

Getting a Research Project Approved at the Atlanta VA: Brief Outline and Contact information

Determine if your project meets the definition of VA Research

What is VA Research? VA research is research that is conducted by VA investigators (serving on compensated, WOC, or IPA appointments) while on VA time. The research may be funded by VA, by other sponsors, or be unfunded. VA research must have R&D Committee approval.

Determine if you can be a VA Investigator

What is a VA Investigator? A VA investigator is any individual who conducts research approved by the VA R&D committee while acting under a VA appointment on VA time, including full and part-time compensated employees, trainees, without compensation (WOC) employees, and individuals appointed or detailed to VA under the Intergovernmental Personnel Act (IPA) of 1970. **NOTE:** *Contractors cannot be VA Investigators. Trainees (e.g., students, residents, or fellows of any profession) may serve as participants, but not as PIs within a VA facility, and their chosen PI must be sufficiently experienced in the trainee's research interest and responsible for oversight of the trainee and the overall research project. Trainees or students must be enrolled in an institution with an educational affiliate agreement with the Atlanta VA, or appointed to a VA training program that does not need external institutional sponsorship.*

All submission information and forms can be found on the Atlanta VAMC

website:<http://www.atlanta.va.gov/services/research/Investigators.asp>

Or via the Electronic Request to Review Research Proposal system (access via the VA Intranet only):

<https://vaww.gateway.research.va.gov/errrp/>

1. **To begin the process of engaging in a project, you will need to set up an AREF online account.** To create new account, click [Create NEW Account](#) and answer the questions and follow the workflow. This account will enable you to accomplish several things.
 - a. Register you and any staff working on projects
 - b. Complete Laboratory Annual Self Inspection Form (LASIF) if needed. (See 3.a below)
 - c. Create your PAGE 18-Investigator data sheet. This form is used to get the PI's information into our local research database as well as the VA national database. On an annual basis we ask PIs to update this information through their AREF account. This also requires an NIH ERA Commons ID
 - i. if you are an Emory or Morehouse faculty member, ask your department to create your Commons ID
 - ii. if you are NOT an Emory faculty member, contact Antonio Laracuentte (Antonio.laracuentte03@va.gov, 404-728-7632) or David Knight (david.knight2@va.gov 404-728-4827).

2. **The Science Information Office** (SIO, see contact information in 6) is your point of contact for all committee operations with the exception of IRB. Point of contact for IRB is Daniel Roysden (droysde@emory.edu at VA 404 -321-6111 ext. 2512 or at Emory 404-712-9749).

3. **What subcommittee approvals do you need for your project?** VA has subcommittees that report to the R&D committee. They include the Subcommittee for Research Safety (SRS), IACUC, and the IRB (Emory IRB, VA CIRB, NCI CIRB). Project submissions to these subcommittees can be done all at the same time, but all relevant subcommittee approvals must be obtained before you can submit for R&D approval.

a. **SRS (Subcommittee for Research Safety)** -must review and approve all new projects. SRS project submissions must be completed for ALL new projects (regardless of the work being conducted) in the electronic submission system (eRRRP): <https://vaww.gateway.research.va.gov/errrp/>. LASIFs are required for all research laboratories at the VA that involve biological hazards, radiation hazards, chemicals, and/or animals. New PIs have 90 days after initiating work in their laboratories to submit a new LASIF. Annually the SRS reviews completed Laboratory Annual Self-Inspection Forms (LASIFs). The SIO office will help PIs with LASIF submissions. This document applies only to:

- i. Projects being conducted at the VA.
- ii. Projects administered by AREF or VA.
- iii. If you are not sure what your project requires, you can contact the Science Information Office or the SRS Chair for clarification.
- iv. If you are using Recombinant DNA, your project will also require Institutional Biosafety Committee approval prior to commencing work. Contact the Science Information Office for more information.

b. **IACUC (Institutional Animal Care and Use Committee)**- must approve all projects involving experiments with animals

- i. All ACORPs must have a veterinary consultation prior to review by the IACUC. Completed ACORPs/animal protocols should be sent to: mhuerka@dar.emory.edu, (in the subject line put "VA Vet consult").
 1. If animals are located at Yerkes, please send your ACORP/animal protocol to vet_consult@rmy.emory.edu for consult.
 2. Location and funding of animal work will dictate what animal committee and form you use to obtain approval. Your submission, regardless of what form/committee, should include a memo with responses to the vet consult.
- ii. Projects that are funded by VA or AREF must be reviewed by the VA IACUC regardless of where the studies will be performed. These projects must use the VA ACORP forms. In rare cases, the Emory animal protocol form will be accepted, but this must be discussed with the SIO and IACUC chair prior to submission.
- iii. For VA or AREF funded projects, and if procedures are performed at Emory, submit to VA IACUC first, then to Emory IACUC. The Science Information Office will forward the approved ACORP/Vet consult to Emory for review.
- iv. Projects funded by sources other than VA or AREF where procedures are performed at the VA must be reviewed by VA IACUC. You may use either the VA ACORP (preferred) or Emory animal protocol forms.
- v. Projects funded by sources other than VA or AREF where procedures are performed at Emory must be reviewed by Emory IACUC.

