



University of Connecticut Health Center

POLICY NUMBER 2006-12

June 23, 2006

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

PURPOSE:

The University of Connecticut Health Center's (UCHC) research billing compliance program will provide for continuous monitoring and institute an audit plan that identifies and collects the type of information to support UCHC 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 UCHC.

POLICY STATEMENT:

Monitoring/Auditing Program:

The objective of the Research Financial Monitoring/Auditing Program is to provide UCHC 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.

[Hyperlink to Financial Compliance Monitoring/Auditing Procedures](#)

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 UCHC 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 UCHC 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 (UCHC) 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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NEW POLICY: June 23, 2006