
**REPORT TO THE SENATE ARMED SERVICES
COMMITTEE AND THE HOUSE OF REPRESENTATIVES
NATIONAL SECURITY COMMITTEE**

on

**Department of Defense
Animal Care and Use Programs 1997**

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LIST OF ACRONYMS

AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care International
AALAS	American Association of Laboratory Animal Science
ACLAM	American College of Laboratory Animal Medicine
APHIS	Animal and Plant Health Inspection Service
ASBREM	Armed Services Biomedical Research Evaluation and Management
AWA	Animal Welfare Act
AWIC	Animal Welfare Information Center
BRD	Biomedical Research Database
CNS	Central Nervous System
CRISP	Computer Retrieval Information on Scientific Projects
DDR&E	Director, Defense Research and Engineering
DoD	Department of Defense
DTIC	Defense Technical Information Center
FDA	Food and Drug Administration
FEDRIP	Federal Research in Progress
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IG	Inspector General
ILAR	Institute of Laboratory Animal Research
IRAG	Interagency Regulatory Alternatives Group
JDL	Joint Directors of Laboratories
JTCG	Joint Technology Coordinating Groups
LAM	Laboratory Animal Medicine
MATRIS	Manpower and Training Research Information Services
NIH	National Institutes of Health
NMR	Nuclear Magnetic Resonance
NOS	Nitric Oxide Synthase
NRC	National Research Council
OPRR	Office for the Protection from Research Risks
OSD	Office of the Secretary of Defense
PCR	Polymerase Chain Reaction
PHS	Public Health Service
POC	Point of Contact (Primary Contact)
RDT&E	Research, Development, Test, and Evaluation
S&T	Science and Technology
STO	Science and Technology Objective
TAPSTEM	Training and Personnel Systems Science and Technology Evaluation and Management
USAMRMC	United States Army Medical Research and Materiel Command
USDA	United States Department of Agriculture
VEE	Venezuelan Equine Encephalitis
WRAIR	Walter Reed Army Institute of Research

SECTION I

INTRODUCTION/OVERVIEW

This is the Fiscal Year (FY) 1997 Report to Congress on Department of Defense Animal Care and Use Programs. In addition to a general overview, this report provides a detailed accounting of Department of Defense (DoD) animal use; to include its publicly accessible database, animal care and use oversight procedures, Institutional Animal Care and Use Committees (IACUCs), alternatives to animal use programs, Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) status, and animal use.

The report covers animal research conducted by the DoD including education, training, and testing both in DoD laboratories and by extramural projects funded by the Department for FY97. This report does not include information on animals used by the DoD solely for the purpose of food preparation for human or animal consumption, ceremonial activities, recreation, or the training, care, and use of military working animals.

I.1 REQUIREMENTS FOR USE OF ANIMALS IN THE DoD

Department of Defense use of animals in research, development, education, and training is critical to sustained technological superiority in military operations in defense of our national interests. The DoD's biomedical research, development, test, and evaluation (RDT&E) and training programs that are dependent on animal use ultimately translate into improved military readiness as well as reduction in morbidity and mortality associated with military operations. These programs contribute directly to ensuring that service men and women maximize their capabilities to survive the numerous and various hazards they face around the world. Additionally, many examples of the humanitarian benefits of the DoD investment in animal research that are shared on an international basis improve the quality of life of both humans and animals. Several prime examples of the humanitarian benefits of DoD research efforts

are: the Junin vaccine that has provided critical protection for more than 120,000 individuals in endemic areas of Argentina against the ravages of Argentinian hemorrhagic fever; DoD-developed Venezuelan equine encephalitis (VEE), eastern equine encephalitis, and western equine encephalitis vaccines that have been used to limit and control epidemics of VEE in Venezuela and Colombia in 1995, and to protect occupational workers in vaccine production plants around the world. In addition to being important public health tools, the equine encephalitides vaccines are obviously critical adjuncts to animal health programs around the world.

Biomedical research has benefited greatly from animal use alternatives such as non-living systems, cell and tissue culture, and computer technology. However, complex human organ systems interactions, in addition to environmental factors and confounding variables, necessitate the continued judicious use of animal models in DoD programs. Although many innovative animal use alternatives have been developed and are in use by Department scientists, situations remain in which there are no acceptable non-animal alternatives available. As new advances, technologies and breakthroughs in animal use alternatives occur, the DoD will embrace them whenever possible. The chapter on alternatives in this report gives a full accounting of the aggressive programs and numerous animal use alternatives implemented in DoD laboratories.

Disease remains a major cause of death and disability in military operations and conflicts. During Operations Desert Storm and Restore Hope, outbreaks of respiratory diseases, diarrheal diseases such as shigellosis, and parasitic diseases such as leishmaniasis and malaria, threatened the health and well-being of our troops. Indeed, the DoD is still assessing and addressing concerns over the long-term effects of various environmental, physical, and medical factors associated with the Persian Gulf Conflict. It is obvious that the health

and well-being of military personnel extend far beyond the immediate scope of the battlefield. We have an irrefutable moral obligation to our soldiers, sailors, airmen, and marines to provide the maximum protection and care possible. DoD researchers are committed to accomplishing this goal, and in many cases, animal-based research is the critical underpinning for the fulfillment of that obligation.

The DoD must develop the materiel and technological means to best protect and sustain the health and well-being of service men and women against all threats, and provide the best medical treatment possible to those who become casualties. This responsibility underlies the need for the DoD to conduct research, and to train and educate military health-care providers in the most effective medical management of battlefield casualties. Battlefield health care must very often be provided in an austere, harsh and hostile environment, hours away from a definitive care hospital, unlike medical counterparts found in civilian emergency medicine and trauma management. A domestic, low velocity projectile gunshot patient in a modern civilian shock and trauma center will be supported and resuscitated by a full complement of medical staff with a plentiful supply of oxygen, fluids, medications, surgical intervention and nursing. The combat casualty may be supported by only a single aidman and the medical supplies, experience, and expertise he can carry.

One of the most critical areas requiring DoD animal use is the compelling need to develop vaccines, drugs, and therapies to protect, sustain and treat service men and women during military operations. These research programs are strongly focused on a myriad of militarily relevant diseases and threats, many of which can result in potentially fatal diseases or conditions that have no known treatments, therapies, or cures. Consequently, there are numerous instances, including medical chemical and biological warfare defense, where animal-based studies are particularly critical. Ethical concerns, as well as regulatory requirements of the Food and Drug Administration (FDA), necessitate that candidate vaccines and drugs be safe and efficacious in laboratory animal models prior to initiation of human use protocols whenever possible. The rationale for this is to prevent the fielding and use of ineffective or dangerous treatments. Indeed, during the final stages of

vaccine and drug development, large-scale safety and efficacy testing is usually conducted using human volunteers. However, in the search for understanding and developing protection against many highly lethal agents, human use protocols are simply not possible. Consequently, carefully regulated animal use is absolutely vital to the success of Department biomedical research programs. The ultimate goal is to maximize the survivability of our troops in all situations.

I.2 DoD POLICY GOVERNING ANIMAL RESEARCH

The Department of Defense is committed to full ethical and regulatory compliance for its animal-based biomedical research programs. DoD has been proactive in increasing the fixed infrastructure and span of control necessary to ensure lawful and efficient execution of programs and maximize oversight of diverse and varied missions. The Department has aggressively implemented focused programs and working documents that optimize standardization of animal care and use at the user level. This enhanced standardization and oversight have improved a historically good system, and made it outstanding.

In 1995, the DoD revised and implemented the directive dealing specifically with animal care and use (DoD Directive 3216.1, "The Use of Animals in DoD Programs," 1995) (Appendix A). This directive strengthens and clarifies requirements for nonaffiliated membership on IACUCs and directs all DoD animal use facilities that maintain animals for research, testing and training to apply for AAALAC accreditation.

The DoD also implemented a Policy Memorandum entitled "Department of Defense (DoD) Policy for Compliance with Federal Regulations and DoD Directives for the Care and Use of Laboratory Animals in DoD-Sponsored Programs" (Appendix B). This 1995 policy letter specifies training requirements for nonaffiliated DoD IACUC members and implements a standard format for animal use protocols (Appendix C), a standard checklist for IACUC inspections (Appendix D), and a standard reporting requirement for all animal use research to support a publicly accessible database (Section II).

All animal research must conform to requirements of the 1966 Animal Welfare Act (P.L. 89-544) as amended in 1970 (P.L. 91-579), 1976 (P.L. 94-279) and 1985 (P.L. 99-198), as well as the National Research Council *Guide for the Care and Use of Laboratory Animals*, (7th rev. edition, 1996), U.S. Government Principles for Animal Use (1985) (Appendix E), and the requirements of the applicable regulations of the United States Department of Agriculture (USDA).

Although the Animal Welfare Act currently exempts mice and rats in the genera *Mus* and *Rattus*, the DoD has long afforded them, along with all other vertebrates, the same consideration given non-exempt species under the Animal Welfare Act. At the same time, DoD biomedical researchers have aggressively developed novel procedures to replace, reduce, and refine the use of animals during experimentation.

