

Good Clinical Research Practice and Human Subject Protection

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Center for Cancer Research, NCI*



Human Subjects Protection

- **Laws, regulations, guidances**
- **Conducting ethical research**
- IRB process
- Informed consent process
- Manage COIs
- Maintain privacy and confidentiality
- Data and safety monitoring

Good Clinical Practice (GCP)

- Standards meant to ensure the rights and well-being of the patient are protected and quality data is provided
- Provides ethical and quality research
- Responsibility for GCP shared by all members of any clinical research enterprise

HSP + Quality Data = GCP

Good Clinical Practice (GCP)

- Compliance with GCP
 - Provides the public with the assurance that the rights, safety and welfare of the subjects are protected and respected
 - Advance scientific knowledge by ensuring data generated by the study trial is accurate, verifiable, and reproducible
- GCP standards are found in both regulations and guidelines
 - Which regulations/guidances to follow depend on the type of research and funding

The Secretary
Deputy Secretary

Chief of Staff

Executive Secretary

Director, Intergovernmental Affairs, & Secretary's Regional Representatives

OHRP

Assistant Secretary for Health

Assistant Secretary for Administration & Management

Assistant Secretary for Budget, Technology, & Finance

Assistant Secretary for Planning & Evaluation

Assistant Secretary for Legislation

Assistant Secretary for Public Affairs

Assistant Secretary, Administration for Children and Families (ACF)

Assistant Secretary, Administration on Aging (AoA)

Administrator, Centers for Medicare & Medicaid Services (CMS)

Director, Agency for Healthcare Research and Quality (AHRQ)

Director, Centers for Disease Control and Prevention (CDC)

Administrator, Agency for Toxic Substances and Disease Registry (ATSDR)

Commissioner, Food and Drug Administration (FDA)

Administrator, Health Resources and Services Administration (HRSA)

Director, Indian Health Service (IHS)

Director, National Institutes of Health (NIH)

Administrator, Substance Abuse and Mental Health Svcs. Administration (SAMHSA)

Director, Program Support Center (PSC)

General Counsel

Office of Public Health Emergency Preparedness

Director, Center for Faith-Based and Community Initiatives

Director, Office for Civil Rights

Inspector General

Chair, Departmental Appeals Board

Director, Office of Global Health Affairs



Which Agencies' Regulations Does the NIH IRP Follow?

Laws, Regulations & Guidances

- Laws
 - Legislative Branch (Congress)
 - Published in the United States Code
- Regulations
 - Executive Branch (Departments & Agencies)
 - Published in the Code of Federal Regulations
- Guidances
 - Agencies
 - Published in the Federal Register

BINDING

Not Binding

Regulations

- DHHS: CFR 45 Part 46
- FDA: CFR 21 Parts 50, 56, 312, 812
- Regulations are open to interpretation
 - 45 CFR 46, Office for Human Research Protections (OHRP) is the interpreter
 - 21 CFR and its subparts are interpreted by the FDA

OHRP: 45 CFR 46

- Regulates protection of human subjects in most federally funded research
- Subpart A: Protection of Human Subjects (1974, revised in 1981, 1991, 2001)
 - Referred to as the Common Rule (1991)

OHRP: 45 CFR 46: Subparts B-D

- Subpart B*: Pregnant Women, Human Fetuses and Neonates in Research (11/13/2001)
- Subpart C*: Biomedical and Behavioral Research Involving Prisoners as Subjects (11/16/1978)
- Subpart D*: Children Involved as Subjects in Research (3/8/1983)

** Recognized as vulnerable population*

FDA: 21 CFR 50 & 56

FDA regulations finalized in Jan, 1981 to be congruent with 45 CFR 46

- 21 CFR Part 50: Protection of Human Subjects focuses on informed consent
- 21 CFR Part 56: Institutional Review Boards describes roles and functions
- Recognizes children as a vulnerable population

45 CFR vs. 21 CFR

- Minor—different missions
- 45 CFR covers all federally funded research by agencies who are signatories to the Common Rule
- 21 CFR covers research on products regulated by the FDA—does not have to be federally funded

FDA Guidances

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

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Regulatory Information

Home > Regulatory Information > Guidances



Guidances
FDA Guidance Documents: General and Cross-Cutting Topics
Advisory Committee Guidance Documents
Clinical Trials Guidance Documents
Combination Products Guidance Documents
Import and Export Guidance Documents
International Conference on Harmonisation (ICH) Guidance Documents
Veterinary International

Guidances

 [Sign up for Guidance Documents email updates.](#)

Guidance documents represent FDA's current thinking on a topic. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations.

