I. PURPOSE

The purpose of the Notification Policy is to allow for improved management of institutional risk through coordination of episodic activities with outside agencies or internal events that could reasonably be expected to lead to reporting to an outside agency.

II. SCOPE

This policy applies to any communications or incidents involving external regulatory or compliance authorities, including but not limited to:

- Office of the Inspector General
- Department of Justice
- Attorney General’s Office (Federal or State)
- Office of Civil Rights
- Office of Human Research Protections
- Nuclear Regulatory Commission (Federal or State)
- National Science Foundation
- Department of Defense
- State Auditors

This policy also applies to “for cause” notifications from agencies such as:

- Occupational Safety and Health Administration
- Food and Drug Administration
- Environmental Protection Agency
- Equal Employment Opportunity Commission
- Department of Labor
- National Institutes of Health or other HHS agencies
- Centers for Medicare & Medicaid Services

Please note: Service of process by a police department should always be reported first to University Counsel (919-684-3955), who will involve the appropriate Compliance Office(s) if needed.
III. BACKGROUND

The University has made a strategic commitment to managing compliance risks at an institutional level. The monitoring of risks by compliance functional areas and the subsequent reporting of those results to the Board of Trustees (through the Audit Committee, Risk and Compliance Steering Committee, and the Duke University Ethics and Compliance Office) addresses day-to-day operational management of risk. Compliance activities by outside regulatory and funding agencies have become a significant part of compliance risk management. Current monitoring activities do not address the analysis or coordination of this risk at an institutional level.

This policy was developed with oversight and approval of the Audit Committee of the Board of Trustees and sets forward the following goals for managing these types of institutional compliance risks:

- Involvement of the right people as early as possible
- Coordinated responses to external audiences to ensure consistency across the institution
- Opportunity for institutional analysis of potential risks and impacts
- Data collection for trend analysis
- Identification of institutional policy or systemic issues

IV. NOTIFICATION PROCESS

Initial notifications or incidents received or identified by individual schools, departments, administrative support areas, faculty or staff, should be immediately reported to the appropriate area specific or general compliance office.

If the appropriate office is not known, notification should go to the Duke University Ethics and Compliance Office (DECO) for referral to the appropriate compliance office.

It is the responsibility of the compliance office first notified to gather the key elements available and continue the notification process.

No response should be given to the agency, other than acknowledgement of receipt, before the action plan, as defined in section V. below, is determined.

Notifications identified as “normal business practice” do not need to go through the notification process UNLESS there is an expectation of an official response to the outside agency.
Subpoenas related to regularly occurring access to and/or copies of records (patient, student or employee) should be handled according to normal Duke University and Duke University Health System (DUHS) policies and procedures.

V. PROCEDURES

Initial Notification

Immediately upon receipt of a notice of regulatory or compliance audit, review or site visit by an outside agency, the appropriate Compliance Office should be notified.

Please note: Notification should also be made for response coordination as early as possible in cases of internal events that could reasonably be expected to lead to reporting to an outside agency or regulatory body.

The “appropriate Compliance Office” is defined for this policy as:
- The DUHS Compliance Office for those issues which primarily impact DUHS (919-668-2573)
- The Duke University Ethics and Compliance Office (DECO) for those issues which primarily impact the SOM/SON and for those issues with impact across Duke or which primarily impact the Duke academic campus (919-684-2475)

The Compliance Office will identify the key elements involved and forward those to:
- University Counsel’s Office (919-684-3955)
- Other Compliance Offices (see above)
- Office of Internal Audits (919-613-7630)
- Compliance Liaison for the specific area (if not the person receiving the outside notice)
- Compliance Owner as identified in the compliance inventory (Dr. Richard Brodhead, Dr. Victor Dzau, Dr. Peter Lange, or Dr. Tallman Trask) and Dr. Trask for any items with potential significant financial risks.

Key Elements:

Initial:
- Who at Duke has been notified?
- Who is the notification from (governmental agency, regulatory body, etc.)?
- When the notice was received and is there action or response dates known?
- What are the identified issues to be addressed?
• Is the scope defined (time periods, defined research types, specific schools, departments, Principal Investigators, etc)?

Close Out:
• When was the “episode” complete?
• Were there any significant findings?
• Will the compliance functional area change their assessment of Institutional Risk level, their monitoring plans or training plans based on the outcome of this episode?

Response Coordination

It is the joint responsibility of the individuals included in the Initial Notification to determine the action plan for response. The action plan should include, but need not be limited to:
• Who will be on point for the institution?
• Who needs to be involved in strategy development?
• Are there institutional parties who only require status updates?
• Will outside resources (such as external counsel) be needed?
• Who must review formal responses sent outside the institution?
• Who should be present when agency representatives are on site?
• Does a communications plan need to be developed?

Reporting

Information related to the key elements and overall trends will be made available to senior leadership in support of their compliance management responsibilities.