Audio: Welcome to module 3. The purpose of this module is to provide an overview of the federal regulations that govern research and to outline the responsibilities of investigators to disclose and appropriately manage conflicts of interest and commitment.
Slide 2

Dramatic Changes to the Research Environment

- Bayh-Dole Act of 1980 encouraged faculty entrepreneurship
- Federal agencies support a variety of grants to move research and technology to market place (SBIR/STTR among others).
- Entrepreneurship creates higher level of risk to integrity of academic research
- Regulations from NIH/PHS
  - Other health related orgs
  - NIJ, EPA

Audio:

- The research environment has changed dramatically over the last 30 years. One important catalyst for change was the Bayh-Dole Act of 1980. As a result of the act, a faculty member who developed a great idea in a laboratory setting using federal grant funds was able to take that idea, patent it, and then start a company to refine that idea for the marketplace. Faculty entrepreneurship got a big boost as a result of the act. The Corporate Research Center adjacent to the Virginia Tech campus was created to help these new technology businesses get their start. And many faculty entrepreneurs, sometimes in partnership with their former graduate students, launched such businesses based on work they had done in a university laboratory.
- In recent decades, the federal government has provided even more support for entrepreneurship, startup companies, and technology transfer through special grant programs called “small business innovation” grants (SBIRs) or technology transfer grants (STTRs). At least as 11 different federal agencies offer grants to small companies in order to move an idea from a laboratory setting into the marketplace. Faculty entrepreneurship and technology transfer have greatly increased as a result. But entrepreneurship can create a new tension around where the faculty member’s primary interest and attention lie. Is their interest with the company that’s on the outside? Or is it with the university where their academic lab and students are located?
- Because of this tension, entrepreneurship creates a higher level of risk to the integrity of academic research and must be managed.
- Federal sponsoring agencies have developed additional requirements for disclosing and managing conflicts of interest in research including Public Health Service. Many Other health related agencies have elected to follow the PHS regulations. Additionally, the National Institutes of Justice and the Environmental Protection Agency have implemented their own conflict of interest requirements for awardees.
As a top research institution we must protect the reputation of Virginia Tech research and researchers through proper disclosure and management of conflicts of interest in research.

- It is important to recognized that perceived conflicts of interest undermine public trust in impartiality of academic research
- Virginia Tech has strongly encouraged “Putting Knowledge to Work” and “Inventing the Future” so that academic research can move from the university laboratory to the marketplace. But that commitment must be balanced with strong policies and adherence to ethical behavior around potential conflicts of interest.
- As a major research university, VT’s reputation for impartial, ethical research is very precious indeed!
In the past, most university policies on conflict of interest depended on the individual investigators to disclose whenever they thought that they had a significant conflict of interest. However, federal sponsors found that this approach did not always work. Too many researchers saw no conflict between a lucrative consulting contract or ownership interest in a company and their university research, and they chose not to disclose. Public Health Service regulations now put the responsibility for disclosure and management of conflict of interest on both the investigator and the institution. Institutions must have strong policies to manage conflict of interest and make sure that all investigators know about the policy through mandatory periodic training. If a management plan is needed to protect the research, the institution must review and monitor the plan to confirm that all conditions of the plan are being implemented. In some cases, the institution is required to disclose financial interests to the sponsor and confirm that a management plan is in place to protect the research.
Federal Regulations

- Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors
  - Appointment of a designated COI Officer
  - Mandatory training for investigators
  - Investigators must be trained prior to execution of an PHS award or within 30 days for non-PHS awards
  - Training must be repeated every 4 years or sooner if significant policy changes are made
- Many Federal agencies require disclosure prior to proposal submission-all require institutions to manage conflicts

Audio:

One of the catalyst for change was the passage of the Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors. Some of the requirements included the:

- Appointment of a designated COI Officer
- Mandatory training for investigators
- Investigators must be trained prior to execution of an PHS award or within 30 days for non-PHS awards
- Training must be repeated every 4 years or sooner if significant policy changes are made
- Many Federal agencies, including the Public Health Service, require disclosure prior to proposal submission and all federal sponsors require institutions to manage conflicts.
Who Is an “Investigator”? 

“Investigator” means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research.

- Sponsors following PHS regulations:
- Subcontractors, consultants, or collaborators are considered investigators for the purposes of this policy, as is anyone identified as key personnel in the proposal or the award agreement.

