

# Detailed Content Outline

	Cognitive Levels			TOTAL
	Recall	Application	Analysis	
<b>1. Standards, Policies, and Procedures</b>	<b>3</b>	<b>11</b>	<b>3</b>	<b>17</b>
A. Conduct a review of policies and procedures				
B. Consult with legal resources				
C. Coding/billing policies and procedures				
1. Evaluate policies and procedures that address overpayments				
2. Confirm internal control procedures for billing accuracy				
D. Code of conduct				
1. Integrate mission, vision and values				
2. Maintain a code of conduct				
3. Ensure code of conduct includes research activities				
E. Maintain compliance program including plan documents				
F. Ensure that a non-retaliation policy exists				
G. Oversee internal and external compliance audit policies and procedures				
H. Ensure maintenance of policies and procedures, including but not limited to the following:				
1. record retention/destruction				
2. conflict of interest				
3. confidentiality, privacy and security				
4. research misconduct				
5. biosafety				
6. human/animal subject protections				
7. other				
I. Ensure maintenance of policies and procedures to address regulatory requirements of agencies, including but not limited to the following:				
1. FDA				
2. USDA				
3. ORI				
4. OCR				
5. OHRP				
6. other				
J. Ensure maintenance of policies on interactions with other research collaborators (e.g., sponsors, physicians, collaborating institutions, pharmaceutical industry)				
K. Recommend governance policies related to research compliance activities				
<b>2. Compliance Program Administration</b>	<b>3</b>	<b>9</b>	<b>3</b>	<b>15</b>
A. Administer a research compliance program (e.g., budget, staffing, risk assessment, internal controls)				
B. Inform governance board/oversight committee of research compliance activities				
C. Collaborate with others to identify best practices				
D. Define the scope of the compliance program consistent with current industry standards				
E. Evaluate the effectiveness of the compliance program on an ongoing basis				
F. Maintain knowledge of current regulatory changes and interpretation of laws				
G. Identify the need for outside expertise				

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<ul style="list-style-type: none"> <li>H. Ensure that the organization has defined the responsibilities, purpose, function and authority of the compliance officer</li> <li>I. Verify that the role of counsel in the compliance process has been defined</li> <li>J. Delineate the responsibilities, purpose and function for all compliance staff</li> <li>K. Incorporate regulatory agencies' guidance/priorities into compliance operations</li> <li>L. Integrate the compliance program into operations</li> <li>M. Develop an annual compliance work plan</li> <li>N. Conduct organizational risk assessments</li> </ul>				
<b>3. Screening and Evaluation of Researchers, Employees, Physicians, Sponsors, Vendors, Contractors, and Others</b>	<b>3</b>	<b>5</b>	<b>0</b>	<b>8</b>
<ul style="list-style-type: none"> <li>A. Ensure the organization has processes in place to identify and disclose conflicts of interest</li> <li>B. Include compliance in all job descriptions</li> <li>C. Include compliance as an element of job evaluation</li> <li>D. Assure background checks are conducted on personnel in accordance with applicable responsibilities, rules and laws</li> <li>E. Assure monitoring of government lists for excluded individuals/entities</li> </ul>				
<b>4. Communication, Education, and Training</b>	<b>3</b>	<b>11</b>	<b>4</b>	<b>18</b>
<ul style="list-style-type: none"> <li>A. Disseminate regulatory guidance material</li> <li>B. Communicate compliance information throughout the organization</li> <li>C. Develop a communication plan</li> <li>D. Provide resources to respond to research compliance questions</li> <li>E. Translate complex laws and regulations into a format employees can understand</li> <li>F. Provide initial and ongoing training to workforce on the following:               <ol style="list-style-type: none"> <li>1. their obligation to accurately document activities</li> <li>2. the compliance aspects of their job responsibilities</li> <li>3. research compliance requirements</li> <li>4. risk specific training for targeted employees</li> </ol> </li> <li>G. Promote a culture of compliance throughout the organization</li> <li>H. Encourage employees to seek guidance and clarification</li> <li>I. Track participation in ongoing compliance training programs</li> <li>J. Validate third parties have received compliance training</li> <li>K. Provide training to the governing board on its compliance program oversight responsibilities</li> </ul>				
<b>5. Monitoring, Auditing, and Internal Reporting Systems</b>	<b>4</b>	<b>6</b>	<b>10</b>	<b>20</b>
<ul style="list-style-type: none"> <li>A. Protect anonymity and confidentiality within legal and practical limits</li> <li>B. Monitor for violations of applicable laws and regulations</li> <li>C. Confirm auditors are independent</li> <li>D. Develop action plans based on risk assessments</li> <li>E. Ensure system(s) exist(s) to report noncompliance (e.g., hotline, helpline, confidential message line, suggestion box)</li> <li>F. Respond to compliance concerns in a timely manner</li> <li>G. Monitor elements of the compliance program</li> </ul>				

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H. Conduct compliance audits including but not limited to the following: <ol style="list-style-type: none"> <li>1. records management</li> <li>2. conflict of interest</li> <li>3. confidentiality, privacy and security</li> <li>4. biosafety</li> <li>5. human/animal subject protections</li> <li>6. grants management</li> <li>7. research billing</li> <li>8. researchers' time and effort</li> <li>9. protocol review and approval</li> <li>10. other</li> </ol> I. Engage in routine monitoring of compliance related activities J. Monitor compliance audit results (e.g., track, trend, evaluate, benchmark) K. Develop annual compliance auditing and monitoring plans L. Coordinate response to audits conducted by external entities M. Ensure audit tools exist N. Monitor implementation of mandated corrective action plans from external parties				
<b>6. Enforcement, Discipline, and Incentives</b>	<b>1</b>	<b>5</b>	<b>2</b>	<b>8</b>
A. Recommend response when noncompliance is substantiated B. Recommend action be proportionate to violation and fair and consistent C. Assure action is consistent with policies and procedures D. Assure actions are documented E. Verify management has taken action(s) when individuals and third parties have been excluded F. Verify corrective action is implemented G. Assure incentives promote and reward compliant and ethical behavior H. Recommend enforcement action to ensure compliance				
<b>7. Investigations and Remedial Measures</b>	<b>2</b>	<b>7</b>	<b>5</b>	<b>14</b>
A. Communicate noncompliance through required channels B. Assure mandated reporting is completed in a timely manner C. Identify root cause of noncompliance D. Collaborate with management to develop corrective action plans for risk mitigation E. Monitor corrective action plans F. Respond to inquiries promptly, thoroughly and discreetly G. Assure fair, objective, timely and discreet investigations are conducted and documented in compliance with applicable standards H. Recommend remedial action in response to identified problems or vulnerabilities I. Cooperate with government inquiries and investigations in a timely manner J. Recognize when legal counsel should be involved in investigations and reporting (e.g., legal privilege, voluntary disclosure)				
<b>Totals</b>	<b>19</b>	<b>54</b>	<b>27</b>	<b>100</b>

Answer key for page 21				
1.D	2.B	3.A	4.A	5.C