

**Conflicts of Interest and Commitment:
A Responsible Conduct of Research Team-Based Learning Module**

Michael F. Verderame¹, Joshua S. Crites², Rebecca L. Volpe², Shane Connelly³, Wayne T. McCormack^{4†}

¹Dept. of Medicine, and Microbiology and Immunology, Penn State College of Medicine

²Dept. of Humanities, Penn State College of Medicine

³Dept. of Psychology, University of Oklahoma

⁴Dept. of Pathology, Immunology & Laboratory Medicine, University of Florida College of Medicine

†Correspondence: Wayne T. McCormack, Ph.D.
Phone (352) 273-9042
E-mail mccormac@ufl.edu

TABLE OF CONTENTS

Student Materials

Learning Objectives & Advance Preparation Assignment	2
Readiness Assurance Test	X
Application Exercise	X

Instructor Guide

Purpose	X
Learning Objectives	X
Advance Preparation Assignment	X
Suggested Lecture Outline	X
Context	X
Facilitation Schema	X
Readiness Assurance Test Item Analysis	X
Application Exercise Facilitator Guide	X
SFNO Case Analysis	X
Acknowledgements	X

This publication was made possible by Grant Number 1 ORIIR130004-01-00 from the Office of Research Integrity (ORI). Contents are solely the responsibility of the authors and do not necessarily represent the official views of the Department of Health and Human Services or ORI.

Learning Objectives

At the conclusion of this section, you should be able to:

1. Summarize the concept of conflict of interest.
2. Describe five broad conceptual areas of conflict of interest.
3. Relate federal and institutional regulations, policies and guidelines regarding conflict of interest to personal responsibilities.
4. Identify key components of a conflict of interest management plan.
5. Critique the effectiveness of conflict of interest management plans, including strengths and limitations
6. Apply the SFNO moral method to the resolution of dilemmas arising from conflicts of interest.

Advance Preparation Assignment

Please use the following materials available from the course management system to learn content for this session before class.

1. Chapter 5: “Conflicts of Interest”, ORI Introduction to the Responsible Conduct of Research, Nicholas H. Steneck, Updated from Revised Printed Edition, June 2004, Office of Research Integrity, U.S. Department of Health and Human Service
(Please read the revised version posted as PDF, not the online version)
2. “Conflicts of Interest” video lecture
3. Crafting a Conflict of Interest Management Plan
<http://www.research.olemiss.edu/coi/management>
4. Federal Definition of Conflict of Interest: *Title 42, Part 50, Subpart F (42CFR50)* of the Federal Code of regulations “*Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought*”
<http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=42:1.0.1.4.23#sp42.1.50.f>
5. Local CoI policy link

Readiness Assurance Test

Please circle your answers below for the individual readiness assurance test. This activity is “closed book”. Be sure to record your answers to turn in on the Scantron sheet (or other answer sheet) provided. For the team readiness assurance test, please use your team’s Immediate Feedback Assessment Technique (IF-AT) scratch-off card.

1. Researchers’ interests can and often do conflict with one another. The best way to handle conflicts of interest is to:
 - A. take special steps to assure that they do not interfere with the responsible practice of research.
 - B. advance knowledge by keeping ideas to oneself until they are fully developed.
 - C. understand that they are inherently wrong and use any means possible to avoid them.
 - D. disclose all perceived or actual conflicts of interest to the university Research Integrity Officer.

2. The 1980 Congressional law known as the Bayh-Dole Act gives ownership of ideas developed with public funding to:
 - A. the federal government.
 - B. research institutions.
 - C. researchers.
 - D. both researchers and research institutions.

3. Conflicts of commitment arise from situations that place competing demands on researchers’ time and loyalties. When a researcher submits a new research project proposal that is related to an existing funded project, the best way to allocate salary on the new proposal would be to:
 - A. charge both funding sources for the same time if the projects have identical specific aims.
 - B. charge additional time on the new proposal to cover extra work the researcher is doing for the existing funded project, provided all commitments to both projects can be met.
 - C. seek advice if unsure whether a particular commitment of time is allowed under institutional or federal policies.
 - D. request percent effort on the new grant proposal that will give it highest chance of being funded.