I.3 BENEFITS OF ANIMAL RESEARCH

DoD's laboratories and extramural contractors provide the capability to solve the medical and non-medical problems of the future through the efforts of internationally renowned medical and scientific experts working in state-of-the-art facilities and in the field. The Department conducts or funds research, development, training and evaluation to sustain the operational capabilities of today's service men and women. As noted in the previous section, many of these programs require the use of animals to meet their mission requirements. These programs result in many benefits for both the military and civilian sector (Table I-1). The military benefits from programs that do research in areas that currently threaten military personnel such as combat trauma, chemical and biological agents, infectious diseases not endemic to the United States, directed energy, and occupationally unique health hazards from military operations and environmental extremes. These research programs focus heavily on the prevention of casualties; these efforts contribute significantly to the readiness and sustainment of the DoD's warfighting capability, and also to a significant reduction in the number of casualties reaching the medical treatment facilities. In addition, the DoD is involved in medical research that directly benefits the civilian population such as research in breast cancer, cardiovascular disease, trauma care and treatment, respiratory injuries,

Table I-1 Animal Use Benefits

Medical

FDA safety and efficacy testing prior to use in humans
 Vaccine development
 Participation in Phases 2, 3, and 4 drug evaluations
 Gulf War illnesses
 Breast cancer research
 Identification and control of insect vectors of infectious disease
 Understanding of decompression and predict susceptibility to oxygen seizures
 Development of new techniques for mechanically assisting respiration
 Establish potential hazards of military nerve agents to humans
 Prevention and diagnosis of human Schistosomiasis
 Detection of visual impairments caused by high G loads
 Identification of medical countermeasures for botulinum toxin
 Identification of an antiviral drug as a potential therapy for filoviruses such as Ebola
 Development and testing of a unique bandage utilizing fibrin glue for dramatic control of massive hemorrhage
 Development of models of acute lung injury that mimic neonatal and adult disorders
 Development of drugs that enhance acquisition of information and prolong retention of memory

Clinical

Improvement in patient care
 Bridging the gap between science and bedside treatment
 Better understanding of general anesthetics during surgery

Non-Medical

Development of biosensors
 Identification of environmental toxins

Training

Special forces medical training
 Advanced trauma life support training
 Graduate medical training in surgical techniques

Alternatives

Development of alternatives to replace, reduce, and refine the use of animals

burns, and specific surgical procedures. A list of specific benefits by research category is shown at Appendix F.

Besides the medical benefits of animal research there are many other non-medical and training benefits. The development of biosensors and the identification of environmental toxins benefit both the military and civilian communities. The DoD has many exceptional medical and scientific educational programs that train both medical personnel and scientists. While these people are in the military, the DoD reaps the benefit of this training; once they leave the military, this benefit is realized by the civilian community. The development of alternatives to animal use by the DoD provides an extra value to both communities and to animals as they discover ways to reduce or replace the use of animals. Also refinement research results in more humane methods of performing research that is applied in many types of research settings.

I.4 SCOPE OF REPORT

This report provides a comprehensive accounting of DoD biomedical research and animal care and use programs. There are sections that include in-depth discussions of:

- a. Publicly accessible information on Department research (Section II),
- b. Policies and procedures for oversight of Department animal care and use programs (Section III),
- c. AAALAC accreditation for Department animal care and use programs (Section IV),
- d. DoD animal use profiles (Section V), and
- e. DoD initiatives to promote alternative methods that replace, reduce, or refine animal use (Section VI).

I.4.1 Publicly Accessible Information on Animal Use in the DoD

On October 1, 1995, the Department of Defense implemented a publicly accessible database analogous to the National Institutes of Health Computer Retrieval of Information on Scientific Projects System. The DoD Biomedical Research Database (BRD) is available online to the public,

and is composed of succinct summaries of Department research projects, allowing interested individuals easy access to Department research information. The cost of animal-based research is presented by work unit summary in the BRD. In order to prevent duplication, this information is not presented in this report. More information on accessing the database is presented in Section II.

I.4.2 Oversight of DoD Animal Care and Use Programs

DoD animal use oversight is reviewed in Section III. In general, internal and external oversight provisions for animal research conducted by the DoD are at least as stringent as those for research in any other department of the federal government, and in many ways exceed the standards. As a matter of policy, the DoD abides by the applicable federal regulations pertaining to animal care and use, including provisions for oversight. All DoD facilities and extramural institutions sponsored by the DoD must submit proposals for animal use to an IACUC. The IACUCs review proposed animal protocols to ensure compliance with the Animal Welfare Act, and address concerns of the community. The DoD Directive 3216.1 (1995) establishes oversight requirements that exceed the provisions of the Animal Welfare Act. Each IACUC serves as an independent decision-making body for the institution and establishes policy for the care and use of animals at that facility in accordance with applicable DoD directives, federal law and regulations.

The DoD has developed and implemented a standardized protocol format for use by all of its units (Appendix C). It includes requirements for search of Federal Research in Progress database or an equivalent database and the Defense Technical Information Center database to prevent duplication of ongoing federally funded research. The principal investigator must justify the use of animals, including consideration of alternatives, justify the choice of species and the number of subjects, and include a literature search and assurance that the work does not needlessly duplicate prior experimentation. The protocol must specify procedures to be used with animals, methods to avoid or minimize pain, include a literature search for possible alternatives, qualifications of the

individuals conducting procedures with animals, and disposition of animals at the termination of the work.

The IACUC ensures that personnel involved in animal-based studies are properly trained and, if necessary, establishes a training program to support the staff. The IACUC inspects facilities and animal care programs at least twice annually, and prepares a written report including a plan to address deficiencies. It enforces compliance with procedures specified in the protocols by conducting inspections, evaluating and, if necessary, investigating reports of deviation from approved procedures. The IACUC of each facility performs semiannual program reviews of all animal use areas. The DoD 1995 Policy Letter strengthens that process by establishing a standardized semiannual review checklist that outlines the areas required for IACUC review. This guidance is consistent with the recommendations of the DoD Inspector General (IG) report of February 1994 (Appendix G). A formal report of inspection shall be prepared twice annually, noting the use of the checklist, and indicating all major and minor deficiencies, a plan for correction of deficiencies, signatures of a majority of IACUC members, and a statement indicating whether there are or are not minority opinions. Finally, the IACUC serves as an impartial investigator of reports of violations of good animal practices and is empowered to suspend the use of animals for protocols not conducted in accordance with the Animal Welfare Act or institutional policy.

DoD Directive 3216.1 (revised in 1995) clarifies composition, membership, and training requirements of the IACUC. The 1995 changes address the House Armed Services Committee's request to improve community representation and to appoint animal advocates to the Department's IACUCs, consistent with a recommendation of the IG Report of February 1994. The revised Directive (1995) increases the minimum membership of all DoD IACUCs from three to five. In addition, it specifies that

"there shall be at least one non-scientific member on the IACUC. In addition, there shall be at least one member representing the general community interest who is nonaffiliated with the research facility.

The nonaffiliated member and the non-scientific membership can be filled by the same person. To ensure community representation at each meeting and inspection, an alternate to the nonaffiliated member shall be designated for all IACUCs having a single nonaffiliated membership."

Each DoD IACUC has increased its membership to comply with this Directive.

This Directive exceeds the requirements of the Animal Welfare Act and is further strengthened by the DoD 1995 Policy Letter which requires a minimum of 8 hours of training for new non-affiliated members. In support of this training, the DoD developed a program consisting of a set of topics and recommended resources that may be used by individual IACUCs.

Responsibility for oversight of the Department's science and technology programs rests with the Director, Defense Research and Engineering (DDR&E). The staff, in conjunction with representatives from the Services, annually review the science and technology efforts to ensure they are fully coordinated and without unnecessary duplication of effort. The preponderance of animal use within the Department occurs in biomedical programs. These activities receive specific oversight from the Armed Services Biomedical Research Evaluation and Management (ASBREM) Committee, which was created by congressional direction in 1981. The ASBREM Committee is chaired by the DDR&E and co-chaired by the Assistant Secretary of Defense (Health Affairs). The overall biomedical effort is carefully integrated and reviewed to eliminate unjustified duplication of effort by seven subordinate Joint Technology Coordinating Groups reporting to the co-chairpersons.

I.4.3 Accreditation of DoD Laboratories by AAALAC

Animal use programs in the DoD strive to meet all the requirements of AAALAC. AAALAC accreditation is recognized as the "Gold Standard" for animal care and use programs. DoD Directive 3216.1 (1995) states that all DoD laboratories that maintain animals for use in research, testing or

training shall apply for AAALAC accreditation. Currently there are 34 DoD animal facilities worldwide, of these 33 (97%) are accredited.

Over the past 5 years, the DoD has been resolute in pursuing AAALAC accreditation for all of the facilities that use animals in research. This diligence has resulted in an increase in accreditation from 60% in 1993 to 97% today.

I.4.4 DoD Animal Use Profiles by Research Category

A profile of DoD animal use is provided in Section V. In this report, a detailed system was adopted for classifying animal use that includes 8 categories with 23 subcategories: 8 medical research, 4 non-medical research, 3 clinical research, 2 training, and 6 other categories of studies and use. Detailed charts and graphs are included in Section V.

In 1997, the DoD used 316,048 animals, which is a 1% decrease from FY96. Of these, 22,014 (7%) were USDA reportable species as defined in the Animal Welfare Act of 1985. Table I-2 summarizes the major animal use statistics for DoD research. In addition, it should be noted that no animals were used for development or testing of offensive weapons. During the time that the DoD has been reporting animal use to Congress (1993-1997), there has been a 43% decrease in the total number of animals used.

