Office of Research Infrastructure Programs
National Institutes of Health
Department of Health and Human Services

Division of Comparative Medicine

Program Guidelines

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Division of Comparative Medicine Website

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INTRODUCTION

The Office of Research Infrastructure Programs (ORIP), located within the NIH Office of the Director's Division of Program Coordination, Planning, and Strategic Initiatives, advances the NIH biomedical research mission by supporting research resources, including animal models for basic and translational research, cutting-edge scientific instrumentation, construction and modernization of research facilities, research training opportunities for veterinary scientists, and small business funding. Through continued engagement with NIH institutes, centers, and offices (ICOs) and the biomedical research community, ORIP empowers and expands existing programs and develops new initiatives to support NIH research at the forefront of scientific progress. The Division of Comparative Medicine (DCM), one of ORIP's major components, supports basic, preclinical, and translational animal models (e.g., rodents, fruit flies, fish, amphibians, swine, nonhuman primates [NHPs]), cultured cells, and informatics systems for use by biomedical scientists. DCM facilitates research to develop new animal models and shared resources that distribute, characterize, maintain, and archive these models for use by other biomedical researchers, as well as provide services to the community to improve rigor and reproducibility of the biomedical research. Other resources support and supply biological materials and reagents, including cells, tissues, organs, and medically important venoms for research. Resources that facilitate genetic analysis and experimental manipulation of a variety of model systems function to make highly specialized technologies easily accessible to a much larger scientific community. Information on model organisms can help researchers determine appropriate models to investigate scientific questions by identifying specific model systems with particular tissues, molecular pathways, protein interaction networks, or signaling pathways similar to those known to be associated with human health problems. DCM supports resources that are applicable to two or more NIH categorical institutes and centers (ICs). See the Comparative Medicine Resources fact sheet or the next section discussing DCM's research interests for a more detailed explanation.

DCM also invests in programs that provide specialized biomedical research training, with a special emphasis on veterinarians, who already possess strong clinical backgrounds and familiarity with numerous species and expertise in comparative medicine. These professionals are given the mentoring, support, and experience they need to become highly valuable members of multidisciplinary research teams, as well as principal investigators on their own biomedical research projects. DCM also has a special interest in early-stage investigators (ESIs) who are studying HIV/AIDS using NHP models. Other awards are available to facilitate the reentry of individuals into active research careers after an interruption for family responsibilities or other qualifying circumstances.

DCM participates in NIH's Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, which seek to facilitate the commercialization of innovative and potentially transformative technologies. DCM has a special interest in attracting innovative SBIR/STTR projects that benefit research communities associated with ORIP's mission, especially in technologies related to improvements in animal models for human disease and the care, use, and management of laboratory animals.

RESEARCH AREAS OF INTEREST

DCM invests in initiatives that are broadly applicable to important biomedical research problems that are of interest to two or more NIH categorical ICs. If your research interest is specific to a particular disease, you should investigate opportunities at the NIH IC most closely associated with that disease. This requirement does not apply to DCM career development awards.

Consultation with the DCM staff member assigned to a specific program at least 10 weeks prior to the application due date is strongly encouraged. If requested, staff will consider whether the proposed research project meets ORIP's goals and mission and whether it meets the requirement as a broadly applicable research initiative.

Broadly applicable research initiatives include the following:

- Research to develop new or complementary animal models for human diseases, as well as resources to provide disease models, biomaterials, and reagents for use by biomedical researchers
- Studies that are designed to enhance the quality and reproducibility of biomedical research through enhancements in animal models
- Tools that enable researchers to select the most appropriate disease models based on their phenomes (i.e., the biochemical, molecular, physiological, and anatomical characteristics of an organism or of a specific organ, tissue, or cell within that organism)
- Postdoctoral research and career development training programs with a special emphasis on assisting veterinarians in becoming productive biomedical researchers and essential participants in the effort to improve human health
- Training and research support for ESIs who are studying HIV/AIDS using NHP models

DCM's programs, briefly described below, are accomplished through a variety of mechanisms and include grants, cooperative agreements, and contracts.

PROGRAM DESCRIPTIONS

The brief descriptions of the DCM programs below are followed by more detailed descriptions of the specific award mechanisms available. Individuals interested in more detailed information about a particular program should consult the relevant section of the ORIP website or contact the DCM staff person assigned to a specific program, either by email or phone. Individuals with more general questions may contact the DCM Division Director, Dr. Stephanie Murphy, at stephanie.murphy@nih.gov or 301-435-0744.

