

Duke University Compliance Program Elements

The Duke University Compliance Program is based on the Office of Inspector General of the U.S. Health and Human Services' (OIG) Compliance Program Guidance and U.S. Federal Sentencing Guidelines for effective compliance programs:

1. Code of Conduct

The university's "Statement of Ethical Principles and Code of Conduct" and Duke Medicine's Code of Conduct – entitled "Integrity in Action" – present the fundamental principles and values that guide the institution's activities. Both provide an overview of key regulations and framework for performance of activities throughout the university and are provided to all faculty and staff during orientation.

2. High-level Compliance Officer and Compliance Committee

The CCO reports to the executive director, audit risk and compliance and the ARCC of the university board, which approves the OARC audit and compliance annual plans and receives status reports on the work plan and other important issues. The Risk and Compliance Steering Committee (RCSC) reviews the work plan prior to submission to the ARCC and receives updates on other compliance-related activities.

3. Compliance Policies and Procedures

Duke University has established internal controls, policies and quality assurance processes. OARC's auditing process tests for adherence to applicable policies and procedures.

4. Open Lines of Communication

Duke University supports a compliance environment that fosters communication throughout the organization without concern of retribution. There are three toll-free hotlines: the Compliance and Fraud Reporting Hotline, the Integrity line and the Privacy line. There is an internal Animal Welfare Hotline maintained directly by the Office of Animal Welfare Assurance which serves as an emergency response line for animal health and safety issues.

5. Training and Education

Throughout the university, there are various venues for training and education. The compliance program works with the research community and university offices such as the Duke Office of Clinical Research and Research Costing Compliance to provide training and hosting of forums to educate individuals about regulatory compliance requirements. For areas with mandatory annual compliance education, the compliance program tracks education completion and provides reports to management.

6. Monitoring, Centralized Compliance Reviews and Auditing

The compliance program provides oversight of monitoring activities across the university focusing on the institutional risks. The compliance program ensures that compliance monitoring is performed by compliance liaisons and that the monitoring activities are tailored to the level of risk. The compliance program ensures that monitoring results are appropriately reported, evaluated and acted upon as needed.

The compliance program performs centralized compliance reviews or departmental compliance reviews of identified institutional areas that may be at risk for non-compliance. These centralized compliance reviews are reflected in the compliance work plan approved annually by the ARCC of the

university board of trustees. These efforts are complimented by OARC Audit Division's horizontal process audits in compliance related infrastructure and internal controls. OARC also provides advice and consultation in preparation for external agency audits including assistance with the external audit responses.

Status reports of all monitoring, centralized compliance reviews and departmental compliance review related activities are presented to the ARCC of the university board at least two times per year.

7. Response to Deficiencies

Based upon OARC's centralized compliance review findings, monitoring results, audit findings, investigations or other instances of identified deficiencies or non-compliance, corrective action plans may need to be implemented. OARC assists units and liaisons in developing plans to strengthen internal controls to appropriately address identified issues. OARC verifies that corrective actions are completed prior to closing a centralized compliance review. Where a corrective action requires a repayment, the office verifies that the repayment is made to the affected governmental and/or non-governmental payers.

8. Enforcement

OARC consults with Human Resources, the Office of Institutional Equity, and the Office of University Counsel to agree upon disciplinary sanctions where appropriate.

The compliance program is advised by the RCSC, comprised of the president (as chair), the chancellor of the health system, the provost, the executive vice president, the dean of the School of Medicine, general counsel and a school dean appointed by the president.