National Center for Research Resources
National Institutes of Health
Department of Health and Human Services

Division of Comparative Medicine

Program Guidelines

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Division of Comparative Medicine Web Page

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INTRODUCTION

The National Center for Research Resources (NCRR) 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. NCRR'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.

The four Divisions administered and managed by NCRR are:

- Biomedical Technology Research and Research Resources
- Clinical Research Resources
- Comparative Medicine
- Research Infrastructure

NCRR's Division of Comparative Medicine (DCM) supports the biomedical and health research community in the general area of comparative medicine. The DCM also meets needs for a variety of biological materials, such as cell cultures and computer models related to animal or cell research. Major DCM objectives are to assist in providing animal-related resources to investigators and to be responsive to the public concerns and legal requirements for ensuring that laboratory animals are properly cared for and used in a humane manner. Laboratory animals include mammalian or non-mammalian animals used or intended for use in research, research training, biological testing, or related purposes. Through grants, cooperative agreements, and contracts, the DCM supports National Primate Research Centers (NPRCs), the Chimpanzee Sanctuary System, laboratory animal research projects, development of animal models, pre- and postdoctoral research career development training for veterinarians, and a variety of research and resource facilities.

PROGRAM DESCRIPTIONS

The DCM administers the following five programs:

The Laboratory Animal Sciences (LAS) Program supports animal research, related resources, and career development with grants, cooperative agreements, and contracts. The program supports activities to develop, characterize, and improve mammalian animal models for human disease and to diagnose, study, and control diseases of laboratory animals. Research and resource grants help establish, maintain, and improve special types of animal colonies to meet research needs; improve and ensure the health and quality of laboratory animals; and determine environmental and welfare requirements of animals. Training in research related to laboratory animal science, comparative pathology, and specialties related to applications that improve and extend healthy lives and prevent illness is supported at both the pre- and postdoctoral levels.

Biological Models and Materials Research (BMMR) is the focus for extramural research activities in the exploration and development of non-mammalian models for biomedical research. The program supports research to develop and broaden the utility of models, including non-mammalian organisms, cell cultures, and non-biological systems (i.e., mathematical and computer modeling). BMMR 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 non-mammalian 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.

National Primate Research Centers (NPRCs) provide support for the operation of a national network of highly specialized centers. These centers provide facilities for nonhuman primate research, experienced personnel, and appropriate research environments. NPRCs support the development of nonhuman primate models and other research resources required to conduct biomedical research for a better understanding of human health problems and disease processes.

The AIDS Animal Models Program supports research and resources that identify, develop, and make available animal models for AIDS-related investigations. Investigator-initiated research project grants comprise the majority of awards made under this program. The Chimpanzee Biomedical Research Program is a part of this program and is supported through cooperative agreements and contracts.

The Chimpanzee Sanctuary System supports a resource for providing lifetime care for chimpanzees. The establishment and support of the federally supported Chimpanzee Sanctuary System was mandated by Congress to provide a resource primarily for federally owned animals or the support of chimpanzees that are no longer needed in biomedical or behavioral research. This program is supported through a contract with a private nonprofit entity, administered by the DCM.

Additional information on programs and resources currently supported by the DCM is available on the NCRR Web site. Potential applicants are encouraged to contact DCM staff at (301) 435-0744.

AWARD MECHANISMS

The DCM sponsors the following types of activities. This listing is not intended to imply that potential support is strictly limited to the activities described. Staff welcomes the discussion of potential applications in related areas.

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 and examples of such research include:

- **Animal Models:** Develop and characterize natural and 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 germ plasm.

- **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 non-traditional species for research.

- **Regenerative Medicine:** Develop animal models for gene and cellular-based therapies of disease; isolate and characterize animal stem cells.

- **Animal Disease:** Detect and characterize diseases that may interfere with research and compromise animal welfare, support studies related to development of vaccines and 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, stock, or strain 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 Public Health Service 398 Application Form 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 Associate Director at least 6 weeks prior to submitting an application.

The following review criteria will be used in the evaluation of research project grants:

1. **Significance.** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

2. **Approach.** Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

3. **Innovation.** Does the project employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

4. **Investigator.** Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the Principal Investigator (PI) and other researchers (if any)?

