

Aurora Health Care, Inc.

**Monitoring and Review of Research Protocols
and Associated Billing**

April, 2004

PURPOSE:

The purpose of this procedure is to ensure that Aurora Health Care, Inc. research billing compliance program is accomplishing its objectives, provides the types of information/data to be requested and to make the research sites aware of its obligation to support Aurora research compliance monitoring and auditing activities.

SCOPE:

This procedure applies to all sites conducting clinical research in Aurora Hospitals and Clinics (Aurora) facilities.

BACKGROUND:

As part of any effective compliance program, it is essential to have a monitoring and auditing component. "The use of audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem areas," is one of the seven minimum components of a comprehensive compliance program.

Monitoring assists Aurora in determining whether its research compliance program is working, i.e., whether individuals are properly carrying out their responsibilities and claims are submitted appropriately. Monitoring is an excellent way to ascertain if any problem areas exist and focus efforts on resolving those problems.

MONITORING PLAN:

- The Human Research Quality Improvement Plan (HRQI) was developed to describe how Aurora will evaluate the research compliance program on an ongoing basis. HRQI will develop key monitoring indicators and tools to carry out the monitoring process. (The HRQI Program document is available for review. See the Research Compliance web-site.)
- HRQI will conduct periodic monitoring of each research function and its compliance with Aurora standards and procedures relating to the operational aspects of that function.

INFORMATION FROM FUNCTIONAL AREAS:

HRQI will monitor billing records, IRB records and principal investigator records. Individuals or departments will be asked to provide the appropriate data/information including as example:

- Billing Records
- Informed Consent Forms
- IRB Protocol Files
- Investigator files and/or documents

MONITORING GUIDELINES:

HRQI has developed a Monitoring Program that describes in detail the monitoring process.

All potential errors that are identified when monitoring a research site will be described by the monitor on the Corrective Action Plan template and presented to the manager of the area and the Research Compliance Officer. The Research Compliance Officer will refer the outcome of the analysis to the department director. The monitor will work with the department director on the corrective action plan.

REFUNDING:

Any errors that result in a refund will follow Aurora's existing policies and procedures for refunding identified through the monitoring and auditing activities.

RESULTS:

- HRQI will complete a written evaluation of the monitoring results. If issues of concern are found, a corrective action plan will be developed for the impacted area. The department/area will receive feedback concerning the outcome of the monitoring.
- HRQI will report the results of its monitoring to the Director of Clinical Research, the Research Compliance Officer and the Research Compliance Committee.
- The Director of Clinical Research will report the monitoring results to the IRB and Institutional Official.
- The Research Compliance Officer will report the monitoring results to the Director, Corporate Compliance and Chief Compliance Officer.

PROCESS FOR CORRECTIVE ACTION PLAN:

HRQI will work with the department/area in developing a corrective action plan for any errors found during the monitoring period.