THE BLACK BOOK crisis and communications manual

3RD EDITION

adapted and distributed in north carolina by the north carolina association for biomedical research

originally published by the california biomedical research association

3rd edition, revised and updated © 2010, north carolina association for biomedical research (ncabr) all rights reserved.

> 2nd edition, © 2003. 1st edition, © 2000.

originally published by the california biomedical research association distributed with permission in north carolina by ncabr

ncabr
p.o. box 19469
raleigh, nc 27619-9469
919.785.1034
ncabr.org
aboutbioscience.org

CBRA GRATEFULLY ACKNOWLEDGES THE FOLLOWING ORGANIZATIONS FOR THEIR ASSISTANCE, SAMPLE MATERIALS AND INFORMATION, WHICH CONTRIBUTED TO THE DEVELOPMENT OF THIS MANUAL:

NEW JERSEY ASSOCIATION FOR BIOMEDICAL RESEARCH
MASSACHUSETTS SOCIETY FOR MEDICAL RESEARCH
AMERICANS FOR MEDICAL PROGRESS
FOUNDATION FOR BIOMEDICAL RESEARCH
NATIONAL ASSOCIATION FOR BIOMEDICAL RESEARCH

section 4: information about biomedical research and the role of animals

Statistics About Animals in Research

Note: All statistics referenced in section 4 are the most current available.

- 95 percent of all animals needed for medical and scientific inquiry in the United States are rodents (rats and mice) bred specifically for this purpose. Together, dogs, cats and nonhuman primates account for *less than* than 1 percent of all animals used annually in medical research.
- The majority of dogs and cats used for U.S. medical research about two-thirds were bred specifically for research.
- With few exceptions, nearly all the nonhuman primates needed for research are bred at designated primate centers and other institutions throughout the United States.
- Approximately 4 percent of animals used in U.S. research are pigs, sheep, rabbits, frogs, fish and other species (excluding rodents, dogs, cats and nonhuman primates).
- Approximately 85 million cats and 75 million dogs are owned as pets in the United States.
- 56 percent of dogs and 71 percent of cats (roughly 9.6 million dogs and cats) that enter U.S.
 pounds or animal shelters are euthanized each year because they were not claimed by owners or
 adopted by others.
- More cats are euthanized than dogs in the United States because cats are more likely to enter a shelter without owner identification.
- Only 15 percent of dogs and 2 percent of cats that enter U.S. animal shelters are claimed or reunited with their owners, while 25 percent of dogs and 24 percent of cats that enter animal shelters are adopted by others.
- Wildlife biologists estimate that more than 1 million animals are killed each day by automobiles in the United States.
- Approximately 4 percent of dogs and 3 percent of cats that had been scheduled for euthanasia are released to research each year in the United States.
- The number of cats used for research in the United States has dropped by 66 percent since 1967.
 The number of dogs used has dropped by 67 percent.
- The *total* number of dogs and cats used in U.S. research represents about 0.02 percent of all animals killed by automobiles or euthanized in pounds each year in the United States.

Without Animal Research...

Without animal research, each of the following things would happen in the United States:

- Polio would kill or cripple thousands of unvaccinated children and adults this year.
- Each year, many of the 2.6 million newborns with jaundice would instead develop cerebral palsy, which now is preventable through phototherapy.
- Most of the 3 million insulin-dependent diabetics would be dead.
- The United States would experience 1.5 million cases of rubella annually. Each year since 2001, fewer than 100 cases have been reported.
- About 72 million people would be at risk of death from heart attack, stroke or kidney failure from lack of medication to control their high blood pressure.
- The more than 230,000 people with arthritis who receive hip replacements each year would instead be confined to wheelchairs or be able to walk only with great pain.
- More than 1.4 million people would lose vision in at least one eye because cataract surgery would be impossible.
- Death would be a certainty for the nearly 20,000 patients who receive kidney transplants each year.
- There would be no kidney dialysis to extend the lives of the more than 500,000 patients with endstage renal disease.
- Doctors would have no chemotherapy to save the 85 percent of children who now survive acute lymphocyte leukemia.
- Hundreds of thousands of people disabled by stroke and head injury would not benefit from rehabilitation techniques developed in animals.
- New surgical procedures to repair congenital heart defects, spine defects and brain trauma would have to be abandoned or tried for the first time on children.
- A cure for diabetes would be beyond reach. The new medical devices for controlling and monitoring those with diabetes would not exist.
- The number and variety of medications that keep HIV infections under control would not be available.

