

ORIP SERCA Guidelines

Special Emphasis Research Career Award (SERCA, K01) in Pathology and Comparative Medicine

Supplementary Program Guidelines for Mentored Research Scientist Development Awards (K01) — November 2019

I. Introduction

These guidelines summarize current policies governing the Special Emphasis Research Career Award (SERCA) in Pathology and Comparative Medicine, which is offered by the [Division of Comparative Medicine \(DCM\)](#), Office of Research Infrastructure Programs (ORIP), National Institutes of Health (NIH). (Potential applicants should also refer to the guide for Mentored Research Scientist Development Award, “Parent K01 [PA-19-126](#). SERCA differs from the Parent K01 in certain specifics described below.) This award is solely intended to assist graduate veterinarians become independent biomedical investigators who direct their research careers to the broad fields of comparative and/or translational medicine. These guidelines are supplementary to the

[Division of Comparative Medicine Program Guidelines](#) (November 2019).

The SERCA award emphasizes in-depth research experience in a variety of basic and clinical science disciplines. The overall program should be focused around a central concept; for example, the pathologic evaluation 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 successfully compete for independent research support.

II. Background

Laboratory animals are invaluable models that accelerate biomedical research’s understanding of the mechanism(s) of development and progression of human diseases. Evolving technologies and tools for genetic modification will allow new generations of animal models that will be more predictive of human therapeutic outcomes. SERCA is intended to stimulate the development of veterinary researchers with interests in comparative medicine and related research problems. Examples of research needs and opportunities in this area include but are not limited to:

- Animal Models: identification, development, and characterization of spontaneous and engineered vertebrate animal models that advance the understanding of various types of human diseases.
- Pathogenesis: use of clinical, gross, and histologic pathology, coupled with state-of-the-art technologies to identify and characterize molecular, metabolic, or

other alterations in embryonic and postnatal development, which result from genetic alterations in laboratory animals.

- **Biotechnology:** tools, technologies, and protocols for cryopreservation of sperm and germplasm; development of technologies for isolating, propagating, and preserving pluripotent stem cells and inducing stem cells of animals to differentiate along specific pathways *in vitro* and *in vivo*.
- **Normative Biology:** animal genetics; animal behavior; animal nutrition and reproductive physiology; identification and characterization of non-traditional species for biomedical research.
- **Animal Disease:** detection and characterization of diseases that may interfere with biomedical research and compromise animal welfare; vaccine development; and development of animals genetically resistant to disease.
- **Animal Welfare:** improved methods for evaluating and alleviating pain, distress and discomfort; development of environmental enrichment; and improved housing and maintenance technology.

III. Objectives of the Award

The objectives of SERCA are as follows:

- To encourage the development of veterinarians working as biomedical researchers. This mechanism provides graduate veterinarians (DVM or VMD) support for protected research time as mentored investigators. The goal is to enable these individuals to become competitive for research careers in academia as independently funded biomedical scientists.
- To encourage research-oriented veterinarians to develop independent research skills and gain experience in the methods, state-of-the art technologies, and experimental approaches required to advance modern biomedical research.
- To increase the pool of veterinary researchers with the combination of clinical and research expertise in animal science to further develop and care for animal models essential for biomedical research.

IV. Provisions of the Award

SERCA provides five years of support for veterinary researchers who wish to become trained in the conceptual and technical skills needed for basic/clinical biomedical research investigation. The number of awards made each year is subject to the availability of funds.

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 required for the development of the particular research effort proposed in the application. If required, the awardee may pursue training in different laboratories to obtain the necessary expertise. A designated mentor, together with the applicant, is responsible for the overall planning, direction, and execution of the program.

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. SERCA is not a mechanism to obtain a Ph.D. degree or to support residency training, however, research performed under the SERCA may be used to satisfy the experimental work requirements for a Ph.D. degree.

During the final two years of SERCA support, it is expected that the awardees should demonstrate increasing independence in planning, designing, and conducting research in addition to seeking independent research funding.

