

PROFESSIONAL INTEGRITY: BEST PRACTICES FOR PUBLISHING YOUR RESEARCH

Conflicts of Interest

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Conflicts of Interest

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Conflicts of Interest Module Table of Contents

		Page
I.	Pedagogy	1
II.	Module Objectives	4
III.	Instructor Guide	5
	Activity A: Journal Conflicts of Interest Guidelines	8
	Activity B: Using the ICMJE Conflicts of Interest Form	9
	Activity C: Conflicts of Interest Case Studies	10
	Activity D: My Conflicts of Interest Checklist	14
	Presentation Slides and Text	15
	References and Resources	28
IV.	Student Handouts	29
	Activity A: Journal Conflicts of Interest Guidelines	31
	Activity B: Using the ICMJE Conflicts of Interest Form	32
	Activity C: Conflicts of Interest Case Studies	33
	Activity D: My Conflicts of Interest Checklist	36
	Student Slide Handout	38

I. Pedagogy

This module is designed to promote best practices in publication ethics for life scientists and biomedical engineers who publish research papers. The goal is for students to not only understand professional standards of practice in research manuscript development but also to be able to apply these standards to their own work AND to be prepared to teach them to their own students in the future. Toward that end, this module employs student-centered learning strategies that engage students across the spectrum of Bloom's taxonomy (see below). For best impact, students should not simply sit and listen or read and answer questions. Instead, we encourage you to use multiple teaching methods and activities that engage students in actively exploring the topic. Some suggestions you will find in this module include:

- **Interactive Lecture:** The lecture slides and notes include a number of places to stop and engage students in working out a problem, discussing a policy, or reviewing a case study.
- Think/Pair/Share: Often part of an Interactive Lecture, students are given a problem to address first on their own, and then they are asked to share their responses with a partner, followed by sharing with the whole class.
- Voting Cards: Particularly when discussing ethics issues, students prefer not to raise their hands to indicate their answer to a group question. Consider using voting cards with a simple large-print "Yes" on one side and "No" on the other. Everyone raises their hands and votes and you can quickly visualize the class response. An alternative is "thumbs up/thumbs down" but this is harder to see.
- My Best Practice Checklists: These are working documents each student develops to use now and in the future as their personal checklists of best practice in publication ethics.
- **PASS IT ON:** As part of their My Best Practice Checklists, students should make a plan for teaching publication ethics to their future trainees.

Instructors can pick and choose which activities and resources they want to use from the module. However, we encourage you to consider using the Learning Cycle approach because of its rich opportunities for student-centered learning. Alternatively, the Homework/Interactive Lecture/Activities (HILA) approach can be used when class time is limited. Both approaches are outlined below.

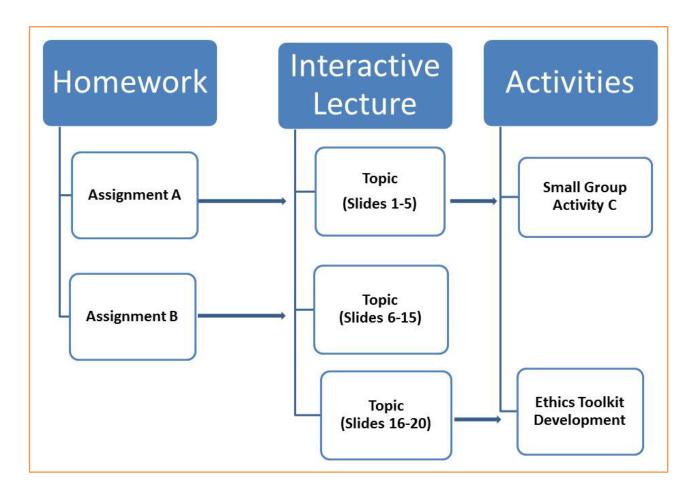
Learning Cycle

- **Engage**: Piques students' interest in the topic and poses questions or issues that capture their thinking. *Examples*: News articles on ethics violations and examples of manipulated figures.
- **Explore**: Students explore and ask questions, investigate via inquiry, make observations, and test hypotheses. Students should generate additional questions by the end of the exploration phase. *Examples*: Case study that students must try to resolve individually or in groups without additional information on professional standards of practice (these would be readdressed in the elaborate phase below), compare CV's of researchers, interpret letters from editors including comments/questions from reviewers, or write a letter to the editor describing figure manipulation in a manuscript to be submitted.

