**Human Research Education Requirements**

**Research Education for Research Staff Engaged in Human Subjects Research Projects at the [INSERT FACILITY INITIALS HERE]**

1. **Objectives:**
2. To ensure that all persons within the VHA research program are qualified and meet all VA research educational requirements.
3. To detail the duties and responsibilities, through the completion of a research Scope of Practice (ScOP), of personnel who have direct or indirect contact with patients and who have access to Protected Health Information (PHI).
4. This process supplements the current medical center credentialing process for physicians, residents, nurses and other clinical staff.
5. **Types of Personnel Engaged in Human Subjects Research:**
6. Principal Investigator: Responsible for all aspects of the research project.
7. Personnel with direct contact: Employees who perform procedures, interviews, telephone calls to research subjects, or clinical interventions with patients during the conduct of a research project.
8. Personnel with indirect contact: Employees, who do not interact directly with patients, but manage and/or collect study data and PHI (i.e. retrospective chart review), or handle previously collected human specimens, for research purposes.

**3. Responsibilities:**

1. VA research education must occur prior to beginning any research duties and/or contact with patients.
2. Principal Investigators (PI) and other research personnel, who are part of a research team engaged in the conduct of research involving human subjects, must be authorized by [INSERT FACILITY INITIALS HERE] Research Service. This applies to all personnel regardless of the source of compensation (affiliate, VA, non profit, or other entity) or type of appointment (VA paid or Without Compensation).
3. The PI must complete a Research ScOP outlining the specific research-related duties that will be delegated to research personnel. The PI and all Co-Investigators are also required to complete a ScOP.

**4. The Research Scope of Practice (ScOP):** The documentation of duties requested by personnel engaged in human subjects research and is granted by the PI.

1. Is reviewed at least annually to ensure that it remains appropriate.
2. Is updated when new duties are assigned or others deleted.
3. Is signed by research staff, PI, & ACOS for Research.
4. Assignment is appropriate as it relates to education, experience, and training of individual.
5. It is mandatory that research staff do not perform any duties or practice beyond what is allowed in the ScOP. For example, if your ScOP does not list that you are permitted to obtain consent, then you are not permitted to obtain consent.

**5. [INSERT FACILITY INITIALS HERE] Research Education and Training Coordinator:** The Coordinator is the Atlanta contact for becoming VA research credentialed. She manages the credentialing process and assigns courses and forms. The courses and forms are dependent upon what the research duties are, if there is direct or indirect contact with human subjects, if there are biological specimens, and if there are licensed personnel. Research staff begins the credentialing process by registering on the AREF website: <http://www.atlaref.org/> .

All research personnel engaged in Human Subjects Research take (as applicable to the research):

A - TMS - VA Privacy and Information Security Awareness and Rules of Behavior Course

B - TMS - Infection Control: Bloodborne Pathogens and Tuberculosis

C - TMS - Privacy and HIPAA – if direct contact or access to PHI

D - CITI Biosafety for personnel that handle biological specimens (phlebotomy/CSC lab)- annually

E - CITI VA Human Research Modules

**EXAMPLES:**

1. If a researcher intends to conduct a research healthcare survey in the lobby of the facility that collects identifiable information from subjects, he/she would need to be trained in A, C, D, and E.
2. If a researcher will be collecting biospecimens (venipuncture), he/she is required to complete all modules (A-E).

CITI training is required every three years and TMS training is required annually.

Contact info: *insert education and training contact information.*

**6. VetPro:**

1. VetPro is an Internet-enabled data bank for the credentialing of VHA health care providers that facilitates completion of a uniform, accurate, and complete credentials file.
2. All licensed research staff or those with the ability to obtain a license must undergo the VetPro credentialing process. This pertains to MDs, RN, NPs, PAs, LPNs, LCSWs and other licensed personnel.
3. Must be Vetpro’d before engaging in direct contact with patients.
4. Must be Vetpro’d if VA paid
5. Must be VetPro’d if research project has a VA off-site waiver and staff members are seeing study subjects at that site.
6. Must be VetPro’d if you are [affiliate name] staff and study subjects are only signing VA ICF and not an [affiliate name] ICF.
7. Don’t need to be VetPro’d if you are [affiliate name] staff and seeing VA patients ONLY at [affiliate name]. Study subjects in this case are signing both an Emory and VA ICF.