4. The 1980 Congressional law known as the Bayh-Dole Act seeks to ensure that the investment in research is used to stimulate economic growth by encouraging _____ to have financial interests in research results.
 - A. the federal government
 - B. researchers
 - C. research institutions
 - D. both researchers and research institutions

5. Researchers are expected to avoid conflicts of interest in proposing, conducting, reporting, and reviewing research. Current law requires individual researchers to:
 - A. make final decisions about what constitutes conflicts of interest.
 - B. fully disclose all potential conflicts of interest.
 - C. eliminate all sources of significant conflict of interest.
 - D. report your conflict management plan to the institution’s Research Integrity Officer.

Conflicts of Interest & Commitment

6. Conflicts of interests are not inherently wrong. The best first step to properly managing potential financial conflicts of interest is to:
- report significant financial conflicts of interest before the research is undertaken.
 - eliminate the financial conflict of interest (*e.g.*, sell your financial interest in the company).
 - disclose your financial conflict of interest in grant proposals.
 - report your financial conflict of interest to your institution's Research Integrity Officer.
7. Professor Smith is paid as a consultant by a private company based on her scientific expertise. How can she best manage potential conflicts of interest related to research funded by that company?
- Divest her financial interest in the company by giving it to an immediate family member.
 - Ask colleagues to monitor the research, including checking the results for accuracy and objectivity.
 - Avoid conducting research funded by the company for which Dr. Smith is a consultant.
 - Report the potential conflict of interest and seek a final decision about whether and how to manage the conflict.
8. How do the Public Health Service and the National Institutes of Health currently define a ***significant financial interest*** in a relevant company, *i.e.*, a company either sponsoring the research or potentially benefiting from the results of the research?
- Ownership of any stocks in any publicly traded company that is related to the research regardless of the total value.
 - Equity holdings in a privately held company that are >\$5,000.
 - Income from a privately held company that is >\$5,000 in a 12 month period.
 - Greater than \$5,000 invested in a mutual fund that holds stock in a company directly related to the research.
9. The use of equipment and/or supplies purchased with public funds to advance other research interests is:
- allowed for any research desired by the Principal Investigator.
 - specifically allowed by the government to test the feasibility of other pilot projects.
 - a harmless practice because the equipment is not in constant use.
 - not allowed to support private research or personal projects.
10. The Public Health Service (PHS) and the National Science Foundation (NSF) adopted conflict of interest policies in the mid-1990's, which established administrative procedures:
- outlining how financial conflicts should be managed within institutions.
 - that are dictated by Congressional legislation.
 - for eliminating all financial conflicts of interest.
 - for reporting all conflicts of interest after research is funded.

Application Exercise

Before reading the case scenario, please spend up to 5 minutes writing your personal definition of conflict of interest and commitment.

Discuss your definition with your teammates and spend up to 5 minutes writing a unified definition of conflict of interest and commitment for your team. We will revisit your definitions at the end of the session.

HotChem, Inc.

Part A. Professor Boris Roby in the Chemistry Department of Hudson University (HU) is collaborating with Professor Kimberly Knowles in the Biology Department. Their collaborative research is yielding some very exciting results in cancer therapy, including a potentially effective new drug for pancreatic cancer. They submitted an invention disclosure to the University; after careful review the University declines to pursue this invention because the pancreatic cancer is relatively rare (and thus the drug is unlikely to recoup its development costs). Convinced their drug will save lives, they decide to form **HotChem, Inc.**, a company they hope will be able to market a new cancer drug. In doing so, they hire Dr. Ward, a longtime colleague at Banting University, to become President of the company. Dr. Knowles becomes the Chief Scientific Officer and Dr. Roby the Vice President for Business Development. They are both listed as Officers of HotChem. Knowles and Roby did not disclose this relationship to the HU because the University was not interested in the intellectual property arising from this work.

