

SCOPE OF PRACTICE FORM FOR RESEARCH STAFF

1. PURPOSE. To define the policy and procedures for approval of the designated roles and responsibilities of research staff in research projects that involve human subjects, animals, database studies, health system research and basis laboratory.

2. POLICY. All individuals involved in research activities at the VA St. Louis Health Care System ("VASTLHCS") must receive approval for their participation through the VASTLHCS Research Office by going through the appropriate Research committee/subcommittee, i.e.: Research and Development Committee (RDC); Institutional Review Board (IRB); Institutional Animal Care and Use Committee (IACUC); Subcommittee for Research Safety (SRS) and following the Research and Education Service's (R&E) submission process. A Scope of Practice Form must be developed for all individuals in research that defines the parameters and functions of their duties and responsibilities. Research personnel may **not** participate in a research protocol until all requirements of this policy are met. All personnel working in research are expected at all times to function within the limits of their training, credentialing, privileging, Scope, and appointment at the VA St. Louis Health Care System. An individual's role in research may not exceed or allow them to function in any capacity that they would not be authorized to carry out in routine clinical practice. Research staff must meet all requirements for the job to which they are appointed.

a. Personnel may have only the roles and responsibilities, as defined by their approved Scope, that are appropriate to their level of training, specific license, and clinical credentials. Licensed research personnel may **not** perform or be trained to perform procedures outside of those allowed under their respective license and credentialing. Research staff with credentials, clinical privileges, and a Scope already granted by the medical center as part of their clinical appointment, still may need a separate Scope for research since all activities for research may not be covered by the medical center process.

b. Non-licensed research personnel, including but not limited to individuals who have an MD, DO, BSN, or MSN degree, without licensure (excluding those in an ACGME approved training program), are not allowed to perform duties that would be considered part of their professional practice. Any procedures that, according to the VASTLHCS bylaws, would require consent of the patient in a standard (non-research) patient care setting may **not** be performed by non-licensed research personnel. Unlicensed research personnel may not be trained to do procedures that require a professional license.

c. Unlicensed research personnel working as research coordinators or research fellows may obtain informed consent if competency verification has occurred and is documented on the Research Scope. However, unlicensed research personnel (excluding those in an ACGME approved clinical training program) may not use their educational degree after their signature on IRB approved consent forms or on Research Staff Contact lists. Furthermore, unlicensed research personnel may not display their educational degree (e.g. M.D. or R.N. on a name tag) in any way that would convey to the research participant or staff that he/she is a licensed practicing clinician.

3. ACTION.

a. Accountability:

(1) Research Office: will provide required forms and instructions for completing the Scope to all research staff actively engaged in approved VASTLHCS research, provide the employee with a copy of the approved Scope or notification if the Scope is not approved, and maintain a copy in the Research Office file. The Research Office will track the completion of Scopes annually from the date of the previously approved Scope.

(2) Supervisors: Principal investigators (or if the Scope is for the Principal or Responsible Investigator, then the Principal or Responsible Investigators' Section or Service Chief, Department Chair, etc.) must verify the employee's competency to perform the roles and responsibilities identified on the Scope. Principal Investigators (Section or Service Chief, Department Chair, etc.) will verify that the approved Scope accurately defines the activities of research personnel at least annually by the anniversary date of the previous approved Scope.

(3) Research Staff: Must work within the developed Scope and not take on any duties or perform any procedures that are beyond their allowed practice. Update their supervisor immediately if their credentialing or licensure changes so that the scope may be updated appropriately.

(4) Associate Chief of Staff (ACOS) for Research and Chief of Staff will review and approve the Scope.

b. Procedures.

(1) Principal and Responsible Investigators must complete and submit the Scope to the Research Office as part of either initial submission, when an individual is first added to their RDC, IRB, IACUC or SRS R&D research approved protocol(s), or whenever the duties of the employee are modified. Principal and Responsible Investigators must annually verify that the approved Scope accurately defines the activities of research personnel. Investigators should retain a fully executed copy of the employee's Scope with the Investigators files, after it is signed by the ACOS for Research. It is the responsibility of the principal investigator to make sure the personnel listed on their studies have current, signed scope of practices. Principal Investigators are also responsible for keeping the list of personnel on their studies up-to-date and submitting appropriate amendments as needed.

(2) The ACOS for Research or designee will review the Research Scope annually and approve if the requested roles and responsibilities are appropriate.

(3) The Research Office will provide the employee with a copy of the approved and fully executed Scope or notification of disapproval if the Scope could not be approved as submitted. The new or reviewed Scope will be entered into the R&D Training log and a hard copy kept in the Research Office.

(4) The Education/Training Coordinator will retain a log of the scope of practices for all personnel involved in active research studies. He/she is responsible for reminding our researchers to keep their scope of practice form current. The Coordinator will email each researcher, copying their PI, 60 days in advance of their scope of practice expiration date, asking them to update their scope of practice form, signing it, having their PI sign it, and returning to the Coordinator within seven business days (a specific suspense date will be indicated). If it is not received by the suspense date, the Coordinator will repeat this process at 30 days. The scope of practice form must also contain any updates or changes needed. The Coordinator's email to each researcher will include the statement, "If your scope of practice is not signed by the researcher and the PI and returned by the expiration date, you will be removed from the research study and the study may be placed on administrative hold."