**7. Registered Nurses:**

1. Must be Vetpro’d
2. May perform office duties while waiting for Vetpro if:
	1. Vetpro process has been initiated
	2. Are VA research credentialed
	3. Have immunizations record verified by [INSERT FACILITY INITIALS HERE] Occupational Health Services
	4. All required TMS trainings are completed
	5. Are listed in eIRB as study staff
	6. No shadowing permitted
	7. Scope of Practice specifically lists only office duties that do not involve interacting with study subjects. (i.e. protocol submissions, protocol review, attend sponsor meetings). Once Vetpro’d, Scope of Practice should be changed to reflect engagement in direct patient contact. Send to facility POC for education.
	8. Access to PHI is allowed

**8. Human Studies Orientation (HSO):**

* HSO is a 3 hour course that is held at the [INSERT FACILITY INITIALS HERE] on the second and fourth Thursday of each month. This course reviews PI responsibilities, research staff responsibilities, and all [INSERT FACILITY INITIALS HERE] policies and procedures that pertain to Human Subjects research.
* All research personnel engaged with human subjects research are required to take this course.
* All VA PIs, VA Co-Investigators, and Pharm D’s are required to take this course, regardless if they have direct or indirect human contact.
* May be eligible for a waiver if: processing lab specimens, statisticians, data analysts

**9. Engaged in VA Human Subjects Research:**

* You are engaged in VAHuman Subjects research if performing research duties at the [INSERT FACILITY INITIALS HERE] OR,
* You are engaged in VA Human Subjects research if you are funded by a VA project OR,
* You are engaged in VA Human Subjects research if you are participating in a project that has an approved off-site waiver OR,
* You are engaged in VA Human Subjects research if performing research specific duties that are not part of normal tour of duty (i.e. ICU nurse implementing research survey) OR,
* You are engaged in VA Human Subjects research if listed in a protocol application as VA research staff

**10. Not engaged in VA Human Subjects Research:**

* You are not considered engaged in VA Human Subjects research if you are performing your normal clinical duties during your normal tour of duty (i.e. oncology nurse hanging investigational chemotherapy drug, research pharmacist, phlebotomist, ECG technician, interventionalist collecting clinical specimens)
* You are not considered engaged in VA Human Subjects research if you are not listed on the research protocol. However, there are some situations where you need to be provided and read a copy of the research protocol to understand the limits of what you are being asked to do.

EXAMPLES:

* + 1. You are a pharmacist who has been asked to distribute a medication in support of the protocol
		2. You are an interventionalist who has been asked to collect clinical specimens for research
		3. Oncology nurse hanging an investigational drug

**11. IRB**

* Clearly state where research staff will be engaged in research on initial submission and on amendments. See staff matrix below.
* Do not list research staff members in eIRB if not accessing PHI and not interacting with patients

Example of Staff Matrix.

|  |  |  |
| --- | --- | --- |
| **Study Staff** | **VA**  | **Emory** |
|  |  |  |
| **Dr. Zack Smith** | **X** | **X** |
| **Judy Coordinator** | **X** |  |
| **John Coordinator** |  | **X** |
| **Sally statistician** | **X** | **X** |
|  |  |  |

**Appendix 1 Scope of Practice Application**

**SCOPE OF PRACTICE FOR RESEARCH STAFF**

This Scope of Practice is specific to the research duties and responsibilities granted to staff by the listed Principal Investigator (PI) and/ or secondary supervisor for the term of the appointment. The scope of practice is not intended to replace the clinical scope of practice.

