

SCOPE OF RESEARCH PRACTICE (SORP) FORM FOR RESEARCH STAFF

1. **PURPOSE.** To outline the processes for ensuring that all individuals conducting research at the VA St. Louis Health Care System (VASTLHCS) are conducting their duties in accordance with an approved scope of research practice document.
2. **POLICY.** Each member of the research team must have a Scope of Research Practice approved by the ACOS/R&E. The Scope of Research Practice is specific to the duties and responsibilities of the research staff member. This document defines the duties the individual is allowed to perform for research purposes and is required for all research personnel (clinical and non-clinical). The Scope of Research Practice must be consistent with the occupational category under which the individual was hired and it must not include any duties for which the individual is not qualified. All personnel working in research are expected at all times to function within the limits of their training, credentialing, privileging, Scope of Research Practice, and appointment at the VA St. Louis Health Care System. Current Scopes of Research Practice must be retained by the Research Office, the employee, and the Principal Investigator.

The VASTLHCS requires that all members of the research team, even those with clinical privileges, a functional statement or equivalent, maintain a Scope of Research Practice.

Research Scopes of Practice are intended to cover all duties that the individual may perform on any study so as to facilitate a single Research Scope of Practice for research personnel. The research employee and the ACOS/R&E will determine the duties and responsibilities the employee may perform and will document the agreement by completing and signing the Research Scope of Practice form. At the time of study submission to the relevant subcommittees and RDC for approval, the study specific delegation of duties for the research employee is to be submitted on a Delegation of Responsibilities and Signature log.

3. **ACTION.**

- a. **Accountability:**

1. All research personnel, including clinicians with clinical scope of practice statements, or clinical privileges, or clinical functional statements, must have a research scope of practice statement as described herein.
 2. Anyone providing clinical services (e.g. cognitive behavioral counselling, medication prescription, diagnostic evaluations, therapeutic interventions) under the auspices of an IRB-approved research protocol must be credentialed and have appropriate clinical privileges at the St. Louis VA unless the individual provides the services under the supervision of another VA provider, named on the protocol, who has the requisite privileges at the St. Louis VA.
 3. Research personnel must have all required licenses, registrations, or certifications to perform a given procedure, intervention, or other activity in the research setting and practice only within the scope allowed by such licenses, registrations, or certifications.
 4. The Scope of Research Practice must be revised whenever duties are added or removed. Note that it is important when initiating the Research Scope of Practice that research personnel include all duties for which he/she may complete to ensure a comprehensive document and minimal changes to the SORP. When necessary to add or remove duties, it is the responsibility of the individual to

send a revised Scope of Research Practice for ACOS/R&E signature and request his/her PI send an amended Research Delegation of Responsibility and Signature Log to the relevant subcommittee at any time duties are added or removed.

b. Procedures.

1. Review and Signatures. Each scope of practice must be reviewed and signed by the individual and the ACOS/R&E prior to the research personnel engaging in research. The ACOS Implementation Memo will not be sent to the PI for study initiation until all study member Scopes of Research Practice are signed. A copy of the fully executed document will be returned to the research team member and the PI.
2. Initial Review. It is the responsibility of the administrative staff of the committee of record (i.e. RDC, IRB, IACUC or SRS) to ensure that each person listed as research personnel on a project submitted for initial review has a Research Scope of Practice on file with the research office and a corresponding Delegation of Responsibility and Signature Log is submitted with the study documents and retained in the Research Office.
3. Record Retention. It is the responsibility of the employee to retain a copy of his/her Scope of Research Practice and ensure review and ACOS/R&E signature by the annual review date. The PI(s) must maintain a copy of each study team member's Scope of Research Practice. The Research Service office must also retain a copy on the research server.
4. Annual Reminder. The Research Service office will send an email notification at least 30 days prior to the annual review date to all research personnel reminding him/her to review and verify by initialing and dating the Scope of Research Practice that no duties have changed. A signed copy of the initialed and dated Scope of Research Practice is due in the Research Office no later than five business days prior to the annual review date for ACOS review and signature.
5. Annual Review. Principal Investigators will confirm that each employee's Research Scope of Practice is up-to-date by endorsing an item on the continuing review form from the relevant oversight committee (IRB, IACUC, SRS, or RDC) for each project.

c. Compliance.

1. In addition, every year the ACOS/R&E or delegate will audit approximately 20 randomly selected scopes of practice. The audit will consist of a telephone or in-person interview with the employee and/or his/her supervisor focusing on the actual activities that the employee is performing. These will be compared to the activities approved on Scope of Research Practice form.
2. Scopes of Practice Research Office Record Retention. To facilitate scope of practice reviews, the Research Service will maintain a record of each individual's name, contact information, date of initial scope of practice, date of annual review, and a copy of the most recent signed Scope of Research Practice.

