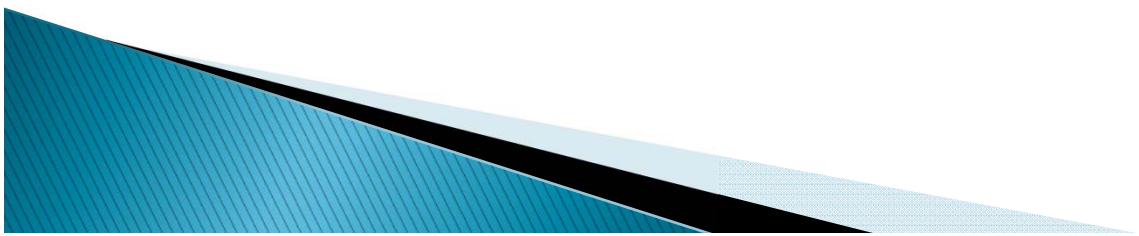
IRB BASICS

Research Support Services
Human Subjects Protection Program

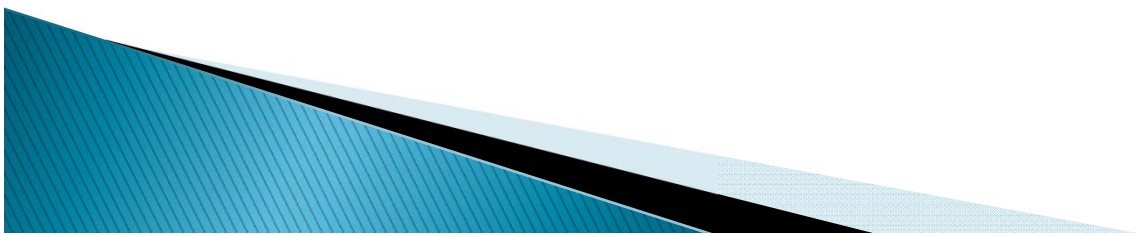
University of Memphis

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.

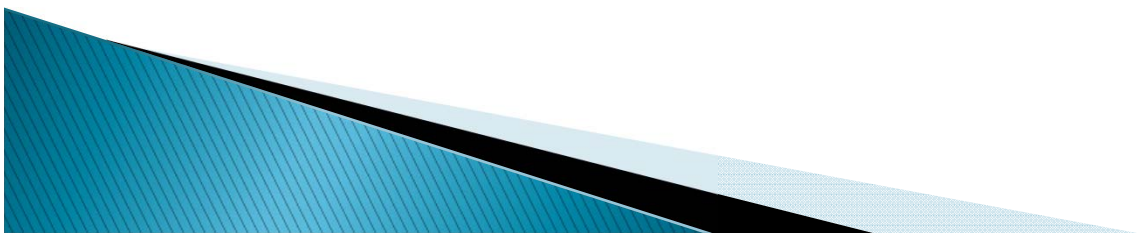


The Belmont Report



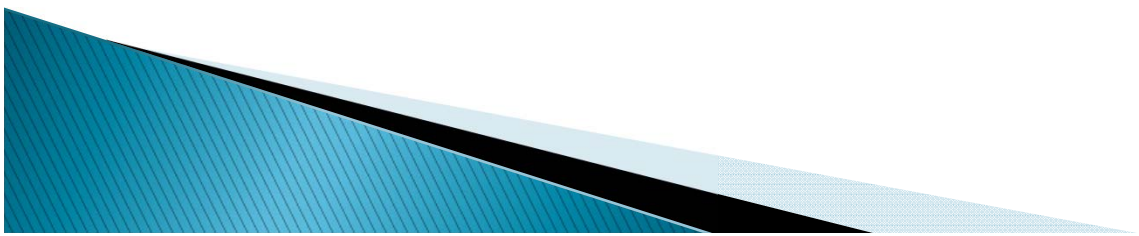
The Basic Principles of the Belmont Report

