# **James H. Quillen VAMC**

##### Research Employee Scope of Practice

|  |  |
| --- | --- |
| 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 Employee 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.

*Note: Research Employees are not allowed to 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, e.g., an unlicensed physician may not do any procedures that would be considered the practice of medicine (e.g., perform history and physical examination, order or alter medication prescriptions, interpret laboratory results, give medical advice, etc.).*

**PROCEDURES:**

A Research Employee 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.

*Note: The Research Employee initials what is requested and the Principal Investigator initials what is granted or not granted.*

#### Not

**Routine Duties Requested Granted** *OR*  **Granted**

**1. Screens patients to determine study eligibility**

**criteria by reviewing patient medical information**

**or interviewing subjects. \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_**

**2. Demonstrates proficiency with VISTA/CPRS**

**computer system by scheduling subjects**

**research visits, documenting progress notes,**

**initiating orders, consults, etc. \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_**

**3. Accesses identifiable patient medical information**

**while maintaining patient confidentiality. \_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_**

**4. Develops recruitment methods to be utilized**

**in the study \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_**

1. **Performs venipuncture to obtain specific specimens**

**required by study protocol (requires demonstrated**

**and documented competencies) \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_**

**Requested Granted** *OR* **Not Granted**

1. **Initiates intravenous (IV) therapy and**

**administers IV solutions and medications \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_**

1. **Collects and handles various types of**

**human specimens \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_**

1. **Prepares and/or initiates submission of**

**regulatory documents to ETSU/VA IRB**

**and VA R&D committee and sponsor \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_**

1. **Provides education and instruction of study**

**medication use, administration, storage, side**

**effects, and notifies adverse drug reactions to**

**study site \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_**

1. **Provides education regarding study activities**

**to patient, relatives, and Medical Center staff**

**as necessary per protocol \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_**

1. **Maintains complete and accurate data**

**collection in case report forms and source**

**documents \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_**

1. **Initiates and/or expedites requests for**

**consultation, special tests, or studies**

**following the Investigator’s approval \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_**

1. **Obtains and organizes data such as test**

**results, diaries/cards, or other necessary**

**information for the study \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_**

1. **Is authorized to obtain informed consent from**

**research subject(s) and is knowledgeable to**

**perform the informed consent “process” \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_**

**MISCELLANEOUS DUTIES (if applicable):**

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

1.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Research Employee 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 employee 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 employee’s duties/ responsibilities, utilization guidelines and/or hospital policies.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator/ Supervisor Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Alternate Supervisor (if applicable) Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Research Employee Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

OFFICE USE ONLY:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

ACOS/Research & Development Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Chair, Clinical Executive Board (if applicable) Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical Center Director (if applicable) Date