Policy Title: Maine Medical Center as the Secondary Institution for Research Policy-Inpatients and Ambulatory Surgery

Policy Summary: Maine Medical Center patients who are enrolled in an investigational drug trial at another institution may continue their treatment while hospitalized under the direction of their attending physician.

Policies:
1. An attending physician may prescribe investigational drugs for a patient enrolled in a drug trial approved by an Institutional Review Board at another facility while the patient is hospitalized at Maine Medical Center.
2. Residents, nurse practitioners, physician assistants, may not prescribe investigational medications unless they are a sub-investigator in a trial approved by the Institutional Review Board (IRB) of Maine Medical Center unless they obtain a verbal confirmation from the attending physician and note such in the medical record.
3. Medical students may not prescribe investigational drugs.
4. Clinical Research conducted at the Maine Medical Center shall be in accordance with The Joint Commission and all federal and state laws and regulations. Researchers will adhere to the standards outlined in the Food and Drug Administration’s Good Clinical Practice Consolidated Guideline to assure that the rights, safety, and well being of trial subjects are protected and that the clinical trial data are credible.
5. Investigational drug trials include protocols for drugs that are not FDA-approved and post-marketing studies of FDA-approved drugs

Procedures:
1. A complete medication order is written in the patient’s medical record or entered into the electronic medication information system by the attending physician. (i.e. Drug or placebo, 200 mcg, PO q 24 hours).
   a) The order must include a notation that the patient is using their own supply
   b) The order must reflect that this is a study (Drug or placebo; Drug Study; etc.).
2. The attending physician obtains a copy of the signed informed consent, protocol or research summary, and emergency telephone number(s) from the principal investigator at the primary institution as soon as possible, preferably prior to drug administration.
   a) Emergency telephone number(s) must include, at a minimum, the number of the principal investigator, and
   b) Copies of the consent, and protocol or research summary, and telephone number(s) are sent immediately to the Department of Pharmacy Services, and
   c) Copies are also maintained in the patient’s medical record (chart).
3. Prior to the administration of any dose, nursing sends the medication supply to the pharmacist, who determines that:
a) The medication is clearly and properly labeled, including directions for storage;
b) The contents of the container are positively identified (contact primary institution if necessary).

4. Self-administration of research drugs is not permitted.

5. Drug information pertinent to the safe and proper use of the investigational drug is available in the medical record.

6. An auxiliary label with the date and pharmacist’s initials is attached to the medication container to verify Procedure Statement 3 is complete.


8. The research drug is stored in the pharmacy whenever possible.
   a) If the medication is stored in the pharmacy, Form 143046, “Patients’ Drugs Stored in Pharmacy” is completed.
   b) One copy is inserted in the medical record and the remaining copies are attached to the drug.
      i) The medication is stored in the research section of the pharmacy.
         (1) Controlled substances are stored in the vault.
         (2) Medication is dispensed on reorder only.
         (3) Upon discharge, the medication will be signed for at the pharmacy window by the patient or their family, agent, or nurse.
   c) If the medication is stored on the nursing unit, it will be kept in the medication room or in the medication room refrigerator, whichever is appropriate.
      i) Research medications are not to be stored at the patient’s bedside unless they are locked.
      ii) Controlled substances will be stored in the Automated Dispensing Cabinets (ADC).

9. Registered nurses or other authorized staff may administer research medications, provided that they have a basic understanding of the research, protocol and drug effects.

10. In situations where the protocol is not immediately available and it would be detrimental to withhold the medication, the physician will be responsible for administration and will not delegate or assign this responsibility.

11. Administration is documented in EMAR (electronic medication administration record), if available, or in the patient’s medical record.

12. All original drug containers (bottles, vials, etc.) are to be kept with the drug supply and returned to the patient on discharge.

13. The pharmacist and/or the prescribing physician assist the patient’s family in obtaining additional drug supply from the primary institution, if necessary.

14. The following documents are submitted by the attending physician to the Maine Medical Center IRB within 5 working days:
   a) Complete research protocol or research summary (from the primary institution’s principal investigator)
   b) IRB letter of approval (from the primary institution’s principal investigator)
   c) Continuation of Treatment Form (from MMC pharmacy: Appendix B)
   d) Signed informed consent (from primary institution’s principal investigator).
Reference:
Adapted from Food and Drug Administration Information Sheets, Guidance for Institutional Review Boards and Clinical Investigators.
According to 45 CFR 46, Department of Health and Human Services Protection of Human Subjects
Related Policies: IRB policy SC 502, Categories of Research
ASHP Guidelines on Clinical Drug Research
AAHRPP- The Association for the Accreditation of Human Research Protection Programs

Original Date: 5/16/03

Review Date(s): 5/16/03, 8/16/04, 12/16/05

Committee(s) Approval and Date(s):
Pharmacy and Therapeutics Committee, 6/19/09
Institutional Policy Committee, 7/20/09

Approved By: ____________________________ Date: ___________
Director of Pharmacy

Approved By: ____________________________ Date: ___________
Vice President of Operations
APPENDIX A
CONTINUATION OF TREATMENT FORM

MMC As Secondary Institution for Research

The policy and procedures to be followed when a patient is admitted to MMC for continuation of research from another institution:

The principal investigator at the primary institution must assume the research involving an investigational agent (drug or device), while the research subject is at MMC (the secondary institution). The principal investigator at the primary institution must forward to the MMC investigator all pertinent documents the patient signed there, copies of the full protocol, and a cover letter to the MMC investigator of the intent to have research treatment continued at MMC. To remain in compliance with FDA regulations, all pertinent documents must be submitted to MMC IRB prior to any continuation of treatment at MMC. MMC investigator will then forward a copy of the MMC IRB approval for continuation of treatment to the primary institution. Within five (5) working days, the MMC physician will submit to the IRB a clinical updated report on the progress of the patient to the investigator treatment.

Date of MMC Admission: ________________________________
Patient’s Initials: ________________________________
Primary Institution: ________________________________
Primary Investigator’s Name: ________________________________
Investigator at MMC: ________________________________

I do acknowledge and accept the responsibility for supervising the continued use of investigational protocol, entitled:

________________________________________________________________________
________________________________________________________________________

(Signature of the Investigator at MMC) (Date)

I have reviewed copies of the study protocol, signed informed consent and IRB approval from the primary research institution. A copy of this agreement will be sent to the primary physician/institution.

_________________________ (MMC IRB Coordinator) __________________________ (Date)
Appendix B
Maine Medical Center Research Medication
Drug Information Guideline

This patient is enrolled in an investigational drug trial at another institution. Under the direction of their Maine Medical Center attending physician, they may continue their therapy while hospitalized (see Institutional Policy, Secondary Institution for Research).

This drug data sheet summarizes information pertinent to the use of the drug. Contact the attending physician, research pharmacist or pharmacy for further information.

Please read and sign this sheet prior to medication administration.

1. Drug designation and common synonyms:
2. Dosage form and strength:
3. Pharmacology:
4. Usual dosage range, including dosage schedule and route of administration:
5. Indications pursued in this study:
6. Specific aims:
7. Expected therapeutic effect to be studied:
8. Expected and potential adverse effects:
9. Interactions:
10. Contraindications:
11. Storage requirements:
12. Instructions for dosage preparation and administration:
13. Instructions for disposition of unused doses.

Signed: ________________________________ Name: ___________________________
Date: __________________________________

Signed: ________________________________ Name: ___________________________
Date: __________________________________

Signed: ________________________________ Name: ___________________________
Date: __________________________________