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12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited.			12b. DISTRIBUTION CODE
13. ABSTRACT (Maximum 200 Words) The Institute for Laboratory Animal Research (ILAR) is a component of the Division on Earth and Life Studies (DELS) at The National Academies. The Department of the Army {PRIVATE }has provided partial support for ILAR for many years to enable to ILAR fulfill its mission. ILAR was founded in 1952 and is a national and international leader in developing guidelines for animal care, breeding, and use; descriptions of animal models for human diseases and physiological processes; and reports on specific issues of humane care and use of laboratory animals. ILAR's mission is to help improve the availability, quality, care, and humane and scientifically valid use of laboratory animals and to disseminate its reports and other relevant information to the biomedical and laboratory animal science communities. ILAR accomplishes its goals through its core program, which is carried out by the staff, and its special-project program, which is carried out by NRC-appointed committees with staff assistance. A 15-member Council composed of experts in laboratory animal medicine, zoology, genetics, medicine, ethics, and related biomedical sciences directs both programs. The Army funds partially support general office operations, the Animal Models and Genetic Stocks Information Program, publication of <i>ILAR Journal</i> , and work of the Council.			
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INTRODUCTION

For many years the Army has provided partial core support to the Institute for Laboratory Animal Research (ILAR), a component of the National Research Council (NRC). Formerly contained within the Commission on Life Sciences, ILAR is now part of a larger division of the NRC, called the Division on Earth and Life Studies. The NRC is the operating arm of the National Academy of Sciences, a private, nonprofit organization that was created in 1863 by congressional charter to serve as an official advisor to the federal government on questions of science and technology.

Founded in 1952, ILAR is both a national and international leader in developing guidelines for animal care, breeding, and use; descriptions of animal models for human diseases and physiological processes; and reports on specific issues of scientific and humane use of laboratory animals. ILAR disseminates this information to the biomedical and laboratory animal science communities by wide distribution of its reports as well as through presentations and exhibits at national meetings. These guidelines from the National Academy of Sciences serve as important indications to members of the U.S. Congress and other government officials, the press, and the public of the high quality of care provided to laboratory animals. ILAR's mission is to help improve the availability, quality, care, and humane and scientifically valid use of laboratory animals.

Recognized experts in fields appropriate to the required tasks carry out ILAR's studies, like all those of the NRC. These experts serve on a volunteer basis, without compensation. As a part of the NRC, ILAR has access to this country's most knowledgeable and distinguished laboratory animal and biomedical scientists, who provide objective counsel on laboratory animal issues. Many of the experts used by ILAR are also members of the National Academy of Sciences or the Institute of Medicine. In some cases, ILAR utilizes scientists from other countries.

Independent NRC-appointed experts in the subject area extensively review reports of NRC studies before they are released. They are prepared in sufficient quantity to ensure distribution to the sponsor, experts, and other relevant parties in accordance with Academy policy. Reports are usually made available to the public without restriction.

ILAR'S GOALS

Since its founding, ILAR has provided guidance and information on laboratory animal matters to the federal government, the biomedical and laboratory animal science communities, and the public. In keeping with its mission, ILAR continually seeks to strengthen and refine its existing programs and to initiate new programs that will assist government officials; scientists who use animals in research, testing, and education; and the institutional animal care and use committees that monitor animal use. ILAR's goals are as follows:

- to provide a forum within the National Academy of Sciences for the Department of Defense to discuss issues and develop guidance for laboratory animal-related matters;
- to continue to serve on behalf of biomedical science and education as an authoritative voice within the U.S., and on behalf of the U.S. scientists internationally;
- to promote humane and appropriate care and use of laboratory animals;
- to provide scientific guidance on laboratory animal-related issues to agencies of the federal government and others on request;
- to provide information on laboratory animal matters to government officials, laboratory animal and other biomedical scientists, institutional animal care and use committees, and the public;
- to promote the use of standardized nomenclature for accurately defining and identifying genetic stocks of animals;
- to assist developing countries in attaining quality laboratory animal science programs through dissemination of information including the translation of ILAR reports;
- to promote cost-effective ways to preserve valuable animal models;
- to sponsor workshops in areas of importance to the laboratory animal community; and
- to increase access to information about appropriate biological models and methods through ILAR's home page, databases, publications, and resources of the ILAR Associates program, including the quarterly *ILAR Journal*.

