

RESEARCH EMPLOYEE SCOPE OF PRACTICE FORM

Durham VA Health Care System

PURPOSE: This SOP outlines general tasks that the research employee is permitted to perform under the supervision of a PI(s) in conjunction with an approved protocol(s). An individual must submit a new SOP if there are changes in his/her duties/responsibilities, credentials, licensure, etc. **All research personnel (paid employees, WOC employees, and IPA employees) must have a current Employee SOP before they can participate in any research-related activities.**

BY SIGNING THIS FORM, YOU ARE ACKNOWLEDGING THE FOLLOWING:

1. The research staff that performs any activity or duty in the conduct of research that requires clinical privileges already holds those clinical privileges or will obtain those clinical privileges from the Durham VA Health Care system as either a license independent practitioner or dependent practitioner.
2. The duties outlined in this form will not be performed by this employee before they confirm that this form has all the appropriate signatures, including the signature of the Associate Chief of Staff of Research and Development (ACOS/R&D).
3. Any changes to employee duties will be submitted to R&D for review before any of those duties are executed.
 - a. **Changes to the list of PIs** the employee works with can be submitted via a PI Update form
 - b. **Changes to any of the duties outlined here** will be submitted via a new Employee SOP form.
4. The research employee and their direct supervisor have discussed and determined the duties the employee may perform and have documented this agreement by completing this form
5. Each Principal Investigator is responsible for the conduct of his/her study and must sign that s/he agrees that the employee is capable to perform the assigned duties for those protocols in which s/he acts as the Principal Investigator. Regardless of supervisor, the Principal Investigator assumes all responsibility for the conduct of staff and for research performed under their protocol.
6. All research personnel must have a current Research SOP before they can participate in any research-related activities. Any research staff member or Principal Investigator that performs any activity or duty in the conduct of research that requires clinical privileges must already hold those clinical privileges or must obtain those clinical privileges from the Durham VA Medical Center as either a licensed independent or dependent practitioner.
7. Any research staff who collect patient vital signs and/or performs venipuncture must be up-to-date on the annual trainings required to perform these research functions. **Employees who collect vital signs and/or draw blood from patients must submit a signed competency checklist form(s) (attached to the end of this document) with this Employee Scope of Practice form.**
8. Individuals are responsible for keeping records of their SOP with their signature, their supervisor's signature, and all applicable PI signatures.

Please direct all questions about this form, as well as completed forms, to Ida Crew (Ida.Crew@va.gov) in the Research and Development Service.

Employee Name (Print)	Employee E-mail Address
Degree(s)	Licensure
List:	List:
Employee Type	Direct Supervisor (Print name)
VA-paid WOC IPA Other	

My duties require me to...	YES	NO	If yes, complete:
...work with human research subjects			Section A
...work with animal research subjects			Section B
...work in a laboratory setting			Section C
...work with multiple Principle Investigators			Section D
...collect patient vital signs or blood samples			Section(s) F and/or G

***Please make sure you complete all relevant sections based on your selections above.**

SECTION A: HUMAN RESEARCH

HUMAN RESEARCH DUTIES	Employee	Supervisor
1. Prepare study initiation activities.		
2. Prepare/submit required documents for committee review.		
3. Develop recruitment methods.		
4. Screen patients to determine study eligibility by accessing PHI and/or by interviewing potential research subjects.		
5. Use VistA/CPRS to manage research subjects per the research protocol.		
6. Obtain informed consent and utilize the informed consent/HIPAA process.		
7. Provide education regarding study activities to patients, relatives, and Medical Center staff as necessary per protocols.		
8. Obtain and organize data such as tests, results, diaries or other necessary information, per assigned protocols		
9. Maintain or facilitate complete and accurate data collection for relevant source documents and reports.		
10. Provide education and instruction on health behaviors, or similar activities covered by written instructions to be conveyed to the study participant.		
11. Provide education and instruction of study medication use, administration, storage, and side effects.		
12. Delivery of study medication after being ordered by a clinician and dispensed by a pharmacist.		
ACTIVITIES THAT MAY RESULT IN EXPOSURE TO HUMAN BLOOD, BODY FLUID, OR TISSUES		
13. Collection and handling of human specimens.		
14. Transporting human specimens within the medical center.		
15. Collect patient vital signs. <i>**If box is checked, complete and submit the Durham VAMC Research Vital Sign Competency Initial and Annual Review Checklist (Section F).</i>		
16. Perform venipuncture. * <i>*If box is checked, complete and submit the Durham VAMC Research Blood Collection Competency Initial and Annual Review Checklist (Section G).</i>		
STATISTICAL AND DATA MANAGEMENT		
17. Access PHI to perform statistical analysis or programming to produce reports and create data sets as needed. <i>All confidentiality rules and procedures apply.</i>		
18. Provide statistical and/or programming support per protocol(s).		
19. Provide computer (hardware & software) support per protocol(s).		
HUMAN RESEARCH MISCELLANEOUS DUTIES AND PROCEDURES		
Describe:		

