Core B: Clinical Trials Core

Core Co-Directors

Robert L. Keith, MD
D. Ross Camidge, MD PhD

Core Manager: Mary K. Jackson

The goal of the Clinical Trials Core (CTC) is to provide support for clinical trials designed and implemented for SPORE projects. The support includes assistance with trial preparation, regulatory issues, data safety and monitoring, auditing, conduct, and reporting. Our increasing understanding of the molecular basis of lung cancer has reinforced the need to continue conducting studies which involve the collection of both clinical data and specimens for molecular analyses. This translational approach allows for the investigation of biological pathways of lung carcinogenesis in human tissue, and acts as a powerful tool in the evaluation of novel strategies for the prevention, screening, early detection, and treatment of lung cancer. The CTC has been essential in translating the science generated from each of the individual projects.

The CTC has played a crucial role in the Colorado SPORE due the nature of our trials. Our trials have largely focused on chemoprevention, early detection, and tissue acquisition, and have robust enrollments and specimens. Trial subjects are predominantly enrolled from pulmonary clinics at affiliated Hospitals where Cancer Center personnel are not located. These are high risk subjects who do not yet have lung cancer. In addition, specialized training is required for the collection and handling of large numbers of specimens from each procedure at each visit. Special processing to allow separation of diagnostic tissue from remnant tissue and for cell culture is required. The Clinical Trials Core utilizes two databases. The SPORE Bioinformatics core provides a biorepository database that manages the storage and retrieval of biospecimens related to SPORE trials. This database also tracks all SPORE study subjects, enrollments, and personnel providing key statistics for grant reporting. The NCIs Center for Bioinformatics provided our remote data capture management system in Oracle Clinical, and this provides a full suite of capabilities to facilitate study design, data entry, replication, and discrepancy management. We have a team of clinical research associates expertly trained to accrue subjects and collect data/tissue samples for all SPORE-supported trials. All data is entered into a web database designed to link the clinical information to the biological correlative studies for future analyses. During the previous five year funding period there have been 9 trials supported by the Clinical Trials Core and these trials have enrolled 931 subjects. Additional trials are being actively planned based on basic
science and clinical discoveries. The CTC support has led to 47 publications involving all of the projects and to multiple vertical collaborations and subsequent trials.