Potential applicants seeking information on funding opportunities can investigate ORIP-specific opportunities but should also visit the general NIH Grants and Funding website.

DCM supports a variety of resource and research centers that develop and provide animal models for human biology and disease and related services to biomedical researchers around the world.

These centers develop, characterize, house, preserve (e.g., cryopreservation, vitrification), and distribute both wild-type reference strains of animals and mutant strains. Depositing animals with rare and useful mutations at repositories can protect them from loss due to disease or accident and lower the costs of maintaining them. Resources funded by DCM ensure that the genetic backgrounds of wild-type and mutant animals do not undergo dramatic changes over time and that the animals are free of specific pathogens, thus enhancing the rigor and reproducibility of experiments performed by investigators in different laboratories. Continuous research activities by the scientists at these resource sites generate new knowledge and enhance the overall value of the resources to the research community.

Invertebrate Research Models

Biomedical research investigators have used organisms ranging from ciliates and flies to worms and marine invertebrates to understand many aspects of human physiology, genetics, aging, development, and disease. DCM supports resources that supply critical research materials and services, such as cultured cell lines, genetic stocks, technical training, and online informational systems on these types of model organisms for the benefit of the entire biomedical research community. Consult the list of invertebrate resources on the ORIP website. Additional information can also be found on the Invertebrate Models fact sheet.

Vertebrate Research Models

Vertebrate models (e.g., rodents, fish, amphibians, swine, NHPs) have long played a central role in biomedical research because they share much in common with humans with respect to genetics, development, physiology, behavior, and disease. DCM is interested in research that broadens the utility of human disease models. Some examples of vertebrate research models are given below. Consult the list of vertebrate resources on the ORIP website.

Aquatic Models

Aquatic species—such as zebrafish, swordfish, frog, and salamander—serve as important models for studying human development, behavior, and disease. Because some of these species have short reproductive cycles and transparent eggs and embryos, researchers are able to easily observe them as they grow and develop. Comparing the genes of these organisms with their human homologs enables researchers to explore their specific functions. Research related to these model organisms has led to an increased understanding of the biologic basis of a number of human disorders. Aquatic models have been important in studies of gene function, protein interactions, and various pathological processes in humans. DCM supports aquatic resources to develop, preserve, and maintain critical genetic stocks and biological materials and to share online information. Consult the list of aquatic resources on the ORIP website. Additional information can be found on the Aquatic Models fact sheet.

Rodent Models

Rodents can be conveniently housed in the large numbers needed for statistical significance and reproducible experimental results. The procedures for creating inbred strains, as well as the methodology for other genetic manipulations, are well developed in rodents, making them invaluable for biomedical research on human health and disease. Mice are particularly

important early in the preclinical development pipeline because of their genetic tractability and similarities to humans in development, physiology, metabolism, and disease.

DCM supports repositories for highly specialized rodent species and models, including those in which specific genes have been disabled (i.e., knockouts), rodents carrying specific mutations useful for research, germfree animals, and others. DCM also supports funding for hypothesis-driven, investigator-initiated research to develop, characterize, utilize, and preserve a wide range of new rodent models for human disease conditions and use them to test genome editing and reagent delivery technologies for gene therapy. Furthermore, DCM supports studies of biological materials that speed up the process of biomedical discovery and facilitate translational research moving from the basic science lab into the clinical research setting in the shortest period of time. Consult the list of rodent resources on the ORIP website. Additional information can also be found on the Rodent Resources fact sheet.

Swine Models

Domestic swine (*Sus scrofa domesticus*) are related closely to humans in terms of anatomy, genetics, and physiology, with their organs sharing common functional features and size. Swine have proven to be useful models for coronary artery disease; diabetes; heart, lung, kidney, and pancreatic islet xenotransplantation; hemophilia; obesity; hypertension; and other cardiovascular diseases and interventions, such as congenital heart disease modeling and pediatrics heart transplantation. The program includes the National Swine Resource and Research Center, which creates swine models as requested by the scientific community and serves as a repository and distribution center for these and other valuable swine models, as well as additional resources, such as biomaterials, reagents, and cultures that serve the biomedical community at large. The program also includes more specialized swine resources supporting stem cell–based regenerative medicine, stem cell therapy, and somatic cell genome editing. Additional information can be found on the Swine Models Centers and Research Resources fact sheet.

