The U.S. Federal Sentencing Guidelines describe the elements considered when determining whether an organization has an effective compliance program: "an organization shall (1) exercise due diligence to prevent and detect criminal conduct and (2) otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law." The minimum elements required to demonstrate these points are as follows.

<table>
<thead>
<tr>
<th>DUKE UNIVERSITY COMPLIANCE PROGRAM STANDARD</th>
<th>GOVERNANCE</th>
<th>PROGRAM DEVELOPMENT and OVERSIGHT</th>
<th>RISK OWNERSHIP</th>
<th>AUDIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audit, Risk and Compliance Committee (ARCC)</td>
<td>Risk and Compliance Steering Committee (RCSC)</td>
<td>Overall - Duke University Compliance Program and Duke University Health System (DUHS) Compliance Office</td>
<td>Senior Leadership and Operational Management</td>
<td>Compliance Liaisons</td>
</tr>
</tbody>
</table>

**STANDARD 1:**

Establishment of standards and procedures to prevent and detect criminal conduct.

- Review major compliance policies.
- Review and approve major compliance policies.
- Provide policy and procedural guidance to liaisons. Provide recommendations to RCSC and insight to ARCC related to major policies.
- Manage operations in accordance with approved policies and procedures. Implement operational controls to support compliance.
- Develop and implement policies and procedures related to assigned compliance risks.
- Ensure appropriate processes are in place to manage compliance risks.
- Demonstrate that mechanisms are in place to identify problem areas and to prevent, detect and correct noncompliant behavior. Assist management in ensuring appropriate processes are in place to address compliance risks.
- Provide guidance to management on appropriate controls and processes to address identified risks. Audit defined processes, where appropriate, to assess operational adequacy of compliance controls and procedures, and to assess compliance with regulatory requirements.

**STANDARD 2A:**

Governing authority to have knowledge of program content and operations, and oversight of program implementation and effectiveness.

- Approve Duke University Compliance Program structure and management. Ensure adequacy of resources to implement program.
- Review and approve annual compliance plan. Review periodic reports to assess implementation and efficacy of Duke University Compliance Program.
- Provide internal leadership to Duke University Compliance Program and report to ARCC.
- Open access and scheduled reporting to senior leadership (RCSC) and ARCC.
- Report, as appropriate, on management responses to key compliance risks.
- Access to ARCC through senior management and the Compliance Program.
- Open access and scheduled reporting to senior leadership and the ARCC.

**STANDARD 2B:**

High-level personnel shall ensure an effective program; specific individual(s) within high-level personnel shall be assigned overall responsibility for the program.

- Approve Duke University Compliance Program structure and management.
- The RCSC has the overall responsibility for the design and effectiveness of the Duke University Compliance Program.
- The Duke University Compliance Program serves as the operational management arm of the program reporting to the RCSC.
- N/A
- N/A
- N/A