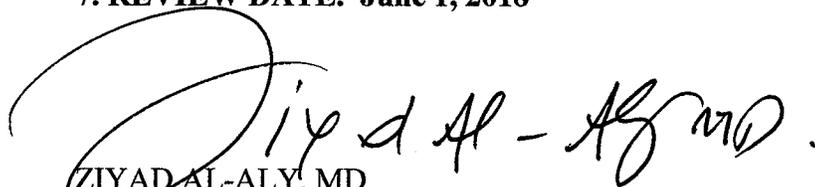
(5) Subcommittee administrators and subcommittee members will also be responsible for reviewing the scope of practice forms closely, making sure they are current and properly signed. The subcommittee administrators will work with the Coordinator to assist him/her in keeping the scope of practice log up-to-date with the latest study personnel changes.

4. REFERENCES. VHA Handbook 1200.01, VHA Handbook 1200.05, VHA Handbook 1200.07, and VHA Handbook 1058.01.

5. RESCISSIONS. Research Service SOP 151-205 dated November 21, 2013

6. RESPONSIBILITY. Associate Chief of Staff for Research.

7. REVIEW DATE. June 1, 2018



ZIYAD AL-ALY, MD
ACOS, Research and Education Service

ATTACHMENTS:

- Attachment A – Human Study Scope of Practice Form for Research
- Attachment B – Animal Study Scope of Practice Form for Research

VA St. Louis Health Care System
 SCOPE OF PRACTICE
 Clinical and Health Services Research Investigators and Study Staff

NAME
STUDY ROLE
SUPERVISORS (Responsible or Principal Investigators)
ALTERNATIVE SUPERVISOR (If Applicable)
EXPIRATION DATE (Annually, From Date of ACOS for Research Signature)

The Scope of Practice Form is specific to the duties and responsibilities of each research study team member. Each person who works on a study must review, sign, and date their Scope of Practice Form annually, updating as necessary. A Scope of Practice form must be completed/reviewed annually for all research personnel, including Principal & Responsible Investigators

ROUTINE DUTIES	YES	NO
1. Prepare and coordinate study activities including: initiation, study activities, conferences, and data exchange between sites		
2. Submit regulatory documents to St. Louis VA IRB, VA R&D Committee, Sponsor, and other approved regulatory agencies		
3. Develop and implement recruitment and adherence methods to be utilized in the study		
4. Perform the informed consent process		
5. Screen patients to determine study eligibility criteria by review of a patient's medical information or by subject interviews		
6. Access patient medical information while maintaining confidentiality		
7. Utilize VISTA/CPRS computer systems to schedule subjects' research visits, document progress notes, initiate orders, consults, etc.		
8. Provide education regarding study activities to patient, relatives and medical center staff as necessary per protocol		
9. Dispense study medications		
10. Provide subject education and instruction of study medication use, storage, possible side effects and procedure to notify the study site of any adverse reactions		
11. Initiate and administer medication therapies.		
12. Collect various types of human specimens as described in study protocol		
13. Handle, package and ship human specimens to study labs		
14. Initiate and/or expedite request for consultation, special tests or studies		
15. Maintain complete and accurate data collection in case report forms and source documents		
16. Performs or supervises data collection and management for the study		
17. Obtain and organize data, such as study databases, tests results, diaries/cards or other necessary information for the study		
18. Conduct/assist with statistical analysis of de-identified and aggregate level data		
19. Conceptualize, design, and implement data analyses		
20. Interpret results and prepare manuscripts		
Additional duties not included in categories above:		

PRINCIPAL INVESTIGATOR STATEMENT:

VA St. Louis Health Care System
SCOPE OF PRACTICE.
Clinical and Health Services Research Investigators and Study Staff

This Scope of Practice Form was reviewed and discussed with the study team member on the date of signature below. After reviewing his/her education, clinical competency, qualifications, research practice involving human subjects, peer reviews, and individual skills, I certify that he/she possesses the skills to safely perform the aforementioned duties/procedures. Both the study team member and I are familiar with all duties/procedures granted or not granted in this Scope of Practice Form. We agree to abide by the parameters of this Scope of Practice Form, and all applicable hospital policies and regulations. We also agree to notify the Office of the ACOS for Research and Development, prior to implementation, should there be a need to broaden the Scope of Practice Form. This Scope of Practice Form will be reviewed annually, amended as necessary to reflect changes in the study team member's duties/ responsibilities, utilization guidelines and/or hospital policies, and submitted to Research Service for signature by the ACOS for R&E.

