Division of Comparative Medicine

Program Guidelines

- Program Descriptions
- Award Mechanisms
- Review of Applications
- Instructions for Applicants

An Administrative Document Issued by the Office of Research Infrastructure Programs (ORIP)

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Division of Comparative Medicine Web Page

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INTRODUCTION

The Office of Research Infrastructure Programs (ORIP) is a focal point within the National Institutes of Health (NIH) for the administration and management of extramural programs that offer new opportunities for biomedical research and research training on an institutional, regional, or national basis. ORIP's mission is to complement and support the programs of the other NIH components by assisting eligible institutions and investigators to develop and access specialized research capabilities and opportunities otherwise not available to them.

One of ORIP's three Components is the Division of Comparative Medicine (DCM). DCM supports the biomedical and health research community in the general area of comparative medicine that impacts two or more NIH categorical institutes or centers.

Major DCM objectives are to:

- Assist in providing animal-related resources to investigators, research in the development or improvement of mammalian and non-mammalian animal models for human diseases/conditions
- Support studies designed to enhance animal welfare
- Provide a variety of biological materials (such as cell cultures and computer models) related to biological and cell research
- Support pre- and postdoctoral research and career development training for veterinarians

The DCM objectives, described under Program Descriptions, are accomplished through grants, cooperative agreements, and contracts.

PROGRAM DESCRIPTIONS

A succinct description of DCM programs is covered in this section. Individuals interested in obtaining more detailed information about a particular program are strongly encouraged to consult the ORIP web site or contact the DCM program staff at 301-435-0744. Potential applicants seeking information on funding opportunities for specific programs should also visit the NIH Funding Opportunity Announcement (FOA) web site at http://grants.nih.gov/grants/guide/index.html.

The DCM administers the following programs:

Aquatics Models, including zebrafish, other fish species, and marine slugs, can serve as models for studying human development, behavior and disease. Because of their short reproductive cycles and transparent eggs, they offer researchers the ability to easily observe them as they develop. By comparing human genes with those of these organisms, researchers can identify potential functions of specific genes, allowing them to better understand the underlying basis of genetic disorders in people. Aquatic models have been important in studies of gene function, protein interactions and pathological processes related to humans. DCM supports aquatic models of research through funding the development and maintenance of critical genetic stocks, biological materials and online information.

Comparative Models are the focus for extramural research activities in the exploration and development of

mammalian and non-mammalian models for biomedical research. The program supports research to develop and broaden the utility of animal models, cell cultures, and non-biological systems (i.e., mathematical and computer modeling). The Division of Comparative Medicine also supports resources that supply critical biological materials, such as cultures or genetic stocks, and non-biological materials, including on-line information on model organisms, to the research community. Through these resources, investigators have access to widely used organisms ranging from yeast, mutant flies, and worms to marine invertebrates and vertebrates. In addition, research to develop resources that broaden the utility of models is of interest. Examples of such resources include, but are not limited to, genetic maps, transgenic animals, and stem cells.

Nonhuman Primate Resources: The DCM supports a comprehensive group of resources and individual projects that: a) Develop non-human primate (NHP) models of human disease; b) Provide infrastructure and expertise that facilitate the use of NHPs for all areas of biomedical research; c) Develop methods to enhance the welfare of captive NHPs. Included in this program are: a) the eight National Primate Research Centers (NPRCs), which provide access to virtually all NHP species that serve as models for a variety of human diseases; b) more specialized NHP Resources, each of which concentrates on a single species; c) research projects that help develop specific NHP disease models, reagents, or methods needed for the study of human physiology or disease.

The Chimpanzee Management Program supports long-term, cost-effective housing and maintenance at ORIP-supported facilities for chimpanzees, including both research and retirement facilities. ORIP provides programmatic oversight of the facilities and ensures they comply with the Animal Welfare Act, and other regulations and policies concerning laboratory animal care and use.

