



Collaboration Guidance for VA and UF Investigators

Collaboration between the University of Florida (UF) and the North Florida/South Georgia Veterans Health System (NF/SGVHS) provides significant benefits to research, education, and clinical care at both institutions. Many research and clinical faculty members hold dual-appointments with UF/VA, which enhances their professional success and career satisfaction.

VA Research: NF/SGVHS offers collaboration with top-notch scientists and provides access to cutting-edge research laboratories and equipment. Affiliation with NF/SGVHS allows access to intramural funding from the US Department of Veterans Affairs in the areas of biomedical, clinical, rehabilitation, and/or health services research. VA research opportunities also include shared equipment grants, access to the Million Veteran Program (MVP) genomic dataset and national VA Computerized Patient Record System (i.e., electronic medical records), ability to recruit Veteran research participants, and more. In collaboration with the North Florida Foundation for Research and Education (NFFRE), funding from intramural and extramural research awards can flow between UF and NF/SGVHS to promote successful collaborations. NF/SGVHS is home to multiple centers engaged in VA research, including the Brain Rehabilitation Research Center (BRRC), Veterans Rural Health Resource Center (VRHRC), and Geriatric Research Education and Clinical Center (GRECC).

VA Education: NF/SGVHS plays a crucial role in the educational missions of the Department of Veterans Affairs and UF. Each year, NF/SGVHS provides the following funding and resources:

- training for over 200 UF students in 25 different graduate medical education programs. Medical residencies are offered in dental general practice, pharmacy, physical therapy, post baccalaureate nursing, primary care optometry, psychiatric-mental health nurse practitioner, and psychology.
- nearly half of the faculty effort required to operate the UF College of Medicine's residency program.
- UF students in several graduate programs benefit from VA research infrastructure to support thesis and dissertation projects. Post-doctoral associates also obtain training and research opportunities at the VA. These collaborations benefit the UF Colleges of Medicine, Public Health and Health Professions, Engineering, Health and Human Performance, and others.
- continuing education opportunities to employees through various programs such as Lean Six Sigma (process improvement and work efficiency), Franklin Covey Leadership series, AHA Basic Life Support courses, High Reliability Organization (safety in complex environments), and root cause analysis simulations.

VA Clinical Care: NF/SGVHS is the largest and most complex VA healthcare system in the United States. It is comprised of two medical centers (Gainesville and Lake City), a Domiciliary, and 24 clinics located throughout a 50-county catchment area (including in Jacksonville, Tallahassee, Lake City, Ocala, and The Villages). The VA is on the cutting edge of medical innovation, such as through initiatives in geriatric care, nursing home care, zero patient harm, rural health, virtual care, suicide prevention, vaccination, and many other areas. Many VA clinicians also enjoy protected research time to engage in clinical and basic research that leads to innovations in Veterans health.

NF/SGVHS Research: Facts and Figures

- Comprehensive webpage with guidance for Research Investigators and Coordinators:
<https://www.nffre-research.org/va-research-resources>

- Approximately \$10 million in research expenditures during fiscal year 2022.
- Over 23,500 square feet of dedicated research space, including for human and animal research.
- 45 Principal Investigators, including PhD scientists and clinician-scientists.
- 40 Research Coordinators and 15 Administrative Professionals.
- Approximately 200 additional Research Service employees on paid personnel agreements or volunteer agreements, most of whom are UF faculty, post-doctoral associates, graduate students, and undergraduate trainees.
- NF/SGVHS has its own Human Research Protection Program, and works with several external Institutional Review Boards including UF IRB, VA Central IRB, Advarra, WCG, and the National Cancer Institute IRB. Most investigator-initiated research projects use the UF IRB, thereby providing a consistent and familiar process for UF affiliated investigators.
- NF/SGVHS has its own Veterinary Medical Unit and Institutional Animal Care and Use Committee, as well as extensive collaboration with UF animal research facilities and committees.
- The Brain Rehabilitation Research Center has been continuously funded since 1999 by the VA Rehabilitation Research and Development Service. The center award provides over \$1 million/year in administrative infrastructure to support center-affiliated research and investigators in their work on mechanisms and treatment of disability with injury/disease of the central nervous system.
- The Veterans Rural Health Resource Center in NF/SGVHS is one of only 5 national centers funded by the VA Office of Rural Health. The center supports research locally and across the country that focuses on improving health and independent living of Veterans who live in rural areas.
- The Geriatrics Research, Education, and Clinical Center (GRECC) is one of 20 centers in the nation that is focused on optimizing geriatric research and care. GRECC teams of scientists and clinicians test new models of clinical care to improve health, safety, and quality of life for older Veterans and their caregivers.
- NF/SGVHS is a site for the Million Veteran Program, which is a national research program studying how genes, lifestyle, military experiences, and exposures affect health and wellness in Veterans.

