Concept Clearance – Reissue of Development of Animal Models and Related Biological Materials for Research (R21)

The R21 program, "Development of Animal Models and Related Biological Materials for Research (R21)", was initiated in 2007. The R21 grant mechanism in general is intended to encourage exploratory/developmental research by providing support for the early and conceptual stages of project development. The project period of an R21 grant may not exceed two years and is not renewable. The total direct costs for the two-year project period may not exceed $275,000 and no more than $200,000 in direct cost may be requested in any single year. The goals of ORIP's Animal Models R21 program include supporting the development of animal models that are more predictable and accessible, and addressing the need for technology advancements, including those in genomics, and gene editing, in order to develop better animal models. These goals align well with ORIP's mission of "awarding grants to support research resource, such as animal models of human diseases." This program also facilitates ORIP's strategic plan as it relates to the "development and enhancement of models of human disease as well as expansion and accessibility of these models…" and to providing "better models of human disease conditions of interest to multiple NIH ICs."

The ORIP's Animal Models R21 program encourages highly innovative research to develop and characterize animal models, related technologies, and biological materials for the study of human disease. It also seeks to improve diagnosis and control of diseases that might interfere with animal use for biomedical research. As part of ORIP's trans-NIH emphasis, a unique feature of the R21 program is that the animal models, technologies, and biological materials proposed must be directly relevant to the research interests of multiple NIH Institutes or Centers.

Between Fiscal Years 2012 and 2018, an average of 50 applications per year were submitted and an average of nine awards were made annually under the ORIP's Animal Models R21 program. This is a success rate of approximately 19%. The most common research topic for R21 awards is model development, accounting for approximately 70% of all awards (followed by technology development). Approximately 50% of all awards focus on mouse models, followed in prevalence by the fly, rat and rabbit models. Additional models supported by the R21 program includes nonhuman primates, swine, *Xenopus*, zebrafish, spiny mouse, dog and opossum. Approximately 50% of ORIP R21 awardees have later received various additional types of awards, such as R01s, R21s and P30s, from as many as 12 separate NIH Institutes.

Considering the demands for new or improved animal models to advance our understanding of complex human diseases, ORIP requests the concept clearance from the Council of Councils to renew support for the "Development of Animal Models and Related Biological Materials for Research (R21)" program.