A Primer on FDA Resources for Clinical Investigators

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Policy Analyst

Office of Good Clinical Practice

Clinical Trials and Human Subject Protection
Bioresearch Monitoring Program (BIMO)
BIMO Inspection Metrics
HSP/BIMO Initiative
Regulations
Report Problems to FDA
Complaints relating to Clinical trials
Guidance Documents (Including Information Sheets) and Notices
Proposed Regulations and Draft Guidances
Compliance & Enforcement
Educational Materials
Replies to Inquiries to FDA on Good Clinical Practice
FDA's Role: ClinicalTrials.gov Information

Resources for You

- ClinicalTrials.gov (NIH)
- FDA Basics
- FDA Basics for Industry
- Laws Enforced by FDA
- Freedom of Information
- Dockets Management
- Approvals of FDA-Regulated Products
- Websites with Information About Clinical Trials

Clinical Trials and Human Subject Protection

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Workshops and Meetings

In The News

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Regulations

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FDA Regulations Relating to Good Clinical Practice and Clinical Tri

Get e-mail updates when this information changes.

FDA regulations governing the conduct of clinical trials describe good clinical practices (GCPs) f with both human and non-human animal subjects

- Electronic Records; Electronic Signatures (21 CFR Part 11)
- Regulatory Hearing Before the Food and Drug Administration (21 CFR Part 16)
- Protection of Human Subjects (Informed Consent) (21 CFR Part 50)
- Additional Safeguards for Children in Clinical Investigations of Food and Drug Administration-Regulated Products (21 CFR Parts 50 and 56)
- Informed Consent Elements (21 CFR 50.25(c))
- Exception From General Requirements for Informed Consent (21 CFR 50.23(e))
- Financial Disclosure by Clinical Investigators (21 CFR Part 54)
- Institutional Review Boards (21 CFR Part 56)
- Good Laboratory Practice for Nonclinical Laboratory Studies (21 CFR Part 58)
- Investigational New Drug Application (21 CFR Part 312)
- Foreign Clinical Trials not conducted under an IND (21 CFR 312.120)
- Expanded Access to Investigational Drugs for Treatment Use (PDF - 216KB)
- Charging for Investigational Drugs (PDF - 204KB)
- Form 1571 (Investigational New Drug Application)
- Form 1572 (Statement of Investigator)
- Applications for FDA Approval to Market a New Drug (21 CFR Part 314)
- Bioavailability and Bioequivalence Requirements (21 CFR Part 320)
- New Animal Drugs for Investigational Use (21 CFR Part 511)
- New Animal Drug Applications (21 CFR Part 514)
- Applications for FDA Approval of a Biologic License (21 CF
- Investigational Device Exemptions (21 CFR Part 812)
- Premarket Approval of Medical Devices (21 CFR Part 814)

Preambles to GCP Regulations

Each time Congress enacts a law affecting products regulated develops rules to implement the law. The FDA takes various s variety of documents in the Federal Register announcing the rule, and offering the public the opportunity to comment on the explains the legal issues and basis for the proposal, and provi submit written data, views, or arguments on the proposal. Any subsequent publications that are part of the agency's decision-making process.

The "preamble" to each of these publications includes all of the printed information immediately preceding the codified regulation. The preamble provides information about the regulation such as why the regulation is being proposed, the FDA's interpretation of the meaning and impact of the proposed regulation, and in those cases where the agency has solicited public comment, the agency's review and commentary on those comments . The preamble

Links to electronic Code of Federal Regulations

Preambles contain useful background information including public comments and FDA's analysis pertaining to the final rule

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Science & Research

Guidance Documents (Including Information Sheets) and Notices

Guidance documents accessible from this page represent the Agency's current thinking on good clinical practice (GCP) and the conduct of clinical trials. As with all guidance documents, they do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations. However, in many places throughout these documents, specific regulations are cited and the requirements of the regulations are reiterated. The regulations are enforceable.

Notices accessible from this page are those that have been published by the Agency that contain important information about good clinical practices and the conduct of clinical trials.