As time goes by, HotChem is able to attract significant amounts of federal and nonfederal sponsored research funding as well as venture capital funding. In an effort to maximize their research capacity, HotChem issues subcontracts to HU, one each with Knowles and Roby as principal investigator (PI). Everything seems to be working out well for all concerned. The relationship with HU is enhancing HotChem's funding proposals and helps tremendously in attracting a steady stream of funding. HU is obtaining sponsored funding through the subcontracts which enables the university to buy new equipment, place graduate students on exciting projects, hire two post-docs, and recover indirect costs.

HotChem's financial department identifies an angel investor, Rebecca Wolford, who is very interested supporting cancer research after losing her husband to pancreatic cancer. She is not informed that Roby and Knowles are also faculty members at HU and she places her trust, *and several million dollars*, into HotChem's drug discovery program, further supporting work at HU.

1. Which, if any, of the following situations represents a conflict of interest?
 - A. The fact that Professors Roby and Knowles have a relationship with HotChem.
 - B. The fact that the angel investor does not know that Roby and Knowles are faculty members at HU.
 - C. The fact that HU has entered into subcontracts with HotChem.
 - D. The fact that graduate students are being supported by a contract from HotChem.

Conflicts of Interest & Commitment

2. In a casual lunchtime discussion with a new biology faculty member, Roby and Knowles mention their company and the latest interesting results. The colleague asks if they have filed the appropriate conflict of interest documents with the University. Later that afternoon, Roby and Knowles discuss whether they should now disclose their significant financial interest (SFI) to the University. What is the best course of action at this point?

- A. Craft a conflict of interest management plan and file it with HotChem.
- B. Discuss their situation with the Technology Development Officer at HU to determine if there is a conflict of interest.
- C. File a SFI disclosure with HU.
- D. Wait for the University to contact them.

3. If they decide to file their University's Conflict of Interest Disclosure, which is the *most important* element to disclose?

- A. That they are employed by HotChem as company officers.
- B. That they receive compensation from HotChem.
- C. That they have sponsored funding from HotChem to support continuing research.
- D. That they have funding from HotChem to support trainees in their University lab

HotChem, Inc.

Part B. As the work progresses, one of the senior graduate students, Avery Broderick, conducts pre-clinical experiments in rats to test the efficacy of the lead compound; these experiments reveal that this compound is very promising with significant efficacy. Avery's thesis committee expects this experiment to be the final data for his doctoral dissertation, and Avery is hoping to defend in the next 6 months because he has lined up a postdoctoral position at a prestigious west coast university. Professor Knowles has Avery send the blood samples and data to the company for a full analysis. After 9 months, Avery has still not received the analysis of the data (pharmacokinetics, pharmacodynamics, *etc.*) that would allow him to finish his dissertation, despite repeated requests by Avery to Professor Knowles and to the company. He is becoming quite anxious, and concerned that he will never see the data necessary to complete his dissertation. Professor Knowles is unconcerned.

4. There are a number of stakeholders with competing interests in this scenario. Which stakeholder should be given top priority?
 - A. Rebecca Wolford (the angel investor)
 - B. HotChem, Inc.
 - C. Hudson University
 - D. Avery Broderick (the graduate student)
 - E. Other

5. Professors Roby and Knowles decide to develop a Conflict of Interest management plan. What is the most important consideration for such a plan?
 - A. The opportunity for conflict between generating new knowledge versus generating profits.
 - B. The University's desire to protect its reputation as an impartial source of knowledge.
 - C. Minimizing the risk of being forced to step down from their corporate positions.
 - D. Minimizing the risks to intellectual freedom and intellectual property rights.

