

## IACUC POLICIES, PROCEDURES, and GUIDELINES

### ANIMAL PROTOCOL REQUIREMENTS FOR THE PRODUCTION OF CUSTOM ANTIBODIES

Custom polyclonal and monoclonal antibodies are those produced either from antigen provided by the contracting investigator or through the generation of a specific polypeptide that is then used to immunize animals to produce antibodies. The purchase of custom polyclonal and monoclonal antibodies requires the submission and approval of an animal use protocol through the Institutional Animal Care and Use Committee (IACUC).

The Public Health Service first clarified this requirement in 1995 in an OPRR REPORTS (Number 95-02, Animal Welfare, March 8, 1995) distributed to all PHS-funded institutions (<http://grants.nih.gov/grants/olaw/references/dc95-3.htm>);

“A common example of this is the production of antibodies using antigens provided by an investigator ("custom" antibodies) in animals. Institutions and investigators should be aware that if animals are utilized to produce such antibodies for use in PHS-supported research, the organization producing those antibodies must either have on file with OPRR (now OLAW) an approved Animal Welfare Assurance (Assurance) or be included as a component of the applicant organization's Assurance. In addition, if species covered by the Animal Welfare Act are utilized, the producer must be registered as a "Research Facility" with the U.S. Department of Agriculture (USDA).”

The Public Health Service requirements were further clarified in 2001 with the release of a Notice in the Federal Register (NOT-OD-01-017, February 12, 2001) [<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-017.html>];

“If both institutions have full PHS Assurances, they may exercise discretion in determining which IACUC reviews research protocols and under which institutional program the research will be performed. It is recommended that if an IACUC defers protocol review to another IACUC, then documentation of the review should be maintained by both committees. Similarly, an IACUC would want to know about any significant questions or issues raised during a semiannual program inspection by another IACUC of a facility housing a research activity for which that IACUC bears some responsibility or exposure.”

In deferring the majority of the protocol review to the contracted production agency, the IACUC retains responsibility to obtain documentation indicating the activity was reviewed and approved by the IACUC of the contracted producer and that the contracted producer is a registered facility with the USDA and possesses a valid PHS Assurance. In instances where investigators are using vertebrate animals in their research endeavor and must submit an animal use protocol for IACUC review and approval, this can be easily accomplished in the e-Sirius<sup>®</sup> protocol system. One of the last sections in the e-Sirius<sup>®</sup> protocol asks the investigator to indicate if they are contracting for outside antibody production and if they respond “yes” requests the necessary additional information for IACUC approval. In instances where the investigator’s research does not require the use vertebrate animals except for the production of antibodies, the abbreviated “IACUC Protocol Application Form: Custom-made Antibodies” can be used to request IACUC review and approval.

In reviewing an application for contracted polyclonal or monoclonal antibody production the IACUC office shall verify that the contracted agency or firm has a valid PHS assurance and, if a covered species is involved, that the agency or firm is registered with the United States Department of Agriculture as a Research Facility. A copy of the contracted agency or firm’s IACUC protocol approval and date shall be included in the e-Sirius<sup>®</sup> protocol file as an attachment.

The University of Kentucky IACUC also retains a responsibility to ensure that the contracted production is scientifically justified, minimizes pain and distress to the animals involved, and is not duplicative. Ideally, when available, a complete copy of the polyclonal or monoclonal antibody protocol being used by the contracted agency or firm, including details concerning adjuvants used, the injection protocol, and analgesics used will be submitted and attached to the e-Sirius<sup>®</sup> protocol file. If the complete protocol is not available, the investigator should provide the information requested in the “IACUC Protocol Application Form; Custom-made Antibodies” application and the IACUC office shall attempt to obtain a copy of the approved IACUC protocol from the contractor for attachment to the e-Sirius<sup>®</sup> protocol file. The investigator must make a good faith effort to identify and use commercially available antibodies potentially suitable for the proposed work. The use of on-line antibody search engines (<http://www.abcam.com/>) should be an integral component of the search for “duplication.” The databases searched, the date of the search, and the results are required entries on the “IACUC Protocol Application Form: Custom-made Antibodies” form. If antibodies are commercially available and your research requires custom-made antibodies, scientific justification must be provided as to why the commercially available antibodies were deemed unacceptable.