- There would be no hope of finding a safe and effective cure for AIDS.
- Development of techniques that may help restore function to paralyzed victims of spinal cord injuries could not continue.
- The 30,000 young people with cystic fibrosis would have little hope of a normal lifespan.
- The 250,000 to 350,000 people with multiple sclerosis would lose the promise of new treatments for the symptoms of this degenerative disease.
- Thousands of schizophrenics would be institutionalized because of lack of understanding of the disease and means to treat it.
- Methods to prevent many cancers never would be found because theories about genetic and environmental causative factors cannot be tested in humans.
- The thousands of children who are born each year due to developments and treatments for infertility never would be born.
- Improvement of hearing through electronic stimulation of the inner ear might never benefit any of the 36 million people with hearing impairment.
- Instead of being eradicated, naturally occurring smallpox would instead continue unchecked and many others would join the 2 million people already killed by the disease since 1900.
- Researchers would be unable to clarify the cause of Alzheimer's disease. Without that knowledge, the prognosis for the 5 million Alzheimer's victims would remain bleak.
- The development of urgently needed new drugs to treat heart disease, cancer and a host of other diseases would be curtailed severely.
- Millions of dogs, cats, other pets and farm animals would have died from anthrax, distemper, canine parvovirus, feline leukemia, rabies and the more than 200 other diseases that now are preventable in animals thanks to animal research.

Animal Research Benefits to Humans and Animals

Benefits to Humans

- Heart disease research
- Coronary bypass surgery
- Stroke treatment
- High blood pressure drugs
- Anemia treatment
- Cancer research
- Chemotherapy drugs
- Organ transplants
- Diabetes research and treatment
- Emphysema research and treatment
- Allergy research and treatment
- Kidney disease treatment
- Development of vaccines for polio, measles, rubella, diphtheria, tetanus and whooping cough
- Infant care
- Alzheimer's disease
- Nutritional treatment for pellagra
- Development of life-saving drugs (e.g. antibiotics, insulin)
- Glaucoma research
- Birth defects research and treatment
- Cystic fibrosis research
- Muscular dystrophy research
- Multiple sclerosis research
- Burn treatment
- Arthritis research
- Artificial joint replacements
- Artificial limb development and testing
- AIDS research
- · Tooth and gum disease research

Benefits to Animals

- · Vaccines for rabies, distemper, parvovirus and infectious hepatitis
- Treatment for parasites (e.g. heartworm, hookworm)
- Nutrition research for pet food
- Feline leukemia research
- Vaccines for livestock diseases (e.g. hog cholera, anthrax, tetanus, blue tongue in sheep)
- Treatment for vitamin and mineral deficiencies (e.g. rickets, white muscle disease in cattle)
- Vaccine for Newcastle disease in poultry
- Embryo transfer techniques to improve breeding
- Orthopedic surgery and rehabilitation techniques for horses
- Artificial joints for dogs with hip dysplasia

- Genetic research for inherited diseases in pedigree animals
- Pet cancer and heart disease treatment
- Tooth and gum disease research

Roles Played by Specific Animals in Biomedical Research

Primates

- Polio vaccine
- In vitro fertilization
- Aging
- Alzheimer's disease
- AIDS
- Gum disease
- Brain tumors
- Malaria
- Alcoholic sclerosis
- German measles
- Periodontal disease
- Parkinson's disease

Pigs

- Dermal tests (patches for travel sickness)
- Plastic and reconstructive surgery
- Cardiovascular research (heart transplants, pacemakers)
- Studies of stress
- Hardening of arteries
- Brain tumors
- Hernias
- Appendicitis

Sheep

- Human pregnancy research
- · Fetal alcohol syndrome
- Anthrax vaccine
- Shunt for dialysis machine
- Joint reconstruction
- Organ transplants

Ferrets

- Influenza virus
- Reproductive research
- Canine distemper
- Toxicology research

Chinchillas

- Hearing
- Cholera vaccine
- Sleep research
- Middle ear infections

Guinea Pigs

- Diphtheria vaccine
- Whooping cough
- Immune systems (antibodies)
- Scurvy

Opossums

Esophagus studies

Chickens

- Cancer research
- Brain tumors

Lobsters

- Motor coordination diseases
- Muscular dystrophy

Hamsters

- Lyme disease
- Diabetes

Woodchucks

 Link between hepatitis B and human live cancer

Leeches

- Stimulating blood circulation in reattached fingers
- Antibiotics, possible anti-cancer agents (leech saliva)
- Nervous system disorders
- Multiple sclerosis

Marine Sponges

Human immune system

Mice

- Abnormal fetal development
- Organ transplants
- Cancer
- Heart disease, blood clotting disorders
- Deafness, epilepsy, muscular dystrophy
- Brain dysfunction
- Genetic models
- Pneumonia
- How addictive drugs affect offspring
- Whooping cough and yellow fever vaccines

Rats

- Hardening of arteries
- Arthritis
- Diabetes
- · High blood pressure
- Organ transplants

Rabbits

- Rabies vaccine
- Garre's disease
- Eye and ear infections
- Emphysema
- Cancer
- Diabetes
- Eye surgery
- Skin disorders
- Rheumatoid arthritis
- Whooping cough
- Bubonic plague

