Proposed Financial Conflict of Interest Training Video Script

Syracuse University

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Script Slide Number

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Hello, my name is Jesse and I'm here today to guide you through the process of filling out your financial conflict of interest disclosure—abbreviated to F.C.O.I.. In addition to being university policy for all external grantees, disclosure is also required by a number of prominent funding agencies. This video, which is a required part of the disclosure, is designed to help smooth the process of disclosure and to inform you of the ethics and rationale behind it, and hopefully answer any questions you might have. In total, the tutorial will take roughly 20 minutes.

This training is divided into two parts. The first part, which you are already watching, introduces you to the core concepts of the FCOI and the ethical imperatives the drive the process. I will introduce the three primary reasons for FCOI and then examine three example cases that will be used to illuminate our process. This video is roughly nine and a half minutes long.

In the second part of the training, I will explain how Syracuse University has addressed these ethical concerns while remaining sensitive to the needs of our own people, especially the confidentiality of you, the researcher. This video is roughly nine minutes long.

My first task is to define a few of the terms that we will come across regularly in this video and the disclosure itself. The first, and most important is, of course, "financial conflict of interest" itself. A financial conflict of interest is a state that occurs when a researcher, or his or her spouse or dependents, has a significant financial interest that could directly and significantly affect the design, conduct or reporting of a research project.

That seems pretty straightforward, but what is a significant financial interest?

Well a "financial interest" is anything of monetary value, whether or not that value is readily ascertainable. So, an outside entity giving a researcher piece of new, experimental research equipment is still considered a financial interest regardless of the fact that it may not have a fixed price on the market.

However, not all financial interests are equal and funders rely upon the filter of "significance" to zero in on what is important. SU has adopted a disclosure policy which captures all of the significance qualifiers for the most important funders so that investigators need only fill out one disclosure annually, regardless of how many funding providers they interact with.

In most cases, this means that we view "significant financial interests" as anything of a value of at least \$5,000 or 5% ownership in an outside entity, whether that be direct payments, stock options or gifts in kind. This means that if you own more than 5% of the stake any company, even one not that is not publicly traded, it is considered a significant financial interest.	1-7
Two special cases are when researchers have travel sponsored by entities outside of normal travel funding within grants and when researchers sit upon executive or scientific boards of outside entities. In these cases, researchers are required to disclose all incidences regardless of the amount or existence of renumeration.	1-8
There are a number of exclusions to the disclosures that are important to note here. Reseachers need not disclose payments made by or through Syracuse University,	1-9
any other accredited research institution or institution of higher education,	1-10
an agency of the Federal, State or Local Governments,	1-11
investments that exist in an aggregate—such as a mutual fund or retirement account—for which you do not control the investment decisions,	1-12
or an entity that qualifies under Phase one funding applications for the Small Business Innovation Research award.	1-13
Two final definitions that are of importance here are of "investigator" and "research." This disclosure is designed for those who are investigators, which "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," so it may include may include outside collaborators or consultants. For projects that involve investigators from outside of SU, please contact the Office of Sponsored Programs for more information on disclosure requirements. For the purposes of FCOI disclosure, the "investigator's" financial interests also includes those of his or her spouse and any dependent children.	1-14
"Research" is "a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development.	1-15
These disclosure requirements can seem at first brush rather imposing and mere definition does not tell us the underlying "why," the logic behind disclosure. In this next section I will explain why a rigorous management of our FCOIs in all of our interest, including researchers, the institution and as member of a society that benefits from, and relies upon the creation of new knowledge.	1-16

