I. BACKGROUND Federal regulations provide a mechanism for a single IACUC member, designated by the chair, to perform an initial or continuing review of a protocol or to review a modification to a protocol and recommend approval or modifications to secure approval.

II. SCOPE The purpose of this policy is to describe the use of Designated Member Review (DMR) by the OHSU IACUCs. This policy applies to initial, continuing, and modification reviews of protocols submitted to the IACUCs.

III. POLICY The OHSU IACUCs may utilize DMR for any of their reviews. Assignment to full committee review is done according to risk-based criteria. Characteristics of protocols for which an IACUC member might request full committee review include, but are not limited to:

a. Withholding analgesics for a painful procedure – i.e., unrelieved pain or discomfort (Category E);
b. Survival surgery;
c. Multiple major surgeries;
d. Prolonged restraint;
e. New procedures that represent an increase in pain over already approved procedures;
f. Food/water withheld for longer than 16 hours;
g. Any increase in number of non-human primate subjects for an approved protocol; or
h. Any procedure/protocol for which an IACUC member requests full committee review, per IV.c. below.

IV. PROCEDURES

a. The IACUC chair(s) will evaluate initial, continuing, and modification submissions according to the criteria listed in section III above and decide if the submission may be referred to the IACUC for acceptance of DMR.
b. When DMR is recommended by the chair, all members of the IACUC will be polled for agreement and given a reasonable amount of time (generally, two business days) to indicate disagreement. Written descriptions of all proposed activities that involve the care and use of animals shall be available to all IACUC members and any member of the IACUC may obtain, upon request, full committee review of those activities.
c. If full Committee review is requested by any member for a proposed activity, the protocol will be scheduled for review at a convened meeting of a quorum of the IACUC.
d. Absent dissension with the recommendation for DMR, the chair(s) will assign the DMR to an appropriate IACUC member. Veterinarian review may also be assigned when
protocols or modifications involve procedures that may result in pain, discomfort, post-operative infection or bleeding, or similar complications.

e. A designated reviewer may request veterinary review as part of the designated review process.

f. A designated reviewer may approve a protocol as submitted, require modifications to secure approval of the protocol, or remand the protocol for full committee review. A designated reviewer may not disapprove a protocol.

V. AUTHORITY

a. PHS Policy IV.B: "Implementation by Institutions." The IACUC shall, with respect to PHS-conducted or supported activities:

i. Review and approve, require modifications in (to secure approval) or withhold approval of those components of PHS-conducted or supported activities related to the care and use of animals as specified in IV.C. of this Policy;

ii. Review and approve, require modifications in (to secure approval); or

iii. Withhold approval of proposed significant changes regarding the use of animals in ongoing activities.

http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples

b. AWA 9 CFR 2.31(d)(2): "Institutional Animal Care and Use Committee." Prior to IACUC review, each member of the committee shall be provided with a list of proposed activities to be reviewed. Written descriptions of all proposed activities that involve the care and use of animals shall be available to all IACUC members, and any member of the IACUC may obtain, upon request, full Committee review of those activities. If full Committee review is not requested, at least one member of the IACUC, designated by the chairman and qualified to conduct the review, shall review those activities, and shall have the authority to approve, require modifications in (to secure approval), or request full Committee review of any of those activities. If full Committee review is requested for a proposed activity, approval of that activity may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.


c. OLAW Notice NOT-OD-09-035: “Background.” To conduct DMR, the following conditions must be met: all members of the IACUC must be given an opportunity to call for FCR [Full Committee Review], either for each individual protocol or by previously established written standard procedure, as described above. If, and only if, no member requests FCR], the protocol may be reviewed by one or more qualified members appointed by the Chair. (PHS Policy IV.C.2)

DMR may result in approval, a requirement for modifications (to secure approval), or referral to the full committee for review. DMR may not result in withholding of approval. (PHS Policy IV.C.2)

If an IACUC uses DMR, the approval date is the date that the designated member(s) approve the study. Animal work conducted before this date must be reported to OLAW as a serious noncompliance with the PHS Policy.