5. **Environment.** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

II. EXPLORATORY/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. Unless otherwise specified through an announcement, review criteria are the same as for R01 grants. 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. The DCM R21 grant program normally accepts applications only in response to announcements that specify this mechanism or after consultation with DCM program staff. Applicants are encouraged to consult with program staff as early as possible to be advised whether the R21 mechanism is appropriate. Applicants also are strongly encouraged to consult the NIH Exploratory/Developmental Research Grant Award Web page.

Funds awarded through R21 grants are not to be used to supplement or substitute for projects currently supported by Federal or non-Federal funds or to provide interim support for projects under review. Although R21 grants are not renewable, they are expected to provide the opportunity to collect sufficient preliminary data to apply for future support from either the NCRR or other NIH ICs. Applications should be prepared in accordance with PHS 398 (latest revision) instructions. Page and appendix limitations beyond those stated in the PHS 398 may apply, depending on the specific announcement. Applications must be submitted using the PHS 398 Application Form by the deadlines prescribed on the Schedule of Standard Receipt Dates. For additional information, please refer to Program Announcement, PA-03-107, "NIH Exploratory/Developmental Research Grant Award (R21)," published in the *NIH Guide to Grants and Contracts,* April 18, 2003, hereafter referred to as the *"NIH Guide."*

III. RESOURCE-RELATED RESEARCH PROJECT GRANTS (R24)

Resource-related Research Project Grants (R24) are investigator-initiated projects that predominantly support applied studies to characterize and develop new resources or to improve existing ones. Resources are defined as animal, cell culture, or computer/mathematics models that have the potential for becoming well-used systems for research projects. These grants are intended to support research projects contributing to the knowledge of a model system that will make the model more useful and more accessible to the research community. The models of interest to NCRR are limited to those that span the interests of two or more categorical NIH ICs. The research areas that are appropriate for support with the R24 grant mechanism are identical with those for R01 grants supported by NCRR. Review criteria are similar to those for an R01. In addition, the applicant must demonstrate a need for the resource in the biomedical community. Applicants are encouraged to include letters of support from investigators outside of the applicant institution who would use the resource.

Applications must be submitted using the PHS 398 Application Form by the deadlines prescribed on the Schedule of Standard Receipt Dates. In addition, applicants requesting $500,000 or more in direct costs for any year must obtain approval from a DCM Health Scientist Administrator or the DCM Associate Director at least 6 weeks prior to submitting an application.

IV. SCIENTIFIC MEETING GRANTS (R13, U13)

Information concerning Scientific Meeting Grants is provided in Program Announcement PAR-03-176, " NIH Support For Conferences And Scientific Meetings," published in the *NIH Guide,* September 24, 2003, and on the NIH Conference Grants Web page. An application for a conference grant must include a letter from the appropriate NIH IC staff documenting advance permission to submit an R13 or U13 application. The NCRR Conference Grant Contact is given on the aforementioned NIH Conference Grants Web page. To obtain permission to submit a Conference Grant to NCRR, the applicant must first contact a DCM staff member or the NCRR Conference Grant Contact and provide information about the proposed meeting. This should occur no later than 6 weeks before the receipt date of the application (see below for receipt dates). If the meeting is appropriate to DCM, the Conference Grant Contact will provide the applicant with a letter indicating advance permission to submit the application. A copy of this letter must be submitted with the application. The letter does not imply that the conference grant

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

The application should provide a detailed description of the objectives, scientific program, and logistics of the meeting and describe the format and agenda. The application also should provide a detailed justification for the meeting, including the scientific need, the timeliness, and the utility of the meeting to the scientific community. The composition and role of the organizing committee and the names and credentials of the key participants in the meeting should be provided, as well as indications that they have committed themselves to participating in the program. The expected number of attendees, type of audience, and the mechanism of their selection should be stated. Plans for publicity for the meeting, selection of participants, and publication of proceedings should be included. Information about all related meetings held on the subject during the last 3 years should be provided. If this is one of a series of periodic meetings, the last meeting and its value to the research community should be described briefly. The application must include evidence of appropriate representation of women, racial/ethnic minorities, persons with disabilities, and other individuals who traditionally have been underrepresented in science. These individuals must be included in all aspects of planning, organizing, and implementing NIH-sponsored and/or supported meetings.

