

**Legal Issues and Policies Pertaining to Faculty's Instructional Role****Case Study A: Intersection of Academic, Research, Health, Safety and Personal Proprietary Interests**

In mid-October, an Engineering faculty member Dr. Catherine Researcheagle learned of a National Science Foundation (NSF) funding opportunity to encourage K-12 students to study STEM in college. The submission deadline is November 1<sup>st</sup>, and despite the quick turnaround time, her limited experience in sponsored research, and recommended institutional proposal preparation timeline, she decided to apply anyway. Dr. Researcheagle owns a software development company that has produced a novel program to teach coding skills, and she sees this as a great opportunity to evaluate it compared to the most used program for coding education. She has decided to propose an on-campus workshop for high school students for the following summer. Because of the tight deadline, Dr. Researcheagle does not work with the Office of Grants and Contracts (OG&C) to develop a thorough budget for the project. Additionally, there was not enough time for the Office of Grants and Contracts and her College leadership to thoroughly review the proposal prior to submission. At the time of submission, a Financial Conflict of Interest disclosure form is required, which Dr. Researcheagle submits, disclosing her ownership interest in the software development company.

In April, Dr. Researcheagle was notified by NSF that her proposal was selected for funding. As a condition of receiving the award the sponsor requires Institutional Review Board (IRB) approval and an executed management plan for the perceived financial conflict of interest before her work can commence. The IRB requirement is foreign to Dr. Researcheagle, who has never conducted research with human subjects before, so she contacts the Office of Research Protections (ORP) for a meeting to get some help. In addition to the IRB documentation, she has heard that there are specific requirements that must be met when working with minors. For the summer coding program, she intends to have high school students come in once a week for three weeks, and then finalize the program with a weekend "Coding Marathon" that will end with a presentation of projects and an award ceremony for all participants. Dr. Researcheagle is not sure what her next steps should be but looks forward to asking ORP representatives for assistance.

While working through the required institutional requirements to accept the grant, the fire alarm goes off in CEER. Since she feels very pressed for time, Dr. Researcheagle does not leave her desk and continues working, knowing that she only has a few minutes until the scheduled meeting with ORP to discuss IRB requirements anyway. When she does eventually leave for the meeting, she trips on an uneven sidewalk and falls, spraining her wrist and scraping the palm of her hand, which begins to bleed. When Dr. Researcheagle arrives in Middleton Hall, she asks one of the employees there, Olivia Conscience, to help her bandage her hand. Dr. Researcheagle is now late to her meeting and demands Olivia help her further by cleaning up the first aid area, pleading "come on, just take care of the rest of this for me. If not, I will be even later for my meeting, and if I lose this grant, I doubt your supervisor will be very happy". Olivia does so, throwing blood-soaked paper towels in the regular bathroom trash. Upon reflection later that day, Olivia feels very conflicted about the pressure she felt to help Dr. Researcheagle in that way and potentially putting herself and the custodial staff at risk.

1. Please identify the issues raised by this scenario.

2. What should Dr. Researcheagle have considered prior to deciding to submit the proposal? Who else should have been consulted in making the decision to proceed under the circumstances?
3. What could Dr. Researcheagle have done to better position herself for successful implementation of her new award? In addition to the IRB policies, are there other policies that Dr. Researcheagle should know about? Where should she go for help?
4. Why is Olivia Conscience concerned?
5. What should Dr. Researcheagle have done differently related to the fire alarm and to her fall?
6. What are Olivia Conscience's options?

