



National Center for Research Resources

National Institutes of Health

Department of Health and Human Services

Comparative Medicine

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

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Contact Information:

Comparative Medicine
National Center for Research Resources
National Institutes of Health
One Rockledge Centre, Suite 6030
6705 Rockledge Drive
Bethesda, MD 20892

phone: (301) 435-0744

fax: (301) 480-3819

e-mail: CMPDir@ncrr.nih.gov

Comparative Medicine area Web site:
<http://www.ncrr.nih.gov/compmed.htm>

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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 areas administered and managed by NCRR are:

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

NCRR's Comparative Medicine (CM) area meets the needs of the biomedical and health research community in the general area of comparative medicine. The CM area also meets needs for a variety of biological materials such as cell cultures and computer models related to animal or cell research. Major CM area objectives are to assist in meeting the animal-related resource needs of investigators and to be responsive to the public demand and legal requirements for assuring that laboratory animals are properly cared for and used in a humane manner. Laboratory animals include any mammalian or non-mammalian animal used or intended for use in research, research training, experimentation, biological testing, or related purposes. Through grants, cooperative agreements, and contracts, the CM area supports regional primate research centers, laboratory animal research projects, development of animal models, postdoctoral training, research career development, and a variety of research and resource facilities.

GUIDELINES FOR THE COMPARATIVE MEDICINE AREA
of the National Center for Research Resources, National Institutes of Health

PROGRAM DESCRIPTIONS

The National Center for Research Resources (NCRR), Comparative Medicine (CM) area has four components.

Laboratory Animal Sciences (LAS) supports animal research, related resources and training with grants, cooperative agreements, and contracts. The program awards grants 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 to improve and assure the health and quality of laboratory animals, determine environmental and welfare requirements of animals, and establish and maintain special types of animal colonies to meet research needs. Training in laboratory animal science, comparative pathology, and comparative medicine is supported at the postdoctoral level.

Biological Models and Materials Research (BMMR) is the focus for extramural research activities in the exploration and development of nonmammalian models for biomedical research. The program supports research to develop and broaden the utility of models including cell cultures, nonmammalian organisms, and nonbiological systems such as 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 embryonic stem cells. The BMMR program accomplishes its goals through funding investigator-initiated research projects grants, animal and biological material resource grants, exploratory/developmental grants, resource-related project grants, contracts, and cooperative agreements.

Regional Primate Research Centers (RPRCs) 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 to 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. Additional information on the RPRC program is presented in a separate document, entitled, "RPRCs-Information for Program Guidelines."

AIDS Animal Models (AAM) supports research and resources that identify, develop, and make available animal models for AIDS-related investigations. The bulk of this program consists of investigator-initiated research project grants (R01, R24). The Chimpanzee Biomedical Research Program is supported through cooperative agreements (U42).

Additional information on programs and resources currently supported by the CM area is available on the World Wide Web at <http://www.ncrr.nih.gov>. Potential applicants are encouraged to contact CM area staff at (301) 435-0744.

AWARD MECHANISMS

The following types of activities are sponsored by the CM area of the NCRR. 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 CM area, NCRR, supports basic research projects related to laboratory animal science and medicine and model systems related to animal research that do not fall within the categorical interest of a single institute or center (IC) of the National Institutes of Health (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 nonmammalian species, as well as cell culture systems and integrative computer models.
- **Biotechnology:** Improve transgenic technology, cryopreservation methods and reproductive biology.
- **Normative Biology:** Includes animal genetics, animal behavior, identification and characterization of non-traditional species for research, animal nutrition and reproductive physiology.
- **Animal Disease:** Detect and characterize diseases that may interfere with research and compromise animal welfare, vaccine development, and development of animals genetically resistant to disease.
- **Animal Welfare:** Improve methods for evaluating and alleviating pain, distress, and discomfort; development and evaluation of environmental enrichment techniques; and improved housing and husbandry technology.

Research projects are limited to those that span the interests of two or more categorical NIH ICs. Such projects should be designed to establish, expand, or improve the usefulness 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 biologic 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 its value as a research model. 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 (PHS) 398 application form (latest revision) on any of the three regular dates indicated on page 20 for new or renewal research project grant applications.