I.4.5 DoD Initiatives to Promote Alternative Methods that Replace, Reduce, and Refine the Use of Animals

Congress requested that the DoD establish aggressive programs to replace, reduce, and refine current use of animals. A review of DoD programs and initiatives to develop and implement alternatives to animal research is reviewed in Section VI. Alternatives presented are those developed by DoD investigators and the general and specific alternatives implemented by the DoD in 1997.

Animal research is an essential part of the scientific process, but it is only initiated after due consideration of alternatives. The DoD uses a

Table I-2 Summary of DoD Animal Use Statistics

Total Animal Use by Species	% of Total
Rodents, fish, amphibians and birds	97.21
Rabbits	0.86
Farm animals (i.e., sheep, pigs, cows, horses)	1.11
Dogs, cats, nonhuman primates, marine mammals	0.71
Other	0.12

Percentages may not add up to 100% due to rounding of calculations.

Total Animal Use by Category	% of Use
Medical RDT&E	77.95
Non-Medical RDT&E	5.31
Clinical Investigation	10.13
Adjuncts/ Alternatives	3.82
Training & Instructional	1.17
Breeding Stock	0.02
Classified Secret or Above	0.20
Other	1.40

Percentages may not add up to 100% due to rounding of calculations.

Standard Protocol Format that specifically requires each investigator to consider alternatives to the use of animals and to justify the animal model selected. In addition, all protocols that involve unrelieved pain or discomfort require consultation with a veterinarian prior to IACUC review, and a specific database search for scientifically acceptable alternatives to the proposed method. Each protocol that involves animals in research or training must explain the need for the animal research and defend the choice of species as the most scientifically valid model. Often, economies of time and resources are gained when scientifically valid alternatives to animal use are available. Our review of current animal research reveals that scientists in the DoD

have developed or adopted many alternative methods based on ethical considerations and other inherent benefits. Table I-3 presents examples of alternatives developed by the Department in FY97 to replace, reduce and refine the use of animals. In addition, the Department sponsors conferences and workshops to promote alternatives to animal research. The DoD has funded the Institute of Laboratory Animal Research (ILAR) of the National Research Council to develop institutional training materials, education, and publications in support of DoD laboratory animal care and use programs since 1987. The Department has resolved to maintain this important collaboration by providing in excess of \$100,000 annually for the ILAR Program. The IACUC process also includes a strong emphasis on consideration of alternatives in all new protocols.

In conclusion, it is the policy of the DoD that animal utilization will be conducted in full compliance with the Animal Welfare Act and that animals are used in research only when scientifically acceptable alternatives are not available. At the same time, the use of animals in research is essential to protect the health and lives of military personnel; therefore, the DoD will be engaged in biomedical research that involves the use of animals for the foreseeable future.

Table I-3 *Examples of Alternatives for Replacement, Reduction, and Refinement of the Animals Developed or Being Developed by the DoD*

- The DoD is developing environmental enrichment programs for nonhuman primates and ferrets.
- Artificial human skin is used to study inflammatory responses to heat and medical countermeasures against vesicant agents.
- DoD investigators have developed an artificial eye with lenses that can mimic the focusing characteristics of the eye.
- A technique was developed to examine individual neurons in culture, eliminating the need for intracranial surgery.
- Using cell culture assay for initial determination of antiviral activity greatly reduces (>90%) the number of compounds requiring testing in animals.
- Realistic biophysical models computationally simulate the damage processes induced by lasers as accurately as possible.
- Isolated perfused porcine skin flap technique generates more precise data, thus reducing the number of experimental replicates (animals) needed to obtain data on the dermal adsorption of chemicals.

SECTION II

PUBLICLY ACCESSIBLE INFORMATION ON ANIMAL USE IN THE DoD

II.1 CONGRESSIONAL REQUEST INFORMATION

House Armed Services Committee Report 4301 (1995) requested the Secretary of Defense to "develop a mechanism for providing Congress and interested constituents with timely information... about [Department of Defense (DoD)] animal use programs, projects and activities, both intramural and extramural." In response to this request, and to serve the interest of both the scientific community and general public, the Department has implemented a publicly accessible database called the Department of Defense Biomedical Research Database (BRD). The BRD is a database containing succinct summaries of the Department's research projects involving the use of animals. This database is analogous to the National Institutes of Health (NIH) Computer Retrieval of Information on Scientific Projects (CRISP) System. The CRISP System is a biomedical database containing information on research projects supported by the United States Public Health Service, as well as information on intramural research programs of the NIH and the Food and Drug Administration. The BRD became accessible to the public through the Internet on October 1, 1995. It is located on the Manpower and Training Research Information Services (MATRIS) home page.

II.2 THE FY96 BIOMEDICAL RESEARCH DATABASE

The data in the FY96 BRD were developed from the current work unit summary system of the Defense Technical Information Center (DTIC). DoD organizations performing research, development, test and evaluation (RDT&E) projects are currently mandated to provide annual reports of research to the DTIC. The DTIC maintains these work unit summaries in a database. While the majority of DoD animal use occurs in RDT&E projects, some work is performed in clinical investigations programs that are not mandated to provide work

unit summaries to the DTIC. Therefore, the DoD directed that these non-RDT&E DoD animal research projects develop summaries to be entered into the BRD. The areas of research, testing and training in the FY96 BRD include, but are not limited to, the following: infectious diseases, biological hazards, toxicology, medical chemical defense, medical biological defense, clinical medicine, clinical surgery, physical protection, training, graduate medical education and instruction.

Military activities that house, care, or use animals provided a work unit summary for any animal-based research. The FY96 BRD contained summaries and was made accessible to the public on October 1, 1997. A work unit summary may refer to a single protocol or a series of protocols that are performed in a given category of animal use. The summaries include the following information:

Title: Title of the work unit.

Funding Fiscal Year: The funding for the entire work for a given fiscal year. The funding includes civilian salaries, cost of animals, cost of materials, cost of human-based research, cost of non-animal based research, etc. - all costs related to the work unit except military salaries.

POC/Author: The primary contact (POC) for the work unit is usually the Public Affairs Office.

POC Address: The complete mailing address of the POC.

Performing Organization: The name of the activity where the work is performed.

Objective and Approach: This section is a narrative on the objectives and the approach of the work unit. This narrative provides a general summary of the work.

Indexing Terms (Descriptors): A list of indexing terms or keywords. The keywords

contain "animals" and the term for any animal types which may be used in the work unit (e.g., guinea pigs, rats).

These summaries were compiled into the BRD and organized into a presentation format for the Internet.

II.3 ACCESS AND USE OF THE BIOMEDICAL RESEARCH DATABASE

The BRD can be accessed at:

<http://dticam.dtic.mil/dodbr>

The BRD home page shown in Figure II-1 is a searchable database. To perform a search, click on Search. This will bring up the DoD BRD search page. The database can be searched by title, keywords, description or specific demographic

fields (Figure II-2). The results of the search will produce a hypertext list of titles (Figure II-3). To access a particular summary, click on the specific title and the summary will appear (Figure II-4).

II.4 FY97 UPDATE OF THE BIOMEDICAL RESEARCH DATABASE

The DoD will make all FY97 work unit summaries of animal use in research, testing, education, and training available to the public this year. All military activities that house, care, and/or use animals have provided summary information on any animal research, testing, education, or training work for the FY97 BRD. The cost of FY97 animal-based research is presented by work unit summary in the BRD. In order to prevent duplication, this information is not presented in this report. These data will become available to the public on October 1, 1998.

