

# Who gets to be a PI?

Every three years, the IACUC at Great Eastern University met to review its own standard operating procedures (SOP) to assure they were up to date and compliant with federal regulations and policies. SOP III-42 stated that the Principal Investigator (PI) of an IACUC protocol is the person who has the responsibility and authority to direct the animal activities on the protocol. SOP III-42 had always been interpreted by the IACUC as allowing postdoctoral scholars (postdocs) to function as PIs, as long as the postdoc's faculty mentor was listed on the protocol as the postdoc's sponsor. This interpretation was now being questioned by Dr. Jamie Matthews, an assistant professor of cell biology, who said that the SOP seemed to contradict itself. "How is it possible," she asked, "to be a PI with the responsibility of directing an animal research project if you have

to have a faculty mentor overseeing or guiding you?" She wanted to know if a postdoc would have the authority to spend a mentor's grant money if, for example, the IACUC requested a pilot study or if a mentor's oversight would be required if a postdoc had a grant of his or her own. Matthews said that she wasn't trying to be a trouble maker; rather, she envisioned unnecessary research delays or animal welfare problems if a financial, personnel, or significant scientific problem arose and the mentor wasn't immediately available. Did the postdoc have or not have the authority to handle such problems?

Larry Covelli, the IACUC chairman, responded that the problems Matthews envisioned had never occurred during the many years he had chaired the IACUC, but if the committee thought that an SOP change was

needed, it could vote for that change. However, as the discussion progressed it became clear that other members on the committee, especially the more senior faculty, were perfectly happy with the SOP as it was currently written because they saw the SOP as a good training mechanism for their postdocs and less work for them.

Do you think that Matthews has reasonable concerns? How do you think the Great Eastern IACUC should resolve the issue raised by Matthews?

**Jerald Silverman**

*University of Massachusetts Medical School,  
Worcester, Massachusetts, USA.*

*e-mail: [Jerald.Silverman@umassmed.edu](mailto:Jerald.Silverman@umassmed.edu)*

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# Determining PI status

This scenario reviews the concept of who should be a Principal Investigator (PI) on an animal use protocol. It defines a PI as the person who has the responsibility and authority to direct the animal activities on a protocol. An IACUC member, Dr. Matthews, raises the question since Great Eastern University allows postdocs to be PIs, as long as the postdoc's faculty mentor is listed on the protocol as the postdoc's sponsor, how can the postdoc as the PI have the responsibility of directing an animal research project? Will the postdoc have the authority to direct and pay for a pilot study or deal with financial, personnel or significant scientific problems if they arose and the mentor was not available?

Dr. Matthews' concerns are valid in that the PI has many very important responsibilities as the leader of the research project and the signatory on the grant award. He/she sets the tone and assigns responsibilities to staff and collaborators. Publication of the final results is a central responsibility of PIs and so they are obliged to meet all requirements regarding publication and access to results. The PI is also required to comply with university policies as they relate to data security, confidentiality, data ownership, intellectual property, and copyright<sup>1</sup>. The PI is responsible for submitting an application to use animals in research, teaching or testing, as well as modifying or renewing existing research projects that use animals<sup>2</sup>. There must be assurance that the animal use section of any associated grant accurately reflects

the animals used. The PI also ensures that the research staff is well trained on animal handling and the procedures outlined in the protocol, along with remaining current on techniques that help to reduce, replace or refine animal procedures<sup>2</sup>. The PI ensures that distress, discomfort or pain in the research animals is limited to that which is unavoidable in the conduct of valid scientific research or teaching and that the study is performed with due consideration for relevance to human or animal health, the advancement of knowledge, or the good of society<sup>2</sup>. The PI must make sure the animals are well cared for and that emergency veterinary care is administered to animals showing evidence of pain or illness, in addition to routine veterinary care, as prescribed for individual species. The PI understands that it is her/his responsibility to have available current emergency contact information for relevant personnel<sup>2</sup>.