If you believe an FDA employee is not following FDA's Good Guidance Practice regulations (21 CFR 10.115) or the Office of Management and Budget's Bulletin No. 07-02(M-07-07) Final Bulletin for Agency Good Guidance Practices (January 18, 2007), you should contact the employee's supervisor in the issuing office or Center. If the issue is not resolved, contact the next highest supervisor or the Center's Ombudsman. If the issue is still not resolved, contact the FDA's Office of the Ombudsman at:

10903 New Hampshire Avenue
WO 32, Room 4231
Silver Spring, MD 20993
Phone: 301-796-8530
Fax: 301-847-8628
Email: Ombuds@oc.fda.gov

Guidance by Topic

- [General and Cross-Cutting Topics](#)
- [Animal and Veterinary](#)
- [Biologics](#)
- [Color Additives](#)
- [Cosmetics](#)
- [Drugs](#)
- [Food](#)
- [Medical Devices](#)
- [Radiation-Emitting Products](#)
- [Tobacco Products](#)

OHRP Guidances

Policy & Guidance

Welcome to the OHRP Policy and Guidance library!

OHRP has published a variety of policy and regulatory guidance materials to assist the research community in conducting ethical research that is in compliance with the HHS regulations. These include guidance documents and frequently asked questions (FAQs) addressing various topics, findings in the form of OHRP letters addressing regulatory issues, and other media including decision tree graphics and educational videos.

To facilitate access to this library, materials are organized into categories that should be intuitive for the research community, and are also listed alphabetically below under Policy Index. Location of a particular item within a category does not suggest that it may not be relevant to other users or under other categories, and in some instances items are cross-referenced. However, in most cases we expect that users should be able to quickly locate items of interest. The following provides a quick guide:

- **Policy Index** provides an alphabetical list of all individual documents, as a way to conveniently access policy and guidance material.
- **Informed Consent** groups documents that address autonomy and consent issues.
- **Institutional Issues** groups documents that will be of particular concern to institutions, such as management of an IRB and conduct of IRB meetings, determination of institutional-level engagement in human subjects research, and institutional reporting requirements.
- **For Investigators** groups documents that will be of particular interest to research investigators, such as how to handle subject withdrawal from a protocol, how to assess unanticipated problems and adverse events that may occur during the conduct of research, and the general responsibilities of research investigators.
- **Vulnerable Populations** includes guidance addressing vulnerable groups such as children, prisoners, and subjects for whom a certificate of confidentiality may offer appropriate additional protections.
- **Biological Materials & Data** groups OHRP's guidance addressing issues such as research using human subjects data and biological samples, and application of the Genetic Information Nondiscrimination Act (GINA) in research.
- **Protocol Review** groups information addressing the categories and criteria for approval of human subjects research under the HHS regulations, including guidance on exempt and expedited review determinations and continuing review.
- **Frequently Asked Questions** groups all sets of frequently asked questions in one place. The questions also appear with the category to which they relate.
- **Checklists & Decision Trees** groups decision charts and checklists that have been developed for the IRB community.

All documents in the Policy and Guidance section of the OHRP website reflect current regulatory guidance and findings, including older materials published by OHRP's predecessor organization, the Office for Protection from Research Risks.

OHRP Home

About OHRP

Regulations

Policy & Guidance

Policy Index

Informed Consent

Institutional Issues

For Investigators

Vulnerable Populations

Protocol Review

Biological Materials & Data

Frequently Asked Questions

Correspondence

Checklists & Decision Trees

IRBs & Assurances

International

Compliance Oversight

Education

Advisory Committee (SACHRP)

News Room

Archived Materials

Contact OHRP

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceutical for Human Use (ICH)

- Drug regulatory authorities + representatives from pharmaceutical trade associations in Europe, Japan, and the U.S.
- Mission: to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration, thereby reducing duplication of testing and reporting carried out during the research and development of new medicines.