Principal Investigator	Date	Initials
Additional Principal Investigator	Date	Initials
Additional Principal Investigator/Alternate Supervisor	Date	Initials
Study Team Member	Date	Initials
ACOS Research Service Line	Date	Initials

Annual Review and Renewals (If no changes are made to this document)

Date	Study Team Member Initials	PI Initials	ACOS of Research Initials

VA St. Louis Health Care System
SCOPE OF PRACTICE.
 Basic Laboratory and Animal Research

This Scope of Practice delineates the duties and responsibilities of each research employee conducting basic laboratory/animal research at VASTLHCS, including investigators and research staff. It covers all research activities and projects conducted by the employee. Employees that are designated as Principal Investigator (PI) for any research study will direct and be responsible for all aspects of the research, and supervise any other investigators and research staff. For research staff, a secondary supervisor may be designated (e.g., another investigator; laboratory manager). The investigator primarily responsible for supervising the employee (“supervising investigator”) must review and approve this scope of practice. If the employee is an investigator, the ACOR for Research will review and approve the scope of practice. Each employee working in basic laboratory or animal research, including PIs, should have a single scope of practice which covers all research duties, even if that employee works on multiple projects.

EMPLOYEE'S NAME:
EMPLOYEE'S TITLE:
EMPLOYEE WILL FUNCTION AS: <input type="checkbox"/> Investigator <input type="checkbox"/> Research Staff
SUPERVISING INVESTIGATOR (E.G., PI or ACOS FOR RESEARCH)
SECONDARY SUPERVISOR, IF APPLICABLE (E.G., SECOND INVESTIGATOR, LAB MANAGER):
LICENSURE TYPE: <input type="checkbox"/> MD <input type="checkbox"/> NURSE PRACTITIONER <input type="checkbox"/> DVM <input type="checkbox"/> NONE <input type="checkbox"/> Ph.D. <input type="checkbox"/> RN <input type="checkbox"/> OTHER: _____

This Scope of Practice is specific to the duties and responsibilities of the research employee named above. The employee is specifically authorized to conduct laboratory research activities with the following materials (check as applicable):

- Animals
- Human or non-human tissues, cells or sub cellular specimens (e.g. DNA, RNA, etc.)
- Radioactive isotopes or radiation procedures
- Microbial agents (bacteria, viruses, other pathogens)
- Chemicals
- Recombinant DNA
- Controlled Substances
- Poisonous, Toxic, venomous plants/animals

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The employee should work with their PIs to complete this form to assure concurrence of understanding regarding responsibilities. Indicate "Yes" if assigned that responsibility/duty and "No" if not assigned that responsibility/duty.

	RESEARCH-RELATED DUTIES	YES	NO
1	Collaborates with principal investigator on various protocols and procedures.		
2	Manages research studies at the direction of the principal investigator.		
3	Directly supervises other study personnel.		
4	Acts as a liaison between Research Administration and the principal investigator in all matters relating to the lab.		
5	Submits required administration paperwork for audits, quality assurance and computer support.		
6	Maintains inventory and assumes purchasing duties.		
7	Responsible for maintaining the laboratory's chemical inventory.		
8	Responsible for proper operation and safety of the day today operation of the laboratory.		
9	Responsible for maintaining a research laboratory that is compliant with all safety, administrative and security requirements.		
10	Animal husbandry which is complaint with all applicable standards.		
11	Collects and handles various types of animal specimens.		
12	Performs assays and/or other experimental laboratory procedures and activities independently.		
13	Performs research procedures involved animals as outlined in the approved Animal Component of Research Protocol (ACORP).		
14	Handles hazardous chemicals or agents in manner which is compliant with all applicable standards.		
15	Designs research projects/develops research protocols.		
16	Assists and advises in experimental design in the laboratory.		
17	Improves and if necessary develops new laboratory procedures by use of the pertinent scientific literature and in consultation with the principal investigator.		
18	Educates lab personnel as directed by the principal investigator.		
19	Instructs post doc fellows in new and advanced laboratory techniques.		
20	Reviews data collected in the course of the investigation.		
21	Assists and collaborates on findings which may be published in peer reviewed journals.		
22	Prepares reports and manuscripts for publication.		
23	Supports research in an administrative, technical or compliance capacity that is not specific to a research study.		
	OTHER DUTIES (Listed Below)		
24			
25			
26			
27			

RESEARCH EMPLOYEE'S STATEMENT:

This Scope of Practice outlines duties and responsibilities delegated to me by the Principal Investigator(s) regarding research study conduct. The principal Investigator(s) 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 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 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, all applicable hospital policies and regulation. This Scope of Practice will be reviewed every two (2) years and amended as necessary to reflect changes in the employee's duties and responsibilities and utilization guidelines and/or hospital policies.

SUPERVISING INVESTIGATOR SIGNATURE

DATE

SECONDARY SUPERVISOR SIGNATURE

DATE

INSTITUTIONAL APPROVALS:

ACOS, Research Service

DATE

Annual Review and Renewals (If no changes are made to this document)

Date	Study Team Member Initials	PI Initials	ACOS of Research Initials
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____