If NCRR determines that there is sufficient need to have substantial involvement in the planning and conduct of a scientific meeting, then NCRR program staff may determine that a cooperative agreement (U13) award would be appropriate.

Applications for conference grants must use the PHS 398 Application Form, which may be submitted after the applicant has requested and received a letter from NCRR staff documenting advance permission to submit an R13 or U13 application. Although highly unlikely for a conference grant, applicants requesting $500,000 or more in direct costs for any year must obtain approval from a DCM Health Scientist Administrator or the DCM Associate Director at least 6 weeks prior to submitting an application. Applications will be accepted on April 15, August 15, and December 15. The receipt date selected should allow ample time to review the application, make an award, and plan the meeting.

V. SPECIAL EMPHASIS RESEARCH CAREER AWARD GRANTS (K01)

The Special Emphasis Research Career Award (SERCA) in Pathology and Comparative Medicine is a Mentored Research Scientist Development Award intended to assist graduate veterinarians who have experience in laboratory animal science-related activities to become independent investigators in research related to comparative medicine. The NCRR SERCA Guidelines should be consulted when preparing a SERCA application. The NCRR SERCA guidelines are supplementary to the trans-NIH Program Announcement, PA-00-019, "Mentored Research Scientist Development Award (K01)," published in the *NIH Guide,* December 2, 1999.

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 grantees. During the first 3 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. Exposure to several research disciplines may be proposed if it is appropriate for the development of a focused research effort. The awardee may pursue this training in different laboratories to obtain the necessary expertise. However, a primary mentor will have overall responsibility for helping to guide the SERCA awardee. In some cases, these activities will be part of a career development program designed by the awardee, following formal training in laboratory animal medicine/comparative pathology or postdoctoral research experience in another area of comparative medicine. 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 thesis requirements for a Ph.D. degree.

The final 2 years of SERCA support, which follow the 3-year initial project period, should demonstrate increasing independence in the planning, design, and conduct of research. As part of the continuing non-competing application for year 4 of the SERCA award, the grantee should include a detailed research plan for years 4 and 5, using the format for a typical R01 application. This proposal, along with overall progress during the initial 3 years of SERCA support, will be considered by DCM staff in determining the candidate's eligibility for funding during the fourth and fifth years.

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. 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. Where feasible, women, minority individuals, and individuals with disabilities should be

involved as mentors and serve as role models. 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. Minorities, women, and individuals with disabilities are encouraged to apply. 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. The applicant should contact the DCM office and ask to speak with the Health Scientist Administrator who has programmatic responsibility for the SERCA.

Applications must be submitted using the PHS 398 Application Form, adhering to the specific instructions for Research Career Awards. Applications should be received by the deadlines prescribed on the Schedule of Standard of Receipt Dates. AIDS-related SERCA applications should be submitted on the due dates for AIDS-related applications.

VI. MIDCAREER INVESTIGATOR AWARDS IN MOUSE PATHOBIOLOGY RESEARCH (K26)

The purpose of the Midcareer Investigator Award in Mouse Pathobiology Research (K26) is to provide support for established midcareer mouse pathobiologists, affording them protected time to devote to research involving mice and to act as mentors for beginning investigators. The target candidates are outstanding scientists engaged in mouse pathobiology research who are within 15 years of completion of their specialty training, who can demonstrate the need for a period of intensive research focus as a means of enhancing their research careers, and who are committed to mentoring the next generation of mouse pathobiologists. The award is intended to further the research and mentoring endeavors of outstanding mouse pathobiologists, to enable them to expand their potential to make significant contributions to their field of research, and to act as mentors for beginning investigators.

The prospective candidate for the Midcareer Investigator Award in Mouse Pathobiology 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. All programs should be carefully tailored to meet the individual needs of the candidate and must include a

description of a research project that meets the definition of mouse pathobiology research. In addition, the candidate should have a demonstrated record of conducting meritorious pathobiology research, have experience in mentoring (or demonstrate mentoring capabilities) and should describe mentoring activities that will involve beginning investigators with little or no research experience. The candidate must have significant, peer-reviewed research support at the time of application for this program. This award is intended to enable the candidate to devote a greater percent of his/her effort to mouse pathobiology research.

