

MANAGEMENT OF INVESTIGATIONAL DRUGS PROCEDURES

OBJECTIVES: To outline the procedure for managing investigational drugs at the Atlanta VA

Prior to R & D Submission:

- About two weeks prior to submission, discuss the details regarding the study drug dispensing with the Clinical Research Pharmacist and provide a copy of the research protocol and Investigator Brochure for review and approval
- Complete and upload into ERRRP, a PI signed Assessment of Pharmacy Impact Form and send it to the Clinical Research Pharmacist. The Assessment of Pharmacy Impact Form is available at <http://www.atlaref.org/forms/vamc.cfm>
- Complete and upload into ERRRP then send to the Clinical Research Pharmacist, a PI signed Investigational Drug Information Record (VA Form 10-9012) for each drug that will be used in the clinical trial. VA Form 10-9012 is available at <http://www.atlaref.org/forms/vamc.cfm>

At time of approval

- The Clinical Research Pharmacist will review, approve and also sign the Assessment of Pharmacy Impact Form.

After receiving IRB and R&D approval:

- Provide a copy of the FDA 1572 Form (if applicable)
- If the PI is functioning as both the investigator and sponsor (IND holder) the PI must submit an IRB approved plan for fulfilling both investigator and sponsor responsibilities.
- Provide a copy of the IRB and R&D Committee approval letters and approved consent form to the Clinical Research Pharmacist
- Notify the Clinical Research Pharmacist of the Method of Disposition of Used and Unused Investigational Drug
- When drug is received by Pharmacy, contact the Research Pharmacist to set up the study drug(s) in the Research Medication Menu Option in CPRS. This usually takes 1 week for completion.

When a subject is enrolled:

- Provide a copy of the signed and dated Informed Consent Form to the Clinical Research Pharmacist for each enrolled subject before or when placing the first drug order
- Scan VA Form 10-9012 in CPRS (Computerized Patient Record System) upon each subject enrollment in the study. Send to Medical Records for scanning; accompanied by Research Documents Scanning Request.

During the study:

- Notify the Clinical Research Pharmacist of Serious or Unanticipated Adverse Events
- Provide the pharmacy with monthly scheduled dispense dates and times, subject ID, name and last four of social security number
- Provide the Research Pharmacist with updated versions of protocols, investigator brochures, informed consents and accompanying IRB and R&D approvals.
- If changes need to be made to the authorized prescribers, an updated 10-9012 should be provided to the Research Pharmacist
- Inform the Chief of the Pharmacy Service, the Research Pharmacist and the IRB in writing when a study involving investigational drugs has been suspended

At end of study:

- Notify the pharmacy of study termination and provide them with the IRB termination letter and R&D committee termination (if possible at this time)
- Notify pharmacy when study records are to be sent off-site so Pharmacy records can accompany

PROCEDURES FOR ORDERING INVESTIGATIONAL DRUGS:

The PI, or authorized person must have access to the "Research Medications" menu option in CPRS in order to place drug orders. Follow the instructions below:

- I. Select the patient for whom you are placing the order
- II. Select the Orders Tab in CPRS
- III. You will be prompted to enter a **PROVIDER**; select the PI. The PI will receive an "alert" to sign the order once it has been entered.
- IV. Select the Research Medications Menu Option
- V. Place orders for Investigational Drugs under the Research Clinic location assigned to your research study. (If the research participant is an inpatient CPRS will default to the inpatient location and you will not be prompted for this information)
- VI. If you do not have a specific Research Clinic for your study, place order under the "Research Study" clinic location in CPRS
- VII. Select the "Research Medications" menu option
- VIII. Click "OK" and the Research Medications menu will display a list with research study names and respective authorized prescribers

- IX. Select the research study for which you will place the Investigational Drug order. All drugs associated with the study will be displayed.
- X. Select the drug to be ordered
- XI. If multiple medications are ordered, hold the control key down and select (by clicking on each one) all drugs needed
- XII. The order screen for the medications will be displayed. If changes are needed in the dose or frequency, they can be made at this point
- XIII. If displayed information is correct, click on "Accept" and this will take you back to the main menu
- XIV. When finished ordering medications, select "Done" in the upper right corner
- XV. The new Order will be displayed in BOLD BLUE and will be ready to be signed
- XVI. The order will be placed and the PI will receive an alert in CPRS to sign the order
- XVII. Send an email (via PKI), or a fax to (404) 417-1809 to alert the Clinical Research Pharmacist that an electronic order has been placed

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