POLICY: MONITORING/AUDITING POLICY FOR THE RESEARCH BILLING COMPLIANCE PROGRAM FOR CLINICAL RESEARCH/TRIALS

PURPOSE:
UConn Health research billing compliance program will provide for continuous monitoring and institute an audit plan that identifies and collects the type of information to support UConn Health research compliance monitoring and auditing activities.

SCOPE:
This policy applies to all research-related activities from medical, behavioral, social science, outcomes and health services research involving human subjects conducted within UConn Health.

POLICY STATEMENT:
Monitoring/Auditing Program:
The objective of the Research Financial Monitoring/Auditing Program is to provide UConn Health Investigators with:
1. An internal mechanism for quality assurance, quality improvement and education pursuant to research financial compliance and clinical trials
2. Practical support in the process of designing clinical trials budgets, assigning protocol induced costs (PIC) and Routine Costs (RC), identifying and complying with all institutional policies and state and federal regulations and laws.

DEFINITIONS OF TYPES OF RESEARCH FINANCIAL AUDITS
1. Random Audit for Financial Compliance
   • Scheduled audit: This type of review is considered a full audit. Focus of review includes budget review, delineation of PIC and RC, adherence to the Medicare National Coverage Decision (NCD), adherence to UConn Health research financial policies and state laws and regulation, appropriate approval from Medicaid and other third party payors for payment of routine cost associated with a clinical trial.
   • Unscheduled audit: This type of audit is done to assess one or two elements of the full audit, such as budget delineation or patient charges.
2. For Cause Audit for Financial Compliance
   This is performed when concerns regarding research financial compliance are brought
to the attention of the Human Subjects Protection Office (HSPO), Institutional
Review Board (IRB) or Research Compliance.

ELEMENTS OF AN AUDIT

1. Roles and Responsibilities
   A. The following items will be reviewed to understand the roles and
      responsibilities of the research team as it relates to financial compliance and
      clinical research:
      • Budget Workbook
      • Delineation of PIC and RC
      • Adherence to UConn Health policies: opening a clinical trial, identifying
        research patients and establishing a unique research billing number
      • Verification of Continuous Monitoring Process (CMP) by study staff.

2. Compliance/Case Review
   A. Assessment of compliance with (UConn Health) Policies:
      • Research patient billing policies and procedures.
      • Designation of PIC and RC
      • Opening a clinical trial
      • Identification of research patients
      • Attainment of Billing Employer Account Number (BEAN)
      • Correct billing procedure for charges
      • Identification of errors and corrective plan of action
   B. Assessment of compliance with State of Connecticut regulation and laws
      relevant to billing of patients on clinical trials.
   C. Assessment of compliance with Federal regulations and laws relevant to
      billing of patients on clinical trials.

3. Informed Consent
   A. Confirm consistency between contract, protocol and approved Informed
      Consent as it relates to financial compliance.
   B. Confirm consistency between Informed Consent and actual patient charges as
      it relates to financial compliance.

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Bruce M. Koeppen, M.D.  7/27/06
Dean for Academic Affairs  Date

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Peter Albertsen, M.D.  7/27/06
Associate Dean, Clinical and Translational Research  Date

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Peter J. Deckers, M.D.  7/27/06
Executive Vice President for Health Affairs  Date

NEW POLICY:  June 23, 2006