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. Candidates must be working in a research environment conducting mouse pathobiology research and have significant peer-reviewed research support as Principal or Co-Investigators.

The institution must have a well-established research and career development program. 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 mentoring program. The remainder of the candidate's time may be devoted to other clinical, teaching, or research pursuits consonant with the objectives of the award. 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. The institution must demonstrate the availability of beginning research-oriented investigators who will be mentored.

The award provides up to 5 consecutive years of support without the possibility for competing renewal. The application should emphasize three components. These include descriptions of: 1.) the qualifications of the candidate as a trained mouse pathobiologist, including strong support by the institution; 2.) the mentoring plan of future scientists in mouse pathobiology; and 3.) the research plan that should resemble an abbreviated R01 application that meets the definition of a biomedical research project related to human health.

For detailed information on allowable costs and information that must be included in the application, please refer to Program Announcement, PAR-01-064, "Midcareer Investigator Award in Mouse Pathobiology Research," published in the *NIH Guide*, March 7, 2001. Applications must be submitted using the PHS 398 Application Form, adhering to the additional instructions for Research Career Awards. Applications should be submitted 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 Associate Director at least 6 weeks prior to submitting such an application.

VII. 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 for Small Business Innovation Research Grant Applications" and "Omnibus Solicitation for Small Business Technology Transfer Grant." 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 using the Public Health Service 398 Application Form 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 Associate Director at least 6 weeks prior to submitting such an application. Prospective applicants are encouraged to contact DCM staff for advice before submitting SBIR or STTR applications.

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

Animal resource grants are used to provide support for special colonies of laboratory animals, including nonhuman primates, as well as other resources such as cultures (cells, tissues, and organs) and genetic stocks that serve the biomedical research community at large. Support for such resources is limited to those that span the interests of two or more categorical NIH ICs. Special colonies of research animals are defined as animals that are valuable for biomedical research but are not generally available to investigators because of issues related to breeding, maintenance, or procurement.

These resource centers must have the four following characteristics: 1.) There must be demonstrated need for the resource in the research community; 2.) the resource must serve the needs of investigators in a variety of research areas where work is sponsored by categorical NIH ICs. If the user community is very narrow or limited to the applicant institution, support for the animal resource should be sought from the appropriate NIH categorical IC; 3.) the resource must be available to investigators on a local, regional, and national basis; and 4.) the resource must have a research component to generate new information that is relevant to the resource. Typically, the research component will comprise about 10-20 percent of the direct costs associated with the P40 grant.

An objective of animal resource grants is that the project should progress toward self-sufficiency in a reasonable period. Therefore, costs specifically associated with the establishment, improvement, or expansion of supply and long-term resource maintenance should be recovered

from users through a charge schedule acceptable to the NIH. Gross income earned by the recipient that is directly generated by a supported activity or earned as a result of the award (Program Income) must be estimated.

P40 applications must be submitted using the Public Health Service 398 Application Form by the deadlines prescribed for Center grants on the Schedule of Standard of Receipt Dates. Prospective applicants should discuss the P40 application with DCM staff prior to submission. Applicants requesting $500,000 or more in direct costs for any year must obtain approval from a DCM Health Scientist Administrator or the DCM Associate Director at least 6 weeks prior to submitting such an application.

The following review criteria will be used in evaluation of P40 applications:

1. **Significance.** What will be the impact of this resource on biomedical research?

2. **Approach.** Is the resource designed to effectively provide a service to the research community?

3. **Innovation.** Are the design of the resource and the method of providing service innovative?

4. **Need.** Is there a demonstrated need for the resource in the biomedical research community?

5. **Investigator.** Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the PI and other researchers?

6. **Research Component.** Is the research to be performed of value to the resource? Is the research innovative and significant?

7. **Environment.** Does the environment contribute to the probability of success of the resource? Is there evidence of institutional support for the resource?

