

Guidelines for Technical Review of Animal Experiment Research of Medical Devices Part I: Decision-making Principles

I. Preface

Scientific and reasonable methods shall be adopted for safety and effectiveness evaluation of medical devices. Animal experiment is one of important means, which belongs to an important research in product design and development and can provides corresponding evidence support for product design and approval; if it is necessary to implement clinical trials, it can provide support for availability of medical devices for human research, decrease risk of clinical trial subjects and users and provide references for clinical trial design.

However, not all medical devices require verification of product safety and effectiveness through animal experiments. In order to provide guidance on determining indispensability of animal experiments, this Guidelines is prepared specially.

This Guidelines is the first part of technical review guidelines series for animal experiment research of medical devices and are decision-making principles to determine whether to implement animal experiments of medical devices. Please refer to guiding principles in other parts for contents in other aspects related to animal experiment design.

These Principles are technical guidance documents used by applicants and technical review personnel, which do not involve registration and approval and other administrative matters, and are not executed compulsorily as legal regulations. In case there are other methods conforming to regulatory requirements, they also can be adopted, but sufficient research data and verification data shall be provided. These Principles shall be used under the premise that related regulations shall be observed.

This Guidelines has been developed under the current regulations and standard systems and the current level of cognition. With the continuous improvement of regulations and standards and the development of science and technology, relevant contents of this Guidelines shall also be adjusted promptly as appropriate.

II. Scope of Application

This Guidelines is applicable to determine whether it is necessary to carry out in vivo experiments on living animals for medical devices, excluding research on non-living animals, in vitro tissues or organs.

Refer to this Guidelines for the following conditions:

- (I) When the applicant of medical devices determines whether it is necessary to carry out animal experiments in design and development stage;
- (II) When regulation authority of medical devices evaluates the necessity of carrying out animal experiments in the link of technical evaluation.

This Guidelines does not replace GB/T 16886 series standards and other technical documents related to biological evaluation of medical devices. In case biocompatibility of medical devices is evaluated through animal experiments, GB/T 16886 series standards and other technical documents related to biological evaluation shall also be observed.

In case guidelines aimed at specific products are issued, guidelines of corresponding products shall also be observed.

This Guidelines is not applicable to in vitro diagnostic reagents of medical device management.

At the time of ethical review of clinical trial of medical devices, refer to applicable parts of this Guidelines to evaluate necessity of preclinical animal experiment.

III. Basic decision-making principles

At the time of determine whether to carry out animal experiments in the design and development stage of medical devices, it is suggested to consider animal welfare ethics principle and risk management principle.

(I) Animal welfare ethics principle

The applicant is required to observe “replacement, reduction and refinement” principle of animal experiments, namely 3R principle.

**It is the end of preview.
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