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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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 (DPCPSI), advances the NIH's biomedical research mission through its support of intellectual, physical, and human infrastructure. ORIP's infrastructure support accelerates innovation and discoveries across a variety of medical fields.

The Division of Comparative Medicine (DCM), one of ORIP's major components, supports comparative models of human disease that use animals (e.g., rodents, invertebrates, nonhuman primates), cultured cells, and informatics systems for use by biomedical scientists. The DCM supports research to develop new animal models as well as shared resources to distribute, characterize, maintain, and archive these models for use by other biomedical researchers. Other resources support and supply biological materials and reagents including cells, tissues, organs, and medically important venoms for research. Resources that facilitate the 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 systems can help researchers identify specific model systems with particular tissues, molecular pathways, and protein interaction networks similar to those known to be associated with human health problems. The DCM supports infrastructure that is applicable to two or more NIH Institutes and Centers (ICs). See the next section on the DCM's research interests for a more detailed explanation.

The DCM also invests in programs that provide specialized biomedical research training for veterinarians, who already possess strong clinical backgrounds and familiarity with numerous species, and experience with 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. Other awards are available to help increase diversity in the biomedical workforce or facilitate the re-entry of individuals into active research careers after an interruption for family responsibilities or other qualifying circumstances.

The DCM participates in NIH's Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs that seek to facilitate the commercialization of innovative and potentially transformative technologies. The DCM has a special interest in technologies that relate to improvements in animal models of human disease, and the care, use, and management of laboratory animals.

RESEARCH AREAS OF INTEREST

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

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.

These initiatives include:

- Research to develop new animal models of 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 improvements in animal models.

- Next generation information management systems that enable researchers to select the most appropriate disease models based on their phenomes, i.e., the physical, biochemical, and molecular characteristics of an organism or of a specific organ, tissue, or cell within that organism.

- Pre- and postdoctoral research and career development training programs that are designed to assist veterinarians in becoming productive biomedical researchers and essential participants in the effort to improve human health.

The 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 Funding Opportunities and Notices website.

The DCM supports a variety of resource and research centers that develop animal models of human biology and disease and provide them to biomedical researchers around the world. These centers develop, characterize, house, cryopreserve and distribute both wild-type reference strains of animals as well as 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 the 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 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 flies to worms, ciliates, and marine invertebrates in order to understand many aspects of human physiology, genetics, aging, development, and disease. The DCM supports resources that supply critical research materials and services, such as cultured cell lines, genetic stocks, technical training, and on-line informational systems on these types of model organisms for the benefit of the entire biomedical research community. Consult the Invertebrate Models section of the DCM website for a listing of supported resources. Additional information can also be found at the Invertebrate Models fact sheet.

Vertebrate Research Models:

Vertebrate models (e.g., rodents, swine, nonhuman primates, zebrafish) 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. The DCM is interested in research that broadens the utility of human disease models. Some examples of vertebrate research models are given below. Consult the Vertebrate Models section of the DCM website for a listing of supported resources.

Aquatic Research Models:

Aquatic species such as zebrafish, frogs, salamander, and marine slug serve as important models for studying human development, behavior, and disease. Because some of these species have short reproductive cycles and transparent eggs, 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 in 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. The DCM supports aquatic models through funding the development, preservation, and maintenance of critical genetic stocks, biological materials, and online information. Consult the DCM website for a listing of supported resources. Additional information can also be found at the Aquatic Models fact sheet.

Rodent Models:

Rodents can be conveniently housed in the large numbers needed for statistical significance and reproducible experimental results. Many years of selective breeding in mice and rats have given rise to a large number of inbred “strains” in which individuals are all nearly genetically identical to one another. 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 into human health and disease.

The DCM supports repositories for highly specialized rodent species and models including those in which specific genes have been disabled (knockouts), rodents carrying specific mutations useful for research, germfree mice, and others. The DCM also supports funding for hypothesis-driven investigator-initiated research to develop, characterize, utilize, or preserve a wide range of new rodent models of human disease conditions. The DCM also 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 DCM website for a listing of supported resources. Additional information can also be found at the Rodent Resources fact sheet.