IX. CONTRACTS AND COOPERATIVE AGREEMENTS

Contracts. A contract is normally used to acquire a product or service to help NCRR achieve a specific objective. Using this mechanism, the NCRR formally specifies the activity through a "statement of work." Contracts are awarded based on response to Requests for Proposals (RFPs) published on the Federal Business Opportunities (Fed Biz Opps) Web site, 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 NCRR staff to conduct the activity. Cooperative agreement proposals are solicited as initiatives

of 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.

X. 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 with a basic core of knowledge, as well as the skills and motivation 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.) Individual Predoctoral Fellowship Award for Minority Students (F31, PA-03-067 or subsequent publications) and Postdoctoral Fellowship Awards (F32, PA-03-067 or subsequent publications); 2.) Institutional Training Grant for Veterinarians (T32, PA-02-109 or subsequent publications); Training Grant for Veterinary Students in Animal-Oriented, Hypothesis-Based Research (T32, PA-01-138 and NOT-RR-02-010); and 3.) Professional Student Short-Term Research Training Grant (T35). The trans-NIH NRSA guidelines can be found in PA-02-109, "NIH National Research Service Award Institutional Research Training Grants (T32)" published in the *NIH Guide*, May 16, 2002 and specifically for NCRR (PA-01-038) in September 20, 2001. Research areas of interest to the DCM are identical to those described previously for R01 applications. Each type of award is described below.

Individual Ruth L. Kirschstein Predoctoral (F31) and Postdoctoral (F32) Fellowships:
Applicants to both fellowships must be citizen or non-citizen nationals of the United States at the time of application or must have been lawfully admitted to the United States for permanent residence. Predoctoral awards are only awarded to qualifying minority students.
Prior to receiving an F32 award, applicants must have also received a D.V.M., V.M.D., or equivalent veterinary degree from an accredited domestic or foreign institution or hold a Ph.D. or equivalent degree. Training fellowships may be requested for periods of 1, 2, or 3 years. Individual postdoctoral fellows generally may not receive more than 3 years of NRSA support, including any combination of support from institutional and individual NRSA awards. Fellowship awards include a stipend (the level of which is based on the experience of the fellow) and an allowance to the sponsoring institution. The proposed training may be part of a research degree program. Fellows are required to pursue their research training on a full-time basis and confine clinical duties to those that are related to the research training area. Applicants must arrange for an appointment to a host institution and be accepted by a sponsor who is qualified to supervise the training and research experience. Carefully selected graduate courses, taken for credit, should be included in each trainee's research training program. These may include, as indicated by individual needs, courses in statistics, genetics, scientific communication, and research methodology, as well as advanced courses in the area of the trainee's proposed research. Research training is best accomplished by active participation in ongoing research programs and in association with skilled, experienced investigators. Research training should include experience in the following: 1.) formulation of significant research problems; 2.) critical review

of the scientific literature; 3.) design of experiments and preparation of research protocols; 4.) laboratory methodology; 5.) data analysis; 6.) biostatistics; 7.) preparation for and presentation of data at scientific meetings, and 8.) report and manuscript preparation.

Research skills should be developed over the entire tenure of training. The time allocated to research experience should be at least 2 years. Early experience may involve participation in ongoing research as part of a team effort. However, emphasis should be placed on an individually initiated research project that is at least equivalent to one required for a thesis. For a detailed description of the requirements for these awards, please refer to Program Announcement, PA-03-067, "Ruth L. Kirschstein National Research Service Awards for Individual Postdoctoral Fellows (F32)" published in the *NIH Guide*, February 6, 2003. Applications must be submitted using the PHS 416-1 Application Form by the deadlines prescribed on the Schedule of Standard of Receipt Dates.

Institutional Ruth L. Kirschstein Training Grants (T32): The purpose of the NRSA Institutional Training Grant for Veterinarians (T32) 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 applications that improve and extend healthy lives and prevent illness. This training may be incorporated into the requirements for a research degree 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 training is in direct support of national goals in the biomedical sciences that involve animal-based research, since approximately half of the research sponsored by the NIH includes the use of one or more types of animal models of human disease. The broad knowledge of veterinarians in whole animal-based biology, coupled with specialized research training provided by this program in comparative medicine, pathology, molecular biology and other related biomedical areas, will equip trainees with strong foundations for research careers in biomedicine.