Rodent Models represent the most frequently used species in biomedical research. They share much in common with humans with respect to genetics, development, physiology, behavior and disease, their use provides reproducible experimental results and the methodology for their genetic manipulations is well developed. The rodent models are essential to many important biomedical discoveries related to human health. To ensure that such resources are accessible to the biomedical research community, DCM supports programs that engage in ongoing, peer-reviewed, health-related research to establish special animal colonies and genetic stocks. Additionally, continuous research activities by core scientists at these resource sites generate new knowledge and enhancing the overall value of these resources to the biomedical research community. DCM also supports repositories for specialized rodent model/ species, e.g. knockouts, mutant, gnotobiotic mice, and other rodent genetic models. The Division's funding also supports hypothesis-driven investigator-initiated research to develop, characterize, utilize or preserve a wide range of new rodent models for the human disease conditions and biological materials which allows speeding up the process of biomedical discovery and moving from basic science and clinical research to the health services in shortest period of time. These models must be applicable to two or more NIH Institutes or Centers.

Career Development, Training, and Education Opportunities: DCM support training programs to enhance the research careers of junior scientists or their mentors. Scientists experienced in comparative medicine make important contributions to animal, molecular and genomic studies that benefit human health. Through its training programs, DCM funds investigators who conduct basic research or evaluate new therapies in clinical trials. Designed to address the growing need for research trained veterinarians, these programs are geared toward research clinicians, pathobiologists, 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, reproductive biology, regenerative medicine, and screening for and control of selected laboratory animal diseases. Following are some of the training opportunities available:

- Predoctoral short-term and institutional summer training grants for veterinary students, who want to further their interest or develop skills in biomedical research careers.
- Institutional Post-doctoral Training Grants designed to encourage veterinarians to consider careers in biomedical research. Awards are made directly to universities and other research institutions that provide advanced training in comparative medicine or comparative pathology biomedical or translational research.
- Career Development Mentored Awards designed for veterinary scientists (recipients hold a professional veterinary degree).
- NIH Pathway to Independence awards offer promising postdoctoral scientists both mentored and independent research support awards.

Small Business Opportunities: DCM is committed to increasing small business participation in federally supported research and development by encouraging the private-sector to commercialize technology developed with federal support. It accomplishes this through the federal government's Small Business Innovation Research and Small Business Technology Transfer programs.

Support for Conferences and Scientific Meetings: These grants support high quality conferences/scientific meetings that are relevant to the scientific mission 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. Grant support for conferences or scientific meeting may only cover a small portion of the activity.

Additional information on programs and resources currently supported by the DCM is available on the <u>DPCPSI/ORIP web site</u>. Potential applicants are encouraged to contact DCM staff at (301) 435-0744.

AWARD MECHANISMS

The DCM sponsors the following activities. This listing is not intended to imply that potential support is strictly limited to the activities described. Staff welcomes and encourages the discussion of potential applications using different activities. While the Funding Opportunity Announcement (FOA) link is provided here for program mechanisms, it is incumbent upon the potential applicant to assure that the FOA used is the current one.

I. RESEARCH PROJECT GRANTS (R01)

The DCM supports investigator initiated basic research projects related to laboratory animal science and medicine and model systems involving animal research that do not fall within the categorical interest of a single institute or center (IC) of NIH Categories(topic need to impact two or more categorical Institutes or Centers). Examples of such research include:

- Animal Models: Develop and characterize natural or induced animal models for human biology and disease. Model systems include both mammalian and non-mammalian species, as well as cell culture systems and integrative computer models.
- Reproductive Biology: Improve methods for producing transgenic and genetically identical animals and for cryopreservation of biological materials, including germplasm.

- Fundamental Biology of Animal Systems: Perform investigations of 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 therapies of disease; isolate and characterize animal stem cells and improve techniques to move them into clinical practice.
- **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 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 using the <u>application form</u> identified in the Funding Opportunity Announcement (FOA) <u>PA-10-067</u>: Research Project Grant (Parent R01) and submitted by the deadlines <u>noted in the FOA</u>. Applicants requesting \$500,000 or more in direct costs for any year must obtain approval from a DCM Health Scientist Administrator or the DCM Director at least 8 weeks prior to submitting an application.