Cats

- Brain research (epilepsy)
- AIDS
- Leukemia
- Cataract surgery
- Lupus
- Deafness
- Spinal cord injuries
- Diabetes
- Glaucoma

Dogs

- Study of behavior
- Heart transplant
- Kidney transplant
- Aging
- Artificial hips and joints
- Diabetes
- Rabies
- Gingivitis
- Rickets
- Cardiac pacemakers
- Cardiac stints
- Angioplasties

Armadillos

Leprosy

Frogs

Cancer (antibiotics in skin)

Salamanders

Heart attacks

Snakes

Biological activity at the cell surface

Flies

Genetic research

Electric Eels

- Nervous system disorders
- Multiple sclerosis

Zebrafish

- Genetics
- Blindness, deafness, mental retardation

Horses

Lockjaw (tetanus)

Frequently Asked Questions

1. Are animals really necessary to biomedical research?

It is unethical and illegal to experiment on humans. For example, it would be unethical to expose humans to the potential of risk without having some data from testing on another living organism. Humans are complex, therefore it is necessary to research and test on animals that are similar to humans to obtain reliable and effective results.

New drugs, devices and procedures must receive legal approval from the FDA before being given to humans. In fact, almost every major medical advance in the last century is due to research with animals. Research on animals provides necessary information to predict how a new drug or procedure will affect humans.

Such medical advancements include the prevention of measles, diphtheria, mumps, whooping cough and polio. Medications to treat mental illness, chemotherapy to treat cancer, antibiotics to treat infectious diseases, heart and cardiovascular surgery, and organ transplants are some of the additional medical benefits from animal research.

Scientists must test medical treatments for effectiveness and new drugs for safety before using them on humans. Small animals bred specially for laboratory use — usually rats and mice — are used to identify any undesired side effects of new drugs, such as infertility, miscarriage, birth defects, liver damage and cancer-causing potential. Once new drugs are proven safe in animal studies, they may be used in clinical studies on human volunteers. These volunteers have the assurance that they may fare better — and will not fare worse — than if they were given standard treatment or no treatment at all.

New surgical techniques also must be devised carefully and tested in living, breathing, whole organ systems with pulmonary and circulatory systems much like those in humans. The physicians and physicians-in-training who perform today's delicate cardiac, ear, eye, pulmonary and brain surgeries must develop the necessary skills before patients' lives are entrusted to their care. Computer models, cell cultures and artificial substances cannot yet simulate flesh, muscle, blood, bone and organs working together in the living system.

If we were to abolish the use of live animals entirely, we would be unable to investigate the effects of how one system (e.g. the nervous system) interacts with another (e.g. the immune system or endocrine system), while monitoring side effects (e.g. effects on respiration, kidney function or heart rate). For specific examples, read about research on birth defects and implications for microsurgery.

2. Because animals and humans are so different, isn't animal research scientific fraud?

There are many similarities between humans and various species of animals.

CATS have helped us know more about sleep disorders such as SIDS, sleep apnea and epilepsy.
 Cats represent less than 1 percent of animals used in research. Their contributions are valuable not only to humans, but to the feline population, too. Vaccines for feline leukemia and feline

distemper were developed using cats. Other studies involving cats cover vision disorders such as lazy eye, the nervous system and toxoplasmosis, which is caused by a parasite that can infect humans.

- DOGS also represent less than 1 percent of animals used in research. A vaccine for canine
 parvovirus was developed using the dog model. This animal has contributed to our understanding
 of diabetes and to the development of the heart-lung machine and the first successful kidney
 transplant. Much of what we know about the human heart and lungs has come from studies with
 dogs.
- PRIMATES share 98 percent of human genes. Much of what we know about the brain, heart disease, Alzheimer's, AIDS, viruses, hepatitis and cancer has come from MONKEYS and CHIMPANZEES. Primate research has led to many valuable medical breakthroughs. The polio vaccine was developed using primates, as was the treatment of the RH disease. Other research areas involving primates include malaria, heart disease and dental research.
- MICE have contributed to our understanding of cancer, aging and immunology, including AIDS.
 Much of what we know about the immune system has come from studies with mice.
- **RATS** are used as models for Alzheimer's, hypertension, diabetes, cancer and dental studies.
- RABBITS have contributed to studies involving eyes and ears, the immune system and cholesterol.
- PIGS have hearts very similar to ours, a fact that has led to the development of new drugs for heart disease. Pigs also have contributed to studies on skin disease and burn treatments.
- **SHEEP** were used in finding a vaccine for anthrax. This is a bacterial disease that affects cattle and can be transmitted to humans. Sheep also are models for treatment of kidney failure.
- WOODCHUCKS are used in studies of hepatitis B, a viral disease that affects not only humans, but animals and wildlife, too.
- GUINEA PIGS are used in nutritional studies as well as in studies of the immune system.
- Many species of FISH are used in studies of liver cancer, diabetes, immune systems, vision and heart disease.