4. DEFINITIONS:

AO/R: Administrative Officer for Research

ACOS/R&E: Associate Chief of Staff for Research and Education

IACUC: Institutional Animal Care and Use Committee

IRB: Institutional Review Board

PI: Principal Investigator

R&D: Research and Development

RDC: Research and Development Committee

SRS: Subcommittee on Research Safety

VA Research: Research conducted by VA investigators (serving on compensated, work without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointments) while on VA time, utilizing VA resources (e.g. equipment), or on VA property including space leased to, or used by VA. The research may be funded by VA, by other sponsors, or be unfunded.

5. APPENDICES. VA St. Louis Health Care System Scope of Research Practice, Delegation of Responsibility and Signature Log

6. REFERENCES.

VHA Handbook 1200.01

VHA Handbook 1200.05

VHA Handbook 1200.07

VHA Handbook 1058.01

7. RESCISSIONS. Research Service SOP 151-205, June 1, 2015

8. RESPONSIBILITY. Associate Chief of Staff for Research and Education

9. REVIEW DATE. June 1, 2020



ZIYAD AL-ALY, MD

ACOS, Research and Education Service

VA St. Louis Health Care System Scope of Research Practice

NAME (LAST NAME, FIRST NAME)	
JOB TITLE (check all that apply)	STAFF LICENSURE (check all that apply)
<input type="checkbox"/> PI / Co-I / Sub-I <input type="checkbox"/> Resident/Fellow <input type="checkbox"/> Research Coordinator <input type="checkbox"/> Animal lab staff <input type="checkbox"/> Research Assistant <input type="checkbox"/> Wet Lab Staff <input type="checkbox"/> Administrative Support <input type="checkbox"/> Other: _____	<input type="checkbox"/> None <input type="checkbox"/> DO/MD <input type="checkbox"/> PhD <input type="checkbox"/> NP/PA; <input type="checkbox"/> DNP/RN <input type="checkbox"/> LPN <input type="checkbox"/> RD <input type="checkbox"/> DVM <input type="checkbox"/> Other: _____
EMPLOYEE TYPE:	LICENSED OR ELIGIBLE FOR LICENSE
<input type="checkbox"/> VA-paid <input type="checkbox"/> IPA <input type="checkbox"/> WOC <input type="checkbox"/> Other List affiliation, if any: _____	<input type="checkbox"/> YES <input type="checkbox"/> NO
CLINICAL PRIVILEGES AND/OR CREDENTIALS <input type="checkbox"/> N/A	
1. Outside of research, are you clinically privileged and/or credentialed at STLVAHCS? <input type="checkbox"/> YES <input type="checkbox"/> NO 2. Are you using your clinical privileges and/or credentials as part of your research activities? <input type="checkbox"/> YES <input type="checkbox"/> NO	

This *Scope of Research Practice (SORP)* is specific to the duties and responsibilities of the research staff member named above. The research staff member (employee, IPA, or WOC) is specifically authorized to conduct research with the responsibilities approved below in conjunction with approved research protocols. Only one SORP is required for each staff member. When Research personnel are involved in multiple studies this scope of practice should encompass all of the duties that the individual is authorized to perform. Approved duties must be consistent with his/her qualifications, education, and training. This document does not waive the responsibility to secure St. Louis VA Health Care System clinical privileges for any licensed independent provider under VHA Directive 1100.19, Credentialing & Privileging or nursing credentialing and boarding process. A revised SORP must be submitted and approved prior to implementing any changes in the described duties/responsibilities.

Instructions: The research staff member and the ACOS/R&E will determine the duties and responsibilities the person may perform and will document the agreement by completing and signing this form. The duties must be approved ACOS/ R&E. The research staff member is responsible for reviewing annually and updating his/her Scope of Research Practice (SORP) as necessary to reflect changes in duties/responsibilities, utilization guidelines and/or medical center policies. The original signed copy of this document will be maintained in the Research & Education Office.

Each Principal Investigator is responsible for the conduct of his/her study and must review each study member's approved duties to ensure that the specific protocol duties are encompassed in the approved listing and that no duties beyond this scope will be added without prior approval and SORP revision.

Please check all boxes in each section unless you check N/A for that section.