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. 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 which 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. Applications must be submitted using the PHS-398 application form (latest revision) on any of the three regular dates indicated on page 20 for new or renewal research project grant applications.

III. SCIENTIFIC MEETING GRANTS (R13, U13)

Prospective applicants are encouraged to inquire about CM area interest in a proposed conference prior to submission of an application. The application should provide a detailed description of the objectives, scientific program, and logistics of the meeting and describe the format and agenda of the meeting. The application also should provide a detailed justification for the meeting, including the scientific need, the timeliness, and the usefulness 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 whether 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 three years should be provided. If this is one of a series of periodic meetings, the last meeting and its value should be described briefly.

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. Specific terms and conditions of award should be obtained from CM area staff.

Applications for conference grants must use grant application Form PHS 398 (latest revision) and must be submitted at least six months prior to the meeting. The receipt date selected should allow ample time to review the application, make an award, and plan the meeting. Detailed instructions and information for applying for a conference grant are published in the *NIH Guide for Grants and Contracts (NIH Guide)*, October 30, 1998.

IV. SPECIAL EMPHASIS RESEARCH CAREER AWARD GRANTS (K01)

The Special Emphasis Research Career Award (SERCA) in Pathology and Comparative Medicine is intended to assist graduate veterinarians who have experience in laboratory animal science-related activities to become independent biomedical research investigators in research related to comparative medicine. These guidelines are supplementary to the trans-NIH announcement titled, "Mentored Research Scientist Development Award," *NIH Guide* Vol. 24, No. 15, April 28, 1995.

The SERCA award emphasizes in-depth research experience in a variety of basic and clinical scientific disciplines. The overall program should be focused around a central research question; for example, the elucidation of disease mechanisms of induced and spontaneous mutant animals such as mice, rats, or zebrafish and other aquatic species. Upon completion of the award, candidates should have acquired the knowledge and the skills necessary to compete for independent research support. The SERCA is intended to stimulate the development of biomedical researchers with interests in comparative medicine and related research problems.

Examples of research needs and opportunities in this area include:

- **Animal Models:** Discover and develop natural and induced animal models of human biology and disease.
- **Pathology:** Train in the use of molecular and immunological techniques to pursue basic mechanisms of disease, and to identify and characterize alterations in embryonic and postnatal development which result from genetic alterations in laboratory animals.
- **Biotechnology:** Improve transgenic animal technology; cryopreservation methods; creation of genetically identical animals.
- **Normative Biology:** Includes animal genetics; animal behavior, identification and characterization of non-traditional species for research; animal nutrition and reproductive physiology.
- **Animal Disease:** Detect and characterize of diseases that may interfere with research and compromise animal welfare; vaccine development; and development of animals genetically resistant to disease.
- **Animal Welfare:** Improve methods for evaluating and alleviating pain, distress and discomfort; development of environmental enrichment; and improved housing and maintenance technology.

The objectives of the SERCA grant program are to:

- **Encourage** research-oriented veterinarians to develop independent research skills and gain experience in advanced methods and experimental approaches that will allow them to conduct animal-based research as independent investigators.
- **Increase** the pool of veterinary researchers who can conduct animal-based studies using advanced technologies to address disease problems.
- **Provide** individuals with experience and expertise in approaches to assess the results of molecular genetic alterations on the development and health of laboratory animals.
- **Provide** support for qualified individuals to pursue programs of research in basic and clinical research disciplines related to comparative medicine. These areas include the investigation of health problems in laboratory animals and the development of appropriate animal models for use in studies of human disease.

The SERCA provides five years of support for individuals who wish to become trained in the conceptual and technical skills needed for basic and clinical animal research investigation.

During the first three 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, such as physiology, biochemistry, genetics, immunology, pathology, microbiology, experimental surgery, pharmacology, nutrition, and epidemiology 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.

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 post-doctoral 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 two years of SERCA support, which follow the three-year initial project period, should demonstrate increasing independence in the planning, design, and conduct of the research. The awardee must submit a research project application three months prior to completion of the third year of SERCA support that outlines the proposed investigation. This research proposal, of the awardee's own design, should be an outgrowth of the research findings during the initial three years of the SERCA award. The proposal, along with overall progress during the initial three years of SERCA support, will be peer-reviewed and considered by the CM area staff in determining the candidate's eligibility for funding during the fourth and fifth years. The reviewer's comments will be provided to the SERCA awardee and should be used as constructive guidance for the final two years of the research.