Because of the numerous and sometime complex requirements to be a PI, it is suggested that postdocs along with graduate students, visiting scientists, and research associates only be allowed assignment as Co-Investigators under the direction of a PI. Individuals listed on animal use protocols as PIs should be of the rank of tenure track faculty, emeritus faculty, clinical faculty, scholar/scientist, or lecturer. These positions would have the ability to apply for and become funded for animal research projects and thereby would be able to assume supervisory, scientific, ethical and financial support for such a project. Postdoctoral

fellows, graduate students, visiting scientists, and research associates would likely not be able to obtain significant funding and assume financial and ethical responsibility for an animal use protocol. The transition from student to responsible investigator occurs during this time and requires learning and being mentored. Individuals can and should assume supervisory, scientific, and ethical roles in research under the mentorship of faculty who have more experience in conducting animal studies and ultimately hold the ethical and financial responsibility for the study should any noncompliance violations occur requiring review by the IACUC or outside regulatory agencies. We also suggest that postdocs and others be actively involved in writing, modifying, and amending animal use protocols. The period during which a postdoc is mentored should be used to learn the role of PI, without the ultimate responsibility that a PI holds, so that they become well-trained, productive research scientists themselves.

**Karen L. Rogers**

*Indiana University, Bloomington, Indiana, USA.*

*e-mail: [rogerkar@iu.edu](mailto:rogerkar@iu.edu)*

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# Modify the SOP

Dr. Matthews expressed reasonable concerns about the Great Eastern University IACUC's long-standing interpretation of SOP III-42. Presuming that this SOP does not clearly delineate the requirements to serve as a Principal Investigator (PI) or as a researcher's delegate in certain matters, it is not appropriate for the IACUC to embrace implicit meanings for convenience's sake, creating "...less work for them (PIs)."

OLAW's FAQ page defines the Principal Investigator as, "...the individual(s) judged by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the grant."<sup>1</sup> The USDA *Animal Welfare Regulations* document defines a PI as one who is, "...responsible for a proposal to conduct research and for the design and implementation of research involving animals."<sup>2</sup> As a rule, research organizations recognize clinical researchers, tenured-track faculty, and scientists as appropriately trained and suitably skilled individuals that may be considered for the role of PI. The contributors to and editors of *Management of Animal Care and Use Programs in Research, Education, and Testing* further note, "The responsibility for actual study conduct obligates the PI to both the funding agency or sponsor and the public through regulatory agencies via the IACUC or EOB."<sup>3</sup> Moreover, the 8<sup>th</sup> edition of the *Guide* acknowledges the parties that are ultimately responsible for animal care and use programs are: "...both the institution and the **principal investigator** (PI) can begin to address their shared obligations for humane animal care and use."<sup>4</sup>

While eligible to receive funding from some sources, postdoctoral (postdoc) fellows are in a transitional phase rather than occupying a position of final research authority. The postdoctoral step is important to fulfill before assuming the role of a researcher/PI. While many individuals at this point in their career are conscientious and scientifically talented, it is essential for postdocs to dedicate time to experiential learning at a progressive level, *ipsa vitae experiential*.

Thus, SOP III-42 should be revised to include language describing who may serve as a PI, outlining the responsibilities

## A WORD FROM APHIS AND OLAW

*In response to the issues posed in this scenario, the US Department of Agriculture - Animal Plant Health Inspection Service (USDA-APHIS) and the National Institutes of Health - Office of Laboratory Animal Welfare (NIH-OLAW) provide the following clarifications:*

In this scenario, the Institutional Animal Care and Use Committee (IACUC) is reconsidering its standard operating procedure for who can be a Principal Investigator (PI) on an IACUC protocol. Great Eastern's SOP allows a postdoctoral scholar (postdoc) to function as PI if the faculty mentor is listed on the protocol as the sponsor.

The Animal Welfare Act Regulations (AWAR) requires all persons involved in animal use to be qualified to perform their duties and designates the research facility as being responsible for providing training and instruction<sup>1</sup>. The PI is defined as "an employee of a research facility, or other person associated with a research facility, responsible for a proposal to conduct research and for the design and implementation of research involving animals."<sup>2</sup> The regulations also outline the responsibilities of the PI which include but are not limited to: consulting the Attending Veterinarian on painful/distressful procedures, considering alternatives to painful/distressful procedures, and providing the appropriate medications for procedures causing more than momentary or slight pain/distress unless withholding is scientifically justified in writing<sup>3,4</sup>. As a result, it is the responsibility of the IACUC to determine whether persons designated as the PI using an AWA regulated species meet the definition and fulfill the qualifications and responsibilities as set forth by the regulations.