Nonhuman Primate Models

DCM supports resources and individual research projects that develop NHP models for human disease. These resources provide infrastructure and expertise to facilitate NHP use in biomedical research and develop methods that enhance their welfare. The program includes seven National Primate Research Centers (NPRCs), which provide access to several NHP species serving as models for a variety of human diseases and basic science. The program also includes more specialized NHP resources that concentrate on a single species. DCM supports research projects that help develop specific NHP disease models, reagents, or methods needed for the study of human health and disease. Consult the list of nonhuman primate resources on the ORIP website. Additional information can also be found on the Nonhuman Primate Resources fact sheet.

Genetic, Biological, and Information Resources

ORIP supports a variety of resources that provide genetic analysis and biological materials, such as cultures, reagents, and online information about model organisms used in biomedical research. Services available through these resources include genetically engineered model organisms, diagnostic services, cell lines, human tissues, snake venoms, and information

systems that can help researchers identify specific model systems, particularly tissues, molecular pathways, and protein interaction networks similar to those known to be associated with human health problems. Consult the list of genetic, biological, and information resources on the ORIP website. Additional information can also be found on the Biological Materials and Reagents fact sheet.

Training and Career Development Opportunities

DCM offers training and career development support for individuals with D.V.M., V.M.D., or Ph.D. degrees. These programs enhance the research careers of early-career scientists or their mentors. DCM has a special interest in biomedical scientists with veterinary degrees because they can offer distinct perspectives and expertise on translational biomedical research through their comparative understanding of human health and disease in the context of animal models. In addition to serving as principal investigators, veterinary scientists can also make unique recommendations regarding development, refinement, and reproducibility of disease models, as well as the advancement of laboratory animal maintenance and care.

DCM's programs are designed to address the growing need for research-trained veterinarians and to ensure that a sufficient number of individuals are trained in disciplines to meet the needs of the research community. Additional information also can be found on the Training and Career Development Resources fact sheet. These programs are geared toward research clinicians, pathologists, and specialists interested in research topics that include, but are not limited to, development, characterization, and archiving of animal models for human disease; development of animal-based genetic and genomic tools; phenotyping that covers the spectrum from clinical to molecular; reproductive biology; regenerative medicine; new approach methodologies (NAMs); and surveillance and control of selected laboratory animal diseases. Available training opportunities include the following:

Career Development Grants

These include three distinct types of Mentored Research Scientist Development Awards (K01), including a Special Emphasis Research Career Award (SERCA) in Comparative or Translational Medicine, a K01 focused on ESIs using NHP models (PAR-23-073), and a K01 focused on HIV/AIDS scholars using NHP models (PAR-23-225).

Institutional Research Training Grants

These awards are designed to encourage veterinarians to consider careers in biomedical research. Awards are made to institutions for support of Postdoctoral Programs (T32) for graduate veterinarians.

Mentoring Opportunities

Administrative supplements to existing ORIP grants enable the principal investigator to support additional individuals who are reentering the workforce after an interruption for family responsibilities or other qualifying circumstances. This opportunity is not limited to veterinary scientists.

NIH Loan Repayment Program

Extramural Loan Repayment Programs (LRPs) provide for the repayment of educational loan debt up to $50,000 annually for qualified health professionals performing research within the mission of NIH and supported by domestic, nonprofit, or government entities. ORIP cannot be listed as the primary institution but can be listed as a secondary institution on new applications. The research must be directly related to the ORIP mission. Specifically, proposed research investigations must be applicable to the interests of two or more of the categorical NIH ICs. In addition, projects that predominantly address the research interests of one NIH IC, but that are peripherally related to the research interests of other ICs, will not be considered appropriate. ORIP will give higher priority to applicants with the D.V.M./V.M.D. degree or an equivalent. Consult the NIH LRP website for more information.