- Explain: Students and instructors use questioning/discussion, reference materials (print and online), expert presentations, and other resources to gain a better understanding of the key principles of the lesson and how they apply to the questions raised by students in the explore phase.
- **Elaborate**: Students apply what they have learned to real scenarios. *Examples*: Students revise their response to the explore phase case study using the principles and knowledge gained in the explain phase, and then do the same for a new case study or, ideally, their own work. Create a personal action plan or checklist for professional standards to use in the future.
- Evaluate: Evaluation occurs through each phase, with evidence collected of both student
 understanding of key principles and information and their ability to apply it to new situations and
 problems. Examples: Changes in approach to case study before and after the explain phase.
 Personal action plan/checklist addresses the key principles of professional practice. Key
 principles are applied appropriately to new case studies. Can also include quizzes or tests of
 content knowledge of professional standards of practice.

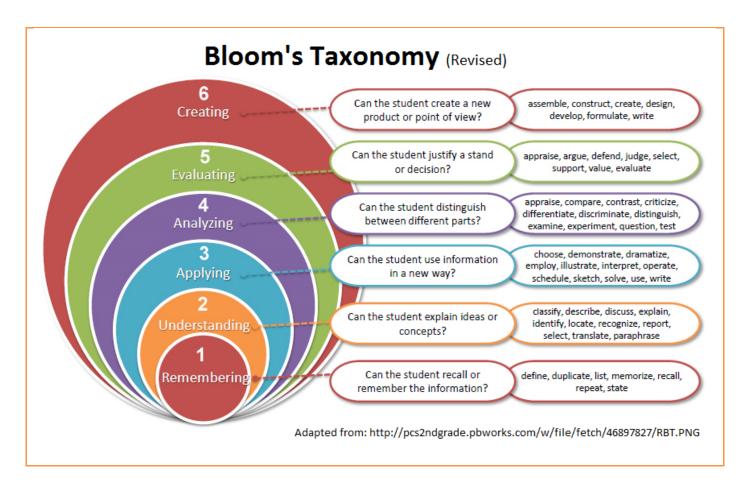
Homework/Interactive Lecture/Activities (HILA)

Homework activities are discussed either during the Interactive Lecture or during follow up activities.



Bloom's Taxonomy

Bloom's Taxonomy (established 1956, revised 2001) helps educators more effectively structure their teaching, student learning, and assessment of skills and knowledge. Organizing learning objectives by Blooms Taxonomy helps educators assure that lessons do not focus solely on memorizing basic knowledge but also challenge students to apply what they learn, evaluate new situations, and create solutions to challenging problems. Higher level objectives engage students in learning situations that are more complex and abstract. Overall, the professional ethics lessons in this series of seven modules focus strongly on the higher Bloom's levels (5 – Evaluating (20%) and 6 – Creating (21%)) in addition to including objectives for basic knowledge (Level 2 – Understanding (30%)) and application (Level 3 – Applying (14%)).



Student Handouts

The student section of this guide is formatted for easy duplication. This guide is also available as an MS Word (.doc) file (See References). We encourage you to provide both printed and .doc formats to students. The lessons are designed to help students create a personalized guide for their future work; developing their notes and best practices plans in a .doc format will help students use as well as modify their plans in the future.

II. Module Objectives

Students will be able to:		
Identify different types of interests in research and potential Conflicts of Interest	Levels	
(COIs) in publishing and to be able to provide examples of each.	2,3	
Design effective and appropriate ways to manage potential COI situations as an author, a reviewer and an editor.	6	
3. Describe and apply best practices for dealing with conflicts of interest in publishing to ensure full disclosure of research study intent and potential bias to editors, reviewers and readers.	2,3	

III. Instructor Guide

Target Audience

The module can be used with both graduate students and undergraduate students. It was initially designed for early career graduate students in biological science, medical science, or biological engineering graduate programs. Graduate students are likely to be somewhat aware of the academic publishing process but may not have had first-hand experience. Undergraduate students engaged in research and scientific writing may also find the materials useful.