## Short Answers to Discussion Questions

1. Please identify the issues raised by this scenario.
  - a. Potential conflicts of interest (See Policies: [Financial Conflict of Interest in Research](#) and [Conflicts of Interest and Business Ethics](#))
  - b. Lack of knowledge of applicable procedures:
    - i. Grant submission timeline and resources
    - ii. Minors on campus
    - iii. Protection of human subjects
    - iv. Following standard timelines
    - v. Workplace safety - injury reporting and handling potential biohazards
    - vi. Fire Safety
2. What could Dr. Researcheagle have done to better at the time of her grant application?
  - a. Work with all available resources (OG&C, ORP, dept. chair, research dean, UCO, IRB).
  - b. Consider the grant submission timeline.
  - c. Consider the compliance requirements that must be in place for securing regulatory approvals.
3. In addition to the IRB policies, are there other policies that Dr. Researcheagle should know about? Where should she go for help?
  - a. Dr. Researcheagle should become familiar with the [Minors in Villanova University Programs Policy](#) and possibly the [Minors in the Laboratory policy](#). Since she will be working with minors she should also review the [Child Abuse Reporting Policy](#).
  - b. Dr. Researcheagle should become familiar with the [Full-time Faculty Handbook](#)'s section on Consulting, Outside Teaching, and Professional Work.
  - c. Dr. Researcheagle should review the [Responsible Conduct of Research](#) policy.
  - d. Dr. Researcheagle should contact the University Compliance Office so that the Program Assessment team can assess the summer coding program for various risk, legal and compliance requirements.
4. Why is Olivia Conscience concerned?
  - a. She was asked to do something she wasn't qualified to do (first aid, handling biohazards).
  - b. Disposing of bloody paper towels in the trash is a risk to custodial staff.
5. What should Dr. Researcheagle have done differently related to the fire alarm and to her fall?
  - a. Fire alarm: leave building immediately and assemble at muster point.
  - b. Fall: call Public Safety who would respond with medical aid.
  - c. Dr. Researcheagle should let her supervisor know of the incident so that they can submit an injury report.
6. What are Olivia Conscience's options?
  - a. Disclose the experience to her supervisor for discussion and advice.
  - b. If Olivia is not comfortable with options, she could call the EthicsPoint hotline and request guidance and assistance regarding the activities.

## **Conflicts of Interest**

**Answer:** Dr. Researcheagle's use of coding education software produced by the company she owns in the research project is prohibited absent prior written disclosure by her and approval by the University.

The case scenario presents potential conflicts of interest under two separate University policies: The University's **Conflicts of Interest and Business Ethics Policy** and the **Financial Conflict of Interest in Research Policy**. The main takeaway is that when there is any potential conflict of interest under applicable law or University policy, the faculty member must disclose this potential conflict to his/her chair or dean for initial guidance. In all instances, the University requires the disclosure be made in writing.

When the potential conflict involves externally funded research or work with human subjects, disclosure must also be made to Villanova and possibly to the sponsor. In many instances, a management plan is required to proactively manage a potential conflict of interest. Villanova applies the Public Health Service agency, 42 CFR Part 50, Subpart F, 'Promoting Objectivity in Research' requirements for all externally sponsored research. The purpose of the regulation is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of funded research is free from bias resulting from Investigator financial conflicts of interest. Therefore, it is critical that Dr. Researcheagle understands her obligations to disclose any real or perceived potential conflict of interest, so the situation can be evaluated and managed accordingly. Since the regulation is a term and condition of all NSF grant and cooperative agreement awards, compliance with the requirements is a condition of funding.

## **Related References**

**Business Ethics:** Dr. Researcheagle's use of coding education software produced by the company she owns in the research project falls under the University's [Conflicts of Interest and Business Ethics](#). The essence of this policy is that all employees will conduct the University's business with integrity, in compliance with applicable laws, and in a manner that excludes consideration of personal advantage.

The policy provides that "[e]mployees shall avoid any situation which involves or may involve a conflict between their personal interest and the interests of the University" and requires that employees disclose in writing potential conflicts of interest to the President and appropriate Vice President for review and resolution as to whether the employee can make decisions regarding the utilization of the University's resources. In the case of faculty, review, and resolution of conflicts under this policy is made by the Provost.

**Research:** Since the activity that Dr. Researcheagle is involved in constitutes research, University policy and federal law require that Dr. Researcheagle disclose to Villanova the Investigator's Significant Financial Interests under the University's [Financial Conflict of Interest in Research Policy](#).

