

Center for Devices and Radiological Health

Guidance on IDE Policies and Procedures

This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind the FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

IDE Staff
Office of Device Evaluation
Center for Devices and Radiological Health

Issued on: January 20, 1998

Comments and suggestions may be submitted at any time for Agency consideration to the IDE Staff, HFZ-403, Office of Device Evaluation, 9200 Corporate Boulevard, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact the IDE Staff at (301) 594-1190. This guidance replaces the guidance entitled, "Clarifications of IDE Policies and Procedures" (September 13, 1991).

Vintage Documents from Clinical Device Group

Is this the document you are looking for? Just email us [here](#) to obtain the entire copy of the FDA January 1998 "Guidance on IDE Policies and Procedures," free and with our compliments.

Best regards,
Nancy J Stark, PhD
President, Clinical Device Group Inc

Click on [whitepapers](#) to opt-in to our whitepapers mailing list.

IDE POLICIES AND PROCEDURES

TABLE OF CONTENTS:

Chapter I General IDE Policies

- *Pre-IDE Process*
 - *Pre-IDE Meetings*
 - *"Informal Guidance" Meetings*
 - *"Formal Guidance" Meetings*
 - *Pre-IDE Submissions*
 - *Interactive IDE Review*

- *Informed Consent Documents*
- *Extensions for Submitting Additional Information to an IDE*
- *Monitoring of Clinical Investigations*
- *Counting Investigational Sites in an IDE*
- *Clinical Study Sites Located Outside the United States*
- *Transfer of IDE Sponsorship*
- *United States Agents for Foreign Sponsors*
- *Closing an IDE*
- *Withdrawing Approval of an IDE*
- *SOPs for BIMO and IDE Staff Interactions*
- *Exporting Unapproved Medical Devices*
 - *Exporting for Investigational Use*
 - *Exporting for Marketing or in Anticipation of Foreign Marketing Approval*

Chapter II New Regulations Affecting the IDE Program

- *Medicare Program; Criteria and Procedures for Extending Coverage to Certain Devices and Related Services*
- *Emergency Research; Waiver of Informed Consent*
 - *Provisions of the Regulation*
 - *ODE Procedures*
- *Dating of Informed Consent Documents*
- *Disqualification of Clinical Investigators*
- *Investigational Device Exemptions; Treatment Use*
- *Section 201 of the FDA Modernization Act*

Chapter III Expanded Access to Unapproved Devices 18

- *Emergency Use of Unapproved Medical Devices 18*
- *Individual Patient Access to Investigational Devices Intended for Serious Diseases 20*
- *Treatment Use of Investigational Devices 21*
 - *Provisions of the Regulation 21*
 - *Procedures 22*
- *Continued Access to Investigational Devices 24*
Expanded Access Mechanisms for Unapproved Devices -- Table 26

Chapter I *General IDE Policies*

This document is intended to provide guidance¹ to Office of Device Evaluation (ODE) reviewers on issues frequently encountered during the review of Investigational Device Exemptions (IDE) applications. In the first chapter of this document, general issues pertinent to the review of IDE applications are presented. This is followed by a discussion in Chapter II of several new regulations which affect the IDE Program. Finally in Chapter III, the four main mechanisms by which unapproved devices may be made available to patients faced with life-threatening or serious conditions are discussed.

In some cases, rather than repeating information that has been previously provided in ODE Blue Book Memoranda or other guidances, only summary information is presented. Whenever possible, however, specific procedures to be followed are identified, including references to appropriate ODE Blue Book Memoranda and IDE boilerplate letters.

Pre-IDE Process

In order to facilitate the initiation of clinical trials under the IDE regulation, the Food and Drug