### For Office Use Only

**Associate Chief of Staff, Research & Development is in agreement with the duties as outlined in this scope of work.**

# VA Portland Health Care System (VAPORHCS) Institutional Review Board

**IRQ Appendix L – Scope of Work (SOW)**

**Principal Investigator**:

**Project Title:**

**Study Number:**

Name of Employee:

Position/Role on Study:

* Is this a revised SOW for personnel already listed on this study? Yes  No
* Is the individual a student or trainee (e.g., resident or fellow) working on the research to fulfill educational requirements? Yes  No

If Yes, name of educational institution:

* Has the individual earned a new degree or obtained licensure or certification since the time they initially started working on VAPORHCS research? Yes  No  N/A – first study

If Yes, please submit a revised [Education Verification Form](http://www.portland.va.gov/research/documents/staff/education-verification-form.doc).

**This form should be completed by the principal investigator for each individual (including the PI) working on the VAPORHCS portion of the study identified on this form. *If the study includes another research site in addition to the VAPORHCS,* *the answers below should only apply to those procedures conducted on VAPORHCS time.***

#### PROCEDURES:

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| 1. Screens patients to determine study eligibility criteria by reviewing patient medical information or interviewing subjects. |  |  |
| 1. Is knowledgeable of the informed consent process and will obtain informed consent from research subjects for this study (e.g., signed consent and/or informed consent under a waiver of documentation). |  |  |
| 1. Provides education and instruction to subjects or relatives regarding details of study. |  |  |
| 1. Administers questionnaires or conducts mental status or psychosocial exams. |  |  |
| 1. Provides education and instruction to subjects or relatives regarding study medication, including use, administration, storage, side effects and reporting adverse drug reactions to study site. |  |  |
| 1. Prescribes and renews study medication. (If Yes, this individual should be included on the Investigational Drug/Information Record, VA Form 10-9012). |  |  |
| 1. Has responsibility for reviewing laboratory data and other entries in the medical record for the purpose of identifying possible adverse events. |  |  |
| 1. Performs venipuncture. |  |  |
| 1. Places intravenous (IV) lines and administers IV treatment. |  |  |
| * 1. If yes, describe training and steps taken by PI to ensure competency: | | |
| 1. Collects, organizes and/or analyzes documents/data outlined in the IRB-approved protocol. |  |  |
| 1. Uses Electronic Health Record (e.g., CPRS, ERNER) to:  * enter research progress notes, * extract data specified by the IRB-approved protocol, * schedule return visits, and/or * order lab tests, etc. (if non-physician, requires written document from physician)   ***NOTE:****Any entry into the Electronic Health Record recording a laboratory test interpretation, adverse outcome diagnosis, medication prescribing/renewal, physical/mental examination that could be used for clinical care, and/or invasive procedure by a member of the study team who is not licensed, credentialed and privileged to perform those procedures must be co-signed by the PI or the responsible clinician.* |  |  |
| 1. Handles or analyzes **specimens** labeled with any of the 18 HIPAA identifiers or a code number for which the employee has access to the code key (i.e., identifiable specimens). |  |  |
| 1. Ships biological materials (identified or de-identified).   **NOTE:** If Yes, the employee must complete the Biosafety Training located on the Research Office website. |  |  |
| 1. Works with identifiable **data** and/or works with data that is coded and the employee has access to the code key. |  |  |
| 1. Works **only with de-identified** specimens and/or data. |  |  |
| 1. Will work on this project on VAPORHCS property and/or using VAPORHCS resources (e.g., remotely accessing VAPORHCS network). |  |  |
| 1. Interacts with subjects by performing physical examinations or procedures other than those outlined above. |  |  |
| * 1. If yes, list the exam(s)/procedures to be performed:   2. Is the provider credentialed through VETPRO for the exam(s)/procedures? | | |
| 1. Will work on other activities under this protocol not captured by the questions above. |  |  |
| 1. If yes, please describe: | | |

**Employee Assurance**

The principal investigator has discussed all duties/procedures in this Scope of Work with me. I have the necessary training to perform these duties/procedures. I will not engage in duties/procedures for this research project beyond the parameters described here unless this form is amended with all appropriate signatures.

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**Signature of Employee Date**

*(If this Scope of Work is for the PI, sign at “Signature of Principal Investigator” only)*

**Principal Investigator Assurance:**

As supervisor of all employees participating in this project I assure the following:

* I have reviewed the employee’s education, training, and experience detailed in the employment application, licensure or certification as applicable, and references.
* I have provided training specific to this protocol.
* I have discussed all duties/procedures in this Scope of Work with the employee.
* I have reviewed the Code of Conduct Statement for Research with the employee, and I understand my role in maintaining a safe and respectful research environment.
* This employee possesses the skills to safely perform the Scope of Work requested here.
* I have counseled the employee that his/her role in this research project cannot extend beyond the parameters described here.
* I will review the contents of this form on a yearly basis to ensure continued accuracy.
* I will amend this form prior to any change in duties for the employee.

This form outlines my own personal involvement in this project with subjects or their protected health information.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Principal Investigator Date**

**Keep a copy of the signed form for your records**