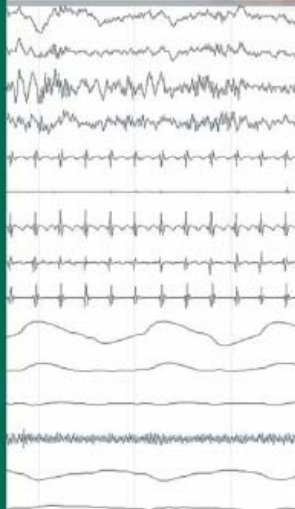
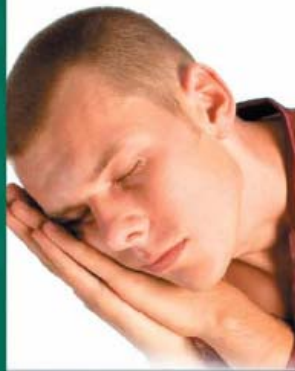


Animal Research Ethics

Sleep Research Society

Prepared by: the Committee on Animal Research Ethics (C.A.R.E.)



38mmHg	38mmHg	38mmHg
99%	99%	99%
78BPM	77BPM	77BPM



Purpose

Members of the Sleep Research Society (SRS) wrote this brochure to tell patients, the public, and health care personnel about the critical role that animals play in helping us to understand and treat sleep disorders.

Research to Improve Sleep and Health

We all recognize the importance of good sleep. Poor sleep, insufficient amounts of sleep, excessive sleepiness, and other problems with sleep can impair the ability to work and learn, increase the likelihood of errors and accidents, and generally reduce the overall quality of life. The National Sleep Foundation estimates that 50-70 million Americans, up to 15% of the population, suffer from sleep problems that disrupt their daily lives. Furthermore, poor sleep can worsen diseases like arthritis, diabetes, and hypertension, but how sleep problems actually do this is not understood.

Good sleep habits can help people get the sleep they need to feel alert and rested. Adjusting sleep habits can also help to reduce sleep disruptions associated with work schedules ("shift work"), travel-related sleepiness (jet lag), and other similar problems. Unfortunately, changing one's behavior cannot correct all problems with sleep. Many sleep disorders have medical causes and must be treated medically. As with other medical illnesses, the causes of sleep disorders and the discovery of good treatments require careful study. This process sometimes requires the use of animals. Sleep in animals is similar in many ways to sleep in humans. Animals have and will continue to help us understand the causes of and find treatments for cures for human sleep disorders.

Over the last 30 years, sleep specialists have used animals as "models" to learn how to improve the health and lives of people with sleep problems. Much of our basic knowledge about how the brain works during normal sleep and waking and how brain function changes during sleep disorders has come from studying animals. Treatments for sleep disorders and other medical conditions are also developed using animals. The long-term goals of sleep researchers are to discover how sleep restores us physically and mentally, to learn how to treat health problems related to inadequate sleep, and to develop preventions, cures, and treatments for sleep disorders.

Here are some examples of common human sleep disorders and how animal research has been critical for understanding and treating these conditions.

Insomnia

About 10%-15% of the population has insomnia. Insomnia can refer to inability to fall asleep, difficulty in staying asleep, or waking up too early. Sometimes insomnia is related to stress or medical problems, sometimes to a patient's use of medication, and sometimes to other kinds of sleep disorders. A common treatment for insomnia is the use of medications. Sleep medications were developed and tested using animals.

Currently, animal research is being used to study how the brain signals it is time to sleep, how it keeps you asleep, and how it wakes you up. This information will help us to better understand the causes of insomnia and to develop better treatments for this difficult sleep problem.

Sleep Apnea

Sleep apnea is a common and serious health problem that occurs in more than 4% of men and 2% of women. You probably know someone with sleep apnea. People with sleep apnea usually snore loudly or breath irregularly when asleep, are excessively sleepy during the day, may unintentionally fall asleep at inappropriate times, and may be overweight. Sleep apnea increases the risk for high blood pressure, heart failure, and stroke. Many people with sleep apnea actually do not know they have it.

People with sleep apnea breathe normally when awake, but during sleep, the muscles of the throat relax too much and block the airway so that the person cannot breathe properly. This periodic narrowing of the airway causes snoring, reduces oxygen levels in the body and the brain, and causes the person to wake up repeatedly to breathe, sometimes dozens of times in one night.

Animal research has helped scientists and doctors learn how the brain controls breathing and muscle activity during sleep and how breathing problems during sleep cause heart disease.

Narcolepsy

Narcolepsy is a life-long disabling condition affecting approximately 250,000 Americans. People with narcolepsy are sleepy and sometimes uncontrollably enter the state of REM sleep (rapid-eye-movement or "dream" sleep). Because muscle tone is reduced during REM sleep, people with narcolepsy will often become weak or paralyzed when they experience intense emotions or when they wake up from sleep. They may be sleepy all day long and may not sleep well at night. Narcolepsy usually starts in adolescence and continues throughout adulthood.

The cause of narcolepsy was a mystery for over a century, but this mystery was recently solved as the result of animal research. In 1999, researchers found that a gene mutation causes narcolepsy in dogs and mice. They used this information to discover that similar problems contribute to human narcolepsy. Many research groups are now studying ways to correct this problem, again using animal models to make sure that new treatments will work well and are safe. This breakthrough will directly affect the medical treatment of patients with narcolepsy, and the lives of many people will ultimately be improved as the result of this discovery in animals.

