

# Human Research Protections

## U.S. Perspectives

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# Objectives

- U.S. Regulations
- IRB Registration
- FWA

# U.S. Regulations

# **National Research Act**

**1974**

**Office for Protection  
from Research Risks  
(OPRR)**

**1974**

**45 CFR 46  
Subpart A**

**1981**

**45 CFR 46**  
**Subpart A,B,C,D**

**1983**

# 45 CFR 46

- Subpart A -- Basic Protections
- Subpart B -- (1975) Pregnant Women, Fetuses, Human In Vitro Fertilization
- Subpart C -- (1978) Prisoners
- Subpart D -- (1983) Children

**Federal Policy for the Protection of  
Human Subjects  
(45 CFR 46 Subpart A)**

**The “Common Rule”**

**June 18, 1991**

**17 Departments and Agencies**

# **Office for Human Research Protections (OHRP)**

**2000**

# Food and Drug Administration



## Regulations:

- IRB - 21 CFR 56
- Informed Consent - 21 CFR 50

# Health and Human Services (HHS) vs. FDA Regulations

- **Basic requirements** for IRBs and for Informed Consent are **congruent**
- **Differences** center on differences in **applicability**
  - HHS regulations based on **federal funding** of research
  - FDA regulations based on use of FDA **regulated product**: drugs, devices, or biologics

**FDA**

A Venn diagram consisting of two overlapping circles. The left circle is blue and contains the text 'FDA'. The right circle is pink and contains the text 'DHHS'. The overlapping area between the two circles is labeled with the text 'IRB'.

**I  
R  
B**

**DHHS**

# Assurances

- “Each institution **engaged** in research which is covered by this policy and which is conducted or supported by a Federal Department or Agency shall provide **written assurance** ... that it will **comply** with the requirements set forth in this policy.” [45 CFR 46.103(a)]
- Approved by **OHRP**

# Assurances

- The institution must **certify** that the research has been reviewed and approved by an IRB.  
[45 CFR 46.103(b)]
- Submitted to funding agency

# Assurances

What is an Institutional Assurance?

- Documentation of institutional **commitment** to comply with the Common Rule
- Principal **method of compliance** oversight

# Assurances

- Required from each institution “engaged” in the research
  - See OHRP guidance on when institutions are engaged in research:

<http://ohrp.osophs.dhhs.gov/humansubjects/assurance/engage.htm>

# IRB Registration System

# IRB Registration System - cont'd.

- All Registered IRBs will be Informed of New Guidance/Updates/Regs.
- Can Track Registered IRBs on OHRP Website

# Federal Wide Assurance (FWA)

# OHRP Federalwide Assurance

- Single Assurance Document
- 1 Institution = 1 Assurance\*
  - \*some international exceptions
- International Standards OK

# OHRP Federalwide Assurance

- All Institutions Eligible
- Web-Based
- IRB Registration
- Rely on own institutional IRB, other institutional IRB, commercial

# OHRP Federalwide Assurance

- No OHRP review of individual applications, protocols, consent documents
- Recommended completion of OHRP Assurance Training Modules (not considered education training)

# OHRP Federalwide Assurance

## Education Training

- Initial & Continuing Education
- IRB Chair, Members, Staff
- Investigators

# OHRP Federalwide Assurance

## Education Training:

- Ethical Principles
- Federal Regulations (45 CFR 46)
- State Law
- Institutional Policy

OHRP


on the World Wide Web

<http://ohrp.osophs.dhhs.gov/polasur.htm>

# OHRP Website

The screenshot shows a Netscape browser window displaying the OHRP website. The browser's address bar shows the URL <http://ohrp.osophs.dhhs.gov/>. The browser's toolbar includes buttons for Back, Forward, Reload, Home, Search, Netscape, Print, Security, Shop, and Stop. The browser's status bar at the bottom reads "Please monitor this status bar for descriptions of OHRP changes."


**Office for Human Research Protections**  
U.S. Department of Health and Human Services

  
"Doing it right...together"

**What's New**

**IRB Registration & Assurance Filing**

**General OHRP Information**

- [How Do You Receive the Latest News?](#) (OHRP-LISTSERV)
- [How Do You Reach the OHRP Office?](#)
- [OHRP Organization and Responsibilities](#)  (Federal Register OHRP announcement - June 13, 2000)


**Human Subject Protection**

- [OHRP IRB Registration and Assurance Filing](#) (information and materials for registering an Institutional Review Board (IRB) and filing an Assurance of Compliance)
- National Human Research Protections Advisory Committee (NHRPAC) [WEBPAGE](#).
- [Human Subject Research Subcommittee Roster](#) (members of

# OHRP Website for FWA/IRBs

The screenshot shows a Netscape browser window with the address bar containing the URL `http://ohrp.osophs.dhhs.gov/irbasur.htm`. The browser's menu bar includes Back, Forward, Reload, Home, Search, Netscape, Print, Security, Shop, and Stop. The toolbar contains icons for Bookmarks, Internet, Lookup, New&Cool, and IMPAC II Web Ap. The page content is as follows:

**Office for Human Research Protections**  
U.S. Department of Health and Human Services

  
"Doing it right...together"

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**What's New**

**IRB Registration & Assurance Filing**

## Procedures for Registering Institutional Review Boards and Filing Federalwide Assurances of Protection for Human Subjects (FWAs)

