IRB BASICS

Research Support Services
Human Subjects Protection Program

University of Memphis
IRB Function

The purpose of an IRB is to review research and to ensure the rights and welfare of human subjects involved in research are adequately protected.
The Belmont Report
The Basic Principles of the Belmont Report

1. Respect for Persons
2. Beneficence
3. Justice
Rules Applied

- **Respect**
  - Informed Consent Process
  - Respect for Privacy
- **Beneficence**
  - Good research design
  - Competent investigators/researchers
  - Favorable risk–benefit analysis
- **Justice**
  - Equitable selections of subjects
IRB Review of Research

Categories

- Full
- Expedited
- Exempt
- Research Not Involving Human Subjects
Decision Charts:

http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.htm
Types of Review

- Initial Review
- Continuing Review
- Modifications
- Adverse Events or Unanticipated Problems
- Noncompliance
- Determination
Criteria for IRB Approval

- Risks are Minimized
- Risks are Reasonable in Relation to Benefits
- Selection of Subjects is Equitable
- Informed Consent will be Sought and Documented
- Research Plan Adequately Provides for Monitoring the Data Collected
- Research Plan Adequately Protects the Privacy of Subjects and Maintains Confidentiality
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards need to be included in the protocol to protect the rights and welfare of these subjects.
The IRB has the authority to:

- Approve
- Require modifications prior to approval
- Table
- Disapprove
- Suspend
- Terminate
Informed Consent

- Information
- Comprehension
- Voluntariness
www.memphis.edu/IRB
Administration Building 315
(901) 678-2705
Over 5.4 million CITI Program courses have been completed since 2000

CITI Program Announcements

Public Access Courses Are No Longer Available (October 2013)
Good Clinical Practice Guide Now Available (September 2013)
Using the New CITI Program Website (August 2013)

Help & Support

How do I register?
Merge duplicate accounts
I forgot my Username or
# Social & Behavioral Research Course

**Required Modules**

- University of Memphis (ID: 14523)
- Belmont Report and CITI Course Introduction (ID: 1127)
- Research and HIPAA Privacy Protections (ID: 14)
- Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)
- History and Ethical Principles - SBE (ID: 490)
- Defining Research with Human Subjects - SBE (ID: 491)
- The Regulations - SBE (ID: 502)
- Assessing Risk - SBE (ID: 503)
- Informed Consent - SBE (ID: 504)
- Privacy and Confidentiality - SBE (ID: 505)
- Research with Prisoners - SBE (ID: 506)
- Research with Children - SBE (ID: 507)
- Research in Public Elementary and Secondary Schools - SBE (ID: 508)
- International Research - SBE (ID: 509)
- Internet Research - SBE (ID: 510)
- Students in Research (ID: 1321)
- Conflicts of Interest in Research Involving Human Subjects (ID: 488)
Biomedical Research

Belmont Report and CITI Course Introduction (ID: 1127)

Conflicts of Interest in Research Involving Human Subjects (ID: 486)

History and Ethical Principles (ID: 498)

International Studies (ID: 971)

Unanticipated Problems and Reporting Requirements in Biomedical Research (ID: 14777)

Students in Research (ID: 1321)

Vulnerable Subjects - Research Involving Prisoners (ID: 8)

Vulnerable Subjects - Research Involving Children (ID: 9)

Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)

FDA-Regulated Research (ID: 12)

Research and HIPAA Privacy Protections (ID: 14)

Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)

Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)

Informed Consent (ID: 3)

Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)

Records-Based Research (ID: 5)

Genetic Research in Human Populations (ID: 6)

Research With Protected Populations - Vulnerable Subjects: An Overview (ID: 7)

Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)

Avoiding Group Harms - International Research Perspectives (ID: 14081)
What happens to my protocol once it is submitted to the IRB?
What kind of timeline should I expect for be able to begin data collection?
What are the responsibilities of the Lead Investigator?