

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

Abbreviations

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

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Privacy and Confidentiality (P/C)	<ul style="list-style-type: none"> • HIPAA privacy rule • research involving medical records • protecting confidentiality of information • IRB requirements and review of studies using information from records 	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • concept • characteristics • DHHS and FDA regulations 	(none)	<ul style="list-style-type: none"> • concept • characteristics • DHHS and FDA regulations
Research Integrity	(none)	(none)	<ul style="list-style-type: none"> • protocol adherence • data accuracy and completeness • reporting research misconduct
Ethical Issues in Community-Engaged Research	(none)	(none)	<ul style="list-style-type: 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](#).

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