

OHRs Information Sheet How to Contact FDA

IND/IDE Contact Information

Questions about medical devices (other than GCP questions)

- www.fda.gov/cdrh/dsma/dsmastaf.html
- dsmica@cdrh.fda.gov
- Manufacturer's assistance: 800-638-2041
- Consumer assistance: 888-INFO-FDA
- Questions about whether a product is subject to IDE regulations: call 240-276-4040

Questions about drug products (other than GCP questions)

- Druginfo@cder.fda.gov
- 301-827-4570
- Questions about whether a product is subject to IND regulations: call 301-827-4570

Questions about biologics (other than GCP questions)

- Octma@cber.fda.gov (consumer oriented)
- Matt@cber.fda.gov (manufacturers's assistance)
- 301-827-2000
- Questions about whether a product is subject to IND regulations: call 301-827-2000

Good Clinical Practice Contacts

- [General Information](#) (Good Clinical Practice Program)
- [Biological Products](#) (Bioresearch Monitoring Branch, CBER)
- [Drug Products](#) (Division of Scientific Investigations, CDER)
- [Medical Devices](#) (Division of Bioresearch Monitoring, CDRH)
- [Enforcement Issues](#) (Office of Enforcement, ORA)

Good Clinical Practice Program (GCPP)

Members of GCPP staff:

- Joanne R. Less, Ph.D., Acting Director, Good Clinical Practice Program
- Patricia M. Beers Block, Special Assistant to the Director and Expert Consumer Safety Officer
- Carolyn Hommel, Expert Consumer Safety Officer
- David A. Lepay, M.D., Ph.D., Senior Advisor for Clinical Science

- Jean Toth-Allen, Ph.D., Biophysicist
- Sara F. Goldkind, M.D., Senior Bioethicist
- Marsha Melvin, Policy Analyst

Contact the Good Clinical Practice Program if you have:

- general questions about FDA good clinical practice regulations and policy
- general questions about the FDA clinical Bioresearch Monitoring Program, and specifically clinical investigator, Institutional Review Board (IRB), sponsor, monitor, and contract research organization programs
- questions about or suggestions related to [FDA's Information Sheets for IRB's and Clinical Investigators](#)
- questions about reports made pursuant to 21 CFR 56.108(b) and 56.113 involving an FDA-regulated product if you do not know which FDA Center has jurisdiction (e.g., drug, medical device, biological product), including:
 - unanticipated problems involving risks to subjects [21 CFR 56.108(b)(1)]
 - serious or continuing noncompliance by an investigator with FDA regulations or with the IRB's determinations [21 CFR 56.108(b)(2)]
 - suspension or termination of IRB approval of a protocol [21 CFR 56.108(b)(3)]

Questions about Good Clinical Practice

Submit questions via email, in writing, or direct them to our general telephone number. We try to respond to each question as soon as possible.

(Please note: FDA cannot comment about products that are in the review process. We cannot comment about clinical trials for specific products, diseases, or conditions. We cannot answer questions about when a new product subject to pre-market approval will be approved or not approved.)

E-mail: gcp.questions@fda.hhs.gov

Telephone: 301-827-3340

Facsimile: 301-827-1169

Write: Food and Drug Administration
Good Clinical Practice Program (HF-34)
Parklawn Building, Room 16-85
5600 Fishers Lane, Rockville, MD 20857

[Report Complaints
Related to Good
Clinical Practice in
FDA-Regulated
Clinical Trials](#)

Biological Products

Bioresearch Monitoring Branch
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research (CBER)
Telephone: 301-827-6221
Facsimile: 301-827-6748

Contact the Bioresearch Monitoring Branch for questions about:

- The legal status of a test article

- Human subject production regulations relating to biologics
- CBER assigned IRB inspections
- CBER assigned Clinical Investigator inspections
- Reports made pursuant to 21 CFR 56.108(b) and 56.113 involving a biologic product including:
 - unanticipated problems involving risks to subjects
 - serious or continuing noncompliance by an investigator with FDA regulations or with the IRB's determinations
 - suspension or termination of IRB approval of a protocol

Drug Products

Division of Scientific Investigations (DSI)

Office of Compliance

Center for Drug Evaluation and Research (CDER)

Contact DSI: www.fda.gov/cder/Offices/DSI/index.htm

Telephone: 301-796-3150

Fax: 301-847-8748

Contact the Division of Scientific Investigations for questions about:

- Human subject protection regulations pertaining to drugs (21 CFR Parts 50, 56, 312, 361)
- CDER-assigned IRB inspections (e.g., FDA-483's)
- Reports made pursuant to 21 CFR 56.108(b) and 56.113 involving a drug product including:
 - unanticipated problems involving risks to subjects [21 CFR 56.108(b)(1)]
 - serious or continuing noncompliance by an investigator with FDA regulations or with the IRB's determinations [21 CFR 56.108(b)(2)]
 - suspension or termination of IRB approval of a protocol [21 CFR 56.108(b)(3)]
- reporting complaints related to human subject protection/Good Clinical Practice in FDA-regulated drug trials

Medical Devices

Division of Bioresearch Monitoring

Office of Compliance

Center for Device and Radiological Health (CDRH)

Phone: 240-276-0125

Fax: 240-276-0128

Web site: www.fda.gov/cdrh/comp/bimo.html

Contact the Division of Bioresearch Monitoring for questions about:

- Human subject protection regulations pertaining to devices [21 CFR Parts 50, 56, and 812]
- Informed consent, standard operating procedures, records and reports
- Serious or continuing noncompliance by an investigator with FDA regulations or with the IRB's determinations involving a medical device [21 CFR 56.108(b)(2)]
- Reporting complaints related to human subject protection/Good Clinical Practice in FDA-regulated medical device trial

Enforcement Information

Division of Compliance Policy

Office of Enforcement

Office of Regulatory Affairs

Telephone: 240-632-6800

Fax: 240-632-6810

Contact the Division of Compliance Policy for questions about:

- questions about the overall FDA Bioresearch Monitoring Program, and specifically the Good Laboratory Practice (GLP, nonclinical laboratories) Program
- general Bioresearch Monitoring program enforcement issues