If the ascites method of monoclonal antibody production is to be used, sufficient information must be provided for the IACUC to “determine that (i) the proposed use is scientifically justified, (ii) methods that avoid or minimize discomfort, distress, and pain (including in vitro methods) have been considered, and (iii) the latter have been found unsuitable.” ([OPRR REPORTS, Number 98-01, November 17, 1997](#)).

The purchase of commercially available polyclonal or monoclonal antibodies does not require the submission of an animal use protocol or approval of the Institutional Animal Care and Use Committee (IACUC). Commercially available antibodies are those already produced and available usually through company catalogs or antibody suppliers such as Abcam (<http://www.abcam.com/>).

Approved and Adopted by the  
Institutional Animal Care and Use Committee  
September 17, 2008

Modified and Approved by the  
Institutional Animal Care and Use Committee  
October 15, 2008

## IACUC Protocol Application Form Custom-made Antibodies (Streamlined Version)

Please complete this form if either of the following conditions applies:

- 1) Your research is funded by the Public Health Service (NIH) and your research requires custom-made antibodies that are not available commercially; or
- 2) Your research is funded by the Public Health Service (NIH) and your research requires custom-made antibodies that are available commercially but you need them custom-made for scientific reasons.

***Please type in your answers!***

Protocol Title (Please complete this title by listing your proteins for which antibodies are required):

Custom-made Antibodies to

Principal Investigator: First Name                      Middle Initial                      Last Name

Campus Address:

Speed Sort:

Email:

Phone:

Funding Source/Agency:

Fund Title:

Sponsor Grant Number.

PI on Grant (If different than PI on Protocol): First Name                      Middle Initial                      Last Name

Synopsis: Explain in layman's terms, how this research relates to human and/or animal medical, physical, physiological or psychological diseases or problems. (Very brief)

Literature Search (Please search antibody databases to assess commercial availability. Recommend <http://www.abcam.com/>) - Databases Searched:

Date Searches Were Conducted:

Results of Search for Unnecessary Duplication (Please indicate whether or not the antibodies you are requiring are commercially available or not:

If the antibody or antibodies are commercially made and your research requires custom-made antibodies, please provide scientific justification for their use here:

Antibodies source(s) name (State the name(s) of the facility/institution producing the custom-made antibodies and a contact name and phone number):

Assurance # (State the PHS Assurance Number(s) of the facility/institution producing the custom-made antibodies if known):

Will the Ascites method be used? Select one: Yes      No

If the Ascites method will be used, please provide justification for using this method:

The ORI-IACUC Office will contact each source referenced above to obtain verification of their PHS Assurance Number and registration with the USDA (if covered species are used in the production), a copy of their IACUC's approval letter to produce these antibodies, and possibly a copy of their entire IACUC protocol. Additional information may be required for IACUC review (especially if the ascites method of antibody production is used).

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Please print out this form, date, and sign below.

Date:

By signing here, \_\_\_\_\_ I certify that I am the Principal Investigator of this IACUC protocol; that I am verifying that all information in the protocol is correct and accurate to the best of my knowledge.

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Please send or fax this document to the ORI-IACUC Office:

Samantha Otte  
222 Bosomworth Health Research Science Bldg  
Campus, 40536-0305  
Phone: 859-257-2934  
FAX: 859-257-9700

OR Ashley Walton  
214A Bosomworth Health Research Science  
Bldg  
Campus, 40536-0305  
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The IACUC is required to review this protocol on an annual basis. The ORI-IACUC Office will contact you a year after approval for any changes and updates.