The existence of conflicts of interest, which hold the possibility of—either 1-17 intentionally or unintentionally—affecting the design, conduct or reporting of a research project can have implications in three areas of great importance. The first is in the possibility of bias affecting the quality of our research, its replicability and reliability, the second is the standing of the University and the wider Academy in the public 1-18 eye. We are concerned over the perceptions of the public, both for our own values of integrity as well as the fact that the public relies upon our ability to remain dispassionate before our research questions. Perceptions of conflict can often have as much impact upon our institutions as any real impact upon the quality of data.. and finally is the interests of our students, especially graduate students involved 1-19 in research. I will now expand upon these three areas with examples. Our first example—Professor A—is a geologist developing safety standards for 1-20 new oil rigs. He has a number of projects, including some that are funded by the Bureau of Land Management and some by private oil companies which pay him in stocks and have appointed him to a scientific advisory board. Professor A is asked to evaluate new BLM rules that may have a direct impact upon his investments and his position in the company. This is a conflict that creates a potential bias which threatens the quality of 1-21 research as Professor A has a vested interest in a particular outcome for his BLM projects.

Our second example—Professor B—is an engineer designing orthopedic devices; she has received numerous grants from both public and corporate sources and is involved in both the testing and development of new devices. Professor B is contacted by a company which designs similar devices, and although she is not currently working on one of their projects, she has done so in the past and may do so in the future. The company has organized a conference in the Bahamas and invites her to speak, promising to pay expenses for her and her spouse. While this does not conflict with either current research or a student's studies, it does threaten the public trust and confidence in our ability to be neutral evaluators of new ideas and (in this case) products.

This is a conflict that threatens the public image of the University and the Academy.

Finally, our third example—Professor C—is a social scientist working to

1-24 develop systems of economic prediction in poorly understood markets. His
theories bear fruit and he decides to begin working as a consultant for companies
working in those countries. To help process data, he hires his graduate advisees.
Their work builds off of his theories and helps the company improve predictions.
Professor C, profiting from these new ideas, is hesitant to allow his students to
publish their theories, and thus loose his market edge. With a delay of
publications, their ability to advance in their degrees is hindered.

This is a conflict that threatens the interests of our students and the quality of their education.

None of these three examples is insurmountable, though all raise deep concerns. 1-26 In the next section, I will first examine why we have developed the disclosure system that we have and how it operates here at Syracuse University.

END OF CLIP 1

This is the second in a two part series on financial conflict of interest disclosures 2-1 for academic researchers at Syracuse University. This video is approximately 9 minutes in length.

In the previous video, I laid out three ethical concerns that lead us to create a FCOI disclosure system. While we may all agree that these three areas are of shared concern for us as Academics, we may still not understand why there is a requirement by the University and funding providers to breach the also-important ethical demands of confidentiality; why can we as researchers not simply be trained to recognize and minimize our own potential conflicts? Is it the case where a few bad apples has ruined the situation for all of us and we now suffer collective punishment?

On the contrary, our disclosure policy—and that of national funding agencies— 2-3 is not based upon a principle of collective punishment, but instead is built upon the understanding which grew up first in the area of human subjects research, that we are unable to properly judge the status of our own conflicts.

So, in the same way that we sometimes need others to look at our research designs and their implications upon our participants, we also need others to look at our significant financial interests and assess their potential for conflict with the quality of our research. We simply have too much at stake to be able to judge them properly; in fact, the very recognition of the existence of FCOIs implies that we are at times unable to manage the tension between our financial and research interests.

This inability to judge our own conflicts, combined with our shared institutional 2-5 interests means that the proper response is one based in the time-honored traditions of peer review and self-governance.

These two tools are combined within the central decision-making body of the FCOI process, the Conflict of Interest Committee, which is made up of faculty and administrators and makes the ultimate determination as to whether and how a conflict should be managed. However, I am getting ahead of myself because we are moving here from the "why" of conflict of interest management to the "how," the SU-specific application of the ethical and legal demands that we face in the area of conflict of interest.

Let me begin by defining "management" itself. Officially, SU defines

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management as "taking action to address a financial conflict of interest, which
can include reducing or eliminating the conflict to ensure, to the extent possible,
that the design, conduct and reporting of research will be free from bias."

