University of Nebraska Medical Center
BREAKTHROUGHS FOR LIFE.

Protocol Review & Monitoring System (PRMS)

POLICIES and PROCEDURES

Fred & Pamela Buffett Cancer Center

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DATA and SAFETY MONITORING COMMITTEE (DSMC)

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PRMS OFFICE WEBSITE

http://www.unmc.edu/cancercenter/research/protocol-review-monitoring-system.html

SEARCHABLE WEBSITE OF ACTIVE CLINICAL TRIALS

http://net.unmc.edu/ctsearch/index_unmc.php

I. INTRODUCTION

The Protocol Review and Monitoring System (PRMS) of the University of Nebraska Medical Center (UNMC) Fred & Pamela Buffett Cancer Center (BCC) provides central management and oversight functions for all cancer-related trials involving human subjects and conducted by members of the BCC.

The PRMS Scientific Review Committee (SRC) is responsible for the following:

- Evaluating all new clinical research protocols for
    - scientific merit
    - adequate resources available to successfully complete the proposed research
- Evaluating all amended clinical research protocols (same objectives as above)
- Monitoring accrual to active protocols
    - ensuring studies meet the stated accrual goals
    - reassessment of recruitment strategies and/or accrual goals when necessary
    - ensuring there are no competing studies with overlapping eligibility criteria for a specific disease indication
    - establishing protocol priority based on NCI guidelines and institutional priorities
- The ongoing annual scientific review of cancer center protocols

The PRMS Audit Committee (AC) reviews audits completed on all BCC investigator-initiated, multi-center intervention trials to ensure the following:

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

The Data and Safety Monitoring Committee (DSMC) monitors all internal toxicities and adverse events occurring on intervention trials sponsored by UNMC ensure the following:

- all investigator-initiated and multi-center institutional therapeutic intervention protocols include a definition of adverse events specific to the protocol; and 2) therapeutic intervention (i.e. disease related) protocols adhere to institutional, FDA, and CTEP guidelines for toxicity and adverse event reporting.

II. RELATIONSHIP BETWEEN THE SRC AND THE IRB

The SRC focuses on the scientific merit, prioritization, and progress of cancer-related research involving human subjects conducted by Fred & Pamela Buffett Cancer Center members and UNMC faculty members. The function of the SRC is complementary to that of the Institutional Review Board (IRB), and does not duplicate the responsibilities of the IRB, which focuses on the protection of human subjects. SRC approval is required before final release or continuation by the IRB is given. This requirement does not apply to protocols in follow-up where subject accrual is complete. The IRB will not issue full approval for any cancer-related study involving human subjects without first receiving notice of approval from the SRC, stating that all scientific requirements for the study have been met.

On a case-by-case basis, however, the IRB may choose to review protocols before they have been submitted to the SRC.

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.

If a protocol is tabled by the SRC at the time of the continuing review, the IRB will review the IRB application for continuing review but will restrict the protocol by halting enrollment of new subjects until the required revisions are completed and SRC approval is granted. Currently enrolled subjects may be able to continue on the study, as determined by a case-by-case review.

III. RELATIONSHIP BETWEEN THE SRC, DSMC, and AC

The SRC, DSMC, and AC function independently of one another; however, both the DSMC and AC submit monthly reports to the SRC for informational purposes. Each committee reports to the Associate Director for Clinical Research of the Fred & Pamela Buffett Cancer Center. For a more complete description of these three committees, see the individual policies for the SRC, the DSMC, and the AC.

IV. TOXICITY AND ADVERSE EVENTS REPORTING (DSMC)

All investigator-initiated and multi-center institutional therapeutic intervention protocols must include a definition of adverse events specific to the protocol. Therapeutic intervention (i.e. disease related) protocols must adhere to institutional, FDA, and CTEP guidelines for toxicity and adverse event reporting (CTE Common Toxicity Criteria can be obtained through the Fred & Pamela Buffett Cancer Center PRMS office or at:

http://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc.htm.

The DSMC monitors all internal toxicities and adverse events that occur on therapeutic intervention trials not monitored by an independent board specifically designed for the individual study.

With the exception of transplant protocols, all internal serious adverse events (expected or unexpected, regardless of attribution) must be reported to the DSMC. For transplant protocols, the DSMC recognizes that certain toxicities are routinely anticipated. The investigator can indicate that a particular toxicity is anticipated for the vast majority of research participants and that such toxicity will therefore not be reported. The DSMC will determine in its initial review of the protocol if such exclusion from standard reporting guidelines is acceptable.

V. ADHERENCE REPORTING

The AC audits and provides oversight of all Fred & Pamela Buffett Cancer Center investigator-initiated institutional, multi-center institutional and other externally peer reviewed therapeutic intervention trials not monitored by an outside body to ensure compliance with institutional regulatory guidelines, confirmation of patient eligibility, adherence to treatments, appropriateness of adverse event monitoring and reporting, and adequacy of patient follow-up as stipulated in the protocol.

If significant concerns are documented that are thought to compromise the safety or scientific integrity of the protocol (i.e. failure to comply with the approved study guidelines regarding adverse event reporting, eligibility criteria, stopping rules, quality data collection, etc.) the AC can request that the SRC evaluate the audit and determine if the protocol should be suspended, until the issues are adequately addressed by the PI, if the study must be closed, or if the study can continue.

All investigator-initiated institutional, multi-center institutional and other externally peer reviewed therapeutic intervention protocols will continue to be audited while patients are receiving protocol-specific treatment. Protocols will no longer be audited when subject accrual, treatment, and/or research related tests are completed. The AC provides a monthly report to the SRC of its review.