

# Clinical Trials Seminar Series

## **What's New in the NIH Office of Human Subjects Research Protections (OHSRP)?**

*Heather Bridge*

*Office of Human Subjects Research Protections*

# Agenda

Background

Website Demonstration

NIH HRPP Training



# Background

The NIH is a Federal institution comprised of the Extramural and Intramural divisions

Research conducted *by* the NIH is under the Intramural Research Program (IRP)

Research *involving humans* at the NIH is under the Human Research Protections Program (HRPP) of the IRP

The Office of Human Subjects Research Protections (OHSRP) supports the Institutional Official for the NIH to provide policy development and regulatory oversight of the HRPP

# Background- continued

The NIH HRPP is seeking accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP)

Policies are being updated to meet AAHRPP requirements

The website was out of date but also did not meet the minimum requirement of this accrediting body

This is where you will find policies and resources related to the NIH HRPP



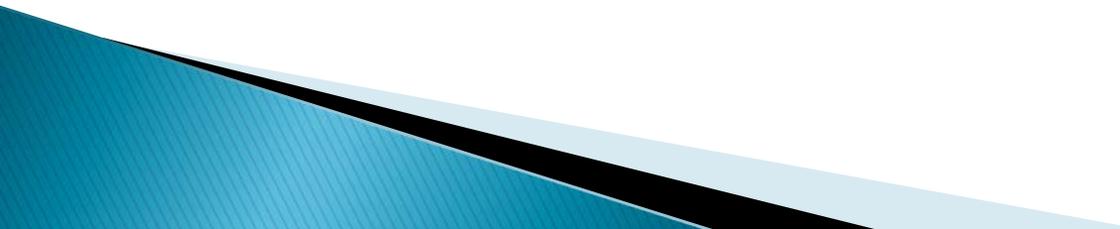
# HRPP Websites

There are two websites for the HRPP program:

- Public page: <http://ohsr.od.nih.gov/>
- NIH page: <https://federation.nih.gov/ohsr/nih/>  
(NIH login required)

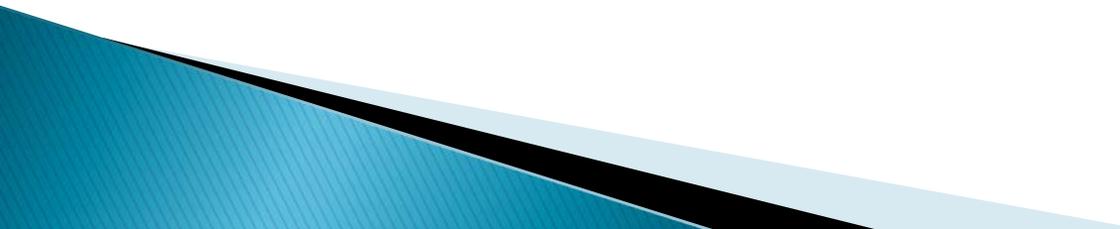
# AUDIENCE

The website has different audiences

- ▶ **Public site:** NIH Staff, Grantees and Human Subjects
  - ▶ **NIH site:** Members of the HRPP, IRBs and Investigators
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# HRPP Training Policies

Training is required every three (3) years

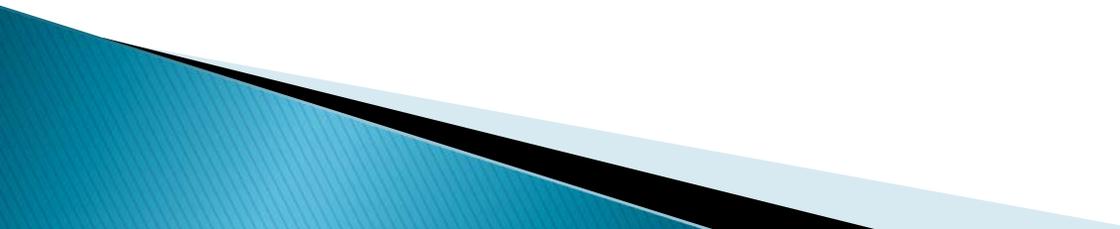
- Ethical Training
  - GCP Training
  - Just-in-time Training
  - Test-out functionality is available on some of the longer courses
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# HRPP Training

- ▶ Training is targeted to both the type and role of the researcher
- ▶ Four learner groups:
  - Clinical Investigators
  - Social Behavioral and Epidemiological Investigators
  - Basic Science Investigators
  - HRPP Staff
- ▶ Role-based by learner group:
  - PI
  - Other research staff
  - Persons who obtain consent

# Training Pages Details

What can you do on the training pages:

- Find your records
  - Locate your training requirements by learner group
  - Access to training resources
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# Training Choices

Some training is offered by more than one vendor

- NIH Clinical Research Training
- GCP Training: NIAID and CITI
- CITI:
  - Biomedical ethical training
  - Social Behavioral
  - GCP

# Training Choices- continued

- NIH Clinical Research Training:
  - Required for Principal Investigators and preferred for Associate Investigators
  - Reflects NIH policy and current FDA guidance
- NIAID GCP: Shorter than CITI GCP but no CMEs
- CITI:
  - Portable to other institutions
  - Option to purchase CMEs for longer courses such as GCP, Biomedical and Social Behavioral
  - Good for fellows who will leave soon and go to other institutions
  - Credit for CITI Courses completed within 12 months at other institutions

# Training Rollout

Follow your IRB's requirements until formal rollout which will coincide with implementation of SOP 25- *Training Requirements for the NIH Human Research Protection Program*

# CONTACT INFO

Office of Human Subjects Research Protections

Office of Intramural Research

National Institutes of Health

10 Center Drive,

Bldg. 10, Room 2C146

Bethesda, MD 20892

Direct: 301-402-4504

Office Main: 301-402-3444

[OHSR\\_NIH\\_DDIR@od.nih.gov](mailto:OHSR_NIH_DDIR@od.nih.gov)