

Cancer Related Trials

Introduction

The oncology Clinical Trials Office (CTO) provides central management and oversight functions for all cancer-related trials that involve human subjects conducted on campus. The CTO is staffed by project coordinators, research nurse coordinators, clinical research assistants, data coordinators, and quality assurance personnel. The CTO staff work alongside the Oncology/Hematology faculty to implement and oversee a diverse range of clinical trials including investigator-initiated, industry-sponsored, national cooperative group, and consortium trials.

Special Review Requirements

All cancer-related trials (adult and pediatric) must be reviewed by The Protocol Review and Monitoring System (PRMS) and the Scientific Review Committee (SRC). The SRC oversees the scientific aspects of cancer-related research that involve human subjects conducted by members of the UNMC faculty and personnel.

The SRC is responsible for:

- evaluating all new and amended clinical research protocols for scientific merit and to ensure that there are adequate resources available to successfully complete the proposed research
- monitoring accrual to active protocols to ensure that studies meet their accrual goals and to require a reassessment of recruitment strategies and accrual goals when necessary
- ensuring that there are no competing studies with overlapping eligibility criteria for a specific disease indication
- establishing priority of each protocol based on National Cancer Institute guidelines and institutional priorities
- performing ongoing annual scientific review of cancer center protocols

The function of the SRC is complementary to the Institutional Review Board (IRB) and does not duplicate the IRB's responsibilities, which focuses on the protection of human subjects.

SRC approval is required before the IRB gives final approval or continuation of a protocol submission. If the investigator fails to obtain SRC approval prior to expiration of the IRB approval period, the protocol will be classified as “approval expired” until all requirements are met. Forms for protocol submission are available on the [PRMS website](#).

Data and Safety Monitoring Support

Data and Safety Monitoring

The Data and Safety Monitoring Committee (DSMC) monitors the safety of research participants enrolled in therapeutic interventional clinical research trials sponsored by UNMC faculty as outlined in the UNMC Data Safety Monitoring Plan (DSMP).

Forms for data and safety monitoring are available on the [PRMS website](#).

Audit Reviews

The PRMS Audit Committee (AC) performs audits and provides oversight on all investigator-initiated therapeutic interventional trials with UNMC as the study source (i.e. sponsor). The role of the Audit Committee is to ensure:

- compliance with institutional regulatory guidelines
- confirmation of patient eligibility
- adherence to treatments
- appropriateness of adverse event monitoring and reporting; and 5) adequacy of patient follow-up as stipulated in the protocol.

For a list of all active cancer related clinical trials conducted at UNMC, visit the [cancer-related clinical trials page](#).

The site links each active trial to information on the [ClinicalTrials.gov](#) website.

The [PRMS website](#) is a useful resource which provides investigators with the most current versions of the SRC, DSMC, and AC Policies and Procedures; Conflict of Interest Policy; submission forms; and meeting dates and submission deadlines.