The Public Health Service Policy does not contain specific guidance on who can serve as PI for research involving animals. The Policy at IVC.1.f states that "the IACUC shall determine that personnel conducting procedures on the species being studied will be appropriately qualified and trained in those procedures."<sup>5</sup> The Policy also states that "no PHS support for an activity involving animals will be provided to an individual unless that individual is affiliated

with or sponsored by an institution which can and does assume responsibility for compliance with the Policy, unless the individual makes other arrangements with the PHS."<sup>6</sup> The flexibility provided by the Policy allows the institution to define the PI within the constraints that it finds acceptable. This differs from the NIH definition of the PI on a grant application: "the individual judged by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the grant"<sup>5,6</sup>. In some cases, postdocs may be the PI on an NIH award, especially with its current interest in supporting early stage investigators<sup>7</sup>. Such postdocs qualify in their own right to serve as PIs using Great Eastern's definition and should list themselves as their own faculty mentor. It is also of note that OLAW allows the individual listed as the PI on the grant to be different from the PI on the IACUC protocol<sup>8</sup>. □

Bernadette Juarez<sup>1</sup> and Patricia Brown<sup>2\*</sup>

<sup>1</sup>Deputy Administrator USDA, APHIS, AC.

<sup>2</sup>Director, OLAW, OER, OD, NIH, HHS.

\*e-mail: brownp@od.nih.gov

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of a PI with regulatory references, and defining requirements and responsibilities for postdoctoral fellows that may serve as a

PI's delegate. Then, the IACUC would review and consider adoption of the newly revised SOP.

It is important for IACUCs to acknowledge the dynamic characteristic of the animal welfare regulatory landscape, in which each member may contribute to, especially in light of the *21<sup>st</sup> Century Cures Act*. IACUCs possess an inherent fluidity as well, given the varied generations of scientists, administrators, safety specialists, and community members that serve. The Great Eastern University IACUC

would benefit considerably by providing recurring, continuing education in the form of conferences and workshops (e.g., IAA Best Practices, IACUC 201/301, SCAW, etc.), enabling all members to refresh perspectives and share best practices.

**Susan Glowacz**

Indiana University, Bloomington, Indiana, USA.  
e-mail: [sglowacz@indiana.edu](mailto:sglowacz@indiana.edu)

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## IACUC SOPs

The Great Eastern University's IACUC was following its accepted practice of reviewing its SOP Manual to ensure compliance with federal regulations and their procedures to maintain the timeliness of these processes. The Merriam-Webster dictionary defines SOP as “established or prescribed methods to be followed routinely for the performance of designated operations or in designated situations”<sup>1</sup>. When Dr. Matthews presented what appeared to be a contradiction in one of these accepted practices, her due diligence was greeted by push back from the IACUC chairman. Her concerns seem reasonable. As is often the case, junior faculty and postdocs are reliant on their sponsor's monetary and lab support. If Dr. Matthews, as a member of the faculty, found the details of SOP III-42 not clear and explicit, her views deserve to be explored by the IACUC. A strong definition of the PI eligibility requirements is critical to the research enterprise. The fact that the IACUC—comprised of faculty

with the most to win or lose—was content with this “learning experience” and the ambiguity it provides is most concerning. I have reviewed several institutions' SOP requirements on PI eligibility<sup>2-4</sup>. They all are clear in their PI definitions. In my experience, the true goal of a SOP is to provide explicit instructions, with no room for individual interpretation. In fact, Great Eastern's IACUC is allowing individual interpretation of SOPs, which leaves them vulnerable from an oversight and compliance perspective. Any requirements by the IACUC for the protocol approval that involve the use of funds or resources that the PI doesn't have outright may result in a delay obtaining that approval. Worse yet, if it impacts animal health or well-being, that delay is more critical to providing continued humane care and use. Great Eastern's IACUC should use this as an opportunity to re-review their SOPs with a more critical eye. They can do this by surveying PIs and key stakeholders or by providing

focus groups, composed of different level academics, to discuss concerns or confusion regarding this SOP or any other. It is almost always better to fix a problem in house, than to try and fix it after it's brought to the institutional official's attention during a site visit.

**Regina Correa-Murphy**

VA Medical Center, West Palm Beach, Florida, USA.  
e-mail: [regina.correa-murphy@va.gov](mailto:regina.correa-murphy@va.gov)

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