## Coverage of Standard Human Subjects Protection Topics

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<tr>
<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  
• 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
- HSR=human subjects research
- SBR=social behavioral research
- IC=informed consent
- P/C=privacy and confidentiality
- CEnR=community-engaged research
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<td>Privacy and Confidentiality (P/C)</td>
<td>• HIPAA privacy rule</td>
<td>• definitions of P/C</td>
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<td>• research involving medical records</td>
<td>• private vs public behavior</td>
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<td>• protecting confidentiality of information</td>
<td>• procedures for protecting P/C</td>
<td>• examples of breaches of/threats to P/C in CEnR</td>
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<td>• IRB requirements and review of studies using information from records</td>
<td>• controlling access to private information</td>
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<td>Vulnerable Populations</td>
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<td>• characteristics</td>
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<td>• DHHS and FDA regulations</td>
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<td>Research Integrity</td>
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<td>• protocol adherence</td>
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<td>Ethical Issues in Community-Engaged Research</td>
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<td>• data accuracy and completeness</td>
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<td>• reporting research misconduct</td>
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*CITI Basic Courses in the Protection of Human Research Subjects
Description of all CITI modules available [here](#).

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IC=informed consent  P/C= privacy and confidentiality  CEnR=community-engaged research