Information Sheets

Final Guidances

ICH Guidance Documents

Page Last Updated: 08/05/2010

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Most Frequently Referenced Guidances for CIs

- **Investigator Responsibilities**
  - https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf
- **FAQ Statement of Investigator (Form FDA-1572)**
  - https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf
- **Financial Disclosure by Clinical Investigators**
  - https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf
- **ICH E6 – Good Clinical Practice Consolidated Guidance**
  - https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

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OGCP's Listserv for notifications of new guidance documents, regulations, etc. as well as FDA webinars

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IRBs.

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Educational Materials

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Useful References

- **Belmont Report**
  Based on the work of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-1978), the Department of Health and Human Services (HHS) revised and expanded its regulations for the protection of human subjects, 45 CFR part 46, in the late 1970s and early 1980s. In 1978, the Commission's report "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" was published. It was named the Belmont Report, for the Belmont Conference Center, where the National Commission met when first drafting the report. (Extracted from information posted on the DHHS OHRP web site on the Belmont Report; see http://www.hhs.gov/ohrp/archive/belmontArchive.html#histReport)
- **Comparison of FDA and HHS Regulations**
  A chart comparing FDA's regulations for human subject protection with those of the Department of Health and Human Services.
- **Determination of Mode of Action in Combination Products (PDF - 13KB)**
  This rule defines "mode of action" and "primary mode of action" and sets forth the algorithm FDA will use to assign combination products to an agency component for regulatory oversight.
- **E-Mail Messages**
  Copies of e-mail messages (including the original inquiry and associated reply(ies)) that have been submitted by the public to the Good Clinical Practice Program's gcp.questions@fda.hhs.gov e-mail account. These e-mail messages have been redacted to the extent permitted by the Freedom of Information Act.
- **"FDA Issues Advice to Make Earliest Stages Of Clinical Drug Development More Efficient"**
  FDA Press Release (Jan. 12, 2006)
- ***Improving Health Through Human Drugs***
  This FDA publication, originally titled *From Test Tube to Patient: Improving Health Through Human Drugs*, tells the story of new drug development in the United States. Articles discuss various aspects of drug development--from test tube to medicine cabinet. This is an excellent primer for learning about the drug development and approval process.
- **FDA and Clinical Drug Trials: A Short History**
- **GCP Training Information**
- **"Innovation or Stagnation? Challenge and Opportunity on the Critical Path to New Medical Products"**
  FDA issued this major report identifying both the problems and potential solutions to the daunting task of ensuring that the unprecedented breakthroughs in medical science are demonstrated to be safe and effective for patients as quickly and inexpensively as possible. Titled "Innovation or Stagnation? Challenge and Opportunity on the Critical Path to New Medical Products," the report carefully examines the "Critical Path" of medical product development -- the crucial steps that determine whether and how quickly a medical discovery becomes a reliable medical treatment for patients.
- **International Compilation of Human Subject Protections (PDF - 877KB)**
  OHRP/DHHS maintains and updates yearly the International Compilation of Human Subject Protections. The

Science & Research

Science and Research Special Topics
Clinical Trials and Human Subject Protection
Educational Materials

Does FDA Conduct GCP Training?

Yes, the Food and Drug Administration (FDA) conducts GCP training. As described below, the agency conducts some GCP training on site, but also partners with other federal agencies and organizations across the United States to conduct additional training. FDA also has recently made GCP training available online.

In the fall of 2009, FDA's Critical Path Initiative launched a Clinical Investigator Training Course targeted at medical professionals who participate in FDA-regulated clinical trials. This 3-day course includes lectures given by senior FDA experts and guest lecturers from industry and academia. It provides FDA's perspectives on new safety concerns, adverse event monitoring, compliance with legal and ethical obligations of clinical research, and acceptable scientific and analytic standards in clinical study design and conduct. See FDA's Clinical Investigator Training Course for further information.

Throughout the year, FDA district offices co-sponsor two-day workshops with the Society of Clinical Research Associates (SoCRA). These conferences are entitled, "FDA Clinical Trial Requirements, Regulations, Compliance, and GCP Conference." FDA personnel from both the co-sponsoring district office and headquarters participate in these workshops. Locations and dates for future workshops are available at the SoCRA website. FDA personnel, from both headquarters and the district offices, also regularly present at meetings of various professional organizations. In addition to SoCRA, these include the Drug Information Association (DIA), Public Responsibility in Medicine and Research (PRIM&R), the Association of Clinical Research Professionals (ACRP), the Regulatory Affairs Professionals Society (RAPS), and others.

