OBJECTIVES

• Overview of compliance and ethics program and function

• Elements of an effective compliance and ethics program

• Status and next steps

• Focus on specific subject matter areas/initiatives
  • Research Compliance
  • Protection of Minors

• Discussion/Questions
Elements of an Effective Compliance and Ethics Program

To have an effective compliance and ethics program, an organization shall—

- exercise due diligence to prevent and detect criminal conduct; and

- otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law
Compliance and Ethics Program

Due diligence and the promotion of an organizational culture that encourages ethical conduct and a commitment to compliance with the law minimally require the following:

1. Standards (Policies, Procedures, Code of Conduct)
2. Oversight and exercise of due diligence
3. Education, training and dissemination of information appropriate to individuals’ roles and responsibilities
4. Auditing and monitoring
5. Reporting (including through anonymous mechanisms)
6. Enforcement (through appropriate incentives and discipline)
7. Response and prevention
8. Risk assessments and program evaluation (continuous improvement)

Standards (Policies, Procedures, Code of Conduct)

• Primary focus is on policies that serve to promote a culture that encourages ethical conduct and a commitment to compliance with the laws applicable to Villanova as an institution of higher education

• Are the institution’s policies easy to access and understand?

• Do the policies represent current practice?

• How does the institution address gaps? New or revised regulatory requirements?
Standards (Policies, Procedures, Code of Conduct)

• VU Policy Prohibiting Illegal, Dishonest, or Fraudulent Conduct:
  – VU committed to upholding the highest standards of honest behavior, ethical conduct and fiduciary responsibility with respect to University funds, resources and property
  – VU expects members of the University community to comply with all applicable laws
  – Policy prohibits illegal, dishonest or fraudulent conduct
  – Policy encourages any person who believes that an incident of illegal, dishonest or fraudulent conduct has been committed to report the incident immediately
  – Policy prohibits retaliation against any individual who files a complaint of illegal, dishonest or fraudulent conduct; or refuses to participate in the conduct in question; or is involved in the investigation
Oversight and Exercise of Due Diligence

• Commonly referred to as “tone at the top”
• Critical to have senior leadership buy-in and support
• Members of the Compliance and Ethics Program Advisory Committee appointed by Rev. Peter M. Donohue, O.S.A., Ph.D., President
• Members include faculty and staff from diverse University areas
Compliance and Ethics Program Advisory Committee and Areas Represented:

<table>
<thead>
<tr>
<th>Academic Affairs</th>
<th>Financial Aid</th>
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<tbody>
<tr>
<td>Robert DeVos, Ph.D., Assoc. Vice Pres. for Instructional Analysis, Professor, Mathematics &amp; Statistics</td>
<td>Bonnie Lee Behm, Dir. of Financial Assistance</td>
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<td><strong>Advancement</strong></td>
<td><strong>Human Resources</strong></td>
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<td><strong>Athletics</strong></td>
<td><strong>Information Technology-UNIT</strong></td>
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<td><strong>Environmental Health &amp; Safety</strong></td>
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<tr>
<td>Robert Morro, Vice Pres. for Facilities Management</td>
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<tr>
<td><strong>Faculty Representative</strong></td>
<td><strong>Research/Sponsored Projects</strong></td>
</tr>
<tr>
<td>Brett T. Wilmot, Ph.D., Assoc. Dir., Ethics Program</td>
<td>Alfonso Ortega, Ph.D., Assoc. Vice Pres. for Research and Graduate Programs</td>
</tr>
<tr>
<td><strong>Finance</strong></td>
<td><strong>Risk Management</strong></td>
</tr>
<tr>
<td>Neil J. Horgan, M.T., Vice Pres. for Finance</td>
<td>Ashlie Feick, Dir. of Insurance and Risk Management</td>
</tr>
<tr>
<td><strong>Student Affairs</strong></td>
<td><strong>Ex-Officio Members</strong></td>
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<tr>
<td><strong>Chairperson</strong></td>
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<td>Leyda L. Benitez, J.D.</td>
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<td>University Compliance Officer</td>
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<td><strong>Ex-Officio Members</strong></td>
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<td>Katie Fischer, Dir. Exec. Comm.</td>
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Education and Training