The SERCA grant is made annually to the awardee's academic institution for each of the five budget periods. Allowable costs may include: awardee's salary, fringe benefits and research support (see the ORIP section of [Table of IC-Specific Information, Requirements and Staff Contacts](#) and Mentored Research Scientist Development Award [Parent K01], [PA-19-126](#)).

V. Criteria for Eligibility

Candidates for a SERCA in Comparative Medicine must:

- Hold a Doctor of Veterinary Medicine degree (or equivalent) from an institution that is listed by the American Veterinary Medical Association (AVMA). (While a PhD degree is not required, all recent SERCA awardees have had both the DVM/VMD and PhD degrees. A discussion with the PO is encouraged for those persons without the PhD but with a strong record of research accomplishment.)
- Not have been previously designated as Principal Investigator (PI) on any research project supported by Federal sources. (Please note that this prohibition includes R03, R21, R36 or SBIR/STTR R41, R42, R43, R44 awards. Inclusion of the listed grant mechanisms is a SERCA specific policy that may not pertain to other NIH K01 awards.) Once an individual has obtained a SERCA however, the awardee is permitted and actively encouraged to apply for additional research grants anytime during the tenure of their K award (see level of effort guidelines

of the K Award Grants Policy Statement, [section 12.3.6](#), for additional information).

- 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.
- Receive appropriate mentoring throughout the duration of the program. 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, possess a permanent academic appointment at the parent institution, and be experienced in postdoctoral research training. **It is strongly advised that the mentor and laboratory for all post-Ph.D. activities should be different from those involved in any earlier doctoral training. (If the same mentor is proposed, applicants should be aware that reviewers will expect a strong justification for that decision.)** The mentor should assist in the initial preparation of the SERCA application. Where feasible, women, minority individuals, and individuals with disabilities should be involved as mentors and serve as role models.

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 (e.g., American Samoa, Guam, Federated State of Micronesia). Individuals in the United States on temporary or student visas are not eligible.

A candidate for SERCA may not concurrently apply for any other NIH award that duplicates the provisions of this award nor have another submitted application pending. SERCA recipients are strongly encouraged to apply for independent research grant support, either federal or private, during the tenure of their K award. SERCA recipients in the final two years of their award will be permitted, provided they remain in mentored status, to reduce their SERCA effort if they have successfully competed for research awards from NIH or any other Federal agency. The effort dedicated to SERCA may never be reduced to less than 50% of full-time professional effort at the grantee organization.

Prospective applicants are encouraged to discuss their potential eligibility for the SERCA program with ORIP staff before preparing an application.

VI. Application Procedures

Latest program announcements: See [ORIP Funding Opportunities](#).

Program Announcement (PA) Number [PA-19-126](#) : Mentored Research Scientist Development Award (Parent K01).

Application and Electronic Submission Information: [How to Apply-Application Guide](#).

For Page Limit Information see [Table of Page Limits](#).

SERCA Application Submission Dates: [Standard Due Dates for \(K series\) Competing Applications](#).

Questions concerning other aspects of SERCA program administration, as well as inquiries related to an applicant's eligibility and appropriate areas of research emphasis, should be directed to the Health Science Administrator who serves as the [contact point for SERCA K01 applications](#).

VII. Review Procedures and Criteria

The application will be reviewed for scientific merit and for programmatic and policy considerations. Applications will be considered for funding on the basis of their overall merits, relevance of the proposal to the research objective of DCM, ORIP, and the availability of funds.

Criteria for Review

In the initial review of the application for scientific merit, particular attention will be given to the candidate's prior training and experience, career potential, research career development plans, proposed research environment, reference reports, institutional commitment, and other relevant information. The applicant must clearly demonstrate that the award will enhance the candidate's development as an independent investigator.

