

PROCEDURE FOR SCANNING THE INVESTIGATIONAL DRUG INFORMATION RECORD - VA FORM 10-9012

1. OBJECTIVES:

- a) Outline procedures for scanning the Investigational Drug Information Record VA Form 10-9012 in CPRS
- b) Provide additional protection for subjects who are participating in research studies involving drugs

2. RESPONSIBILITIES:

- a) The PI or designee is responsible for ensuring that the VA Form 10-9012 is scanned in CPRS right after a subject is randomized in a drug study

3. PROCEDURES:

- a) Before the Form 10-9012 can be scanned, a Research Clinical Progress Note must be entered in the patient's chart so the 10-9012 can be attached to the progress note
- b) Provide a good quality copy of VA Form 10-9012 with the subject's name and last four digits of the social security number on the Patient Identification Box and retain the original
- c) Complete a "Scanning Request for the Investigational Drug Information Record VA Form 10-9012"
- d) Deliver scanning requests to the Clinical Studies Center (CSC), room 11C119
- e) Forms are picked-up at the CSC Monday - Friday
- f) Scanned documents will be available in CPRS for viewing within 48 hours after being picked up
- g) The medical record scanning team will shred the copy after scanning
- h) The PI and Pharmacy keep a copy of VA Form 10-9012 filed in the study binder