• Are employees working in highly regulated areas receiving adequate education and training?
• Is mandatory training being provided and appropriately documented?
  – Are job descriptions tracking education and training requirements?
  – Is mandatory training appropriately documented?
  – Are employees encouraged to ask questions without fear of embarrassment or retaliation?
Auditing and Monitoring

• Institutional Level:
  – Align results of risk assessment with areas to audit/monitor
  – Remember risks can be strategic, financial, operational, compliance and reputational
  – Develop annual work plan
  – Retain discretion and flexibility to adapt/revise annual work plan as needed for new or emerging risk areas
  – Support conduct of internal and external audits

• Project Level:
  – Build safeguards so that once a new process is implemented or revised, it is not forgotten
Reporting

• Vital element of a compliance and ethics program is a mechanism, widely publicized, whereby the institution’s employees and agents may report or seek guidance regarding potential or actual misconduct without fear of retaliation
• This mechanism should allow for anonymous or confidential reporting
• At Villanova, this mechanism is provided through EthicsPoint which can be accessed via toll-free number at 855-236-1443 or at https://secure.ethicspoint.com/domain/media/en/gui/35905/index.html
• The University Compliance Office has created a webpage that provides information to the University community about EthicsPoint: http://www1.villanova.edu/villanova/president/uco/hotline.html
How do I file a Report?

Please note that this will redirect you to the EthicsPoint (EP) webpage for Villanova University or call toll-free at 855-286-1749.

If you call the EthicsPoint toll-free number, you will be greeted by a professionally trained call center staff person. You will be asked to provide the same information that you would provide if you were using the online report form. The interviewer will type your responses into the system and use that to generate an electronic report. These electronic reports have the same security and confidentiality protections as a report that you would enter directly online.

Can my supervisor help me resolve my concerns?

Typically, the best place to raise a concern or ask a question is within your own college or department through supervisory or department channels.

There are many areas within the University that have identified a specific person to handle questions or reports about something you think may be wrong. Please refer to the University Compliance Directory for point persons with compliance responsibilities over diverse subject matter areas. You may access the University Compliance Directory here.

For more information on the Hotline, please refer to the Frequently Asked Questions (FAQs) which are found on EthicsPoint’s webpage for Villanova University.

If you call the EthicsPoint toll-free number, you will be greeted by a professionally trained call center staff person. You will be asked to provide the same information that you would provide if you were using the online report form. The interviewer will type your responses into the system and use that to generate an electronic report. These electronic reports have the same security and confidentiality protections as a report that you would enter directly online.

Remember that this service is NOT to be used in case of emergencies.

For emergencies, DIAL:
- dial 9-4444 (on campus)
- 610-519-4444 (off-campus)
- or 911

Can anybody file a report?

Yes, but you are expected to act in "good faith" when making a report. This means that you are expected to provide information you know or suspect is true. Providing a report based on information you know is false can be hurtful to individuals who have not done anything wrong. Therefore, purposefully filing a false or malicious report can constitute grounds for disciplinary action.
Enforcement, Response and Prevention

• Compliance and ethics program relies upon established processes to enforce the institution’s standards (Examples: academic integrity, student conduct, employment)

• Upon discovery of suspected or actual unlawful conduct, the institution must take reasonable steps to respond appropriately to any violation of law or policy in order to correct such conduct

• Modify and improve upon the institution’s compliance program to prevent future misconduct

• Develop safeguards to prevent retaliation

• Make restitution, where appropriate

• Educate, educate, educate
Compliance Risk Area: Human Subject Research

- Villanova University’s Institutional Review Board (IRB) is responsible for reviewing applications of faculty, students and staff proposing to conduct research that involves human beings.

