The Children’s Hospital of Alabama (TCHA), Department of Pharmacy

**Release of Drugs for Human Research Use**

This form applies to all human subjects research involving patients at TCHA and drugs (FDA-approved or Investigational New Drug [IND]). The TCHA Department of Pharmacy, after receiving a full and complete copy of the protocol, will complete and sign this form. The Principal Investigator (PI) or his/her designee is then notified to review and sign the form. A complete and signed copy is to be included with any protocol submitted for approval by the Institutional Review Board for Human Use ([IRB] UAB Administration Building, Room 470).

Principal Investigator(s):

Coordinator: \_\_\_\_

Protocol Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 A complete protocol is on file with TCHA Pharmacy.

For sponsored Investigational New Drugs, a copy of the sponsor’s IND brochure must also be on file with the TCHA Pharmacy.

 Supplier/Sponsor: Phone:

Receipt and storage procedures have been established as follows:

 Study material to be shipped to: **The Children’s Hospital of Alabama, Pharmacy Department**

**1604 6th Avenue South, Dock A**

**Birmingham, AL 35233**

**ATTN: Adrienne Travis, PharmD**

 Storage locations(s): **TCHA Central Pharmacy**

 Refrigeration required: Yes No

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

 Secure locked location required: Yes No, not a controlled substance

Briefly describe dispensing procedures: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reimbursement of TCHA Pharmacy for services is to be accomplished by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I certify that to the best of my knowledge, institutional policies and procedures regarding investigational drug use will be followed. I will be responsible for disbursement of funds from any corresponding grants to the TCHA Pharmacy Department for services. I further authorize the TCHA Department of Pharmacy to receive, store, and dispense any drug or placebo utilized in this study. According to policy the investigational pharmacist will document the product’s delivery, inventory, the use by participant according to dispensing record, and the return of product or alternative disposition of unused product at the site. The pharmacist will document the records of investigational drugs to include dates, quantities, batch/serial/lot numbers, expiration dates when applicable, and unique code numbers assigned to the investigational products and trial participants.

**Signature of Principal Investigator Date**

I concur that institutional policies and procedures will be followed regarding the TCHA Department of Pharmacy’s role in this study.

**Signature of Director, Department of Pharmacy, TCHA Date**