr NW
Calgary, AB T2N 4N1
CANADA

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