University of Maryland
The Use of Designated Review in IACUC Animal Study Protocol Review

Most Animal Study Protocols (ASP) are reviewed in a convened meeting of the full IACUC. Designated Review (DR) of an Animal Study Protocol is an exception to this policy. Designated Review is conducted by a subset of the IACUC members and occurs outside a convened meeting of the committee. However, any member of the committee at any time may request that a protocol, revisions, or amendments be returned to Full Committee Review (FCR).

The following is the UMCP IACUC policy for when and how Designated Review is permitted. The process for designated review is equally applicable to the review of proposed significant changes to ongoing protocols. For all DR situations, the full IACUC has voted and approved this Policy which stands as prior written approval to conduct business in the following manner, and to allow a unanimous vote of the quorum to make decisions on behalf of the IACUC. Again, any member may request FCR of any protocol or addenda at any time during the process.

1. Designated Review of an Animal Study Protocol may be used in three situations: a) The full quorum of the IACUC reviewed the ASP and voted acceptance pending responses to questions or modifications to the protocol. The modifications sent by the PI may be reviewed by DR. b) A legitimate reason exists for a review to be conducted outside of a regularly scheduled IACUC meeting. c) UMCP Protocols that involve off-campus research approved by that institution’s IACUC.

2. Procedure for DR following full-committee review (1.a., above): Prior to FCR, ASPs are distributed to all committee members and at least two primary reviewers are identified to provide an in-depth evaluation. If questions or modifications to the ASP are identified during the full-committee review, at least two members are identified to review the PI’s response to the committee’s request. Often the Chair and the Attending Veterinarian perform this second review, but other members may be selected including the original primary reviewers.

3. The second situation (1.b., above) occurs when the Chair or the Attending Veterinarian feel that there are circumstances that warrant a review of an ASP prior to the next convened meeting. It is the decision of the IACUC Chair whether the circumstances justify this review. The PI’s time constraint is generally not considered sufficient justification to warrant DR. If the Chair is in agreement, the ASP is sent to all committee members. If any member wishes full-committee review, then the ASP must be reviewed at a convened meeting with a quorum present. A committee member not requesting full-committee review within 5 business days is equivalent to approval of the DR process. If all (not just a quorum) of the voting members reply before the end of five business days, and there are no requests for FCR, the Chair may initiate designated review by referring the protocol to at least two designated reviewers. If the work involves animals in pain category II or III, the PI must also consult a veterinarian familiar with the use of animals in research. If revisions to the ASP are requested by the designated reviewers, the same reviewers must review each subsequent revision. ASPs are not considered approved unless all designated reviewers, the Attending Veterinarian and the Chair agree.

4. The third situation (1.c., above): The Chair of the UMCP IACUC and the Attending Veterinarian may conduct a Designated Review of ASPs that involve a UMCP PI, or graduate student advised by a UMCP PI, and for which the animal work will be done off-campus and has been approved by another institution’s IACUC.