USE OF INVESTIGATIONAL DRUGS

Policy:
FDA drug accountability regulations, Joint Commission accreditation standards, and accreditation standards of the AHRPP human subject’s protection program require a uniform and centralized plan for the management of investigational drugs used in human subject research. The purpose of this policy is to provide guidance for hospital staff who are caring for those patients who are receiving a medication as part of a research protocol.

Procedure:

1. All protocols involving investigational drugs must be approved by the Institutional Review Board (IRB) before they may be initiated.

2. All investigational drugs to be administered to inpatients shall be stored, prepared, and dispensed from the inpatient pharmacy, according to guidelines established by the Investigational Review Board and approved by the Pharmacy & Therapeutics Committee. All medications to be administered or provided for self-administration to outpatients shall be dispensed from the Research Pharmacy.

3. Policies and procedures for the preparation, labeling, dispensing, transport, return and destruction of investigational drugs shall be established by the Pharmacy Director in accordance with federal policy and individual protocol.

4. No human subject may be involved in human subject research as a study participant in research covered by the regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative. The clinical investigator is responsible for ensuring that informed consent is obtained from each research participant before commencing therapy. Informed consent shall be documented by the use of a written consent form approved by the IRB, and signed and dated by the subject or subject’s legally authorized representative at the time of consent. A copy of the LSUHSC-S IRB approved consent signed and dated is to be provided to the Pharmacy for each subject enrolled in the study.

5. It is the responsibility of the principal investigator to provide the Pharmacy with the names of all sub-investigators authorized to prescribe or distribute investigational drugs. No drugs can be released from the Pharmacy until such time as the physician’s order is received in the Pharmacy with the authorized investigator’s signature and IRB approved protocol number. The pharmacy director or designee implements a procedure to be followed for dispensing each drug in the protocol in accordance with the IRB approved protocol.
6. Under no circumstances shall any investigational drug bearing the label “Investigational Drug:
limited by Federal Law to Investigational Use” be used as regular pharmacy stock or for any other
purpose, or study without prior written approval of the IRB, Principal Investigator and sponsor.

7. The Pharmacy will be responsible for maintaining inventory logs which comply with standards
outlined by the protocol or regulatory agencies.

8. A pharmacist may initiate or adjust drug therapy and/or order laboratory tests associated with a
drug study protocol when approved to do so in the approved IRB protocol. Any pharmacist
participating in such a protocol must be trained and deemed competent to participate as described
in the IRB-approved protocol by the principal investigator or his/her designee. Any pharmacist
engaged in research is required to complete and pass all institutional required human subject
protection training.

9. The form “Investigational Drug Information Record” is a portion of the Request for Approval of
Investigational Drugs Involving Use of Human Subjects, which is submitted to the IRB for review.
It is the responsibility of the principal investigator to place, or make available, a copy of each form
in the patient’s medical record so that it is available for all staff. It is expected that the principal
investigator or a designated person familiar with the research will be available to answer questions
that may arise and are not covered in this data. The electronic medical record will contain an
alert for patients involved in research protocols which will alert subsequent care providers of the
patient’s participation in the research protocol.

10. All health care professionals who administer investigational drugs thus are engaged in research,
must have completed all institutional required training and protocol specific requirements as
outlined in the IRB-approved protocol.

11. Medication errors or adverse reactions involving investigational medications must be reported to
the principal investigator, pharmacy, the IRB and the sponsor. The investigator is ultimately
responsible for completing the necessary paperwork in reporting adverse reactions to appropriate
local, state and federal agencies.

Processes for acquisition and staff administration to patients under a research protocol,
(previously distributed via an internal transaction) need to be coordinated through the research
pharmacy.

12. HRPP and pharmacy departments will conduct ongoing quality improvement audits and maintain
quality assurance processes for all aspects of the medication use process involving investigational
drugs.

13. The Human Research Protection Program applies to all LSUHSC-S patients/subjects; therefore,
all LSUHSC-S personnel engaged in human subject research, i.e. administering investigational
drugs or assessing the effect of the investigational product, must follow LSUHSC-S HRPP IRB
standard operating procedures. All personnel administering investigational product or assessing
the effect of the investigational drug must comply with all HRPP/IRB educational requirements
prior to engaging in human subject research.
Approved by Clinical Board: 1/16/01, 2/17/04, 3/20/07, 5/18/10, 11/20/12
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