SECTION B: ANIMAL RESEARCH

HUMAN RESEARCH DUTIES	Employee	Supervisor
1. List species used:		
2. Animal handling.		
3. Animal husbandry activities.		
4. Euthanasia.		
5. Clinical observations.		
6. Recognize signs of pain/distress.		
7. Identify humane endpoints.		
8. Dosing. List routes:		
9. Blood collection. List routes:		
10. Tissue collection.		
11. Animal ID. List type:		
12. Use of infectious, toxic, or hazardous agents.		
13. Surgery, according to protocol.		
ANIMAL RESEARCH MISCELLANEOUS DUTIES AND PROCEDURES		
Describe:		

SECTION C: LABORATORY RESEARCH

LAB RESEARCH DUTIES	Employee	Supervisor
1. Set-up, operate and maintain laboratory equipment. List:		
2. Keep inventories of laboratory supplies.		
3. Order supplies.		
4. Carry out research activities typically performed in a biochemistry or molecular biology lab.		
5. Use of radioactive materials. List:		
6. Use of infectious agents. List:		
7. Use of Recombinant DNA. List:		
8. Use of toxic, hazardous agents. List:		
9. Use of Viral Vectors. List:		
10. Preparation and processing of biological specimens.		
11. Perform cell and tissue culture.		
12. Preparation and processing of animal specimens.		
13. Prepare culture media, chemicals, reagents and solutions.		
14. Perform analytical procedures. List:		
15. Store specimens.		
16. Record data and maintain documents/reports.		
LAB RESEARCH MISCELLANEOUS DUTIES AND PROCEDURES		
Describe:		

SECTION D: PI SIGNATURES

Instructions: The PI for any study for which you have research-related duties must review and agree with the research-related duties permitted to you by your Supervisor. To indicate PI agreement, print the PI name and obtain the PI’s signature and date.

PI Printed Name	PI Signature

*Please remember that the R&D service needs to be notified if any PIs are removed or added to this list. Please use the “Research Scope of Practice: PI Update” form on the DURVAHCS research website **if the only update you need to make is to your list of PIs**. Any changes to employee research duties require the submission of a new Scope of Practice form.

SECTION E: SUPERVISOR, EMPLOYEE, and ACOS/R&D STATEMENTS

Supervisor Statement: This Scope of Practice was reviewed and discussed with the employee on the date shown below. After reviewing the education, competency, qualifications, relevant research experience, peer reviews, and individual skills, I certify that this employee possesses the skills to safely perform the aforementioned duties and procedures. 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 and all applicable hospital policies and regulations.

Printed Supervisor Name	Job Title
Supervisor Signature and Date	

Research Employee/Appointee Statement: This Scope of Practice outlines general tasks I am permitted to undertake in conjunction with an approved protocol. I understand that all research must be approved by the appropriate Durham VAMC research committee(s). If I have questions or concerns, I am encouraged to contact the Durham VAMC Research Office. I also understand that performing tasks beyond this scope of practice, without specific authorization, may lead to disciplinary action. Both my supervisor and I are familiar with all duties and procedures granted in this Scope of Practice. I agree to abide by the parameters of this Scope of Practice and all applicable hospital policies and regulations.

I understand that the research scope of practice cannot be construed to authorize any activities or duties that require clinical privileges at the Durham VA Medical Center unless I hold those clinical privileges as either a licensed independent practitioner or dependent practitioner as granted by the Durham VA Medical Center.

I shall use, disclose, or request protected health information (PHI) to the **minimum amount necessary** to perform my specific job function and to accomplish the intended purpose of the use, disclosure, or request.

Printed Employee/WOC/IPA Name	Job Title
Employee/WOC/IPA Signature and Date	

ACOS/R&D Statement:

I certify that this employee is working within his/her scope of practice and his/her privileges allowed by the Durham VAMC.

Printed ACOS/R&D Name	Job Title
John D. Whited, MD, MHS	ACOS/R&D, Durham VAMC
ACOS/R&D Signature and Date	

*Please note that an employee cannot execute any research duties described on this form before it is signed. Signed Scope of Practice forms will be placed in the following folder:

Please direct any questions or completed Scope of Practice forms to Ida Crew (Ida.Crew@va.gov) in the Research and Development service.

