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

All submission information and forms can be found on the Atlanta VAMC website (http://www.atlanta.va.gov/services/research/Investigators.asp).

1. **To access these forms and get additional information, you will need to set up an AREF online account.** To create new account, go to the AREF website, www.atlaref.org, and click on the link in the upper right hand corner. This account will enable you to accomplish several things.
    a. Completion of the Laboratory Annual Self Inspection Form (LASIF). (See 3.a below)
    b. 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 (February-March) 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 faculty member, ask your department to create your Commons ID
        ii. if you are NOT an Emory faculty member, contact Antonio Laracuente (Antonio.laracuente03@va.gov, 404-728-7632).

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 404-712-9749).

3. **What subcommittee approvals do you need for your project?** These submissions can be done all at the same time, but all approvals must be obtained before you can submit for R&D approval. **Subcommittees include:**
    a. **Subcommittee for Research Safety-Biosafety** (SRS)-must approve specific projects and/or Laboratory Annual Self-Inspection Form (LASIF). LASIF**s** are required for any new laboratory, f**o**r all projects involving biological hazards, radiation hazards, chemicals, and animals. 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.

    b. **IACUC (Institutional Animal Care and Use Committee)**- must approve all projects involving experiments with animals
        i. All protocols 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. If procedures are performed at Emory, submit to VA IACUC first then to Emory IACUC. 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. **Institutional Review Board (IRB)** – all studies involving human subjects or the use of identified human samples or data, must be approved by the IRB (Emory 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. If you don't have one, contact Antonio Laracuente. Laurie Hunt, Human Studies Analyst (laurie.hunt@va.gov, 404-321-6111 ext 4750), can help PIs with their IRB submission which is done through an electronic system called eIRB. If consent forms are needed, she can also make sure they meet VA requirements. We also have an IRB protocol analyst who is assigned to all VA projects to help PIs through the process. His name is Jim Henderson (jshende@emory.edu 404-712-9749).

ii. The only projects that may be reviewed by another IRB are 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 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 INTIATE 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 scan and upload signed copies of any of the following forms: budget, proposal (grant, science portion), assessment of clinical impact, conflict of interest for all PIs and Co-Is, data security checklist, SRS or "Biosafety" approvals, and Emory IRB approvals. Human subjects would include additional forms such as informed consent, HIPAA authorization/revocation as well as others based on what is involved, i.e. drugs, devices. Data security also has additional forms depending on where the data will reside, who it is transferred to, etc. If data or specimens are housed off-site (please contact Laurie Hunt, HSA to determine if an offsite waiver is required), the Information Security Officer would need to be involved.

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). Nakela Jackson (nakela.jackson@va.gov), 404-321-6111 ext 6177, will help you determine what trainings are necessary.
    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).
        ii. VA Specific TMS trainings: These trainings include privacy awareness (for certain staff) and information security awareness.

    b. **Face to Face trainings**
        i. Before engaging in human subject research, PIs and staff need to complete a didactic human subjects training session. Contact the Clinical Studies Center or the SIO office for more information.
            1. If CPRS access is needed, this would be an additional face to face training.
        ii. Veterinary Medical Unit Orientation-Sandy Yurevich, Veterinary Technician, will provide training on VMU procedures.
        iii. Radiation Safety orientation can be scheduled by contacting Sean Riggin (sean.riggin@va.gov; 404-321-6111 x2543)

6. **Contact Information**:

R&D Chair - Machelle Pardue, PhD, mpardue@emory.edu
IACUC Chair - Jennifer L. Gooch, PhD, jgooch@emory.edu
SRS Chair – Mike Fallon, DVM, Michael.Fallon@va.gov
SRS Co-Chair- Sarah Satola, Ph.D., Ssatola@Emory.edu
Veterinarian - Michael Fallon, DVM, PhD, Michael.fallon@va.gov
David Knight, Science Information Officer, David.Knight2@va.gov, 404-728-4827
Priscilla Miller, SIO program assistant, Priscilla.Miller3@va.gov, 404-321-6111 ext 2512
Elizabeth Lively, Research Compliance Officer, Elizabeth.lively@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