

Employee Name:

This Scope of Practice (SOP) is specific to the duties of each research employee as an agent of the study Principal Investigator (PI). 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.

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 practitioner or dependent practitioner.

Instructions: The research employee and his/her **direct supervisor** will discuss and determine the duties the employee may perform and will document the agreement by completing this form. However, 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.**

All employees must complete the information below and **Section E** of this form. Complete **Section A** if you work with human studies; complete **Section B** if you work with animal studies; and complete **Section C** if you work on laboratory studies (you may complete more than one section). If you work with more than one PI then the additional PIs must add their signature to **Section D**.

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 work with human research subjects.	Yes No	If yes, complete Section A, Human Research.
My duties require me to work with animal research subjects.	Yes No	If yes, complete Section B, Animal Research.
My duties require me to work in a laboratory setting.	Yes No	If yes, complete Section C, Laboratory Research.
I work with/for one or more Principal Investigators.	Yes No	If yes, complete Section D, PI Signatures.

SECTION A: HUMAN RESEARCH

Instructions: You and your supervisor will complete this section to indicate the duties you have been trained to perform as they relate to a human research study.

Duties (Section A: Human Research)	Employee	Supervisor
1. Prepare study initiation activities.		
2. Prepare/submit required documents for committee review.		

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Duties (Section A: Human Research, continued)	Employee	Supervisor
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. **If box is checked, complete and submit the Durham VAMC Research Vital Sign Competency Initial and Annual Review Checklist. Link: http://www.durham.va.gov/research/initial_review/Initial_Review.asp		
16. Perform venipuncture. **If box is checked, complete and submit the Durham VAMC Research Blood Collection Competency Initial and Annual Review Checklist. Link: http://www.durham.va.gov/research/initial_review/Initial_Review.asp		

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

20. Describe:		
21. Describe:		

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SECTION B: ANIMAL RESEARCH

Instructions: You and your supervisor will complete this section to indicate the duties you have been trained to perform as they relate to an animal research study.

Duties (Section B: Animal Research)	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		
14. Describe:		
15. Describe:		

SECTION C: LABORATORY RESEARCH

Instructions: You and your supervisor will complete this section to indicate the duties you have been trained to perform as they relate to a laboratory research study.

Duties (Section C: Laboratory Research)	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:		

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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	Supervisor 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	Employee/WOC/IPA 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	ACOS/R&D Date