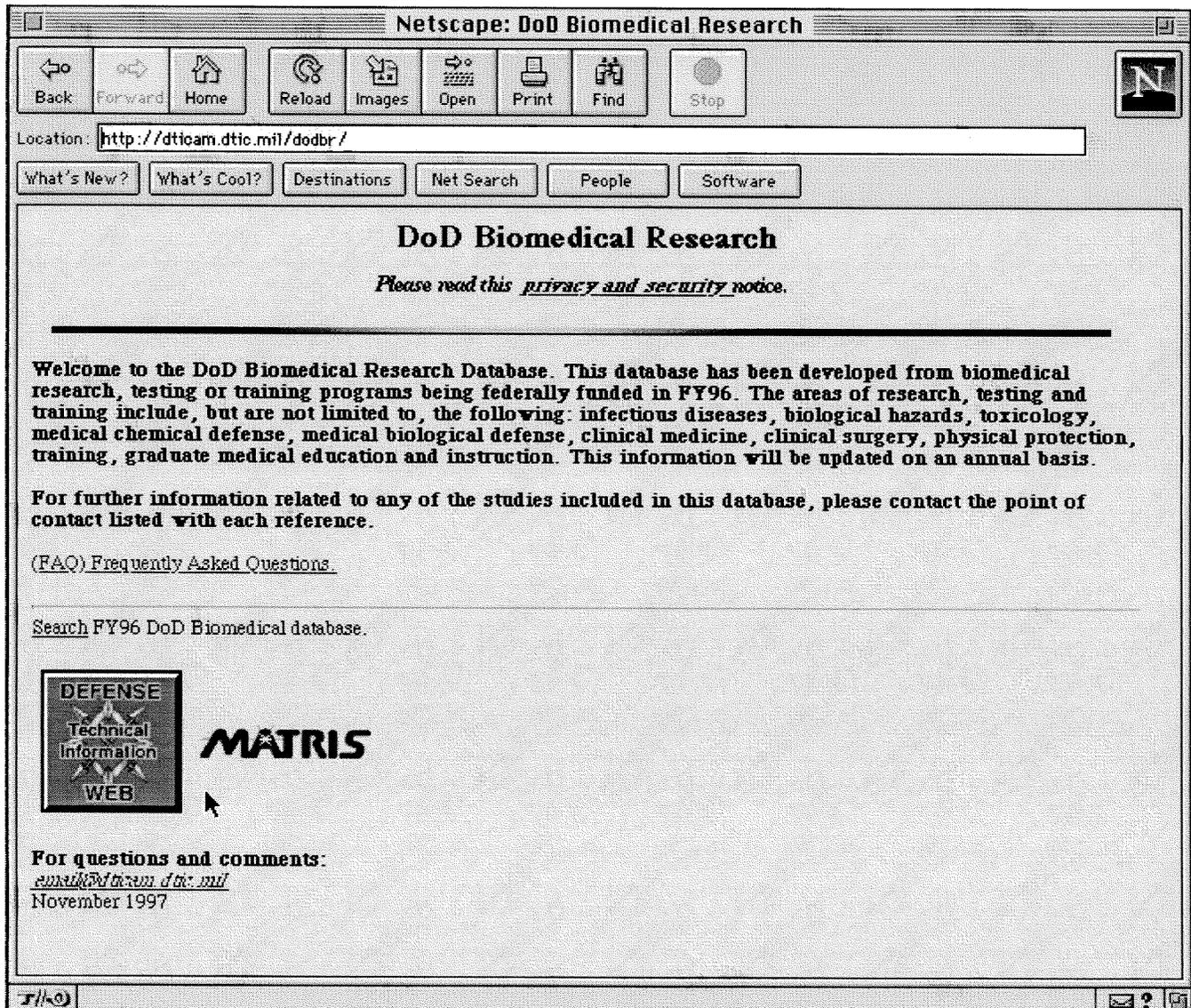


Figure II-1 DoD Biomedical Research Database Home Page

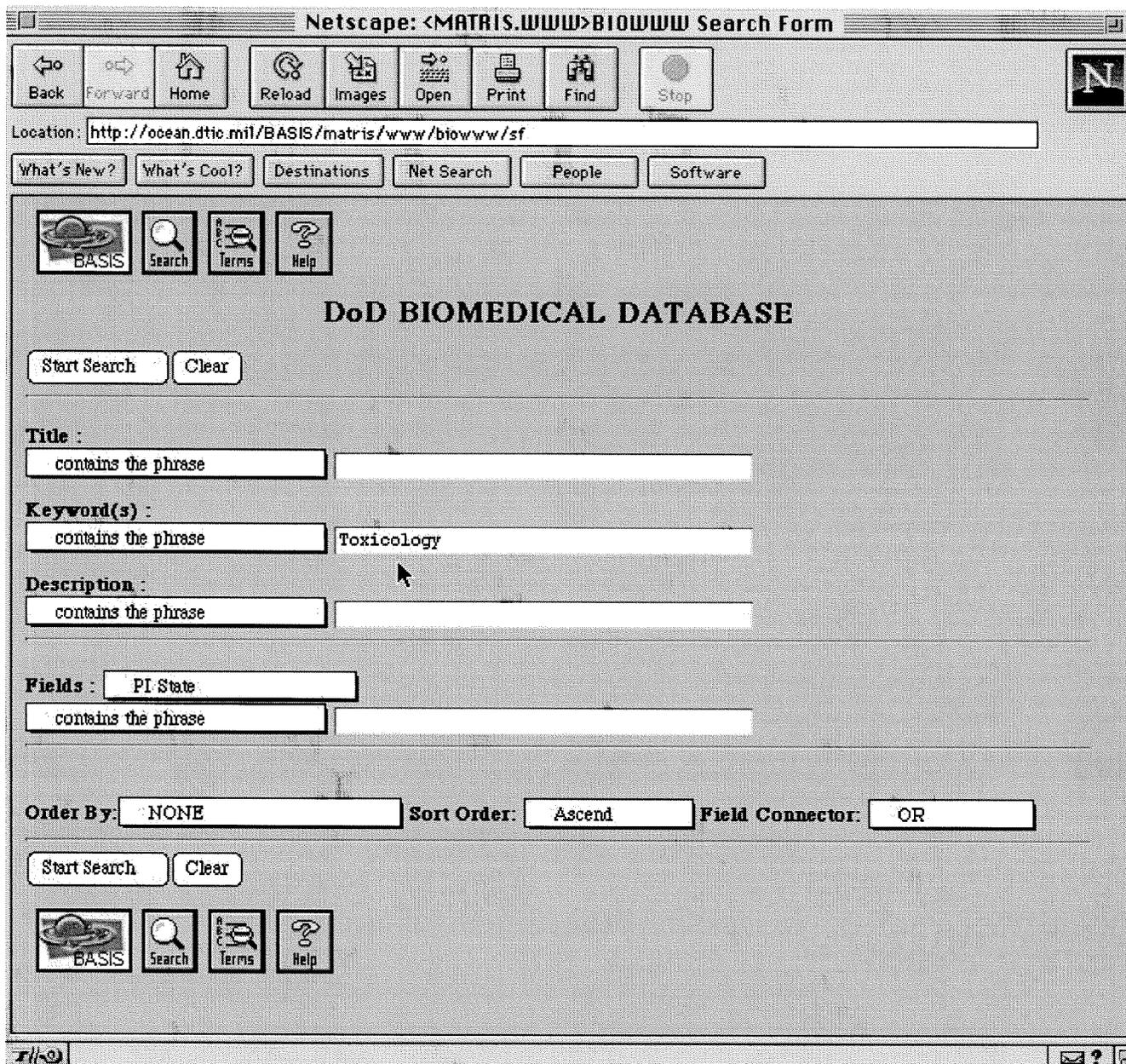


Figure II-2 DoD BRD Search Page

Netscape: <MATRIS.WWW>BIOWWW Documents 1 to 20 of 20

Location: <http://ocean.dtic.mil/BASIS/matris/www/biowww/SDF>

What's New? What's Cool? Destinations Net Search People Software















DoD BIOMEDICAL DATABASE

Documents	Title
1	Toxicity Test Model R&D
2	Evaluation of Biomonitoring Systems for Assessment of Contaminated Waters and Sediments at U. S. Army Installations
3	Acute Inhalation Toxicity of Neutralized GB in Rats by the Munitions Management Device, Version 1 (MMD-1) Wastestream Process
4	Preclinical Toxicology Studies of New Drugs and Vaccines
5	Perform Preclinical Toxicology Studies of New Drugs
6	Screening of Air Force Chemicals
7	Toxicology and Human Health Issues
8	Molecular Mechanisms of Toxicity
9	Hydrocarbon Remediation Issues
10	Species Differences in Skin Penetration
11	Regulation of Metallothionein Gene Expression
12	Reference Dose Development for JP-4 Jet Fuel
13	Persian Gulf Veterans Health Effects Research
14	Biologically Based Pharmacokinetic (PBPK) Models of Water-Soluble Organic Acid
15	Modeling of Retinoic Acid-Induced Limb Dymorphogenesis
16	Assessment of the Toxicity of SFE, A Fire Extinguishant and Potential Substitute for Ozone Depleting Substances in Environments of Potential Military Interest
17	Improved Methods for Evaluating Performance Deficits Induced by Brief Exposures to High Concentrations of Gases or Vapors
18	Health Effects of Imbedded Depleted Uranium
19	Behavioral Assessment of Neurotoxicities Associated with Dideoxynucleoside Administration
20	Detoxication Enzymes as Biomarkers of Toxin Exposure