Investigator’s disclosures must include financial interests of immediate family members.

Audio: Virginia Tech Policy 13010 requires that all investigators disclose potential conflicts of interest related to a sponsored project and complete Virginia Tech conflict of interest training every 4 years. An investigator is defined as the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research.

For Sponsors following PHS regulations:

- Subcontractors, consultants, or collaborators are considered investigators for the purposes of this policy, as is anyone identified as key personnel in the proposal or the award agreement. We must obtain a conflict of interest disclosure from these entities.
- Investigator’s disclosures must include financial interests of immediate family members.
Disclosure Requirements for Research

- Significant Financial Interest (SFI)
  - Deminimus threshold of $5,000 for disclosure of payments from publicly traded entities, or
  - For non-publicly traded entities any equity interest would require disclosure (includes negative equity)
- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research)
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants

Audio:

- A significant financial interest in the context of research is when the investigator receives 5,000 or more in payments from an outside entity reasonably related to his or her institutional responsibilities. For example, if you consult for a publicly-traded company, like 3M or Exxon, and you receive more than $5,000 in consulting fees, then you need to report that income as a significant financial interest.
- For non-publicly traded entities, any equity interest would require disclosure for example a startup company would need to be disclosed to the university, even if the company has negative equity.
- Investigators with a significant financial interest involving their research should provide a public disclosure of financial conflicts of interest when presenting or publishing the research.
- For research projects involving human subject’s research, disclosure of financial conflicts of interest should be disclosed directly to participants on the consent form.
Must disclose:

- Remuneration from external entities including salary and any payment for services – consulting fees, honoraria, paid authorship
- Equity interest, including stock, stock options, or ownership interest
- Royalties paid by entities other than VTIP
- Travel paid for by outside entity if PHS investigator
- Any equity in a non-publicly traded entity related to your institutional responsibilities

Do Not Disclose:

- Salary, royalties, remuneration, travel paid by VT
- Income from investment vehicles, such as mutual funds and retirement accounts not directly controlled by investigator
- Income from seminars, lectures, teaching, or service on advisory committees or review panels sponsored by a federal, state, or local government agency, or U.S. institution of higher education

Disclosure Requirements

Audio:

- Federal regulations and Virginia Tech policy requires that you disclose Consulting fees, honoraria, payments to write a report, equity ownership, stock options, ownership interest of any kind, and royalties from a license from a non-Virginia Tech entity toward the $5,000 threshold for reporting. Any equity in a non-publicly traded entity related to your institutional responsibilities.

- You do not have to report income from Virginia Tech, only income that comes from a third party outside entity. You also don’t have to report retirement investments in mutual funds, since such funds typically do not allow you to personally determine what stocks are purchased or sold. Nor do you need to report income from seminars and lectures at other U.S. universities, academic research institutions, or participating in review panels sponsored by a federal, state, or local (U.S.) government agency.
Some sponsors required conflict of interest disclosure at the time of proposal submission. To meet this federal requirement the lead investigator is required to answer 5 conflict of interest questions on behalf of his/her entire research team. This disclosure encompasses all personnel listed in the proposal budget or named in the statement of work.

- These questions are to identify if anyone on the project has a significant financial interest related to the sponsor, subcontractor, contractual services or cost sharing commitments.
- If any outside entities are employee owned businesses,
- if anyone on the budget or statement of work has a familial relationship with others on the project, or
- If any project personnel has or plans to consult for the sponsor.

It is the responsibility of the lead investigator, not other Virginia tech staff members, to answer these questions. By answering these questions the lead investigator is assuring the university that he/she has knowledge regarding any conflicts of interest that exist related to the project. This disclosure should be treated with due diligence and transparency. The COI office will follow up with identified conflicts of interest including conflicts of interest that were not properly disclosed on the proposal approval form.
Travel for PHS Investigators Only

- PHS investigators must also disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities
- Disclosure includes:
  - purpose of the trip
  - identity of the sponsor/organizer
  - destination
  - duration
- However, this disclosure requirement does not apply to travel that is reimbursed or sponsored by:
  - a federal, state, or local government agency,
  - an institution of higher education,
  - an academic teaching hospital,
  - a medical center, or a research institute affiliated with a US institution of higher education.
- [https://secure.research.vt.edu/rcr/](https://secure.research.vt.edu/rcr/)

Audio: Additional disclosures are required of PHS investigators regarding 3rd party reimbursed or sponsored travel related to their institutional responsibilities.