3. Do laboratory animals suffer pain?

The use of animals in research and testing is controlled strictly. Veterinarians and their staff are very involved in the care and treatment of laboratory animals. Their job is to ensure the animals are given proper drugs to eliminate pain or discomfort. Researchers realize that the use of animals is a privilege and that those animals, which are helping us unlock the mysteries of disease, deserve our respect and the best possible care. What's more, a healthy, well-treated animal will provide more reliable and valid scientific results.

4. Are animals abused and mistreated?

Poor animal care is bad research. In addition, mistreatment of animals can cause government agencies to fine and/or close down a research facility. Research funds could be stopped. A researcher convicted of cruelty to animals can be suspended, dismissed, fined and even jailed.

The animal rights movement usually relies on a handful of instances that occurred in the 1970s and early 1980s to bolster its claim that animals in research are being abused "behind closed doors" at a medical facility. Federal legislation in the 1980s significantly strengthened the rules and regulations of animal care to prevent this. In fact, many of the pictures of animals depicted in alleged abuse situations actually are cases where the incidents were staged or the pictures manipulated. In addition, pictures depicting routine animal care, such as spaying and neutering, also are used as "evidence" of animal experimentation.

The fact is that in thousands of studies and experiments since 1980, the National Institutes of Health (NIH) has found only a handful of instances in which sanctions were warranted. These sanctions ranged from investigator or institution reprimands to suspension or loss of NIH funds. To date, only two projects, the "Silver Spring Monkeys" study and a University of Pennsylvania baboon head injury project, have been terminated. Neither researcher involved in these cases was convicted of cruelty to animals.

5. Aren't millions of stolen pets used in research?

A total of 94,724 dogs and cats were used in 2007 for education and research in all United States research facilities. Approximately two-thirds of these animals were bred specifically for research; the rest were purchased from highly regulated Class B animal dealers or from pounds, where the animals otherwise would be put to death. The USDA mandates that animals procured from pounds must be held on the pound's premises for five days and on the dealer's premises for an additional five or 10 days. Therefore, the USDA-mandated holding period is 10 to 15 days, providing ample time for owners to locate lost pets or for unwanted animals to find new homes.

According to Merritt Clifton, editor of the animal rights publication *Animal People*, who conducted the only controlled study of pet theft ever completed in the United States, "There simply isn't the demand now to sustain a high-volume market for stolen pets (in medical research)."

Further, very few states allow dogs to be purchased for research from animal shelters, the pound or unlicensed dealers — the only sources of the potential for domestic pets to enter research. According to the American Humane Association, between 8 and 10 million unclaimed dogs and cats are euthanized at pounds and shelters each year because they have been abandoned by their owners and have not been adopted. In a few instances, some animals already scheduled to be killed by a pound or shelter may be released to research. Laws prohibiting the use of pound animals in research mean that additional animals must be raised specially for research use, which increases costs and the total number of animal deaths.

6. Do we have the right to experiment on animals? What about their rights?

It is important to understand the difference between animal rights and animal welfare. Scientists who use animals in research support animal welfare. They are obligated to give the animals respect and ensure their health and well-being. To do otherwise would be irresponsible and unethical.

Ask yourself the following question: "Do you value animals and humans equally?" Animal rights groups believe animals are equal to — or more valuable than — humans. Each of us must decide if we can accept that, in some cases, animals can be studied in research to help scientists find better treatments and cures to improve the health of humans and other animals.

7. Why can't "alternative" methods replace animal research? Why can't computers replace experiments on animals?

It is the stated aim of all medical researchers to use as few animals as possible. Ultimately, it would be ideal if the use of animals could be replaced totally by nonclinical methods. Researchers use nonanimal models — such as computer models, cell cultures and a number of research methods that complement animal studies — whenever possible.

Computer models are used to screen and determine a toxic level of substances in the beginning of an experiment. Cell and tissue studies are important adjuncts of biomedical research. More recently, computer models have become valuable additions to the array of research tools and techniques.

However, living systems are complex. The nervous system, blood and brain chemistry, gland and organ secretions and immunological responses are interrelated. It is impossible to explore, explain or predict the course of many diseases or the effects of many treatments without observing and testing the entire living system. Therefore, final tests must be done on a living model. Blindness cannot be studied in bacteria, nor can high blood pressure be studied in tissue cultures. Surgery cannot be simulated on computers. To study many common and often devastating disorders, there is no choice but to work with animals whose organs are similar to those of human beings.

In fact, following the recent development of these complementary research models, the USDA reports a reduction in the number of laboratory animals used in research. These computer models and other nonanimal models are built using research data generated from earlier animal studies. Without the knowledge gained from this original animal research, nonanimal models would have no basis and work would not be available. To date, even the most sophisticated technology has not been able to mimic all the complicated interactions among cells, tissues and organs that occur in a living body.