ICH Standards

- 4 major categories of standards are:
 - Quality guidelines
 - chemical and pharmaceutical Quality Assurance
 - Safety guidelines
 - in vitro and in vivo pre-clinical studies
 - Efficacy guidelines
 - clinical studies in human subject
 - E2: data management
 - E6: **Good Clinical Practice (GCP) Guidelines**
 - Multidisciplinary guidelines
 - cross-cutting topics that do not fit into one of the above categories

ICH



[Contact](#) [Glossary](#) [FAQs](#) [Log In](#)

Q S E M



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Training

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Welcome to the ICH official website

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry of Europe, Japan and the US to discuss scientific and technical aspects of drug registration. Since its inception in 1990, ICH has evolved, through its ICH Global Cooperation Group, to respond to the increasingly global face of drug development, so that the benefits of international harmonisation for better global health can be realised worldwide. ICH's mission is to achieve greater harmonisation to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. Download the [ICH 20th Anniversary Publication](#)

Discover ICH Products



Safety Guidelines

ICH has produced a comprehensive set of safety guidelines to uncover potential risks like carcinogenicity, genotoxicity and reprotoxicity. A recent breakthrough has been a non-clinical testing strategy ... [\(more\)](#)

[View All Safety Guidelines](#)

Help to Shape the ICH Guidelines

by responding to one of our consultations. Your contribution will then be considered by the relevant ICH Working Group.

[Draft Guidelines](#)
[Q&A Documents](#)



Recent News

17 September 2013

[Publication of Brochure: Understanding MedDRA](#)

The brochure provides a comprehensive introduction to

Sections of E6

- Glossary of terms
- Principles of ICH GCP
- Institutional Review Board (IRB)/Independent Ethics Committee (IEC)
- Investigator
- Sponsor
- Clinical Trial Protocol and Protocol Amendment(s)
- Investigator's Brochure (IB)
- Essential Documents for the Conduct of a Clinical Trial
 - Site (also known as the Regulatory Binder)
 - Sponsor

**MILESTONES IN THE
HISTORY OF HUMAN
SUBJECTS PROTECTION:**

CAN YOU NAME A FEW?

Nuremberg Code (1947)



- Voluntary consent
- Anticipate scientific benefits
- Benefits outweigh risks
- Animal experiments first
- Avoid suffering
- No intentional death or disability
- Protection from harm
- Subject free to stop
- Qualified investigators
- Investigator will stop if harm occurs

1964: World Medical Association's Declaration of Helsinki

- Statement of ethical principles to guide physicians and other participants in medical research involving human subjects, including medical research on identifiable human material or identifiable data
- Continues to be revised
- Built upon the 10 principles of the *Nuremberg Code* and added that:
 - Interest of the subject should always be given a higher priority than the interests of society
 - Every subject in clinical research should get the best known treatment

1966: NIH Guidelines for Federally Funded Research on Human Experiments

- Institutions receiving NIH funds had to create a committee not connected to the research project to review the study and the informed consent
- Committee tasked with prospectively reviewing studies for:
 - potential risks and benefits of the research
 - methods used to obtain patient consent
- Members were mostly other research physicians, though a few included lawyers and clergy
- Research was no longer based on just the judgment of individual investigators
- For the first time, researchers had to answer to federal regulations and mandatory peer review

Beecher Article

Beecher, H.K. (1966). Ethics and Clinical Research. *New England Journal of Medicine*, 274, 1354-1360.



Henry Knowles Beecher
1904-1976

First time that respected member of the research community focused attention on the need to improve the ethical standards for conducting clinical research in the U.S.

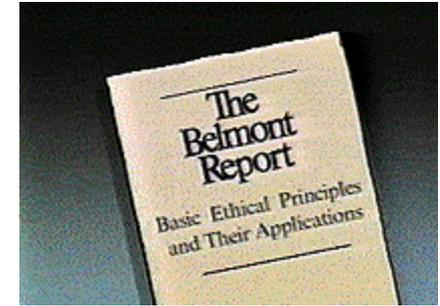
Events Leading to 1973 Congressional Hearings

- Willowbrook Hepatitis Studies (1950's)
- Jewish Chronic Disease Hospital Studies (1960's)
- Milgram Studies of Obedience to Authority (early 1960's)
- San Antonio Contraception Study (early 1970's)
- Tearoom Trade Study (early 1970's)
- Tuskegee (1930's-1970's)