Instructor Tips

- 1) Select the objectives and related activities that you want to address. Edit the PowerPoint Presentation to include the activities and objectives selected.
- 2) The script/key points for the presentation are in the notes section of the PowerPoint slides.
- 3) We encourage you to share 1-2 minute personal stories, when appropriate. Keep the stories positive (i.e., "I had a dilemma and I utilized a best practice...dilemma resolved").
- 4) Allow students to reach conclusions on their own. You are their guide through this class. Facilitate discussion to keep them on task and within time limits.
- 5) Be sure to include the "My Checklist" activity in each unit. This is the major "take away" lesson through which students integrate what they have learned in order to develop: 1) their personal checklists for ethical writing; and 2) their plans for teaching publication ethics best practices to their future trainees.

Teaching Approaches

Learning Cycle and Homework/Interactive Lecture/Activities (HILA) approaches are outlined below.

Evaluation Rubrics and Test Questions

Evaluation rubrics for assignments and test questions are available on request from the authors (email: education@the-aps.org).

Conflicts of Interest Learning Cycle

Engage

• Students should read **Activity C**: Conflicts of Interest Case Studies, Part I: Married to the Hypothesis and answer the questions. This will be discussed the the Elaborate phase.

Explore

- Students should complete Activity A: Journal Conflicts of Interest Guidelines AND Activity B: ICJME Conflicts of Interest Form.
- Both activities will be discussed the the Elaborate phase.

Explain

• Present Interactive Lecture.

Elaborate

- Review Activity C: Case Study I and do remaining case studies in small groups
- Review Activities A and B with students

Evaluate

- Activity D: My Conflicts of Interest Checklist
- Quiz/test questions and answer keys are available from the authors.

Conflicts of Interest Homework/Interactive Lecture/Activities

Homework/Interactive Lecture/Activities

Homework

Journal COI Guidelines (Activity A)

Using the ICMJE Conflict of Interest Form (Activity B)

Presentation

What are interests and potential conflicts of interest?

(Slides 1-9 of PPT)

Conflicts of interest as an author (Slides 10-17 of PPT)

Conflicts of interest as a reviewer (Slides 18-23 of PPT)

Conflicts of interest as an editor (Slides 24-28 of PPT)

Activities

Conflict of Interest Case Studies (Activity C)

My COI Checklist (Activity D)

Activity A

Journal Conflicts of Interest Guidelines

Purpose This activity will allow students to locate and compare conflicts of interest (COI) policies in journals. After completing this activity, students will be able to identify best practices for COI as described by journals.

Objective 3. Describe and apply best practices for dealing with conflict of interest in publishing to ensure full disclosure of research study intent and potential bias to editors, reviewers and readers.

Procedure Learning Cycle: Students complete the Activity A worksheet as an Explore activity. Instructor discusses their responses during the Elaborate phase.

HILA: Students complete the Activity A worksheet before coming to class and review and discuss their answers during the Interactive Lecture.

Activity B

Using the ICMJE Conflicts of Interest Form

Purpose This activity will allow students to apply standard criteria for conflicts of interest (COI) to their own collaborations and projects. After completing this activity, students will be able to generate an appropriate COI statement for their current work/papers based on standard criteria.

- **Objectives** 1. Identify different types of interests in research and potential Conflicts of Interest (COIs) in publishing and be able to provide examples of each;
 - 2. Design effective and appropriate ways to manage potential COI situations in the role of author, reviewer and editor; and
 - 3. Describe and apply best practices for dealing with conflict of interest in publishing to ensure full disclosure of research study intent and potential bias to editors, reviewers and readers.

Procedure Learning Cycle: Activity B should be done in the Explore phase and then discussed in the Elaborate phase.

> HILA: Activity B should be done as homework before the Interactive Lecture and then discussed in small groups after the lecture.

Ask each student to bring a recent abstract on which s/he was an author. Ask students to imagine that their abstract and research is now being translated into a journal manuscript. They should use the URL in Activity B to write an appropriate COI statement for the manuscript using the ICMJE form.