Types of VA Appointments

Paid appointment – VA paid employees work full-time or part-time for the US Department of Veterans Affairs and are eligible for federal benefits. They receive a paycheck from the VA that is separate from compensation provided by UF or other employers. Due to federal regulations, US citizens are given priority for paid appointments. It is rare for non-citizens to be hired to a paid appointment, unless they fill a specialized need and there are no qualified US-citizen applicants to a posting on USAJobs.gov.

Interagency Personnel Act Agreement (IPA) appointment – an IPA is a mechanism for using VA funds to buy out effort from an employee who works for an outside organization. A common example is when UF faculty or post-docs collaborate on a VA funded award (as Co-I, staff, etc.), the IPA mechanism can be used to cover a portion of that person’s UF effort/salary. IPAs cannot be used to fund student or administrative effort. Non-citizens are eligible for IPA appointments.

Without Compensation (WOC) appointment – a WOC is a “volunteer” employee. WOCs are held to a similar standard as paid employees for onboarding and regulatory requirements. Some non-citizens can become WOC employees, but the requirements differ based on visa status. For details, consult with the Administrative Officer for NF/SGVHS Research Service.

Dual Appointments (VA/UF)

- There is a separate document with policy and guidance details on dual-appointments. Please contact the Associate Chief of Staff for Research Service to obtain the latest version of that document.

- Dual appointment refers to compensated employment at both UF and VA. For research faculty, the appointment at each institution is generally treated separately with regard to salary, benefits, leave, assigned duties, etc. A fundamental requirement of dual-appointments is that an employee cannot be paid from both institutions for the same work. There must be a clear distinction between compensated activity at each institution.
- Different departments at UF (even within the same College) may treat the prospects and logistics for dual-appointments quite differently. Many factors come into play, such as the size of the department, the presence of other dual appointed faculty, the relative importance placed on teaching/service/research, the availability of department resources (space, research infrastructure, administrative infrastructure), department expectations for achieving promotion, etc. The UF department chair sets the priorities and policies for the department, so it is important to ensure that goals are in alignment.
- Dual-appointed faculty should pay close attention to salary coverage at each institution. Requests for department-funded effort or “bridge funding” should be made well in advance of the fiscal year in which the salary support is needed. The fiscal years for UF and VA begin July 1st and October 1st, respectively. The availability of bridge funding is not guaranteed.
- VA clinician salaries cannot be paid with VA research dollars (except when the clinician is a Principal Investigator on a VA Career Development Award). Rather, VA clinicians must request protected research time from the NF/SGVHS Chief of Staff.
- Investigators with dual appointments who wish to apply for funding from NIH must have a Memorandum of Understanding (MOU) that defines their work/effort distribution at the two institutions. NIH requires that the MOU include the title of the investigator's appointment, distribution of effort/compensation, responsibilities of the investigator, and signatures from the appropriate officials at each institution. As a local best practice, all dual-appointed investigators should have an MOU regardless of whether NIH funding is involved. Additional guidance and a fillable MOU template are available on the NF/SGVHS Research Service webpage.