Restless Legs Syndrome (RLS)

RLS is a neurological disorder that affects 6%-15% of adults and is characterized by an intense urge to move the legs or other parts of the body. It remains largely undiagnosed. RLS is worse during the evening and nighttime hours, and often makes it difficult to fall asleep or stay asleep. Because of sleep disruptions associated with RLS, this disorder may have a profound effect on daily life.

RLS may occur in families, suggesting a genetic component to this disorder. RLS also may occur together with other medical disorders such as anemia, pregnancy or end-stage renal disease, all conditions associated with iron deficiency. RLS is also associated with damage to the nerves (peripheral neuropathy) and attention deficit disorder (ADD). As such, RLS is a complex disorder that likely has different causes. A significant number of people affected by this disorder also experience periodic limb movements of sleep (PLMS). Treatments for RLS include changes in lifestyle, iron

supplementation, agents that activate the dopamine system, anticonvulsants and pain relievers. Continued research is crucial since no single treatment is entirely effective, and no laboratory test yet exists to determine if an individual has RLS. Recent animal studies suggest that complex spinal cord mechanisms contribute to the generation of RLS. Although animal studies demonstrate possible neurotransmitter systems involved in RLS, continued efforts using genetically engineered laboratory animals are necessary to further our understanding of this disorder that disrupts the sleep of so many people.

REM Behavior Disorder (RBD)

RBD is a serious problem that generally afflicts older men. When normal people enter REM or "dream" sleep, their brains direct the muscles to relax and be still. People with RBD do not have this normal muscle relaxation while dreaming, and so they can act out their dreams physically. Because of this, they can seriously injure themselves or their bed partner. About one-third of patients with RBD later develop a degenerative condition such as Parkinson's disease.

A problem similar to RBD was recognized in animals with minor damage to some parts of the brain. In these animals, the muscles did not relax during sleep, and behaviors like walking, running and even attacking occurred during sleep. Animal research has been used to develop the medical knowledge necessary to successfully treat RBD.

The Process of Animal Research

Alternatives:

Sleep Researchers Study People Whenever Possible

Sleep scientists know that people value medical research, but that people also care about the use and treatment of research animals. Whenever possible, sleep researchers study people. Studying people gives us information on risk factors for sleep disorders and on effective treatments. New technologies for taking pictures inside of the human

brain (brain imaging) allow scientists to actually study the brain "in action" during waking and sleep. Many questions that previously required research with animals can now be explored in people. This new method of studying human sleep is very important because some sleep disorders cannot be imitated in animals.

However, many important research questions simply cannot be studied thoroughly in people. For example, medical ethics prevent doctors from testing new procedures on their patients. Sleep researchers use animals whenever this is the only, or the best, option. For example, brand new drugs or medical devices must be tested for safety and effectiveness in animals before they are tested in people. Few people would prefer to be the first "guinea pig" for a new procedure.

Regulation of Animal Research

Two federal agencies, the Public Health Service and the Department of Agriculture, oversee animal research in the United States. These agencies require institutions that conduct research on animals to maintain a committee (the "Institutional Animal Care and Use Committee," or IACUC) to evaluate all proposed use of animals in testing or experimentation.

The members of the IACUC must include veterinarians, scientists, non-scientists, and people from the community. The IACUC must determine that proposed animal research and testing has scientific value, that the animals are treated humanely, and that the fewest possible number of animals are used.

Care of Research Animals

Research institutions, scientists, and veterinarians work hard to maintain the research animals in good health and to safeguard them from neglect or harm. Animals that are not healthy, comfortable, and free of stress do not make good research subjects, especially for stress-sensitive processes like sleep.

Sources of Animals for Research

Almost all animals used in biomedical research are specifically bred for research use, just as cattle and other species of animals are bred to supply food. Over 90% of the animals used in research are mice and rats, and this percentage continues to grow each year. Other species (hamsters, guinea pigs, rabbits, and even fruit flies, as well as a low percentage of monkeys, dogs, and cats) make up the rest. Even the few dogs and cats used in research are purchased from licensed animal dealers and receive excellent care in research facilities. These important animals are used to study devastating human diseases like narcolepsy, epilepsy, and sudden infant death syndrome. In contrast, millions of unwanted dogs and cats are sent to animal shelters each year and are never adopted.

Choosing Wisely: The Future of Research for Human Health

We all benefit from the use of animals in medical research. The medicines, surgeries, and other procedures that are used to treat sleep disorders and other medical conditions are all developed through vital animal research. This research helps scientists, doctors, and patients to know that new treatments have a good chance of working well and are not likely to cause harm before they are used in people. The study of animals has helped scientists find ways to combat many diseases, including sleep disorders.

Medical history tells us that animals have been necessary for medical progress. Common sense and the many unsolved human health problems we all face tell us that the need for medical research using animals will continue. We sleep researchers believe that the continued responsible and humane use of animals in biomedical research and testing serves the interests of humanity and human health. We will continue to work for the benefit of mankind, and hope that you will carefully consider any opinions that condemn all animal research. Your future depends on a wise choice.

Who are We?

The Sleep Research Society (SRS) is an organization of scientists and physicians that fosters scientific study of sleep and sleep disorders, promotes training and education in sleep research, and provides forums for the exchange of knowledge about sleep. Research conducted by members of the SRS ranges from the study of the smallest molecules to entire human beings. SRS members work in academic and medical departments in universities and in private industry.

The SRS helps scientists and doctors gain and share information on the most current research discoveries, patient treatments, and other topics related to sleep medicine. The overall goal is to bring new cures, treatments, and preventions for sleep disorders from the laboratory to the patient.

Research for Healthy Sleep

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