Download ICMJE Conflicts of Interest form here: http://icmje.org/conflicts-of-interest/

Activity C

Conflicts of Interest Case Studies

Purpose This activity helps students learn to apply best practices for conflict of interest issues in real life scenarios. After completing this activity, students will be able to identify different types of COI and how to deal with each.

- **Objectives** 1. Identify different types of interests in research and potential Conflicts of Interest (COIs) in publishing and be able to provide examples of each;
 - 2. Design effective and appropriate ways to manage potential COI situations in the role of author, reviewer and editor; and
 - 3. Describe and apply best practices for dealing with conflict of interest in publishing to ensure full disclosure of research study intent and potential bias to editors, reviewers and readers.

Procedure Learning Cycle: Activity C should be done as part of the Engage phase (Case Study I) and the Elaborate phase (Review Case Study I and complete remaining case studies).

HILA: Activity C should be done following the Interactive Presentation.

In small groups, one student should read the scenario to the group. After each section, the group should discuss the questions. At the end of the activity, students should write down their answers and be prepared to share with the whole class.

Answers for the Instructor are provided in *italics*.

Case Study I: Married to the Hypothesis

Rachel: I am so frustrated. My advisor wants me to prove that caffeine intake decreases expression of a family of neuromodulators. However, all of my results show either no change or a slight increase in expression. Based on prior studies, my findings make sense as someone has already shown that these proteins do not have caffeine receptors and thus there should be no direct interaction. Of course, the author of that work is my advisor's arch enemy and she does not believe anything that is reported from their lab. What I am supposed to do? She will not let me submit the paper until I show her the results she wants to see.

1. Is the advisor's request to Rachel appropriate?

No. The advisor should not ask a trainee to show a particular result. The advisor should encourage trainees to test a hypothesis and interpret the results obtained. Advisors should not demand that trainees produce specific results.

2. Does the advisor have a conflict of interest?

Yes, it sounds like she does. If the advisor is focused on proving a particular result to a study then she may be disregarding other interpretations of the study. It also sounds like she disregards findings from a competitor's lab. Perhaps, if she carefully considered their findings, she could better interpret her lab's results and more readily contribute to advancing the area of research.

3. Rachel repeats the experiment four more times and one set of results shows a modest decrease. Should Rachel report just that particular result in the manuscript since it "fits" with the story her advisor wants to tell?

If the data are not consistent with the results from the other experiments, then they should not be presented as the representative result in the manuscript. It may be more appropriate to summarize the results from the four repeat experiments and report the overall findings. Selective reporting of specific results that "fit" the hypothesis should be avoided. Rather, one should report results that have proven to be accurate and reproducible.

REMINDER: Encourage students to note ideas they want to add to their My Conflicts of Interest Checklist.

Case Study II: Benefits to Being a Reviewer

Deepti: I helped my advisor review a research article for *AJP-Cell Physiology* and the findings were really interesting. I hope the editor agrees with our recommendation to accept it as some of their findings fit well with my work and may help explain why treatment B only causes an effect in a subset of animals. The manuscript also included a reference to a study that describes how to fractionate adipose tissue into various cellular components, a technique that I desperately need to use. I was thinking about calling the authors to ask them for more information about their results. Matt, I left the manuscript I reviewed on your desk. You may find the new results interesting to your thesis work, as well.

1. Should Deepti have accepted the invitation to review the manuscript? Does she have a conflict of interest?

Likely, yes. It sounds like she is very familiar with the research reported in the paper and could make a good expert reviewer. However, if the intentions of the advisor were to share the paper with Deepti in order to advance her research, then there is a conflict of interest.

2. Is it appropriate for Deepti to contact the authors before the paper is published?

No. She should not contact the authors for more information until the paper is published.

3. Is it appropriate for Deepti to utilize the reference she discovered while reviewing the manuscript for her own work?

Yes. If the paper is publicly available, then she can utilize the information reported in it.

4. Is it appropriate for her to share the unpublished manuscript with Matt?

No. The manuscript should be kept confidential. After reviewing the manuscript, Deepti should have destroyed the paper so that no one else could read it. Some journals do allow reviewers to hold on to the original manuscript if review of a revised version is anticipated. Of course, storing the copy for future use as a peer reviewer comes with the risk that the manuscript may be accessible to others.