Accomplishing the Goals

ILAR accomplishes its goals through its core program, which is carried out by the staff, and its special-project program. The number of studies and size of the staff are dependent on the number of special projects and available funding. Both programs are directed by a 15-member ILAR Council composed of experts in laboratory animal medicine, virology, zoology, genetics, medicine, ethics, and related biomedical sciences.

THE CORE PROGRAM

ILAR Council

The ILAR Council (see addenda for roster) serves four principal functions: 1) to provide program direction and strategic planning; 2) to oversee the information and outreach programs, which consist of the Animal Models and Genetic Stocks Information Program, the ILAR web site, and the quarterly *ILAR Journal*; 3) to oversee special projects; and 4) to direct ILAR's international programs and its participation as the U.S. national member in the International Council of Laboratory Animal Sciences (ICLAS). The international program is discussed in the Special Projects section below. Periodically, the Council meets with other scientists and funding agency administrators to discuss areas in which ILAR might prove useful. It then uses these discussions in strategic planning. The Council occasionally employs core funds to undertake specific, NRC-approved projects itself.

Staff

ILAR is staffed by a director, a managing editor of the *ILAR Journal*, a project assistant who maintains the web page and various databases, an administrative assistant and secretary to the director, and a project director. Under the special projects program, staff works closely with experts to engage in studies, develops working papers, assists in the production of cohesive reports, and conducts literature reviews.

Animal Models and Genetic Stocks Information Program

Some of the most critical information needed by Department of Defense scientists is often the most difficult to obtain, including information on the most appropriate model for the proposed research and, if the model is an animal, to find sources of the model and information on appropriate care. As author of the *Guide for the Care and Use of Laboratory Animals*, ILAR is in a position to assist biomedical researchers, veterinarians, and Institutional Animal Care and Use Committees (IACUCs) in interpreting guidelines for the humane care and use of animals, and fulfilling requirements of the Animal Welfare Act and PHS policy regarding reduction of pain and distress and identification of alternative methodologies. For more than 40 years, ILAR has conducted a program to provide such information. That program, called the Animal Models and Genetic Stocks Information Program, offers assistance in locating sources of animals, selecting appropriate animal models, using standardized nomenclature, and understanding the importance of the use of animals in biomedical and behavioral research and testing. It includes two databases: one (called Animals for Research, AFR) contains commercially available and investigator-held colonies of animals for research; the other is a registry of codes used with standardized nomenclature of rodents and rabbits to identify institutions that maintain breeding colonies. The databases have been incorporated into ILAR's web pages and are available to investigators worldwide. While the AFR database has been a useful resource, it has become impractical to try to maintain an exhaustive list of animal models. This is especially true in the area of genetically modified animals. Given ILAR's limited resources, the Animal Resources Information Subcommittee of ILAR Council decided that it would be more efficient to develop a web-based search engine that would enable investigators to search through all available sources of animal strains and models. To that end, we have implemented a search engine with the capability of searching all of the commercial and private animal breeders, lab animal repositories, and animal resource databases that are linked to ILAR's site, as well as the ILAR website. Current activities are focused on expanding this list of linked websites and partnering with these organizations to provide high level search capabilities.

More recently, ILAR has placed more emphasis on its web site (<http://www.national-academies.org/ilar>) as a source of information on the care and use of laboratory animals. We have revamped the entire web site to make it more user-friendly, added components for different constituencies, and developed a comprehensive search engine to facilitate user interactions.

Having launched the new web site, we have researched various software applications to monitor traffic to the site and are planning to utilize the web statistical package Web Trends. Data from the old web site using this program showed that there were over 56,000 visits to the

ILAR site in 2002, with >13,000 going to the *ILAR Journal* on line. We are anticipating that with the new site, traffic will increase considerably.

Other aspects of ILAR's information program are focused on the ability to interact with scientists and veterinarians at national meetings. ILAR exhibits and/or lectures at these national meetings to enhance our outreach programs and increase the visibility of ILAR's programs and publications. In the last five years of this award, representatives from ILAR have routinely traveled to the national meetings of the Society for Neuroscience, Experimental Biology, the American Association for Laboratory Animal Science, the Society of Toxicology, the Scientists Center for Animal Welfare, and Public Responsibility in Medicine and Research.