Grant Submission and Administration of Award Funds

- Intramural research proposals to the VA Office of Research and Development (ORD) must be submitted and administered by Research Service at NF/SGVHS. VA ORD provides several funding mechanisms, includes R01-equivalent (VA Merit Review awards), R21-equivalent (VA SPiRE awards), K-equivalent (VA Career Development Awards), multi-site clinical trials (Cooperative Studies Program), equipment awards (small and large equipment), and other special funding opportunities. Principal Investigators on awards funded by VA ORD must have a 5/8ths effort VA appointment. Co-Investigators and staff may have lower effort appointments.
- Extramural research proposals
 - **The table in Appendix 1 provides an overview of which organization should submit your proposal and administer the award funds. However, each study is different and should be discussed with leadership from NF/SGVHS, UF, and/or NFFRE to ensure an optimal outcome.**
 - Awards from any sponsor besides VA ORD (i.e., non-VA federal, industry, and foundation) are usually submitted and administered by the North Florida Foundation for Research and Education (NFFRE), if use of VA space/resources are being proposed. However, there are sometimes compelling reasons why UF should administer the award when projects involve both UF and VA space/resources. In these cases, UF can administer awards for projects that are conducted at NF/SGVHS. However, NFFRE should usually be provided a financial subaward to support the VA component, and a Cooperative Research and Development Agreement (CRADA) must be established (VHA Directive 1206). Example CRADA templates are available at https://www.research.va.gov/programs/tech_transfer/model_agreements/default.cfm.
 - Both UF and NFFRE generally charge indirect costs on subawards, although the rate that NFFRE charges to UF is much lower than the rate that UF charges to VA/NFFRE. This may be a factor in deciding who should administer the award when indirect costs must be included within the total budget cap (which is common for industry and foundation sponsors).

- NFFRE is a nonprofit research corporation affiliated with and embedded in the NF/SGVHS. NFFRE serves to advance the research and education missions of NF/SGVHS by administering all non-VA award money, as required by federal regulations. NFFRE can submit grants to federal, industry, and foundation sponsors, and serve as the prime recipient for the award. NFFRE's knowledgeable staff facilitate all aspect of conducting research – grant management, compliance, budgeting, hiring, procurement, travel, etc. For additional information, visit NFFRE's website (<https://www.nffre-research.org/>).
- There is no minimum appointment effort for Principal Investigators on awards funded by non-VA sources (unlike the 5/8ths minimum on intramural VA ORD awards).
- Indirect/Overhead funding from the sponsor: Unlike the indirect/overhead funds that are added to awards from NIH and some other sponsors, awards from the VA Office of Research and Development (ORD) do not include indirect funds directly to the institution or investigator. However, there are research indirect funds (called VERA funds) distributed by the VA at the regional level (in our case, VISN8 which covers most of Florida and Puerto Rico). These VERA funds are distributed to VA Medical Centers in a proportion that is determined by the VISN Director. Then, at the discretion of the NF/SGVHS Executive Director, VERA funds are provided to NF/SGVHS Research Service to support administrative staff positions and infrastructure needs. Research investigators do not have direct access to VERA funds.
- Calculating VA research expenditures: NF/SGVHS must account for all research expenditures pertaining to VA research. Sometimes this easily quantifiable based on a direct VA award from the VA Office of Research and Development (ORD), or by a subaward to NFFRE that covers all of the VA research activity on the study. At other times the VA research component is less easily quantifiable, such as when a UF-paid employee on a “without compensation” VA appointment is conducting research activities. For scenarios like this, NF/SGVHS will ask the investigator to quantify the percentage of the entire study that should be considered VA research. This percentage will be used for annual VA fiscal reporting but has no effect whatsoever on UF's fiscal reporting or management of research funding (in the case of VA/UF collaboration on a study).

How does UF benefit from VA collaboration and dual-appointments?

The most cited disadvantage for VA funded awards is the absence of indirect/overhead funding provided by the sponsor (versus NIH funding, for example). However, this perceived disadvantage is easily outweighed by several benefits:

- VA funding does not have to replace other funding sources, but rather can serve as an additional funding stream to support faculty and research staff salary, equipment purchases, and other research costs. Indeed, VA affiliation opens an entirely new line of intramural funding that is accessible to only a small fraction of the scientists in the country. This includes R01-equivalent (VA Merit Review awards), R21-equivalent (VA SPiRE awards), K-equivalent (VA Career Development Awards), multi-site clinical trials (Cooperative Studies Program), equipment awards (small and large equipment), and other special funding opportunities.
- VA collaboration may provide access to laboratory and office space, shared equipment, administrative support, professional development opportunities (service, mentoring, leadership), and collaborations that do not exist elsewhere. Access to these resources reduces burden on UF infrastructure, and creates new avenues for productivity and success for the investigator.
- When VA investigators join UF as grant-funded research-track faculty, the department essentially gains a faculty member for free (in many cases) or at minimal cost, and can then include that investigator's VA-supported research publications and presentations in the department's portfolio of accomplishments. The department/college will also receive the full benefit of that investigator's future extramural grants submitted through UF. Furthermore, the department/college may not have to provide a full startup package, office space, or lab space (although depending on the situation, the department may choose to provide some of these resources).
- UF departments are often the recipient of VA inter-agency personnel agreements (IPAs), which provide salary support for faculty Co-Is, post-docs, and other UF research employees who collaborate on VA research.