It is important to note that we don't view management as a form of punishment for having a conflict, any more than the Internal Review Board is a punishment for deciding to work with human subjects or the Tenure process is a punishment for dedication to your profession. We instead view management as a form of collegial collaboration between a researcher and a fellow expert—a Conflict Manager—appointed by the Committee who is able to provide guidance in determining how we can avoid having conflicts spill into the content of research.

While it is possible, of course, for a researcher to unilaterally eliminate a conflict 2-9 by eliminating the significant financial interest—such as divesting stocks or resigning from boards—this is sometimes not possible and in those cases Conflict Managers will seek to minimize conflict, rather than eliminate it. This can be done in a number of ways including public disclosure of the conflict in published works, outside supervision of graduate student publication, or the inclusion of a co-principal investigator who does not possess the same significant financial interests.

So, how exactly does Syracuse University handle these issues?

The first step is the one you are involved in now: training. Once you are trained, you only need to have refreshers once every four years.

The next step is disclosure itself. The disclosure is an online questionnaire which appears annually on your MySlice homepage and has been integrated with the general University conflict of interest questionnaire filled out by all employees. It is a series of questions about various potential types of conflicts; when filling this out, you will want to have information on hand about the significant financial interests and contractual obligations of yourself, your spouse and any dependent children. Remember to disclose all Significant Financial Interests, regardless of whether you believe they are potential conflicts or not.	2-12
This is submitted electronically using your Myslice homepage.	2-13
For the majority of submissions, this is the end of the process. You either don't have any significant financial interests or the VP looks at them and determines that they have no connection to your funded research projects. The report is archived until the next year.	2-14
Those who report significant financial interests are forwarded to the Vice President of Research; the VP for research is, at this stage, the only person who is able to see your disclosure in order to protect your confidentiality. The VP for research may ask you for more information at this point.	2-15
For those of you who have reached this point, the process becomes a bit more involved. The VP for Research gathers the pertinent information from your disclosure for the regular Conflict of Interest Committee Meetings. At this meeting, the VP presents the Committee with only such information as to allow them to determine the existence of a conflict, at no point do they have access to your full disclosure. The Committee makes the final determination of whether a Conflict exists and then, upon the recommendation of the VP for Research, suggests a Conflict Manager.	2-16
The Conflict Manager now becomes the point person between the Committee and you, the Investigator, it is this person who will work with you to develop a Management Plan.	2-17
This Plan is a co-creation between the two of you and is then sent to the Committee for approval. Depending on your funders, the Committee then either files the plan or sends it on to the funding agency.	2-18
There is a possibility for a public disclosure of this Conflict and accompanying plan. There are some public agencies—most notably the National Institute of Health—which requires a system of public disclosure of conflicts. At SU, we have adopted a system of passive disclosure: if we are contacted by an outside party about a particular NIH project (for instance), then we will provide them with a special public disclosure, which includes only information on those significant financial interests directly related to the publicly funded project. If you wish to know if your funding agency has a public disclosure policy, please contact the Agency or OSP	2-19

This is basically the layout of the Conflict of Interest system, though there are 2-20 two important special cases that need to be handled. The first is the need for Ad-Hoc disclosures. Normally, disclosure is an annual process. However, there are situations where a researcher's financial interests change—such as due to marriage, inheritance or investment—in these cases, Researchers need to contact the Office of Sponsored Programs to create an ad-hoc disclosure, which functions exactly the same as the annual disclosure.

The other special case is in the rare situation of non-compliance. Non-2-21 compliance occurs when a researcher has not disclosed their significant financial interests in a timely way or has not followed their agreed upon management plan. In these cases, the University requires first an immediate ad-hoc disclosure and then assigns, at least on an interim basis, a Conflict Manager who examines the situation and creates a retrospective review and, if necessary, a mitigation plan. Depending on the funding agency, this plan may need to be sent to them for approval. It is also possible, in cases of gross non-compliance, for funding to be suspended and other disciplinary measures taken by the University.

This completes our financial conflict of interest tutorial and you may now 2-22 proceed with your disclosure. If you have any questions or seek more information, you may email the office of the Vice President for Research at vpr@syr.edu

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