

Scientific Review and Monitoring of Cancer or Cancer-Related Protocols and Research

Policy

All human subject cancer or cancer-related protocols (therapeutic/treatment, prevention, ancillary/companion and correlative), must be reviewed, approved, and monitored by the Kansas Masonic Cancer Research Institute's Protocol Review and Monitoring Committee (PRMC). Approval must be obtained prior to the Principal Investigator beginning the submission process to the Human Subject's Committee (HSC). Monitoring of the ongoing research will take place after all compliance approvals have been completed.

Background

The University of Kansas Medical Center and the Kansas Masonic Cancer Research Institute are committed to striving toward national distinction as a designated National Cancer Institute (NCI) cancer center. Institutions that are dedicated to the advancement of cancer research exemplify scientific excellence and effectively integrate diverse research methods and approaches in focusing on cancer are recognized by the NCI by receiving cancer center designation. These centers integrate basic, clinical, prevention, control and population sciences research. The National Cancer Institute requires that a successful center not only achieve excellence in research but also be organized and run in a manner, so that the research is maximized by critical organizational and administrative characteristics. All NCI designated cancer centers must satisfy characteristics in the areas of *cancer focus, institutional commitment, organizational capabilities, facilities, center director, and interdisciplinary coordination and collaboration*. This policy establishes a mechanism of scientific review and oversight of that research and gives authority to that mechanism.

Purpose

The Protocol Review and Monitoring Committee's (PRMC) purpose is to scientifically review all human subject cancer or cancer-related protocols and establish their relative priority to the institutional mission. In addition, the PRMC is responsible for reviewing the appropriateness of Data and Safety Monitoring plans, monitoring accrual and patient safety for all cancer or cancer-related studies within the institution.

Definitions

Clinical research studies involve the consenting of participants to either participate in a study, provide information (questionnaires, etc.) or specimens such as blood, tissue, etc.

Therapeutic/Treatment: Studies that evaluate new treatments or new ways to use a current or new treatment such as drugs or combinations, therapies, surgical or radiation techniques, or methods of treatment for cancer.

Prevention: Studies that look at cancer prevention, high-risk characteristics, and recurrence.

Ancillary or Companion: Studies that are in addition to or related to another study in order to get additional information on a group of subjects or to look at a different set of variables collected, or a cancer-related study that involves management of disease, quality of life, or follow-up on survival.

Correlative: Laboratory based cancer research involving human participants, human tissue or related by-products.

Responsibilities of the Protocol Review and Monitoring Committee

This policy will follow the aims and purposes outlined below.

It will be the responsibility of the PRMC to:

- Review the scientific merit and progress of all KUMC cancer or cancer-related protocols
- Encourage and promote advancements and collaboration of revolutionary, ground-breaking, and scientifically excellent cancer or cancer-related studies that focus on prevention, early detection, diagnosis, and treatment.
- Monitor protocol accrual and adverse events – develop policy and procedures relating to accrual rates and discontinuation and/or recommendations to the PI
- Receive reports/updates from the Human Subjects Committee and the Data and Safety Monitoring Board and take appropriate steps to ensure data integrity and subject safety of all KUMC clinical trials
- Establish guidelines for determining level of monitoring for each class of protocol
- Provide streamlined process for the submission, review and ethical review of all cancer or cancer-related protocols.
- Recommend to the Kansas Masonic Cancer Research Institute Director or their designee, the closure of any cancer or cancer-related research that does not meet adequate safety standards, scientific merit and/or accrual goals.
- The Director of the Kansas Masonic Cancer Research Institute or their designee retains the ability and authority to close any cancer or cancer-related research based on the recommendations of the PRMC, HSC or the DSMB.

Exemptions

None. This policy applies to all cancer and cancer-related research and investigators conducting such research at the University of Kansas Medical Center and it's affiliated agencies.

Related Policies

***For information regarding submission of protocols, including forms, deadlines, committee review dates and necessary documents; please contact the KMCRI Clinical Trials Office.**