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, reviews and approves MCCRN audit reports 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 Protocol Review Monitoring Committee (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. The MCC Audit Committee is advisory to the DSMC, the MCC Director and the Associate Director for Clinical Translation. The Audit Committee members are comprised of the Audit Committee Chair, Quality Assurance Program Manager, MCC Principal Investigator(s), Assistant Director of MCC CRO and other ad-hoc members with particular expertise of benefit to the audit process as determined by the Audit Committee Chair and Quality Assurance Program Manager. Section 2 of the Markey Cancer Center Internal Audit Manual outlines the responsibilities of:
      i. Audit Committee
      ii. Audit Committee Chair
      iii. Quality Assurance Program Manager
iv. MCC Principal Investigators  
v. Internal Auditors  
vi. Data Safety Monitoring Committee  

b. The ADCT is responsible for assuring compliance by the MCC staff and faculty.

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. Markey Cancer Center Research Network Audit Overview: SOP  
f. Markey Cancer Center/IRB/ORI Coordination SOP: IRB 06-0400  
g. 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. Lesser 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. Principal Investigator (PI): A University of Kentucky faculty member directly responsible for the clinical research protocol conduct.

7. PROCEDURE

a. Sections 3 through 6 of the Markey Cancer Center Internal Audit Manual outline the procedures for:  
   1. scheduling, preparing, and conducting audits  
   2. reporting audit findings and follow up  
b. The Audit Committee meets monthly to ensure timely oversight of MCC internal and MCCRN audit reports.
c. The Audit Committee reviews external audit reports (Cooperative, FDA, NCI…) to ensure that MCC is aware of audit activity and findings. The committee will determine if a for-cause internal audit is necessary.

d. The Quality Assurance Office provides administrative support to the Audit Committee. The audit reports are peer reviewed protected and are confidential and must not be placed in files that may be audited.

e. Audit Committee Minutes are kept by the QA Program Manager and forwarded to the committee for review and approval. The minutes are approved and signed by the Audit Committee Chair. An original copy and scanned copy of the minutes will be housed in the Quality Assurance Office.

8. DOCUMENTATION REQUIREMENTS

a. Section 7 of the Markey Cancer Center Internal Audit Manual outlines the documentation requirements.

9. ATTACHMENTS

a. Markey Cancer Center Internal Audit Manual

10. REFERENCES

a. Section 8 of the Markey Cancer Center Internal Audit Manual documents the list of references.

11. REVISION HISTORY

Revision: 4
Date: 29May2015

   a. Description of change:
      b. Administrative and Editorial changes
      c. Addition of the Quality Assurance Office
      d. Procedure Clarifications
      e. Deletion of Audit Forms

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