

MANAGEMENT OF INVESTIGATIONAL DRUGS PROCEDURES

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

Prior to R & D Submission:

- At least two weeks prior to R&D submission, schedule an appointment with the Clinical Research Pharmacist to discuss investigational drug dispensation. Please provide a copy of the protocol, the Investigator Brochure, the Assessment of Pharmacy Impact Form, and the Investigational Drug Information Record (10-9012) form for her review
- Ask Clinical Research Pharmacist to create Research Medication Menu in CPRS for all staff who will be ordering investigational drug
Clinical Research Pharmacist:

Anthony Alexander, Pharm. D.
Inpatient Pharmacy (119)
VA Medical Center (Atlanta)
1670 Clairmont Rd
Decatur, GA 30033
Tel: (404) 321-6111, ext. 204214
Fax: (404) 417-1809

E-mail: anthony.alexander@va.gov

R&D Submission:

- Upload the Assessment of Pharmacy Impact Form into IRBNet. It only needs to include the Principal Investigators signature. The other signatures will be obtained by the Research Pharmacist. A copy of the signed form will be uploaded into IRBNet by the AVAMC research office
- Complete the Investigational Drug Information Record (VA Form 10-9012) for each drug that will be used in the clinical trial. Add names of all the Authorized Prescribers in section 19. Obtain PI signature in section 20. Upload into IRBNet. Box 21 should be left blank and will be completed by the AVAMC Research Office
<https://www.va.gov/find-forms/about-form-10-9012/>

After receiving IRB and R&D approval:

- Provide a copy of the IRB and R&D Committee approval letters, the approved consent form, and FDA 1572 Form (if applicable) to the Clinical Research Pharmacist
- Receipt, storage, and distribution of the Investigational Drug are performed by the AVAMC Clinical Research Pharmacist. Study teams are not allowed to accept shipment of or store investigational drugs
- Once drug is received by the Research Pharmacy, contact the Research Pharmacist to set up 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

Dispensation:

- Insure that investigational drugs are used according to the approved investigational protocol
- Obtain kit number or study specific order number according to protocol instructions (i.e.: IVRS)
- PI or study staff places order in CPRS for the Investigational Drug. Please see instructions located on the AVAMC research website
https://www.va.gov/files/2022-04/INVESTIGATOR_ORDERING_DRUGS_IN_CPRS.pdf
https://www.va.gov/files/2022-04/COORDINATORS_ORDERING_DRUGS_IN_CPRS.pdf
- Complete the “Fax Template for Investigational Drug Orders” and fax to (404) 417-1809. Perform at least 24 hours in advance when possible.
https://www.va.gov/files/2022-05/FAX_TEMPLATE_for_INVESTIGATIONAL_DRUGS_20220419.pdf
- Research Pharmacy Technician will either deliver the investigational study drug directly to the study team or instruct study team to pick it up at the ground floor inpatient pharmacy, room GC331
- **Study team must confirm and verify correct study drug kit number and research subject’s name prior to dispensation to research subject.** Document in CPRS.
- Scan VA Form 10-9012 in CPRS (Computerized Patient Record System) upon each subject randomization by Research Documents Scanning Request form

During the study:

- Notify the Clinical Research Pharmacist of Related and Unanticipated Adverse Events
- Provide the pharmacy with monthly scheduled dispense dates and times, subject ID, name and last four of social security number
- Return all unused investigational drug and all bottles to the research pharmacy technician. The research pharmacy will perform drug accountability, keep records, and complete disposition according to study protocol and/or local destruction policy
- Investigational drug and/or containers with names and other identifiers must be stored in a locked cabinet in a locked office if stored temporarily in research offices. Study drug may not be kept in unsecured areas.
- Provide the Research Pharmacist with updated versions of protocols, investigator brochures, informed consents and accompanying IRB approval letters for the amendments.
- 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 – Close Out:

- Notify the pharmacy of study termination and provide them with the IRB termination letter and R&D committee termination letter
- Notify pharmacy when study records are to be sent off-site so Pharmacy records can accompany
- Return all unused investigational drug and all bottles to the research pharmacy technician.