All VU investigators who are engaged in, or intend to engage in, an externally funded research project, or who are engaged in, or intend to engage in, research involving human subjects (whether externally funded or not), must disclose to Villanova any Significant Financial Interest (as defined by University policy and Federal law) in order to ensure that any conflict of interest that could directly or significantly affect the design, conduct or reporting of the research project is appropriately managed, reduced or eliminated.

Significant Financial Interests (which include those of the Investigator's spouse and dependent children) that must be disclosed are those that reasonably appear to be related to the Investigator's Institutional Responsibilities including activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels and advisory boards. The disclosure form follows the definition of Significant Financial Interest and asks the Investigator to disclose interests in publicly traded and non-publicly traded entities of specified amounts, income from intellectual property rights, and reimbursement for specified travel.

The disclosure is required no later than the time of proposal submission. For newly acquired Significant Financial Interests, the Investigator must disclose within thirty (30) days and also annually by September 30. The Conflict of Interest disclosure process is available online through the COI Risk Manager system. Positive disclosures are reviewed by the Financial Conflict of Interest in Research Committee to determine whether the Significant Financial Interests are related to the externally funded research (or human subjects research) and could directly and significantly affect the design, conduct or reporting of that research. If so, the Committee meets with the Investigator to discuss and reach a resolution as to how this conflict of interest can be managed, reduced, or eliminated.

Access to the COI Risk Manager system is available via MyNova, and you may also review the University's [Financial Conflict of Interest in Research](#).

**Bottom Line:** Dr. Researcheagle has a responsibility to read, understand and abide by both the Conflicts of Interest and Business Ethics and Financial Conflict of Interest in Research policies as well as any sponsor related policies. Entering into business transactions on behalf of the University with companies in which she has a personal ownership interest without prior written disclosure to the University is generally prohibited. Likewise, Dr. Researcheagle is required to disclose any Significant Financial Interest at the time of proposal submission in order for the University to determine whether such interest is related to the proposed research and can adversely impact the design, conduct or reporting of the research.

Assistance regarding these policies and the conflict disclosure requirements can be directed to various offices including the Office of the Provost, Office of Research Protections, Office of the General Counsel, and the University Compliance Office.

### **Procedures for Submitting a Grant Application**

As an organization submitting sponsored award proposals, Villanova University is responsible for ensuring that applications adhere to Villanova policy, sponsor and award specific requirements, and federal regulations. Proposals that do not align with funding guidelines may be rejected by the sponsor. Additionally, proposals that do not align with compliance requirements expose the University to potential audit risk, and the associated fines and findings.

To ensure that the principal investigator's (PI's) proposal can be evaluated based on the merit of the proposed project and to protect Villanova's assets, the Office of Grants and Contracts (OG&C) provides support to investigators in preparing their sponsored award proposals. The PI should notify the Office of Grants and Contracts of their plans to submit a proposal with as much advance notice as possible, preferably 4-6 months in advance, depending on the complexity of the project.

The timeline was developed with the following in mind:

1. Allows investigators to balance the tasks of developing a project/proposal with all of their other responsibilities.
2. Allows team members the time to provide the maximum benefit to the investigator.
3. Allows reviewers the time for a thoughtful review to provide useful feedback.
4. Allows for planning and preparation around securing institutional regulatory approvals.

Villanova also requires that fully routed and approved proposals be received by the Office of Grants and Contracts three business days prior to the sponsor deadline to receive institutional review through the Office of Grants and Contracts. Proposals submitted outside of that timeline are submitted at the investigator's risk and will require full review prior to acceptance of the award if selected for funding. This can have a significant delay on project implementation and potentially Villanova's ability to accept the award.