**STANDARD 2C:**

- N/A
- N/A
- N/A

5A2 - Attachment A
<table>
<thead>
<tr>
<th>STANDARD 4B:</th>
<th>APPROVED DUKE UNIVERSITY COMPLIANCE PROGRAM STRUCTURE AND MANAGEMENT. ENSURE INDIVIDUALS ASSIGNED RESPONSIBILITY FOR THE PROGRAM HAVE ADEQUATE INSTITUTIONAL AUTHORITY TO IMPLEMENT THE PROGRAM.</th>
<th>APPROVE DUKE UNIVERSITY COMPLIANCE PROGRAM STRUCTURE AND MANAGEMENT. ENSURE INDIVIDUALS ASSIGNED RESPONSIBILITY FOR THE PROGRAM HAVE ADEQUATE INSTITUTIONAL AUTHORITY TO IMPLEMENT THE PROGRAM.</th>
<th>MAINTAIN INVENTORY OF COMPLIANCE RISK OWNERSHIP AND LIAISON ASSIGNMENTS. SUBMIT TO SENIOR LEADERSHIP AT LEAST ANNUALLY FOR REVIEW AND APPROVAL.</th>
<th>WHERE APPROPRIATE, ENSURE COMPLIANCE LIASONS HAVE SUFFICIENT SCOPE OF AUTHORITY TO CARRY OUT COMPLIANCE RESPONSIBILITIES.</th>
<th>DEVELOP AND MAINTAIN COMPLIANCE PLANS FOR ASSIGNED RISKS.</th>
<th>DEVELOP AND MAINTAIN AUDIT PLANS BASED ON PERIODIC RISK ASSESSMENTS.</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPECIFIC INDIVIDUAL(S) WITHIN THE ORGANIZATION SHALL BE DELEGATED DAY-TO-DAY OPERATIONAL RESPONSIBILITY FOR THE DUKE UNIVERSITY COMPLIANCE PROGRAM. TO CARRY OUT SUCH RESPONSIBILITY, SUCH INDIVIDUAL(S) SHALL BE GIVEN ADEQUATE RESOURCES, APPROPRIATE AUTHORITY AND DIRECT ACCESS TO GOVERNING AUTHORITY.</td>
<td>ENSURE ADEQUACY OF RESOURCES.</td>
<td>ENSURE ADEQUACY OF RESOURCES.</td>
<td>DEVELOP GOALS AND OBJECTIVES FOR THE PROGRAM, ASSESS RESOURCE NEEDS, AND SUBMIT BUDGETS FOR REVIEW AND APPROVAL.</td>
<td>WHERE APPROPRIATE, ENSURE COMPLIANCE LIASONS HAVE SUFFICIENT RESOURCES TO SUPPORT COMPLIANCE ACTIVITIES. REVIEW AND APPROVE BUDGET FOR COMPLIANCE PROGRAM.</td>
<td>DEPLOY AND MAINTAIN COMPLIANCE PLANS FOR ASSIGNED AREAS AND SUBMIT BUDGET NEEDS TO SUPPORT PLANS.</td>
<td>ASSESS BUDGET NEEDS RELATED TO COMPLIANCE AND SUBMIT APPROPRIATE BUDGETS FOR REVIEW AND APPROVAL.</td>
</tr>
<tr>
<td>ENSURE APPROPRIATE ACCESS AND COMMUNICATIONS AMONG ARCC, THE DUKE UNIVERSITY BOARD OF TRUSTEES, SENIOR LEADERSHIP AND THE INDIVIDUALS ASSIGNED RESPONSIBILITY FOR THE DUKE UNIVERSITY COMPLIANCE PROGRAM.</td>
<td>ENSURE SIGNIFICANT COMPLIANCE ISSUES ARE COMMUNICATED TO ARCC AND DUKE INTERNAL AUDIENCES AS APPROPRIATE.</td>
<td>SUBMIT PERIODIC REPORTS ON KEY COMPLIANCE RISK AREAS TO SENIOR LEADERSHIP AND ARCC. ENSURE SIGNIFICANT COMPLIANCE ISSUES ARE COMMUNICATED TO SENIOR LEADERSHIP, COUNSEL AND ALL COMPLIANCE OFFICES IN ACCORDANCE WITH NOTIFICATION POLICY.</td>
<td>ENSURE SIGNIFICANT COMPLIANCE ISSUES ARE COMMUNICATED TO SENIOR LEADERSHIP, COUNSEL AND ALL COMPLIANCE OFFICES IN ACCORDANCE WITH NOTIFICATION POLICY.</td>
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<td>ENSURE SIGNIFICANT COMPLIANCE ISSUES ARE COMMUNICATED TO SENIOR LEADERSHIP, COUNSEL AND ALL COMPLIANCE OFFICES IN ACCORDANCE WITH NOTIFICATION POLICY.</td>
<td>SUBMIT PERIODIC REPORTS ON AUDITS AND REVIEWS PERFORMED TO SENIOR LEADERSHIP AND ARCC. ENSURE SIGNIFICANT COMPLIANCE ISSUES ARE COMMUNICATED TO SENIOR LEADERSHIP, COUNSEL AND ALL COMPLIANCE OFFICES IN ACCORDANCE WITH NOTIFICATION POLICY.</td>
</tr>
<tr>
<td>STANDARD 5: IDENTIFICATION OF INDIVIDUAL AND OPERATIONAL RESPONSIBILITIES, INCLUDING DUE DILIGENCE IN DELEGATING SUBSTANTIAL DISCRETIONARY AUTHORITY.</td>
<td>APPROVE DUKE UNIVERSITY COMPLIANCE PROGRAM STRUCTURE AND MANAGEMENT.</td>
<td>APPROVE DUKE UNIVERSITY COMPLIANCE PROGRAM STRUCTURE AND MANAGEMENT.</td>
<td>MAINTAIN INVENTORY OF COMPLIANCE RISK OWNERSHIP AND LIAISON ASSIGNMENTS. REVIEW INSTITUTIONAL SCREENING PROGRAMS TO DETECT ILLEGAL AND UNETHICAL ACTS. ENSURE CONFlict OF INTEREST DISCLOSURES ARE BEING MANAGED AND MONITORED APPROPRIATELY.</td>
<td>FOLLOW POLICIES RELATED TO SCREENING, CONFLICTS OF INTEREST AND APPROPRIATE DELEGATION OF AUTHORITY.</td>
<td>IDENTIFY OPERATIONAL OWNERS OF ASSIGNED COMPLIANCE RISKS.</td>
<td>PROVIDE GUIDANCE TO MANAGEMENT ON APPROPRIATE CONTROLS AND PROCESSES TO ADDRESS IDENTIFIED RISKS. AUDIT DEFINED PROCESSES, WHERE APPROPRIATE, TO ASSESS OPERATIONAL ADEQUACY OF COMPLIANCE CONTROLS AND PROCEDURES AND TO ASSESS COMPLIANCE WITH REGULATORY REQUIREMENTS.</td>