Significantly, scientists are bound by law to investigate these interactions before using a new drug or chemical compound in studies with people. In the early stages of a research study, nonanimal models are used to predict amounts of a chemical compound that would cause irreversible harm to a live animal. It then will be tested in living animals and later tested in living people.

Incidentally, there are strong economic incentives to substitute research animals with computers or other complementary nonanimal methods whenever possible. Research animals are extremely expensive to purchase, house and oversee during the research study.

8. What other methods are used in addition to animals in research?

Mathematical and computer assistance, as well as cell, tissue and organ cultures, are useful in the preliminary stages of research. Mathematical models can improve an experiment's design and help predict an organism's response to varying levels of exposure to a particular chemical. Computer data banks offer the ability to share results with other researchers, which reduces test duplication. Culture tests can give some information about a compound but cannot predict how it will affect a living system. The only way to get a complete picture of how a substance or procedure will affect a living system is to test it on animals.

9. Why are animals used for cosmetic testing?

Testing these products on animals is necessary to ensure our safety.

Until 1938, the United States had no product safety testing laws. Consumers took their chances whenever they took drugs, applied cosmetics or used cleaning products, art supplies or industrial chemicals. In the 1930s, untested products twice caused tragedies: An eyelash dye resulted in numerous cases of blindness and at least one death, and a cough remedy caused 107 deaths. Congress responded in 1938 by passing the Federal Food, Drug, and Cosmetic Act, which required for the first time that all drugs be tested for safety before being marketed. Today, the FDA is only one of several federal agencies that regulate the safety of various consumer products and chemicals.

Cosmetics are listed under the category of product testing. Product safety testing ensures that products such as shampoo, deodorant, sunscreen and household cleaning products are safe when used as directed. The testing provides information for poison control centers and emergency room doctors in the event a product is not used properly. Using products without first being tested can result in permanent harm, including blindness.

Not all product testing involves animals. The federal regulations for the approval of new drugs or pesticides require animal test data, while cosmetic safety laws simply require that product safety be demonstrated. However, even when regulations require some animal data, animals are used sparingly, with every effort to keep the numbers to a minimum.

Scientists first review existing data on the chemicals in the product. If their safety already has been established through prior animal testing and safe human use, no further animal tests may be needed. If the ingredients are very similar to ones already in use, nonanimal tests using cell or tissue cultures may be all that are needed before proceeding directly to clinical studies with human volunteers. If a product includes new chemicals or involves a different kind of use (e.g. an aerosol spray instead of a skin ointment), additional animal and nonanimal tests may be needed to determine whether the new ingredients or new application pose a danger. Database research and computer analysis of the chemical structure or physical and chemical properties of the new ingredient may be used to predict likely effects. Animal tests are used when neither the existing safety information nor nonanimal tests can provide enough information about how the compound could affect human health, animal health and the environment.

10. What happens to the animals once an experiment is completed?

Most animals are euthanized in order to study their tissue. Animals whose tissues are not needed may take part in additional experiments. Most often, the animals are not allowed to take part in more than one major surgical procedure. Other animals are adopted out to families and many others live out their natural lives and are cared for in research facilities, although they never again are used for research.

11. Why do veterinarians, who pledge to take care of sick animals, work with researchers who experiment on them?

Veterinarians choose their career because of their concern for animals — and they are very involved in the care and treatment of laboratory animals. Consequently, laboratory animals are healthier and more comfortable. Veterinarians realize the results of animal research improve the health of both animals and humans.

12. How has animal research helped our pets and other animals?

The same methods that have been developed to prevent and treat diseases in humans have improved the lives of countless animals. More than 80 medicines and vaccines developed for humans now are used to heal pets, farm animals and wildlife. Pets, livestock and animals in zoos live longer, more comfortable and healthier lives as a result of animal research.

Animal research has helped develop animal vaccines to fight diseases such as rabies and distemper in dogs and cats, feline leukemia, infectious hepatitis virus and tetanus. It also has led to treatments for heartworm, therapies for cholera in hogs and preventive techniques for both tuberculosis in cattle and influenza and encephalitis in horses. Where would animal care be today without vaccines against rabies, distemper, feline leukemia, tetanus, parvovirus, infectious hepatitis and anthrax?

Animals have been helped with treatments for artificial joints for dogs, treatments for pet cancer and heart disease, antibiotics for infection and treatments for vitamin deficiency in animal diseases such as rickets. Techniques such as ultrasounds and CT scans commonly are used in veterinary medicine today.

Animal research has helped preserve some nearly extinct species, such as the California condor and the tamarins of Brazil, due to new reproductive techniques being applied to endangered species. It has contributed significantly to programs of artificial insemination in endangered species such as elephants and pandas. In fact, according to *The New York Times*, "Nearly every medical procedure now done on humans is being used or studied for use at the nation's leading companion animal medical centers."