Small Business Opportunities

DCM provides grant opportunities for small businesses to help meet the needs of biomedical researchers for technologies with commercial potential that advance the creation and characterization of animal models, improve animal husbandry and welfare practices, and enhance the rigor and reproducibility of animal research. Furthermore, ORIP promotes innovations that support preclinical research, including the development of NAMs aimed at reducing animal use. This is accomplished through the congressionally mandated SBIR and STTR programs for U.S. small businesses to engage in research and development that has a strong potential for commercialization. These efforts benefit ORIP-supported resources and the broader research community. Additional information can also be found on the SBIR/STTR fact sheet in English or Spanish. Areas of special interest to DCM include the following:

- Development and commercialization of technologies to create, characterize, or improve animal models for human disease
- Methods for production, identification, and preservation of new mammalian or nonmammalian animal models
- Development of methods, equipment, or reagents that facilitate the use of aquatic species for translational research
- Development of novel and emerging technologies for the accurate detection and diagnosis of polymicrobial infections in laboratory animals that support biomedical research
- Technology to improve the care, use, and management of laboratory animals
- Technology for cryogenic or other long-term preservation and revival of *Drosophila*, zebrafish, and other biomedically relevant species

Support for Conferences and Scientific Meetings

Scientific Conference Grants (R13) from DCM support national and international meetings that are organized and financially sponsored by the grantee institution. All meetings must be consistent with the scientific mission and goals of DCM. To ensure DCM's interest in the proposed meeting, prospective grantees *must* contact the relevant ORIP program official for written approval at least 8 weeks *prior* to submission of an application. Should DCM determine

that it desires substantial involvement in the planning and conduct of the scientific meeting, a cooperative agreement (U13)—rather than an R13—will be awarded. Normally, the awarded grant supports only a portion of the entire cost of the conference.

Consult the R13 conference grant FAQs *prior* to contacting the relevant ORIP program official.

AWARD MECHANISMS

DCM sponsors the following activities listed below. This listing is intended to familiarize potential applicants with the various mechanisms in use but does not imply that potential support is strictly limited to the activities described. Program staff encourage and welcome the discussion of potential applications. While notice of funding opportunity (NOFO) links are provided below, it is incumbent upon the potential applicant to ensure that the NOFO cited is current.

Once again, it is important to remember that DCM invests only in initiatives that are broadly applicable to biomedical research problems that are relevant to multiple NIH ICs and must explore multiple body systems or evaluate diseases and processes that impact multiple body systems to align with ORIP's NIH-wide mission. This requirement does not apply to DCM's career development awards. In addition, applicants requesting $500,000 or more in direct costs for any year *must* obtain approval from the DCM Director or other program official at least 8 weeks *prior* to submitting an application (see NOT-OD-23-075).

Research Project Grants (R01)

DCM supports investigator-initiated basic research projects related to animal models for human disease and laboratory animal medicine. The research proposed must not fall solely within the narrow interest of a single ICO. Examples of such research include, but are not limited to, the following:

- **Animal Models:** Develop and characterize animal models for human biology and disease. Model systems of interest include both mammalian and nonmammalian species, as well as cell culture systems and integrative computer models.
- **Genetic Stocks Preservation:** Develop or improve cryogenic or other long-term preservation and revival methods of genetic stocks for ORIP- and other NIH-supported genetic stock repositories.
- **Reproductive Biology:** Improve methods for producing transgenic and genetically identical animals, as well as improved methods for cryopreservation of biological materials, including germplasm.
- **Fundamental Biology of Animal Systems:** Perform investigations into basic aspects of animal models, including, but not limited to, animal genetics, physiology, behavior, nutrition, and identification and characterization of nontraditional species for research.
- **Somatic Cell Genome Therapies:** Develop animal disease models and reporter animals to test therapeutic strategies using genome editing approaches, including safety, efficacy, and translatability.

- **Animal Models for Stem Cell–Based Regenerative Medicine:** Characterization of animal stem cells to improve existing, and create new, animal models for human disease conditions. The intent of this initiative is to facilitate the use of stem cell–based therapies for regenerative medicine.
- **Animal Disease:** Detect and characterize diseases that may interfere with research and compromise animal welfare; support studies related to development of vaccines or of animals genetically resistant to disease.
- **Animal Welfare:** Improve methods for evaluating and alleviating pain, distress, and discomfort; develop and evaluate environmental enrichment techniques; improve housing and husbandry technology; and define, improve, or validate animal care and use procedures affecting research animals.

Research projects should be designed to establish, expand, or improve the utility of a specific model system. The projects may demonstrate the value of a certain animal species, stocks, or strains as a model for naturally occurring disease processes or other biological phenomena related to human health. Projects that attempt to establish a model for a single specific human disease should be directed to the NIH IC that supports research on that specific disease. Pilot studies involving the use of a model that has been developed may be supported only to the extent that such studies may be helpful in defining the model's value as a research tool. Support for full-scale research projects that use the model should be sought from appropriate categorical NIH ICOs or other sources.

