1. PURPOSE
   a. The purpose of this document is to:
      i. Define the Clinical Care and Research Team (CCART) process for protocols being proposed at the University of Kentucky Markey Cancer Center (UKMCC)
      ii. Define the CCART process for monitoring clinical trial accruals at the MCC

2. SCOPE
   a. This procedure applies to all personnel conducting cancer research at the UKMCC or by MCC personnel.
   b. This procedure applies to all clinical trials being proposed at the MCC.

3. CROSS-REFERENCES
   a. Protocol Review and Monitoring Committee SOP
   b. Protocol Closure SOP
   c. University of Kentucky Markey Cancer Center Data and Safety Monitoring Plan

4. ACRONYMS AND ABBREVIATIONS
   a. CCART – Clinical Care and Research Team
   b. ET CCART – Early Therapeutics Clinical Care and Research Team
   c. MCC-CRO– Markey Cancer Center Clinical Research Office BBSRF-Biostatics and Bioinformatics Shared Resource Facility
   d. NCCN – National Comprehensive Cancer Network
   e. SOC – Standard of Care
   f. UK MCC – University of Kentucky’s Markey Cancer Center

5. DEFINITIONS
   a. Clinical Care and Research Team – Team of faculty members responsible for improving clinical care and research performed at the Markey Cancer Center

6. RESPONSIBILITIES AND PROCEDURES
   a. Each CCART is responsible for improving clinical care and research performed at the Markey Cancer Center. Specifically:
      i. Each CCART is responsible for establishing treatment standard of care (SOC) for all stages of disease by adopting literature-based guidelines such as the National
Comprehensive Cancer Network (NCCN) guidelines or comparable national guidelines such as the protocols of the Children’s Oncology Group protocols.

ii. Each CCART is responsible for assuring multidisciplinary care by holding multidisciplinary clinics and/or conferences wherein patients and their treatment plans are discussed.

   1. In these venues, the patient’s relevant clinical findings and the following should be reviewed at a minimum for each patient:
      a. Stage
      b. Histology
      c. Treatment plan
      d. Research study eligibility

iii. Each CCART is responsible for consulting with Cancer Services Director and Patient Care Manager to assure adequate clinic environment including the following:

   1. On-time clinics.
   2. Quality and efficient clinic operations.
   3. Adequate communication between patient, physician, and treating staff.
   5. Advocate for social services.

iv. Each CCART is responsible for participating in review of CCART financial data at least yearly and providing professional consultation so that all charges are accurately accounted for and classified.

v. Each CCART is responsible for providing quality clinical trials:

   1. Each CCART is asked to establish and maintain a comprehensive research portfolio that covers the majority of diagnoses for the CCART’s patient population.
   2. Each CCART is asked to set monthly and annual clinical trial accrual goals.

vi. Each CCART is responsible for collaborating with the MCC staff to identify CCART-specific data collection points, provide consultation and oversight of CCART’s data collection plan, and assure documentation compliance for the following data points:

   1. Stage.
   2. Histology.
   3. Treatment.
   4. Disease response.
   5. Disease status change (relapse, disease progression, etc.).
   6. Any other data the CCART outlined as pertinent.

vii. Each CCART must review the research portfolio at least quarterly for the following:

   1. Protocols open to accrual.
   2. Potential protocols for activation.

      a. The responsibility for protocol prioritization rests with the CCARTs. If two or more protocols compete for subjects or institutional support, protocol approval will be based on CCART priorities. Criteria for prioritization, specific to CCARTs, in order of decreasing importance are 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. Shortfalls of the current portfolio and potential solutions.

4. Problems and resolutions to any accrual problems.

a. Each CCART will monitor accruals and evaluate accrual goals for ongoing protocols monthly.

   i. Protocols that do not accrue patients satisfactorily may be closed per UKMCC Protocol Closure SOP

   vii. Each CCART will be represented by a CCART Representative.

   1. It is the responsibility of the CCART Representative to:

      a. Assure that each CCART is fulfilling all of its clinical and research roles and responsibilities.

      b. Attend PRMC meetings as assigned or assign a designee to attend assigned meetings.

      c. The Early Therapeutics (ET) CCART will also maintain assessment of toxicity, adverse events, dose escalation, and monitoring of all early phase studies, as determined by the director of the MCC-CRO and the ET CCART chair.

   2. Each CCART is responsible for developing its own business meeting schedule and is required to meet every month to meet the responsibilities outlined above. CCARTs may choose to hold a separate research meeting outside the business meeting if needed.

   3. The CCART Representative for each CCART will oversee the meetings and activities of the CCART he/she represents.

   4. The CCART will address, at minimum, each field of the CCART reporting tool (SOP Form 272.00-A).

   5. The CCART Representative or designee must provide the MCC-CRO administrative research assistant with meeting materials, attendance log, and completed CCART Reporting Tool via fax or email.

7. DOCUMENTS AND REQUIREMENTS

   a. Official meeting minutes and approval communication provide documentation of CCART activities.

   b. The CCART Reporting tool will document the meeting activities.

   c. The CCART section of the New Protocol Registration Form will document the CCART decision regarding new protocols reviewed by the CCART.

8. ATTACHMENTS

   a. CCART Reporting Tool
9. REFERENCES
   a. None

10. REVISION HISTORY

   a. Revision: 06
   b. Date: 17 Apr 2015
   c. Description of Change: Administrative

   a. Revision: 05
   b. Date: 27 Nov 2012
   c. Description of Change: Updated document to reflect current processes

   a. Revision: 04
   b. Date: 16 Oct 2012
   c. Description of Change: Updated document to reflect current processes

   a. Revision: 03
   b. Date: 28 Feb 2012
   c. Description of Change: Updated document to reflect current processes

   a. Revision: 02
   b. Date: 14 Nov 2011
   c. Description of Change: Updated to reflect DSMP, to include UKMCC and to include newly created CCART Representative to replace the CCART chairs

   a. Revision: 01
   b. Date: 19 Jan 2011
   c. Description of Change: Added quarterly portfolio review to section 6.a.vii
## Attachment A: CCART Reporting Tool

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<th>Chemo</th>
<th>Radiation</th>
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