II. EXPLORORATORY/DEVELOPMENTAL GRANTS (R21)

The DCM uses the R21 mechanism for the support of innovative, exploratory/developmental research projects. The areas of research for projects to be supported are the same as those listed for consideration for R01 support. Support is limited to 2 years, with a combined budget for direct costs of up to \$275,000 for the two-year period. Because this program is designed to support innovative ideas, preliminary data as evidence of feasibility are not required. Originality of the approach and potential significance of the proposed research are major considerations in the evaluation and should be described in the application. Examples of such research could assess the feasibility of a novel area of investigation or a new experimental system that has the potential to enhance health-related research. Another example could include the unique and innovative use of an existing methodology to explore a new scientific area. These studies may involve considerable risk, but may lead to a breakthrough in a particular area, or to the development of novel techniques, methodologies, models, or applications that could have major impact on a field of biomedical, behavioral, or clinical research. Additional information about the Development of Animal Models and Related Biological Materials for Research

III. RESOURCE-RELATED RESEARCH PROJECT GRANTS (R24)

The DCM R24 mechanism is described in PAR-10-289: Resource Related Research Projects for Development of Animal Models and Related Materials (R24). These grants are aimed at developing, characterizing or improving animal models of human diseases or improving diagnosis and control of diseases of laboratory animals. This FOA applies only to R24 grant applications for potential support by the DCM. The animal models and related materials to be developed must address the research interests of two or more of the categorical NIH Institutes and Centers. In addition, projects that predominantly address the research interests of one NIH Institute or Center, but that are peripherally related to the research interests of other Institutes and Centers will not be considered appropriate. An example of an inappropriate request is one exclusively involving an animal model of cancer.

IV. ANIMAL MODEL AND ANIMAL AND BIOLOGICAL MATERIALS RESOURCE GRANTS (P40)

Animal and Biological Material Resource Centers (P40) is described in PAR-11-001. These grants support national Animal Model, and Animal and Biological Material Resource Centers. 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 distribute defined strains of animals and/or related biological materials to biomedical researchers in a variety of research areas on a local, regional, and national 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, it is critical that all applicants consult with DCM Program staff to be advised on appropriateness of the intended resource plans for this program, competitiveness of a potential application and DCM program priorities. The animal models and related materials to be developed must address the research interests of two or more of the categorical NIH Institutes and Centers. Applicants requesting \$500,000 or more in direct costs for any year must obtain approval from a DCM Health Scientist Administrator or the DCM Director at least 8 weeks prior to submitting an application.

V. NATIONAL PRIMATE RESEARCH CENTERS (NPRCs) (P51, Limited Competition)

The eight NPRCs are supported through the P51 grants. All aspects of P51 grant applications are described in <u>PAR-11-136</u>. 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) (R43, R44) and Small Business Technology Transfer (STTR) (R41, R42) grants are supported through DCM. Research and development interests of DCM include, but are not limited to: control of laboratory animal diseases, improvement of culture and culture conditions, preservation or management of laboratory animals, and methods for identification or production of new mammalian or non-mammalian animal models. Detailed descriptions of research

interests and necessary special instructions applicable to SBIR or STTR grants are found in the solicitations: "Omnibus Solicitation of the NIH, CDC, FDA and ACF for Small Business Innovation Research Grant Applications" and "Omnibus Solicitation of the NIH for Small Business Technology Transfer Grant Applications." These publications are available on the NIH Small Business Funding Opportunities Web page. Complete information regarding the SBIR and STTR programs, including program structure and phasing, funding guidelines, application deadlines, etc. also are on the aforementioned NIH Small Business Funding Opportunities Web page.

Applications must be submitted <u>electronically</u> by the deadlines prescribed on the <u>Schedule of Standard of Receipt Dates</u>. Applicants requesting \$500,000 or more in direct costs for any year must obtain approval from a DCM Health Scientist Administrator or the DCM Director at least 8 weeks prior to submitting such an application. Prospective applicants are encouraged to contact DCM staff for advice before submitting SBIR or STTR applications.