Applications must be submitted electronically using the forms specified in NOFO PA-20-185: *Research Project Grant (Parent R01 Clinical Trial Not Allowed).* See a complete list of ORIP's funding opportunities.

Exploratory/Developmental Grants (R21)

DCM does not accept unsolicited R21 applications. However, DCM encourages R21 research grant applications that are responsive to specific NOFOs that ORIP has announced.

Support is limited to 2 years, with a budget defined within the specific NOFO. Applications for R21 awards should describe high-risk, high-reward projects rather than traditional R01 projects. Long-term projects or projects designed to increase knowledge in a well-established area will not be considered for R21 awards. Applications submitted under this mechanism should be exploratory and novel. These studies should break new ground or extend previous discoveries toward new directions or applications.

Currently, applications may only be submitted in response to the funding announcements listed on ORIP's funding opportunities webpage.

Resource-Related Research Project Grants (R24)

The DCM R24 mechanism is described in RFA-OD-22-013, *Resource-Related Research Projects for Development of Animal Models and Related Materials (R24 Clinical Trials Not Allowed).* These grants are aimed at supporting resource-related research projects to develop and characterize new animal-based resources, enhance existing resources, or acquire deep understanding of a model system to improve the utilization, accessibility, and translational

values of animal models to the research community. Applications for R24 awards can be predominantly research based (if that research potentially leads to the development of resources) or aimed at final development or enhancement of resources (if most of the necessary research has already been carried out). The R24 awards intend to support the development of animal models and related resources that would serve broad research areas. Applications for developing a limited number of resources are not suitable under this mechanism. DCM R24 awards also intend to fund the development of animal-based resources for supporting NIH-wide initiatives, including AIDS, women's health, Alzheimer's disease and related dementias, and the Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN) Initiative. See a complete list of ORIP's funding opportunities.

Animal Model and Animal and Biological Materials Resource Grants (P40)

The DCM P40 mechanism is described in RFA-OD-23-001, *Animal and Biological Material Resource Centers (P40).* These centers provide support for special colonies of laboratory animals, as well as other resources, such as reagents, cultures (cells, tissues, and organs), and genetic stocks that serve the biomedical research community at large. The resource centers for animal models or animal and biological materials collect, maintain, characterize, and preserve defined strains of animals and/or related biological materials and distribute them to biomedical researchers in a variety of research areas on a local, regional, national, and international basis. This funding opportunity is designed to both support continuation of existing resources and develop new ones when appropriate. Prior to preparing an application, applicants are strongly encouraged to consult with the DCM program staff to be advised on the appropriateness of the intended resource plans, the competitiveness of a potential application, and DCM's program priorities. See a complete list of ORIP's funding opportunities.

National Primate Research Centers (NPRCs) (P51, Limited Competition)

Seven NPRCs are supported with P51 grants. All aspects of P51 grant applications are described in PAR-23-126. DCM accepts renewal, resubmission, and revision P51 applications, as appropriate to a specific NPRC. DCM is not accepting new P51 applications at the present time.

Small Business Grants (R41, R42, R43, and R44)

Both SBIR (i.e., R43 and R44) and STTR (i.e., R41 and R42) grants are supported through DCM. Relevant research and development interests of DCM include, but are not limited to, control of laboratory animal pathogens, preservation or management of laboratory animals, and methods for identifying or producing new mammalian or nonmammalian animal models. ORIP has prepared a fact sheet and a resource guide for those seeking more information about its SBIR/STTR programs. Additional information is available on the NIH SBIR/STTR page and DCM Small Business Opportunities page. Applications must be submitted electronically by the deadlines prescribed on the schedule of Standard Due Dates. While DCM will accept SBIR or STTR applications from a number of specific NOFOs, prospective applicants are encouraged to contact the DCM program staff for advice before submitting SBIR or STTR applications. See a complete list of ORIP's funding opportunities.

