1. PURPOSE

The purpose of this document is to:

- Define the Clinical Care and Research Team (CCART) Research meeting process for protocols being proposed at the University of Kentucky Markey Cancer Center (UKMCC)

- Define the CCART Research meeting process for monitoring all active clinical trial, serious adverse events (SAEs), accruals, feasibility and merit score assignment, and priority rank for each individual Research CCART protocols.

2. SCOPE

This procedure applies to all personnel conducting cancer research at the UKMCC or by MCC personnel.

3. RESPONSIBILITIES

All members of the Markey Cancer Center Clinical Research Organization are responsible for complying with this SOP. The Director of Clinical Research Operations is responsible for assuring compliance by the CRO staff.

4. PROCEDURES

A. Each Research CCART is responsible for improving research being performed at the Markey Cancer Center. Specifically:

1. Each Research CCART must review the research portfolio once a month, including but not limited to:
   a. Status of protocols which are currently open to accrual.

2. Review, approval or disapproval of proposed protocols prior to submission to FRC and PRMC.
   a. Review of the scientific value of the protocol as well as the level of interest of members to conduct this protocol, the importance of the protocol to filling a gap in the portfolio, and the focus of the protocol relative to already open and accruing trials.
b. If two or more protocols compete for subjects or institutional support, protocol approval will be based on Research CCART priorities.

c. CCART prioritization will take into account these factors, as well as the relevant scientific contribution of UKMCC members, as follows:

i. Studies that are investigator-initiated from bench to bedside.

ii. Investigator-initiated protocols with currently available drugs containing translational components.

iii. Investigator-initiated trials with currently available drugs without translation.

iv. Cooperative group studies originating from a UKMCC member.

v. Cooperative group studies.

vi. Fully industry-sponsored phase I and pharmacologic studies.

vii. Fully industry-sponsored phase III randomized pivotal studies.

viii. Fully industry-sponsored phase II studies.

3. Review of future possible protocols in the pipeline, e.g.,
   a. Investigator initiated protocols that are in concept stage

   a. Industry, cooperative group, or other external protocols that faculty have been contacted about and should be considered

4. Assessment of gaps in the current portfolio based on the patient population and potential solutions, and potential gaps given anticipated end date of existing protocols

5. Review of problems and identification of solutions to any accrual problems
   a. Each Research CCART will monitor accruals and evaluate accrual goals for ongoing protocols monthly.

      i. Protocols that do not accrue patients satisfactorily may be closed per the Research CCART

6. Review and discuss any SAEs, and action as needed.

B. Each Research CCART meeting will be led by the Research CCART Principal Investigator.

1. Each Research CCART will develop its own meeting schedule; each is required to meet at least once a month.

2. The Research CCART Principal Investigator will chair CCART meetings and oversee the activities of the Research CCART (an alternate/co-chair should be selected for times when the PI is not available).

3. The Research CCART will address each field of the MCC Research CCART meeting summary form.

4. The Research CCART will address each field of the MCC Research CCART Merit Scoring Voting form for each new protocol.

5. FORMS
   MCC Research CCART Merit Score Chairperson Form
   MCC Research CCART Merit Score Voting Form

6. REFERENCES
   N/A

7. REVISIONS HISTORY
   Revision:
   Date:
   Description of change: