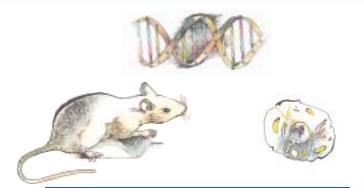
## Questions People Ask About Animals in

50

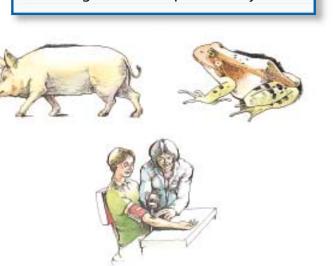
With answers from THE AMERICAN PHYSIOLOGICAL

"Virtually every medical achievement of the last century has depended directly or indirectly on research in animals."

US Public Health Service



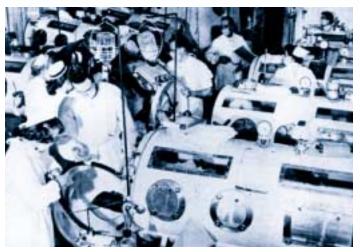
 Physiology is the science of living systems.
Physiologists are scientists who study life processes in humans, animals and plants, and how our organ systems work together to keep us healthy.



The American Physiological Society (APS) was founded in 1887 to foster research into how the organs and systems of the body function. It is the nation's oldest scientific society dedicated to medical research. In 2001, the Society numbered more than 10,000 scientists studying how the bodies of humans and animals work when they are healthy and what goes wrong when they are sick.

The Society sponsors scientific meetings and publishes 14 peerreviewed scientific journals. "Peer-reviewed" means that before an article can be published in an APS journal, it must be reviewed by other scientists in the field who decide whether the study was well-designed and the results mean what the author says they do.

Many physiologists use animals in their research, and the Society has long promoted the highest standards of care for research animals.



This photograph shows a ward of polio patients who needed iron lungs to help them breathe. Such an image looks like ancient history to us now, but to people who lived during the first half of this century, polio was frightening in the same way that AIDS is today. It was an incurable disease that struck healthy young people. It killed only some of its victims, but it left others unable to walk without crutches or to breathe on their own. In the US polio epidemic of 1952, 58,000 new cases were reported and half those victims were left paralyzed.

POLIO has been around for thousands of years, but it had generally been a mild disease. When sanitation techniques improved at the end of the 19<sup>th</sup> century, people stopped getting the mild form of polio when they were babies. Instead, older children and adults got a more serious illness that was extremely contagious, and yet no one knew how it was transmitted.

Animal research was crucial to identifying what caused polio and finding a vaccine. In 1908 Drs. Karl Landsteiner and Erwin Popper proved that polio was an infectious disease by showing that monkeys injected with tissue from a person who died of polio would become ill with the disease. We now know that polio is transmitted when bodily wastes from a person who has the disease contaminate food or water, which then is ingested by another person.

Polio was difficult to stop because it is caused by a virus. Antibiotics such as penicillin were considered "wonder drugs" in the 1940s because they could cure bacterial infections, but they were useless against polio. Viruses are also harder to isolate than bacteria. In 1949 Drs. John Enders, Frederick Robbins, and Thomas Weller made a breakthrough when they figured out how to grow the polio virus in cell cultures. This achievement earned them a Nobel Prize.

During the 1950s, Drs. Jonas Salk and Albert Sabin developed two different polio vaccines. These vaccines "teach" the immune system how to defend itself against polio by exposure to the virus in a killed or weakened form. The vaccines were tested in animals to make sure that they were safe and effective before they were used in people.

Today polio has been virtually eradicated in the industrialized world, but it remains a problem in some developing countries.

#### Why do scientists use animals in research?

# Scientists use animals to learn more about health problems that affect both humans and animals, and to assure the safety of new medical treatments.

Medical researchers need to understand health problems before they can develop ways to treat them. Some diseases and health problems involve processes that can only be studied in a living organism. Animals are necessary to medical research when it is impractical or unethical to use humans.