6. What is the most significant drawback of Professors Roby and Knowles develop their own conflict of interest plans?
 - A. Their plan may not adequately protect the interests of all stakeholders.
 - B. They do not have the expertise to craft an adequate plan.
 - C. This approach will be time intensive and distract them from other important work.
 - D. It is a conflict of interest for them to craft their own conflict of interest plan.

Please revisit your team definition of conflict of interest and commitment, and consider whether you need to revise it further. We will spend the last part of the session discussing your definitions.

INSTRUCTOR GUIDE

Purpose

By the conclusion of this module, learners will be able to understand _____, and apply them in experimental settings. Learners will also have an understanding of _____.
(Briefly mention the relevant ethical principles.)

Learning Objectives

At the conclusion of this section, the learner should be able to:

1. Summarize the concept of conflict of interest. This learning objective is at the Comprehension level of Bloom's taxonomy, and is addressed in the Application Exercise.
2. Describe five broad conceptual areas of conflict of interest. This learning objective is at the Comprehension level of Bloom's taxonomy, and is addressed in the Readiness Assurance Test (RAT).
3. Relate federal and institutional regulations, policies and guidelines regarding conflict of interest to personal responsibilities. This learning objective is at the Application level of Bloom's taxonomy, and is addressed in the RAT and Application Exercise.
4. Identify key components of a conflict of interest management plan. This learning objective is at the Application level of Bloom's taxonomy, and is addressed in the Application Exercise.
5. Critique the effectiveness of conflict of interest management plans, including strengths and limitations. This learning objective is at the Evaluation level of Bloom's taxonomy, and is addressed in the Application Exercise.
6. Apply the SFNO moral method to the resolution of dilemmas arising from conflicts of interest. This learning objective is at the Application level of Bloom's taxonomy, and is addressed in the Application Exercise.

Advance Preparation Assignment

Prior to engagement in this activity, learners should be provided the following materials for self-learning of the basic content BEFORE coming to the team-based learning session. This subject matter may be included in the Readiness Assurance Test items, and provides the knowledge base necessary for problem-solving and decision-making in the Application Exercises. All resources should be made available via the institution's learning management system at least one week in advance of the session.

1. Chapter 5: "Conflicts of Interest", ORI Introduction to the Responsible Conduct of Research, Nicholas H. Steneck, Updated from Revised Printed Edition, June 2004, Office of Research Integrity, U.S. Department of Health and Human Service
Please use the revised PDF version, in which changes to federal regulations are noted.
2. Locally produced video lecture (see suggested lecture outline below). This may be a videotaped lecture or a voice-over PowerPoint presentation.
3. Crafting a Conflict of Interest Management Plan
Link to local institutional website, if available. If none, consider one of these two alternatives:
<http://www.research.olemiss.edu/coi/management>
<http://research.ncsu.edu/sparcs/systems-portal/coi/coi-plan-help/>
4. Federal Definition of Conflict of Interest: *Title 42, Part 50, Subpart F (42CFR50)* of the Federal Code of regulations "*Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought*"
<http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=42:1.0.1.4.23#sp42.1.50.f>
5. Local institutional conflict of interest policy link

Additional Resources

Learners should review and/or refer to the SFNO Method handout found in the first module of this series: "Introduction to Ethical Decision-Making: A Responsible Conduct of Research Team-Based Learning Module" (*include citation*)

Preparation Material: Suggested Lecture Outline

- I. Introduction
 - A. Motivations to do research
 - B. Conflicts of interest are not inherently wrong
- II. Financial Conflicts
 - A. 1980 Bayh-Dole Act
 - B. Federal policies define significant financial conflict
 - C. State and local policies
 - D. Professional societies and journal policies
- III. Conflicts of commitment
 - A. Competing demands
 - B. Allocation of time
 - C. Relationships with students
 - D. Use of resources
 - E. Disclosure of affiliations
 - F. Representing outside entities
- IV. Personal and intellectual conflicts
 - A. Avoiding bias
 - B. Personal conflicts
 - C. Intellectual conflicts
- V. Reporting conflicts
 - A. Managing conflicts of interest
 - 1. Disclosure
 - 2. Monitoring
 - 3. Removal from decision-making process
 - B. Who makes final decisions about managing conflicts of interest

Note to Lecturer: Please see RAT question 8. Check that the thresholds listed are current, and be sure to emphasize them in your lecture comments.

