**Office of Research and Development & Office of Research Oversight**

**Joint Guidance on**

**Presentation of the Results of the Semi-annual Program Review and Facility Inspections**

**to the Medical Center Director.**

In order to clarify the intent and regulatory interpretation of the policy requirements, shown in bold below, the Office of Research and Development (ORD) and the Office of Research Oversight (ORO) jointly issue the following guidance.

**POLICY:**

The Institutional Animal Care and Use Committee (IACUC) is required to perform a semi-annual program review and facility inspection no less frequently than every six months. VHA Policies addressing this review and inspection are found in several sections of VHA Handbook 1200.07

VHA Handbook 1200.07 §8.f(1) states, in part: “Semi-Annual Program and Facility Self-Assessment Reviews. According to the USDA Animal Welfare Act Regulations and Standards (see 9 CFR §2.31(c)(1)) and PHS Policy, the designated VA IACUC must perform a self-assessment review of the program of animal care and research use, and an inspection of the animal facilities and husbandry practices at least every 6 months.”

Two additional sections of VHA Handbook 1200.07 address the presentation of the results of the review and inspection to the Medical Center Director (MCD).

VHA Handbook 1200.07 §8.f(1)(e). A majority (of all voting IACUC members) must vote to approve the report; each member must indicate approval by signatures next to the typed name and committee role. **Then the report must be discussed with the medical facility Director by the IACUC Chairperson, veterinarian, and one or more research administrators (other IACUC members may also attend as dictated by local IACUC policy).** The medical facility Director then must sign the report indicating that the report has been reviewed. (Emphasis in bold added).

VHA Handbook 1200.07 Appendix E §7.e. **Communication with the Medical Facility Director.** VHA Handbook 1200.07 stipulates that a majority of all voting IACUC members must approve the report and indicate their approval by signatures next to their typed names and roles on the committee. **The Veterinary Medical Officer (VMO) and/or the Veterinary Medical Consultant (VMC), the IACUC Chairperson, and the ACOS for R&D must discuss the report in a face to face meeting with the medical facility Director (other IACUC members may also attend);** then the medical facility Director must sign the report indicating that the Director has reviewed the report during a face to face meeting with the IACUC representatives. ***NOTE:*** *The Director's signature does not imply that the Director agrees with the report, but once approved by the IACUC, it may not be altered by any official. A discussion of disputed items may be provided in a cover memo. The Director's signature acknowledges receipt of the report, and verifies that the Director has personally discussed its contents with the IACUC. No other official may sign for the facility Director.* (Emphasis in bold added).

The differences in individuals required to participate between 1200.07 §8.f(1)(e) and 1200.07 Appendix E §7.e as well as the phrase “face to face” have proven to be a source of confusion in the application of this policy. In order to clarify intent and expectations, ORD and ORO have developed the following guidance.

**GUIDANCE:**

ORD and ORO agree that:

1. Facilities must make a good faith attempt to comply with established policy, and include the individuals specified in 1200.07 §8.f(1)(e). However, if a specified individual (excluding the Medical Center Director) cannot participate, said individual may designate an alternate, in writing; this delegation must be documented in the IACUC meeting minutes. The individual delegated must be able to speak authoritatively on behalf of the person he or she represents, and the IACUC Chair must be represented by a voting member of the IACUC. As the Institutional Official responsible for the animal care and use program, the Medical Center Director must always participate personally.

2. A meeting conducted in real time (eg: a teleconference or video conference) fulfils the requirement of a “face to face” meeting; the method of conducting the meeting must be documented in the IACUC meeting minutes.

3. Facilities following this guidance will not be cited by ORO for non-compliance with the above referenced VHA Policy.

**QUESTIONS?** Contact Alice Huang (alice.huang@va.gov, 404-417-1823) or James Trout (james.trout@va.gov, 202-632-7677).