Animals make good research subjects for a variety of reasons. Animals are biologically similar to humans. They are susceptible to many of the same health problems, and they have short life-cycles so they can easily be studied throughout their whole life-span or across several generations. In addition, scientists can easily control the environment around the animal (diet, temperature, lighting, etc.), which would be difficult to do with people. However, the most important reason why animals are used is that it would be wrong to deliberately expose human beings to health risks in order to observe the course of a disease.

Animals are used in research to develop drugs and medical procedures to treat diseases. Scientists may discover such drugs and procedures using alternative research methods that do not involve animals. If the new therapy seems promising, it is tested in animals to see whether it seems to be safe and effective. If the results of the animal studies are good, then human volunteers are asked to take part in a clinical trial. The animal studies are done first to give medical researchers a better idea of what benefits and complications they are likely to see in humans.

DISEASE	DISCOVERY
HEART DISEASE Heart disease and related conditions affect 52 million Americans and cost our nation \$274 billion a year. These conditions are the number one killers of men, women, and children. Death rates are declining because of advances in diagnosis, treatment and prevention made through animal research.	The basic mechanisms of heart disease have been studied in dogs, rats, rabbits, cats, sheep, and pigs. Studies with dogs contributed to our most basic understanding of how to manage heart disease. Techniques to diagnose the workings of the heart — electrocardiography, cardiac catheters, angiograms, and coro- nary blood flow measurement — were developed through research using dogs, as were surgical techniques such as cardiac bypass, angioplasty, and heart transplants.
HIV/AIDS HIV/AIDS currently affects nearly 1 million Americans. There are treatments but still no cure for this disease that cripples the immune system and is fatal in all but a handful of cases.	Our understanding of the retrovirus that causes HIV/AIDS comes in part from studies of similar viruses in chickens, cats, and mon- keys. Promising drugs and possible vaccines are tested first in mice and monkeys before being used in clinical trials with human vol- unteers.
<b>CANCER</b> Treatment of 100 kinds of cancer costs our nation an estimated \$107 billion a year. When cancer strikes, cells multiply uncontrollably, gradually overwhelming the body. In the 1930s, less than one cancer victim in five survived for five years. Today, almost half the people diagnosed with cancer will live at least five years, and some never have a recurrence of their disease. There are 8 million Americans alive today who have had cancer.	The chicken provided one of the earliest models of how cancer grows and spreads. An understanding of how viruses cause tumors and the use of hormone treatments to limit tumor growth were developed using rats, mice, rabbits, chickens, monkeys, and horses. Cancer treatments such as chemotherapy drugs, radiation therapy, and various surgical techniques were developed using rodents, dogs, and monkeys, among others.
<b>BACTERIAL INFECTIONS</b> Bacterial infections are extremely common and affect most people many times during their lives. Although once deadly or disabling, today most are readily treat- able with antibiotics.	The effectiveness of penicillin and other antibiotics as treatments for bacterial infections was established through research using mice and other rodents. Scientists continue to use animals to determine what antibiotics are effective against specific organisms, their toxicity, and their potential side effects.

Many therapies that were developed for human use are now also being used to improve animal health.

#### Do animals have rights?

### Animals have the right to be treated humanely by everyone.

Animals have played a role in human society since civilization began. At first, animals were hunted for food, and their skins and bones were used for clothing, shelter and tools. Later, animals were domesticated and used as beasts of burden, for food and clothing, and eventually for many other purposes. Today most of us accept the idea that people–farmers, pet owners, animal breeders, zoo keepers and research scientists–may use animals but are obliged to treat them decently. The US even has anti-cruelty laws to ensure the humane treatment of animals.

However, some people think that we should change the relationship between humans and animals. They do not accept the notion that it is appropriate for humans to interfere with the lives of animals. This is the guiding philosophy behind what is called the "animal rights movement." Those who accept this view in its entirety reject all human use of animals, whether for food or clothing, as pets or companions, to race or ride for sport, or in medical research and product safety testing.