1. Respect for Persons
2. Beneficence
3. Justice



Rules Applied

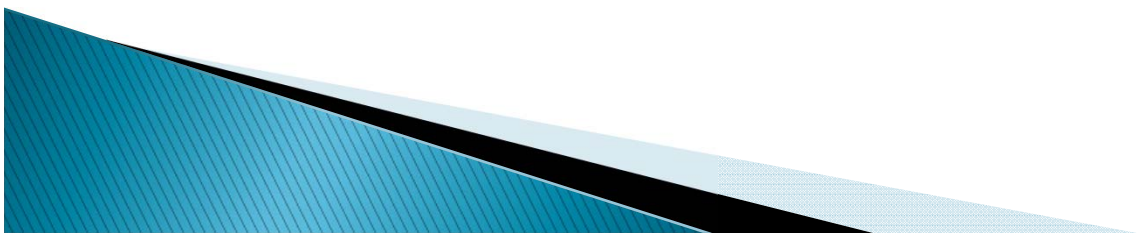
- **Respect**
  - Informed Consent Process
  - Respect for Privacy
- **Beneficence**
  - Good research design
  - Competent investigators/researchers
  - Favorable risk-benefit analysis
- **Justice**
  - Equitable selections of subjects



IRB Review of Research

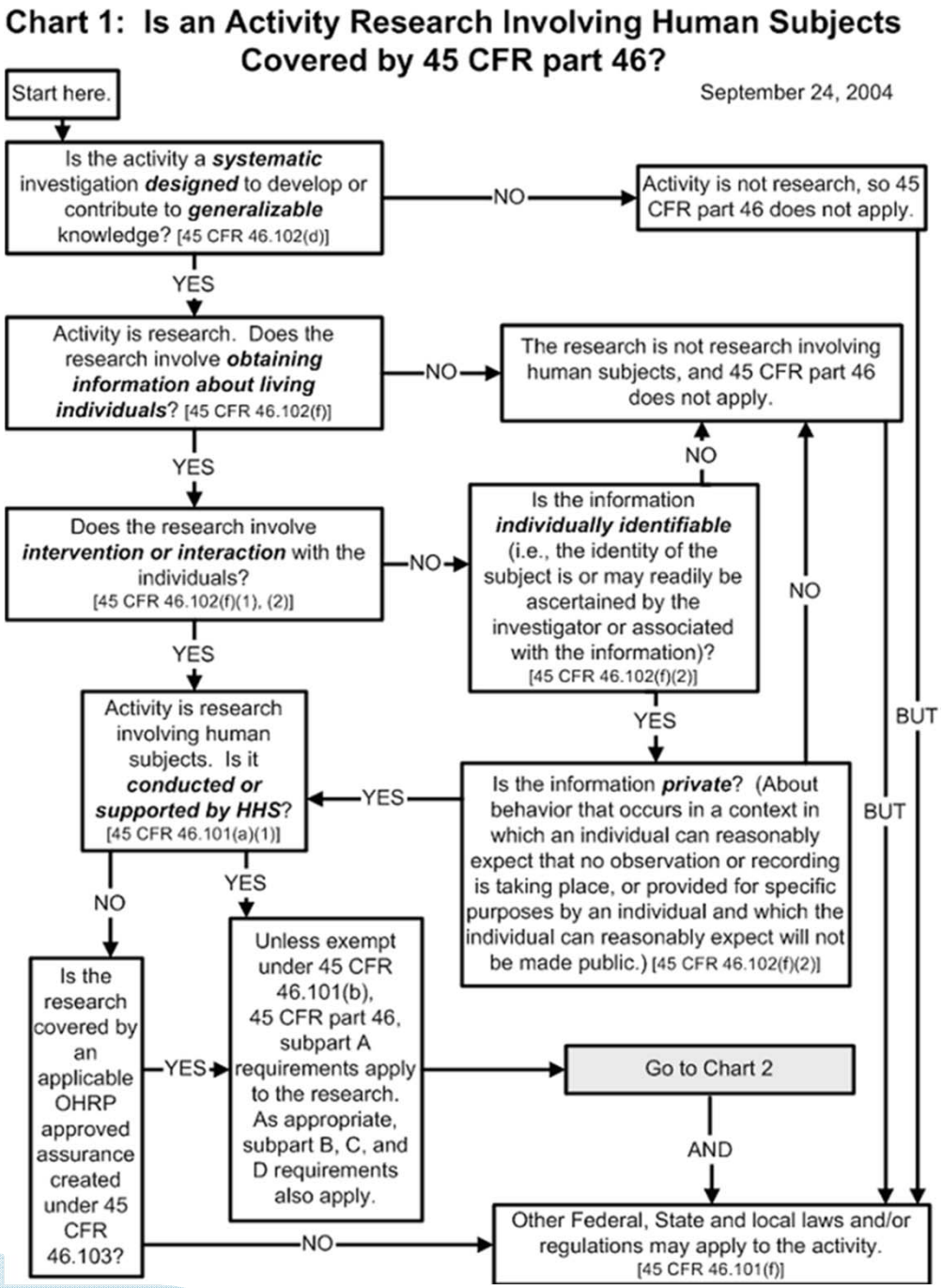
Categories

- Full
- Expedited
- Exempt