Congressional Hearings and the National Research Act

- Congressional Hearing on the Quality of Health Care and Human Experimentation: 1973
 - Consensus: Federal oversight was required to protect rights and welfare of research subjects
- National Research Act: 1974
 - Established the National Commission for protection of Human Subjects of Biomedical and Behavioral Research
 - 1979 Belmont Report
 - DHHS Policies were codified in 1974 as 45 CFR Part 46, Subpart A

Belmont Report (1979)



- Medical practice vs. Research
- Ethical principles guiding human subjects research
 - Respect for persons
 - Beneficence
 - Distributive justice

Application of the Belmont Report

Principle	Application
Respect for Persons <ul style="list-style-type: none">• Individuals are autonomous agents.• Individuals should be treated with respect• Persons with diminished autonomy need additional protection.	
Beneficence <ul style="list-style-type: none">• Human participants should not be harmed.• Research should maximize possible benefits and minimize possible risks.	
Justice <ul style="list-style-type: none">• The benefits and burdens of research must be distributed fairly.	

Application of the Belmont Report

Principle	Application
<p>Respect for Persons</p> <ul style="list-style-type: none">• Individuals are autonomous agents.• Individuals should be treated with respect• Persons with diminished autonomy need additional protection.	<p>Informed Consent</p> <ul style="list-style-type: none">• Participants must be given the opportunity to choose what shall or shall not happen to them• The consent process must include three elements:<ul style="list-style-type: none">• Information sharing• Comprehension• Voluntary participation
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Beneficence <ul style="list-style-type: none">• Human participants should not be harmed.• Research should maximize possible benefits and minimize possible risks.	<ul style="list-style-type: none">• Assessment of risks and benefits by investigator and IRB
Justice <ul style="list-style-type: none">• The benefits and burdens of research must be distributed fairly.	Selection of participants <ul style="list-style-type: none">• Fair procedures and outcomes in the selection of research participants• Eligibility criteria should include those who may benefit and exclude those who may be harmed

1999: A Bad Year for CTs

- Death on Gene Therapy Trial
- Veterans Administration
- Duke University Medical Center
- Outcome:
 - The Office of Human Research Protections (OHRP) was established in 2000 with the US Department of Health and Human Services to increase the focus on protecting human research participants. Former name: Office for Protection from Research Risks (OPRR) and limited to NIH funded research.

Havasupai Case

- Researchers used samples in multiple studies unrelated to diabetes, sharing them with other investigators.
- Examined several genes (schizophrenia, metabolic disorders, alcoholism)
- Two dozen publications based upon the blood samples
 - Many didn't match what subjects thought they donated blood for

Essential Elements of Ethical Research

Eight Elements of Ethical Research:

- Valuable scientific question
- Valid scientific design and methodology
- Fair subject selection
- Balance of risks and benefits
- Independent review
- Informed consent
- Respect for enrolled subjects
- Collaborative partnerships

Emanuel, E.J., Wendler, D., Killen, J., Grady, C. (2004). What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research. *Journal of Infectious Disease*, 189(5):930-937.

Where do the 7 principles come from?

- Nuremberg Code
- Declaration of Helsinki
- Belmont Report
- International Conference on Harmonization
 - GCP Guidelines
- The Common Rule (US 45CFR46 Part A)
- FDA regulations 21CFR parts 50 & 56

Human Research Protections Program (HRPP)

- Research *involving humans* at the NIH is under the Human Research Protections Program (HRPP) of the IRP
- Office of Human Subjects Research Protections ([OHSRP](#)) supports the Institutional Official for the NIH to:
 - Provide policy development
 - Regulatory oversight of the HRPP

NIH Officials lead the NIH HRPP?

The Institutional Official: Michael Gottesman, MD,
Deputy Director of NIH for Intramural Research (DDIR)

Steve Holland, MD,
Deputy Director for Intramural Clinical Research
(DDICR)

Lynnette Nieman, MD, Director,
Office of Human Subjects Research Protections
(OHSRP)

Charlotte Holden, JD, Deputy Director
Office of Human Subjects Research Protections
(OHSRP)

HRPP

HUMAN RESEARCH PROTECTIONS PROGRAM

Intramural Research Program

Home



NIH Intramural Research Resources

This resource is for the NIH Research Staff of the Intramural Research Program (IRP)

Information about the NIH Intramural Research Program (IRP) Human Research Protections Program (HRPP)

