Information Sheet Guidances
Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors

Table of Contents

General

- Frequently Asked Questions *(1998)*
- Cooperative Research *(1998)*
- Non-local IRB Review *(1998)*
- Continuing Review After Study Approval *(1998)*
- Sponsor - Investigator - IRB Interrelationship *(1998)*
- Foreign Clinical Studies, Acceptance of *(2001)*
- Charging for Investigational Products *(1998)*
- Recruiting Study Subjects *(1998)*
- Payment to Research Subjects *(1998)*
- Screening Tests Prior to Study Enrollment *(1998)*
- Informed Consent, A Guide To *(1998)*
- Use of Investigational Products When Subjects Enter a Second Institution *(1998)*
- Coverage of Personal Importations *(2001)*
- Exception from Informed Consent for Studies Conducted in Emergency Settings: Regulatory Language and Excerpts from Preamble *(1998)*
- "Off-Label" and Investigational Use of Marketed Drugs, Biologics and Medical Devices *(1998)*
- Data Retention when Subjects Withdraw (2008)

Drugs and Biologics

- Emergency Use of an Investigational Drug or Biologic *(1998)*
- Treatment Use of Investigational Drugs *(1998)*
- Waiver of IRB Requirements for Drug and Biological Product Studies *(2006)*
- Drug Study Designs *(1998)*
- Evaluation of Gender Differences *(1998)*

Medical Devices

- Frequently Asked Questions about IRB Review of Medical Devices *(2006)*
- Significant Risk and Nonsignificant Risk Medical Device Studies *(2006)*

FDA Operations

- FDA Institutional Review Board Inspections *(2006)*
- FDA Inspections of Clinical Investigators *(2006)*
- Clinical Investigator Regulatory Sanctions *(1998)*

Background

Through FDA's new Information Sheet Guidance Initiative, these Information Sheets will be revised and updated as needed. The date of the most recent revision is listed next to the title.
Learn more about this initiative.

References

- Federal Register Notice: Protection of Human Subjects: Categories of Research That May Be Reviewed by the Institutional Review Board Through an Expedited Review
  [PDF version, 32 KB]
- A Self-evaluation Checklist for IRBs

FDA Good Clinical Practice Program

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