Nonhuman Primate Models:
The DCM supports resources and individual research projects that develop nonhuman primate (NHP) models of 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 virtually all NHP species that serve as models for a variety of human diseases, and includes more specialized NHP Resources, each of which concentrates on a single species. The DCM also supports research projects that help develop specific NHP disease models, reagents, or methods needed for the study of human physiology or disease. Consult the DCM website for a listing of supported resources. Additional information can also be found at the Nonhuman Primate Resources fact sheet.

Genetic, Biological, and Information Resources:

ORIP supports a variety of resources that provide genetic analysis, 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 DCM website for a listing of supported resources.

Career Development Opportunities:

The DCM offers career development support for individuals with DVM, VMD or PhD degrees, as well as predoctoral veterinary students. These programs enhance the research careers of early career scientists or their mentors. The DCM has a special interest in veterinary scientists and biomedical scientists with a veterinary degree as they can offer a distinct perspective and expertise to translational biomedical research through their comparative understanding of human health and disease in the context of preclinical research involving disease 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.

The 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. These programs (see Training and Career Development Resources fact sheet) 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 of human disease; development of animal-based genetic and genomic tools; phenotyping that covers the spectrum from clinical to molecular; reproductive biology; regenerative medicine; and surveillance and control of selected laboratory animal diseases. Training opportunities available include:

Career Development Grants:
These include both the Mentored Research Scientist Development Award (K01) and the Pathway to Independence Award (K99/R00).

Institutional 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 and Summer Programs for Veterinary Students (T35).

Individual Training Grants:
The DCM uses these awards to enable promising predoctoral individuals to pursue biomedical careers that take advantage of both their clinical experience as well as their research training. Students who are matriculated in a combined veterinary degree (DVM or VMD)/PhD program, and who intend to pursue careers as clinician-scientists, can compete for an F30 award. Applicants must propose an integrated research and clinical training plan, and a dissertation research project in scientific health-related fields relevant to the mission of the DCM and NIH.

The DCM makes awards that enable highly qualified veterinary students, or individuals with a degree in veterinary medicine, to obtain mentored research training from outstanding faculty sponsors while conducting their dissertation research in scientific health-related fields relevant to the DCM mission (F31). The DCM also uses the F31 award mechanism to enhance the diversity of the health-related research workforce by supporting the research training of veterinary students or holders of degrees in veterinary medicine from population groups that have been shown to be underrepresented in the biomedical, behavioral, or clinical research workforce.

Mentoring Opportunities:
Administrative supplements to existing ORIP grants enable the Principal Investigator to support additional individuals who can promote diversity in the biomedical research workforce or who are re-entering the workforce after an interruption for family responsibilities or other qualifying circumstances.

NIH Loan Repayment Program:
This program has been expanded to include veterinarians who participate in Clinical Research into human diseases or conditions. Repayment of qualified educational loan

debt up to $50,000 annually is available for qualified health professionals performing research within the mission of NIH and supported by domestic, non-profit institutions, or government entities. Consult the NIH LRP website for more information.

Small Business Opportunities:

The DCM provides grant opportunities for small businesses to help meet the needs of biomedical researchers for technologies to support high-quality, disease-free animal models of human disease and specialized animal research facilities. This is accomplished through the Congressionally mandated SBIR and STTR programs for U.S. small business to engage in R&D that has a strong potential for commercialization. Areas of special interest to the DCM include:

- Development and commercialization of technologies to create, characterize or improve animal models of human disease;
- Methods for production, identification, production or preservation of new mammalian or non-mammalian animal models;
- Development of methods, equipment or reagents that facilitate the use of zebrafish for translational research;
- Development of novel and emerging technologies for the accurate detection and diagnosis of polymicrobial infections in biomedical laboratory animal models;
- Development of innovative methods and tools to control and prevent selected laboratory animal diseases;
- Technology for cryogenic, or other long-term, preservation and revival of *Drosophila* and zebrafish stocks.