Context

Facilitation Schema

These two sections will be added back in when the new MedEdPORTAL Instructor Guide template is available. A draft may be found in the file “Boilerplate for Context and Facil Schema.docx” in the Dropbox folder “TBL Resources”.

RAT Item Analysis

The following item analysis is provided to help users determine the suitability of each item.

- N: Total number of valid responses.
- Difficulty Index: Measure of item difficulty (best if between 40 and 80). Low values indicate a question that is too difficult or an error with the answer key. This item set has 7 items with a difficulty index between 40 and 80.
- Point Biserial: Measure of how well questions discriminate between students (best if greater than 0.1). Negative numbers indicate a question that is flawed in some way, *e.g.*, the better examinees are getting it wrong.
- Answer Frequency: Percentage of responses for answer choice (best if greater than zero).

Question	N	Correct Answer	Difficulty Index	Point Biserial	Answer Frequency			
					% A	% B	% C	% D
1	n	A	x	x	x	x	x	x
2	n	B	x	x	x	x	x	x
3	n	C	x	x	x	x	x	x
4	n	D	x	x	x	x	x	x
5	n	B	x	x	x	x	x	x
6	n	A	x	x	x	x	x	x
7	n	D	x	x	x	x	x	x
8	n	C	x	x	x	x	x	x
9	n	B	x	x	x	x	x	x
10	n	A	x	x	x	x	x	x

Readiness Assurance Test Instructor Guide

Note: Items #1-10 are keyed to IF-AT card D005.

1. Researchers' interests can and often do conflict with one another. The best way to handle conflicts of interest is to:

- A. **take special steps to assure that they do not interfere with the responsible practice of research.**
- B. advance knowledge by keeping ideas to oneself until they are fully developed.
- C. understand that they are inherently wrong and use any means possible to avoid them.
- D. disclose all perceived or actual conflicts of interest to the university Research Integrity Officer.

This item is relevant to Learning Objectives #4 & 5. A is the BEST answer because ... B and C are partially correct but... D is incorrect because ...

2. The 1980 Congressional law known as the Bayh-Dole Act gives ownership of ideas developed with public funding to:

- A. the federal government.
- B. **research institutions.**
- C. researchers.
- D. both researchers and research institutions.

This item is relevant to Learning Objective #3. B is the BEST answer because ... A and C are partially correct but... D is incorrect because ...

3. Conflicts of commitment arise from situations that place competing demands on researchers' time and loyalties. When a researcher submits a new research project proposal that is related to an existing funded project, the best way to allocate salary on the new proposal would be to:

- A. charge both funding sources for the same time if the projects have identical specific aims.
- B. charge additional time on the new proposal to cover extra work the researcher is doing for the existing funded project, provided all commitments to both projects can be met.
- C. **seek advice if unsure whether a particular commitment of time is allowed under institutional or federal policies.**
- D. request percent effort on the new grant proposal that will give it highest chance of being funded.

This item is relevant to Learning Objective #X. C is the BEST answer because ... A and B are partially correct but... D is incorrect because ...

4. The 1980 Congressional law known as the Bayh-Dole Act seeks to ensure that the investment in research is used to stimulate economic growth by encouraging _____ to have financial interests in research results.

- A. the federal government
- B. researchers
- C. research institutions

D. both researchers and research institutions

This item is relevant to Learning Objective #3. D is the BEST answer because ... A and B are partially correct but... C is incorrect because ...

5. Researchers are expected to avoid conflicts of interest in proposing, conducting, reporting, and reviewing research. Current law requires individual researchers to:

A. make final decisions about what constitutes conflicts of interest.

B. fully disclose all potential conflicts of interest.

C. eliminate all sources of significant conflict of interest.

D. report your conflict management plan to the institution's Research Integrity Officer.

This item is relevant to Learning Objective #X. B is the BEST answer because ... A and C are partially correct but... D is incorrect because ...