## **Related References**

[Sponsored Award Proposal Submission Policy](#)

[Recommended Proposal Development Timeline](#)

**Bottom Line:** Even though Dr. Researcheagle was awarded the grant from NSF, she was not prepared for handling the requirements to implement her project, which may impact her ability to carry out the project. If she followed the recommended timeline and worked with her team members (Department Chair, Dean/Research Dean, Research Administration Offices) she would have been supported in preparing for these activities and the project implementation would go much smoother, even if that meant postponing her application for the next round.

Contact the Office of Grants and Contracts @9-4220.

## **Minors on Campus**

All new programs or activities involving minors are assessed by representatives from the University Compliance Office, Office of Insurance and Risk Management, and the Office of the General Counsel who will meet with the Program Directors to discuss the nature and scope of the youth program or activity. During the Program Assessment the group will review requirements of PA Act 153 and University policy including criminal background checks, child abuse prevention and awareness education and training, adult to minor ratios, waivers, and program registration. Program Directors who wish to host a youth program or activity should contact the University Compliance Office to set up a Program Assessment. Minors programs that will take place within a laboratory setting must also follow requirements outlined in the Minors in the Laboratory Policy.

As a mandated reporter, Dr. Researcheagle should review the Child Abuse Reporting policy and understand the process for reporting known or suspected child abuse.

## **Related References**

The University Compliance Office [Minors and Youth Programs webpage](#) contains valuable information and resources regarding how to sponsor, oversee, and operate youth programs and camps.

The [Minors in Villanova University Programs Policy](#) outlines the minimum requirements that must be followed in order to protect minors who participate in youth programs and activities offered by Villanova.

The [Minors in the Laboratory Policy](#) provides additional requirements if the program or activity involving minors will take place in designated laboratories at Villanova.

The [Child Abuse Reporting Policy](#) explains that all Villanova University employees are mandated reporters who must report known or suspected child abuse as well as the process for making such a report.

Additionally, the Minors on Campus Committee has developed the Villanova University [Guidelines for Conducting Virtual Minors Programs and Activities during the COVID-19 Health Emergency](#) to assist Program Directors who wish to move existing programs to a virtual format or develop new virtual programs which involve the participation of minors.

**Bottom Line:** Since Dr. Researcheagle plans to oversee a program or activity involving minors that will take place on the University's campus, she should contact the University Compliance Office to set up a Program Assessment to review the various risk, legal and compliance requirements to host her program. It is recommended that this Program Assessment be conducted early, at least sixty (60) days before the start of the minors program or activity. Contact the University Compliance Office @ 9-8853.

## **Protection of Human Subjects**

**Answer:** Collection of data from human subjects likely constitutes human subjects research, which is subject to review and approval by Villanova's Institutional Review Board (IRB). Often, such research falls into one or more Exemption categories according to federal regulations, but the IRB is the only body that may make the final determination of Exemption. Given that minors are involved in this research, the review process will potentially take more time than if the project involved only adults. Dr. Researcheagle needs to be in contact with the Villanova IRB before conducting such activities and provide plenty of time for the review process. The IRB is not able to rush review processes in circumstances like these, even when a sponsored award is on the line, as the primary function of the Board is to protect the human subjects involved in research.

The students enrolled in this program must be provided the opportunity to decide whether or not to participate in the workshop and also whether or not to have their data collected for the research activities. Since they are minors, their parents must also be given the same choice and it is the PI's responsibility to arrange for that permission and document it. This process is referred to as "informed consent" and is one of the foundational elements of IRB review.

## **Related Reference**

Villanova's [Human Research Protection Program Plan](#) is available on the IRB website and Villanova's Policy Library. All human subjects research is governed by federal regulations found in Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46).

**Bottom Line:** Dr. Researcheagle must contact the Villanova IRB for review and approval of this work, even if it is ultimately determined to be exempt from the regulations. Such a determination is not the purview of the investigator, but the IRB. Dr. Researcheagle may not require the students to participate in research.

Contact the Office of Research Protections @ 9-4228 for additional guidance.