VII. SCIENTIFIC MEETING GRANTS (R13, U13)

Information concerning Scientific Meeting Grants is provided in Program Announcement PA-10-071: DCM Support for Conferences and Scientific Meetings (Parent R13/U13). These grants support high quality conferences/scientific meetings that are relevant to the scientific mission 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. DCM has a scientific purview and different program goals and initiatives that evolved over time. Prior to preparing an application, it is critical that all applicants consult the appropriate IC representative listed in the R13/U13 Website (http://grants.nih.gov/grants/funding/r13/) to obtain current information about IC specific program priorities and policies. This action is of utmost importance because applications with marginal or no relevance to the participating Institutes, Centers, or Offices 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 6 weeks before the application submission date. The letter from the NIH documenting advance permission must be included in 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. In addition, applicants are encouraged to consult the Frequently Asked Questions Website for more detailed information about this program: http://grants.nih.gov/grants/funding/r13/index.htm. The DCM/ORIP Conference Grant Contact is given on the NIH Conference Grants Web page. If DCM determines that there is sufficient need to have substantial involvement in the planning and conduct of a scientific meeting, and then DCM program staff may determine that a cooperative agreement (U13) award would be appropriate.

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

This award is a Mentored Research Scientist Development Award intended to assist graduate veterinarians in a research experience activities to become independent investigators in research related to comparative medicine, biomedical, and translational sciences. DCM SERCA guidelines are supplementary to the trans-NIH Program Announcement, <u>PA-11-190</u>, "Mentored Research Scientist Development Award (K01)".

The SERCA emphasizes in-depth research experience in basic or clinical scientific disciplines. The overall program should be focused around, a central hypothesis-driven research question. Categories and

examples of possible research topics include, but are not limited to those listed for R01 applications above. The SERCA provides 5 years of support for individual trainees. During the first years of SERCA support, the awardee is expected to develop capabilities in basic, applied, or clinical biomedical research. These activities should be focused on a specific research area. A primary mentor will have overall responsibility for helping to guide the SERCA awardee. The SERCA is not a mechanism to obtain a Doctor of Philosophy (Ph.D.) degree. However, the research performed under the SERCA may be used to satisfy the dissertations requirements for a Ph.D. degree.

During the final years of SERCA support the awardee should demonstrate increasing independence in the planning, design, and conduct of research. In addition, applying for funding during this stage is strongly encouraged.

A candidate for a SERCA in Comparative Medicine must:

- 1. Hold a Doctor of Veterinary Medicine (D.V.M. or V.M.D.) or equivalent degree in veterinary medicine from an institution that is recognized by the American Veterinary Medical Association (AVMA).
- 2. Have completed his/her clinical training, including specialty training in a relevant discipline, prior to receiving an award.
- 3. May not concurrently apply for any other NIH career development award nor have another submitted application pending.
- 4. May not have been previously designated as Principal Investigator (PI) on any research project supported by Federal sources. However, the awardee is encouraged to apply as a PI during the last year of the SERCA for outside support that would begin after the SERCA is completed.
- 5. Be nominated by an institution on the basis of his/her personal qualifications, interests, accomplishments, motivation, and potential for a research career. Evidence of the institution's commitment to the candidate's research development must be provided.
- 6. Receive appropriate mentoring throughout the duration of the program. The candidate must name a primary mentor, who, together with the applicant, is responsible for the overall planning, direction, and execution of the program. The mentor must be a recognized senior investigator in the field of the proposed study, hold peer-reviewed research support, hold an academic appointment at the parent institution, and be experienced in postdoctoral research training. The mentor and laboratory for all post-Ph.D. activities should normally be different from those involved in any earlier doctoral training, unless a significantly new learning experience in the same laboratory can be documented in the application. The mentor should assist in the initial preparation of the SERCA application.
- 7. At the time of award, candidates must be citizens or non-citizen nationals of the United States, or have been lawfully admitted to the United States for permanent residence (i.e., in possession of a currently valid Alien Registration Receipt Card I-551, or other legal verification of such status). Individuals in the United States on temporary or student visas are not eligible.

