1. PURPOSE
   a. To describe the procedures for auditing all adult therapeutic cancer clinical trials conducted at the University of Kentucky’s Markey Cancer Center (MCC).
   b. To describe the methods used to verify compliance with the protocol and other requirements.
   c. To describe the methods used to verify adherence to MCC Data and Safety Monitoring Plan.
   d. To describe the methods used to provide information to the study staff regarding Good Clinical Practice (GCP) and data collection and to assure that:
      i. The rights and well-being of human subjects are protected.
      ii. The reported trial data are accurate, complete, and verifiable from source documents.
      iii. The conduct of the trial is in compliance with the currently approved protocol and amendment(s), with GCP, and with applicable regulatory requirement(s).

2. SCOPE
   a. The Audit Committee facilitates the internal audit program of the MCC and reports findings to the Data Safety Monitoring Committee (DSMC), the MCC Director, and the MCC Associate Director for Clinical Translation (ADCT).
   b. This procedure applies to all adult therapeutic cancer-related clinical trials operating under approval from the MCC PRMC.
   c. Unless otherwise required by the DSMC, IITs, early therapeutics (Phase I), and cooperative group trials will be regularly audited by the audit program. The presumption that FDA-monitored studies (i.e., funded by corporate manufacturer of pharmaceuticals or devices) have adequate oversight can be overruled by the PRMC or DSMC.

3. RESPONSIBILITIES
   a. All staff of the MCC Clinical Research Data Management Shared Resource (MCC-CRDM SRF) and all faculty of the MCC will serve as auditors. They will be designated by the Audit Committee Chair, with the support of the Associate Director of Clinical Research and the Director of the Markey Cancer Center, to perform regulatory audits that comply with this Standard Operating Procedure (SOP).
   b. The ADCT is responsible for assuring compliance by the MCC staff.
   c. The Audit Committee Chair and/or the Chair’s designee are responsible for oversight of the audit process.
   d. Refer to section 2 of the Markey Cancer Center Internal Audit Manual.
4. CROSS-REFERENCES

a. Markey Cancer Center Internal Audit Manual
b. University of Kentucky Markey Cancer Center Data and Safety Monitoring Plan
c. Protocol Review and Monitoring Committee Functional Overview: SOP
d. Data Safety and Monitoring Committee Functional Overview – SOP
e. Patient Case Audit Form – MCC-006.00A
f. IRB and ICC Audit Form – MCC-006.00B
g. Pharmacy Audit Form – MCC-006.00C
h. CTMB Audit Tool/Checklist – MCC-006.00D
i. Markey Cancer Center/IRB/ORI Coordination SOP: IRB 06-0400
j. IRB NCI/CIRB SOP: IRB C3-0400

5. ACRONYMS AND ABBREVIATIONS

a. Refer to section 8 of the Markey Cancer Center Internal Audit Manual.

6. DEFINITIONS

a. Audit: A systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's SOPs, GCP, applicable regulatory requirement(s), and ethical standards of the MCC.
b. Routine audit: A planned audit.
c. For-cause audit: An unplanned audit that can occur anytime the MCC Director, ADCT, or the DSMC determines that there is sufficient reason to audit without notice, such as reports of unexpected and/or unreported risks to subjects, failure to comply with federal and/or institutional requirements, or other significant concerns about the conduct of the study.
d. Minor deficiency: A deficiency that is judged not to have a significant impact on the outcome or interpretation of the study and is not described as a major deficiency. An unacceptable frequency of a minor deficiency is treated as a major deficiency in determining the final rating of a component.
e. Major deficiency: A variance from protocol-specific procedures that makes the resulting data questionable or places patients at risk for morbidity.
f. Monitoring: The act of overseeing the progress of a clinical trial and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, SOPs, GCP, and the applicable regulatory requirement(s).
g. Principal Investigator (PI): A University of Kentucky faculty member directly responsible for the clinical research protocol conduct.
h. Sponsor-investigator: An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.
i. Audit Committee: The Audit Committee of the MCC is advisory to the DSMC, the Director of the MCC and the MCC ADCT.

7. PROCEDURE

a. Refer to the Markey Cancer Center Internal Audit Manual
   i. See Section 3 for MCC Internal Audits
ii. See Section 4 for Preparing for the Internal Audit  
iii. See Section 5 for Conducting the Audit  
iv. See Section 6 for Audit Findings and Reporting

8. DOCUMENTATION REQUIREMENTS

a. Refer to section 7 of the Markey Cancer Center Internal Audit Manual.

9. ATTACHMENTS

a. Markey Cancer Center Internal Audit Manual  
b. Patient Case Audit Form – MCC-006.00A  
c. IRB and ICC Audit Form – MCC-006.00B  
d. Pharmacy Audit Form – MCC-006.00C  
e. CTMB Audit Tool/Checklist – MCC-006.00D

10. REFERENCES

a. Refer to section 8 of the Markey Cancer Center Internal Audit Manual for the list of references.

11. REVISION HISTORY

Revision: 3  
Date: 15July2014  
a. Description of change:  
   i. Administrative changes  
   ii. Clarification of processes  
   iii. Addition of the Markey Cancer Center Internal Audit Manual