

Detroit VA Medical Center Scope of Practice for Research Assistants/Coordinators

NAME	SERVICE LINE
PRINCIPAL INVESTIGATOR (PI) / PRIMARY SUPERVISOR	ALTERNATE SUPERVISOR (IF APPLICABLE)

The Scope of Practice is specific to the duties and responsibilities of each Research Assistant/Coordinator as an agent of the listed Principal Investigator and/or alternate supervisor. As such he/she is specifically authorized to conduct research involving human subjects with the responsibilities outlined below. The supervisor must complete, sign and date this Scope of Practice.

PROCEDURES:

A Research Assistant/Coordinator may be authorized to perform the following duties/procedures on a regular and ongoing basis. They may be performed without specific prior discussion/instructions from the Principal Investigator. The Research Assistant/Coordinator initials what is requested and Principal Investigator initials what is granted or not granted. Please see attached instructions before completing this section.

Routine Duties	<u>Requested</u>	<u>Granted</u>	OR	<u>Not Granted</u>
1. Screens patients to determine study eligibility criteria by reviewing patient medical information or interviewing subjects.	_____	_____		_____
2. Develops recruitment methods to be utilized in the study.	_____	_____		_____
3. Performs venipuncture to obtain specific specimens required by study protocol (requires demonstrated and documented competencies).	_____	_____		_____
4. Initiates submission of regulatory documents to WSU IRB, VA R&D committee and sponsor.	_____	_____		_____
5. Prepares study initiation activities.	_____	_____		_____
6. Provides education and instruction of study medication use, administration, storage, side effects and notifies adverse drug reactions to study site.	_____	_____		_____

	<u>Requested</u>	<u>Granted</u> OR <u>Not Granted</u>
7. Provides education regarding study activities to patient, relatives and Medical Center staff as necessary per protocol.	_____	_____
8. Maintains complete and accurate data collection in case report forms and source documents.	_____	_____
9. Initiates and/or expedites requests for consultation, special tests or studies following the Investigator's approval.	_____	_____
10. Obtains and organizes data such as tests results, diaries/cards or other necessary information for the study.	_____	_____
11. Demonstrates proficiency with VISTA/CPRS computer system by scheduling subjects research visits, documenting progress notes, initiating orders, consults, etc.	_____	_____
12. Accesses patient medical information while maintaining patient confidentiality .	_____	_____
13. Is authorized to obtain informed consent from research subject and is knowledgeable to perform the informed consent "process".	_____	_____
14. Initiates intravenous (IV) therapy and Administers IV solutions and medications	_____	_____
15. Collects and handles various types of human specimens	_____	_____

MISCELLANEOUS DUTIES (if applicable):

Mr./Ms. _____ is authorized to perform in the following miscellaneous duties not otherwise specified in this Scope of Practice.

1. _____
2. _____
3. _____

Research Assistant/Coordinator Signature

Date

PRINCIPAL INVESTIGATOR STATEMENT:

Mr. / Ms. _____'s Scope of Practice was reviewed and discussed with him/her on the date of _____. After reviewing his/her education, clinical competency, qualifications, research practice involving human subjects, peer reviews, and individual skills, I certify that he/she possesses the skills to safely perform the aforementioned duties/procedures. Both the research assistant/coordinator and I are familiar with all duties/procedures granted or not granted in this Scope of Practice. We agree to abide by the parameters of this Scope of Practice, all-applicable hospital policies and regulations.

This Scope of Practice will be reviewed every two years and amended as necessary to reflect changes in the research coordinator's duties/ responsibilities, utilization guidelines and/or hospital policies.

Principal Investigator/ Supervisor

Date

Alternate Supervisor

Date

Research Assistant/Coordinator

Date

OFFICE USE ONLY:

ACOS, R&D

Date

Human Resources Specialist
(If necessary)

Date