6. Conflicts of interests are not inherently wrong. The best first step to properly managing potential financial conflicts of interest is to:

A. Report significant financial conflicts of interest before the research is undertaken.

B. Eliminate the financial conflict of interest (e.g., sell your financial interest in the company).

C. Disclose your financial conflict of interest in grant proposals.

D.. Report your financial conflict of interest to your institution's Research Integrity Officer.

This item is relevant to Learning Objective #4. A is the BEST answer because ... B and C are partially correct but... D is incorrect because ...

7. Professor Smith is paid as a consultant by a private company based on her scientific expertise. How can she best manage potential conflicts of interest related to research funded by that company?

A. Divest her financial interest in the company by giving it to an immediate family member.

B. Ask colleagues to monitor the research, including checking the results for accuracy and objectivity.

C. Avoid conducting research funded by the company for which Dr. Smith is a consultant.

D. Report the potential conflict of interest and seek a final decision about whether and how to manage the conflict.

This item is relevant to Learning Objective #X. D is the BEST answer because ... A and B are partially correct but... C is incorrect because ...

8. How do the Public Health Service and the National Institutes of Health currently define a ***significant financial interest*** in a relevant company, *i.e.*, a company either sponsoring the research or potentially benefiting from the results of the research?

A. Ownership of any stocks in any publicly traded company that is related to the research regardless of the total value.

B. Equity holdings in a privately held company that are >\$5,000.

C. Income from a privately held company that is >\$5,000 in a 12 month period.

Conflicts of Interest & Commitment

- D. Greater than \$5,000 invested in a mutual fund that holds stock in a company directly related to the research.

Check that the thresholds listed are current, as they are occasionally changed by the federal government. Dollar amounts should be accurate and consistent in all places, *e.g.*, RAT item, lecture, and readings.

This item is relevant to Learning Objective #X. C is the BEST answer because ... A and B are partially correct but... D is incorrect because ...

9. The use of equipment and/or supplies purchased with public funds to advance other research interests is:

- A. allowed for any research desired by the Principal Investigator.
- B. specifically allowed by the government to test the feasibility of other pilot projects.**
- C. a harmless practice because the equipment is not in constant use.
- D. not allowed to support private research or personal projects.

This item is relevant to Learning Objective #X. B is the BEST answer because ... A and C are partially correct but... D is incorrect because ...

10. The Public Health Service (PHS) and the National Science Foundation (NSF) adopted conflict of interest policies in the mid-1990's, which established administrative procedures:

- A. outlining how financial conflicts should be managed within institutions.**
- B. that are dictated by Congressional legislation.
- C. for eliminating all financial conflicts of interest.
- D. for reporting all conflicts of interest after research is funded.

This item is relevant to Learning Objective #X. A is the BEST answer because ... B and C are partially correct but... D is incorrect because ...

Application Exercise – Instructor’s Guide

The case scenario was adapted from “Cain and Abel”, which is available from Boston College Administrators & RCR at http://ori.hhs.gov/education/products/rcradmin/topics/coi/case_3.shtml (last accessed 7/21/14). Frequencies are provided below (in parentheses) for how many teams selected each answer option, with data pooled from X teams in Y courses.

Space is provided below for notes about team discussion during 2014-15 courses, which will be used for additional facilitator guidelines. Please record the number of teams that choose each answer.

Start this exercise by have each student write his or her personal definition of conflict of interest and commitment. Then have the team craft a unified definition. (up to 5 minutes each) Put the definitions aside until the end of the case, and then (1) have the team revisit their definition and consider whether they need to revise it further, and (2) facilitate an inter-team discussion about how their definitions changed.