Support for Conferences and Scientific Meetings:

Conference grants (R13) from the 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 the DCM. To ensure the 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. Should the 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 grant awarded supports only a portion of the entire cost of the conference. Consult the R13 conference grant FAQ's *prior* to contacting the relevant ORIP program official.

AWARD MECHANISMS

The 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. Staff encourages and welcomes the discussion of potential applications. While Funding Opportunity Announcement (FOA) links are provided below, it is incumbent upon the potential applicant to assure that the FOA cited is current.

Once again, it is important to remember that the DCM only invests in initiatives that are broadly applicable to biomedical research problems that are of interest to *two or more* NIH categorical institutes or centers. (This requirement does not apply to the DCM's career development awards or individual training grants.) 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.

I. Research Project Grants (R01)

The DCM supports investigator-initiated basic research projects related to animal models of human disease and laboratory animal medicine. The research proposed must not fall solely within the categorical interest of a single institute or center (IC). Examples of such research include but are not limited to:

- **Animal Models:** Develop and characterize naturally occurring, or experimentally induced, animal models of human biology and disease. Model systems of interest include both mammalian and non-mammalian 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 either *Drosophila* or zebrafish genetic stocks.

- **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.

- **Regenerative Medicine:** Develop animal models for gene- and cellular-based disease therapies; isolate and characterize animal stem cells and improve techniques to move them into clinical practice.

- **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 particular model system. Grants may be awarded for investigations to 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 particular 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 ICs or other sources.

Applications must be submitted electronically using the forms specified in the Funding Opportunity Announcement (FOA) PA-19-056: *Research Project Grant (Parent R01Clinical Trial Not Allowed)*.

II. Exploratory/Developmental Grants (R21)

The DCM does not accept unsolicited R21 applications. However, the DCM encourages R21 research grant applications that are responsive to specific FOAs that ORIP has announced. Support is limited to 2 years, with a combined budget for direct costs of up to $275,000 for the two-year period. Applications for R21 awards should describe projects distinct from those supported through the traditional R01 mechanism. For example, 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.

Applications may be submitted in response to *Development of Animal Models and Related Biological Materials for Research (R21 Clinical Trial Not Allowed)* found in PAR-19-369.

III. Resource-Related Research Project Grants (R24)

The DCM R24 mechanism is described in RFA-OD-19-027, *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, improve existing resources, or acquire deep understanding of a model system in order 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 trans-NIH initiatives, including AIDS, Women's Health, Alzheimer's Disease and Related Dementias, and BRAIN.

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

Animal and Biological Material Resource Centers (P40) is described in PAR-17-006. 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, preserve, and distribute defined strains of animals and/or related biological materials 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 to 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, competitiveness of a potential application, and the DCM's program priorities.

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

The seven NPRCs are supported through the P51 grants. All aspects of P51 grant applications are described in PAR-17-144. The DCM accepts renewal, resubmission and revision P51 applications, as appropriate to a specific NPRC. The DCM does not accept new P51 applications at the present time.

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

Both Small Business Innovation Research (SBIR), i.e., R43 and R44, and the Small Business Technology Transfer (STTR), i.e., R41 and R42, grants are supported through the DCM. Relevant research and development interests of the DCM include, but are not limited to: control of laboratory animal diseases; preservation or management of laboratory animals; and methods for identification or production of new mammalian or non-mammalian animal models. ORIP has prepared a fact sheet for those seeking more information about its SBIR/STTR programs. Additional information is available at NIH's SBIR/STTR Home and at the DCM's Small Business Opportunities page. Applications must be submitted electronically by the deadlines prescribed on the Schedule of Standard of Receipt Dates. While the DCM will accept SBIR or STTR applications from a number of specific FOAs (e.g., PA-19-272, PA-19-270, PA-16-180, PA-16-181, PA-18-609, PA-18-610) prospective applicants are encouraged to contact the DCM staff for advice before submitting SBIR or STTR applications. See this website for a complete list of ORIP's funding announcements.