- Research Not Involving Human Subjects



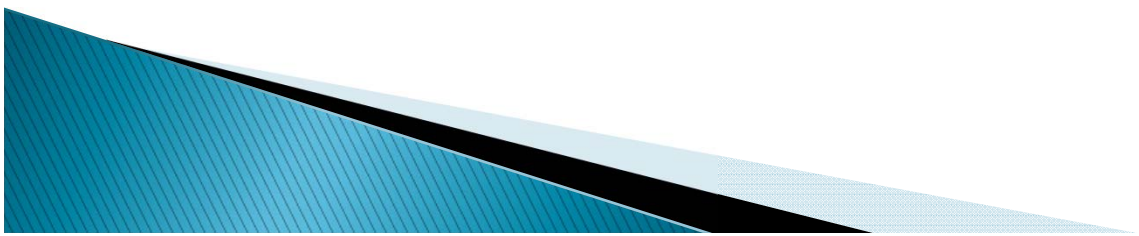
Decision Charts:

http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html



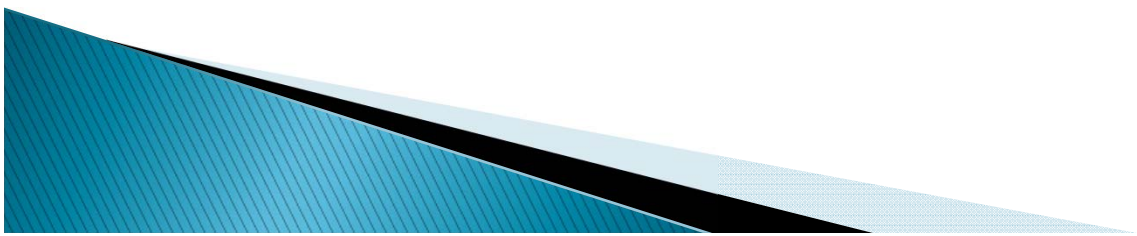
Types of Review

- Initial Review
- Continuing Review
- Modifications
- Adverse Events or Unanticipated Problems
- Noncompliance
- Determination



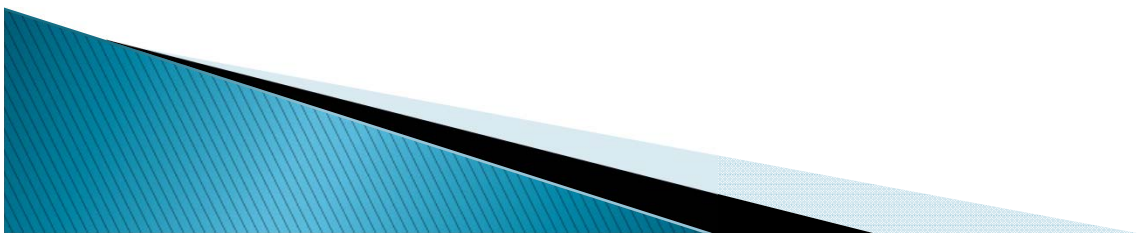
Criteria for IRB Approval

- 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.