- The VA offers a rich environment for research, education, and clinical collaboration. Cross-institution collaboration is viewed favorably when UF departments and colleges are involved in applications for center grants, training grants, and in accreditation efforts, where collaborative environments are evaluated.
- Awards funded by the VA are counted toward UF faculty research productivity in promotion decisions (although tenure decisions may still weigh UF-administered research more heavily).
- For some award types (including funding from the Department of Defense), eligibility for submission and/or likelihood of success is enhanced by active collaboration with the VA.
- Junior investigators may compete for 2-year or 5-year mentored Career Development Awards that offer full VA salary support. Senior investigators benefit by mentoring these junior investigators.
- Senior VA investigators can compete for Research Career Scientist awards, which offer full VA salary support.
- Through cooperative agreements, most VA research spaces provide UF network connections to computers, servers, and informatics resources, ensuring convenient integration of research activities across institutions for dual-appointed faculty.
- Serving Veterans through research is a unique honor that provides career satisfaction to many investigators.

Approval of VA Research Studies

The approval process for research at the VA requires additional steps compared to the approval process at UF. The following people and processes may be involved with study approval at the VA. Guidance for navigating the study approval process is on the VA Research Service webpage (<https://www.nffre-research.org/va-research-resources>) and by contacting the appropriate committee administrators.

Associate Chief of Staff (ACOS) and Deputy Chief of Staff (DCOS) for NF/SGVHS Research Service – The ACOS for Research Service is the “Chief of Research”, and the DCOS is the “Deputy Chief”. Anyone pursuing a dual appointment and/or research study is advised to meet with the ACOS and/or DCOS for guidance. The ACOS reserves the right to modify or disapprove dual-appointments and research studies that are inconsistent with regulations or best practices.

Research and Development (R&D) Committee – The R&D Committee is a local committee at NF/SGVHS that is mandated by VA regulations. It is responsible for setting the strategic direction of Research Service (in collaboration with the ACOS and DCOS) and for final approval of all VA research studies. VA research approved by an IRB or IACUC must still obtain R&DC approval before starting.

IRBNet/VAIRRS – IRBNet is the electronic submission platform (website) that the US Department of Veterans Affairs uses to track all research studies (human and animal) and manage the national research portfolio. It is also known as VAIRRS: VA Innovation and Research Review System. Locally, NF/SGVHS uses IRBNet to track and route studies for approval (much like UF’s myIRB platform). IRBNet does not replace external information systems like UF myIRB or other IRB/IACUC information systems. Rather, researchers will usually need to enter study information into both systems.

Human Research Protection Program (HRPP) – The HRPP is responsible for oversight of VA research using human subjects. The IRB approval process is nested within the HRPP approval process. HRPP reviews studies for VA-specific regulations and also routes studies for review of information security, privacy, and financial conflict of interest.

Institutional Review Board (IRB) – Human research studies are reviewed by IRBs. NF/SGVHS does not have an IRB, but rather relies on several external IRBs to review VA research. These include the UF IRB, VA Central IRB, Advarra, WCG, and the National Cancer Institute IRB.

VA Institutional Animal Care and Use Committee (IACUC) - NF/SGVHS has its own IACUC to review animal research. NF/SGVHS also has a Veterinary Medical Unit (VMU) to house research animals. Currently, only research on rats and mice is permitted.

Subcommittee on Research Safety (SRS) – SRS is a subcommittee of the Research and Development Committee, and is responsible for overseeing safety of research personnel.

Regulatory/Oversight Officers – VA research studies must be approved by the NF/SGVHS Information System Security Officer (ISSO) and Privacy Officer (PO). The roles of ISSO and PO are not specific to research; they serve the entire

healthcare system. Research Service is also monitored by two Research Compliance Officers (RCOs). All of these oversight officers are separate from Research Service, and report to the Director of NF/SGVHS.