- This 3rd party travel disclosure must include the...
  - purpose of the trip
  - identity of the sponsor/organizer
  - destination
  - duration
- However, this disclosure requirement does not apply to travel that is reimbursed or sponsored by:
  - a federal, state, or local government agency,
  - an institution of higher education,
  - an academic teaching hospital,
  - a medical center, or a research institute affiliated with a United States institution of higher education.

- PHS investigators can disclose 3rd party travel online at the link provided on this slide. [https://secure.research.vt.edu/rcr/](https://secure.research.vt.edu/rcr/)
Audio:

There are a number of publicized cases where conflicts of interest had a significant impact on research projects.

- In 2015, the National Science Foundation froze 7 grants due to undisclosed COI related to purchases from employee owned business. In two of three purchase requisitions, faculty members with a stake in the company signed a certification statement that they had no financial or other beneficial interest in the vendor. The grants, all related to underwater communication and exploration, were worth more than $4.6 million. The owners of the company were principal investigators or co-principal investigators in each of the grants. In 2016, NSF resolved the case and six grants were terminated.

- In 2015, an investigator at the University of California San Diego was charged with making false statements to government officials. Specifically, in award proposals, the investigator failed to disclose all of his and his company’s current and pending grants or contracts, thereby overstating the time he could devote to the projects he was applying to receive. The investigator also falsely certified in SBIR proposals submitted to NASA and USAF that he was primarily employed with the company when he was employed full-time at the university both at the time of the proposal submission and during the performance of the grant. The investigator and the company made false statements to be awarded grants or contracts that they likely would not have received but for the deception.

- In 2015, A Lehigh professor and his wife were convicted of fraud related to research grants obtained by their private company. One spouse worked for the university and the other ran the business. The business was not disclosed to the university. The
company obtained a NASA grant and subcontracted to the spouse at the university on proposed two projects for NASA totaling about $700,000 of work. The pair used the NASA grant to funnel money to themselves. The company had no facilities to perform the work and all of the work was carried out at the university. A jury found the couple sent invoices to NASA for research that the company had not performed. They were each convicted of six counts of wire fraud.

• In 2012, the Chronicle of Higher Education ran a story regarding an animal scientist who was involved in research concerning a growth-enhancing drug for cattle. Cattle which had been fed the drug were referred to as bovine Schwarzeneggers since they were larger, heavier, and muscled. The faculty member appeared to move from his role as impartial researcher reporting unbiased and comprehensive research results, to advocate for the company and its product. He gave talks to ranchers to encourage them to use the drug; he brought visitors through his laboratories to showcase the drug research; and he repeatedly allowed the company to use his name in press releases and promotional material about the drug. He downplayed the negative effects of the drug and touted that this drug could revolutionize the beef production system. Upon investigation it was found that his research was supported by the company and he was also a paid consultant with the company, raising questions about his financial interest in the drug research. This drug was eventually pulled from the market.
“Selective inattention” is a mindset where the researcher is predisposed to overlook important data or to misperceive critical observations that do not fit the hoped-for findings.

Bias can creep into every facet of research:

- Choice of research design
- Framing the research questions
- Choosing subjects for the study
- How the data are collected, analyzed, interpreted, and ultimately published

Audio:

Bias can creep into research even if the researcher has no intention of committing fraud or deliberately manipulating the study to his or her advantage. Social scientists call this unconscious bias “selective inattention.” The researcher may be so wedded to a particular theory and expecting to find a particular kind of result that he or she ignores data that fall outside the realm of explanation by that theory. Or perhaps the design of the research study or the research questions is framed in a way that might lead to a favored outcome. This kind of bias can be unconscious and unintentional, but it is relatively common when the researcher has an ideological position, a financial stake, or some other benefit that might come from a particular outcome of the research. Selective inattention is something that we all should be careful about and avoid at all costs.
Other Examples of Actual or Potential COI

- Serving in an executive or managerial capacity in an entity doing business with the University, or where the entity is in one's field of research (advisory board paid or unpaid),
- Diverting research away from the University to any external entity in which the faculty member or member of his or her immediate family has a significant financial interest,
- Making sub award arrangements involving the purchase of goods or services from an entity in which a faculty member or member of his or her immediate family has a significant financial interest,
- Making professional referrals to an entity in which a faculty member or member of his or her immediate family has a significant financial interest,
- Utilizing students, trainees, or other university employees in the faculty member’s private business or consulting.

