

# Living with a Corporate Integrity Agreement

A Partnership of Necessity

# Statutory Authority

- The OIG has exclusion authority based on 42 U.S.C 1320a-7(b) (7). *What this means is the OIG has the authority to exclude the organization or individual from doing business with the Federal government, thus losing all revenue from any Federal program.*

# The “Agreement” has 2 Parts

- The agreement, commonly called a ***Corporate Integrity Agreement (CIA)***, generally takes two forms: one is the actual ***“Settlement Agreement”***, specifying the dollar amount and the other is the ***“Compliance Agreement”***, which details the specifics relative to establishing a compliance program, auditing, annual reporting, etc.

# CIA: The Tool of Choice that Settles Monetary Issues and Addresses Compliance Concerns

- There are over 400 CIAs reflected on the OIG web site (<http://oig.hhs.gov/fraud/cias.html>). A small percentage of these are in academic medicine, more often related to improper billing, or possible violation of the teaching physician rules. Similar lists may be found with other Federal agencies related to research misconduct, e.g. National Institute of Health, Office of Research Integrity, EPA, etc.

# Requirements of the CIA

- General requirements of the CIA mirror the Federal Sentencing Guidelines (Chapter 8) for establishing a compliance program (<http://www.ussc.gov/guidelin.htm>)

# Negotiating the Settlement

- Given the high stakes, particularly the potential loss of Federal revenue, organizations should devote their best talented and most experienced staff members to represent them during this process. This is the time to have your “A” team on the field. Staff assigned to this process should possess strong negotiation skills, tact, and an in depth knowledge of the subject area.

# Major Pitfall

- Common mistakes made by organizations during the investigation include not cooperating fully with (sometimes obstructing justice) and the destruction of documents. When this occurs, the organization's culpability may rise to where the settlement of fines include double or treble damages.

# Turning Lemons to Lemonade

- An upside to the CIA is that it can provide leverage for the Board, Senior Administration, and the Compliance Officer to increase oversight, initiate a culture change, or implement new policy. The status quo must be abandoned: key members of senior management, the faculty, and staff must embrace the mandate for change

# Board Knowledge and Oversight

- Boards and Board members have been increasingly reviewing their responsibilities since the publication of the Sarbanes-Oxley Act of July 30, 2002. While mandated for publicly traded corporations, many non-profit organizations have taken a “Best Practices” approach to comply with the spirit of the law. Subsequently, Audit/Compliance Committees have taken an increasing interest and leadership role in regulatory oversight and external audit engagements. The CIA will undoubtedly be brought to the attention of an organization’s Board and committee structure to provide understanding and future oversight of the CIA mandates. Most certainly, the Chief Compliance Officer (CCO) or Chief Audit Executive (CAE) will be directly interacting and providing mandated reporting to the Board and the respective Audit/Compliance Committee.

# The Role of the Chief Compliance Officer

- The Chief Compliance Officer will be responsible for overall compliance operations to include, billing processes, review of grants and contracts, development of training programs, and the submission of comprehensive reports at least annually to the Board of Trustees and the lead federal agency. He or she will chair an organizational Compliance Committee and coordinate enterprise-wide compliance operations. The CCO will be required to provide the comprehensive annual and institutional attestation report for the mandated period (usually 5 years). A team effort and a supporting institutional structure are requirements for success.

# Summary

- The inertia, lethargy, or the long standing culture of an organization offer leadership challenges. Historical practices, coupled with a failure to stay abreast of change, is analogous to putting one's head in the sand and waiting for the danger to go away. The reality is that regulations change daily, with new ones being published while older ones are thrown out or worse yet, retained to help preserve the arcane nature of the regulatory environment.