ILAR Journal

Work Statement

ILAR Journal, a quarterly, peer-reviewed publication, provides thoughtful and timely information for all those who use, care for, and oversee the use of laboratory animals. The readership of *ILAR Journal* includes more than 3,500 investigators in biomedical and related research, institutional officials, veterinarians, and members of IACUCs. The *ILAR Journal* Editorial Board (a subcommittee of ILAR Council) plans each issue around a chosen theme and carefully solicits authors who can best present a balanced view of the topic. Each article undergoes a rigorous peer review.

The goal of *ILAR Journal* is to provide a unique repository of timely, high quality information on new developments in biomedical research that involve the use of laboratory animals. These developments may include (but are not limited to) information on animal models of human disease, humane care and use of laboratory animals, animal care and use committee issues, ethical issues, and changes in federal and international regulations affecting animal research. The broad target audience includes investigative scientists, veterinarians, animal care staff, government regulators, institutional administrators, students – in fact, everyone involved with the care and use of animals in biomedical research.

The specific aims of the *ILAR Journal* are:

- To be the premier U.S. periodical resource for investigators, institutional animal care and use committee (IACUC) members, and veterinarians involved in writing and/or reviewing protocols for laboratory animal research that must comply with national, and sometimes international, regulations and policies.
- To be one of the primary international resources for scientists on the numerous spontaneous and experimentally produced animal models of human diseases.
- To be a major resource for veterinarians on diseases of laboratory animals, characterization and care of animal models, especially newly emerging genetically modified animals.
- To increase the quality of protocol review by IACUCs by providing a peer-reviewed resource on issues facing the committee. The publication of information written for scientists on animal models, animal diseases, and federal rules and regulations allows cross-fertilization of ideas among bench scientists, veterinarians, animal facility personnel and IACUC members.

- To disseminate this information by providing a publication at minimal cost to all members of the international biomedical community.
- To provide an easily accessible mechanism for members of the scientific community to provide input to the National Research Council on issues that could directly affect the use of animals in biomedical research.

Issues of *ILAR Journal* published in the five years of this grant are listed in the appendix, which lists all of *ILAR's* publications.

Role of ILAR staff and Editorial Board in the overall management of ILAR Journal

The *ILAR Journal* is produced by a full-time Managing Editor, who is a member of *ILAR* staff, with oversight by the *ILAR Journal* Editorial Board. The Editorial Board is made up of 5 Council members, one of whom is the Editor-in-Chief. This group meets three times per year in conjunction with the full Council meeting to plan the structure and authorship of future issues.

Members of the Editorial Board are chosen to represent different segments of the readership and currently include a veterinary pathologist, a bioethicist, a primatologist, a mouse geneticist and a nonhuman primate neuroscientist. This Board approves topics for each issue, provides the names of potential contributors and reviewers, and serves as the ultimate editorial authority. Current members of the Editorial Board are:

- Janet R. Gonder, DVM, Ph.D., Editor-in-Chief, is an independent veterinary consultant who was formerly manager of the laboratory animal department at Baxter Healthcare Corporation. Her expertise is in laboratory animal medicine and occupational health and safety.
- Stephen W. Barthold, DVM, Ph.D. is Professor and Director of the Center of Comparative Medicine at the University of California, Davis and is a member of the Institute of Medicine. His expertise is in veterinary pathology.
- Randall J. Nelson, Ph.D. is a Professor in the Department of Anatomy and Neurobiology, College of Medicine, The University of Tennessee. He is a neuroscientist and an expert in the use of nonhuman primates. His studies concern the role of the somatosensory cortex in receiving signals, integrating the various inputs, and controlling movement.
- Lilly-Marlene Russow, Ph.D. is a Professor in the Department of Philosophy, with a courtesy appointment in the Department of Veterinary Pathobiology at Purdue University. She is a bioethicist who has been extensively involved in ethical issues related to the use of animals in research and well as biotechnology and environment.
- Thomas L. Wolfle, D.V.M., Ph.D, is a past Director of *ILAR*. He is an expert in animal behavior, especially related to the behavior of nonhuman primates. He has had considerable federal government experience in the Air Force and at NIH before joining *ILAR* in 1988.