Figure II-3 Search Results on Toxicology from the BRD

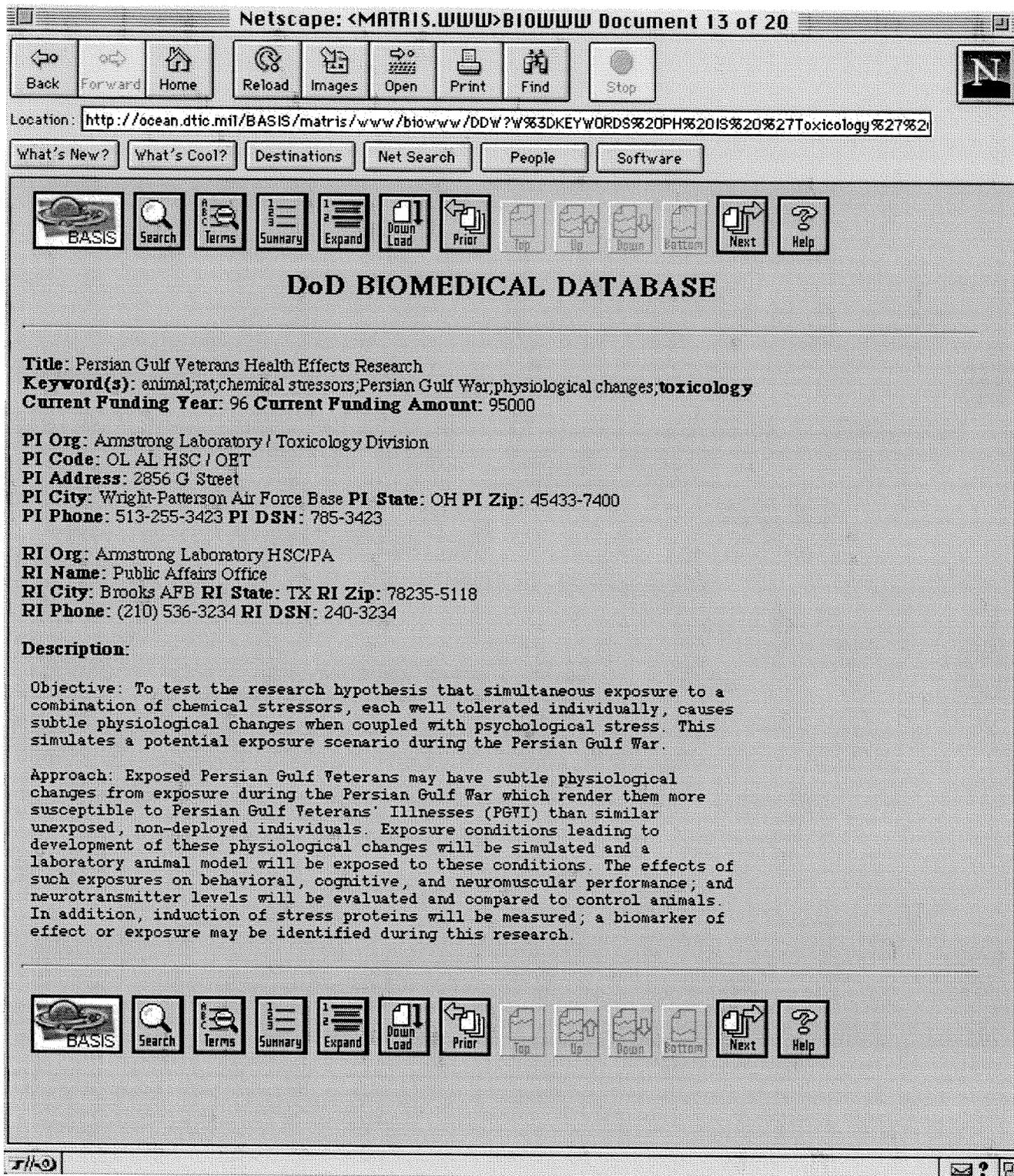


Figure II-4 Sample of Publicly Accessible Summary

SECTION III

OVERSIGHT OF DoD ANIMAL CARE AND USE PROGRAMS

This section of the Department of Defense (DoD) Report to Congress provides a detailed overview of the formal mechanisms and strategies for providing adequate oversight to the Department's numerous animal care and use programs. For the purposes of this report, research is defined as those congressionally authorized science and technology (S&T)-based activities—Title II, Research, Development, Test and Evaluation—of the Military Departments for which funds are appropriated within program elements 6.1 (Basic Research), 6.2 (Exploratory Development) and 6.3 (Advanced Development).

The mechanisms detailed here show a clear and long-standing commitment by the DoD to manage its biomedical research and clinical programs in a systematic, comprehensive, and effective manner. Individual programs are driven by specific mission requirements, and are subjected to a thorough, stratified review and analysis prior to commitment of funds. The DoD uses animals only when necessary to complete its mission, and in full compliance with applicable laws, regulations, and guidelines.

III.1 DETERMINATION OF DoD NEEDS FOR ANIMAL RESEARCH

Determining research needs and plans is a comprehensive process integrated into the DoD's planning, programming, and budgeting mechanisms. Integral elements of these processes are the Department's Research and Development Descriptive Summaries submitted to Congress in justification of the annual budget request. These summaries provide the Office of the Secretary of Defense, the Office of Management and Budget, and Congress with significant detail concerning the accomplishments and future plans of every research project.

Each DoD research laboratory employs its available resources to tailor its organization, staffing, and related infrastructure to best meet its

S&T mission and to support the accountability, responsibility, and authority of its commander. In October 1995, the Department implemented a comprehensive DoD Standard Protocol Format as a basis to justify and document all proposed animal use (Appendix C). The Standard Protocol Format solicits specific information that ensures a thorough review of all animal use proposals by Institutional Animal Care and Use Committees (IACUCs). Although there are minor differences in specific procedural elements in protocol review procedures among DoD facilities, DoD regulations ensure that the overall review mechanisms remain fundamentally similar. The general submission, review, and approval processes are summarized here.

An investigator develops a research protocol in support of Departmental S&T guidance and other supplementing instructions developed within the chain of command, both external and internal to the laboratory. Augmenting the formal S&T coordination and review process is a literature search to verify nonduplication of previous or ongoing research. The Standard Protocol Format requires that a search of Federal Research in Progress (FEDRIP), or its equivalent, and the Defense Technical Information Center (DTIC) database be made for DoD-funded research. An additional search of the scientific literature (MEDLINE, GRATEFUL MED, MEDLARS, AWIC, etc.) is highly recommended. Review and certification that this requirement has been met are integral elements of the review and approval process prior to initiation of a research project.

If animal use is planned for the intended research, the principal investigator must prepare an animal protocol request for submission to the facility IACUC. In addition to the DTIC and FEDRIP search, the Standard Protocol Format requires detailed information regarding results and dates of other on-line database searches (e.g., AWIC, AGRICOLA, CAAT, MEDLINE) that may yield alternatives to painful procedures. Additional

pertinent knowledge and information on the proposed study are gained through review of the scientific literature and participation in scientific meetings, symposia, and workshops detailing other ongoing or completed research.

Since protocols employ DoD resources, individual protocols are reviewed for factors such as military relevance, necessity, scientific merit, and relative research priority. These reviews are normally conducted within the laboratory's command-and-control structure and are characterized by the features of peer review systems.

DoD IACUCs carefully review research proposals involving the care and use of animals for numerous factors, including but not limited to ensuring that (a) the study is based on sound scientific principles; (b) a minimum number of animals are used to achieve the purpose; (c) the lowest phylogenetic species is selected as the appropriate model; (d) there is appropriate use of analgesics and anesthetics or, if required, there is adequate scientific justification for not using anesthetics; (e) the research is not duplicative; (f) the research personnel have the training and experience needed to conduct the research; and (g) the scientific question is of sufficient importance to warrant the use of animals. Additionally, detailed information regarding methodology, techniques, schedules, etc., is required, greatly facilitating a comprehensive and thorough review by IACUCs.

III.2 OVERSIGHT OF ANIMAL CARE AND USE PROGRAMS AND FACILITIES

There are three principal vehicles for oversight of animal care and use programs at DoD research facilities: Major DoD Activities and Service Command Staff, the local IACUC, and the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International.

III.2.1 Military Departments

Each military department has one or more components responsible for oversight and review of its research facilities and animal care and use programs. Periodic reviews, site visits, and inspections are conducted formally, and reports are prepared as required.

The Army's ultimate oversight responsibility is divided between two major commands: the U.S. Army Medical Command and the U.S. Army Materiel Command. In the U.S. Army Medical Command, programmatic guidance and site visits are performed by specialty trained laboratory animal medicine (LAM) veterinarians in the Headquarters, U.S. Army Medical Research and Materiel Command, and the U.S. Army Medical Department Center and School (Veterinary Programs Manager). In the U.S. Army Materiel Command, oversight is provided by a specialty trained LAM veterinarian assigned to the U.S. Army Chemical and Biological Defense Command.

Ultimate responsibility for laboratory animal care and use in the Navy is divided between the Office of the Chief of Naval Research and the Office of the Surgeon General of the Navy. Oversight for both offices is accomplished by a specialty trained LAM veterinarian assigned to the Naval Bureau of Medicine and Surgery and attached for duty with the Naval Medical Research and Development Command. Besides biomedical research oversight, this LAM veterinarian also serves the Naval School of Health Sciences, Bethesda (Clinical Investigations) and the Inspector General at the Naval Bureau of Medicine and Surgery.

III.2.2 IACUCs

The backbone of the review process for all DoD animal-based research is the IACUC review of the research proposal or protocol. DoD Directive 3216.1, "The Use of Animals in DoD Programs," requires all DoD facilities using animals in research to comply with the Animal Welfare Act (AWA). The AWA requires the Chief Executive Officer to appoint an IACUC, qualified through the experience and expertise of its members, to assess the research facility's animal program, facilities, and procedures. The AWA requires that IACUCs have a minimum of three members: an appropriately qualified chairman, at least one member not affiliated with the institution in any way other than as a member of the Committee, and a veterinarian with training or experience in laboratory animal medicine and science. Each DoD IACUC is chaired by an individual with credentials and experience appropriate to the post, typically a senior physician, scientist, or veterinarian. DoD Directive 3216.1 (1995) (Appendix A) clarifies the composition,

membership, and training requirements of the IACUC. This Directive increases the minimum size of all DoD IACUCs from three to five, which is in concert with the National Institutes of Health (NIH) Office for Protection from Research Risks (OPRR) model. In addition, it specifies that

“...there shall be at least one non-scientific member on the IACUC. In addition, there shall be at least one member representing the general community interest who is nonaffiliated with the research facility. The nonaffiliated member and the non-scientific membership can be filled by the same person. To ensure community representation at each meeting and inspection, an alternate to the nonaffiliated member shall be designated for all IACUCs having a single nonaffiliated membership.”