13. How many animals are used in research?

Approximately 20.5 million animals are used annually in research and testing.

Rats and mice bred specially for research account for 95 percent of all animals used in research. Less than one quarter of 1 percent are nonhuman primates. Less than one half of 1 percent are dogs and cats. The remainder include rabbits, guinea pigs, sheep, pigs, fish and insects.

Thanks to genetic research, laboratory animals now can be bred to mimic some human conditions, including tumors. Species that reproduce quickly and have genomes that are very similar to humans are especially useful in understanding diseases and in finding treatments for them. Such animal models for human disease allow scientists to use fewer animals to derive more reliable and faster information than was possible ever before.

14. Where do scientists get their animals?

Most scientists use animals that are bred specially for research.

The animals most commonly used in research are rats, mice and other rodents. Scientists purchase these animals from animal breeders. Small numbers of other animals are used in research, including pigs, sheep, other farm animals, dogs, cats and primates.

Dogs, cats and primates constitute less than 1 percent of research animals — and there are special rules about obtaining them for research. For example, primates from threatened species may not be caught from the wild and must therefore come from breeding colonies. The use of primates, dogs and cats in research is governed by the federal Animal Welfare Act (AWA). The AWA requires that those who sell dogs and cats for research be licensed and requires that research animals be given proper care. Approximately two-thirds of the dogs and cats used in research are bred for research, and the rest are "random source" animals from Class B dealers or pounds and shelters.

Researchers may buy purpose-bred animals from USDA-licensed breeders or raise them in their own breeding colonies. Purpose-bred animals tend to be young, share a common genetic background and are small in size. These characteristics make them suitable for some kinds of research but unsuitable for others. In particular, when scientists want to study heart disease, organ system failure, bone defects or joint disorders, they need to use animals that are large, physiologically mature or even elderly, and that represent a genetically diverse population. Approximately 9.6 million unwanted dogs and cats are killed in our nation's pounds annually. Less than 1 percent of these animals would be needed to provide the random source dogs and cats required for medical research.

The AWA permits scientists to obtain dogs and cats for research directly from pounds. Unfortunately, scientists cannot do so in many places because animal activists have insisted on laws or policies forbidding this. In those cases, scientists must rely upon a second category of USDA-licensed dealers who handle random-source animals. These dealers are allowed to purchase dogs and cats directly from their owners, from pounds and from other USDA-licensed dealers. They must comply with

special record-keeping and -holding provisions to protect against pet theft and to give owners time to recover lost pets.

The USDA is diligent about enforcing these provisions. USDA inspectors use dealer records to check whether the person listed as the owner really did provide the animal. Over the last several years, the USDA has issued steep fines against dealers whose records were incomplete or false, and several who were guilty of serious violations were put out of business. According to the animal activist publication *Animal People*, these law enforcement efforts have "virtually halted thefts for laboratory use."

No scientist would want to use someone's pet, and the AWA has numerous provisions to ensure pet dogs and cats do not accidentally end up as research subjects.

15. What laws protect animals in research?

Animal care and use has many laws, regulations, standards and guidelines to protect animals used in research. The main federal law is the Animal Welfare Act. The Animal and Plant Health Inspection Service within the USDA is responsible for administering the act. It sets standards of cleanliness and care, including veterinary care and the use of painkillers for research animals. The act requires that animal dealers be licensed and inspected. The USDA is required by the act to conduct unannounced visits to all registered research facilities at least once a year.

Under the Department of Health and Human Services, the Public Health Service maintains rules and regulations for animal care and use and maintains the Policy on the Humane Care and Use of Laboratory Animals. The Public Health Service requires all research facilities that receive National Institutes of Health funding to follow these guidelines. In addition, the Office of Laboratory Animal Welfare OLAW within the National Institutes of Health significantly oversees laboratory animal care, maintenance and use.

The Institute of Laboratory Animal Resources, under the National Academy of Sciences, prepares the *Guide for Care and Use of Laboratory Animals*.

Each research facility must have an animal care and use committee (IACUC) that reviews every research project to ensure that animals are treated responsibly and humanely. Such committees are composed of veterinarians, researchers, representatives from the scientific community and at least one community member that is not affiliated with the facility, such as a minister or an employee of the Society for the Prevention of Cruelty to Animals. An IACUC oversees and evaluates all aspects of an institution's animal care and use programs.

In addition to federal and state law, there are a number of associations and societies that work to support and assist biomedical research firms and institutes. Among them are the American Association for Laboratory Animal Science, the Association for Accreditation and Assessment of Laboratory Animal Care and the North Carolina Association for Biomedical Research.