</tr>
<tr>
<td>COMMUNICATE STANDARDS, PROCEDURES AND OTHER ASPECTS OF THE PROGRAM THROUGH TRAINING AND OTHER METHODS OF DISSEMINATION.</td>
<td>ENSURE APPROPRIATE TRAINING AND COMMUNICATIONS ARE IN PLACE.</td>
<td>ENSURE APPROPRIATE TRAINING AND COMMUNICATIONS ARE IN PLACE.</td>
<td>PROVIDE TRAINING, COMMUNICATIONS AND GUIDANCE RELATED TO OVERALL COMPLIANCE AND SELECTED INSTITUTIONAL COMPLIANCE RISK AREAS.</td>
<td>ENSURE OPERATIONAL UNITS HAVE ACCESS TO, AND ARE HELD RESPONSIBLE FOR, RECEIVING COMPLIANCE TRAINING WHERE APPROPRIATE.</td>
<td>PROVIDE TRAINING, COMMUNICATIONS AND GUIDANCE RELATED TO ASSIGNED COMPLIANCE RISK AREAS.</td>
<td>PROVIDE PROCESS, INTERNAL CONTROL AND MANAGEMENT OVERSIGHT AS WELL AS GUIDANCE RELATED TO SELECTED COMPLIANCE RISK AREAS.</td>
</tr>
<tr>
<td>APPROPRIATE GROUPS TO BE ADDRESSED IN COMMUNICATIONS ARE THE GOVERNING AUTHORITY, HIGH-LEVEL PERSONNEL, EMPLOYEES AND AGENTS OF THE ORGANIZATION.</td>
<td>REVIEW PERIODIC REPORTS BY THE DUKE UNIVERSITY COMPLIANCE PROGRAM, AUDIT AND MANAGEMENT IN KEY COMPLIANCE AREAS. THE DUKE UNIVERSITY COMPLIANCE PROGRAM PROVIDES BACKGROUND TO NEW ARCC MEMBERS.</td>
<td>ENSURE OPERATIONAL UNITS HAVE ACCESS TO, AND ARE HELD RESPONSIBLE FOR, RECEIVING COMPLIANCE TRAINING WHERE APPROPRIATE.</td>
<td>REVIEW TRAINING AND COMMUNICATION PLANS RELATED TO SUBJECT SPECIFIC COMPLIANCE AREAS. MONITOR MANDATORY TRAINING COMPLIANCE WHERE APPROPRIATE.</td>
<td>ENSURE OPERATIONAL UNITS HAVE ACCESS TO, AND ARE HELD RESPONSIBLE FOR, RECEIVING COMPLIANCE TRAINING WHERE APPROPRIATE.</td>
<td>PROVIDE TRAINING, COMMUNICATIONS AND GUIDANCE RELATED TO ASSIGNED COMPLIANCE RISK AREAS. MONITOR COMPLIANCE WITH MANDATORY TRAINING REQUIREMENTS.</td>
<td>MONITOR MANDATORY TRAINING COMPLIANCE WHERE APPROPRIATE.</td>
</tr>
<tr>
<td>STANDARD 5A</td>
<td>Review summaries of risk-based monitoring and auditing activities presented at each ARCC meeting.</td>
<td>Review summaries of risk-based monitoring and auditing activities and action plans.</td>
<td>Review liaison reports and summarize for RSIC and ARCC. Provide training to liaisons on risk assessments and key monitoring issues. Review and assess action plans related to monitoring results. Review each year selected monitoring activities that have no reporting requirement.</td>
<td>Implement operational changes, as appropriate, to address monitoring and audit findings.</td>
<td>Develop and implement risk-based monitoring plans for assigned compliance areas. Report monitoring findings to management and the Duke University Compliance Program in accordance with assigned risk levels and Notification Policy. Develop action plans to address findings where appropriate.</td>
<td>Provide guidance to management on appropriate controls and processes to address identified risks. Audit defined processes, where appropriate, to assess operational adequacy of compliance controls and procedures and to assess compliance with regulatory requirements.</td>
</tr>
<tr>
<td>STANDARD 5B</td>
<td>Periodically evaluate the effectiveness of the program, including a risk assessment process.</td>
<td>Periodically evaluate the effectiveness of the program, including a risk assessment process.</td>
<td>In coordination with the other compliance officers, develop recommendations for approval of institutional and highly ranked compliance risks based on liaison risk assessments and results of monitoring and auditing. Submit recommendations to RSIC and ARCC for review and approval.</td>
<td>Report, as appropriate, on management responses to key compliance risks. When appropriate, review and approve individual liaison risk assessments.</td>
<td>Perform risk assessments, including ranking the impact and probability of noncompliance, for areas of assigned risk. Submit inventory updates, rankings and compliance plans to the Duke University Compliance Program. Such rankings will occur as part of the annual Duke University Compliance Program inventory process and whenever significant changes to risk are identified.</td>