The 34 IACUC panels reporting in FY97 averaged just over eight members each. Private civilian, government civilian, and military representation on the panels is 9%, 47%, and 44%, respectively.

The diverse backgrounds/professions of the nonaffiliated and alternate nonaffiliated IACUC members are provided in Appendix H. Currently, 53% of the nonaffiliated members are private sector civilians, the remainder are federal government civilians or military personnel. In accordance with Directive 3216.1, these members represent the community and are not affiliated with (not under the command of) the research facility. Full compliance with the Directive has resulted in an increase in the overall number of DoD IACUC members.

This Directive exceeds the requirements of the AWA and is further strengthened by the DoD 1995 Policy Letter (Appendix B) that directs a minimum of 8 hours of training for the new nonaffiliated members. DoD IACUCs implemented these requirements October 1, 1995. All DoD new nonaffiliated IACUC members received at least 8 hours of training to fulfill the requirement. The total hours of training reported for nonaffiliated, FY97 IACUC panel members averaged 11.8.

Each IACUC has at least one Doctor of Veterinary Medicine with training or experience in

laboratory animal science and medicine who serves as an animal advocate. The U.S. Army Veterinary Corps' formal postgraduate training program in laboratory animal medicine provides didactic training in IACUC composition, function, and regulatory requirements. This training also prepares them to serve as animal advocates. Of the 34 reporting DoD institutions, 14 had 2 or more veterinarians serving on their IACUC panel.

It is a proactive Department policy that nonaffiliated members participate fully in discussions and vote on all research proposals. They are also encouraged to perform unannounced site visits of animal care facilities. In FY97 nonaffiliated members made at least 28 unannounced visits to Department animal facilities.

The IACUC has statutory responsibility for reviewing the facility's animal care and use program and inspecting the animal facilities on a semiannual basis. Consequently, at least once every 6 months, each IACUC performs an in-depth review of the animal care and use program and inspects the animal facilities. To facilitate these inspections, the DoD has developed and implemented a standardized semiannual program review checklist that details the requirements of the review. All DoD IACUCs are currently using the new standardized checklist during their semiannual program reviews. The IACUCs prepare written reports of their evaluations and submit them to the Institutional Official, usually the facility commander. Reports specifically address compliance with the AWA, identify any departures from the Act, and include an explanation for the departure. The report must distinguish between major and minor deficiencies and provide a schedule for resolution of deficiencies.

All DoD IACUCs document their meetings and activities, including the results of inspections, complaints, actions, and training. They are empowered to review and investigate concerns involving the care and use of animals at the research facility resulting from complaints received from the public or in-house workers, or from reports of noncompliance received from laboratory personnel. To facilitate the reporting and resolution of complaints or concerns, facilities commonly place signs or notices in high-traffic areas and in animal-study areas advising both the public and personnel

who work with animals how to contact members of the IACUC, facility commanders, and/or the Inspector General (IG) whenever questions arise concerning humane care and treatment of animals. Among the reporting DoD institutions, three complaints were registered during FY97. DoD facilities have developed a wide variety of proactive and innovative mechanisms to inform the public on how to contact responsible individuals and to ensure that those who work with animals are fully apprised of the requirement to provide humane and ethical care (Appendix I). Additionally, IACUCs make recommendations to the Institutional Official regarding any aspect of the research facility, its animal program, or the training of its personnel; review and approve, require modification to, or withhold approval of new research protocols involving the use of animals; review and approve, require modification to, or withhold approval of proposed significant changes regarding the care and use of animals in ongoing research protocols; and suspend an activity involving animals when they determine that the activity is not being conducted in accordance with its approved protocol.

III.2.3 AAALAC

AAALAC is a nonprofit organization chartered to promote high quality standards of animal care, use, and welfare through the accreditation process.

The AAALAC accreditation process provides scientists and administrators with an independent, rigorous assessment of the organization's animal care and use program. To increase accountability and tracking, a centralized DoD point of contact and database for AAALAC information have been established to enhance monitoring, reporting, and facilitation of the AAALAC accreditation process. An in-depth discussion of the AAALAC accreditation process and a profile of the DoD's participation are provided in Section IV.

III.2.4 Training

The DoD provides extensive veterinary and animal care services for its facilities. Veterinarians with specialty training in LAM direct programs for animal care and use throughout the Department. They serve as a valuable resource to the research staff and the IACUC to ensure that all research methods and maintenance procedures are consistent with the latest principles of animal

medicine, and with the current interpretations and implementing regulations of the AWA. The DoD sponsors formal postdoctoral training programs for veterinarians in LAM, including a nationally recognized, in-house 2-year residency program culminating in specialty board eligibility for certification in the American College of Laboratory Animal Medicine. Many DoD veterinarians attend various university postgraduate LAM training programs resulting in a master's degree in public health or Ph.D. It is significant that approximately 25% of the current membership of American College of Laboratory Animal Medicine, the veterinary specialty most closely associated with animal welfare and laboratory animal care and use, received either all or part of their training in DoD-sponsored LAM training programs. In August 1995, the DoD began a formal postgraduate Master's of Public Health in Laboratory Animal Medicine at the Uniformed Services University of the Health Sciences. This outstanding program provides the Department with a new source of LAM experts who will significantly enhance animal welfare in our research laboratories.

In addition to veterinarians, the DoD trains animal care specialists (Military Occupation Specialty 91T) to assist in the daily management, care, and treatment of laboratory animals. Over the last 30 years, the DoD has trained over 3,600 animal care specialists. Since 1986, the Division of Veterinary Medicine has sponsored the Walter Reed Army Institute of Research (WRAIR) DoD Laboratory Animal Workshop program. Many of the workshops focus on species-specific techniques and handling, while others provide general laboratory animal information required by federal law and other guidelines for the research mission. Successful completion of the workshops fulfills the training requirements for use of those animals in research protocols. The WRAIR DoD Laboratory Animal Workshop FY97 schedule is provided in Appendix J. Additionally, DoD research institutions send appropriate staff to a variety of seminars and workshops sponsored by the National Institutes of Health, other federal agencies, and private institutions dedicated to the proper care and use of research animals. The Annual Public Responsibility in Medicine and Research Meeting is an outstanding example of this type of training.

The DoD provides detailed informational and instructional material to all members of the

IACUC, including nonaffiliated members, to ensure that they are fully cognizant of the numerous responsibilities of IACUC members under the provisions of the AWA. DoD Directive 3216.1 "The Use of Animals in DoD Programs" requires new nonaffiliated IACUC members to receive an initial 8 hours of training and continued training for IACUC members, investigators, and technicians. This requirement went into effect October 1, 1995. Although training is an individual institute's responsibility, the DoD has developed a program consisting of a set of topics and recommended resources to support the training requirement (Appendix K). The topics are meant to be general and allow for tailoring of the training to meet the institute's specific needs. The recommended resources are readily available commercially. Formal training on animal care and use issues is provided to all appropriate personnel in Department research laboratories in accordance with the provisions of the AWA. Examples of training or materials currently provided to IACUC members are detailed in Appendix K. One of the examples listed in Appendix K is the Institute of Laboratory Animal Research (ILAR) publication *Education and Training in the Care and Use of Laboratory Animals*. As one of the major sponsors of this publication, the DoD has established a formal relationship with the National Research Council (NRC), an extension of the National Academy of Sciences. The publication is used as a guide by the DoD and has been translated into five languages. Many countries use this publication as a standard for the care and use of laboratory animals.

III.2.5 Community Visits

Individuals or groups wishing to visit Department facilities need to comply with certain procedural guidelines. All DoD facilities are served by a public affairs office, at either the facility, post, or base. Visits by the public or the press are arranged and coordinated through the appropriate public affairs office. While most facilities described few community visits, two institutions reported hosting over 50 such visits in FY97. DoD facilities are visited by various special interest groups including community and civic groups; animal welfare or animal advocates, groups, or individuals; dignitaries, academia, and teachers; local, state, and national politicians; congressional members and staff; elementary to postdoctoral students; etc. Consequently, a greatly diversified range of

individuals is constantly visiting and observing the quality of Department facilities.

III.2.6 Office for Protection from Research Risk Oversight

A number of DoD research laboratories participate in the NIH grants process. Institutional compliance with The Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) is a prerequisite for granting or continuation of NIH intramural and extramural funding. The formal vehicle for compliance with the PHS Policy is an "Animal Welfare Assurance" negotiated between individual institutions and the OPRR. The principal references for the negotiation of an OPRR "assurance" are the Health Research Extension Act of 1985 (Public Law 99-158, November 20, 1985, "Animals in Research"), the Animal Welfare Act, and NRC's *Guide for the Care and Use of Laboratory Animals*. Consequently, OPRR provides additional oversight to those laboratories that have negotiated OPRR assurances.

III.2.7 Additional Oversight

Within the DoD, individuals may raise animal welfare concerns. This may be with the IACUC, facility commanders, the IG, or the attending veterinarian. Other means of compliance or concern may be voiced through "Waste, Fraud and Abuse Hotlines," or the formal chain of command. Procedures to enhance and facilitate these mechanisms have been implemented in DoD facilities.