VII. Scientific Meeting Grants (R13, U13)

Information concerning Scientific Meeting Grants is provided in Program Announcement PA-18-648. These grant mechanisms provide 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 the DCM. A conference/scientific meeting is defined as a gathering, symposium, seminar, scientific meeting, workshop or any other organized, formal meeting where persons assemble to coordinate, exchange, and disseminate information or to explore or clarify a defined subject, problem, or area of knowledge. To ensure the 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 FAQ's prior to contacting the relevant ORIP program official. Applications with marginal or no relevance for the 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 the 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. Should the DCM determine that there is a need for substantial involvement in the planning and conduct of the scientific meeting, a cooperative agreement (U13)—instead of an R13—may be awarded.

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

The *Special Emphasis Research Career Award in Pathology and Comparative Medicine* is designed to assist graduate veterinarians in a mentored research experience that enables them to become independent investigators in research related to comparative medicine, biomedical research, and translational sciences. The DCM SERCA guidelines are supplementary to the trans-NIH Program Announcement, PA-19-126, 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 (DVM or VMD) support for protected research time as mentored investigators. The goal is to enable these individuals to develop independent research skills and to 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 the DCM 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 FOA 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 for the "K" series in *Standard*

Due Dates for Competing Applications. AIDS-related SERCA applications should be submitted on the due dates for AIDS-related applications.

IX. 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 two years (24 months) of their K01 award the opportunity to apply for R03 Small Grant support (PAR-17-301). 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 over two years) and that provide preliminary data to support a subsequent R01 (or equivalent) application.

X. NIH Pathway to Independence Award (K99/R00)

The *NIH Pathway to Independence Award, PA-19-130* seeks to increase and maintain a strong cohort of new and talented, NIH-supported, independent investigators. This program is designed to facilitate a timely transition of outstanding postdoctoral researchers from mentored, postdoctoral research positions to independent, tenure-track or equivalent faculty positions. The award also provides independent NIH research support during the transition to help these individuals launch competitive, independent research careers. Prospective candidates are strongly encouraged to contact the relevant ORIP staff for specific programmatic and budgetary information.

XI. National Research Service Awards (T32, T35, F30, F31)

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 the DCM is to provide graduate veterinarians or students at veterinary schools or colleges to become participants 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 the 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-18-403. Attention must be given to recruiting and retaining trainees from racial or ethnic groups underrepresented in the biomedical, behavioral and clinical sciences, individuals with disabilities, and individuals from disadvantaged backgrounds. Special justification must be provided for support of candidates who have completed their Ph.D. training prior to, in conjunction with, or after receiving their veterinary medical degrees. 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 the DCM at any time. (Other NIH ICs also 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 DVM 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 in the *Standard Due Dates for Competing Applications*.

Professional Student Short-Term Research Training Grants (T35)

The DCM awards NRSA Short-Term Training for students enrolled in a degree program leading to a DVM or VMD. The goal of these institutional T35 grants is to provide support for research training experience for selected veterinary students for periods of 2-3 months. Awards may be requested for up to 5 years and are renewable. The objective is to attract highly-qualified veterinary students to biomedical and biobehavioral research careers. Applicant institutions must meet the basic eligibility criteria outlined for T32 applications.

Trainees should have successfully completed at least one semester of professional course work. Awards cannot be used to support course work that is required for professional

degrees. Students who receive a stipend in a combined DVM /PhD program are not eligible for this support.

