Principal Investigator Eligibility

Policy Type: Administrative
Responsible Office: Office of Research
Initial Policy Approved: 02/05/2015
Current Revision Approved: New

Policy Statement and Purpose

This policy defines who is permitted to serve as a Principal Investigator (PI) for sponsored projects, human research protocols and animal research protocols. Each activity involves somewhat different responsibilities; therefore, the eligibility requirements are also different. Detailed responsibilities for PIs are identified in the Roles and Responsibilities Matrix found in the “Related Documents” section of this policy. All PIs must complete any mandatory training requirements prior to beginning their research.

SPONSORED PROJECTS

VCU requires that the named Sponsored Project Principal Investigator be classified by VCU as a full-time employee of Virginia Commonwealth University and meet the following eligibility guidelines.

Individuals Eligible to Serve:

Any individual who holds one of the following positions on a full-time basis, or has accepted, in writing, an offer on a full-time basis, can be identified as a Sponsored Project Principal Investigator (PI) and submit proposals to external sponsors. This may include:

- President
- Provost
- Vice President
- Teaching and Research Faculty
- Term (non-tenure track) Faculty
- Administrative and Professional Faculty

Exceptions

Although not a full-time employee, a Pre- or Postdoctoral Scholar may serve as PI for a training grant when required by the sponsor. In addition, on a case-by-case basis, an individual with an appointment other than the above may be permitted Principal Investigator status. Approval of the Vice President for Research and Innovation is required prior to proposal submission. The procedures for submission for a case-by-case review can be found in the procedure section of this policy.
HUMAN RESEARCH PROTOCOLS

Individuals Eligible to Serve:
The Human Subject Research Protocol Principal Investigator must be available to devote adequate time and attention to the study to ensure its responsible conduct. The VCU Institutional Review Board (IRB) requires that the individual holding the title of Human Subject Research Protocol Principal Investigator be a permanent, full-time or part-time employee of Virginia Commonwealth University or the Virginia Commonwealth University Health System Authority.

Exceptions
A non-employee with a VCU faculty appointment who will conduct research within the scope of his/her appointment and provides the following to the IRB for review:

   a) a copy of the appointment letter and
   b) the VCU IRB PI Eligibility Request form completed and signed by the appropriate Department Chair and Dean.

Human Subjects Research Guidelines for Students:
The VCU IRB recognizes that a key component in the educational mission of VCU includes research experience for all students. Students/trainees may not serve as Principal Investigators on human subject research protocols, however, students may submit to the VCU IRB with qualified faculty or staff supervision. The supervisory faculty or staff must be clearly identified as the Principal Investigator on any VCU IRB submission and agree to keep the student informed about all decisions/actions of the IRB.

ANIMAL RESEARCH PROTOCOLS

Individuals Eligible to Serve:
The Animal Research Protocol Principal Investigator must be available to devote adequate time and attention to the study to ensure its responsible conduct. VCU’s Institutional Animal Care and Use Committee (IACUC) requires that the individual holding the title of Animal Research Protocol Principal Investigator be a full-time VCU faculty member or Predoctoral or Postdoctoral Scholar-Trainee.

Exceptions
Individuals who have a contractual relationship with VCU may serve as a PI with approval of the Vice President for Research and Innovation, via the PI Eligibility Exception Form, after demonstrating adequate training to carry out the proposed research, including specific IACUC-required training.

On a case-by-case basis, an individual with an appointment other than the above may be permitted Principal Investigator status. Approval of the Vice President for Research and Innovation is required prior to protocol submission. The procedures for submission for a case-by-case review can be found in the procedure section of this policy.
Animal Research Guidelines for Students:
The VCU IACUC recognizes that a key component in the educational mission of VCU includes research experience for all students. Students, other than Predoctoral or Postdoctoral Scholar-Trainees, may not serve as Principal Investigators on animal research protocols, however, students may submit to the VCU IACUC with qualified faculty or staff supervision. The supervisory faculty or staff must be clearly identified as the Principal Investigator on any VCU IACUC submission, sign the Assurance Statement form, the USDA Pain Category E form (if applicable) and agree to keep the student informed about all decisions/actions of the IACUC.

Noncompliance with this policy may result in disciplinary action up to an including termination. VCU supports an environment free from retaliation. Retaliation against any employee who brings forth good faith concerns, asks clarifying questions, or participating in an investigation is prohibited.

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Who Should Know This Policy

All individuals involved in sponsored programs and/or human or animal research are responsible for knowing this policy and familiarizing themselves with its contents and provisions.

Definitions

Administrative and Professional (A&P) Faculty

Administrative Faculty – Administrative faculty appointments require the performance of work directly related to the management of the education and general activities of the institution, department or subdivision thereof. Incumbents in these positions exercise discretion and independent judgment and generally direct the work of others. The organization reporting relationship normally must go no lower than three levels below the President.
**Professional Faculty** – Professional faculty appointments require advanced learning and experience acquired by prolonged formal instruction and/or specialized work experience. This category is normally limited to librarians, counselors, coaches, lawyers, physicians, dentists, veterinarians and other professional positions serving education, research, athletic, medical, student affairs, and development functions or activities.