[Human Research Protection Program](#) *(NIH login required)*

NIH Federalwide Assurance

FWA#: 00005897
Expires: 2/25/2014



Other Investigators and NIH Grantees

This resource is for persons not employed by the NIH

Investigators who receive NIH Extramural Research grants, also known as, "Grantees" should contact the [NIH Office of Extramural Research \(OER\)](#) for more information



Participate in Clinical Studies

For more information about becoming a research volunteer, select the links below:

[Participate in Clinical Studies at the NIH](#)

[Search for Clinical Trials](#)

Contact us if you have questions or concerns about the NIH Human Research Protection Program (HRPP):

Office of Human Subjects Research Protections (OHSRP)
Building 10, (The Warren G. Magnuson Clinical Center)
Room 2C146, Bethesda, MD 20892-1154

Phone: 301-402-3444
Fax: 301-402-3443

External Resource Links

[ClinicalTrials.gov](#)

[FDA](#)

<http://ohsr.od.nih.gov/>



Human Research Protection Program

NIH Federalwide Assurance
FWA#: 00005897
Expires: 2/25/2014
Go to the OHRP [search page](#) for additional information

The Human Research Protection Program promotes the rights and welfare of human subjects who participate in research conducted by the Intramural Research Program (IRP) of the NIH

[About the HRPP](#)

Office of Human Subjects Research Protections

This office sets the policy and provides regulatory oversight for the HRPP

[Policies and NIH Standard Operating Procedures](#)

Required HRPP Training

NIH IRP Investigators, Research Team Members, IRB Members and OHSRP Staff should select the link below to access the HRPP Training site

[Required HRPP Training](#)



NIH Intramural IRBs

Click the link below to contact each NIH Intramural Institutional Review Board (IRB) Office

[NIH IRB Offices](#)

Committees

[IRB Professional Administrators Committee \(IPAC\)](#)

[Human Subjects Research Advisory Committee \(HSRAC\)](#)

NIH IRB Members

[NIH IRB Member Tools](#)

[NIH IRB Member Training](#)



Investigator Resources

Information and resources for investigators and research staff conducting research in the NIH Intramural Research Program (IRP)

[Guidelines for Research Involving Humans](#)

[Forms, Templates and Tools](#)

NIH Resources

[NIH Resource Links](#)

Regulations and Ethical Guidance

Office of Human Research Protections (OHRP)

[45 CFR 46- The Common Rule](#)

[The Belmont Report](#)

[Search for Federalwide Assurances](#)

[Guidance](#)

Food and Drug Administration (FDA)

[21 CFR 50-Informed Consent and Children](#)

[21 CFR 56- Institutional Review Boards](#)

LATEST NEWS:

PLEASE NOTE: The CITI Training Site has been restored. Access CITI training from "Required HRPP Training" page

New! See "Policies and NIH Standard Operating

Contact OHSRP

Office of Human Subjects Research Protections (OHSRP)
Building 10, (The Warren G. Magnuson Clinical Center)
Room 2C148, Bethesda, MD
20892-1154

Phone: 301-402-3444
Fax: 301-402-3443

External Resources

[ClinicalTrials.gov](#)

[FDA](#)

[OHRP](#)

<https://federation.nih.gov/ohsr/nih/index.php>

SOP #25: Training

- Clinical researchers and clinical research support staff are required to have training commensurate with their roles and responsibilities.
- IRBs may require additional training for investigators who do not demonstrate understanding of specific areas or when investigators undertake a new type of research

Home > Required HRPP Training

Welcome to the NIH HRPP Training Access Page

Introduction

Instructions

Please review the types of research below and click the link below the category that is the best match for the type of research you conduct.

Training Cycle and Proof of Training

All new research staff must complete training before participating on a protocol submitted to an NIH IRB for review. You will need to provide proof of training if you have already completed the Clinical Research Training, the NIH Research Ethics Course and/or GCP training.

Refresher training is required every 3 years.

OHSRP maintains a database of completed training records that will be accessible to NIH Investigators, Clinical Directors, IRB office staff, Protocol Navigators and Human Research Protections Program (HRPP) staff. However, you should download and retain completion certificates for all courses that you complete successfully.