Prospective applicants are encouraged to discuss their eligibility for the SERCA program with DCM staff before preparing an application. It is critical that applicants follow the instructions in the <u>SF 424 (R&R)</u> <u>Application Guide</u>, especially <u>Supplemental Instructions to the SF424 (R&R) for Preparing an Individual Research Career Development Award (CDA) Application ("K" Series)</u> 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 (<u>PA-11-190</u>), adhering to the specific instructions for Research Career Awards. Applications should be received by the deadlines prescribed on the <u>Schedule of Standard of Receipt Dates</u>. AIDS-related SERCA applications should be submitted on the due dates for AIDS-related applications.

IX. Midcareer Investigator Award in Mouse Pathobiology and Comprehensive Phenotyping Research (K26)

Supports established, outstanding pathobiologists by providing protected time for mouse pathobiology and comprehensive phenotyping research as well as mentoring of junior investigators, thus increasing the number of future qualified pathobiologists. The target candidates are scientists engaged in mouse pathobiology research and phenotyping who can demonstrate the need for a period of intensive research focus as a means of enhancing their research careers, and commitment to mentoring the next generation of mouse pathobiologists.

The prospective candidate for the Midcareer Investigator Award in Mouse Pathobiology and Comprehensive Phenotyping Research should propose a period of research consistent with his/her research and/or clinical experience and with the proposed further development of his/her research skills. The proposed program should be tailored carefully to meet the individual needs of the candidate and must include a description of meritorious past research projects that meet the definition of mouse pathobiology research and comprehensive phenotyping. In addition, the candidate should have a demonstrated record of mentoring and should describe mentoring activities that will involve pathobiology and phenotyping investigators who have little or no research experience. The trainees will be exposed to comprehensive mouse pathobiology and phenotyping through hands-on training in diverse biomedical disciplines and supervised interaction with principal investigator. They eventually will become skilled mouse investigators who can fill the growing need for such professionals.

Most candidates for this award will have a D.V.M. (or equivalent degree) from an institution recognized by the AVMA. In addition, individuals holding other clinical (e.g., M.D.) or research (e.g., Ph.D.) degree(s) may apply for the award if they have demonstrated the necessary expertise to perform high-quality, funded research in mouse pathobiology and comprehensive mouse phenotyping. At the time of application, the candidate should have a demonstrated record of significant, ongoing peer-reviewed research support in the field of mouse pathobiology and/or comprehensive phenotyping, either as a Principal Investigator or co-investigator.

The institution must be able to demonstrate a commitment to the candidate as a productive, independent investigator. The candidate and institution must be able to describe a career program that will utilize the relevant research and educational resources, and the institution must certify that the candidate will be released from other duties and be able to devote up to 50 percent effort (with a minimum 25 percent effort) to a mouse pathobiology research and comprehensive phenotyping as well as mentoring program. The research phase of an award period must be devoted to mouse pathobiology research in scientific areas relevant to the career goals of the candidate.

For detailed information on allowable costs and information that must be included in the application, please refer to Program Announcement, <u>PAR-12-021</u>, "Midcareer Investigator Award in Mouse Pathobiology Research," published in the *NIH Guide*, November 17, 2011. Applications must be submitted using the <u>PHS 398 Application Form</u>, adhering to the additional instructions for Research Career Awards. Applications should be submitted by the deadlines prescribed on the <u>Schedule of Standard of Receipt Dates</u>.

X. ACADEMIC RESEARCH ENHANCEMENT AWARDS (R15)

The DCM participates in the Academic Research Enhancement Award (AREA) Program. AREA grants support individual research projects in the biomedical and behavioral sciences conducted by faculty, and involving their undergraduate students, who are located in health professional schools and other academic components that have not been major recipients of NIH research grant funds. Information on AREA grants including program guidelines, application due dates, and a list of ineligible institutions--is available on the <u>AREA Web page</u>.

