

Iowa City VA Health Care System Scope of Practice for Research Personnel Human Subjects Research

RESEARCH PERSONNEL NAME
PRINCIPAL INVESTIGATOR (PI) / PRIMARY SUPERVISOR

This Scope of Practice is specific to the duties and responsibilities of the above individual, as an agent of the listed Principal Investigator. The employee is specifically authorized to conduct research involving human subjects with the responsibilities outlined below. Under no circumstance may anyone perform research duties outside their approved Scope of Practice for research. The Principal Investigator remains responsible at all times for the conduct of the employee and must complete, sign and date this Scope of Practice.

PROCEDURES:

A Research employee may be authorized to perform the following duties and procedures on a regular and ongoing basis. They may be performed without specific prior discussion/instructions from the Principal Investigator. The Principal Investigator must check the appropriate box that pertains to the Research employees' position. The original signed copy of this document must be maintained in the employee's file in the Research and Development Office.

Routine Duties	Applicable	Not Applicable
1. Screens patients to determine study eligibility criteria by reviewing patient medical information or interviewing subjects. Comments/Exceptions:		
2. Develops recruitment methods to be utilized in the study. Comments/Exceptions:		
3. Performs venipuncture to obtain specific specimens required by study protocol (requires demonstrated and documented competencies Comments/Exceptions:		
4. Initiates submission of regulatory documents to IRB, VA R&D committee and sponsor. Comments/Exceptions:		
5. Prepares study initiation activities. Comments/Exceptions:		

Dated: 7/1/2013

6. Provides education and instruction of study medication use, administration, storage, side effects and notifies adverse drug reactions to the study site. Comments/Exceptions:		
7. Provides education regarding study activities to patient, relatives, and Health Care System staff as necessary per protocol. Comments/Exceptions:		
8. Maintains complete and accurate data collection in case report forms and source documents. Comments/Exceptions:		
9. Initiates and/or expedites requests for consultation, special tests or studies following the Investigator's approval. Comments/Exceptions:		
10. Obtains and organizes data such as test results, diaries/cards or other necessary information for the study. Comments/Exceptions:		
11. Demonstrates proficiency with VISTA/CPRS computer system by scheduling subjects research visits, documenting progress notes, initiating orders, consults, etc. Comments/Exceptions:		
12. Accesses patient medical information while maintaining patient confidentiality. Comments/Exceptions:		
13. Authorized to obtain informed consent from research subject and is knowledgeable to perform the informed consent "process". Comments/Exceptions:		
14. Initiates intravenous (IV) therapy and administers IV solutions and medications. Comments/Exceptions:		
15. Collects and handles various types of human specimens. Comments/Exceptions:		

Miscellaneous Duties (if applicable):

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

This Scope of practice for research does not grant you clinical privileges. If clinical privileges are needed, you will need to contact the research office for assistance.

PRINCIPAL INVESTIGATOR STATEMENT:

This Scope of Practice was reviewed and discussed. We certify that the employee possesses the skills to safely perform the aforementioned duties/procedures. We agree to abide by the parameters of this Scope of Practice and all applicable hospital policies and regulations.

This Scope of Practice will be reviewed **annually** and amended as necessary to reflect changes in the duties/responsibilities, utilization guidelines and/or hospital policies.

We understand that the employee must not perform any procedures which constitute the practice of the profession for which they may be eligible for but did not obtain a license, registration, or certification. For example, an unlicensed physician may not do any procedures that would be considered the practice of medicine (e.g., perform history and physical examinations, order or alter medication prescriptions, interpret laboratory results, give medical advice, etc.)

Employee Signature

Date

If you are the Principal Investigator completing this form, please sign as Employee and have your Supervisor/ Service Chief sign below

Principal Investigator/Supervisor

Date

Associate Chief of Staff for Research & Development

Date

ANNUAL REVIEW OF SCOPE OF PRACTICE

The Scope of Practice must be reviewed with necessary changes made if needed and signed on an annual basis. Please keep a copy and send the original to the VA Research Office (151).

Annual Review	Date
PI Sign _____ Employee Sign _____	
PI Sign _____ Employee Sign _____	
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