16. What are some of the medical advances made as a result of using animals in research?

The list is almost endless. Virtually every major medical advance in the past century has depended on animal research. Some examples are:

- Vaccines against polio, diphtheria, mumps, measles, rubella and smallpox
- Open heart surgery
- Kidney, liver, heart, lung and pancreas transplantation
- Antibiotics and medications for ulcers, mental illness, arthritis, asthma, epilepsy and high blood pressure
- Treatment for many forms of cancer, including leukemia, lymphoma, breast cancer and Hodgkin's disease
- Development of artificial blood vessels
- Measurements related to stroke recovery
- "Clot buster" drugs used for the treatment of heart attack and stroke
- Development of treatments for cystic fibrosis
- Treatment for pneumonia and influenza
- External filtration of blood for patients awaiting liver transplant
- Advances in a vaccine and therapy for HIV/AIDS

In addition, many of the advances in veterinary medicine are the direct result of research with animals.

- Vaccines for rabies, heartworm, feline leukemia and many other pharmaceutical products used to promote health in animals have been developed as a result of animal research.
- The parvovirus vaccine, routinely administered by veterinarians, has saved the lives of many dogs.
- Pacemakers for both humans and animals were developed through research on dogs.
- Research in reproductive physiology on animals has helped save certain species from extinction.

17. Why do some people still experience side effects after a compound has been found safe in animals?

Even after years of intensive study and a comprehensive evaluation of all the data, medicines sometimes cause unexpected side effects in general use. Those who campaign against animal research frequently cite such side effects as an argument against animal testing — but to do so is to misunderstand the careful, step-by-step nature of the research process.

No one expects animal studies to provide all the necessary information, and final decisions never are made solely on the basis of animal testing. Rather, animal studies enable researchers to move as close as possible to the human situation before a new medicine is tested and used in people. All medicines approved by the FDA, even those later found to have unexpected side effects, passed all the testing stages, including nonanimal, animal and human research.

No amount of testing can guarantee to identify all of the possible side effects for every person who may take a medicine. For instance, a reaction that occurs at a rate of 1 in 100,000 people — or even

at a more frequent rate of 1 in 10,000 — might not be seen until very large numbers of people use the medicine. On the other hand, no human ever should be put at risk because of a reluctance to do the necessary and adequate testing on animals.

18. Do researchers care about the animals they use?

Researchers are no different from other people in their attitudes toward animals. Scientists are concerned about their research animals, both for humane reasons and because healthy test animals are necessary for valid research results. Stressed animals don't yield reliable data. In addition to humane considerations, it is in the scientist's best interest to ensure the well-being of his or her research animals. That is why researchers constantly are looking for ways to provide enrichment for animals in their care. This can be something as simple as a food supplement or toys, or it could mean changing their enclosures to allow the animals to socialize.

19. Why test on animals instead of humans?

Not all compounds are tested on whole animals before being tested on humans. In some instances, in vitro techniques are a perfectly suitable substitute for whole animals. For example, in vitro techniques might be used to determine whether a reformulated topical antibacterial ointment or sunscreen is likely to cause skin irritation in humans, and if so, to what degree. If the compound passes the in vitro test, it might then be tested directly on humans without first using whole animals.

Second, humans are used extensively in tests, sometimes after initial testing on whole animals and sometimes without such testing. Studies of this sort are called clinical trials; usually no fewer than three clinical trials are conducted prior to a compound being approved by the FDA.

The first clinical trial is made up of a small group of volunteers. If the compound is shown to be safe and effective with this group, it then is tested in a second group that is larger than the first. If the results from the second group are positive, it then moves to the third clinical trial, which usually involves a very large group of volunteers. Only after passing through this extensive process, which includes both human and animal testing, will a compound be approved by the FDA for general use.

There are, of course, philosophical and ethical issues to consider. On the most basic level, most of us believe it is important for medical doctors to understand the healthy body and diseases as well as other health-related conditions that can diminish our quality of life (e.g. trauma, aging and birth defects).

In conducting research to further this understanding, the best model for research must be considered. Should we use whole living animals when acceptable alternatives exist? Most people would say no.

And most people would say that it is unethical to use human beings as the initial experimental subjects for many types of basic research (especially those requiring invasive procedures). Nor would most people say it is ethical to use humans for the initial "whole animal" tests of promising

compounds whose direct effects and side effects cannot be predicted with reasonable confidence from *in vitro* studies alone.

20. What is the difference between "animal rights" and "animal welfare"?

"Animal rights" is the belief that animals are not ours to use — for food, clothing, entertainment or experimentation. There are dozens of animal rights groups in the United States. These groups vary greatly in the type of opposition they display to the varying uses of animals and in how they oppose these uses. Some groups only oppose using animals in research, while others oppose the use of animal products in clothing (e.g. leather shoes, fur coats, wool sweaters and silk shirts). Methods of protest vary from educational outreach in elementary schools to vandalism, arson, harassment and physical attacks. As of 2005, the FBI listed an animal rights group, the Animal Liberation Front, and its sister organization, the Earth Liberation Front, as the top two domestic terrorist groups in the United States.