Candidates for a SERCA in Comparative Medicine must:

1. Hold a Doctor of Veterinary Medicine (D.V.M. or V.M.D.) degree (or equivalent) from an institution that is recognized by the American Veterinary Medical Association (AVMA).
2. Have completed their clinical training, including specialty training, in a relevant discipline, prior to receiving an award.
3. Not have been previously designated as PI on any research project supported by sources from outside his/her institution. However, the awardee is encouraged to apply as a PI during the last year of the SERCA award for outside support that would begin after the SERCA is completed.
4. 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. It is not essential that the applicant institution commit itself to the eventual placement of the candidate on its permanent faculty, but it is expected that the institution will select candidates with excellent potential for such an appointment.

5. 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. Candidates must name a primary mentor, who together with the applicant, is responsible for the planning, direction, and execution of the program. The mentor(s) must be a recognized senior investigator(s) 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.

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). Non-citizen nationals are usually those born in possessions of the United States (i.e., American Samoa and Swains Island). Individuals in the United States on temporary or student visas are not eligible.

A candidate for the SERCA may not concurrently apply for any other NIH award that duplicates the provisions of this award nor have another submitted application pending. SERCA award recipients are strongly encouraged to apply for independent research grant support, either Federal or private, during the last year of this award.

Prospective applicants are encouraged to discuss their potential eligibility for the SERCA program with CM area staff before preparing an application. SERCA applications may be submitted on any one of the three annual receipt dates (June 1, October 1, or February 1). Prior contact with the Director, Laboratory Animal Sciences Program, NCRR CM area, is encouraged. Applications must be submitted on PHS Form 398 (latest revision), including the additional instructions for Research Career Awards.

V. 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 pathobiologists to allow them protected time to devote to mouse pathobiology research and to act as mentors for beginning investigators. The target candidates are outstanding scientists engaged in pathobiology research who are within 15 years 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, 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 and 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) from an institution recognized by the AVMA. In addition, individuals holding other clinical (such as an M.D.) or research (such as a Ph.D.) degree(s) may apply for the award if they have been certified or have demonstrated the necessary expertise to perform high quality, funded research in mouse pathobiology. Candidates must have completed their specialty or research training within 15 years of submitting the application, and there is no age limit for candidates. In exceptional circumstances, the period of eligibility may be extended if it can be demonstrated that candidates had an interruption in their career progression due to family or personal circumstances. Candidates must be working in a research environment, conducting mouse pathobiology research and have significant peer-reviewed research support.

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 five consecutive years of support.

For detailed information on allowable costs and information that must be included in the application, please refer to Program Announcement (PA), PAR-99-065, "Midcareer Investigator Award in Mouse Pathobiology Research," published in the *NIH Guide*, February 19, 1999. Applications must be submitted on the PHS Form 398 (latest revision), including the additional instructions for Research Career Awards.

VI. SMALL BUSINESS GRANTS

Both Small Business Innovation Research (SBIR) (R43; R44) and Small Business Technology Transfer (STTR) (R41; R42) grants are supported through the CM area. Grants are awarded for research in the development of biomedical methods and technology that relate to improvements in laboratory animal care, use, and management. Research and development interests in the CM area include, but are not limited to: control of laboratory animal diseases; improvement of culture, preservation, or management of laboratory animals; and methods for identification of, or production of new animal models. Detailed descriptions of research interests and necessary special instructions to apply for 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 are published each year and can be obtained in hard copy from:

PHS SBIR/STTR Solicitation Office
13685 Baltimore Avenue
Laurel, MD 20707-5096
Phone: (301) 206-9385
Fax: (301) 206-9722
E-mail: 2y@cu.nih.gov

Or in electronic form on the NIH Web site at: <http://www.nih.gov/grants/funding/sbir.htm>.

The three annual receipt dates for SBIR applications are April 15, August 15, and December 15. Receipt dates for STTR applications are April 1, August 1, and December 1. Prospective applicants are encouraged to contact CM area staff for advice before submitting SBIR or STTR applications. In addition, prospective applicants are encouraged to consult with the NIH small business program staff representative for NCCR:

Dr. Louise E. Ramm
National Center for Research Resources
Building 31, Room 3B11
Bethesda, MD 20892-5662
Telephone: (301) 435-0879
FAX: (301) 402-0006
E-mail: louiser@ncrr.nih.gov

VII. 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. Examples of activities that these resource grants support include colonies of special research animals,

registries, reference centers, newsletters, and other information sources related to the resource. The applicant must demonstrate a need for the resource in the research community.