INDICATE SCOPE STATUS	
<input type="checkbox"/> New	<input type="checkbox"/> Revised

VA St. Louis Health Care System Scope of Research Practice

A. Regulatory/Administrative/Scientific Tasks -may require competencies, credentials, and/or privileges		YES	NO
<input type="checkbox"/> N/A, Proceed to Section B			
1	Provide scientific and/or technical guidance and leadership to individuals / institutions in health-related research areas	<input type="checkbox"/>	<input type="checkbox"/>
2	Develop, consult on, coordinate, and/or deliver training/educational health-related programs/presentations for research purposes	<input type="checkbox"/>	<input type="checkbox"/>
3	Review, evaluate, oversee, and/or provide technical assistance in the development of grants, cooperative agreements, memorandum of understanding, or other mechanisms for joint endeavors between federal, state, local, or private sector health entities	<input type="checkbox"/>	<input type="checkbox"/>
4	Serve as Principal Investigator, Co-Principal Investigator, or Responsible Investigator; thereby, providing oversight of the study and all study staff	<input type="checkbox"/>	<input type="checkbox"/>
5	Prepare and coordinate study activities including: initiation, study activities, conferences, and data exchange between sites	<input type="checkbox"/>	<input type="checkbox"/>
6	Prepare and submit regulatory documents to applicable regulatory committees, Sponsor and other approved regulatory agencies, and maintain study regulatory documentation	<input type="checkbox"/>	<input type="checkbox"/>
7	Conceptualize, design, and implement data analyses	<input type="checkbox"/>	<input type="checkbox"/>
8	Perform or supervise statistical analysis of de-identified and aggregate level data	<input type="checkbox"/>	<input type="checkbox"/>
9	Interpret results and prepare manuscripts	<input type="checkbox"/>	<input type="checkbox"/>
10	Develop and implement recruitment and adherence methods to be utilized in study	<input type="checkbox"/>	<input type="checkbox"/>
11	Monitor the cost, management, and overall technical performance of a contract/fund after award	<input type="checkbox"/>	<input type="checkbox"/>
12	Obtain, organize, and transcribe data such as test results, data collected on questionnaires, and other information needed for the study	<input type="checkbox"/>	<input type="checkbox"/>
13	Prepare vouchers for subject payment pursuant to approved payment method and schedule	<input type="checkbox"/>	<input type="checkbox"/>

B. Study-Participant Related Tasks-may require competencies, credentials, and/or privileges		YES	NO
<input type="checkbox"/> N/A, Proceed to Section C.			
14	Authorized to perform the informed consent process	<input type="checkbox"/>	<input type="checkbox"/>
15	Screen potential subjects to determine study eligibility by accessing PHI or by subject interview	<input type="checkbox"/>	<input type="checkbox"/>
16	Collect and maintain accurate and complete data collection in case report forms and source documents	<input type="checkbox"/>	<input type="checkbox"/>
17	Utilize Vista/CPRS to schedule subjects' research visits, documenting all subject encounters, initiating orders, consults, etc. while maintain confidentiality	<input type="checkbox"/>	<input type="checkbox"/>
18	Initiate diagnostic testing or consultation	<input type="checkbox"/>	<input type="checkbox"/>
19	Perform subjects exams per protocol	<input type="checkbox"/>	<input type="checkbox"/>
20	Report laboratory results and other diagnostic testing to PI, study sponsor and other appropriate personnel in a timely manner	<input type="checkbox"/>	<input type="checkbox"/>
21	Evaluate health results or problems including lab or other tests results and possible AEs	<input type="checkbox"/>	<input type="checkbox"/>
22	Provide education and instruction regarding study activities to subjects, relatives, and Medical Center staff as necessary	<input type="checkbox"/>	<input type="checkbox"/>
23	Collect human specimens as described in the protocol	<input type="checkbox"/>	<input type="checkbox"/>
24	Process/handle human specimens	<input type="checkbox"/>	<input type="checkbox"/>
25	Package and ship biological materials	<input type="checkbox"/>	<input type="checkbox"/>
26	Order, or adjust medications or investigational drugs	<input type="checkbox"/>	<input type="checkbox"/>
27	Prepare and dispense medications or investigational drugs	<input type="checkbox"/>	<input type="checkbox"/>
28	Provide participant education and instruction on the use of study medication, including administration, storage, side effects and how to notify researcher of adverse drug reactions	<input type="checkbox"/>	<input type="checkbox"/>
29	Drug Accountability: Obtains study medication from pharmacist, dispenses medication to participant per protocol, counts returned medications if applicable, disposes of returned medication per protocol and pharmacy policy	<input type="checkbox"/>	<input type="checkbox"/>