1. Which, if any, of the following situations represents a conflict of interest?

- | | # teams |
|--|---------|
| A. The fact that Professors Roby and Knowles have a relationship with HotChem. | (__) |
| B. The fact that the angel investor does not know that Roby and Knowles are faculty members at HU. | (__) |
| C. The fact that HU has entered into subcontracts with HotChem. | (__) |
| D. The fact that graduate students are being supported by a contract from HotChem. | (__) |

Please record notes from class discussion here.

A.

B.

C.

D.

NOTES:

A. Having a relationship isn’t inherently a CoI.

B and D are *consequences* of the primary CoI.

C is the primary CoI given the financial relationship between the University and the company with the faculty members on both sides.

Conflicts of Interest & Commitment

2. In a casual lunchtime discussion with a new biology faculty member, Roby and Knowles mention their company and the latest interesting results. The colleague asks if they have filed the appropriate conflict of interest documents with the University. Later that afternoon, Roby and Knowles discuss whether they should now disclose their significant financial interest (SFI) to the University. What is the best course of action at this point?

- | | # teams |
|---|---------|
| A. Craft a conflict of interest management plan and file it with HotChem. | () |
| B. Discuss their situation with the Technology Development Officer at HU to determining if there is a conflict of interest. | () |
| C. File a SFI disclosure with HU. | () |
| D. Wait for the University to contact them. | () |

Please record notes from class discussion here.

A.

B.

C.

D.

As part of this discussion, students should start using SFNO to identify if the primary concern is with stakeholders, facts or norms. Prompt them if it does not happen spontaneously.

- A. While A sounds good, it leaves the University (and particularly the trainees) unaware of the conflict.
- B. Having a discussion with the University is appropriate, but the Technology Development Officer probably isn't the best person.
- C. Clearly they should take this step.
- D. The relevant individuals at the University may not be aware of the situation.

The discussion could include to whom the Professors might turn for help on CoI disclosure and management. [This issue could be the subject of a question in the future to drive this point home if necessary.]

Conflicts of Interest & Commitment

3. If they decide to file their University's Conflict of Interest Disclosure, which is the *most important* element to disclose?

- | | # teams |
|---|---------|
| A. That they are employed by HotChem as company officers. | () |
| B. That they receive compensation from HotChem. | () |
| C. That they have sponsored funding from HotChem to support continuing research. | () |
| D. That they have funding from HotChem to support trainees in their University lab. | () |

Please record notes from class discussion here.

A.

B.

C.

D.

Note: This is an opportunity to begin the adjudication process (if students haven't already done so).

- A. Arguably the MOST important – this clearly defines the level of financial CoI; everything else flows from this relationship.
- B. Compensation does not necessarily mean control over the company's actions.
- C. Having sponsored funding is not inherently a CoI.
- D. Very important – in the absence of University oversight are the interests of the *students*.

Conflicts of Interest & Commitment

4. There are a number of stakeholders with competing interests in this scenario. Which stakeholder should be given top priority?

- | | # teams |
|--|---------|
| A. Rebecca Wolford (the angel investor). | () |
| B. HotChem, Inc. | () |
| C. Hudson University. | () |
| D. Avery Broderick (the graduate student). | () |
| E. Other | () |

Please record notes from class discussion here.

A.

B.

C.

D.

The fact that the experiments reveal the compound is “very promising” is meant to suggest that HotChem is refusing to release the results to the student for commercial reasons.

Possible answers for “Other”: society (high-functioning research enterprise regularly bringing new treatments to improve public health); individual patients (better treatments leading to higher quality of life), *etc.*

This question is an opportunity to encourage learners to consider others perspectives. For example, perhaps the student doesn’t recognize the intellectual property issues that might be holding up the distribution of the data. Conversely, the Professors may be so focused on the company that they forget to consider the student’s dilemma. As part of this discussion, the “cultural” differences between an academic institution and a for-profit company could be discussed. [These issues could be the subject of a question in the future to further drive these points home if necessary.]