These resource centers must have three basic characteristics. First, the resource must have a research component to generate new information that is relevant to the resource. Second, 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. Third, the resource must be available to investigators on a local, regional, and national basis.

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. Some of the costs specifically associated with the establishment, improvement, or expansion of special resources may be supported by P40 grants. Support for such resources is limited to those that span the interests of two or more categorical NIH ICs. 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.

An objective of animal resource grants is that the project should progress toward self-sufficiency in a reasonable period of time. 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 (see General Instructions for Applicants, below). Applications should be submitted on grant application Form PHS 398 (latest revision).

Note: All P40s are center grants and initial submissions, revised applications, and competing continuation center grant applications are all due on February 1, June 1, or October 1 application receipt dates. Prospective applicants are encouraged to discuss their P40 application with CM area staff prior to submission.

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?

VIII. EXPLORATORY/DEVELOPMENTAL GRANTS (R21)

The CM area 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. The primary use of the R21 mechanism is to help applicants acquire preliminary data in subject areas for use in preparing R01/R24 applications. Support is limited to two years, at a maximum level of \$100,000 (direct cost) per year. Because this program is designed to support innovative ideas, preliminary data as evidence of feasibility are not required. However, the applicant does have the responsibility for developing a sound research plan. Unless specified otherwise through an announcement, review criteria are the same as those for R01 grants. However, originality of the approach and potential significance of the proposed research are major considerations in the evaluation. The CM area R21 grant program normally accepts applications only in response to announcements that specify this mechanism or after consultation with, and on the agreement of, program staff. These funds are not to be used to supplement or supplant projects currently supported by Federal or non-Federal funds, nor to provide interim support for projects under review. Although these grants are not renewable, they are expected to provide the opportunity to collect sufficient preliminary data to apply for future support from either the NCCR 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 are accepted as stipulated above, on regular receipt dates for research grants.

IX. CONTRACTS AND COOPERATIVE AGREEMENTS

Contracts. A contract is normally used to acquire a product or service to help NCCR achieve a specific objective. Using this mechanism, the NCCR formally specifies the activity through a “statement of work.” Contracts are awarded based on Requests for Proposals (RFPs) published in the *NIH Guide* and on the NCCR Web site.

Cooperative Agreements. A cooperative agreement is used to complement grant-supported activities. It is an assistance mechanism in which substantial programmatic involvement on the part of NCCR staff is necessary for the conduct of the activity. Cooperative agreement proposals are solicited as an initiative of the NCCR CM area and are intended to support projects with highly specific aims.

X. NATIONAL RESEARCH SERVICE AWARDS

The purpose of the National Research Service Awards (NRSA) program is to help ensure that well-trained scientific manpower 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 CM area 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 CM area makes the following types of NRSA awards: 1) Individual Predoctoral Fellowship (F31) and Postdoctoral Fellowship (F32); 2) Institutional Training Grant (T32); and 3) Professional Student Short-Term Research Training Grant (T35). The trans-NIH NRSA guidelines are published in the *NIH Guide*, Volume 26, Number 21, June 20, 1997. Areas of research of interest to the CM area are identical to those described previously for R01 applications.

Each type of award is described below.

Individual 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. Prior to an F32 award, they must have also received a D.V.M., V.M.D., or equivalent, from an accredited domestic or foreign institution or hold a Ph.D. or equivalent degree. Training fellowships may be requested for periods of one, two, or three years. Individual postdoctoral fellows generally may not receive more than three 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 research problem. 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:

- formulation of significant research problems,
- critical review of the scientific literature,
- design of experiments and preparation of research protocols,
- laboratory methodology,
- data analysis,

- biostatistics,
- preparation for and presentation of data at scientific meetings, and
- 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 two 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.

The Application for Public Health Service Individual National Research Service Award (PHS-416-1) should be used. NIH provides an information statement concerning F32 applications at <http://www.nih.gov/grants/guide/pa-files/PA-99-025.html>. The three receipt dates for F32 applications are April 5, August 5, and December 5.

