**EAST ALABAMA MEDICAL CENTER**
**POLICY CONCERNING DRUGS FOR RESEARCH USE**

The East Alabama Medical Center has an established policy and procedure regarding the storage and distribution of drugs to be used in research on humans, whether these drugs are FDA approved or in an Investigational New Drug (IND) status. Investigators planning such research in the hospital and outpatient clinics are expected to comply with the implementation of these procedures. One purpose of this policy is to insure that there is a central location in the hospital where information can be obtained regarding any research drug being used in the hospital and clinics. Secondly, the policy is intended to assist the principle investigator with the procedures relating to the storage and distribution of drugs in order to improve efficiency and accuracy.

Hospital policy states that all drugs for patient research use within the East Alabama Medical Center shall be registered with the Department of Pharmacy and the Pharmacy and Therapeutics Committee. In addition, all such drugs shall be stored and dispensed from the Pharmacy. A form covering Release of Drugs for Human Research Use, signed by the Director of the Department of Pharmacy, signifies adherence to these policies. The Institutional Review Board for Human Use has made receipt of the Release a prerequisite for protocol review.

Investigators planning drug studies are asked to contact the Department of Pharmacy for a complete copy of the policy and to make arrangements for proper storage and distribution of the drugs. A copy of the complete research protocol must be delivered to the Department of Pharmacy. The release form will be signed once arrangements for receipt, storage, and dispensing of the drug have been agreed upon.

**EAST ALABAMA MEDICAL CENTER**
**DEPARTMENT OF PHARMACY**

**RELEASE OF DRUGS FOR HUMAN RESEARCH USE**

This form is to be completed and included with any protocol being submitted for approval by the Institutional Review Board for Human Use. It is to apply whenever the research involves drugs, whether these are FDA approved or in an Investigational New Drug (IND) status.

Principle Investigator(s): _____ Protocol Title: _____
_____
_____

_____ A complete protocol is on file with the Pharmacy.
In the case of sponsored Investigational New Drugs, a copy of the sponsor's IND brochure must be on file with the Pharmacy.

_____ If a controlled substance is involved, authorized prescribers must be duly registered.

_____ Receipt and storage procedures have been established as follows:
Study material to be shipped to: _____ Storage location(s): _____

_____ Briefly describe dispensing procedures: Following randomization, instructions are in the Assent I protocol and in each kit.

_____ Reimbursement for Pharmacy services is to be accomplished by:
Fee to patient (per dose or course?)
Fee to grant (per dose or course?)
Other (describe) None

I certify that, to the best of my knowledge, institutional policies and procedures regarding investigational drug use will be followed. I further authorize the Department of Pharmacy to receive, store, and dispense any drug or placebo utilized in this study.

_____ _____
Date Principle Investigator

I concur that institutional policies and procedures will be followed in regard to the Department of Pharmacy's role in this study.

_____ _____
Date Director, Department of Pharmacy