DEPARTMENT OF VETERANS AFFAIRS
South Texas Veterans Health Care System
San Antonio, Texas 78229-4404

Pharmacy Service
119PR-15-002
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RESEARCH PHARMACY STANDARD OPERATING PROCEDURES (SOP)
Handling of Investigational Antineoplastic Drugs

1. **PURPOSE**: To establish standard operating procedures (SOP) for those responsible for the control, distribution, preparation, dispensing, and protocol file maintenance of investigational antineoplastic drugs for the South Texas Veterans Health Care System (STVHCS).

2. **POLICY**: It is STVHCS policy that all study protocols involving investigational antineoplastic drug performed within STVHCS must be conducted in accordance with the responsibilities detailed under this SOP.

   a. The research pharmacist will notify the oncology clinical pharmacy specialist of upcoming study protocols involving antineoplastic drugs, concurrent medications, comparators, or rescue medications for adequate and timely review.

   b. The oncology clinical pharmacy specialist will provide support and guidance regarding any protocol involving antineoplastic drugs.

   c. The research pharmacist will be responsible for protocol review, the preparation of and final approval from the principal investigator for Evaluations of STVHCS Research Pharmacy Resources for Clinical Research.

   d. An oncology clinical pharmacy specialist will review protocols, informed consent forms, VA Forms 10-9012 and order sets of any study protocol involving investigational antineoplastic drugs prior to the initiation of a study protocol and address any questions or concerns to appropriate research staff and study personnel or the research pharmacist. Once reviewed, the oncology clinical pharmacist specialist will submit the revised forms, if applicable, back to the research pharmacist.

   e. Definitions

      (1) Antineoplastic: inhibits or prevents development, maturation and proliferation of malignant cells.

      (2) Comparator Drug: A comparator drug is an agent that the investigational drug(s) is being compared to in a clinical trial. A comparator drug may be the current standard of care for the disease state being studied.

      (3) Investigational Drug: An investigational drug is a chemical or biological drug that is used in a clinical investigation.

         a. An investigational drug can be:

1. A new chemical compound, which has not been released by the Food and Drug Administration (FDA) for general use, or

2. An approved drug that is being studied for an approved or unapproved use, dose, dosage form, administration schedule, or under an Investigational New Drug (IND) application, in a controlled, randomized, or blinded clinical trial.

b. Concurrent medications, comparators, or rescue medications used in the investigational trial that are not the drug(s) being studied are not defined as investigational drugs unless they are not commercially approved or not available through commercial channels. Prescription drugs, over-the-counter drugs, nutritional supplements, herbal preparations, and legend items used for diagnosis or treatment and meeting the definition in (a) above, are considered investigational drugs.

3. ACTION:

a. Investigational antineoplastic drugs that are received from a VA Affiliate

(1) Research Pharmacist

(a) The research pharmacist will maintain responsibility of these drugs as described in *Research Pharmacy Standard Operating Procedures (SOP) Investigational Drugs from a VA Affiliate.*

(b) The research pharmacist will operate in accordance with *Research Pharmacy Standard Operating Procedures (SOP) Handling of Investigational Drugs and Devices.*

(2) Oncology Clinical Pharmacy Specialist

(a) The oncology clinical pharmacy will defer to the research pharmacist regarding correspondence, drug management, accountability, processing and dispensing.

b. Investigational antineoplastic drugs provided by the principle investigator or sponsor and stored in the Research Pharmacy

(1) Research Pharmacist

(a) The research pharmacist will assume responsibility of protocol file maintenance and drug accountability for each study protocol involving investigational antineoplastic drugs as detailed in *Research Pharmacy Service SOP Handling of Investigational Drugs and Devices.*

(b) The Oncology Clinical Pharmacy Specialist will provide the research pharmacist with signed written orders prior to investigation drug preparation. The research pharmacist is then responsible for placing the electronic orders into VistA.

(2) Oncology Clinical Pharmacy Specialist

(a) The oncology clinical pharmacy specialist will assume responsibility for providing signed written orders to the research pharmacist.

(b) All investigational antineoplastic drugs will be compounded in the oncology pharmacy sterile IV room by the pharmacy technicians to be overseen by the oncology pharmacist.

c. Concurrent medications, comparator drugs considered the current standard of care, or rescue medications used in a study protocol

(1) Research Pharmacist

(a) The research pharmacist will defer to the oncology pharmacist regarding correspondence, drug management, accountability, processing and dispensing.

(2) Oncology Pharmacist

(a) All antineoplastic drugs, concurrent medications, comparators, or rescue medications dispensed and/or adminstered to a study participant that are not considered to be investigational drugs will be procured, received, stored, prepared, dispensed, disposed of and accounted for by the oncology pharmacy according to standard clinical practice.

4. **REFERENCES**: VHA Handbook 1108.04, Research Pharmacy SOP Investigational Drugs from a VA Affiliate, Research Pharmacy SOP Handling of Investigational Drugs and Devices.

5. **RESPONSIBILITY:** Chief of Pharmacy (119)

6. **RESCISSIONS:** None

7. **RECERTIFICATION**: December of 2019

PETER T. TRANG, RPh, MBA
Chief, Pharmacy Service