- The IRB policies and procedures apply to any and all research activity that involves human subjects (large or small scale, preliminary, pilot or fully designed studies, student or faculty research, funded or non-funded research, regardless of level of risk to study participants).

- All research that involves human beings must be reviewed by the IRB before initiating the research study. This includes analysis of existing large data sets, interview of participants, and all other research by faculty, students, or staff that involves human beings in any way.

- Source: Slide Content Courtesy of Dr. Suzanne Smeltzer, Chair, Villanova University Institutional Review Board.
Compliance Risk Area: Human Subject Research

- Definition of “research” under federal regulations is extremely broad:
  - Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
    - 45 CFR Section 46.102 (d)

- Principal Investigator(s) and Key Personnel must complete:
  - CITI online training on Human Subject Protections as part of the project submission process
    - [https://www1.villanova.edu/villanova/vpaa/orgp/research/ora/training.html](https://www1.villanova.edu/villanova/vpaa/orgp/research/ora/training.html)
  - Financial Conflict of Interest in Research Disclosure Form
Compliance Risk Area: Human Subject Research

For more information regarding human subject research and the IRB please visit:

https://www1.villanova.edu/villanova/vpaa/orgp/research/ora/compliance/board.html

http://www.hhs.gov/ohrp/index.html

Contact:
Susan Stearsman
Director, Office of Research Administration
610-519-4221
susan.stearsman@villanova.edu

Contact:
Suzanne Smeltzer, Ed.D, RN, FAAN
Director, Center for Nursing Research & Professor; Chair, VU IRB
610-519-6828
suzanne.smeltzer @villanova.edu
Compliance Risk Area: Protection of Minors

• Two main policies to protect minors during activities and programs taking place on campus, in University facilities, or under the authority of the University at off-campus locations

• Villanova University Child Abuse Reporting Policy

• Faculty and staff who come into contact with children must report suspected or confirmed child abuse

• Students and volunteers of Villanova who accept responsibility for a child as part of a program, activity or service sponsored by Villanova are also required to report
Compliance Risk Area: Protection of Minors

- Villanova University Child Abuse Reporting Policy
  
  - Duty is to report child abuse you actually know about, see, or have reasonable cause to suspect
  
  - Includes physical, sexual, mental, emotional abuse and neglect
  
  - Reports must be made to the Pennsylvania Department of Human Services ("DHS") toll-free ChildLine at (800) 932-0313; within 48 hours of your oral report, you must follow up with a written report to DHS or the county agency assigned to the case
  
  - Subsequent to the report to DHS, reports must also be made to the Director of Public Safety at: 610-519-6982; david.tedjeske@villanova.edu
  
  - Alternate: Executive Vice President at: 610-519-4532; ken.valosky@villanova.edu
Compliance Risk Area: Protection of Minors

- **Minors in Villanova University Programs Policy**
  - Website dedicated to Minors and Youth Programs: [http://www1.villanova.edu/villanova/president/uco/minors.html](http://www1.villanova.edu/villanova/president/uco/minors.html)
  - Explains criminal background checks and education and training requirements
  - Minors Programs must be registered via the Online Registration System: [https://www1.villanova.edu/villanova/president/uco/minors/registration_secure.html](https://www1.villanova.edu/villanova/president/uco/minors/registration_secure.html)
  - Workshops take place on a monthly basis and upon request
  - Questions can be referred to:

    | Leyda Benitez            | Tracey Pachman             |
    |-------------------------|---------------------------|
    | University Compliance Officer | Associate General Counsel |
    | Co-Chair, Minors on Campus Committee | Co-Chair, Minors on Campus Committee |
    | 610-519-3976             | 610-519-5335              |
    | leyda.benitez@villanova.edu | tracey.pachman@villanova.edu |
Discussion/Questions