In regard to AREA grants, the DCM is primarily interested in those research areas listed for R01 grants, above. Applications must <u>apply electronically</u> by the deadlines prescribed on the <u>Schedule of Standard of Receipt Dates</u>. Applicants may request up to \$300,000 in direct costs plus applicable Facilities & Administrative (F&A)/indirect costs for the entire project period of up to 3 years.

Potential applicants are encouraged to contact the ORIP AREA program representative:

Dr. Miguel Contreras, Health Scientist Administrator Office of Research Infrastructure Programs, 6701 Democracy Boulevard, Room 945 Bethesda, MD 20892-4874

Telephone: (301) 594-9410

Fax: (301) 480-3819

E-mail: miguel.contreras@nih.gov

XI. NATIONAL RESEARCH SERVICE AWARDS

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 graduates 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. To achieve its training goals, the DCM makes the following types of NRSA awards:

- 1). Institutional Training Grant for Veterinarians and Training Grant for Veterinary Students in Animal-Oriented, Hypothesis-Based Research (T32, PA-11-184,).
- 2). Professional Student Short-Term Research Training Grant (T35). The trans-NIH NRSA guidelines can be found in <u>PA-11-185</u>, Research areas of interest to the DCM are identical to those described previously for R01 applications. Each type of award is described below.

Institutional Ruth L. Kirschstein Training Grants (T32-Post Doctoral)

The purpose of the T32 NRSA Institutional Training Grant for Veterinarians program offered by the DCM is to provide support for training highly qualified veterinarians for research careers in biomedical areas related to comparative medicine, comparative pathology, or research related to translational research that improve and extend healthy lives and prevent illness. 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 independent grant funding.

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-11-184 NIH NRSA Institutional Research Training Grants (T32)", published in the NIH Guide, March 21, 2011. 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. An important requirement of institutional training programs sponsored by the DCM is that all applicants must have completed their veterinary medical training. 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 and PHS awarding units 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. Consideration will be given, on a case-by-case basis, to formal requests for reasonable extensions beyond the normal 3year training period to enable a trainee to complete the advanced degree requirements. 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 on the Schedule of Standard of Receipt Dates. Applicants requesting \$500,000 or more in direct costs for any year must obtain approval from a DCM Health Scientist Administrator or the DCM Director at least 8 weeks prior to submitting such an application.

Training Grant for Veterinary Students in Animal-Oriented, Hypothesis-Based Research (T32)

DCM awards these pre-doctoral training grants to eligible research institutions to support individuals pursuing a degree in veterinary medicine (D.V.M. or V.M.D.) for a 1-year training opportunity in hypothesis-based laboratory animal medicine, comparative medicine or pathology, or related areas in biomedical research. Applicant institutions must have the staff and facilities required to provide a high-quality training environment in biomedical research for the supervised and mentored training of veterinary students pursuing research careers. Applicant institutions must meet the basic eligibility criteria outlined for T32 applications. The application should describe a plan for widely advertising the program and for recruiting underrepresented minorities. DCM will support a maximum of three trainees for 12-month duration per budget period. All training activities must be on a full-time basis during the training sequence. Institutions that train veterinary students in animal-oriented, hypothesis-based research grants must submit their T32 applications on the SF 424 by the deadlines prescribed on the Schedule of Standard of Receipt Dates. Institutions can have only one active NRSA T32 award for Veterinary Students at any time. Please refer to Program Announcement PA-11-184 NIH NRSA Institutional Research Training Grants (T32), published in the NIH Guide, March 21, 2011

Professional Student Short -Term Research Training Grants (T35)

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 D.V.M. /Ph.D. program are not eligible for this support.

