



## What is Biomedical Research?

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Biomedical research is the broad area of science that involves the investigation of the biological process and the causes of disease through careful experimentation, observation, laboratory work, analysis, and testing. Scientists expand this knowledge base to discover ways to prevent ill-health, and to develop beneficial products, medications, and procedures to treat and cure diseases and conditions that cause illness and death in ourselves, our families and friends, our pets, farm animals, and wildlife. Biomedical research requires the input and participation of many individuals from both the life and physical sciences, with many different backgrounds and skills. Such a research team might include medical doctors, veterinarians, computer scientists, engineers, technicians, researchers, and a variety of scientists from the different fields of the life sciences.

***The Scientific Method:*** observation, hypothesis, experimentation, and conclusion.

***Basic research*** is conducted to increase fundamental scientific knowledge, and to expand our understanding about how processes in living organisms develop and function. It provides the building blocks upon which other types of biomedical research are based.

***Applied research*** is directed towards specific goals and discoveries, such as the development of a new medication, medical device, or a surgical procedure. It involves using existing knowledge (gained from basic research) and methodically expanding this knowledge to address the specific medical problem.

***In vitro research*** (from Latin meaning “in the glass”) – bacteria, cell, tissue, and organ cultures done in laboratories.

***Ex vivo research*** (from Latin meaning “out of the living”) refers to experimentation done in or on living cells or tissues taken from an organism and cultured in a laboratory apparatus, outside the organism. The living cultured cells serve as models of the whole organism, reducing the need for in vivo research.

***In vivo research*** (from Latin meaning “in the living”) takes place inside an organism – experimentation done in or on the living tissue of the whole body. Pre-clinical trials and clinical trials are examples of this type of research.

***Pre-clinical trials*** involve non-human animal models, and assist researchers in furthering their knowledge and in discovering more effective methods for diagnosing, treating, and curing diseases that affect both humans *and* animals. Because animals are biologically similar to humans and are susceptible to many of the same diseases and health problems, researchers use animals as models during more advanced stages of biomedical research. Approximately 95 percent of *all* research animals in the United States are rats, mice, and other rodents bred specifically for laboratory research. Pre-clinical trials are an essential part of the biomedical research process because nothing can substitute for the complex functions of the whole, living organism.

Researchers avoid the use of animals in research whenever it is possible, and continue to search for alternative methods. They subscribe to **The 3 Rs** – (Reduction, Refinement, and Replacement). Reduction refers to methods that result in fewer animals being used to acquire the needed information. This, in some studies, *eliminates* the use of animals. Refinement concerns the manner in which the animals are treated. This includes new and more effective anesthetics and analgesics, species-appropriate housing, and enrichment activities. Replacement means using methods that do not involve whole animals. Computer models and cell and tissues cultures are examples.

**Clinical trials** take place in a hospital or a clinical setting, and involve informed human volunteers to gauge the safety and effectiveness of drugs, procedures, or medical devices. Human studies can only begin after exhaustive studies and regulatory evaluation, including pre-clinical trials, have been conducted. There are three major phases of clinical trials, all done in careful coordination and with the approval of the U.S. Food and Drug Administration (FDA), before approval for general use is gained, or is rejected.

### **Why are Animals Needed in Biomedical Research?**

The use of animals in some types of research is essential to the development of new and more effective methods for diagnosing and treating diseases that affect both humans and animals. Medical researchers need to understand health problems before they can develop ways to treat them. Scientists use animals to learn more about such problems, and to assure the safety of new medical treatments. Some diseases and health problems involve processes that can only be studied in living organisms. Animals are necessary to medical research because it is impractical, illegal, and unethical to use humans in early phases of research.

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 some species, like mice and fish, generally have shorter 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 animals (diet, temperature, lighting), which would be difficult to do with people. Finally, a primary reason why animals are used is that most people feel it would be wrong to deliberately expose human beings to health risks in order to observe the course of a disease.