Conflicts of Interest & Commitment

5. Professors Roby and Knowles decide to develop a Conflict of Interest management plan. What is the most important consideration for such a plan?

- | | # teams |
|---|---------|
| A. The opportunity for conflict between generating new knowledge versus generating profits. | () |
| B. The University's desire to protect its reputation as an impartial source of knowledge. | () |
| C. Minimizing the risk of being forced to step down from their corporate positions. | () |
| D. Minimizing the risks to intellectual freedom and intellectual property rights. | () |

Please record notes from class discussion here.

A.

B.

C.

D.

A. Not necessarily just financial profits, but "profits" of reputation, *etc.*

Conflicts of Interest & Commitment

6. What is the most significant drawback of Professors Roby and Knowles develop their own conflict of interest plans?

- | | # teams |
|--|---------|
| A. Their plan may not adequately protect the interests of all stakeholders. | () |
| B. They do not have the expertise to craft an adequate plan. | () |
| C. This approach will be time intensive and distract them from other important work. | () |
| D. It is a conflict of interest for them to craft their own conflict of interest plan. | () |

Please record notes from class discussion here.

A.

B.

C.

D.

CoI plans are ultimately the responsibility of Conflict of Interest Officers. This answer highlights the risk of investigators crafting their own plan.

Close the session by asking the teams to revisit their definitions of conflict of interest and commitment, and consider whether they need to revise it further. Facilitate an inter-team discussion about how their definitions changed as a result of the case discussion.

Learning point: There will be layers of complexity to any research scenario involving potential conflict of interest. A simple definition may not capture those complexities.

SFNO Case Analysis

This case analysis provides an overview of the SFNO moral method that should be used by learners during the application exercise. More detailed discussion may be found in the Instructor's Guide for relevant application questions.

1. Identify the question/dilemma you want to resolve.
2. Organize the information
 - Stakeholders: Who has a stake in the decision being made?
 - May be a bulleted list
 - Facts: What facts are relevant to a solution? Which might generate disagreement?
 - May be a bulleted list
 - Norms: What ethical principles, norms or values are at stake? What professional codes or laws? Which are most relevant? Which conflict and/or generate disagreement?
 - May be a bulleted list
 - Options: What actions deserve serious consideration? If the ideal is not possible, which compromises are most attractive? (*Note – options are usually addressed via application questions*)
 - May be a bulleted list
3. Identify which conceptual “bucket” contains the primary conflict.
4. Adjudicate between competing stakeholders, facts and/or norms, depending upon where the primary conflict lies.
 - Stakeholders
 1. Are there reasons to give priority to the interests of one stakeholder over another?
 2. Who is invested with decision-making authority?
 - Facts
 1. Resolving mundane facts requires research to identify the correct answer.
 2. Resolving facts of probability is more difficult, however the same process of research and consultation with experts should be followed.
 3. Resolving disagreements concerning worldviews is difficult; adhere to a set institutional process.
 - Norms

When a proposed action conflicts with a generally followed norm, it may be justified if it meets the following criteria:

 1. **Necessity**: Is it necessary to infringe on the values or norms under consideration in order to achieve the intended goal?
 2. **Effectiveness**: Will the action be effective in achieving the desired goal?
 3. **Proportionality**: Is the desired goal important enough to justify overriding another principle or value?
 4. **Least Infringement**: Is the policy or action designed to minimize the infringement of the principle or value that conflicts with it?
 5. **Proper Process**: Has the decision been made using the proper process?

Acknowledgments

The authors thank *(list team members involved in the review of this module that are not included as coauthors)* for helpful discussions and review of this module before publication.

William L. Allen (University of Florida College of Medicine)

Jeffry A. Engler (University of Alabama at Birmingham Graduate School)

Victoria H. Freedman (Albert Einstein College of Medicine)

Cynthia W. Garvan (University of Florida College of Nursing)

Paul M. Haidet (Penn State College of Medicine)

Joel W. Hockensmith (University of Virginia School of Medicine)