1. PURPOSE
   a. The purpose of this document is to describe the function of the Data and Safety Monitoring Committee (DSMC), an integral part of the Quality Assurance process for protocols being conducted at the University of Kentucky (UK) Markey Cancer Center (MCC) and Markey Cancer Center Research Network (MCCRN).

2. SCOPE
   a. This procedure applies to all MCC and MCCRN personnel.
   b. This procedure applies to all clinical trials approved by the MCC Protocol Review and Monitoring Committee (PRMC).

3. RESPONSIBILITIES
   a. The DSMC assures patient safety and protocol compliance.
   b. The DSMC Chair oversees the activities of the committee.

4. CROSS-REFERENCES
   a. University of Kentucky Markey Cancer Center Data and Safety Monitoring Plan
   b. Protocol Review and Monitoring Committee Functional Overview: SOP No.: MCC-002.03
   c. MCC Audit Committee Functional and Administrative SOP
   d. Markey Cancer Center Research Network Audit Overview SOP
   e. Markey Cancer Center/IRB/ORI Coordination SOP: IRB 06-0500
   f. IRB NCI/CIRB SOP: IRB C3-0400
5. ACRONYMS AND ABBREVIATIONS
   a. BBSRF – Biostatistics and Bioinformatics Shared Resource Facility
   b. CRA – Clinical Research Associate
   c. DSMB – Data and Safety Monitoring Board
   d. DSMC – Data and Safety Monitoring Committee
   e. IRB – Institutional Review Board
   f. MCC-CRO – Markey Cancer Center Clinical Research Office
   g. SAE – Serious Adverse Event
   h. SOP – Standard Operating Procedure
   i. MCC – Markey Cancer Center
   j. MCCRN - Markey Cancer Center Research Network
   k. PI – Principal Investigator
   l. PRMC – Protocol Review and Monitoring Committee
   m. UK – University of Kentucky

6. MEMBERSHIP
   a. The Chair of the DSMC is appointed for a three-year term by the MCC Director.
   b. Membership
      Committee members are appointed by the Chair and approved by the Director and serve three year terms. Ad-hoc members may be appointed by the Chair, as needed. One of the voting members will serve as Vice Chair appointed by the Chair.
      i. Voting members:
         1. The committee Chair.
         2. Four (4) members who are active investigators appointed for a three-year term.
         3. The Associate Director for Clinical Translation.
         4. A biostatistician from the BBSRF.
         5. A pharmacist from within the MCC and/or Investigational Drug Service.
         6. A nurse.
      
      ii. Non-voting members:
         1. The Assistant Director of the MCC Clinical Research Office (CRO)
         2. The Medical Director of the Clinical Research Office (CRO)
         3. DSMC Coordinator for the meetings
         4. Member, Cancer Research Informatics Shared Resource Facility (CRI SRF)
5. Patient Care Manager, MCC Chemotherapy and Infusion Center
6. Quality Assurance Program Manager
7. MCCRN Project Coordinator (when applicable)

7. PROCEDURE
   a. In order for the meeting to take place, at minimum, the following must be present at the meeting:
      i. Committee chair or designee
      ii. Three clinical research members of the DSMC
      iii. A biostatistician from the MCC BBSRF
   b. The principal investigator (PI) or designee for each protocol to be reviewed is requested to be present but will not be considered a voting committee member.
   c. A clinical research associate (CRA) for each protocol to be reviewed is requested to be present but will not be considered a voting committee member.
   d. If a protocol is not represented by the study CRA or the PI, the review may be delayed until the next DSMC meeting, if deemed necessary by the DSMC.
   e. Abstention from monitoring review or voting by committee members will be accepted only if the committee member has a conflict of interest and/or a lack of expertise in the scientific subject of the protocol. A committee member who is an investigator on a study will be asked to recuse themselves from the review process.
   f. All studies are required to be reviewed as determined by the PRMC.
   g. Studies with a status of ‘closed to accrual’ that have patients in follow up do not require review unless SAEs or deviations have been reported since the previous DSMC meeting.
   h. Review of Audit Reports
      i. Final audit reports will be provided to all attendees of the DSMC one week prior to the meeting with the expectation that all will review the report prior to the meeting. The report(s) will be presented by the Audit Committee Chair or designee for discussion with the DSMC. The DSMC will determine the appropriate action based on the audit report as follows: “Acceptable”, Acceptable, needs follow-up” or “Unacceptable.”
      ii. A cover letter summarizing the nature of the discrepancies and their resulting requirements will be sent to the PI, The Director of Clinical Research Operations, the MCC Director, and the Associate Director
for Clinical Research, the DSMC Chair and the PRMC Chair. Additionally, if it is determined that the study should be closed or suspended, all sponsoring agencies and relevant regulatory agencies will be notified.

i. Post Meeting:
   i. Investigators and CRAs will receive a DSMC memo indicating the committee determination as listed above with any requests for action.
   ii. In addition, copies of the DSMC Memo will be forwarded to the appropriate people based on the following DSMC decisions:
       1. Approved – Enrollment may continue.
       2. Close to accrual – Close enrollment.
       3. Temporarily Close to Accrual – Delinquent progress report, need for corrective action plan.
   iii. Minutes of the meeting will be reviewed by the DSMC Chairperson and/or Vice Chair and final minutes will be signed and filed in the Clinical Research Office (CRO).

8. DOCUMENTATION REQUIREMENTS
   a. DSMC minutes and approval letters will document DSMC decisions as well as meeting attendance details.
   b. Attendance logs, meeting minutes, meeting memos and meeting materials will be maintained in the MCC CRO.

9. ATTACHMENTS
   a. None

10. REFERENCES
    b. 45 CFR 46.102(h)(i)

11. REVISION HISTORY
    a. Revision: 04
       i. Date: 27 November 2012
       ii. Description of change:
           1. Administrative changes
           2. Changes to reflect current practice
b. Revision:05
   i. Date: 15 April 2015
   ii. Description of changes:
       1. Administrative changes
       2. Clarified Audit Committee final assessments
       3. Addition of MCCRN