Institutional Training Grants (T32): The purpose of the NRSA Institutional Training Grant (T32) program offered by the CM area is to provide support for training highly-qualified veterinarians for research careers in biomedical areas related to comparative medicine and/or comparative pathology. 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 include 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 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 types of 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 (postdoctoral trainees) as outlined in the *NIH Guide*, Volume 26, Number 16, May 16, 1997. 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 degree. An important requirement of institutional training programs sponsored by NCRR's CM area is that all applicants must have completed their veterinary medical training and at least one year of training in a clinical discipline or comparative medicine and/or comparative

pathology prior to their acceptance as a research trainee. This prior training must be funded by other sources and must include relevant experience concerning intercurrent diseases of laboratory animals, disease treatment and control measures, diagnostic pathology and surgery. In addition, trainees should have a working knowledge of all laws, regulations, and policies related to the care and use of laboratory animals. The institutional training environment must include a high-quality core of academic scientists in the area(s) of comparative medicine and/or comparative pathology.

Trainees are required to pursue their research training on a full-time basis, devoting at least 40 hours-per-week to the program. Within the 40 hours-per-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. In addition, all trainees are expected to maintain and enhance their clinical skills in laboratory animal medicine and animal resource management. Consideration will be given, on a case-by-case basis, to formal requests for reasonable extensions beyond the normal three-year training period to enable a trainee to complete the advanced degree requirements.

Professional Student Short-Term Research Training Grants (T35): The CM area awards NRSA Short-Term Training: Students in Health Professional Schools (STSHPS) institutional grants to biomedical research institutions to further research manpower development objectives in laboratory animal science, laboratory animal medicine, comparative medicine, and comparative pathology. The STSHPS grant provides support for research training experience for selected veterinary students for periods of two to three months. Awards may be requested for up to five 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. Only one application may be submitted for the single receipt date of January 10 each year and institutions can have only one active STSHPS award at any time (other NIH ICs and PHS awarding units also sponsor STSHPS awards). 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 are in combined D.V.M., V.M.D./Ph.D. programs 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. NCCR's STSHPS grants will support a minimum of four, and a maximum of 32, trainees per budget period. All training activities must be on a full-time basis during a training sequence.

Applications for this award should be made on Form PHS-398. The trans-NIH guidelines, Notice 98-009, are found in the *NIH Guide* of February 6, 1998.

XI. ACADEMIC RESEARCH ENHANCEMENT AWARDS (R15)

The CM area participates in the Academic Research Enhancement Award (AREA) program. The purpose of this program is to stimulate research in educational institutions that provide baccalaureate training for a significant number of the Nation's research scientists, but that have not been major recipients of NIH support. AREA funds are intended to support new or ongoing health-related research projects by faculty members in eligible institutions. The CM area is interested in research in laboratory animal sciences, including the etiology, pathogenesis, and control of laboratory animal diseases, as well as the environmental requirements of laboratory animals. The CM area interests also include the development of biomedical research methods employing nonmammalian organisms, tissues or cell culture, and mathematical or computer modeling. Details on eligibility, areas of interest, and application instructions are in PA-99-062, published in the *NIH Guide*, February 11, 1999, and as updated periodically. Applicants are encouraged to contact the NCRR AREA program representative:

Dr. Louise E. Ramm
National Center for Research Resources
Building 31, Room 3B11
Bethesda, MD 20892-5662
Phone: (301) 435-0879
Fax: (301) 402-0006
E-mail: louiser@ncrr.nih.gov

XII. SUPPLEMENTS

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

Research Supplements for Individuals With Disabilities

NIH Guide Publication Date: 11/07/1997

Volume: 26

Number: 37

<http://www.nih.gov/grants/guide/1997/97.11.07/n2.html>

Under this initiative, 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 ongoing research grants. The NIH initiative is designed to

extend opportunities to individuals with qualifying disabilities who are capable of entering or resuming research careers.

The plan provides funding at several different stages in a research career: high school students, undergraduate students, graduate research assistants, individuals in postdoctoral training, investigators developing independent research careers, and established investigators who become disabled.

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 (HHS) funding mechanism. Applications should be submitted through the CM area staff person assigned to the parent grant.