Mentoring Research Trainees at NF/SGVHS and UF

Any trainee who is working onsite at NF/SGVHS or accessing VA computer systems must have a VA appointment (see the section on VA Appointments for more information). “Without compensation” (WOC) appointments are common for trainees who are affiliated with UF, but should only be sought for those who intend to be substantially engaged in VA research. This is because there is considerable administrative effort involved with setting up and maintaining WOC appointments, both for the trainee and for Research Service administrative staff. A rule of thumb is that WOC trainees should commit to at least 10 hours of VA work per week, for at least one semester.

VA Post-Doctoral Associates

VA post-doctoral associates are usually VA-paid employees who are funded by a VA Career Development Award (CDA). CDAs are mentored awards that typically include a mentoring team of 3-4 experienced investigators. The primary mentor must be a VA investigator. Other mentors can be from UF or other external organizations. However, keep in mind that reviewers of a career development proposal may look more favorably on VA mentors because it implies a strong VA research environment and VA-aligned research topic.

UF Post-Doctoral Associates

UF post-docs are usually funded by extramural research grants (investigator-initiated research, or a training grant such as an NIH T32). The primary mentor is typically a UF faculty member who is affiliated with the grant. VA-only investigators can usually serve on post-doctoral mentoring committees.

UF post-docs who have been employed for at least 3 months are also eligible to obtain salary support with VA ORD funding through an Interagency Personnel Act Agreement (IPA).

UF Graduate students

There are four types of committee members for UF graduate students: Chair, Internal Member, External Member, and Special Member. Full details are on the UF Graduate School website, but a brief summary is presented here:

- *Committee Chair*: must be a UF faculty member with Graduate Faculty Status at both the university level and in the applicable graduate program, and typically is a primary faculty member in the department(s) that house the graduate program.
A faculty member who meets the Graduate Faculty Status criteria but is not a primary faculty member in the department might be approvable as a Co-Chair, at the discretion of department/program leadership.
- *Internal Committee Member*: must be a UF faculty member with Graduate Faculty Status at both the university level and in the applicable graduate program, and can be either primary faculty with the applicable department(s), or can be faculty in a different department.
- *External Committee Member*: UF faculty member with Graduate Faculty Status at the university level but not in the applicable graduate program. A graduate committee is often required to have an External Member.
- *A Special Member*: a person with expertise in the student’s research area, but who does not hold UF Graduate Faculty status. A VA-only investigator can be requested to serve as a Special Member on a graduate student committee when she/he has expertise that is relevant to the student’s research area.

Different graduate programs have different rules pertaining to financial support of graduate students. Some programs will not enroll a graduate student unless there is a full financial support package in place for tuition and stipend (which may be comprised of grant funding, scholarships, teaching assistantships, etc.). Other programs will allow students to enroll without a financial support package (i.e., the student would be responsible for paying their own tuition). Likewise, some programs will not allow students to hold outside employment, while other programs do not restrict outside employment. It is important to speak to the program director to understand all requirements for the specific graduate program.

VA ORD funding cannot be used to pay graduate student tuition or stipend. However, if allowed by the graduate program, the student can be employed as a research assistant at NF/SGVHS. Careful consideration should be made about whether the rate of pay is adequate to allow the student to afford tuition costs. Like all VA employees, the student would be expected to have a defined tour of duty and work onsite on VA research duties (or on an approved telework agreement). Paid employees should not be attending classes or working on academic assignments during their VA tour of duty. A part-time VA appointment would often make the most sense.

Keep in mind that graduate students often have very little disposable income, and investigators/mentors should not take chances with precarious financial arrangements. Do not accept a graduate student unless there is a solid and well-vetted plan to support the financial stability and academic success of that student.

UF Undergraduate students

Undergraduate students can be very helpful, but also require careful supervision. Anyone planning to recruit undergraduate students to assist with research should have a solid plan for ensuring the student is well-trained, well-supervised, and accountable. Many UF department have programs set up for connecting undergraduate students with research opportunities. Investigators can also recruit undergraduate research trainees through the UF Center for Undergraduate Research (<https://cur.aa.ufl.edu/>).

A UF faculty appointment is generally required to serve as a formal or primary mentor to a UF student (such as for a student engaged in research for course credit). An exception to this may be when NF/SGVHS is recognized as an internship site for academic programs that require students to complete an internship. Informal mentoring or serving as a mentoring committee member may not require a UF appointment, but it depends on the specific situation.

