CIRTification
COMMUNITY INVOLVEMENT IN RESEARCH

UIC UNIVERSITY OF ILLINOIS AT CHICAGO CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

COVERAGE OF STANDARD HUMAN SUBJECTS PROTECTION TOPICS

Content Area	CITI* Biomedical	CITI* SBR	CIRTification**
Introduction to Research/ Defining Research with Human Subjects	(none)	interpretation of definitions of terms "human subject" and "research" for SBR)	• Key Research Terms • "How Does Human Research Happen" • Is It Research?
History of Research Abuse, Ethics and Federal Regulations	• history of abuses in research that led to federal regs	• history of abuses in research • development of federal regulations from SBR perspective • why ethics are necessary for HSR	• history of abuses in research • development of federal regulations in response to abuse • necessity of federal regulations for HSP
Ethical Principles	• Belmont Principles	• Belmont Principles	• Belmont Principles • community engagement as an ethical protection
Federal Regulations	• requirements for conducting HSR	• overview of federal regulations • pertinence to SBR • requirements for/ types of review necessary for SBR	• overview of federal regulations
Institutional Review Boards	• role, authority • composition • submission process • review process • other compliance issues (e.g., FDA)	• composition • functions • review process	• composition (including community representation) • review process
Informed Consent (IC)	• required and optional elements • obtaining IC • waivers of IC	• required and optional elements • obtaining IC • waivers of IC	• information, understanding, and voluntariness • required and optional elements • IC role play
Risk/Benefit	• vulnerable groups • examples of research harms • strategies to reduce risk of group harm	• identifying risks • evaluating risks vs. potential benefits • managing risks • addressing risks during the IC process	• severity and types of risks • group risks • possible protections • fair distribution of risks and benefits

Abbreviations

HSP=human subjects protections
IC=informed consent
HSR=human subjects research
P/C= privacy and confidentiality
SBR=social behavioral research
CEnR=community-engaged research

CIRTification
COMMUNITY INVOLVEMENT IN RESEARCH

UIC UNIVERSITY OF ILLINOIS AT CHICAGO CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

Content Area	CITI* Biomedical	CITI* SBR	CIRTification**
Privacy and Confidentiality (P/C)	• HIPAA privacy rule • research involving medical records • protecting confidentiality of information • IRB requirements and review of studies using information from records	• definitions of P/C • private vs public behavior • procedures for protecting P/C controlling access to private information • reporting laws and certificates of confidentiality • exempt research	• definitions of P/C • how to maintain participants' privacy and keep research information confidential • examples of breaches of/threats to P/C in CEnR • HIPAA privacy rule
Vulnerable Populations	• concept • characteristics • DHHS and FDA regulations	(none)	• concept • characteristics • DHHS and FDA regulations
Research Integrity	(none)	(none)	• protocol adherence • data accuracy and completeness • reporting research misconduct
Ethical Issues in Community-Engaged Research	(none)	(none)	• Group harms • Recruitment • Challenges to P/C • Challenges to IC with vulnerable populations (e.g., illiteracy, limited access to services) • All examples and case studies involve CEnR projects • Why academic researchers engage communities • Additional protections that CE can provide

*CITI Basic Courses in the Protection of Human Research Subjects
Description of all CITI modules available here.

Abbreviations

HSP=human subjects protections
IC=informed consent
HSR=human subjects research
P/C= privacy and confidentiality
SBR=social behavioral research
CEnR=community-engaged research