<table>
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<th>Content Area</th>
<th>CITI* Biomedical</th>
<th>CITI* SBR</th>
<th>CIRTification**</th>
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</table>
| 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 | • history of abuses in research  
|                                                 |                  | • why ethics are necessary for HSR | • 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 | • composition (including community representation)  
|                                                 |                  | • review process | • 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  
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)                | • 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](#).