

CENTRAL STATE HOSPITAL
PROCEDURE

SUBJECT: **RESEARCH**

ANNUAL REVIEW MONTH: May

RESPONSIBLE FOR REVIEW: Chairperson of Central State Hospital
(CSH)Research Committee (RC)

LAST REVIEW COMPLETED: May 2008

The procedure is described below: (1) preparation, review, approval and monitoring of research proposals/projects.

Participants: Research Investigator
Chairperson of CSH Research Committee (RC)
Chairperson, Rights & Ethics Function Team (REFT)
Director, Legal and Special Services (LSSO)
Other individuals/committees, as appropriate
CSH Research Committee (RC) members
Chief Executive Officer (CEO)
Chief Medical Officer (CMO)
Service Chief/Department Head/Office Director

**PREPARATION, REVIEW, APPROVAL AND MONITORING OF
RESEARCH PROPOSALS/PROJECTS**

Research Investigator

1. Obtain from the Chairperson, CSH Research Committee (RC) a packet of instructions and forms necessary for preparation and submission of a research proposal.
2. Prepare research proposal and submit the original and copies (as noted in packet) to the Chairperson, CSH RC.

- a. Necessary forms include: Georgia Department of Human Resources Human Research Review Board Request for Approval of Research Activity, CSH Research Activity Approval Page, Preliminary Review of Research Proposal - Section I, Narrative Description of Project, Vita of Principal Investigator (s), Letter of Agreement (if applicable), Informed Consent Form (if applicable), Informed Notification Letter (if applicable), and statement of orientation training in regards to confidentiality, informed consent and human rights.
- b. Necessary signatures include: DHR project sponsor (if applicable), faculty sponsor (if applicable), principal investigator, immediate supervisor, division /department/office head where investigator is employed, division/department/ office head where research is to be conducted, medical director where research is to be conducted and chairperson of the appropriate professional service committee (if applicable).

Chairperson, CSH RC

1. Screen research proposal for completeness.
2. Forward copy of research proposal to:
 - a. Chairperson of the Rights and Ethics Function Team for review, approval or disapproval, recommendations and signature.
 - b. Director, Legal and Special Services for review, approval or disapproval, recommendations and signature.
 - c. Other individuals or committees deemed appropriate.

Chairperson, REFT:
Director, LSSO;
Other individuals/
committees as
appropriate

Complete Section II of Preliminary Review of Research Proposal Form and return to Chairperson, CSH RC.

- a. Committee chairperson may designate one or more committee members to review and evaluate research proposal.

Chairperson, CSH RC

Assign research proposal to a CSH RC member for review, recommendations and presentation at the next RC meeting.

Reviewing CSH RC member

Present research proposal along with recommendations at the CSH RC meeting.

Research Investigator

Be present at CSH RC meeting to answer any questions that may arise.

CSH RC

Recommend unconditional approval, conditional approval (citing specific conditions for approval) or disapproval.

Chairperson, CSH RC

Complete Report of Project Review by Auxiliary Research Review Committee Form.

- a. Forward approved research proposal (assuring conditions cited in conditional approval have been corrected) to CEO and CMO for review and signatures.

CEO and CMO

Review research proposal and, if approved, sign CSH Research Approval page and return to Chairperson, CSH RC.

Chairperson, CSH RC

1. Send approved proposal to Executive Secretary of DHR Institutional Review Board (IRB) and request approval if the research proposal involves human subjects.
2. Notify research investigator of the disposition of research proposal.
3. Place research proposal in a confidential file and maintain.

4. Assure inservice education and training is completed and documented on a training roster for hospital employees who prescribe, dispense and administer research drugs.

CMO

Notify division/department/office head that a research project is to be conducted in his/her area of responsibility and give name of authorized research investigator(s).

**Division/Department/
Office Head**

1. Assign a staff member to provide liaison when the research investigator is not a CSH employee.
2. Assure proper personnel in area of responsibility are aware of research project and authorized research investigator.
3. Assure coordination between staff and research investigators concerning proper procedure for obtaining and placement of informed consent forms or informed notification letters (INL) in client's medical record.

Research Investigator

Implement the recommendations of review process.

- a. Assure consent forms or informed notification letter, if applicable, are obtained and signed properly prior to initiation of the actual research.
- b. Assure signed consent forms/INLs are placed in client medical record.
- c. Complete and submit Quarterly Research Project Status Report, any ADR's and any other pertinent information concerning the research project.
- d. Provide a listing of clients and their location, if informed consent forms were obtained or if INLs are mailed.
- e. Provide inservice education and training for hospital employees who prescribe, dispense and administer research drugs, and assure that the Chairperson, CSH RC receives copies of the documentation of the train

ing.

- f. Provide the CSH RC with reports from other IRBs that have reviewed the project.

Chairperson, CSH RC

- 1. Contact research investigator regarding any delinquent Quarterly Research Project Status Reports.
- 2. Screen Quarterly Research Project Status Reports and other submitted information for completeness and for any potential problems that may arise, and provide follow-up.
- 3. Place submitted reports and other information in appropriate research project file.
- 4. Forward copies of submitted reports and other information to Executive Secretary of Department Human Resources, IRB.
- 5. Assign RC members to monitor client's medical record on a random basis to insure that signed informed consent forms/ INLs are present as indicated on the Quarterly Research Project Status Report (if applicable).

Reviewing CSH RC

- 1. Do a random check of client's medical record to insure that informed consent forms/INLS are present (if applicable).

Member

- 2. Report findings to Chairperson of CSH RC.

Chairperson, CSH RC

Prepare agenda packets for distribution to the members of the CSH RC ten (10) days prior to the scheduled meetings of the RC.

CSH RC

Review Quarterly Research Project Status Reports and other pertinent information.

Research Investigator.

- 1. Prepare and submit Research Project Final Report to Chairperson, CSH RC.

2. If requested by CSH RC, present an oral presentation on the completed research project to CSH staff members.

CSH RC

Review Research Project Final Report.

Chairperson, CSH RC

1. Forward Research Project Final Report to Executive Secretary of Department of Human Resources, IRB.
2. Assure completed Research Project is maintained in a confidential file.

Approved:

This procedure has been approved by the CEO and CMO in July 2008.