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## USING OF LIVING OBJECTS IN BIOMEDICAL RESEARCH. ALTERNATIVE METHODS OF BIOMEDICAL RESEARCH. INTERNATIONAL AND NATIONAL REGULATIVE DOCUMENTS.

Using animals as research subjects in medical investigations is widely condemned on two grounds: first, because it wrongly violates the rights of animals, and second, because it wrongly imposes on sentient creatures much avoidable suffering. Neither of these arguments is sound. The first relies on a mistaken understanding of rights; the second relies on a mistaken calculation of consequences. Both deserve definitive dismissal.

Alternative methods of biomedical research:

Adjunct testing methods (non-animal models) are used in nearly all phases of biomedical research. In some research, however, these adjunct methods alone cannot provide scientists and researchers with the definitive assessment of how substances will interact in complex organisms. For ethical, regulatory, and scientific reasons compounds must be tested on living systems – made up of interrelated organs and organ systems – before they can be tried in human beings. Mathematical and computer aids as well as cell, tissue, and organ cultures are all 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.

Regulatory documents:

Essential documents are commonly referred to as regulatory documents. ICH GCP guidance defines essential documents as “those documents which individually and collectively permit evaluation of the conduct of the clinical trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements.”

A trial master file should be established at the beginning of any research study and maintained throughout the study.