Animal rights, as a movement, originated following the 1975 publication of the book *Animal Liberation*, by Peter Singer. The book drew comparisons between discrimination against humans (racism) and discrimination against animals (speciesism).

"Animal welfare" is a term that arose after the 1966 enactment of the federal Animal Welfare Act. The term is used by government-employed research compliance inspectors and veterinarians/scientists employed by companies, hospitals and universities that perform animal research, all of whom are charged with ensuring detailed regulations are followed when using animals in research. People who promote animal welfare condone the controlled use of animals in research under the strict guidelines of the Animal Welfare Act and its numerous amendments. Proactive animal welfare advocates also adopt the same high standards for the use of rats, mice and birds in research, which are not included in the Animal Welfare Act.

21. What are the "Three R's"?

All researchers subscribe to the "Three R's": reduction, refinement and replacement. These are guideposts to lessen animal use in research, including product safety testing. In 1959, two British scientists, William M.S. Russell and Rex Burch, first described the "Three R's" in *The Principles of Humane Experimental Technique*.

REDUCTION

Reduction refers to methods that result in fewer animals being used to acquire the needed information. For example, scientists are developing a number of *in vitro* tests to assess eye and skin irritation. In an *in vitro* test, scientists apply a substance to human or animal cells/tissues in a laboratory container rather than in a living animal. This reduces, or in some cases eliminates, the use of animals in eye and skin irritation safety evaluations. Overall, working toward reduction means fewer animals are being used in medical research. Scientists now are able to be more confident in the results they achieve. This confidence means fewer animals are required to ensure the results are valid.

REFINEMENT

Refinement concerns the manner in which animals are treated. This covers areas such as animal housing and veterinary care. The principle of refinement ensures that animals involved in scientific research are treated with care and respect. Refinements alter procedures to eliminate or minimize discomfort, including new and more effective anesthetics and analgesics, species-appropriate housing and enrichment activities. Enrichment activities mean that, whenever possible, animals are housed in groups rather than in individual cages and that they play with materials similar to those found in their natural habitats. These activities alleviate boredom and enhance psychological well-being.

REPLACEMENT

Replacement means substituting conscious living higher animals with insentient material. These insentient materials include computer modeling, cell cultures and *in vitro* techniques. These techniques can replace some of the existing animal tests in some cases, but it will be many years before nonanimal techniques make all animal tests redundant. One example of progress is the fact that laboratories no longer use rabbits for pregnancy tests. In the past, technicians injected a urine extract from a woman into a rabbit and later tested the rabbit to see if the injection had caused the animal to ovulate. If so, the pregnancy test was positive. Imagine the numbers of animals used to determine pregnancy in a single year! Today, however, a simple, commercially available test achieves the same result.

Quotes From Animal Rights Activists

"The life of an ant and the life of my child should be accorded equal respect."

MICHAEL FOX, HUMANE SOCIETY OF THE UNITED STATES

"I wish everyone would get up and go into the labs and get the animals out and burn them down."

INGRID NEWKIRK, PRESIDENT AND FOUNDER, PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS (PETA)

"There is no rational basis for saying that a human being has special rights. A rat is a pig is a dog is a boy. They're all mammals."

INGRID NEWKIRK

"Everything we are doing lays the foundation for the one day when animals will have rights. ... We need to get in their faces and sue the animal users so often they don't know which courtroom they're supposed to appear in next."

VALERIE STANLEY, ATTORNEY, ANIMAL LEGAL DEFENSE FUND

"We're looking for good lawsuits that will establish the interests of animals as a legitimate area of concern in the law."

INGRID NEWKIRK

"Even if animal research produced a cure for AIDS, we'd be against it."

"If we really believe that animals have the same right to be free from pain and suffering at our hands, then of course we're going to be blowing things up and smashing windows. ... I think it would be great if all of the fast food outlets, slaughterhouses, these laboratories and the banks that fund them exploded tomorrow."

BRUCE FRIEDRICH, PETA

"Our nonviolent tactics are not as effective. We ask nicely for years and get nothing. Someone makes a threat, and it works."

INGRID NEWKIRK

"Arson, property destruction, burglary and theft are acceptable crimes when used for the animal cause."

ALEX PACHECO, DIRECTOR, PETA

"In the end I think it would be lovely if we stopped this whole notion of pets all together."

INGRID NEWKIRK

"The cat, like the dog, must disappear. ...We should cut the domestic cat free from our dominance by neutering, neutering and more neutering, until our pathetic version of the cat ceases to exist."

JOHN BRYANT, FETTERED KINGDOMS: AN EXAMINATION OF A CHANGING ETHIC