<td>Review institutional risk assessments to determine appropriate inclusion in audit and monitoring plans.</td>
</tr>
<tr>
<td>STANDARD 5C</td>
<td>Have and publicize a system for employees and agents to seek guidance or report potential or actual noncompliance without fear of retaliation.</td>
<td>Ensure adequate resources are available for identification and investigation of questions, concerns and reports of noncompliance.</td>
<td>Promote and manage Compliance and Fraud Hotline. Ensure compliance with Duke non-retailation policy. Provide easy access, through a web portal, to Duke compliance resources. Facilitate access to subject-specific compliance resources.</td>
<td>Ensure all management staff are educated on accessing compliance resources available. Ensure Duke non-retailation policy is followed and enforced by all levels of management.</td>
<td>Provide easy access to subject-specific compliance resources. Ensure appropriate management of compliance reports made to specific areas and notify appropriate management and compliance offices.</td>
<td>Provide follow-up on hotline calls as appropriate.</td>
</tr>
<tr>
<td>STANDARD 6</td>
<td>Program shall be promoted and enforced consistently throughout the organization, including appropriate incentives for compliance and appropriate disciplinary measures for noncompliance.</td>
<td>Review major compliance policies.</td>
<td>Ensure staff and managers are held accountable for following policies related to compliance. Ensure appropriate disciplinary actions are followed.</td>
<td>Ensure staff and managers are held accountable for following policies related to compliance. Ensure appropriate disciplinary actions are followed.</td>
<td>Develop and promote subject-specific issues consistent with Duke policies.</td>
<td>Provide guidance to management on appropriate controls and processes to address identified risks. Audit defined processes, where appropriate, to assess operational adequacy of compliance controls and procedures.</td>
</tr>
<tr>
<td>STANDARD 7</td>
<td>Ensure program compliance through monitoring and auditing.</td>
<td>Review periodic reports to ensure reasonable efficacy of program related to institutional compliance risk areas.</td>
<td>Use monitoring results and other risk information to assess compliance processes and program effectiveness.</td>
<td>Communicate issues related to compliance risks encountered in operations.</td>
<td>Use monitoring results and other risk information to improve compliance processes.</td>
<td>Submit periodic reports on audits and reviews of key compliance risk areas to senior leadership and ARCC.</td>
</tr>
</tbody>
</table>
When noncompliance occurs, the organization must take reasonable steps to respond appropriately, including steps to remedy harm and to act to prevent further similar conduct.

| Review reports and plans related to incidents of significant noncompliance. | Approve Notification Policy defining key players and processes to be used for investigations of noncompliance. Approve, where appropriate, remediation plan and process or policy changes. | Assess incidents and the associated plans to ensure appropriate corrective and remediation actions are taken. Track incidents and reports resulting from Notification Policy. | Implement operational changes, as appropriate, to address monitoring and audit findings. | Assess incidents and the associated plans to ensure appropriate actions are taken. Forward information to management and compliance in accordance with Notification Policy. | Audit defined processes, where appropriate, to assess potential areas of weakness leading to noncompliance. Provide guidance on policy issues and, where appropriate, monitor to ensure appropriate corrective and remediation actions have been taken. |