

OFFICE OF EXTRAMURAL RESEARCH GUIDANCE CONCERNING THE PRODUCTION OF  
MONOCLONAL ANTIBODIES IN ANIMALS

Release Date: February 3, 2000

NOTICE: OD-00-019

National Institutes of Health

This Notice provides guidance to Public Health Service (PHS) awardee institutions and Institutional Animal Care and Use Committees (IACUCs) on avoiding or minimizing discomfort, distress, and pain to animals in the production of monoclonal antibodies (mAbs), in accordance with the PHS Policy on Humane Care and Use of Laboratory Animals.

BACKGROUND

On December 10, 1999, the NIH Director responded to a petition by the American Anti-Vivisection Society to prohibit the routine use of animals in the production of mAbs. That response endorses the conclusions and recommendations of the National Research Council (NRC) report "Monoclonal Antibody Production. It reiterates the applicable federal animal welfare standards, affirms existing guidance from the Office for Protection from Research Risks on policy implementation at the institutional level, and lists important information resources and NIH-supported core facilities with tissue culture capabilities.

GUIDANCE TO AWARDEE INSTITUTIONS

Institutions should examine their current IACUC practices regarding the review and approval of proposals to produce mAbs in animals. The IACUC semiannual evaluation of the institutional program of animal care and use is an appropriate mechanism for accomplishing this self-evaluation. Institutions should use the guidance in the following documents as the basis for evaluation:

- o November 17, 1997 OPRR "Dear Colleague" letter at:  
<http://grants.nih.gov/grants/olaw/references/dc98-01.htm>
- o the NRC Monoclonal Antibody Production Report at:  
<http://grants.nih.gov/grants/policy/antibodies.pdf>
- o the NIH Director's December 10, 1999 letter at:  
<http://grants.nih.gov/grants/olaw/references/resp121099.pdf>

Institutions currently following the November 1997 OPRR guidance need not make additional changes in order to be in compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/phspol.htm>). The NRC Report and the NIH Director's response should be used as additional resources to assist IACUCs in making scientifically and ethically informed assessments of all future proposals to use the mouse ascites method of mAb production.

INQUIRIES

For questions or further information, contact:

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Office for Protection from Research Risks

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