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C. Laboratory Related Tasks —may require competencies, credentials, and/or privileges		YES	NO
<input type="checkbox"/> If the employee does not work in a laboratory, please check here and proceed to section D.			
30	Approved to conduct research with the following materials (check all that apply). <input type="checkbox"/> Human or non-human tissues, cells or sub cellular specimens (e.g. DNA, RNA, etc.) <input type="checkbox"/> Radioactive isotopes or radiation procedures <input type="checkbox"/> Microbial agents (bacteria, viruses, other pathogens) <input type="checkbox"/> Chemicals <input type="checkbox"/> Recombinant DNA <input type="checkbox"/> Controlled Substances <input type="checkbox"/> Poisonous, Toxic, venomous plants/animals	<input type="checkbox"/>	<input type="checkbox"/>
31	Maintain inventory and assume purchasing duties	<input type="checkbox"/>	<input type="checkbox"/>
32	Handles hazardous chemicals or agents in manner which is compliant with all applicable standards	<input type="checkbox"/>	<input type="checkbox"/>
33	Store supplies and approved materials and ensure appropriate storage conditions and security in a manner that is compliant with all applicable standards	<input type="checkbox"/>	<input type="checkbox"/>
34	Safe and appropriate use and disposal of all approved materials in accordance with approved protocols and in compliance with all applicable standards	<input type="checkbox"/>	<input type="checkbox"/>
35	Responsible for proper operation and safety of the lab management and operation	<input type="checkbox"/>	<input type="checkbox"/>
36	Responsible for maintaining a research laboratory that is compliant with all safety, administrative and security requirements	<input type="checkbox"/>	<input type="checkbox"/>
37	Perform assays and/or other experimental laboratory procedures and activities independently	<input type="checkbox"/>	<input type="checkbox"/>
38	Carry out experiments with the guidance of supervisor; ability to troubleshoot experimental problems with some assistance	<input type="checkbox"/>	<input type="checkbox"/>
39	Set up, maintain and operate complex laboratory equipment: Centrifuges, HPLC, spectrophotometer, fluorimeter, scintillation counter, gamma counter, phosphoimager, electrophoresis apparatus, chromatography, etc.	<input type="checkbox"/>	<input type="checkbox"/>
40	Use safety and containment equipment	<input type="checkbox"/>	<input type="checkbox"/>
41	Maintain meticulous laboratory notes to ensure validity of experiments	<input type="checkbox"/>	<input type="checkbox"/>
42	Safe handling and processing of human specimens if research laboratory tests are required per protocol	<input type="checkbox"/>	<input type="checkbox"/>
43	Maintain and organize chemical / reagent inventory	<input type="checkbox"/>	<input type="checkbox"/>
44	Ship biological materials or specimens	<input type="checkbox"/>	<input type="checkbox"/>
D. Animal Subject Routine Tasks —may require competencies, credentials, and/or privileges		YES	NO
<input type="checkbox"/> If the employee does not work with animals check here and proceed to the following section.			
45	Does not directly handle live animals; performs or supervises statistical analysis of de-identified and aggregate level data	<input type="checkbox"/>	<input type="checkbox"/>
46	Works with the following species: <input type="checkbox"/> Mice <input type="checkbox"/> Rats <input type="checkbox"/> Guinea Pigs <input type="checkbox"/> Rabbits <input type="checkbox"/> Swine <input type="checkbox"/> Other species _____	<input type="checkbox"/>	<input type="checkbox"/>
47	Is knowledgeable about the ethical and safe handling of animals and performs procedures involving animals (e.g. tailing, surgery, and/or behavioral interventions).	<input type="checkbox"/>	<input type="checkbox"/>
48	Perform special husbandry and/or practices as required	<input type="checkbox"/>	<input type="checkbox"/>
49	Perform surgical procedures on small animals	<input type="checkbox"/>	<input type="checkbox"/>
50	Perform surgical procedures on large animals	<input type="checkbox"/>	<input type="checkbox"/>
51	Administer euthanasia for animals in approved ACORPs	<input type="checkbox"/>	<input type="checkbox"/>
52	Obtain and processes blood specimens from animals	<input type="checkbox"/>	<input type="checkbox"/>
53	Administer injections	<input type="checkbox"/>	<input type="checkbox"/>
54	Administer substances orally	<input type="checkbox"/>	<input type="checkbox"/>
55	Work with breeding colony protocols	<input type="checkbox"/>	<input type="checkbox"/>
56	Use safe procedures involving animals and use protective equipment appropriately (e.g. gloves, mask, eye protection, protective clothing)	<input type="checkbox"/>	<input type="checkbox"/>
57	Order laboratory animals	<input type="checkbox"/>	<input type="checkbox"/>

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MISCELLANEOUS DUTIES (if applicable):

The above individual is authorized to perform the following miscellaneous duties not otherwise specified in this Scope of Practice.