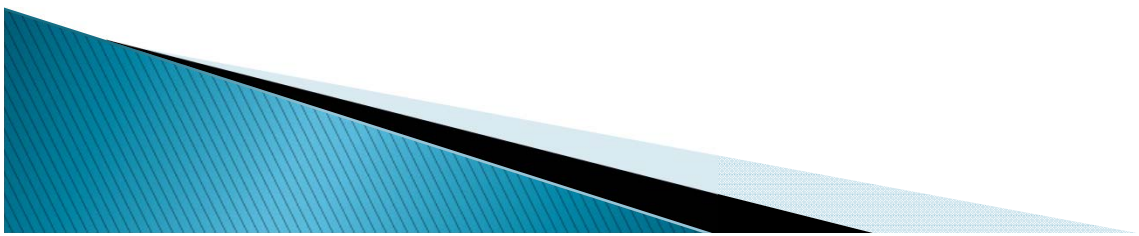
The IRB has the authority to:

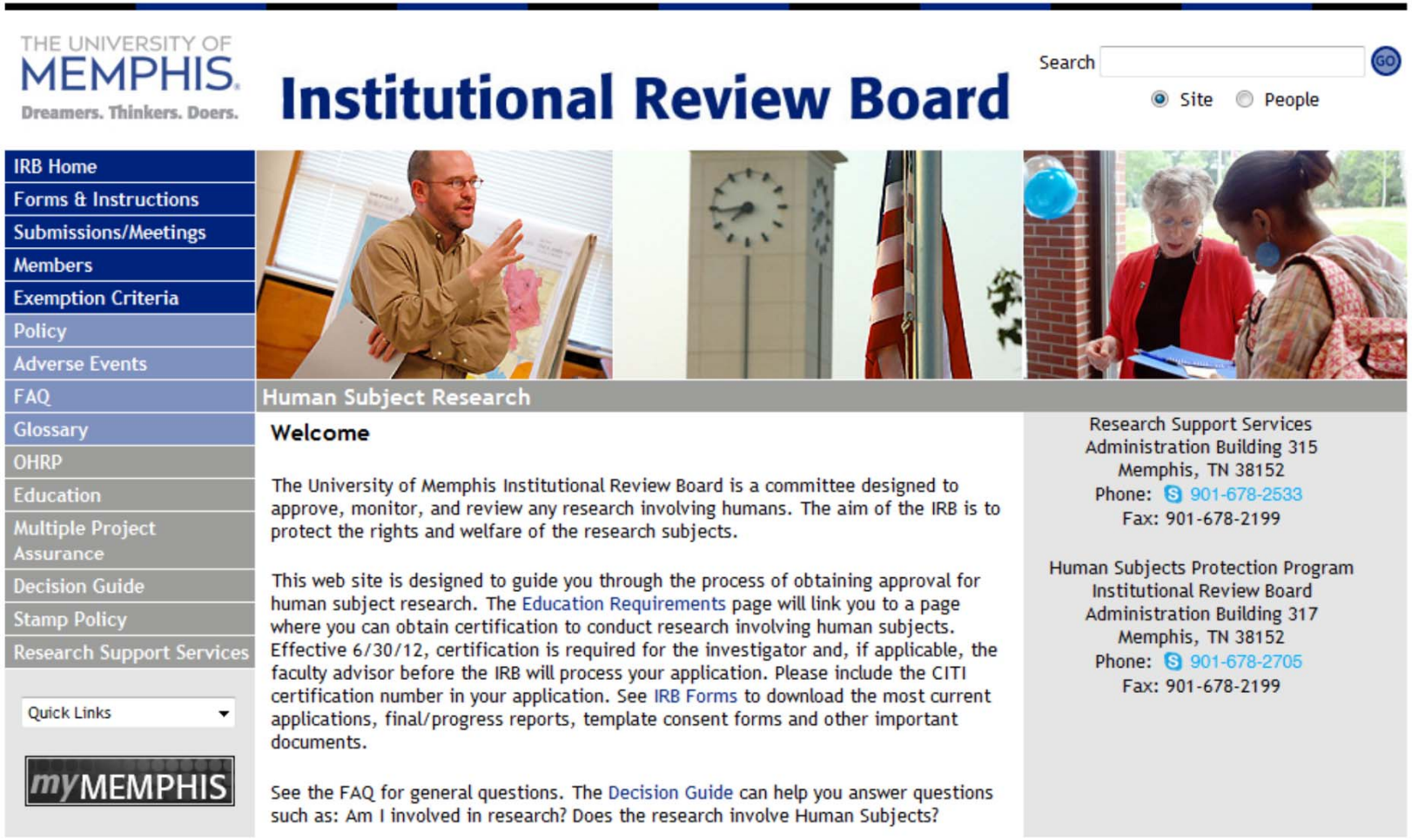
- **Approve**
- **Require modifications** prior to approval
- **Table**
- **Disapprove**
- **Suspend**
- **Terminate**