Scientific Meeting Grants (R13)

Information concerning Scientific Meeting Grants (R13) is provided in Program Announcement PA-25-080. This grant mechanism provides support for national and international meetings that are organized and financially sponsored by the grantee institution. Normally, the grant awarded supports only a portion of the entire cost of the conference. All meetings must be consistent with the scientific mission and goals of DCM. A conference or scientific meeting is defined as a gathering, symposium, seminar, scientific meeting, workshop, or any other organized, formal meeting where people assemble to coordinate, exchange, and disseminate information or to explore or clarify a defined subject, problem, or area of knowledge. To ensure DCM's interest in the proposed meeting, prospective grantees *must* contact the relevant ORIP program official for written approval *prior* to submission of an application.

Consult the R13 conference grant FAQs *prior* to contacting the relevant ORIP program official. Applications with marginal or no relevance for DCM will not be accepted for review or possible funding.

Advance permission to submit an application must be requested early in the process and no later than 8 weeks before the application submission date. The letter from NIH that documents the advance permission must be included with the Cover Letter component of this application. The letter does not imply that the conference grant application will be funded.

Funding depends on the results of the merit review of the application and the availability of funds.

The Special Emphasis Research Career Award (SERCA) (K01)

The Special Emphasis Research Career Award in Pathology and Comparative Medicine (SERCA) K01 is designed to assist graduate veterinarians in mentored research experiences that enable them to become independent investigators in research related to comparative medicine, biomedical research, and translational sciences. The DCM SERCA guidelines are supplementary to the NIH-wide Program Announcement, PA-24-176, Mentored Research Scientist Development Award (Parent K01). Please note that SERCA differs from the parent K01 in certain specifics.

SERCA seeks to encourage the development of veterinarians working as biomedical researchers. This award provides graduate veterinarians (D.V.M. or V.M.D.) support for protected research time as mentored investigators. The goal is to enable these individuals to develop independent research skills and become competitive for research careers in academia as independently funded biomedical scientists. SERCA will increase the pool of veterinary researchers with a combination of clinical and research expertise in animal science to further develop and care for animal models essential for biomedical research.

Prospective applicants are encouraged to discuss their eligibility for the SERCA program with DCM program staff before preparing an application. It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide, especially section 7 on *Supplemental Instructions to the SF424 (R&R) for Preparing an Individual Research Career Development Award (CDA) Application ("K" Series),* except where instructed to do otherwise (in the NOFO

or in a Notice from the *NIH Guide for Grants and Contracts*). Applications must be submitted electronically and adhere to the specific instructions for Research Career Awards. Applications should be received by the deadlines prescribed in the Standard Due Dates for the new applications in the "K series." AIDS-related SERCA applications should be submitted on the due dates for AIDS-related applications.

Small Grant Program for ORIP Veterinary Scientist SERCA K01 Recipients (R03 Limited Competition)

This program provides ORIP-supported SERCA K01 awardees who have completed the first 2 years (24 months) of their K01 award the opportunity to apply for R03 Small Grant support (PAR-23-127). ORIP seeks to enhance the capability of ORIP SERCA K01 awardees to conduct research as they complete their transition to fully independent investigator status. ORIP's R03 mechanism supports different types of projects, including but not limited to, pilot and feasibility studies; secondary analysis of existing data; small, self-contained research projects; development of research methodology; and development of new research technology. The R03 is therefore intended to support research projects that can be achieved in a short period of time with limited resources ($150,000 direct costs over 2 years) and that provide preliminary data to support a subsequent R01 (or equivalent) application.

Early-Stage Investigators Using Nonhuman Primate Research Models (K01)

The Early-Stage Investigators Using Nonhuman Primate Research Models K01 (PAR-23-073) provides ESIs with support and "protected time" (up to 5 years) for intensive, research-focused career development program activities. These activities must be conducted under the guidance of an experienced mentorship team with expertise in both the preclinical application of NHP models and the translation of the results from such studies to clinical application. The focus of this program is to increase the number of highly skilled scientists using NHP models to address complex translational biomedical research designed to foster translation of outcomes into the clinic. The expectation is that through this sustained period of research career development and training, awardees will launch independent research careers and become competitive for new research project grant (e.g., R01) funding. ORIP will contribute up to $75,000 per year toward the salary of the career award recipient. ORIP will contribute $100,000 per year toward the research development costs of the award recipient. ORIP will support applications only from ESIs who are veterinary scientists. Veterinary scientists are individuals with a D.V.M., V.M.D., or equivalent degree who are engaged in biomedical research. Also see the companion funding opportunity (PAR-21-109) Early-Stage Investigator Research Using Nonhuman Primate (NHP) Models (R21 Clinical Trial Not Allowed).