Because of their unique training and expertise in veterinary medicine, graduates of the institutional training programs are often required, in addition to their activities as research scientists, to assume responsibilities that require a working knowledge of various animal resource-related issues. These include clinical and diagnostic medicine, selection of optimal anesthetics for specific types of research projects, resource management, training of research staff in the humane care and use of laboratory animals, and selecting the most appropriate animal models for particular studies. These activities are extremely important to ensure that high-quality, animal-based research is carried out and that the health and integrity of institutional laboratory animal colonies are protected.

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-02-109, "NIH NRSA Institutional Research Training Grants (T32)," published in the *NIH Guide*, May 16, 2002. 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 for Veterinarians 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 3-year training period to enable a trainee to complete the advanced degree requirements. Institutions that request NRSA Institutional Training Grants must submit their T32 applications using the PHS 398 Application Form 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 Associate Director at least 6 weeks prior to submitting such an application.

NCRR Training Grant for Veterinary Students in Animal-Oriented, Hypothesis-Based Research (T32): NCRR awards these 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. NCRR will support a maximum of three trainees for a 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 PHS 398 Application Form 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 Associate Director at least 6 weeks prior to submitting such an application. Institutions can have only one active NRSA T32 award for Veterinary Students at any time. Please refer to Program Announcement, PA-01-138, "NCRR Training Grant for Veterinary Students in Animal-Oriented, Hypothesis-Based Research," published in the *NIH Guide,* September 20, 2001, and Notice, NOT-RR-02-010, "NCRR Training Grant for Veterinary Students in Animal-Oriented, Hypothesis-Based Research: Change in Provision of the Award," published in the *NIH Guide,* August 28, 2002.

Professional Student Short-Term Research Training Grants (T35): DCM awards NRSA Short-Term Training: Students in Health Professional Schools (STSHPS) institutional grants to biomedical research institutions to further research staffing development objectives in laboratory animal science, laboratory animal medicine, comparative medicine, comparative pathology, and research related to applications that improve and extend healthy lives and prevent illness. The

STSHPS grant provides 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 for biomedical and biobehavioral research careers. Applicant institutions must meet the basic eligibility criteria outlined for T32 applications. Applications must be submitted using the PHS 398 Application Form by the deadlines prescribed on the Schedule of Standard of Receipt Dates. Institutions can have only one current active STSHPS award at any time. Institutions must have the staff and facilities required for the proposed program and be responsible for the selection and appointment of trainees.

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. Because STSHPS grants are intended to introduce students to research in cases where they might not otherwise have an opportunity to gain such experience, 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 behavioral sciences. Training is not restricted to activities in a single discipline. Placement of students in an institution's strongest research and 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. NCRR's STSHPS 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. Please refer to Notice, NOT-98-009, "NRSA Short-Term Institutional Research Training Grants (T35)," published in the *NIH Guide*, February 2, 1998 and Notice, NOT-RR-02-006, "Change in Receipt Dates for NRSA T35s," published in the *NIH Guide*, March 9, 2000.

XI. 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 AREA Web page.

In regard to AREA grants, the DCM is primarily interested in those research areas listed for R01 grants, above. Applications must be submitted using the PHS 398 Application Form 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 Associate Director at least 6 weeks prior to submitting such an application. Potential applicants are encouraged to contact the NCRR AREA program representative:

Dr. Louise E. Ramm

National Center for Research Resources
6701 Democracy Boulevard, Room 902
Bethesda, MD 20892-4874
Telephone: (301) 435-0875
Fax: (301) 480-3658
E-mail: RammL@mail.nih.gov

XII. SUPPLEMENTS

The following three 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 for Individuals with Disabilities are described in Program Announcement, PA-05-015, "Research Supplements to Promote Diversity in Health-Related Research," published in the *NIH Guide,* November 19, 2004. Under this program, individuals with disabilities are encouraged to pursue biomedical research careers in areas within the missions of all the awarding components of the NIH through supplemental awards to certain types of ongoing research grants. The NIH program is designed to extend opportunities to individuals with qualifying disabilities who are capable of entering or resuming research careers. The program provides funding at several different stages in a research career, as described in the aforementioned PA-05-015. The research supplement programs for individuals with disabilities have been designed to attract individuals with disabilities into research careers and are not intended to provide an alternative means of supporting disabled individuals who already receive support from a research grant or a research training grant or any other Department of Health and Human Services (DHHS) funding mechanism. Applications should be submitted through the DCM program staff person assigned to the parent grant.