- c. **IRB (Institutional Review Board)** – all studies involving human subjects or the use of identified human samples or data, must be approved by an IRB (Emory IRB, NCI IRB, or VA Central IRB)
- i. VA PIs obtaining approval from the Emory IRB must have an Emory sponsored account to submit to the Emory IRB. Study team members listed in the IRB submission require an Emory account (can be sponsored). If you do not have one, contact your PI or department administrator for a sponsored Emory account.
 - ii. We have an IRB Liaison who is assigned to all VA projects to help PIs through the process. The Liaison can help PIs with their IRB submission which is done through an electronic system called eIRB. If consent forms are needed, he can also make sure they meet VA requirements. Please contact Daniel Roysden (droysde@emory.edu at VA 404-321-6111 ext. 2512 or at Emory 404-712-9749).
 - iii. Projects submitted to the Emory IRB require a pre-review by the PO and ISO and the IRB Liaison. This is via the eRRRP submission:
<https://vaww.gateway.research.va.gov/errrp/>.
 - iv. The only projects that may be reviewed by another IRB are NCI projects, multi-site VA funded studies such as Cooperative studies and Merit Awards that are reviewed by the VA Central IRB.

4. R&D approval-

- a. **ALL relevant subcommittee approvals must be obtained before your project can be submitted for review by the R&D Committee. NO WORK CAN BE PERFORMED ON A PROJECT UNTIL NOTIFICATION TO INITIATE RESEARCH HAS BEEN PROVIDED BY THE ACOS/R.**
- b. The basic R&D submission is an electronic submission to eRRRP:
<https://vaww.gateway.research.va.gov/errrp/>. Based on the type of research you are doing, you may also be required to upload copies of any of the following forms: budget, proposal (grant, science portion), Collaborative Research Worksheet (CRW), assessment of clinical impact (signed by PI), Pharmacy Impact (signed by PI), SRS or “Biosafety” approvals, Research Data Inventory (RDI) and Emory IRB approvals. Human subjects would include additional IRB approved forms such as informed consent, HIPAA authorization/revocation as well as others based on what is involved, i.e. drugs, devices.

5. **Training**-to perform research at the Atlanta VA, numerous training requirements must be satisfied for all research personnel (including the PI, technicians, coordinators, etc). The WOC Coordinator (WOCCoordinator@atlaref.org), 404-321-6111 ext. 6177, will help you determine what trainings are necessary. Current training requirements can be found at
http://www.atlanta.va.gov/Docs/VA_Training_Requirements.pdf

a. **Computer Trainings:**

- i. CITI Program: PIs and all project staff must complete CITI training requirements for VA. The courses required depend on the type of project you will be conducting. CITI courses include human research, species specific animal trainings, post procedure care of rodents, biosafety training, biosecurity training, waste anesthetic gas training, DOT shipping training, radiation safety training, and Conflict of Interest training (required for all PIs and staff). CITI training is available on any computer at
<https://about.citiprogram.org/en/homepage/>.

- ii. VA Specific TMS trainings: These trainings include privacy awareness (for certain staff) and information security awareness. TMS (<https://www.tms.va.gov/learning/user/login.do>) training is ONLY available through VA computers. If you do not have access to a VA computer, you may come to the Research Office to complete your training.

b. Face to Face trainings

- i. Before personnel engage with human subjects, they must complete a didactic human subjects training session.
- ii. Veterinary Medical Unit Orientation-Sandra Meyer, (Sandra.meyer@va.gov, ext. 2514) Veterinary Technician, will provide training on VMU procedures.
- iii. Radiation Safety orientation can be scheduled by contacting Sean Riggan (sean.riggan@va.gov; 404-321-6111 x2543)

6. Contact Information:

R&D Chair - Mabelle Pardue, Ph.D., mabelle.pardue@bme.gatech.edu

IACUC Chair – Jeffrey Boatright, Ph.D. jboatri@emory.edu

SRS Chair – William Shafer, Ph.D. Wshafer@emory.edu

IBC Chair – Michael Fallon, DVM, Michael.Fallon@va.gov

Veterinarian - Michael Fallon, DVM, PhD, Michael.fallon@va.gov

David Knight, Science Information Officer, David.Knight2@va.gov, 404-728-4827

Derek Key, SIO program assistant, derek.key@va.gov, 404-321-6111 ext. 1458

Rodney Thompson, Research Compliance Officer, Rodney.Thompson8@va.gov, 404-321-6111 ext. 6964

Antonio Laracuente, Director of Research Operations, Antonio.laracuente03@va.gov, 404-728-7632

Michael Hart, Associate Chief of Staff for Research, Michael.hart3@va.gov, 404-728-7632

Daniel Roysden, VA IRB Liaison, droysde@emory.edu VA 404 -321-6111 ext. 2512 Emory 404-712-9749

Kallie Medbery, WOC Coordinator, mary.medbery@va.gov, 404-321-6111 ext. 6177