HIV/AIDS Scholars Using Nonhuman Primate (NHP) Models (K01)

The HIV/AIDS Scholars K01 (PAR-23-225) provides ESIs with 3 years of mentored career development to prepare for independent research careers using NHPs as preclinical models for HIV/AIDS. The high cost and time required to perform NHP studies make it challenging for ESIs to transition to independent positions. HIV/AIDS scholars receive salary and research support and guidance from an experienced mentorship team with expertise in both the preclinical application of NHP HIV/AIDS models and in translation of the results from such studies to clinical application in humans. By enhancing critical aspects of career development—

such as grantsmanship, networking, and the ability to translate results from animals to the clinic—awardees prepare to launch independent research careers and become competitive for new research project grant funding (e.g., R01). The program brings participants together annually for the Conference for Early-Stage HIV/AIDS Researchers using Nonhuman Primate Models. Also see the companion funding opportunity (PAR-25-165) Early-Stage Investigator HIV/AIDS Research Using Nonhuman Primate (NHP) Models (R21 Clinical Trial Not Allowed).

National Research Service Awards (T32)

The purpose of the National Research Service Awards (NRSA) program is to help ensure that well-trained scientists will be available in adequate numbers and in appropriate research areas for the Nation's biomedical and behavioral research. The goal of training supported by DCM is to engage graduate veterinarians in biomedical or biobehavioral research. Experience with scientific methodology and research procedures is an essential feature of such training, which should provide a sound foundation for trainees to later conduct independent or collaborative research. Awards are not intended to support residency training. Each type of award is described below.

Institutional Ruth L. Kirschstein Training Grants (T32–Postdoctoral)

The purpose of the T32 *NRSA Institutional Training Grant for Veterinarians* program offered by DCM is to provide support for training highly qualified graduate veterinarians to enter research careers in biomedical areas related to comparative medicine, comparative pathology, or translational research. This training may be incorporated into the requirements for a research degree program; however, an advanced degree program is not required to receive support under this program. The research accomplished under this training program should result in first-author publications in peer-reviewed scientific journals and should provide the trainee with the necessary tools to successfully compete for career development awards (e.g., K01, K99) or independent grant funding (e.g., R01, R21).

The eligibility requirements and provisions for the applicant institution and trainees are supplementary to, and in accordance with, the guidelines and provisions for NRSA Institutional Research Training Grants. Please refer to Program Announcement PA-25-168. Any prior training in a clinical discipline must be completed with funding obtained by other sources. The institutional training environment must include a high-quality core of academic scientists in the area of research training. Institutions can have only one active NRSA T32 Institutional Training Grant funded by DCM at any time. (Other NIH ICs sponsor similar awards.)

Trainees are required to pursue their research training on a full-time basis, devoting at least 40 hours/week to the program. Within the 40 hours/week training period, research trainees in clinical areas must devote their time to the proposed research training and must confine clinical duties to those that are an integral part of the research training experience.

Postdoctoral trainees must have received, as of the beginning date of the appointment, their D.V.M. or equivalent degree. Documentation by an authorized official of the degree-granting institution certifying all degree requirements have been met prior to the beginning date of the training appointment is acceptable.

Institutions that request NRSA Institutional Training Grants must submit their T32 applications following the instructions in the SF 424 (R&R) Application Guide. Applications must be received by the deadlines prescribed for new applications in the guidance on Standard Due Dates.

Supplements to Promote Reentry into Research Careers

The following types of administrative supplements are available for some parent grants. Applicants are advised to carefully read the eligibility criteria and provisions and to consult with relevant ORIP staff before applying. These applications are submitted directly to DCM staff rather than to the NIH Center for Scientific Review.

Research Supplements to Promote Re-Entry, Re-integration into, and Re-training in Health-Related Research Careers (NOT-OD-23-170) are administrative supplements to provide full- or part-time mentored research training experiences for individuals with high potential to reenter, reintegrate into, or retrain in an active research career after an interruption for family responsibilities or other qualifying circumstances, as described below. The supplement grants are intended to provide these scientists with an opportunity to update or extend their research skills and knowledge and prepare them to reestablish or revitalize their careers in basic biomedical, behavioral, clinical, translational, or social science research. It is anticipated that by the completion of the supplement support period, the awardee will be prepared to apply for a fellowship (F), career development (K) award, or research award (R); an SBIR/STTR grant; or other type of independent research support. Applications should be submitted through the grants management staff and DCM program staff assigned to the parent grant.