Informed Consent

- **Information**
- **Comprehension**
- **Voluntariness**





www.memphis.edu/IRB

Administration Building 315

(901) 678-2705

USA - English

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Good Clinical Practice Guide Now Available (September 2013)

Using the New CITI Program Website (August 2013)

Help & Support

How do I register?

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Social & Behavioral Research Course

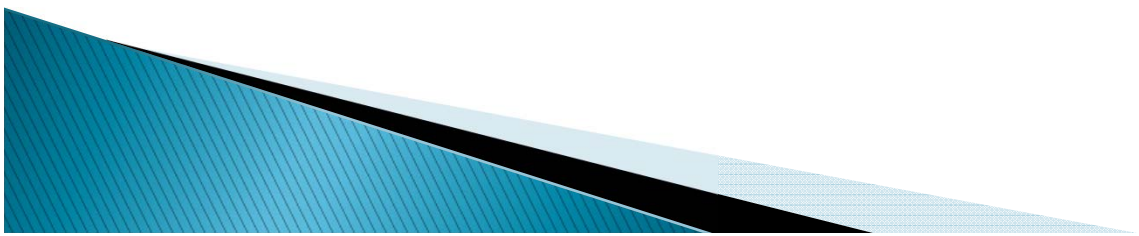
Required Modules

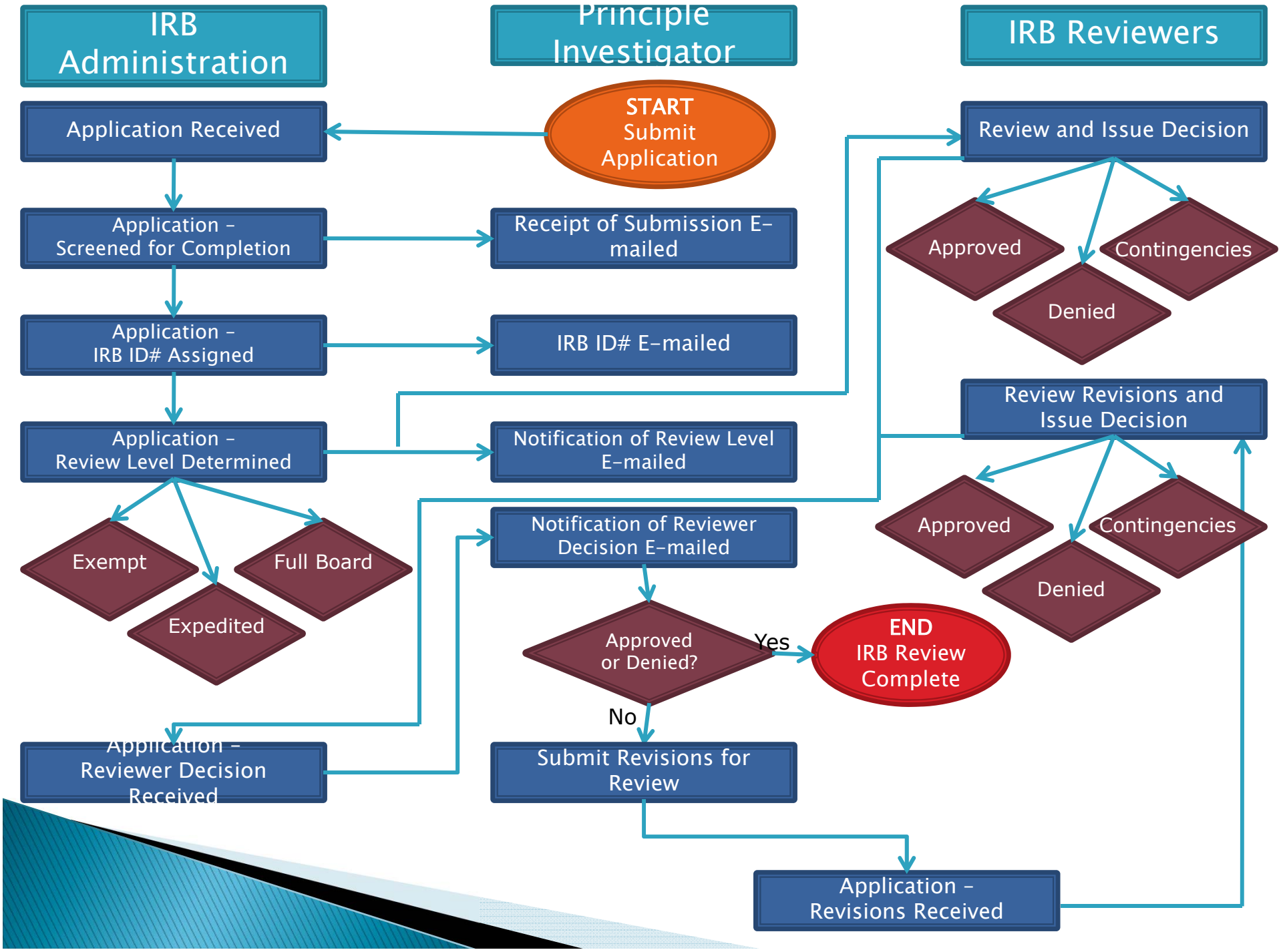
- University of Memphis (ID: 14523)
- Belmont Report and CITI Course Introduction (ID: 1127)
- Research and HIPAA Privacy Protections (ID: 14)
- Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)
- History and Ethical Principles - SBE (ID: 490)
- Defining Research with Human Subjects - 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