Audio:

- There are other ways conflict of interest can occur. Companies often seek the expertise of faculty members, asking them to serve on a scientific advisory board or board of directors to help advise their company. In such a role, you may not be the company owner, but there is still a potential conflict of interest. You might be in a position to feed early results from your university laboratory to that company so that it receives advance notice about research findings that might influence product development and ultimately the value of its stock. As researchers at a public institution, we try to present our work in a public venue or journal without giving advantage to a company with which we are associated outside the context of our university responsibilities.
- The next three bullets on the slide concern prohibitions dictated by Virginia law. As employees of the Commonwealth, we are prohibited from using our public positions for personal gain. You should not make research referrals to your own private business if that research could have gone through Virginia Tech. You should not refer business to your spouse’s company instead of the university, and you should not make referrals elsewhere. All of these are against state law and is considered diverting business away from the university, causing a detriment to the university and creating a financial gain for yourself or for an immediate family member.
- The university is aware of the potential for exploitation or coercion of students, trainees, or employees when they are employed in a university employee’s private business or consulting. In these situations protections must be in place to assure that students or employees are not being diverted from institutional or academic responsibilities.
What Happens If I Disclose a Significant Financial Interest Related to My Research?

- Develop a project-specific management plan approved by the university
- A generic management plan may be acceptable when faculty-owner does not intend to participate in VT research funded by his or her company

Principles for good management plans:

- **Transparency**
- **Separation**
- **Independence**
- **Oversight**

Audio:

- If a significant financial interest or other conflict of interest has been identified on a research project a management plan should be developed to manage the conflict. This management plan must be approved by the University.
- A generic management plan may be acceptable when faculty-owner does not intend to participate in VT research funded by his or her company
- There are four general Principles for good management plans:
  - Transparency is the full disclosure of the conflict so that administrators can effectively evaluate the risk.
  - The separation of duties so that there are people doing different aspects of the work.
  - It may be appropriate to insert a non-conflicted person to oversee the research to ensure independence of that work from undue influence.
  - An oversight committee may be appropriate when the conflict is significant and spans multiple projects. The oversight committee makeup should include the appropriate individuals that can monitor project activities for transparency, separation of duties, and independence from undue influence.
Common Management Strategies

- An acceptable management plan usually includes a combination of strategies, such as:
  - Targeted public disclosure of the nature of significant financial interests, in publications and presentations, to sponsors, collaborators and trainees, patients, staff, or research participants (sample language on COI website)
  - Financial management of research project by independent party such as a department head or uninvolved co-PI;
  - Assignment of principal investigator status to a neutral senior colleague with appropriate expertise;
  - Monitoring by independent reviewers;
  - Disqualification from participation in all or a portion of the activity
  - Familial COI-Reporting structure and financial separation

Audio:

If the investigator reports a significant financial interest of some kind and that interest is related to a potential research project, we will require the development of a management plan.

An acceptable management plan usually includes a combination of strategies, such as:

- Targeted disclosure when delivering presentation or submitting a research article for publication. For example, if you give a research presentation at a national conference that involves your private company, you should state at the beginning of the presentation that you have a personal interest in the research that has been disclosed and managed in accordance with Virginia Tech’s policies. You’re letting listeners know that you had a personal interest in this research and they can weigh that fact when they listen to the findings. A similar disclosure should take place to sponsors, collaborators and trainees, patients, staff, or research participants (sample language on COI website).

- Another strategy in mitigating a conflict is to identify by an independent party such as a department head or a non-conflicted co-PI to manage the financial aspects of the research project. So if you are a faculty member who owns a business at the Corporate Research Center and who is funding research at Virginia Tech, you will not be allowed to manage the finances of that contract on the university side because you could divert resources from that contract back to your company in some way.

- The management plan could assign a neutral senior colleague with appropriate expertise as a principal investigator on the project. We may also require that
someone else be the principal investigator for the university contract because you are so involved with the company side of the project that you really can’t be impartial about the research that is going on within the university. Someone else may need to serve as the principal investigator to supervise graduate students and oversee the research.