Other members of the Editorial Board over the last five years include:

- Margaret Landi, VMD, Director of Laboratory Animal Science, GlaxoSmithKline, King of Prussia, PA (Editor-in-Chief, 1998-2000).

- Gerald F. Gebhart, PhD, Chairman of Pharmacology, University of Iowa College of Medicine (Editor-in-Chief, 2000-2002).
- Charles McCarthy, PhD, Professor, Kennedy Institute of Ethics, Georgetown University.
- Gail E. Herman, MD, PhD, Department of Pediatrics, Ohio State University Medical School

ILAR Associates Program

In an effort to increase ILAR's information resources and to better leverage funding from core and project sponsors to support other activities, ILAR initiated an Associates program in 1997. Individuals and institutions that subscribe to the Associates program help defray the cost of publishing the *Journal*. ILAR Associates receive the *ILAR Journal* (number of copies varies with level of Associate membership) and a 20% discount on all ILAR and other National Academy Press publications. ILAR Associates represent the best of US biomedical and laboratory animal scientists and serve as an important audience to receive, critique, and provide guidance to ILAR's programs. ILAR's core sponsors are valuable members of the Associates program.

Future Issues of ILAR Journal

The Editorial Board must identify topics for future issues of ILAR Journal well in advance. The following issues (with anticipated publication date) are in some stage of production:

- Volume 44 (4) *Physiological Research Outside the Laboratory* (July 2003)
- Volume 45 (1) *Comparing Nontraditional Animal Models* (December 2003)
- Volume 45 (2) *Animal Models in the Study of Women's Health* (March 2004)
- Volume 45 (3) *Animal Models of Diabetes* (June 2004)

Other topics of high priority for future issues include animal models for biodefense and emerging diseases, care and welfare of animals with implants, environmental estrogens/endocrine disrupting agents, strategies for development and validation of animal models, and animal models of obesity.

ICLAS and International Activities

ILAR has had a long history of interest in international laboratory animal science. Historically, this interest has sought to assist young investigators in developing countries through dissemination of reports (some translated into foreign languages to increase their usefulness) and participation in international meetings that support young investigators. In 1988, ILAR became the U.S. national member of the International Council for Laboratory Animal Science (ICLAS), with support from member agencies of the Interagency Research Animal Committee (IRAC). This membership affords a conduit for U.S. investigators to develop and conduct an active international program in laboratory animal science. One goal of the U.S. membership in ICLAS was to streamline ICLAS management and programs to better represent U.S. scientists in the international community. Following are the major international efforts of ILAR.

Report Translations

ILAR's most longstanding international effort has been to have our seminal publication the *Guide for the Care and Use of Laboratory Animals* (the *Guide*) translated into as many languages as possible. The *Guide* is used as the standard for laboratory animal care by the Public Health Service in the U.S., and by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International in their certification of animal facilities throughout the world. The *Guide* has been translated into French, Spanish, Portuguese, Thai, Japanese, Korean, Arabic, Russian, and two versions of Chinese. An Indonesian version has recently been submitted for review.

Another of ILAR's reports, *Occupational Health and Safety in the Care and Use of Research Animals*, was recently published in Japanese and is now being translated into Korean. Translation of ILAR reports is carefully monitored and each translation is reviewed for its faithfulness to the English version before permission is granted for its publication.

International Council for Laboratory Animal Science (ICLAS)

ILAR supports the activities of ICLAS through its participation as the US representative. ICLAS is an international scientific organization dedicated to advancing human and animal health by promoting the ethical care and use of laboratory animals in research worldwide. ICLAS was established in 1956 under the auspices of UNESCO, and interacts in an official capacity with the World Health Organization (WHO), the International Council of Scientific Unions (ICSU), the Council for International Organizations of Medical Sciences (CIOMS), and the World Veterinary Association (WVA). ICLAS sponsors meetings throughout the world, but focuses particularly on third world countries, where animal care conditions are in need of improvement. Through ICLAS, ILAR provides guidance in the field of laboratory animal science to scientists in developing countries. Dr. Steven Pakes, former chair of ILAR Council, is currently the President of ICLAS and makes yearly presentations on the progress of ICLAS activities to the Council.