The application should describe a plan for widely advertising the program and for the recruitment of minorities that are presently underrepresented nationally in the biomedical and biobehavioral sciences. Training is not restricted to activities in a single discipline. Placement of students in an institution's strongest research training programs that may involve basic or clinical research, or a combination of both, is encouraged. Applicants are further expected to employ approaches that will nurture a sense among trainees of belonging to a community of scientists. ORIP's T35 grants will support a minimum of four trainees per budget period. 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 on the Schedule of Standard of Receipt Dates. 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-11-185, NIH NRSA Short-Term Institutional Research Training Grants (T35).

XII. SUPPLEMENTS

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 DCM staff before applying. These applications are submitted directly to DCM staff, rather than to the NIH Center for Scientific Review.

Research Supplements to Promote Diversity in Health-Related Research are described in http://grants.nih.gov/grants/guide/pa-files/PA-08-190.html. Funds are available for administrative supplements to improve the diversity of the research workforce by supporting and recruiting students, post doctorates, and eligible investigators from groups that have been shown to be underrepresented. Although the administrative supplements supported under this program provide funding for less than one percent of all individuals involved in NIH supported research, the NIH has found these awards to be an effective means of encouraging institutions to recruit from currently underrepresented groups. 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 shown to be 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 or a research training grant or any other DHHS funding mechanism.

Research Supplements to Promote Re-Entry into Biomedical and Behavioral Research Careers are described in http://grants.nih.gov/grants/guide/pa-files/PA-08-191.html. Funds are available for administrative supplements to research grants to support individuals with high potential to re-enter an

active research career after a qualifying interruption for family or other responsibilities. 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 or a research training grant or any other DHHS funding mechanism. Applications should be submitted through the DCM program staff assigned to the parent grant.

XIII. CONTRACTS AND COOPERATIVE AGREEMENTS

Contracts

A contract is normally used to acquire a product or service to help DCM achieve a specific objective. Using this mechanism, DCM formally specifies the activity through a "statement of work." Contracts are awarded based on response to Requests for Proposals (RFPs) published on the <u>Federal Business</u>

<u>Opportunities (Fed Biz Opps) Web site</u>, in the *NIH Guide*, and other NIH and Federal government Web sites. Contract proposals receive a technical review based upon the evaluation factors listed in the RFP.

Cooperative Agreements

A cooperative agreement is used to complement grant-supported activities. It is an assistance mechanism that requires substantial programmatic involvement by DCM staff to conduct the activity. Cooperative agreement proposals are solicited by the DCM and are intended to support projects with highly specific aims that are not appropriate for grant support through the other mechanisms described in this document

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 DCM RFAs. Examples of two programs that have utilized RFAs in the past and could be utilized in the future are listed below:

Applications for Research Education Programs for Laboratory Animal Medicine Veterinarians (R25)

Under this FOA, DCM solicited Research Education Grant (R25) applications to provide research education for veterinarians interested in pursuing a career in Laboratory Animal Medicine. It is 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 is to prepare veterinarians to be competent and proficient in the field of Laboratory Animal Medicine in support of biomedical investigations, with emphasis on performing collaborative research, development and maintenance of animal models in support of translational research activities, and to provide professional direction for animal resource/research programs.

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 (D.V.M., V.M.D. 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 (D.V.M., V.M.D. 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 initial review of applications directed towards programs in the DCM may be conducted by special review groups established by the National Center for Advancing Translational Sciences (NCATS), or by the Center for Scientific Review (CSR) study sections. The second level of the peer review process is conducted by NIH Council of Councils, Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI). Review criteria are listed in each Funding Opportunity Announcement (FOA).

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 by legislation. All grant applications must list the applicable FOA; otherwise, the application will not be accepted for review. SERCA (K01), Midcareer Investigator Awards in Mouse Pathobiology Research (K26), 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. In addition, special eligibility requirements in the program guidelines 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, <u>Title 45</u>, <u>Subchapter A</u>, <u>Part 74</u>, or <u>Part 92</u>, the applicable cost principles, <u>Revised NIH Grants Policy Statement</u>, and supplemental guidelines published for specific programs.

Coordination Required to Develop Applications

Potential applicants should consider discussing a proposed application with 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.