**Section A: General Information**

|  |  |
| --- | --- |
| **EMPLOYEE’S NAME**  | **EMPLOYEE’S TITLE** |
|  |  |
| **PRINCIPAL INVESTIGATOR (PI)** | **SECONDARY SUPERVISOR:** |
|  |  |
| **VA CREDENTIALING & PRIVILEGING**  | **LICENSURE TYPE**  |
|  Are you currently credentialed and privileged at the Atlanta VAMC to perform patient care activities?  [ ]  YES [ ]  NO**If yes, please amend your clinical scope of practice with Human Resources Credentialing** | Are you a licensed professional? [ ]  Yes [ ]  NO If yes, indicate type of license:[ ]  MD [ ]  NP [ ]  RN [ ]  Other (specify):      |
| **SELECT ONE OF THE CHOICES BELOW TO DETERMINE EMPLOYEE ENGAGEMENT STATUS** |
| **[ ]  ENGAGED IN HUMAN SUBJECTS RESEARCH is defined as** research employees who perform procedures, interviews, telephone calls to research subjects, clinical interventions with patients, manage identifiable study data, have access to medical records, or handle identified human specimens, for research purposes.  | **[ ]  NOT ENGAGED: REGULATORY ONLY – NO PHI** Research employees who prepare/maintain regulatory study documents only and have no access to PHI  |
| **[ ]  NOT ENGAGED: DE-IDENTIFIED DATA ANALYSIS ONLY** Research employees who only manage and analyze de-identified research data and will not have access to PHI.  |

**Section B: Role Description**

|  |
| --- |
| **Investigator, please briefly describe the employee’s role on the study (i.e. what they will be doing on a day-to-day basis). Please also include any miscellaneous duties which may not be covered in section C.**  |
|  |

**Section C: Delegation of Duties – Review and discuss with your supervisor**

The PI may or may not grant permission for the research employee to perform the duties listed below. Some duties may require additional credentialing and competencies. Review and discuss duties listed below with your supervisor. The employee should initial duties requested and the PI must initial duties granted and not granted.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Research-Related Duties** | **Employee****Requested** | **PI****Granted** | **PI****Not Granted** |
|  | **Prepares regulatory documents** for the IRB, R&DC and the study sponsor and organizes study binder. |  |  |  |
|  | **Prepares study initiation** **activities** and materials, etc. |  |  |  |
|  | **Screens research subjects** to determine study eligibility criteria by reviewing their electronic medical record  |  |  |  |
|  | **Recruits research subjects** and/or provides education about study activities to research subjects, relatives and Medical Center staff. |  |  |  |
|  | **Obtains Written Informed Consent** from research subjects |  |  |  |
|  | **Collects Data** and records in the case report forms and source documents |  |  |  |
|  | **Manages and/or analyzes study data** |  |  |  |
|  | **Documents Research encounters** in the research subjects Computerized Patient Medical Record (CPRS) |  |  |  |
|  | **May initiate an order for research-related tests/procedures in CPRS** |  |  |  |
|  | **May initiate/transcribe an order for an investigational drug in CPRS**  |  |  |  |
|  | **Posts Research Flags in the patient’s medical record** (when required by R&D Committee) |  |  |  |
|  | **Provides study medication** to participants and instructions about use, storage and potential side effects of the study drug. In addition, keeps accurate drug accountability records |  |  |  |
|  | **Obtains and records vital signs** (requires competencies) |  |  |  |
|  | **Obtains biological specimens** from research subjects |  |  |  |
|  | **Performs venipuncture** (requirescompletion of phlebotomy training with CSC Manager, Jane Guidot) |  |  |  |
|  | **Other Clinical interventions/duties:** (specify and all lines as necessary) |  |  |  |
|  | **Handles reimbursement procedures** for research subjects |  |  |  |

**Section D: Research Participation Eligibility Determination and Acknowledgement**

In order to participate in Research at the [Insert Facility Name Here] Healthcare System all staff must currently be in possession of, or have the ability to obtain, one of the appointments listed below. Please initial next to your applicable appointment type.

**VA Paid Staff**

* Paid by Research Service Line: **\_\_\_\_\_\_\_\_\_\_**

I am or will be hired by the Atlanta VA HCS through the Research service line. Upon the termination of my employment, I will notify the Research Office and cease all research activities and/or access to research data.