International Workshops

As part of ILAR core activities, ILAR has sponsored meetings first with scientists from the U.S. and Japan, and more recently on a more comprehensive international basis. The two most recent reports from U.S. – Japan meetings are titled *Microbial and Phenotypic Definition of Rats and Mice* (1999) and *Microbial Status and Genetic Evaluation of Mice and Rats* (2000). In April 2002, ILAR sponsored an international meeting entitled: *International Perspectives – The Future of Nonhuman Primate Resources*. This conference brought together participants from six continents to address international strategies and practices for providing nonhuman primates needed for biomedical research while ensuring appropriate conservation practices. The proceedings from this meeting are in the process of publication. By promoting the harmonization of methods for the care and use of animals, ILAR hopes to improve the quality of information exchange among countries and ultimately reduce the number of animals used. ILAR also cosponsored two U.S./Brazil meetings (in 1999 and 2001) on The Future of Animal Research. The purpose of these meetings was bring together scientists and veterinarians to develop stronger ties between the two countries, to exchange perspectives about laboratory animal science, to explore future directions for research in this field and to create opportunities for exchanges of

scientists and students. ILAR is planning another international meeting for 2003 that will address changes in laboratory animal regulations throughout the world, focusing on the need to base regulations on sound science.

Observer Status at the Council of Europe

In 1999, ILAR was granted observer status to the Council of Europe in the preparation of guidelines for the protection of live animals used for experimental and other scientific purposes. The goal of the Council of Europe is to harmonize guidelines throughout Europe and it is desirable to have these guidelines harmonized with regulations and guidelines in the U.S. Since the *Guide* provides the basis for many of the current U.S. guidelines, it is useful and efficient for ILAR to be an observer to this process and have the opportunity to comment.

Foreign Participation in ILAR Activities

In the last few years, ILAR has purposely increased foreign participation in its Council and ad hoc committees. Currently, two Council members are from the European Union, Dr. Michael Festing from the U.K. and Dr. Coenraad Hendrikson from The Netherlands. Both of these individuals are intimately involved with the current and developing policies in Europe that will affect the U.S. They provide valuable insights and guidance for ILAR's international activities. ILAR also has international representation on its Committee on Guidelines for the Care and Use of Animals in Neuroscience and Behavioral Research in the person of Dr. Anne-Dominique Degryse, who is the head of Laboratory Animal Resources at the Centre de Recherche Pierre Fabre in Paris. Dr. Degryse also serves on the advisory council for the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC), the independent, international accrediting organization for laboratory animal facilities.

Future Activities

In all likelihood, ILAR will become more involved in international activities in the future. The need for greater international involvement arises from a common desire to harmonize guidelines and standards for laboratory animal care across the world with the goals of improving animal welfare, conserving animal resources, and improving scientific interchange through detailed characterization of the animals used in research.

SPECIAL PROJECTS

Projects are developed in response to specific requests from government agencies and private organizations or on the initiative of staff or of ILAR Council. Although contracts and grants from federal agencies, foundations, and private organizations support these projects, they are never completely separate from the core program because the Council is involved during each step of the process. This sponsorship provided by this grant is recognized in each published ILAR report. The

Council reviews each project extensively before it is undertaken, examines the qualifications of experts, oversees the progress of the project to ensure that it is accomplished in a timely manner, and reviews and signs off on each report as a part of the NRC review process. In addition, ILAR reports are frequently published as special inserts of the core-supported *ILAR Journal*. The following are examples of recently completed projects, or projects that are under way or which will begin when funding has been received.

PROJECTS IN PROGRESS

Increasing Veterinary Involvement in Biomedical Research

A study will be done in which an appointed committee will address issues surrounding recruitment and training of veterinarians in two areas of critical need: comparative medicine/pathology and clinical management of laboratory animal facilities.

PROSPECTIVE ACTIVITIES (APPROVED PROJECTS IN NEED OF FUNDING)

Guidelines for the Humane Transportation of Laboratory Animals

A committee will be appointed to address problems associated with transportation of laboratory animals. Among the issues to be considered are: animal welfare, availability of services, regulatory oversight and permitting problems, import/export requirements, transport of biological specimens and potential biosecurity concerns. The resulting report will provide recommendations to improve transportation practices that will benefit the research community as well as the animals.