Contracts and Cooperative Agreements

Contracts

DCM uses contracts to acquire products or services necessary to achieve its specific objectives. DCM will specify the products or services desired in a detailed Statement of Work. Contracts are awarded based on an offeror's proposal submitted in response to a Request for Proposals (RFP) published on the Contract Opportunities webpage, in the *NIH Guide for Grants and Contracts,* and on other NIH and federal government websites. Each contract proposal submitted by an offeror will receive a detailed technical review based upon the evaluation factors listed in the RFP.

Cooperative Agreements

DCM typically uses cooperative agreements to complement grant-supported activities. Cooperative agreements are employed in situations that require substantial programmatic involvement by the DCM staff in order to successfully conduct the required activity.

Cooperative agreement proposals are solicited by DCM using such mechanisms as the U24, U42, U54, and UM1 and are intended to support projects with very specific requirements that are not appropriate for grant support through the other mechanisms described in this document. Interested parties can check for current opportunities by monitoring the ORIP Funding Opportunities page in addition to the NIH Grants and Funding website.

Periodic Issuance of Requests for Applications (RFA)

DCM will occasionally issue a Request for Applications (RFA) for specialized programs. An RFA is a formal statement that solicits grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives. Regular monitoring of the NIH Guide and the DCM webpage is necessary to keep abreast of DCM's RFAs. Current RFAs include RFA-OD-22-013, *Resource-Related Research Projects for Development of Animal Models and Related Materials (R24 Clinical Trials Not Allowed),* and RFA-OD-23-001, *Animal and Biological Material Resource Centers (P40)*.

REVIEW OF APPLICATIONS

The first level of review for applications submitted to DCM is administered by the Center for Scientific Review (CSR). All grant applications must list the applicable NOFO or the application may not be accepted for review. All review criteria and considerations are listed in each particular NOFO. Unless the NOFO specifies otherwise, standard NIH review procedures will be followed. The assigned Scientific Review Group can designate a submitted application as "Not Discussed" or, after a full discussion, assign a final priority score (the NIH scoring system is described in NOT-OD-09-024). Applicants are informed about the results of this review in a Summary Statement. An application's priority score will be considered by ORIP staff as a part of the funding decision process.

The second level of review for DCM is conducted by the NIH Council of Councils (COC), Division of Program Coordination, Planning, and Strategic Initiatives. The COC will consider letters of appeal that are based on a defined set of issues, such as evidence that the initial review was biased or presented an unrecognized conflict of interest. The second level of review conducted by the COC is not a second scientific review. The COC will never change a priority score assigned by the initial peer review process. The COC will either recommend an application for funding, recommend that an application not be funded, or defer a decision to allow the application to be reviewed again by the study section. The COC must recommend an application for funding for ORIP to make the award. However, the COC does *not* make the final funding decision. That responsibility lies with the DCM Director in consultation with the ORIP Director.

GENERAL INSTRUCTIONS FOR APPLICANTS

Eligibility

In general, NIH grants may be awarded to public and private nonprofit organizations and institutions (including institutions of higher education, hospitals, and nonprofit research institutes), both domestic and foreign (with some exceptions, see below), and, in rare cases, to individuals. For-profit organizations are eligible to receive awards under all NIH programs unless specifically excluded. SERCA (K01), Institutional Training Grants (T32), Animal Resource (P40), and SBIR (R43 and R44) awards are limited to domestic institutions. Consult the NOFO to determine whether special eligibility requirements may apply.

Administrative Standards and Cost Standards

All awards are subject to HHS regulations on the administration of grants found in the Code of Federal Regulations, Title 45, Subtitle A, Part 74 or Part 92; the applicable cost principles; the revised *NIH Grants Policy Statement*; and supplemental guidelines published for specific programs.

Coordination Required to Develop Applications

Potential applicants should consider discussing proposed applications with DCM program staff before submitting them. These discussions will provide a clearer understanding of program policies and guidelines. Applicants should also discuss competing continuation applications with staff to determine whether future plans for the project conform to current policies.

Additional Information

Murphy, S.J., and Grieder, F.B. 2015. "Dos and don'ts of developing an NIH grant application." Available at: https://orip.nih.gov/sites/default/files/DosAndDonts_508.pdf.