- Depending upon the nature of the conflict, it may be appropriate to assign independent reviewers to ensure the conditions of the management plan are carried out and the risk of bias is reduced;

- If your relationship with the outside entity is so complicated that we can’t disentangle it, then we may not be able to accept that contract at Virginia Tech or you may not be allowed to work on the project. This happens rarely, but it may occur to protect the fact and perception of integrity of research conducted at Virginia Tech.

- When a familial conflict of interest exists such as spouses working on a research project where one spouse is supervising the work of the other spouse a management plan should be developed outlining the reporting structure and ensuring financial separation.
Management Plan: Protecting Graduate Students and Postdocs

- Disclosure of faculty advisor’s (or supervisor’s) personal financial interest in the research (use form: RESEARCH AGREEMENT FOR STUDENTS AND POSTDOCTORAL ASSOCIATES)
- Discussion with grad program director or department head and associate dean for research/grad studies about rights and responsibilities, scope of work and relationship with thesis/dissertation research
- Appointment of co-chair for student’s committee

Audio:

- Students and postdoctoral scholars are particularly vulnerable to exploitation therefore the conflict of interest policy introduces some important protections for these early-career researchers. Virginia Tech’s policy is based on the assumption that students and postdoctoral fellows may genuinely benefit from working with a company or on a consulting arrangement, but they must have some protections and avenues of appeal should they feel exploited. This is done through a form called a research agreement for students and postdoctoral associates.

- Students are informed of the potential conflict of interest associated with their funding source and meet with neutral third parties in the department and college to discuss the benefits and risks of participation in such projects.

- If the student is funded by a sponsored grant provided by the faculty advisor’s own company, there must be a co-advisor assigned to assure that the student’s academic progress is not jeopardized.

- The student signs a form documenting that they have been informed of the potential conflict of interest and that they are participating voluntarily.

- A copy of the research agreement must be sent to the Conflict of Interest Office and the Graduate School.
The university is committed to fulfilling the requirements established by the Public Health Service (PHS) regulations. Anyone who meets the definition of investigator must be trained and have all of their disclosure documents in order before the first dollar of a PHS grant can be spent. For researchers who are funded on grants from other federal, state, or government agencies, or from industry, there is 30 day period in order to achieve compliance for training.

If there is egregious non-compliance the COI office can freeze projects until compliance is obtained.

A retrospective review may be required for misleading or inaccurate reporting of significant financial interests.

Compliance in fact and spirit with the conflict of interest policy is very serious business for the university and for our sponsors therefore willful non-compliance can lead to dismissal for cause even for tenured faculty members.

COI Office will periodically follow up on all management plans and report to sponsors as appropriate
If a significant financial interest is not disclosed but discovered during the project the Public Health Service and those following PHS rules require that the university complete a retrospective review. A retrospective review includes conducting an investigation to determine if bias was found in the research, report the findings and what actions were taken to mitigate the conflict. PHS may allow the project to continue or terminate the project. For non-PHS project, the COI office along with appropriate administrators would conduct a review to determine if the project is at risk for bias.
Purpose of COI Awareness

- To inform employees of their responsibility to remain vigilant regarding potential conflicts of interest and commitment
- To provide examples of situations where COI may occur
- To increase awareness of your responsibility to disclose conflicts of interest and commitment and to manage those conflicts appropriately

- Basic principles:
  - If in doubt, disclose!
  - The Prudent Person Test
  - When it comes to conflict of interest, perception of a potential bias based on personal interest is just as important to address as an actual conflict.

Audio:

- To inform employees of their responsibility to remain vigilant regarding potential conflicts of interest and commitment
- To inform employees of the situations where conflicts may occur and to Increase awareness of your responsibility to disclose conflicts of interest and commitment and manage those conflicts appropriately.
- There are three basic principles of conflict of interest and commitment awareness:
  - If in doubt, disclose! Or at least as questions. The COI office is here to help employees navigate policies and procedures regarding conflict of interest and commitment.
  - Ask yourself if the situation was written up in the Roanoke Times, Chronicle of Higher Education, or on YouTube, would a reader/viewer be concerned or suspicious?
  - When it comes to conflict of interest, perception of a potential bias based on personal interest is just as important to address as an actual conflict.
Audio: You can find additional information including contact information on the conflict of interest website. Thank for participating in this conflict of interest training. Please complete the quiz linked at the bottom of the CITI page to receive credit for completing this tutorial.