Research Supplements for Underrepresented Minorities

NIH Guide Publication Date: 11/07/1997

Volume: 26

Number: 37

<http://www.nih.gov/grants/guide/1997/97.11.07/n1.html>

Although the NIH currently provides opportunities for minorities through the traditional research grant programs and through special initiatives supported by various components of the NIH, these administrative supplements, in addition, are available to increase the number of underrepresented minority scientists participating in biomedical and behavioral research.

The mechanisms described in this announcement are designed to attract underrepresented minorities into biomedical and biobehavioral research and provide support for research experiences at grantee institutions for minorities 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 CM area staff person assigned to the parent grant.

Supplements to Promote Reentry into Biomedical and Behavioral Research Careers

NIH Guide Publication Date: 08/08/1997

Volume: 26

Number: 26

PA Number: PA-97-088

<http://www.nih.gov/grants/guide/1997/97.08.08/supplements-to-promo10.html>

This initiative 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-time 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 (R or P) award.

The following guidelines will generally be applied with discretion by the individual NIH ICs: In general, the duration of the career interruption should be for at least two years and no more than eight years. Examples of qualifying interruptions would 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, Deputy, Director, NCRR, at the earliest possible stage to discuss any unique situations.

Dr. Louise E. Ramm
National Center for Research Resources
Building 31, Room 3B11
Bethesda, MD 20892-5662
Phone: (301) 435-0879
Fax: (301) 402-0006
E-mail: louiser@ncrr.nih.gov

REVIEW OF APPLICATIONS

The initial review of applications directed towards programs in the CM area may be conducted by several Initial Review Groups (IRGs), i.e., 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, NCRR.

The following are regular receipt dates for the different types of applications, except where noted as otherwise.

RECEIPT, REVIEW, AND AWARD CYCLES

**Application
Receipt Dates**

Types of Applications	Cycle I	Cycle II	Cycle III
All Institutional National Research Service Awards*	January 10	May 10	September 10
New Research Grant, Conferences, and Research Career Awards. All (new, competing, revised and supplemental) Program Project* and Center Grants*	February 1	June 1	October 1
Competing Continuation, Supplemental, and Revised Research Grants, Conferences, and Research Career Awards	March 1	July 1	November 1
Interactive Research Project Grants (IRPGs)	February 15	June 15	October 15
All AIDS-Related Grants	May 1	September 1	January 2
Scientific Merit Review	June-July	October-November	February-March
Advisory Council Review	September-October	January-February	May-June
Earliest Project Start Date	December	April	July

**Review and
Award Schedule**

*For these specialized grant applications, consult with the appropriate PHS awarding component prior to the preparation of an application. Note that NIH applicants are required to contact IC program staff if requesting \$500,000 or more in direct costs for any year.

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 non-profit 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 apply.

Administrative Standards and Cost Standards. All awards are subject to the HHS regulations on the administration of grants found at 45 Code of Federal Regulations 74 or 92, the applicable cost principles, the *NIH Grants Policy Statement*, and supplemental guidelines published for specific programs.

Coordination Required to Develop Applications. Applicants should consider discussing a proposed application with CM area staff before the application is submitted. These discussions may provide clearer understanding of the program policies and guidelines. The applicant should also discuss a competing continuation application with staff to determine if future plans for the project conform with 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 noncompeting 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 NCCR program and grants management staff for the use of program income over and above \$25,000 per budget period. Inquiries should be made to:

Director
Comparative Medicine area
National Center for Research Resources
One Rockledge Centre, Suite 6030
6705 Rockledge Centre
Bethesda, MD 20892-7965
Phone: (301) 435-0744
Fax: (301) 480-3819

Application Form. The most current revision of Form PHS 398, Application for Research Grant, should be used for grant applications seeking CM area support. However, special forms are required for certain types of applications as noted above (e.g., F32 and R43/44 awards). Application kits are available in the business offices of most institutions. An application kit may also be requested from:

Division of Extramural Outreach and Information Resources
Office of Extramural Research
National Institutes of Health
6701 Rockledge Drive
Bethesda, Maryland 20892-7910
Phone: (301) 435-0714

Forms are available on the World Wide Web:
http://www.nih.gov/grants/funding/phs398/forms_toc.html.