## **Workplace Safety**

**Answer:** Dr. Researcheagle has suffered a work-related injury.

## **Related Reference**

Villanova University [Emergency Guidebook](#) and [Workers' Compensation Policy](#). When someone suffers an injury, Public Safety must be called. Provide name, location, phone number and information regarding the injury and stay on the line until the operator gives direction to hang up. Seriously injured persons should not be moved unless there is a life-threatening emergency, i.e., a fire in the building. Public Safety personnel are trained in first aid and will call additional medical personnel if necessary. At that time, the victim can decide if (s)he wants further care.

Dr. Researcheagle's supervisor is responsible for reporting the injury to Villanova's workers' compensation insurer, PMA, and to complete an injury investigation report, so Dr. Researcheagle must notify them of the injury. Failure to immediately report an injury may result in delays or difficulties in receiving compensated medical care.

**Bottom Line:** Contact Public Safety @ 9-4444 for trained assistance.

## **Handling Potential Biohazards**

**Answer:** It is not permissible for Olivia Conscience to assist Dr. Researcheagle with her injury management or clean up the first aid area.

## **Related Reference**

Villanova University [Bloodborne Pathogen Exposure Control Plan](#). Only Villanova employees whose job descriptions include possible exposure to bloodborne pathogens receive training in protective measures; so, Olivia Conscience is probably untrained. It is inappropriate to ask an untrained person to handle these kinds of materials. If chemicals were used in the clean-up efforts, Olivia should refer to Villanova's on-line repository of Safety Data Sheets on the [Environmental Health and Safety web page](#).



Any material that has been contaminated with human blood or other potentially infectious materials must be properly disposed of through the medical waste program. It must not be thrown in the general trash.

**Bottom Line:** Only those who have completed training in bloodborne pathogen exposure control should handle any bodily fluids. Contaminated materials must be disposed of through the proper waste program.

Contact Environmental Health and Safety @ 9-3801 for additional guidance.

## **Fire Safety**

**Answer:** All personnel must immediately evacuate the building while the alarm is sounding.

## **Related Reference**

Villanova University [Emergency Guidebook](#) and the [NovaSafe App](#). Leave the building as soon as the alarm sounds through the nearest exit. If time permits, stabilize lab procedures, turn off stoves and ovens, unplug or disable any device that could make a dangerous situation worse.

Report to the designated muster location when leaving the building. Do not leave the muster point until you receive additional instructions from Public Safety.

Remaining in the building creates unnecessary risk for the employee/student and for first responders who will attempt to rescue a person believed to still be in danger.

Additional instructions may be communicated through NOVA Alert.

**Bottom Line:** If a fire alarm is activated, immediately exit the building using the nearest exit and report to the muster area. Remain at the muster area until given further instructions.

## **Fear of Retaliation**

**Answer:** Not Permissible, retaliation in any form is prohibited.

## **Related References**

[Policy Prohibiting Illegal, Dishonest, or Fraudulent Conduct](#)

[Ethics and Compliance Hotline \(EthicsPoint\)](#)

The University, through its [Policy Prohibiting Illegal, Dishonest or Fraudulent Conduct](#) policy, prohibits and does not tolerate retaliation against any individual who files a complaint of illegal, dishonest, or fraudulent conduct; is involved as a witness or participant in the complaint or investigation process; or refuses to engage in illegal, dishonest, or fraudulent conduct. Engaging in such retaliation can result in disciplinary action, up to and including dismissal from the University.

Villanova University has contracted with EthicsPoint an independent third party to provide a confidential Internet and telephone-based reporting tool to give University faculty, staff, and students an anonymous and confidential way to address misconduct in the workplace or classroom setting due to mismanagement of funds, fraud, or other violations of law or University policy.

**Bottom line:** Members of the University community are strongly encouraged to ask questions and raise concerns. Anyone expressing such a concern or making a report is protected from retaliation.

Questions regarding EthicsPoint can be directed to the University Compliance Office @ 9-5466.

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