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

ORIP's Strategic Plan 2021-2025 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 multiple purposes for the broad research community, including the creation, collection, characterization, preservation, distribution, and enhancement of animal models, as well as supports 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 NIH-wide emphasis, Centers and Resources to be developed must address the research interests of multiple NIH Institutes, Centers, and Offices (ICOs). 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 marketing or distribution plans, 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 prioritization of new strains and materials to be maintained and distributed.

ORIP's current Centers portfolio includes grants which develop and distribute biological materials (natural toxins, reagents), informatics (Genetic Centers for *Drosophila* and *C. elegans*, Neuroanatomy with Neurotropic viruses) and animal models from the most often used biomedical research species, such as nonhuman primates (macaques, baboons, squirrel monkeys, and vervets), rodents (mice and rats), amphibians (*Xenopus* and *Ambystoma*), fish (zebrafish and platy fish/swordtails), and invertebrates (*Drosophila*, *Aplysia*, and *Tetrahymena*), showing this portfolio's wide utility to investigators. Examples of use and impact measures monitored by ORIP and each center include NIH funding support by ICO of PIs supported by resources and services from a Center, number of stocks and biomaterials collected and distributed over time by a Center, as well as number of scientific manuscripts and papers published by a Center's supported 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 rare diseases and other diseases such 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 HIV/AIDS related research. 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 Resource Programs in supporting investigators and research programs spanning topics across nearly all NIH Institutes and Centers, ORIP requests concept clearance from the Council of Councils to continue support for the "Animal Model and Animal and Biological Materials Center and Resource Programs."