In 1975, Australian philosopher Peter Singer wrote a book called Animal Liberation in which he argued that humans should not use animals. Singer's ideas are based on utilitarianism, one of many philosophies developed in the 17th and 18th centuries to help people decide what is right and wrong without invoking the Bible or other moral authorities. Utilitarians say we should judge actions strictly upon their consequences. That is, an action is good if it will provide the greatest benefit to the largest number of individuals. Singer took this notion further and said that when we calculate consequences, we must take into account the interests not only of human beings but also of animals that can experience pain and pleasure. If we fail to consider these animals' interests, or if we give human beings special consideration, we are guilty of "speciesism." To Singer, animal research is morally acceptable if the benefits to humans or animals used clearly outweigh the harm to the animals used in the research. He usually concludes that the cost to the animals outweighs the benefit to others.

Another animal rights view was put forth by American philosopher Tom Regan in a 1983 book, The Case for Animal Rights. Regan holds that people as well as many animals are entitled to certain rights simply because they have a basic understanding of the world and some sense of what they want from life. Regan's version of this rights-based philosophy says that most mammals older than one year qualify for basic rights, e.g., the right to live without human interference. Regan argues that it is wrong to deprive animals of their rights or for humans to use animals to serve their own needs and interests.

Singer, Regan, and others have used explanations of animal rights to win agreement with their belief that human beings should not use animals. However, this is a radical notion, given all the ways that human beings are dependent upon animals for life and livelihood. A more common-sense approach is to recognize that there are compelling reasons to use animals for medical research and other purposes, and at the same time to affirm our obligation to treat animals with compassion. Those who work with research animals – scientists, veterinarians, and animal care technicians – care about them. They recognize that using animals in research is a privilege that carries with it the responsibility to treat those animals humanely.

### Do scientists care about the animals' comfort? Animal comfort is a primary concern in how experiments are conducted.

Both the Animal Welfare Act and the Public Health Service Policy on Humane Care and Use of Laboratory Animals require every research proposal to be reviewed by an institutional animal care and use committee or "IACUC." The purpose of IACUC review is to consider the research plan from the animal's point of view. IACUC approval is not granted until the researcher has shown that he or she has selected the most appropriate species and the minimum number of animals needed to produce scientifically valid results. The researcher must explain why research procedures that might be painful are necessary and what will be done to keep the animals as comfortable as possible. Research may not proceed without this approval. The IACUC also has the authority to halt research in progress if concerns about animal welfare arise.

Most of the time, either the experiment is not painful or else pain-relieving drugs are given as part of the research protocol. A few experiments do involve painful procedures because pain is being studied or drugs would interfere with the research. In such cases, scientists are morally and legally obligated to ensure that the procedures are necessary. The institution will not allow such projects to proceed until the IACUC approves them.

Those who work with research animals — scientists, veterinarians, and animal care technicians — care about them. They recognize that using animals in research is a privilege that carries with it the responsibility to treat those animals humanely. Furthermore, pain and distress can literally change how the body functions, so it is also in the best interest of science to provide good animal care.

#### What animals are used in research?

# The overwhelming majority of animals used in research are rats and mice.

It is estimated that 90% of the animals used for research and testing are rats and mice. They are used to screen promising drug treatments for



diseases such as hypertension, various kinds of cancer, and spinal cord injury; as hosts for viruses; and to test products for toxicity. Specially bred mice now are being used to determine how specific genes function.

Dogs, cats, and primates account for about 1% of all the animals used in research. This research has made many important contributions to human health, as well as leading to healthier lives for these and other animals.

**DOGS:** The cardiovascular and respiratory systems of dogs are similar to those of human beings. Dogs have been used to study heart disease and to develop drug treatments and surgical procedures, including coronary bypass surgery, pacemaker implantation, heart valve insertion, and angioplasty. Dogs have also been used for transplant research and research on how to overcome immune system rejection.

CATS: The neurological system of the cat is very much like that of

human beings. A great deal of information has been collected about how cats' sensory systems work. Cats are used in research on the transmission of visual information from the eye to the brain, hearing disorders, and brain and spinal cord injuries.

**PRIMATES:** Non-human primates were used in research on Rh disease, which affects babies whose blood type differs from that of their mothers. Baboon research led to a new



technique now being tested in humans that allows cancerous bone marrow cells to be removed without destroying healthy ones. Monkeys are used to test drugs to combat malaria, Parkinson's disease, and spinal cord injuries.

> No scientist would want to use someone's pet, and the Animal Welfare Act has numerous provisions to make certain that pet dogs and cats do not accidentally end up as research subjects.