The function of the IACUC and the role of an ombudsman are augmented by the Department's IG. An ombudsman is defined by Webster's dictionary as "a government official charged with investigating citizens' complaints against the government." The Humane Society of the United States, a witness at the April 7, 1992 hearing on The Use of Animals in Research by the Department of Defense before the House Armed Services Committee, offered the Ombudsman Program at the Massachusetts Institute of Technology as an example of a model program. This program consists of an ombudsman assigned to the university president's office to hear complaints regardless of the nature. These include personnel complaints, sexual harassment, animal welfare, etc.

The DoD assigns this responsibility to its IG and respective Inspectors General of the Military Departments. In addition, military bases and large organizations on military bases have their own Inspectors General who fulfill this function. Significantly, complaints to IG can be made anonymously. Also of note is the fact that IG investigations are conducted with complete autonomy, and are completely insulated and immune to pressure from the chain of command.

Oversight of extramural (contract) animal-based research is provided for in DoD Directive 3216.1 (1995). It states that

a. "all extramural research proposals using live animals shall be administratively reviewed by a DoD veterinarian trained or experienced in laboratory animal science and medicine before grant or contract award."

b. "the most recent USDA inspection reports are provided or obtained for the facility under consideration for a research contract or grant using animals, and that during the term of the award, the most recent USDA inspection reports be reviewed on an annual basis."

c. "a DoD veterinarian trained or experienced in laboratory animal science and medicine shall conduct an initial site visit to evaluate animal care and use programs at contract facilities performing DoD-sponsored research using nonhuman primates, marine mammals, dogs, cats, or proposals deemed to warrant review. The initial site visit shall occur within 6 months of when the facility has taken delivery of the animals under DoD contract or grant award. Any facility receiving a DoD-funded grant or contract for animal-based research shall notify the DoD component sponsor and shall have a site inspection within 30 days of notification of loss of AAALAC accreditation for cause, or notification that the facility is under USDA investigation. Site inspections for cause shall evaluate and ensure the adequacy of animal care and use in DoD-sponsored programs, and provide recommendations to the sponsoring DoD component about continued funding support of the research."

As directed by DoD Directive 3216.1, all nonhuman primate protocols receive an additional centralized review external to the research facility.

III.3 CHAIN OF COMMAND OVER ANIMAL CARE AND USE PROGRAMS

The chain of command is designed to resolve problems at the lowest possible level. It provides control and communication among various components of organizations. Each link in the chain of command is a level of responsibility and authority that extends from the President of the United States, as Commander in Chief, down to the lowest supervisory level. Different levels within the chain have different responsibilities and authority. Each level in the chain is responsible for a lower level and accountable to a higher one. Every individual in the military is part of the chain of command and is accountable to it.

III.4 AVOIDANCE OF UNINTENDED DUPLICATION OF RESEARCH

Both the DoD and Congress have a long history of concern about the potential for unintended duplication of Defense research. Within the past decade, the Department has initiated significant improvements in its mechanisms for coordination, and joint planning and review of its research programs.

In 1981, Congress expressed concerns about the potential for unnecessary duplication of biomedical research among the Military Departments (H.R. 96-1317). This resulted in the DoD proposing an Armed Services Biomedical Research Evaluation and Management (ASBREM) Committee to coordinate biomedical research planning and the conduct of biomedical research among the Military Departments. Congress fully endorsed and built upon this proposal by establishing DoD Lead Agencies for major elements of the biomedical research programs for which there were either no, or very few, service-unique requirements (H.R. 97-332). For example, the Army was designated the DoD Lead Agency for military infectious disease and combat maxillofacial research while the Navy was designated DoD Lead Agency for preventive and emergency dentistry research. The ASBREM Committee established Joint Technology Coordinating Groups (JTCGs), consisting of directors of biomedical research programs and representatives of biomedical research laboratories, to coordinate all DoD biomedical research planning and execution. The ASBREM Committee process

has proven to be highly effective at eliminating unnecessary duplication of biomedical research.

The ASBREM Committee process became the model for joint DoD coordination initiatives. Responsibility for joint coordination, planning, execution, and review of the Department's S&T programs was assigned to joint oversight bodies: the Joint Directors of Laboratories (JDL), the ASBREM Committee, the Training and Personnel

Systems Science and Technology Evaluation and Management (TAPSTEM) Committee, and the Joint Engineers. The resulting technology area responsibilities are shown in Figure III-1. Joint S&T oversight bodies are assisted in execution of their responsibilities by subordinate S&T coordinating groups that are focused on coordination of specific technology areas. For example, the ASBREM Committee is supported by the JTCGs (Figure III-2), and the JDL is supported by separate technology panels.

