**OFFICE OF RESEARCH AND DEVELOPMENT**

**VETERANS HEALTH ADMINISTRATION**

**Who Is Qualified to Serve**

**As The NSM or the NAM on the IACUC?**

DATE: August 13, 2015

It continues to be challenging for many to determine who is eligible to fill each of two critical voting positions on the IACUC: the non-affiliated member (NAM), and the non-scientific member (NSM).  In light of recent discussions with the Office of Laboratory Animal Welfare (OLAW) and the guidance published in June by OLAW (NOT-OD-15-109), we understand that the criteria that we provided several years ago must be updated. Revised lists of criteria are provided below, to reflect the newer definitions that are now being applied. These have been reviewed by OLAW for consistency with their requirements, and acknowledged for purposes of oversight by the VA Office of Research Oversight (ORO). If you have any questions about this issue, please contact Dr. Alice Huang (alice.huang@va.gov), office of the CVMO, or OLAW Division of Assurances (olawdoa@mail.nih.gov ).

YOUR ACTION IS NEEDED: Please review the criteria below and check to make sure that your NAM(s) and NSM(s) qualify for the positions they are appointed to. If any of them is not eligible, take immediate steps to recruit eligible person(s).  This is critical: If you don’t have qualified individuals in the NAM and NSM positions, your IACUC is improperly constituted and nothing that it does counts as an official action of the IACUC.  At best, that would mean that everything that requires IACUC action must wait until a qualified NAM and a qualified NSM are officially appointed. If this is not recognized in time, work that is done with animals, on the understanding that IACUC approval has been granted, may turn out to be work done without IACUC approval, which has to be self-reported. Even if no work has been done, the result can be far more aggravation than anyone wants to deal with: identifying all of the affected protocols and other actions, notifying investigators that protocols that they had been told were approved actually have not been approved after all, rescheduling all the business items for the IACUC to act on after it is reconstituted, and on and on.

Following are the criteria that have been reviewed by OLAW for accuracy (Keep in mind that individuals who are not qualified to serve as the NAM or NSM may still be eligible to serve on the IACUC as full regular voting members. The criteria below relate only to service in those specific roles.):

Non-Scientific Member (NSM, “Lay member”)

1.  General regulatory intent.  The NSM should be a person whose appointment can reasonably be expected to reassure the public that the IACUC includes a member who can speak for the appropriate care and use of research animals, without bias in favor of the interests of scientists involved in animal research. According to the new OLAW guidance, a person who has “a naïve attitude with regard to science and scientific activities” and is “without scientific training meets the Policy's intent”. Keep in mind that the term “scientific” is used broadly when determining whether a candidate is eligible to serve as the NSM, and includes many more people than just those who qualify to serve as what is commonly referred to as the “scientific member”: The “scientific member” must have specific scientific qualifications (PHS Policy requires a “practicing scientist experienced in animal research“), while candidates with scientific qualifications in a general sense (even if they are not currently practicing and have not had experience with animal research) are disqualified as the NSM.

2.  The most common reasons for a candidate to be DISQUALIFIED for the role of NSM are listed below. If EITHER of these is true, the candidate definitely cannot serve as the NSM.

* The NSM candidate’s current primary occupation or prior training is related to carrying out research involving animals. This means that anyone who carries out research procedures on animals, has training in such activities, or is otherwise named on any protocol for performing research with animals, is disqualified from serving as the NSM. (This disqualifies animal technicians who perform even routine procedures like providing anesthesia, during research procedures.)
* The candidate is responsible for directing others to perform research procedures on animals. (This disqualifies the PI of a project involving animal research, even if the PI does not personally perform any of the procedures on the animals.)

3.  If neither of the descriptions in NSM item 2 (above) applies, consider whether the candidate meets the general regulatory intent (NSM item 1, above). The following are examples of individuals who OLAW considers not qualified to serve as the NSM because they would be perceived as likely to be biased in favor of the interests of scientists involved in animal research: the VMU Supervisor, a health care provider, an active scientist (even in a field that does not involve animal research, such as botany, geology, or mathematics), and someone who was involved in animal research in the past (even if the person is no longer a practicing scientist).

4.  Because it can be unclear from an individual’s occupation or training whether or not he or she is qualified to serve as the NSM, OLAW says that “the institution should maintain written documentation of the reason for the categorization” for any NSM whose qualifications might be called into question.

Non-Affiliated Member (NAM, “Community Member”, “Public Member”)

1.  General regulatory intent: The NAM should be a person whose appointment can reasonably be expected to reassure the public that the IACUC includes a member who can speak for the interests of the general community with regard to ensuring the appropriate care and use of research animals.  This excludes people who use or have used laboratory animals.

2.  The most common reasons for a candidate to be DISQUALIFIED for the role of NAM are listed below. If ANY of these is true, the person definitely cannot serve as the NAM.

* The NAM candidate works with research animals.
* The NAM candidate serves on some other committee or subcommittee at the VA facility, or is part of the immediate family of someone who does.
* The NAM candidate volunteers in some other capacity at the VA facility, or is part of the immediate family of someone who does.
* The NAM candidate is an employee of the local VA facility, or is part of the immediate family of someone who is. (Note that receiving retirement benefits from the Department of Veterans Affairs does not disqualify a candidate, as those benefits are not paid by the local VA facility, and are not contingent on current performance.)
* The NAM candidate serves on the animal care and use committee at another institution that collaborates with the VA facility, or is part of the immediate family of someone who does. (This means that a member of the safety committee or IRB at a collaborating institution is not automatically disqualified from serving as the VA NAM. Of course, if that other committee interacts closely with the VA, members of the other committee would have an affiliation with the VA and be disqualified from serving as the NAM.)
* The NAM candidate is involved in an animal research program as an employee of an institution that collaborates with the VA facility, or is part of the immediate family of someone who is. (This would disqualify the histology technician or the secretary who works for an investigator who uses animals at a collaborating institution, but would not bar a nurse at the collaborating institution whose duties are 100% clinical, from serving as the VA NAM.)

3. NOTE: A NAM candidate is no longer disqualified by receiving medical treatment or other benefits from the local facility.

OLAW recognizes that these definitions are changed from the definitions that have been applied in the past, and has announced that “institutions are expected to implement and comply with the guidance by the 2015 annual report, due January 31, 2016, or by the next Assurance renewal, whichever comes first” (<http://grants.nih.gov/grants/olaw/newsarchive_2015.htm>, June 10, 2015). If your committee needs to find a new NSM or NAM, it may be useful to make inquiries among individuals in the following groups, as they are likely to meet the qualification criteria above and be willing and able to serve:

Local members of the clergy

Insurance adjusters

Retirees

Real estate agents

Volunteer firefighters or security personnel

Faculty members of the ethics department of a local university

Do not hesitate to contact the office of the CVMO, or OLAW, if you have specific questions about your local situation.