Undergraduate research assistants are not typically compensated by the VA, due to difficulties with hiring regulations and Human Resources timelines when using VA-administered awards. However, projects with extramural funding administered by NFFRE may have an easier path toward providing compensation to undergraduate research assistants.

Miscellaneous

Data Sharing – collaborative research studies may require a Data Use Agreement (DUA) and/or Cooperative Research and Development Agreement (CRADA) that outlines data storage, access, and security. For full details, contact the VA or NFFRE administrative team, and the committee that will oversee your study (Human Research Protection Program or Institutional Animal Care and Use Committee).

Intellectual Property - Research involving intellectual property (patents, inventions, copyrights, etc.) must carefully consider laws and regulations pertaining to both VA (Federal) and UF (State of Florida). For details contact the VA Technology Transfer Program and UF Tech Licensing.

Non-Veteran Enrollment – Veterans are normally given first priority for participation in VA research. If Veteran enrollment is unlikely to meet the recruitment needs of the study, then enrollment of non-Veterans can be requested/reviewed/approved by the NF/SGVHS Research and Development Committee. Approval is also required when a study requires non-Veteran research subjects, such as when conducting research interviews with caregivers, family members, or healthcare providers.

Offsite waiver – VA-funded research must occur at VA facilities, unless an offsite waiver has been approved. Full offsite waivers are rarely approved, but partial offsite waivers are relatively common. Approval of a waiver depends on the funding source, nature of the research, and various other factors.

Property Pass – VA-owned equipment must remain at a VA facility, unless a property pass has been approved. The property pass should remain with the equipment at all times when outside VA premises, and must be renewed annually.

Disciplinary Actions – For dual appointed investigators, disciplinary actions or termination of appointment at either institution must be reported to the supervisor at the other institution. The investigator is responsible for ensuring this occurs.

Collaboration Opportunities – to learn more about potential collaborators at UF, visit the UF Faculty Insights page: <https://ufl.discovery.academicanalytics.com/>

Appendix 1

		Who will submit the proposal and administer the funds?		
Sponsor	Primary Research Site	VA-only Investigator	Dual-appointed Investigator	UF-only Investigator
Dept of Veterans Affairs	NF/SGVHS	VA Research Service	VA Research Service	VA Research Service If successful will require a VA dual-appointment for the PI (≥ 5/8ths effort).
Dept of Veterans Affairs	UF	May be allowable with a partial offsite waiver, or may not be allowable. Consult with ACOS/DCOS and UF collaborator. If allowed, proposal will be submitted by VA Research Service. The project might also require a UF site PI depending on the need for department-controlled space or resources.	May be allowable with a partial offsite waiver, or may not be allowable. Consult with ACOS/DCOS and UF Dept Chair. If allowed, proposal will be submitted by VA Research Service. If successful will require that the VA appointment for the PI is ≥ 5/8ths effort.	May be allowable with a partial offsite waiver, or may not be allowable. Consult with ACOS/DCOS and UF Dept Chair. If allowed, proposal will be submitted by VA Research Service. If successful will require a VA dual-appointment for the PI (with ≥ 5/8ths effort).
Non-VA Govt, Industry, Foundation, Other	NF/SGVHS	NFFRE	NFFRE (preferably) or UF (when justified). Consult with ACOS/DCOS, NFFRE Director, and UF Dept Chair. If administered by UF, a subward to NFFRE is usually necessary.	NFFRE (preferably) or UF (when justified). Consult with ACOS/DCOS, NFFRE Director, and UF Dept Chair. If administered by UF, a subward to NFFRE is usually necessary. If successful will require a VA dual-appointment or a VA-affiliated site PI.
Non-VA Govt, Industry, Foundation, Other	UF	May or may not be allowable. Consult with ACOS/DCOS, NFFRE Director, and UF collaborator. If allowed, proposal must be submitted through NFFRE. The project might also require a UF site PI depending on the need for department-controlled space or resources.	UF If there is any use of NF/SGVHS space or resources, a financial subward to NFFRE is usually necessary. A Cooperative Research and Development Agreement (CRADA) is also required.	UF If there is any use of NF/SGVHS space or resources, a financial subward to NFFRE is usually necessary and there would need to be a VA-affiliated site PI. A Cooperative Research and Development Agreement (CRADA) is also required.