

## **RESOURCES AND REGULATIONS**

### **WEB-BASED TRAINING**

#### **Collaborative IRB Training Initiative**

[www.miami.edu/citireg/](http://www.miami.edu/citireg/)

**Six Category I, CME credits available for this course.**

Goodwyn IRB is pleased to offer the Collaborative IRB Training Initiative (CITI) online training courses to all who conduct research using human subjects.

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

[http://137.187.206.145/cbttng\\_ohrp/assurance/newuserreg\\_1.asp](http://137.187.206.145/cbttng_ohrp/assurance/newuserreg_1.asp)

**Certificate available upon successful completion.**

OHRP offers Human Subject Assurance Training that focuses on understanding the responsibilities involved in an institutional program of human subject protection.

#### **National Institutes of Health (NIH)**

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

**Certificate available upon successful completion.**

The NIH computer based training was developed for NIH staff but can be used by other individuals seeking training on protection of human subjects in research.

### **REGULATIONS**

#### **DHHS Regulations for the Protection of Human Subjects (45 CFR Part 46)**

[http://www.access.gpo.gov/nara/cfr/waisidx\\_99/45cfr46\\_99.html](http://www.access.gpo.gov/nara/cfr/waisidx_99/45cfr46_99.html)

#### **DHHS Standards for Privacy of Individually Identifiable Health Information (45 CFR Part 160 and 164) <http://www.hhs.gov/ocr/hipaa/>**

#### **Food and Drug Administration (FDA):**

Title 21, Part 50 (Informed Consent):

[http://www.access.gpo.gov/nara/cfr/waisidx\\_99/21cfr50\\_99.html](http://www.access.gpo.gov/nara/cfr/waisidx_99/21cfr50_99.html).

Title 21, Part 56 (Institutional Review Boards):

[http://www.access.gpo.gov/nara/cfr/waisidx\\_99/21cfr56\\_99.html](http://www.access.gpo.gov/nara/cfr/waisidx_99/21cfr56_99.html).

Title 21, Part 312 (Investigational New Drug Application):

[http://www.access.gpo.gov/nara/cfr/waisidx\\_99/21cfr312\\_99.html](http://www.access.gpo.gov/nara/cfr/waisidx_99/21cfr312_99.html).

Title 21, Part 812 (Investigational Device Exemption):

[http://www.access.gpo.gov/nara/cfr/waisidx\\_99/21cfr812\\_99.html](http://www.access.gpo.gov/nara/cfr/waisidx_99/21cfr812_99.html).

## **GUIDANCE**

### **Good Clinical Practice Guidelines (ICH)**

<http://www.fda.gov/cder/guidance/959fnl.pdf>

The International ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects.

### **The Belmont Report**

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm>

This report outlines basic principles and guidelines for human subjects research.

### **FDA IRB Information Sheets**

<http://www.fda.gov/oc/oha/IRB/toc.html>

These information sheets present the Food and Drug Administration's (FDA) current guidance on protection of human subjects in research. Topics include, among others: answers to FAQs, informed consent guidance, list of various regulations and their differences, and information on continuing review.

### **The American Medical Association – Ethical Opinion Regarding Research Conflict of Interests**

[http://www.ama-assn.org/apps/pf\\_online/pf\\_online?f\\_n=browse&doc=policyfiles/CEJA/E-8.0315.HTM](http://www.ama-assn.org/apps/pf_online/pf_online?f_n=browse&doc=policyfiles/CEJA/E-8.0315.HTM)