

November 13, 2008

MEMORANDUM

TO: Principal Investigators, Faculty, Research Nurses, Study Coordinators and Staff

FROM: Barbara F. Atkinson MD
Executive Vice Chancellor
Executive Dean, School of Medicine



As the University of Kansas Cancer Center (KUCC) and the University of Kansas Medical Center continue to pursue NCI designation, we are refining the organizational structure and processes of the KUCC. To further streamline study start-up processes and timelines based on models from other designated cancer centers, the Research Institute (RI)/Clinical Research Development Office (CRDO) will transition all of the regulatory components of cancer therapeutic intervention trials to KUCC. At this time all investigators will continue to work with the RI for all budget-related processes. The KUCC will implement financial and budget functionality in the future in conjunction with the Velos enterprise-wide clinical research system implementation, and this transition will be communicated to all investigators at the appropriate time. Finally, it should be noted that the RI will continue to handle the contracts for all of these trials and this function will not be transitioned.

TYPES OF STUDIES IMPACTED *

The studies that will be impacted by this transition are cancer therapeutic intervention trials defined as clinical trials with therapeutic intent using drugs, radiation, surgery, and/or biological agents. In addition to these trials, the KUCC will also be assuming the regulatory responsibilities for the Bone Marrow Transplant Program studies for patients with malignant disease as well as related supportive care studies.

**Exceptions include: registries; quality of life; ancillary, companion or correlative studies associated with an ongoing therapeutic study or associated with the treatment of cancer patients will be evaluated on a case by case basis.*

TYPES OF STUDIES NOT IMPACTED

Studies that will not be transitioning the regulatory components to the KUCC fall into the following major groups:

- Breast Cancer Prevention Program (i.e., chemoprevention, modulation of cancer risk using nutrition, supplements, etc.)
- Preventive Medicine and Public Health Department Studies (i.e. early detection, smoking cessation, epidemiological, observational, screening, behavioral)
- Integrative Medicine
- Bone Marrow Transplant Program non-malignant studies

- Hematology non-malignant studies
- Studies utilizing the Western IRB. Per institutional memo, these will still be handled in conjunction with the RI/CRDO. The KUCC and RI/CRDO will issue a new SOP regarding regulatory processes for Western IRB studies.

FUNCTIONS TO BE TRANSITIONED

The regulatory components that will be transitioning are as follows:

Study start-up processes (i.e., regulatory documents, PRMC and HSC submissions, INDs, consent form development, Radiation Safety Committee submissions, other institutional committee submissions, as appropriate (e.g., IRSC) and the clinicaltrials.gov web posting/updates)

Ongoing protocol and consent form amendments/revisions

Annual recertifications to PRMC and HSC

Adverse Event reporting to the HSC and DSMB (if applicable)

Study termination

Miscellaneous HSC submissions related to the study

TIMING OF TRANSITION

Effective November 10, 2008, all NEW studies should be initiated with the KUCC Clinical Trials Shared Resource (CTSR) Regulatory and Research Assurance Office. For active studies in process, we will plan to transition those studies over a period of 90 days. The transition of these studies will begin November 10, 2008. Each investigator will be receiving a list of their specific studies that will be included in this transition as well as the contact information for the appropriate regulatory coordinator who will be supporting their studies. Sponsors, CROs, as well as various institutional review committees will also be provided a list of studies included in this transition.