Update of the report *Recognition and Alleviation of Pain and Distress in Laboratory Animals*

A study committee will update the ILAR report *Recognition and Alleviation of Pain and Distress in Laboratory Animals*. The committee will reevaluate current best use practices relating to pain and distress in laboratory animals in light of the current literature and knowledge base. The issues to be reevaluated include the current, working definition of distress; reporting classifications for pain and distress; anesthesia and euthanasia. The committee will also investigate, debate, and establish best use practices for management and reporting classifications of pain and distress in genetically modified animals, unrelieved pain as a scientifically justified consequence, and use of food and water restriction.

Laboratory Animal Management: Rodents

A study committee will update the current edition of *Laboratory Animal Management: Rodents*. The committee will identify current best practices in laboratory rodent care and use and incorporate these changes into the revision. This effort will adopt a focus on performance standard guidelines as reflected in the current edition of the *Guide for the Care and Use of Laboratory Animals*. Additional topics for which best practices must be identified or established

include: care and use of genetically modified rodents; environmental enrichment of laboratory rodents; exposure management of laboratory rodent allergens.

Laboratory Animal Housing

The 1978 ILAR report titled *Laboratory Animal Housing* will be updated using modern technical criteria for animal research facility design including performance criteria, description of the animal environment, requirements for hazardous agent containment, and cost-effectiveness of various designs for new construction as well as renovation.

Current ILAR Council Members (with areas of expertise) and Staff

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ILAR PUBLICATIONS 1998-2003

ILAR Journal Issues

- Volume 39 (1) *Animal Well-being: Immune Function, Behavior, Morphology, and Psychoneuroimmunology* (1998)
Volume 39 (2-3) *Comparative Gene Mapping* (1998)
Volume 39 (4) *Opportunistic Infections in Laboratory Rats and Mice* (1998)
Volume 40 (1) *Bioethics of Laboratory Animal Research* (1999)
Volume 40 (2) *Animal Models of Human Vision* (1999)
Volume 40 (3) *Animal Models of Pain* (1999)
Volume 40 (4) *Animal Models of Inflammation* (1999)
Volume 41 (1) *The Squirrel Monkey in Biomedical and Behavioral Research* (2000)
Volume 41 (2) *Humane Endpoints for Animals Used in Biomedical Research and Testing* (2000)
Volume 41 (3) *Mouse Behavioral Models in Biomedical Research* (2000)
Volume 41 (4) *Cryobiology of Embryos, Germ Cells, and Ovaries* (2000)
Volume 42 (1) *Laboratory Animal Allergy* (2001)
Volume 42 (2) *Animal Models of Hepatitis* (2001)
Volume 42 (3) *Impact of Noninvasive Technology on Animal Research* (2001)
Volume 42 (4) *Fish Models in Biomedical Research* (2001)
Volume 43 (1) *Implications of Human-Animal Interactions and Bonds in the Laboratory* (2002)
Volume 43 (2) *Mouse Models of Human Disease* (2002)
Volume 43 (3) *Advanced Physiological Monitoring in Animals* (2002)
Volume 43 (Suppl) *Proceedings of the June 2001 ICLAS/CCAC International Symposium on Regulatory Testing and Animal Welfare* (2002)
Volume 43 (4) *Principles of Experimental Design in Biomedical Research* (2002)
Volume 44 (1) *Occupational Health and Safety in Biomedical Research* (2003)
Volume 44 (2) *Animal Models of Stroke and Rehabilitation* (2003)
Volume 44 (3) *Behavioral Research Outside the Laboratory* (2003)

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Response to USDA/APHIS/Animal Care Draft Policy on Environmental Enhancement for Nonhuman Primates (1999)
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Definition of Pain and Distress and Reporting Requirements for Laboratory Animals. Proceedings of the Workshop Held June 22, 2000 (2000)
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Kathleen Beil, Administrative Assistant, 1998-present.
Susan Vaupel, Managing Editor of ILAR Journal, 1998-present.
Marsha Williams, Project Assistant, 1998-2001.
Marsha Barrett, Project Assistant, 2001-present.
Jennifer Obernier, Program Officer, 2001-present.