Research Supplements for Underrepresented Minorities and to Promote Diversity are also described in PA-05-015. These administrative supplements are available to individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds. Detailed eligibility criteria are described in the full announcement. The mechanisms described in this announcement are designed to attract underrepresented individuals into biomedical and biobehavioral research and provide support for research experiences at grantee institutions for individuals throughout the continuum from high school to the faculty level. 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.

Supplements to Promote Reentry into Biomedical and Behavioral Research Careers are described in Program Announcement, PA-04-126, "Supplements to Promote Reentry Into Biomedical and Behavioral Research Careers," published in the *NIH Guide,* July 9, 2004. This program is designed to support individuals (women or men) with high potential to reenter an active research career after taking time off to care for children or parents or to attend to other

family responsibilities. The aim of these administrative supplements is to encourage fully trained individuals to reenter research careers within the missions of all the program areas of NIH. This program will provide administrative supplements to existing NIH research grants for the purpose of supporting full- or part-time research by these individuals in a program geared to bring their existing research skills and knowledge up to date. It is anticipated that at the completion of the supplement, the reentry scientist will be in a position to apply for a career development (K) award or for a research award.

The following guidelines will generally be applied with discretion by the individual NIH ICs: The duration of the career interruption should be for at least 2 years and no more than 8 years. Examples of qualifying interruptions could include child rearing; an incapacitating illness or injury of the candidate, spouse, partner, or a member of the immediate family; relocation to accommodate a spouse, partner, or other close family member; pursuit of non-research endeavors that would permit earlier retirement of debt incurred in obtaining a doctoral degree; and military service.

The program is not intended to support graduate or postdoctoral training and is not intended to support career changes from non-research to research careers for individuals without prior research training. Generally, at the time of application, a candidate should not be engaged in full-time, paid research activities. Because the NIH ICs may have varying degrees of flexibility in interpreting and implementing the reentry program, potential applicants should consult with Dr. Louise Ramm, NCRR, at the earliest possible stage to discuss any unique situations.

Dr. Louise E. Ramm
National Center for Research Resources
6701 Democracy Boulevard, Room 902
Bethesda, MD 20892-4874
Telephone: (301) 435-0875
Fax: (301) 480-3658
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REVIEW OF APPLICATIONS

The initial review of applications directed towards programs in the DCM may be conducted by the CM Review Committee, special review groups established by NCRR, or by the Center for Scientific Review Study Sections. The second level of the peer review process is conducted by the National Advisory Research Resources Council (NARRC). The NARRC makes recommendations to the Director of NCRR.

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, and, in rare cases, to individuals. For-profit organizations

are eligible to receive awards under all NIH programs unless specifically excluded by legislation. 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, Title 45, Subchapter A, Part 74, or Part 92, the applicable cost principles, NOT-OD-04-009: *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 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.

Program Income. Program income is gross income earned by the recipient that is directly generated by a supported activity or earned as a result of the award. An estimate of the amount and source of program income expected to be generated as a result of an award must be included on the Checklist Page of all competing and non-competing continuation applications. Net program income earned during a budget period must be reported on the long-form Financial Status Report (except for program income earned as a result of inventions, to which special rules apply). Costs incident to the generation of program income may be deducted from gross income to determine the net amount to be reported, provided these costs have not been charged to the award. For grants subject to the expanded authorities, program income may be used by the grant recipient to further eligible project or program objectives. For grants excluded from the expanded authorities (e.g., resource grants), the first $25,000 of net program income earned during a budget period may be used by the grant recipient to further eligible project or program objectives. These grantees must obtain approval from NCRR program and grants management staff for the use of program income over and above $25,000 per budget period. Inquiries should be made to:

Associate Director
Division of Comparative Medicine
National Center for Research Resources, NIH
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