[Search for Completed Training Records](#)

Policy

The policy regarding training requirements for research staff of the NIH Intramural Research Program is addressed in HRPP SOP 25. For more

<https://federation.nih.gov/ohsr/nih/investigator-training.php>



Types of Research



Clinical Research

Clinical research is defined as research with humans that involve interactions or interventions. This includes: studies of healthy physiology or mechanisms of disease; therapies or interventions for disease; clinical trials; or studies to develop new technologies related to disease. Studies may or may not involve FDA-regulated research. Identifiable specimen or data collections or repositories that support clinical research also are included under this category of research.

Training:

If you are a Principal Investigator, Associate Investigator, Research Contact, Study Coordinator or a person who obtains informed consent select the link below:

- [Clinical Research Staff](#)



Epidemiological and Behavioral Research

Epidemiological or Behavioral Research investigates individual or group characteristics or behavior including: collections of data from voice, video, digital, and imaging recordings; research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices or social behavior; research employing survey, interview or oral history, focus groups; or human factor evaluation. Identifiable specimen or data collections that support behavioral or epidemiological study are also included under this category of research.

Training:

If you are a Principal Investigator, Associate Investigator, Research Contact, Study Coordinator or a person who obtains informed consent select the link below:

- [Epidemiological or Social Behavioral Research Staff](#)



Clinical Research

Instructions

Training is based on your role or the type of research you conduct. For example, clinical research staff that conduct FDA-regulated research must take a Good Clinical Practice (GCP) course, while clinical research staff that conduct natural history studies or only obtain informed consent do not.

Review the categories below to determine which courses you are required to complete. Additionally, review the Just-in-Time and optional courses. Just-in-Time courses are quick 10-15 minute courses that can be taken before starting a protocol that involves special populations such as children or genetic or stem cell research. Your IC may have additional training requirements.

Refresher courses are required every 3 years.

Download and retain completion certificates for all courses that you complete successfully.

Required Courses

Clinical Research Staff conducting FDA-regulated Research (involving an IND, BB IND, IDE or ITP)

- Either the NIH Clinical Research Training (CRT) course without the regulatory module or CITI Biomedical module; or Ethical and Regulatory Aspects of Clinical Research offered annually

CITI Training Information

- There is a test-out option for the following CITI module: CITI Good Clinical Practice
- To test-out of a required course, the user must score 80% in the required content area.
- Modules take 20-30 minutes to complete.
- If the user cannot complete training, the user should complete the current module and return to the course at a later time.
- The user must achieve a score of 80% for each module quiz in order to receive a Certificate of Completion for each module.
- If you have taken CITI courses at another institution in the last 12 months and would like credit for those



Just-in-Time or Optional Courses

Just-in-Time CITI courses will be required if you conduct research involving these areas, but are otherwise optional. Note that the GCP courses are optional, if you do not conduct FDA-regulated research.

Just-in-Time CITI courses:

- Biomedical- Vulnerable Subjects - Research with Children
- Biomedical- Vulnerable Subjects- Research with Pregnant Women, Human Fetuses or Neonates
- Biomedical- Vulnerable Subjects- Research with Prisoners
- Biomedical- Vulnerable Subjects- Workers/Employees
- Genetic Research in Human Populations
- Stem Cell Research Oversight
- International Studies- ICH Overview and ICH- Comparison Between ICH GCP E6 and US FDA Regulations

Training Links

- [Clinical Research Training Course](#)
- [NIAID GCP Training](#)
- [CITI Courses](#)
- [Ethical and Regulatory Aspects of Clinical Research offered annually by CC Bioethics](#)

[Back to Top](#)

Education credits for a fee for more information select "CME/CEU Credits" by your completed course work on the CITI landing page.

What is AAHRPP?

The Association for the Accreditation of Human Research Protection Programs, (AAHRPP) promotes high-quality research through an accreditation process that helps organizations worldwide strengthen their human research protection programs (HRPPs).

Why Did the NIH pursue accreditation?

- To undergo a comprehensive self-evaluation to ensure that NIH follows federal regulations and local policies in a uniform way
- To set policies in writing if they do not exist
- To streamline processes
- To harmonize IRB and IC processes and policies
- To identify and disseminate best practices

Summary

- Conduct research according to GCP, laws, regulations, guidances
- Conduct ethical research
- Understand our HRPP including:
 - SOPs
 - Training requirements
 - AAHRP accreditation