

Regulations and Guidance

Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services: OHRP Home Page <http://www.hhs.gov/ohrp/>

- [45 CFR 46](#) Federal Policy for the Protection of Human Subjects (Basic DHHS Policy for Protection of Human Research Subjects)
- [FWA Program](#) [Federal Wide Assurance Program](#) - The Federal Policy (Common Rule) for the protection of human subjects at requires that each institution "engaged" in Federally-supported human subject research file an "Assurance" of protection for human subjects. The Assurance formalizes the institution's commitment to protect human subjects. The requirement to file an Assurance includes both "awardee" and collaborating "performance site" institutions.
- [FWA Instructions](#) This is a link to step-by-step instructions for how to file an FWA in the USA and the actual form:
- [HIPAA](#) Office of Civil Rights (OCR) - The Department of Health and Human Services, through the Office for Civil Rights enforces the privacy rule, Health Insurance Portability and Accountability Act (HIPAA)
- [Financial Relationships](#) The Department of Health and Human Services (HHS) announces a final guidance document for Institutional Review Boards (IRBs), investigators, research institutions, and other interested parties, entitled "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Protection".
<http://www.hhs.gov/news/press/2004pres/20040512.html>.
<http://ohrp.osophs.dhhs.gov/humansubjects/finreltn/finalguid.pdf>
- [Coded Private Information or Specimen](#) This is a link to a document applying to research involving coded private information or human biological specimens that is conducted or supported by (HHS)Department of Health and Human Services.
<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>
- [Decision Charts](#) The Office for Human Research Protections (OHRP)provides graphic aids as a guide for institutional review boards (IRBs), investigators, and others who determine whether an activity is research involving human subjects that require review by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS)

regulations at 45 CFR part 46.

<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>

[International
Guidance](#)

The Office for Human Research Protections has developed an International Compilation of Human Research Protections which lists the laws, regulations, and guidelines of over 50 countries where DHHS funded or supported research is conducted.

<http://www.hhs.gov/ohrp/international/index.html#NatIPol>

U.S. Food and Drug Association (FDA) - FDA Home page <http://www.fda.gov>

FDA Industry Portal <http://www.fda.gov/oc/industry/>

Center for Drug Evaluation in Research (CDER) <http://www.fda.gov/cder/>

Center for Devices and Radiological Health Devices (CDRH) <http://www.fda.gov/cdrh/index.html>

Pediatric Medical Devices <http://www.fda.gov/cdrh/pediatricdevices/>

Center for Biologics Evaluation in Research (CBER) <http://www.fda.gov/cber/index.html>

[21 CFR 50](#)

Protection of Human Subjects, including general requirements for Informed Consent

[21 CFR 54](#)

Financial Disclosure by Clinical Investigators

[21 CFR 56](#)

Institutional Review Boards

[21 CFR 312](#)

Investigational New Drug Application

[21 CFR 812](#)

Investigational Device Exemptions

[Monitoring Clinical Trials](#)

FDA Guidance for Monitoring Clinical Investigations. The purpose of this guideline is to present acceptable approaches to monitoring clinical investigations.

[Guidance for Institutional
Review Boards and Clinical
Investigators 1998 Update](#)

This document represents the agency's current guidance on protection of human subjects of research. It is published as Level 2 guidance in accordance with the FDA "Good Guidance Practices."

[FDA Information Sheets](#)

FDA Information Sheets, Guidance for Institutional Review Boards, and Clinical Investigators

[Humanitarian Use Device](#)

Guidance compiled by CRRI.

HIPAA

CRRRI releases [Guidance for Obtaining Authorization for the Use of Protected Health Information](#).

CRRRI Releases HIPAA FAQ

Privacy Rule basic terms, Consent, Recruitment, and Adverse Events

This [HIPAA FAQ](#) document addresses commonly asked HIPAA questions.

CRRRI Releases [HIPAA Privacy Rule Authorization Agreement Template](#)

Additional HIPAA information may be found in the following online resources:

[HHS HIPAA FAQs](#)

[Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule](#)

[NIH HIPAA FAQs](#)

[California Office of HIPAA Implementation](#)

National Institutes of Health (NIH) <http://www.nih.gov>

- NIH Office of Biotechnology Activities has published a resource on informed consent in gene transfer research. <http://www4.od.nih.gov/oba/rac/ic/>
- NIH policy on the inclusion of women and minorities as subjects in clinical research [Guidelines on Women and Minorities](#)
- Guidelines on the inclusion of children in research involving human subjects, including, but not limited to, clinical trials, supported or conducted by the NIH. [Inclusion of Children Policy Implementation](#)
- A statement from NIH offering points to consider to assist IRBs and clinical investigators in their efforts to protect research participants who are or may become decisionally impaired. [Research Involving Individuals with Questionable Capacity to Consent: Points to Consider](#)
- Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. <http://grants1.nih.gov/grants/policy/coc/index.htm>

International Organizations

GCP - Good Clinical Practices

<http://www.fda.gov/oc/gcp/>

ICH Good Clinical Practices (GCP) - This is a link to the FDA division responsible for overseeing Good Clinical Practice (GCP). GCP is a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials.

International Conference on Harmonisation (ICH)

<http://www.ich.org/>

This website offers access to all guidance documents produced by ICH

Council For International Organizations of Medical Sciences

<http://www.cioms.ch>

The Council for International Organizations of Medical Sciences (CIOMS) is an international, non-government, non-profit organization established jointly by WHO and UNESCO in 1949.

World Medical Association

<http://www.wma.net>

The World Medical Association (WMA) is an international organization representing physicians. The organization was created to ensure the independence of physicians, and to work for the highest possible standards of ethical behavior and care by physicians, at all times.

International Association of Bioethics

<http://www.bioethics-international.org>

The International Association of Bioethics aims to be truly international, linking all those working in bioethics and related fields, facilitating mutual contacts, and encouraging the discussion of cross-cultural aspects of bioethics.

International Bioethics Committee, United Nations Educational and Cultural Organization

<http://www.unesco.org/ibc/>

The main objective of UNESCO is to contribute to peace and security in the world by promoting collaboration among nations through education, science, culture and communication in order to further universal respect for justice, for the rule of law and for the human rights and fundamental freedoms which are affirmed for the peoples of

the world, without distinction of race, sex,
language or religion, by the Charter of the United
Nations.