- 58. _____
- 59. _____
- 60. _____
- 61. _____
- 62. _____
- 63. _____
- 64. _____
- 65. _____
- 66. _____

NOTICE TO LICENSED PROFESSIONALS:

Individuals found to be working outside their clinical privileges as granted by the VA St. Louis Health Care System will be subject to disciplinary action and possible reporting to other applicable agencies.

RESEARCH PERSONNEL'S STATEMENT:

This Scope of Research Practice outlines general duties I am permitted to undertake in conjunction with a VASTLHCS approved protocol. I understand that all research must be approved by all applicable R&D Committees. If I have questions or concerns, I am encouraged to contact the Research & Education Office.

I also understand that performing tasks beyond this Scope of Research Practice without specific authorization may lead to disciplinary action. Tasks granted in this Scope of Research Practice are consistent with my qualifications, education, and training. I agree to abide by the parameters of this Scope of Research Practice and all VASTLHCS policies and regulations.

I am fully aware that I must not perform any procedures which constitute the practice of the profession for which I 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.

Personnel Signature

Date

ACOS/R&E Statement:

I certify this individual possesses the skills to safely perform the aforementioned duties and procedures. This Scope of Research Practice will be reviewed annually and amended as necessary to reflect changes in the individual's duties/ responsibilities.

ACOS/R&E

Date

**VA St. Louis Health Care System
Scope of Research Practice**

Annual Review: The attached Scope of Research Practice has been reviewed by the individual and the ACOS for Research and Education and has been determined to be current.

Personnel Signature/Date	
ACOS-R&E Signature/Date	

Personnel Signature/Date	
ACOS-R&E Signature/Date	

Personnel Signature/Date	
ACOS-R&E Signature/Date	

Personnel Signature/Date	
ACOS-R&E Signature/Date	

Personnel Signature/Date	
ACOS-R&E Signature/Date	

Personnel Signature/Date	
ACOS-R&E Signature/Date	

VA St. Louis Healthcare System Research Delegation of Responsibility and Signature Log

All personnel performing protocol procedures as part of a VA St. Louis RDC approved research project must be listed on this log. Start and end dates refer to the period that the individual is completing any work on the study. The Start Date must be on or before the first date that any study activities were completed by the staff member and should not occur until appropriate committee approval. The PI must ensure that staff members do not start the tasks until appropriate committee and departmental approvals are obtained. This document must be completed annually and submitted with the continuing review application. It must also be updated and submitted with any new staff amendment request or when staff roles and/or responsibilities change.

Protocol Title:

Responsibilities and Commitments

- Ensure that work does not commence on study until ACOS Implementation memo is received.
- Ensure the protection of every research subject.
- Ensure that all members of the research team comply with the findings, determinations, and requirements of the Institutional Review Board.
- Ensure compliance with the informed consent process.
- Ensure no changes in approved research are initiated without prior Subcommittee approval, except where necessary to eliminate apparent immediate harm to subjects.
- Adhere to all VA reportable event requirements and study sponsor reporting requirements, if applicable.ⁱ
- Ensure all study team members are appropriately credentialed, privileged, and have completed all required VA training.
- Grant access as required to properly authorized personnel and officials, following required reporting requirements to the Research Office.
- Ensure compliance with all applicable investigational drug processes if applicable.ⁱⁱ
- Ensure research data repository compliance if applicable.ⁱⁱⁱ
- Maintain all study-related records, including the investigator's research records, for at least six years after the end of the fiscal year of completion of the research project and/or as long as bound by other Federal requirements and /or contractual agreement if longer than 6 years.^{iv}
- If the VASTLHCS is a Coordinating Site, the principal investigator must ensure each participating site engaged in the research has IRB approval and any other appropriate institutional approvals prior to enrollment of participants, maintaining documentation as required.
- If the VASTLHCS is a Participating Site of a multi-site study, the principal investigator has overall responsibility for the conduct of the study at the VA institution.

***Investigator/Responsible Investigator:** My signature below reflects that I understand that I hold ultimate responsibility for the conduction of the trial. I have read the information contained in this document and agree to abide by the regulations governing human studies at the VA St. Louis Health Care System. As the principal investigator of this study, I will ensure that all personnel are familiar with the protocol and are trained in policies governing human studies. I understand that my signature for each listed staff member indicates that I have reviewed that individual's research scope of practice and the task delegated for this specific study are not beyond the approved scope. A copy of this log will be retained in my regulatory binder for future reference.

First and Last Name	RI or PI	Signature*	Initials	Date