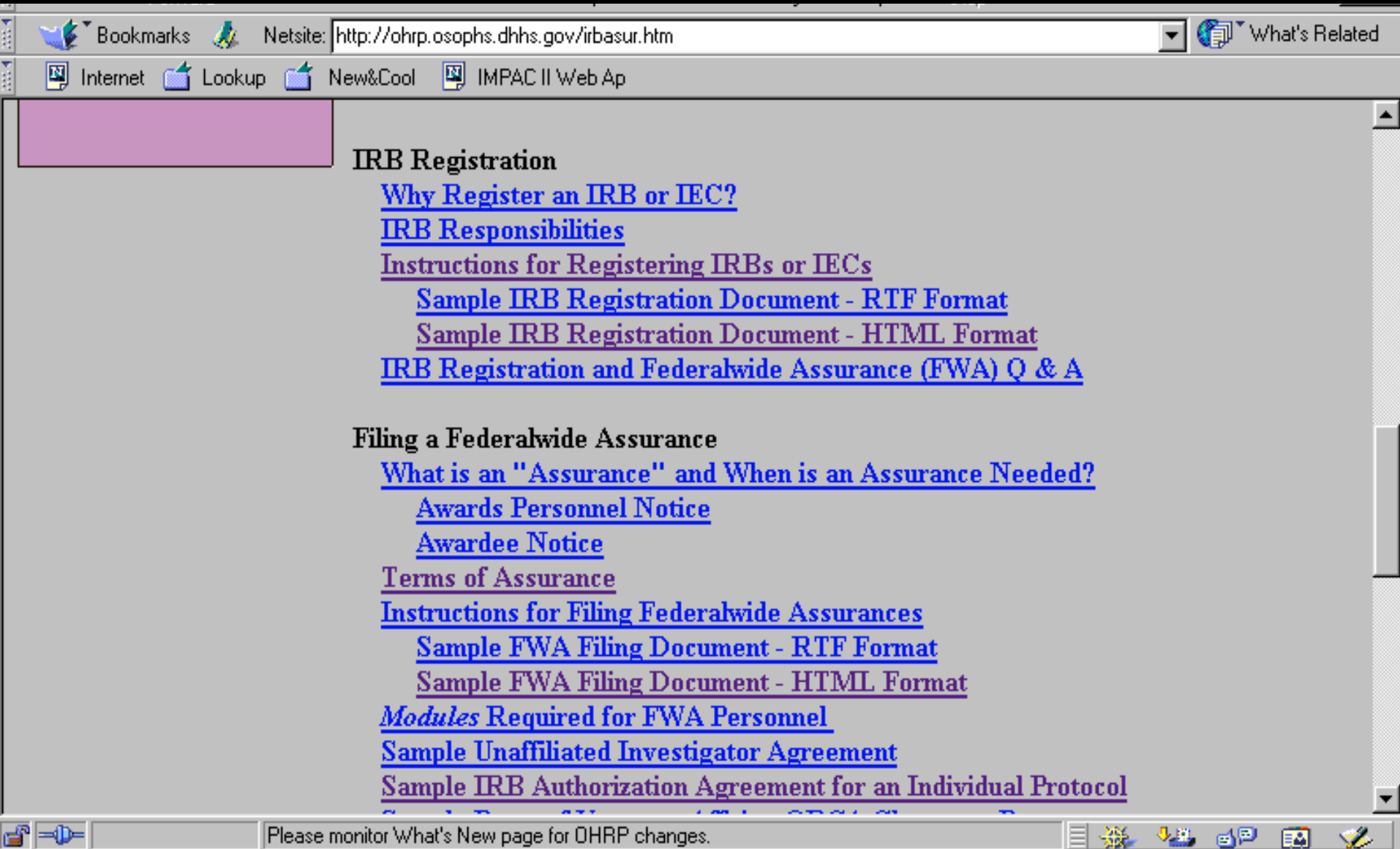
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This website introduces a process through which Institutional Review Boards (IRBs) and (international) Independent Ethics Committees (IECs) can register with HHS and thereby receive timely information from HHS about the protection of human subjects.

The website also introduces a simplified process for filing Institutional Assurances of Protection for Human Subjects with the HHS Office for Human Research Protections (OHRP). Assurances approved under this

Please monitor 'What's New' page for OHRP changes.

# FWA – Where to Start



The screenshot shows a Netscape browser window with the address bar containing the URL <http://ohrp.osophs.dhhs.gov/irbasur.htm>. The browser's toolbar includes icons for Bookmarks, Internet, Lookup, New&Cool, and IMPAC II Web Ap. The page content is organized into two main sections, each with a list of blue, underlined links.

**IRB Registration**

- [Why Register an IRB or IEC?](#)
- [IRB Responsibilities](#)
- [Instructions for Registering IRBs or IECs](#)
  - [Sample IRB Registration Document - RTF Format](#)
  - [Sample IRB Registration Document - HTML Format](#)
- [IRB Registration and Federalwide Assurance \(FWA\) Q & A](#)

**Filing a Federalwide Assurance**

- [What is an "Assurance" and When is an Assurance Needed?](#)
- [Awards Personnel Notice](#)
- [Awardee Notice](#)
- [Terms of Assurance](#)
- [Instructions for Filing Federalwide Assurances](#)
  - [Sample FWA Filing Document - RTF Format](#)
  - [Sample FWA Filing Document - HTML Format](#)
- [Modules Required for FWA Personnel](#)
- [Sample Unaffiliated Investigator Agreement](#)
- [Sample IRB Authorization Agreement for an Individual Protocol](#)

At the bottom of the browser window, a status bar displays the text: "Please monitor What's New page for OHRP changes." The system tray on the right side of the taskbar contains several icons, including a help icon, a network icon, and a volume icon.

# Shared Goals

Promoting Research

Protecting Human Subjects

# Shared Responsibilities

- Investigators
- IRB (chair, members, administrator)
- Institutional Chief Executive Officer