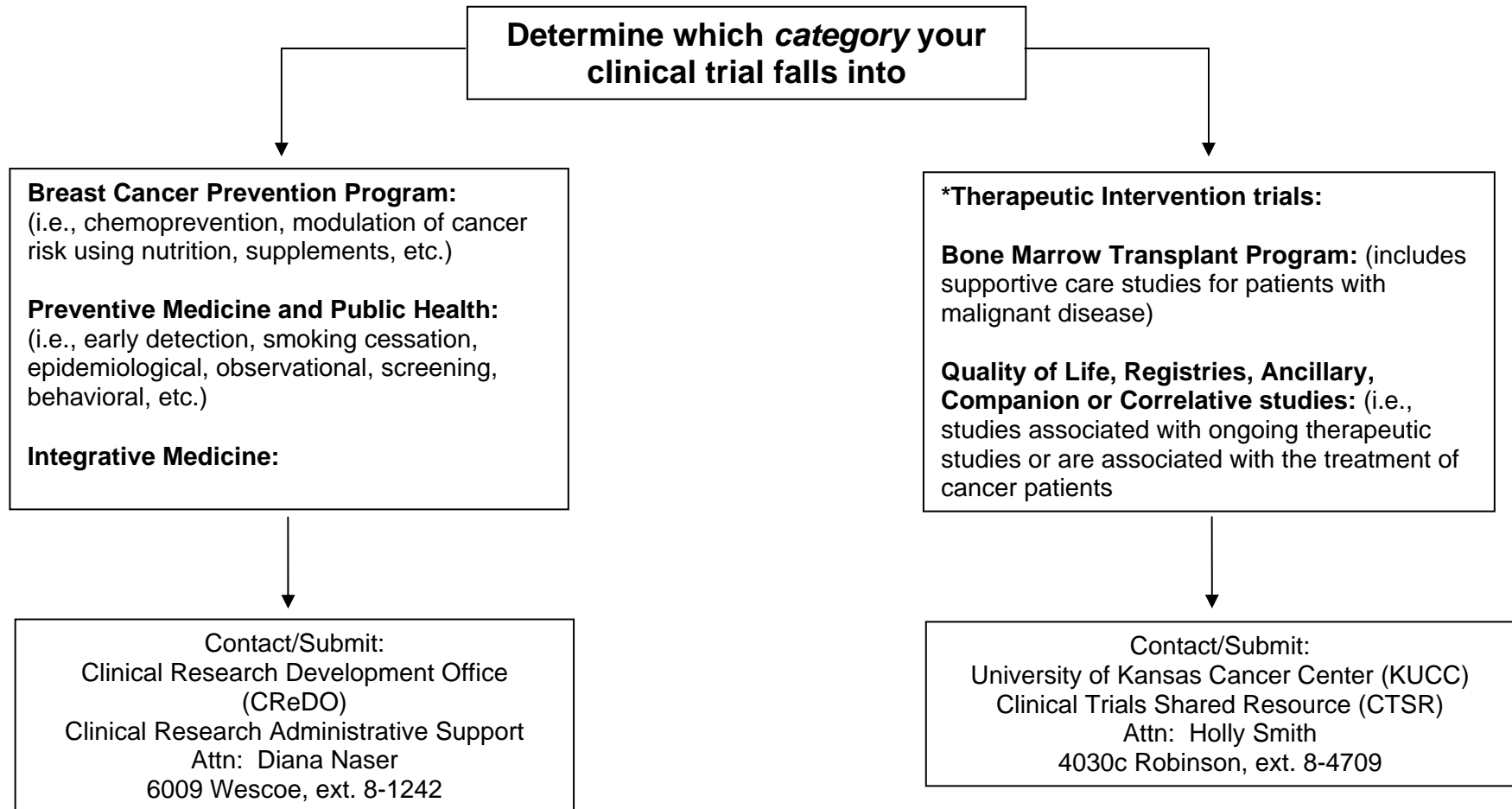
The RI/CRDO will work closely with the KUCC CTSR to effect the transition of these studies as well to transfer any pertinent knowledge related to these studies.

The Human Subjects Committee (HSC) will also post on their website these process changes for cancer therapeutic intervention trials and will also post the submission process for such trials. A memo for each study transitioning to the KUCC will also be forwarded to both the HSC and the respective study Principal Investigator from the RI/CRDO.

For questions at this time, please contact Holly Smith, Executive Director, Clinical Trials Shared Resource, University of Kansas Medical Center, 913-588-4709, hmsmith@kumc.edu and Diana Naser, RN, Executive Director, Clinical Research Administration, CRDO at 913-588-1242, dnaser@kumc.edu.

University of Kansas Medical Center Clinical Trial Processing for Cancer and Cancer Related Studies

What constitutes a cancer clinical trial? *A cancer clinical trial is a scientific research study designed to answer a question(s) with the goal of identifying safer and more effective approaches to the prevention, screening, diagnosis and treatment of cancer.*



*Therapeutic intervention trials: *Clinical trials with therapeutic intent using drugs, radiation, surgery, and/or biological agents.*