SECTION F: VITAL SIGN COMPETENCY

Durham VAMC Research Vital Sign Competency Initial and Annual Review Checklist^{1,2}

*EXEMPT/Licensed Independent Practitioner

Research staff member: _____
Printed Name Signature Date

_____ (*initials*) The requirement to complete this competency does not apply because I am currently subject to an annual competency (e.g., a RN). If this waiver applies, you only need to submit this document ONE TIME unless the status of your waiver changes.

If the above waiver does not apply, observe the research staff member perform the following activities. If proficiency is demonstrated check proficient and initial. Complete each section, as applicable for each staff member authorized to collect vital signs.

Preceptor: _____
Printed Name Signature/Date

1. General Activities (Required Field).

Technique	Proficient	Initials
Gather proper equipment		
Perform proper hand hygiene		
Identify research subject		
Inform research subject of procedures to be performed		

2. Blood Pressure (Manual). If not applicable check here:

Technique	Proficient	Initials
Place research subject in proper position		
Place cuff on arm oriented correctly over the brachial artery		
Place manometer so dial can be visualized		
Place stethoscope in ears		
Inflate cuff to appropriate pressure (beyond a palpable pulse)		
Place stethoscope diaphragm over brachial artery		
Deflate cuff evenly (approx. 2-4 mm per second)		
Note pressure where first sound is heard (systolic)		
Note pressure where sound disappears (diastolic)		
Deflate and remove cuff, record BP		

¹ Licensed Independent Practitioners (e.g., M.D.), including Residents, holding core privileges to collect vital signs are exempt from completing this competency checklist and are not required to submit this document to the DVAMC Research Office.

² Completion of this form does not constitute training.

3. Blood Pressure +/- Pulse Rate (Electronic). If not applicable check here: __

Technique	Proficient	Initials
Place research subject in proper position		
Place cuff on arm oriented correctly over the brachial artery		
Per device specifications, activate cuff inflation and deflation		
Read blood pressure results from device		
If applicable, read pulse rate results from device Not applicable: _____		
Remove cuff, record BP and pulse		

4. Measuring Temperature (Tympanic/Oral). If not applicable check here: __

Technique	Proficient	Initials
Insert cover onto probe		
Insert covered probe under tongue/in ear canal		
Wait for completion signal (mouth) Activate the device for reading (ear)		
Read temperature results from device		
Remove probe and discard cover and record results		

5. Measuring Pulse (Manual). If not applicable check here: __

Technique	Proficient	Initials
Place research subject in proper position		
Palpate an appropriate and available artery (e.g., brachial or radial) with fingertips		
Count pulse for one minute or fraction of a minute with appropriate multiplier		

6. Measuring Respirations. If not applicable check here: __

Technique	Proficient	Initials
Place research subject in proper position		
Count respirations for one minute or fraction of a minute with appropriate multiplier		

Submit this form at **Initial Review and annually thereafter, or when adding vital sign collection authority** for all staff members authorized by the Principal Investigator to collect human vital signs.

SECTION G: BLOOD COLLECTION COMPETENCY

Durham VAMC Research Blood Collection Competency Initial and Annual Review Checklist^{1,2}

Research staff member: _____
Printed Name Signature/Date

_____ (*initials*) The requirement to complete this competency does not apply because of at least one of the following: (a) I am currently subject to an annual competency (e.g., a RN), (b) I am employed as a phlebotomist by Pathology and Laboratory Medicine. If this waiver applies, you only need to submit this document **ONE TIME** unless the status of your waiver changes.

If the above waiver does not apply, observe the research staff member perform the following activities. After the employee demonstrates proficiency, check each item and initial.

Preceptor: _____
Printed Name Signature/Date

1. Selection and use of appropriate equipment and supplies:

Materials	Proficient	Initials
Gloves		
Needle device		
Alcohol swabs		
Blood collection container (check expiration dates)		
Tourniquet		
Tape/ Gauze, bandage		
Correct labels		

2. Collection Technique:

Technique	Proficient	Initials
Handwashing		
Study Subject Identification		
Selection of venipuncture site		
Donning/Doffing PPE (gloves)		
Application of tourniquet/removal		
Palpation of vein		
Cleansing of site		
Proper use of needle device		
Proper use of collection container		
Inspection of needle		
Needle angle and bevel		
Dressing of site		
Collection container labeling		

Submit this form at **Initial Review and annually thereafter**, or when **adding blood collection authority**, for all staff members authorized by the Principal Investigator to collect human blood samples.

¹ Licensed Independent Practitioners (e.g., M.D.), including Residents, holding core privileges to perform phlebotomy are exempt from completing this competency checklist and are not required to submit this document to the DVAMC Research Office.

² Completion of this form does not constitute training.