

Concept Clearance - Reissue of Animal Models and Animal Biological Materials Center and Resource Programs

ORIP's Strategic Plan emphasizes development and enhancement of research-related center and resource programs to promote accessibility to animal models and biological materials and exploration of ways to improve the reproducibility of research using disease models. ORIP supports many Center and Resource Programs that serve several purposes for the wide research community, including the creation, collection, characterization, preservation, distribution and enhancement of animal models as well as supporting collaborative research that links current personalized medicine efforts in human subjects with advances in animal genomics and genetic manipulation technologies. Additionally, some Centers and Resources provide informatics tools, data, biological materials, or services that support research projects from the scientific community. As part of ORIP's trans-NIH emphasis, Centers and Resources to be developed must address the research interests of multiple NIH Institutes and Centers. Applications must show significant need for the proposed Centers and Resources by the biomedical research community. Furthermore, such Centers and Resources must be available and utilized by investigators on a national basis. To ensure use, document impact, and preserve valuable materials and animals, applications must include a marketing plan, outreach strategies, approaches for tracking metrics, and a disaster response plan. Additionally, many Centers and Resources appoint an External Advisory Committee to provide guidance on their operations and on prioritization of new strains and materials to be maintained and distributed.

Between Fiscal Years (FY) 2013 to 2019, 29 Center and 14 Pilot Center applications have been received and 22 awards have been made to support 19 Centers and 3 Pilot Centers. A widely used measure of the impact of any research program is the number of scientific publications published by Center-supported investigators. The Center and Pilot Center awards funded between FY 2013 and FY 2019 have produced 288 publications in peer reviewed journals.

ORIP's current Centers portfolio includes grants which develop and distribute biological materials (natural toxins, reagents), informatics (Genetic Centers for *Drosophila* and *C. elegans*, Referral Center for Animal Models of Human Genetic Disease, Neuroanatomy with Neurotropic Viruses) and animal models from the most often used biomedical research species, such as nonhuman primates (macaques, baboons, squirrel monkeys, vervets), rodents (mice and rats), amphibians (*Xenopus*, *Ambystoma*), fish (zebrafish), and invertebrates (*Drosophila*, *Aplysia*, *Tetrahymena*), showing this portfolio's wide utility to investigators.

ORIP has also supported three Pilot Centers for Precision Disease Modeling. Each Center consists of an interdisciplinary research team of scientists and physicians organized to address specific medical problems by creating new animal models to more precisely mimic patient-specific disease processes and to develop innovative treatment options. Current technology permits specific genetic modifications in model animal species, as well as the ability to replace specific cells and tissues, resulting in phenotypes that are closely analogous to human patients. These new animal models have accelerated the generation of precision diagnostic and therapeutic approaches for such diseases as cancer, Alzheimer's disease, and diabetes.

There is significant involvement of program staff with ORIP's current Resource Programs portfolio to ensure that collections and distribution, which are generally focused on a specific purpose, are aligned with NIH priorities. For example, the National Swine Resource and Research Center creates and distributes swine models used for xenotransplantation and disease-specific research and preclinical studies. Ten awards are currently supporting Centers at eight institutions across the country to provide specific pathogen-free macaques for AIDS research. Lastly, the Human Tissue and Organ Research Resource distributes human tissues using standardized protocols to investigators across a variety of research fields and disciplines.

Based on the success of these Centers, Pilot Centers, and Resources in supporting investigators and research programs spanning topics across nearly all NIH Institutes and Centers, ORIP requests the concept clearance from the Council of Councils to continue support for the "Animal Model and Animal and Biological Materials Center and Resource Programs".