The application must present strategies to be used in the recruitment of individuals from underrepresented groups. Training should not be restricted to activities in a single discipline. Placement of students in research training programs that involve basic or clinical research, or a combination of both, is encouraged. Applicants should design programs that will nurture a sense of belonging to a community of scientists among their trainees. All training activities must be on a full-time basis during a training sequence. Applications must be submitted using the SF424 by the deadlines prescribed in the *Standard Due Dates for Competing Applications*. Institutions can have only one current active T35 award at any time. Institutions must have the staff and facilities required for the proposed program and are responsible for the selection and appointment of trainees. Please refer to Program Announcement PA-18-404, NIH NRSA Short-Term Institutional Research Training Grants (T35).

Individual Predoctoral MD/PhD or Other Dual-Doctoral Degree Fellowship (F30)

The DCM participates in this program in order to enhance the integrated research and clinical training of promising predoctoral students, who are matriculated in a combined DVM/PhD program and who intend to pursue careers as clinician-scientists. Applicants must propose an integrated research and clinical training plan and a dissertation research project in scientific health-related fields relevant to the DCM mission. The fellowship experience is expected to clearly enhance the individuals' potential to develop into productive, independent clinician-scientists. Please refer to Program Announcement PA-19-192 (or PA-19-191 if at an institution with an NIH -funded institutional predoctoral dual-degree training program) for additional information. Potential applicants are encouraged to contact the relevant ORIP staff member to make certain that their application is responsive to the DCM's requirements.

Predoctoral Individual National Research Service Awards (F31)

The DCM also makes awards that enable highly qualified veterinary students, or individuals with a degree in veterinary medicine, to obtain mentored research training from outstanding faculty sponsors while conducting their dissertation research in scientific health-related fields relevant to the DCM mission (F31). The proposed mentored research training must reflect the applicant's dissertation research project and is expected to clearly enhance the individual's potential to develop into a productive, independent research scientist. Refer to PA-18-671 for additional information. Potential applicants are encouraged to contact the relevant ORIP staff member to make certain that their application is responsive to the DCM's requirements.

The DCM also uses the F31 grant mechanism to enhance the diversity of the health-related research workforce by supporting the research training of highly qualified veterinary students or graduate veterinarians from population groups that have been shown to be underrepresented in the biomedical, biobehavioral, or clinical research workforce. Such individuals include those from underrepresented racial and ethnic groups, those with disabilities, and those from disadvantaged backgrounds. Through this award program,

promising veterinary students and graduate veterinarians will obtain individualized, mentored research training from outstanding faculty sponsors while conducting well-defined research projects in scientific health-related fields relevant to the DCM. The proposed mentored research training is expected to clearly enhance the individual's potential to develop into a productive, independent research scientist. Refer to PA-19-196 for additional information. Potential applicants are encouraged to contact the relevant ORIP staff member to make certain that their application is responsive to the DCM's requirements.

XII. Supplements to Promote Diversity and Re-entry 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 the DCM staff rather than to the NIH Center for Scientific Review.

Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogeneous teams. *Research Supplements to Promote Diversity in Health-Related Research, PA-18-906* are administrative supplements that improve the diversity of the research workforce by supporting and recruiting students, postdoctoral trainees, and eligible investigators from groups that have been historically underrepresented in health-related science. Administrative supplements must support work within the scope of the original project. Candidates eligible for support under this supplement program include individuals at various career levels who come from groups that have been historically underrepresented in science. Such candidates include individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds. Detailed eligibility criteria are described in the full announcement. These research supplements are not intended to provide an alternative means of supporting individuals who already receive support from a research grant, a training grant, or any other DHHS funding mechanism. Applications should be submitted through the grants management and the DCM program staff assigned to the parent grant.

Research Supplements to Promote Re-Entry into Biomedical and Behavioral Research Careers, PA-18-592 are administrative supplements that support individuals with high potential to re-enter an active research career after an interruption for family responsibilities or other qualifying circumstances. For a comprehensive listing of qualifying interruptions, see the full announcement. These research supplements are not intended to provide an alternative means of supporting individuals who already receive support from a research grant, a training grant, or any other DHHS funding mechanism. Applications should be submitted through the grants management and the DCM program staff assigned to the parent grant.