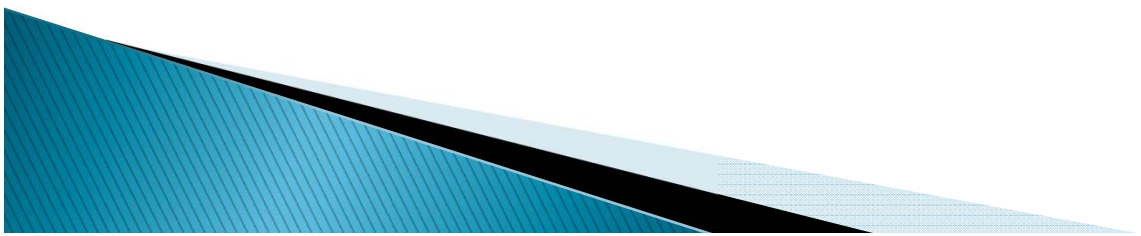
- Belmont Report and CITI Course Introduction (ID: 1127)
- Conflicts of Interest in Research Involving Human Subjects (ID: 488)
- History and Ethical Principles (ID: 498)
- International Studies (ID: 971)
- Unanticipated Problems and Reporting Requirements in Biomedical Research (ID: 14777)
- Students 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?




IRB Administration
Principle Investigator
IRB Reviewers
START Submit Application
Application Received
Application – Screened for Completion
Receipt of Submission E-mailed
Application – IRB ID# Assigned
IRB ID# E-mailed
Application – Review Level Determined
Notification of Review Level E-mailed
Exempt
Full Board
Expedited
Notification of Reviewer Decision E-mailed
Approved or Denied?
Yes
END IRB Review Complete
No
Application – Reviewer Decision Received
Submit Revisions for Review
Application – Revisions Received
Review and Issue Decision
Approved
Contingencies
Denied
Review Revisions and Issue Decision
Approved
Contingencies
Denied

What kind of timeline should I expect for be able to begin data collection?



What are the responsibilities of the Lead Investigator?