### Where do scientists get their animals? Most scientists use animals that are specially bred for research.

The animals most commonly used in research are rats, mice, and other rodents. These animals are bred for research, and scientists purchase them 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 comprise about 1% of research animals, and there are special rules about obtaining them for research. For example, primates from endangered or threatened species may not be caught from the wild and must therefore come from breeding colonies. The use of 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 must be licensed and requires that research animals be given proper care. According to the USDA, the number of dogs and cats in research in 1996 was 60% lower than in 1973, the first year these statistics were collected. The National Association for Biomedical Research estimates that about half the dogs and cats used in research in 1996 were bred for research, and the other half were "random source" animals.

Researchers may buy purpose-bred animals from USDA-licensed breeders or raise them in their own breeding colonies. Purposebred animals tend to be young, share a common genetic background, and be 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. Every year, 6-10 million unwanted dogs and cats are killed in our nation's pounds. Less than 1% 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, in many places, scientists cannot do so 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's 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 March 1998 issue of the animal activist publication *Animal People*, those law enforcement efforts had "virtually halted thefts for laboratory use."

Are there alternatives to the use of animals?

Scientists look for ways to reduce the numbers of animals needed to obtain valid results, refine experimental techniques, and replace animals with other research methods.

Medical research is an evolving process in which questions are examined in different ways to find answers. Scientists use non-animal methods such as cell and tissue cultures and computer modeling whenever possible. When they believe that animals should be used, they are required by law in many cases to show that animals are necessary to the research. In recent years, technology has permitted the development of many new approaches. However, each has both advantages and limitations.

Cell and tissue cultures are used to study individual cells, genes, and molecules. These help us understand how biological processes operate. Information gained from such research can sometimes be used to create mathematical and computer models that predict how a molecule may interact with its environment. Such models often provide important clues to solving medical mysteries, but the story doesn't end there.

Sometimes studies of simple living creatures such as bacteria, yeast, roundworms, or fruit flies can provide insight into dynamic biological processes. Studies with these creatures have provided a wealth of knowledge about how specific genes work. This can be very useful information since many similar genes are also present in humans and other mammals. Also, the most basic workings of the brain and nervous system have been studied extensively in squid and other mollusks.

But the body's organs and systems interact in sophisticated ways. These biological and chemical processes cannot be understood fully by looking at simple organisms or isolated molecules or cells. Cause and effect relationships discovered within cells or between molecules may operate quite differently when the same process is studied in an intact organism. That is why it is important to study whole animals including humans as well as isolated molecules and cells.

Human beings and other mammals are complex organisms, and our health problems cannot be studied fully in animals that do not have the same organs. So scientists usually must look to other mammals to study human diseases. Scientists select an animal model based upon what is already known about the physiological similarities between that species and humans. With many diseases, there is also a progression of studies that starts by asking simple questions using mice and rats and culminates by asking more complex ones using species with greater similarities to humans, such as cats, dogs, pigs, sheep, or nonhuman primates. Because of the many and varied

interactions among the human body's organs and systems, not only diseases, but also new drugs, vaccines, and surgical techniques must be studied in whole animals to assure their safety and effectiveness.



## Why are cosmetics and other products tested on animals?

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

Up until 1938, our nation 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, there were two cases where untested products 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 they are marketed. Today the Food and Drug Administration is only one of several

federal agencies that regulate the safety of various consumer products and chemicals.

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 where some animal data are required, animals are used sparingly, and every effort is made to keep the numbers to a minimum.

Scientists first review existing data on the chemicals in the product. If their safety has already 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, non-animal tests using cell or tissue cultures may be all that is needed before proceeding directly to clinical studies with human volunteers. If a product includes new chemicals or involves a different kind of use (i.e., an aerosol spray instead of a skin ointment), then additional animal and non-animal 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 non-animal tests can provide enough information about how the compound could affect human or animal health or the environment.

THE AMERICAN PHYSIOLOGICAL SOCIETY

How are research animals protected?

The federal Animal Welfare Act (AWA) is the key law governing research with animals.

The AWA was first passed in 1966 and has been amended several times since then.

