Remote Production of Custom Antibodies

372.1 Policy: 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 IACUC retains responsibility to obtain documentation indicating the antibody production protocols were 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 that are using vertebrate animals in their research have a current animal use protocol, requesting approval for production of a custom antibody should be submitted as an amendment of the existing protocol. The amendment should include justification for the production and an indication that the production is not duplicative. 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 should be included in the amendment. The amendment should also identify the company that will produce the custom antibody and verify whether they have protocol assurance documentation already in the IACUC file or if they are a new company that needs to provide those assurances.

In reviewing an application for contracted polyclonal or monoclonal antibody production the Emory 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 of approval shall be filed with the IACUC office and available to investigators or oversight officials upon request. If the investigator chooses to use a vendor for antibody production that does not have these assurances on file, they must provide the production company's contact information so the IACUC office can obtain these assurances. The production of the custom antibody cannot be ordered until these assurances are provided.

If the ascites method of monoclonal antibody production is to be used, sufficient information must be provided to 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."

372.1 Definitions of Key Terms Specific to this Policy: 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.

372.2 Applicability: This policy applies to all Emory research related activities that fall under the IACUC's jurisdiction.

372.3 Background: 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 review 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."

372.4 Document Properties:
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