



**THE UNIVERSITY OF TOLEDO  
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE**

SUBJECT: Antibody Procurement

DATE: March 16, 2022

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**Guideline for Procurement of Custom Antibodies**

**Background**

The generation of custom antibodies is an activity involving vertebrate animals and is covered by Public Health Service (PHS) Policy. Custom monoclonal and polyclonal antibodies are critical research reagents, which require immunization of a living animal host, to be created. Antibodies are considered customized if produced using antigen(s) provided by, or at the request of, the investigator (i.e., not purchased off-the-shelf).

The University of Toledo is an NIH OLAW-Assured Institution. For all such institutions, NIH Office of Laboratory Animal Welfare (OLAW) requires that all custom antibodies must be obtained from entities (i.e. companies, institutions) that hold a PHS approved Animal Welfare Assurance. An entity producing custom antibodies for an awardee must have or obtain a PHS Assurance. Not all entities, especially those not based in the United States, have a PHS Assurance and therefore may not adhere to these required animal welfare standards. PIs must use only those entities that adhere to these federal animal welfare standards. A list of entities with a PHS Approved Animal Welfare Assurance can be found in the references below. In addition to a PHS Assurance, the entity must be registered with the USDA if the species used to produce the antibodies is regulated by the USDA-APHIS. If the entity that is producing the custom antibodies does not have a PHS Assurance number, the custom antibody cannot be used in any *in vitro* or *in vivo* experiments.

**Procedures**

Prior to procurement of the custom antibodies, approval from the UToledo IACUC is required. To obtain approval, the following must be submitted to the IACUC office at [IACUC@utoledo.edu](mailto:IACUC@utoledo.edu):

1. The producing entity's PHS Assurance ID and link to the entity webpage listing the Assurance number (if available).
2. If the species used to produce the antibodies is regulated by the USDA-APHIS, the producer of custom antibodies must be registered as a "Research Facility" with the U.S. Department of Agriculture (USDA)
3. One of the following is required:
  - a) The approved UToledo IACUC protocol that includes production of the custom antibodies. All procedures, including the creation of the project-specific custom

antibodies and/or identification of the entity that will produce the antibodies must be included.

- b) If the UToledo PI does not require an IACUC protocol for the intended research (*i.e.*, *in-vitro* research), a letter from the UToledo IACUC verifying that the entity providing the custom antibodies adheres to the PHS Policy will be sent to the PI after all the required documentation is submitted to the IACUC office.
4. Verification of the project specific IACUC approval for the production of the antibodies must be completed prior to obtaining custom antibodies

If sending an antigen to an institution/vendor to produce custom antibodies, a Material Transfer Checklist (MTA) must be filled out and must include the receiving entity's PHS Assurance ID. MTAs are processed through the Office of Research & Sponsored Programs, Technology Transfer Office.

## References

1. Office of Laboratory Animal Welfare (OLAW), NIH.  
[http://grants.nih.gov/grants/olaw/faqs.htm#App\\_2](http://grants.nih.gov/grants/olaw/faqs.htm#App_2)
2. Office of Laboratory Animal Welfare (OLAW), NIH.  
<https://olaw.nih.gov/guidance/obtaining-an-assurance.htm>
3. Office of Laboratory Animal Welfare (OLAW), NIH.  
[Institutions with a PHS Approved Animal Welfare Assurance \(nih.gov\)](#)