### The Animal Welfare Act:

- Regulates the use of dogs, cats, primates, guinea pigs, hamsters, rabbits and farm animals in research, teaching, and testing.
- Requires that all proposals to use animals be reviewed and approved by an institutional animal care and use committee whose membership includes, at a minimum, an experienced scientist, a veterinarian, and an individual who is not affiliated with the institution.
- Requires animals to be provided with adequate food, living space, and veterinary attention in buildings that are clean and properly lighted, ventilated, and temperature controlled. In addition, dogs must receive appropriate exercise, and primates must be provided with an environment that will assure their psychological well-being.
- Requires research facilities to register with and animal dealers to be licensed by the US Department of Agriculture (USDA), which conducts periodic inspections of their compliance with AWA regulations. Significant or repeated violations of the AWA may result in fines or other enforcement actions.
- Requires the USDA to report annually to Congress on the numbers of regulated animals used in research and involved in potentially painful experiments for which no pain-relieving drugs were used.

The National Institutes of Health (NIH) and most other federal funding agencies also require scientists to use the Guide for the Care and Use of Laboratory Animals to determine appropriate standards for animal care.

### The Guide for the Care and Use of Laboratory Animals:

- Offers expert advice and the latest scientific research on how to care for various species of animals to meet scientific, technical, and humane standards.
- Provides guidelines for designing and operating an animal care program that fulfills the requirements of the Animal Welfare Act and the Public Health Service Policy.

© 2001 The American Physiological Society TEXT BY: Alice Ra'anan, The American Physiological Society DESIGN BY: Thomas Stiltz, Visual Thinking, Inc. The 1985 Health Research Extension Act requires all medical research funded through the NIH to conform with the Public Health Service Policy on Humane Care and Use of Laboratory Animals.

### The Public Health Service Policy on Humane Care and Use of Laboratory Animals:

- Requires institutional animal care and use committee review and approval for all research using vertebrate animals that is funded by Public Health Service agencies.
- Requires animal care to be provided according to the standards set forth in the Animal Welfare Act and the *Guide for the Care and Use of Laboratory Animals.*
- Requires each institution conducting Public Health Servicesponsored research to file a written assurance with NIH detailing how it will provide an acceptable program of animal care and use oversight.
- Requires grantees to follow the "US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."
- Requires that significant problems with animal care must be reported to the Public Health Service. Failure to correct violations can result in the research funding being suspended or revoked.



### INFORMATION SOURCES

#### ANIMAL WELFARE ACT

The USDA's Animal and Plant Health Inspection Service is responsible for enforcing the Animal Welfare Act. The legislation, its implementing regulations, and the USDA's annual enforcement reports are available on the USDA website at **http://www.aphis.usda.gov/ac/publications.html**.

#### PUBLIC HEALTH SERVICE POLICIES

- The PHS Policy on Humane Care and Use of Animals is available on the web at http://grants.nih.gov/grants/olaw/references/phspol.htm.
- The PHS Statement on The Importance of Animals in Biomedical and Behavioral Research is available on the web at http://www.the-aps.org/pub\_affairs/humane/pa\_phspolcy.htm.
- The Guide for the Care and Use of Laboratory Animals (7<sup>th</sup> edition) is available on the web at http://www.nap.edu/readingroom/books/labrats.

#### AMERICAN PHYSIOLOGICAL SOCIETY

- Information on the humane use of animals in biomedical research is available on the APS web site at http://www.the-aps.org/pub\_affairs/pa\_animal.html
- This brochure (Questions People Ask About Animals in Research) is available on the web at http://www.the-aps.org/pub\_affairs/animals/index.html in HTML and PDF formats. Write to the address below to obtain a single copy.
- The APS Guide to Internet Resources on animals in research is available on the web at http://www.the-aps.org/pub\_affairs/links/pa\_guide.htm.

#### ADDITIONAL INFORMATION

- Americans for Medical Progress (http://www.ampef.org)
- Foundation for Biomedical Research (http://www.fbresearch.org)
- Join Hands (http://www.joinhand.org)



The American Physiological Society 9650 Rockville Pike Bethesda, Maryland 20814-3991 301-530-7118 FAX: 301-571-8305 WEB: http://www.the-aps.org