FDA routinely collaborates with the Office for Human Research Protections and the Department of Veterans Affairs on regional programs focused on human subject protection in regulated research. Information about these programs is available at:

- The Educational Materials/Workshops page on FDA's Good Clinical Practice Web site
- The Conferences page on the Office for Human Research Protections Web site

Both the Center for Drug Evaluation (CDER) and the Center for Devices and Radiological Health (CDRH) provide online training relevant to clinical trials on their respective websites. These training programs are accessible at CDERLearn and CDRH Learn respectively.

Other agencies in the Department of Health and Human Services do provide training in this area:

- Online training on human subject protection is provided by the Office for Human Research Protections.
- Clinical Research Training is a course developed by the National Institutes of Health to train its own investigators. It may be accessed by others to enhance their knowledge of clinical research.

Finally, there are numerous references related to good clinical practice (GCP) and human subject protection (HSP), available on FDA's website, including:

- FDA's GCP and HSP regulations found in Title 21 of the *Code of Federal Regulations*, Parts 50, 54, 56, 312, and 812
- the preambles related to these regulations
- ICH E6 Good Clinical Practice Consolidated Guidance [261KB PDF]
- FDA Information Sheets for IRBs and Clinical Investigators
- Compliance Program Guidance Manuals
- FDA guidance for industry: Finalized documents and draft guidance documents (and proposed regulations).

HSP/BIMO Initiative
Regulations
Report Problems to FDA
Complaints relating to Clinical trials
Guidance Documents (Including Information Sheets) and Notices
Proposed Regulations and Draft Guidances
Compliance & Enforcement
Educational Materials
Replies to Inquiries to FDA on Good Clinical Practice
FDA's Role: ClinicalTrials.gov Information

Compliance/Enforcement

Resources for You

- ClinicalTrials.gov (NIH)
- FDA Basics
- FDA Basics for Industry
- Laws Enforced by FDA
- Freedom of Information
- Dockets Management
- Approvals of FDA-Regulated Products
- Websites with Information About Clinical Trials

Adherence to the principles of good clinical practices (GCPs), including adequate human subject protection (HSP) is universally recognized as a critical requirement to the conduct of research involving human subjects. Many countries have adopted GCP principles as laws and/or regulations. The Food and Drug Administration's (FDA's) regulations for the conduct of clinical trials, which have been in effect since the 1970s, address both GCP and HSP. These FDA regulations and guidance documents are accessible from this site. International GCP guidance documents on which FDA has collaborated and that have been adopted as official FDA guidance are also be found here. Finally, this site includes links to other sites relevant to the conduct of clinical trials, both nationally and internationally.

Bioresearch Monitoring

FDA's bioresearch monitoring (BIMO) program conducts on-site inspections of both clinical and nonclinical studies performed to support research and marketing applications/submissions to the agency. Links to the compliance programs for each inspection type and contact information for each Center's BIMO program are also accessible from this site.

Office of Good Clinical Practice

n statement on

Sign up for Good Clinical Practice/Human Subject Protection e-mail updates

Implementation of CT.gov Databank

In June 2009, FDA redesigned its web site. As a result, some links (URLs) embedded within Guidance documents, Rules, and other documents are no longer valid. If you find a link that does not work, please try searching for the document using the document's title. For additional assistance, go to Contact FDA. We apologize for any inconvenience this redesign might have caused.

Workshops and Meetings

Guidance for Institutions and IRBs."

- Minutes of Institutional Review Board (IRB) Meetings: Guidance for Institutions and IRBs (November 2015)
- Acceptance of Medical Device Clinical Data from Studies Conducted Outside the United States - Draft Guidance for Industry and Food and Drug Administration Staff (PDF - 649KB)
- Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers (PDF - 110KB)
- FDA Announcement to extend the comment period on the draft guidance document entitled "Informed Consent Information Sheet"
- Informed Consent Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors (July 15, 2014)
- FDA's HSP/BIMO Initiative Accomplishments: Update June 2014
- Good Clinical Practice: Previous "In the News" Items

Contact FDA

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We're here to help…

Really!!!!!!!!

Thank you!

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