



Western Michigan University

Office of the Vice President for Research

SUBJECT: Required Training for Human Subject's Researchers

Human Subjects Researchers:

The Human Subjects Institutional Review Board, in conjunction with the Office of the Vice President for Research, has initiated a policy for researcher human subjects training. Our policy to assure that all researchers are trained in human subjects protections issues necessary for the university's compliance with federal requirements. As a researcher using human subjects in your research, it is important that you follow this policy and associated procedures.

Our policy requires training of all faculty, staff, and students involved with human subjects research. The procedure is to use a web-based training program. Training must occur prior to the final approval or annual renewal of a protocol. The policy is effective June 1, 2005.

The materials offer researchers the opportunity to complete training at their convenience. The modules can be accessed directly at www.citiprogram.org or through the WMU HSIRB web site at <http://www.wmich.edu/research/compliance/hsirb>.

CITI Course in Protections of Human Research Subjects

Required Modules for Human Subjects Researchers:

Group 1 Social & Behavioral Sciences Researchers (13 + required modules)

Assessing Risk - SBE
Avoiding Group Harms - U.S. Research Perspectives
Belmont Report and CITI Course Introduction
Conflicts of Interest in Research Involving Human Subjects
Cultural Competence in Research
Defining Research with Human Subjects - SBE
History and Ethical Principles - SBE
Informed Consent - SBE
Privacy and Confidentiality - SBE
Records-Based Research
The Federal Regulations - SBE
Vulnerable Subjects - Research Involving Workers/Employees
Western Michigan University

IRB Reference Resource - Basic Course

If your research involves children add:

Research with Children – SBE
Research in Public Elementary and Secondary Schools SBE
Vulnerable Subjects – Researching Involving Children

If your research involves prisoners, incarcerated individuals, or the prison system add:

Research with Prisoners – SBE
Vulnerable Subjects – Research Involving Prisoners

Group 2 Medical Model Research Investigators (13 + required modules)

(Protocols from the following units may follow a medical model: Alcohol and Drug Abuse, Biology, Biometrics, Chemistry, Exercise Physiology, Music Therapy, Nursing, Occupational Therapy, Physician Assistant, Physics, Psychology, Speech Pathology & Audiology, Unified Clinics, etc.)

Avoiding Group Harms - U.S. Research Perspectives
Basic Institutional Review Board (IRB) Regulations and Review Process
Belmont Report and CITI Course Introduction
Conflicts of Interest in Research Involving Human Subjects
Cultural Competence in Research
History and Ethics of Human Subjects Research
Informed Consent
Populations in Research Requiring Additional Considerations and/or Protections
Records-Based Research
Research and HIPAA Privacy Protections
Social and Behavioral Research (SBR) for Biomedical Researchers
Vulnerable Subjects - Research Involving Workers/Employees
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IRB Reference Resource - Basic Course

If your research includes prisoners add:

Research with Prisoners – SBE
Vulnerable Subjects – Research Involving Prisoners

If your research includes children:

Research with Children – SBE
Research in Public Elementary and Secondary Schools SBE
Vulnerable Subjects – Researching Involving Children

If your research includes genetic information:

Genetic Research in Human Populations

If your research includes pregnant women and/or fetuses:

Vulnerable Subjects – Research Involving Pregnant Women, Human Fetuses, and Neonates

If you are doing research at a VA hospital:

Human Subjects Research at the VA

If your research includes drugs or medical devices:

FDA-Regulated Research

Add the following if relevant to your research:

Humanitarian Use Devices (HUDs)
Phase 1 Research: Understanding Phase 1 Research
Phase 1 Research: Protecting Phase 1 Subjects

Group 3 Administrators:

Cultural Competence in Research

Introduction

History and Ethical Principles - SBE

Defining Research with Human Subjects - SBE

The Federal Regulations – SBE

Assessing Risk - SBE

Informed Consent - SBE

Privacy and Confidentiality - SBE

Western Michigan University

(Add additional modules related to research being conducted in your department or college)

Required Modules for HSIRB members:

Group 4 IRB Member (All 29 modules)

If you have questions, please contact the Associate Director Research Compliance, at 387-8293 or ovpr-hsirb@wmich.edu.