

Aurora Health Care, Inc

Research Compliance Program Policy

April, 2004

POLICY:

It is the policy of the Aurora Health Care, Inc. Hospitals and Clinics (Aurora) to consistently and fully comply with all laws, regulations, and ethical guidelines pertaining to the conduct of research within Aurora facilities.

GOAL:

The goal of the Research Compliance Program (Program) is to ensure that all research conducted by Aurora and/or within Aurora facilities is conducted in compliance with applicable laws, regulations, guidelines and Aurora policies.

SCOPE OF PROGRAM:

This policy applies to all research conducted by Aurora and/or within Aurora facilities.

PROGRAM OVERVIEW:

Primary accountability for implementation of the Program is vested with each Aurora facility where the research will be conducted and the supporting departments; Department of Clinical Research and Research Subject Protection Program Office and the Central Business Office. Aurora will assign and communicate accountabilities to appropriate individuals. Individuals with primary accountability for compliance will necessarily obtain and rely upon the cooperation of investigators conducting research studies within Aurora. The major tools of the Program include documentation, education, monitoring and reporting.

The Program is designed to:

1. Document and track all research projects being conducted by Aurora or within Aurora facilities.
2. Provide education to investigators regarding their responsibilities to (a) inform the Aurora Research Administration Department of all research proposals, (b) submit all such studies for review by Aurora and (c) comply with all applicable laws, regulations and ethical guidelines in the conduct of research.
3. Provide education to involved staff at Aurora facilities regarding their responsibilities to comply with applicable laws and regulations including but not limited to, provisions relating to billing for research related health care services.

4. Provide education to Institutional Review Board (IRB) members regarding their responsibilities under laws and regulations governing the protection of human subjects.
5. Monitor the conduct of research studies for compliance with applicable laws and regulations.
6. Report issues of noncompliance to appropriate levels of management for correction.
7. Report to the Aurora Compliance Committee on the status of compliance with the Program throughout Aurora.

DOCUMENTATION:

In all cases, published law and regulations shall serve as baseline documentation of Aurora's expectations regarding the conduct of research activities. Aurora will supplement published law and regulations with policies and procedures which identify Aurora's expectations with regard to compliance and which clearly assign accountability for satisfying such expectations.

EDUCATION:

Compliance and Program related education will be provided to all effected Aurora employees as appropriate to each individual's role in the conduct of research related activities. Investigators will be educated as to Aurora's research policies. Education will focus on making individuals accountable for compliance, awareness of such accountability, and the expectations for their performance.

MONITORING:

Aurora will monitor selected studies for compliance. Periodic general audits will be performed as necessary to measure the effectiveness of the Program. Issue-specific audits will be performed as necessary to evaluate Aurora's compliance in any identified area. Follow-up audits will be performed as necessary to measure the success of any remedial actions implemented following periodic and issue-specific audits.

EMPLOYEE REPORTING:

All Aurora employees are expected to report any good faith belief of any violation of law or regulation relating to the conduct of research by or within Aurora facilities. Employees are assured that they shall not be subject to any form of retaliation in the terms and conditions of their employment based on such reporting.

Employees shall make required reports to their supervisors, unless for some reason the employee is uncomfortable making a report to his/her supervisor or has concerns that the supervisor will not take appropriate action in response to a report. In such situations, the employee should contact the compliance officer, or contact the Compliance Hotline at 888-847-6331.