**Term Faculty**
Term faculty appointments are generally full-time appointments for a specified term and do not lead to tenure. Term faculty members hold the same basic benefits and rights and responsibilities as tenured or tenure-eligible faculty in accordance with the University’s Academic Rights and Responsibilities policy except that they shall not be afforded tenure or tenure eligibility.

Term faculty may be employed to work on a specific project or series of projects that may involve teaching, research, or service or some combination of these activities. Employment of faculty in project-related positions is limited by the funds available and prior notice of termination or non-renewal varies according to the job category. Term faculty supported by restricted funds may be subject to different terms of notification of non-renewal that shall be specified in the letter of appointment in accordance with VCU’s Promotion and Tenure (P&T) policy.

Term faculty are appointed at the rank of professor, associate professor, assistant professor or instructor. A term appointment may be for a term of one to five years and is renewable.

**Institutional Official**
The Institutional Official is the individual at VCU who is authorized to legally commit on behalf of VCU that the requirements of the Animal Welfare Final Rule (9 C.F.R., Parts 1, 2, and 3) will be met. The Institutional Official at VCU is the Vice President for Research and Innovation.

**Predoctoral or Postdoctoral Scholar – Trainee**
A pre- or post-doctoral individual supported by an extramurally funded fellowship or traineeship for mentored training where the extramural sponsor requires that the Trainee be named as the PI on the sponsored award. Trainees receive a stipend to pursue an individually defined training program and are paid through a University account but not through the University payroll system.

**Principal Investigator**

- **Sponsored Project PI** - The Principal Investigator of a sponsored project is the individual with overall responsibility for the conduct of research or other activity described in a proposal or an award; and/or the individual with fiduciary responsibility for an award's management.
- **Human Subject Research Protocol PI** - the Principal Investigator of a human research protocol is the individual with ultimate responsibility for the conduct of the activities described in the protocol and for protecting the rights and welfare of human participants involved in the research.
- **Animal Research Protocol PI** - the Principal Investigator of an animal research protocol is the individual with ultimate responsibility for the conduct of the activities described in the protocol.
**Teaching and Research (T&R) Faculty**

Positions in this category have specific assignments that customarily require instruction, research and public service as their principal activity. These positions have academic ranks designated as Professor, Associate Professor, Assistant Professor or Instructor. Additionally, faculty rank of Research Associate or Research Assistant may be used under appropriate circumstances. The University offers tenure to certain faculty based on an extensive peer review and administrative process.

**Contacts**

The Office of Sponsored Programs officially interprets this policy as it applies to sponsored projects and the Office of Research Subjects Protection officially interprets this policy as it applies to human and animal research protocols. The Office of Sponsored Programs and/or the Office of Research Subjects Protection is/are responsible for obtaining approval for any revisions as required by the policy Creating and Maintaining Policies and Procedures through the appropriate governance structures. Please direct policy questions to the Office of Sponsored Programs for sponsored projects or the Office of Research Subjects Protection for human or animal protocols.

**Procedures**

Individuals eligible to serve as Principal Investigator under this policy should be listed on all appropriate documents for the particular sponsored project or protocol.

Individuals who are not eligible may apply for an exception, the outcome of which is dependent on a case-by-case review.

To apply for a case-by-case review for sponsored projects or animal protocols, the individual should complete and submit the PI Eligibility Exception Form found in the “Forms” section of this policy. To apply for a case-by-case review for human research protocols, the individual should complete and submit the VCU IRB Principal Investigator Eligibility Form found in the “Forms” section of this policy.

Requests should be made for a specific project and for a specified period of time.

In making the case by case determination, several factors are considered; however, special attention will be applied to:

1. Commitment of proposed PI to project timeline and project administration
2. Academic quality of proposal
3. Qualifications of proposed PI
4. Relevance and importance of proposal to other University interests.

Individuals requesting case-by-case review requests should submit them to:
- Sponsored Projects: dirospa@vcu.edu
- Animal Protocols: Include with protocol application materials
- Human Subjects: Include with protocol application materials
The Vice President for Research and Innovation, in his sole discretion, makes the final decision on approval of PI eligibility exception requests.

**Forms**

1. VCU IRB Principal Investigator Eligibility Form
2. PI Eligibility Exception Form (Sponsored Projects and Animal Protocols)

**Related Documents**

1. Roles and Responsibilities Matrix

**Revision History**

This policy supersedes the following archived policies:

None – New Policy

**FAQs**

1. I am completing a traineeship application. Who should be listed as the Principal Investigator?

   Sponsor requirements determine who is listed as the Principal Investigator. Some sponsors require that the trainee be listed as the Principal Investigator; other sponsors require that the fellow’s mentor be listed. Please follow sponsor instructions.

2. I am retiring from VCU, can I continue to hold the position of Principal Investigator for a sponsored project?

   No. Review the Re-employment of Retirees policy for procedures for the part-time employment of retirees.