XIII. Contracts and Cooperative Agreements

Contracts

The DCM uses contracts to acquire products or services necessary to achieve its specific objectives. The DCM will specify the products or services desired in a detailed, written "statement of work." Contracts are awarded based on an offeror's proposal submitted in response to a Request for Proposals (RFPs) published on the Federal Business Opportunities (Fed Biz Opps) Website, in the *NIH Guide for Grants and Contracts,* and 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

The 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 the DCM, using mechanisms such as the U42 and U54, 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 Funding Opportunities and Notices site.

XIV. Periodic Issuance of Requests for Applications (RFA)

The DCM will issue a Request for Applications (RFA) for specialized programs on an "as needed" basis. These Funding Opportunity Announcements (FOA) typically provide a small window of opportunity for eligible individuals and institutions to apply for support for a specific program. In contrast to Program Announcements (PA), these FOAs are not solicited on a continuous basis but instead are published in the NIH Guide for Grants and Contracts (NIH Guide) with a defined opening and closing date for receipt of applications. Regular monitoring of the NIH Guide and the DCM web page is necessary to keep abreast of the DCM's RFAs. Listed below are two *historical examples* of programs that have utilized RFAs *in the past* and could be utilized again in the future:

Historical Example #1–Applications for Research Education Programs for Laboratory Animal Medicine Veterinarians (R25)

Under this FOA, the DCM solicited Research Education Grant (R25) applications to provide research education for veterinarians interested in pursuing a career in Laboratory Animal Medicine. It was designed to increase the number of veterinarians trained in laboratory animal medicine in order to address the shortage of these specialty-trained individuals serving the biomedical research community. The primary objective was to prepare veterinarians to be competent and proficient in the field of Laboratory Animal Medicine in support of biomedical investigations. Special emphasis was placed on performing collaborative research, development and maintenance of animal models in support of translational research activities, and the provision of professional direction for animal resource/research programs.

Historical Example #2–Applications for Short-Term Research Career Enhancement Opportunities for Established Veterinarians (K18)

Awards under this FOA provide a short-term, specialized research career opportunity for established veterinarians (DVM, VMD or equivalent) with an interest in comparative medicine and translational research. The term of the award may range from 6-24 months. Awardees are expected to be at the Associate or Full Professor level (or equivalent in a non-academic setting). The focus is to support the research career enhancement for established veterinarian researchers (DVM, VMD, or equivalent) using animal models in translational research. The intent of this FOA is to provide grantees with protected time to achieve a shift in the focus of their research direction or to learn new research techniques or procedures relevant to their ongoing research projects and to the DCM mission.

REVIEW OF APPLICATIONS

The first level of review for applications submitted to the DCM is administered by the Center for Scientific Review (CSR). All grant applications must list the applicable FOA or the application may not be accepted for review. All review criteria and considerations are listed in each particular FOA. Unless the FOA specifies otherwise, standard NIH review procedures will be followed. The assigned Scientific Review Group can designate a submitted application as "Not Recommended for Further Consideration" or, after a full discussion, assign a 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 the DCM is conducted by the NIH Council of Councils (COC), Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI). 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 re-reviewed by the study section. The COC must recommend an application for funding in order 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), Short-Term Institutional Research Training Grants (T35), Animal Resource (P40), and SBIR (R43 and R44) awards are limited to domestic institutions. Consult the FOA to determine whether special eligibility requirements may apply.

Administrative Standards and Cost Standards
All awards are subject to DHHS 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, Revised *NIH Grants Policy Statement,* and supplemental guidelines published for specific programs.

Coordination Required to Develop Applications

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

Additional Information

Murphy, S.J. and Grieder, F.B., *Do's and Don'ts of Developing an NIH Grant Application* available at:
https://orip.nih.gov/sites/default/files/Do%27s%20and%20Don%27ts_508.pdf