- Applicant: The applicant's prior training, research experience, potential for a biomedical research career, experience and commitment to comparative medicine and related areas of research will be considered. Emphasis will be placed on potential, productivity, and commitment; obtaining a Ph.D. degree (either before or during the award) will be of less importance. Evidence of prior participation in a research project (e.g., publications, abstracts or presentations) will be important. To be most competitive, candidates should have clinical training and/or experience in laboratory animal science/comparative medicine.
- The Career Development Plan (CDP): It is important to recognize that the K01 is

different from an NIH R01 research grant. The CDP is an extremely important part of your application. The K01 allows five years of protected time to develop your research career. Use your CDP to explain to the study section, in an organized and detailed fashion, how you plan to use this time, what you expect to learn, and how this will advance your career goals.

- The Research Plan: The major criterion used in evaluating the research plan and the associated training will be its likelihood to develop an independent, creative investigator. Proposals based primarily on methodology or on the acquisition of descriptive information will not be received well. The proposal need not be applicable directly to laboratory animal problems but should be focused around a central biomedical concept or hypothesis that will provide opportunities for research training in the initial years and sufficient preliminary data for a meritorious research application for the final two years of the award. While it is expected that exposure to methodologies in different laboratories may be useful, such training should be limited to that which is necessary for successful development of the applicant's independent research proposal.
- The Mentor(s): The mentor should be a productive senior investigator with appropriate expertise in the proposed area of research, have prior experience in providing postdoctoral research training, a history of independent research funding, and have a strong commitment to the training and guidance of the applicant. **Ideally, in order to provide the applicant with a maximum breadth of exposure, the mentor should be a different individual than the person who previously provided doctoral or laboratory animal science training. This requirement may be waived if the research focus is so narrow that another suitable mentor cannot be identified. If research leading to a Ph.D. degree is part of the initial years of the award, the mentor should be changed after the degree has been obtained. If the same mentor is proposed, applicants should be aware that reviewers would expect a strong justification for that decision.**
- Research Environment: The research environment should be one that will not only provide the applicant with the necessary training, but will also provide exposure to a broad spectrum of research interests through seminars, symposia, journal clubs, etc.

VIII. Program Administration

The Division of Comparative Medicine, Office of Research Infrastructure Programs administers SERCA in accordance with the Public Health Service Grants Policy Statement for research grants and other relevant policies.

As part of the annual application for continuation support, the grantee institution must submit a statement that summarizes the awardee's activities relevant to the award; a

detailed description of the awardee's progress in the program; and the extent and nature of his/her other activities such as administration, service in an advisory capacity to public or private nonprofit organizations, outside lectures, and professional practice and/or consultation. The final progress report must include a list of all publications and a list of all grant applications submitted during the years of funding. For additional information please see [Research Performance Progress Report \(RPPR\)](#) and [Non-Competing Continuation Progress Report \(PHS 2590\)](#).

Second- and third-year SERCA awardees will receive an invitation to participate in a career development workshop organized for new investigators and conducted at the annual National Veterinary Scholars Program. This workshop, sponsored by Boehringer Ingelheim, is designed to assist new investigators as they transition to independence, search for a permanent position, negotiate a startup package, etc. SERCA grantees are encouraged to attend this workshop once during the second or third year of their award and may use their grant funds to defray the costs related to participating in this event. For information about current and past programs visit <http://www.merialscholars.com/national-symposium>

All SERCA grantees are required to prepare an NIH-type research grant (R01, R03, R21, etc.) and have it evaluated by a committee appointed by their mentor during the 4th year of SERCA funding. The mentor must prepare an evaluation letter summarizing the committee's review of the grantee's research proposal and submit it the ORIP Program official responsible for the K01 SERCA awards not later than two months prior to the end of the 4th year. Failure to submit this letter may delay the release of funds for the final year of the award.

In carrying out its stewardship of human resource-related programs, ORIP may request information needed to assess the effectiveness of the SERCA program. Accordingly, SERCA recipients are hereby notified that they may be contacted after the completion of the award period for updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities and other information that may be helpful in evaluating the program outcomes.

Questions concerning other aspects of SERCA program administration, as well as inquiries related to an applicant's eligibility and appropriate areas of research emphasis, should be directed to the Health Science Administrator who serves as the [contact point for SERCA K01 applications](#).

Questions concerning fiscal matters should be directed to:
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