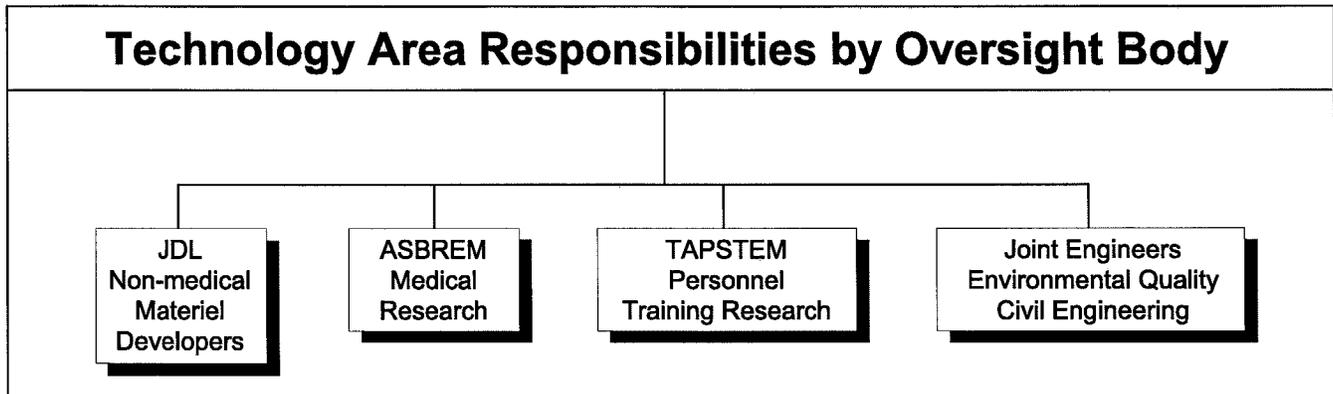


Figure III-1 DoD Technology Area Responsibilities

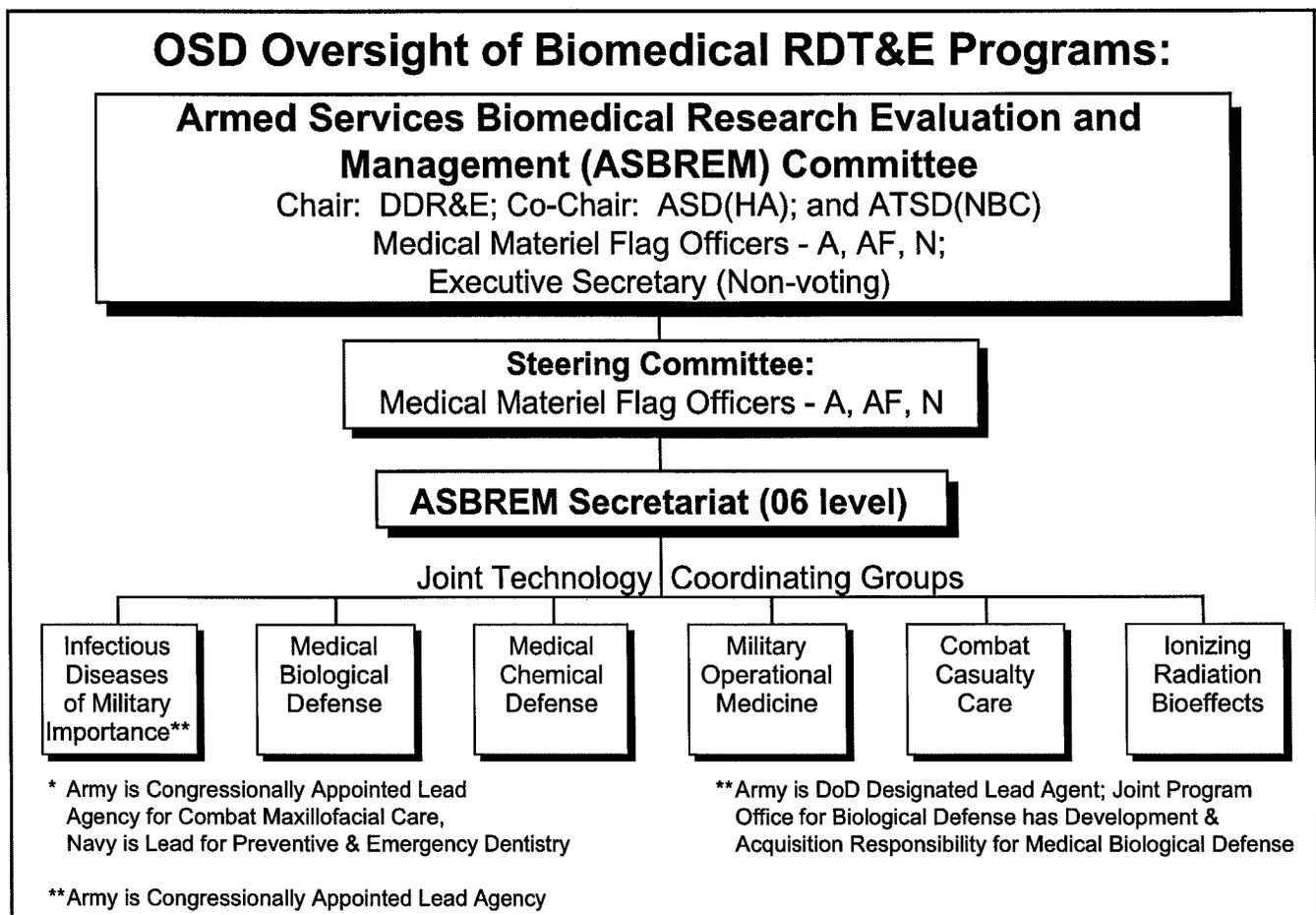


Figure III-2 Structure of ASBREM Committee

In addition to these formal coordination and review processes to eliminate research duplication, there are a number of less formal mechanisms that provide significant disincentives for research duplication. Competition, both in-house and extramural, for research support is a prominent feature of S&T; each year large numbers of scientifically meritorious research proposals cannot be funded due to shrinking resources and funding shortages. In most cases the professional stature of individual scientists or engineers among their peers is measured by their individual and original contributions to the scientific literature. There is little if any reward for unnecessarily duplicating the work of others; such actions often have significant negative impact on how the scientist or engineer is viewed by peers and on the ability to secure research support. Additionally, within the DoD civilian personnel system, scientists' and engineers' pay grades are determined in part by the level of individual scientific and technological contributions. One outcome of research is publication of a manuscript in a professional journal. A sample listing of journals with DoD animal research publications is found in Appendix L. Peer-reviewed journals critique the research during the review process, leading to an overall enhancement of the research process and to validation of both the scientific merit and necessity of the research. These less formal, relatively unquantifiable, disincentives substantially augment and buttress the Department's formal mechanisms for regulating and avoiding unnecessary research duplication within its S&T programs.

III.5 AVOIDANCE OF UNNECESSARY RESEARCH

The same factors that effectively prevent unwarranted duplication of research are applied to prevent unnecessary research. Additionally, through Cooperative Research and Development Agreements, the Department has increased its emphasis on leveraging and exploiting, for Defense needs, S&T investments from other federal agencies, U.S. industry, and academic institutions, and the international scientific community. Past descriptions of Defense S&T "spin-off" have been supplanted by programs intended to "spin-on"

accomplishments by others as well as to optimize the dual-use potential of the Defense S&T investment. The foundation of Defense S&T strategy is the application of S&T accomplishments to sustain Defense technological superiority through efficient and responsive modernization of our warfighting capabilities.

III.6 SUMMARY

Biomedical research using animals is highly structured and regulated in the United States, being governed by numerous laws, regulations, and policies. Consequently, the DoD has a number of stratified formal and informal mechanisms for reviewing, regulating, and executing its biomedical research mission and animal care and use programs. Research performed by the DoD receives close programmatic, scientific, and regulatory scrutiny, being carefully reviewed by various offices, committees, and program managers before it is funded or implemented. These reviews serve to determine the necessity to the mission, provide oversight of animal care and use, and avoid unnecessary or unintended duplication of research.

Individual IACUCs provide oversight of animal care and use programs and research. They also provide training and information about animal care and use, and ensure the humane use of animals in research. Each DoD facility's IG is also an effective means for investigation of concerns about the necessity of animal use, as well as the ethical treatment and humane care of animals used in DoD research.

Over the past decade, the DoD, in concert with Congress, has streamlined and greatly improved coordination of its S&T activities to avoid unnecessary duplication and provide a focused program of research responsive to the DoD's unique and wide-ranging needs.

When viewed in its totality, the Department's significant progress and investment in administration, infrastructure, standardization, training, and oversight of animal use are indeed impressive, and can serve as useful models for the rest of the biomedical research community.

SECTION IV

AAALAC ACCREDITATION OF DoD LABORATORIES

The Department of Defense (DoD) recognizes the benefits of accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). With the publication of the Joint Regulation on the Use of Animals in DoD programs, June 1, 1984 (AR 70-18), the DoD implemented more stringent animal care and use requirements than those required by statute. The Joint Regulation established uniform procedures, policies, and responsibilities for the use of animals in the DoD. The DoD has elevated the requirement with the current DoD Directive 3216.1 (1995), which states that "all DoD laboratories that maintain animals for use in research, testing or training shall apply for AAALAC accreditation." The Joint Service Regulation also cites the National Research Council (NRC) publication, *Guide for the Care and Use of Laboratory Animals*, which is the principal document used by AAALAC in its accreditation process. The animal care and husbandry standards and requirements contained in the Guide are designed to provide an environment that ensures proper care and humane treatment are given to all animals used in research, testing, and training. This care requires scientific and professional judgment based on knowledge of the husbandry needs of each species, as well as the special requirements of the research program.

IV.1 AAALAC ACCREDITATION

AAALAC accreditation is widely accepted by the scientific community, and viewed as an extremely desirable feature of the Department's animal care and use programs. The Association is highly respected as an independent organization that evaluates the quality of laboratory animal care and use. Accreditation covers all aspects of animal care to include institutional policies; laboratory animal husbandry; veterinary care; facility physical plant; support facilities; and special areas of breeding colony operations and animal research involving hazardous agents such as radioactive substances, infectious agents, or toxic chemicals.

The independent and external peer review that is fundamental to continuing AAALAC accreditation is valuable to any program. All AAALAC findings highlight program strengths and identify potential weaknesses. Laboratories maintaining accreditation demonstrate a high degree of accountability and program excellence. AAALAC standards stress the appropriate appointment, composition, and empowerment of an Institutional Animal Care and Use Committee (IACUC). This Committee is responsible for monitoring and evaluating all aspects of the institution's program that uses animals for teaching and/or research purposes. IACUC functions are addressed in Section III of this report.

IV.2 DoD PROGRAM REVIEWS

The DoD utilizes external peer review by the Joint Commission for Accreditation of Health Organizations to evaluate many of its programs such as drug screening laboratories and military medical facilities. At the same time, the DoD recognizes the diversity of mission operations and global reach of the military mission. There are situations where external peer reviews are not cost effective due to remote locale, limited scope of operations, or host nation sovereignty. In these cases, equivalency standards can be applied and effectively monitored. The Joint Service Regulation and Service-conducted inspections of facilities implement the requirements of the Animal Welfare Act and the 1996 NRC *Guide for the Care and Use of Laboratory Animals*.

The DoD is committed to continuing its full participation in the AAALAC accreditation process in order to effect external peer review for assessing program compliance with regulations, guidance, and ethical responsibility.

IV.3 DoD AAALAC ACCREDITED PROGRAMS

The number of DoD AAALAC accredited programs that maintain animals for research testing and training has significantly increased over the past 5 years (Figure IV-1). Of the 34 DoD facilities worldwide reporting animal use, 33 (97%) are AAALAC accredited. This percentage reflects the DoD's commitment to accrediting all of its animal care and use programs.

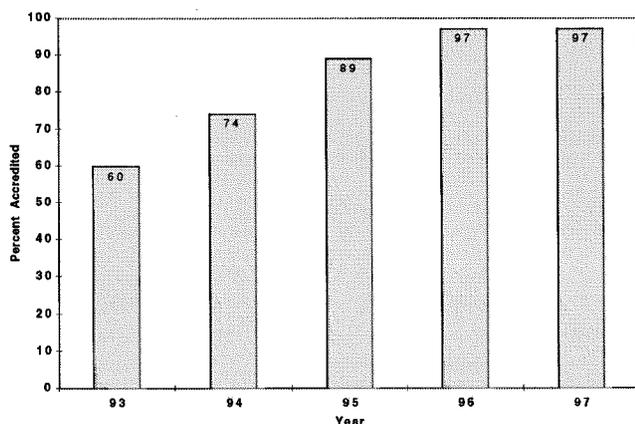


Figure IV-1 DoD AAALAC Accreditation at Time of Publication of the FY93-97 Reports

IV.4 AAALAC ACCREDITATION STATUS FOR U.S. DoD PROGRAMS

There are 30 programs in the United States that maintain animals for research, testing, or training for the DoD. All programs in the U.S. are accredited by AAALAC. In addition, there are four DoD

animal use programs that share DoD AAALAC accredited facilities. These programs are small detachments that are assigned to DoD bases and therefore share their animal care and use facilities. Appendix M provides additional information on AAALAC accreditation by program.

IV.5 AAALAC ACCREDITATION STATUS FOR DoD OVERSEAS PROGRAMS

There are four DoD programs using animals outside the United States. In foreign countries, the accreditation process is often complicated by issues of sovereignty; local governments have their own regulations and policies that must be considered. Renegotiation of various agreements may be involved in construction or renovation projects. Despite these and various other impediments, the DoD has raised the standard of excellence in its animal care and use programs by receiving full accreditation in three of its four overseas laboratories. The Naval Medical Research Detachment in Lima, Peru, was the first laboratory in South America to have received AAALAC accreditation. The Naval Medical Research Unit #2 in Jakarta, Indonesia, and the Naval Medical Research Unit #3 in Cairo, Egypt were the first to be accredited in Southeast Asia and Africa, respectively. The Armed Forces Research Institute of Medical Sciences in Thailand, which was being renovated during FY97, is the only non-AAALAC accredited facility.