

**UNIVERSITY OF CALIFORNIA, SAN DIEGO  
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE**

**Policy on Monoclonal Antibody Production**

The Institutional Animal Care and Use Committee will not approve the use of the ascites method to produce monoclonal antibodies unless the investigator uses the following criteria to justify that the use of animals is necessary when completing the Animal Protocol Application:

1. The proposed use of animals is scientifically justified;
2. Methods that avoid or minimize discomfort, distress and pain (including *in vitro* methods) have been considered; and
3. The latter have been found unsuitable.

In order to be in compliance with current NIH policy, it is the responsibility of the Institutional Animal Care and Use Committee (IACUC) to critically evaluate these criteria and appropriately document that the three criteria listed above have been fulfilled.<sup>1</sup> The 1997 workshop on alternatives in Monoclonal Antibody Production concluded that *in vitro* methods for MAb production should be the accepted method because the ascites method causes pain and suffering.<sup>1,2</sup> Thus use of the ascites method should be the exception and should require rigorous and well-documented justification. Justification should not be based solely on cost or convenience.<sup>2</sup> If adequate justification is not provided for an exception, then *in vitro* methods are required.<sup>2</sup>

If it is determined by the IACUC that the ascites method to product MABs is justified, the investigator should do everything possible to reduce the number of animals used and to minimize pain and distress. Mice used for ascites production may experience problems such as respiratory distress, circulatory shock, difficulty walking, drinking and eating (with resulting dehydration). Furthermore, mice may develop solid tumors during the process. In order to minimize pain and suffering, mice should be observed by the investigator daily including weekends and holidays to monitor the degree of abdominal distention and signs of illness. Ascites fluid should be removed by peritoneal tap before abdominal distention is great enough to cause discomfort or interfere with normal activity. The maximum frequency of taps is every other day. Mice should be euthanized when they show signs of illness such as huddling, ruffled coat, reluctance to move when touched and cold ears. To avoid dehydration, supplements such as moistened chow can be provided. Subcutaneous fluid therapy may be indicated.

References:

<sup>1</sup> OLAW Reports, National Institutes of Health, 11/17/97

<sup>2</sup> "Conclusions & Recommendations, Alternatives in Monoclonal Antibody Production" - Workshop of Johns Hopkins Center for Alternatives OLAW