* Paid by Other AVAHCS Service Line: **\_\_\_\_\_\_\_\_\_\_**

I am or will be hired by the Atlanta VA HCS through the \_\_\_\_\_\_\_\_\_\_\_\_\_\_ service line. However, I have protected time for participation in Research activities. I will only participate in Research activities during my protected time. Upon the termination of my employment, I will notify the Research Office and cease all research activities and/or access to research data.

**Affiliate**

* Medical Fellow, Resident or Rotating Medical Student: **\_\_\_\_\_\_\_\_\_\_**

I am a current medical fellow, resident or medical student on clinical rotations at the Atlanta VA Healthcare System and have been onboarded by the Education service line. Upon graduation, I will notify the Research Office and cease all research activities and/or access to research data.

**Intergovernmental Personnel Agreement (IPA)**

* Paid via IPA: **\_\_\_\_\_\_\_\_\_\_**

I am currently being paid via an Intergovernmental Personnel Agreement between my institution and the Atlanta VA HCS. When/if my IPA is terminated, I will cease all Research activities and will no longer access any Research data. If I will continue to be paid for my participation in research, not through an IPA, I will work with the Research Office to secure a WOC appointment.

**Without Compensation Appointment (WOC)**

* Paid by Other Entity (AREF, CDC, Affiliated Academic Institution): **\_\_\_\_\_\_\_\_\_\_**

I am an employee of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and will be compensated for my participation in Research service. I have obtained or am in the process of obtaining a WOC appointment through Research Service. Upon the termination of my employment, I will notify the Research Office and cease all research activities and/or access to research data.

* Licensed Medical Doctor: **\_\_\_\_\_\_\_\_\_\_**

I am a Licensed Physician that is not paid by the Atlanta VA Health Care System. However, I have been credentialed and obtained a WOC appointment through one of the clinical service lines at the AVAHCS. Upon the termination of my WOC appointment, I will notify the Research Office and cease all research activities and/or access to research data.

* Student at Affiliated University (Emory, GT, GSU, Morehouse SoM): **\_\_\_\_\_\_\_\_\_\_**

I am currently an undergraduate or graduate student at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ with an anticipated graduation date of \_\_\_\_\_\_\_\_\_\_\_. I have obtained or am in the process of obtaining a WOC appointment through Research Service. Upon graduation or termination of my enrollment, I will notify the Research Office and cease all research activities and/or access to research data.

**Section E: Certifications**

**NOTICE TO LICENSED PROFESSIONALS:**

Licensed professionals should be credentialed by VA Human Resources – Credentialing Office. Individuals found to be working outside their privileges as granted by the Atlanta VAMC will be subject to disciplinary action.

**PHLEBOTOMY TRAINING:**

If you requested to perform venipuncture in Section C., you must attend phlebotomy training by scheduleing with [insert site contact here]. You may not perform venipuncture until you have competed this training.

**LAB TRAINING:**

If you will be handling biological specimens at any point while working on a research study additional training and paperwork is required. Please contact [Insert facility POC here] to ensure you have completed these requirements.

**RESEARCH EMPLOYEE’S STATEMENT:**

This Scope of Practice outlines the duties and responsibilities regarding research study conduct delegated to me by the Principal Investigator. The Principal Investigator and I are familiar with all the duties and procedures granted in this Scope of Practice. I agree to abide by the parameters of this Scope of Practice and all-applicable VA policies and regulations. I agree to amend my Scope of Practice as required and at any time my research duties change.

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

Research Employee’s Signature Date

**PRINCIPAL INVESTIGATOR’S STATEMENT:**

This Scope of Practice was reviewed and discussed with my employee on the date shown below. I certify that this employee possesses the skills to safely perform the duties and procedures as lsited. Both the employee and I are familiar with all duties and procedures granted in this Scope of Practice. We agree to abide by the parameters of this Scope of Practice, all-applicable hospital policies and regulations. The PI is responsible for amending this scope as necessary to reflect changes in the employee’s research duties and responsibilities and/or appointment status.

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

Principal Investigator  Date

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

Secondary Supervisor  Date

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

**OFFICE USE ONLY**

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

Manager, Clinical Studies Center Date

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

ACOS for Research Service Line Date