Matt should not read the paper until it is published. Imagine how you would feel if you knew that a reviewer passed your manuscript around for everyone in their lab to read prior to its being publicly available. The lab now has an unfair advantage over others in the field, including the author's because they could proceed with related questions prior to everyone else.

REMINDER: Encourage students to note ideas they want to add to their My Conflicts of Interest Checklist.

Case Study III: My Studies Can't be Published

Diane (fellow postdoc): Hey Raj, you look a little frustrated, what's going on?

Raj: Remember when Dr. Smith gave me all those new reagents to test in our disease model cell line? Well, some of the reagents worked really well and others didn't work at all. I spoke with Dr. Smith last week about writing up the study. I spent half a year characterizing the effects of the reagents on the cell model, and I think the data are really interesting. Dr. Smith said that he would have to check with the biotech company that provided the reagents to see if we could publish it. I was a little confused when he said that, but I figured that there would be no reason why we couldn't publish it. Then today he said that the company does not want the data published. They just wanted to see what would happen in our model. Six months. I spent six months on a study and I can't even publish it! Dr. Smith went on to tell me about his most recent consulting trip for the company in Hawaii. It sounds to me like he is getting a lot of perks while I am just working with no consideration for my time and career.

- 1. Who are the stakeholders and what are their interests in the research?

 Raj, Dr. Smith, and the biotech company. Possibly the academic institution and the funding agency for Raj's work also have an interest.
 - Raj's interests are to publish the interesting study and receive credit for the work.
 - Dr. Smith's interests are to establish a good relationship with the biotech company, to support trainees in his lab, to share his expertise with relevant sponsors, and to receive financial support for the expertise (free reagents, nice trips, consulting

fees, etc.).

- The biotech company's interests are to utilize experts in the field to advance their understanding of how their new reagents work in the most profitable and fastest way possible. The company may also have an interest in publishing the results because it could provide data to support their efforts.
- The academic institution's interests are to facilitate productive interactions between researchers and companies that support innovation and research productivity. It is not clear whether a contract was established between Dr. Smith and the biotech company. Many universities do not allow MTA's or other industry agreements that infringe on the right to publish, especially if students or trainees are involved. However, companies can request a reasonable delay to review the manuscript before submission (30-60 days is typical).
- The funding agency sponsoring Raj's work may have an interest in the study if funds from the agency supported aspects of this research. If the biotech company only provided select reagents and did not pay for the related experimental tools and the work is related to work proposed on a grant, then the funding agency would want the results from the studies to be shared and published. The funding agency has an interest in seeing the work published- to show public relevance and to show a return on their investment in the research.

2. Should the data be reported?

It depends on the agreement made between Dr. Smith/the institution/and the biotech company. Who has the rights to the data, the institution or the biotech company? If it is considered to be the biotech company's data, then Raj may not be able to report it.

3. If the company did agree to allow the data to be published, what potential conflicts of interest should Raj and his advisor declare to the journal?

They should declare the consulting activities by the Dr. Smith and the arrangement with the company (i.e., collaboration or receipt of materials in kind).

REMINDER: Encourage students to note ideas they want to add to their My Conflicts of Interest Checklist.

Activity D

My Conflicts of Interest Checklist

Purpose Students will develop a checklist based on course material that they can use now and in the future to guide ethical text preparation in terms of conflicts of interest. They should use materials from the activities, readings, and the Interactive Lecture. After completing the activity, students should have a checklist for conflicts of interest considerations AND a plan for teaching best practices to their students.

Objective 3. Describe and apply best practices for dealing with conflict of interest in publishing to ensure full disclosure of research study intent and potential bias to editors, reviewers and readers.

Procedure Learning Cycle: Complete in the Evaluate phase. Students should do this individually but will want to share their lists in class or with the instructor. HILA: Activity D should be done after the Interactive Lecture. Students should do this individually but will want to share their lists in class or with the instructor.

> The following provides material from the module that students may want to include in their checklist in some format. Students should create a checklist that works for THEM, not simply recreate this list. Encourage them to include these two definitions/resources and to include information on the questions below.

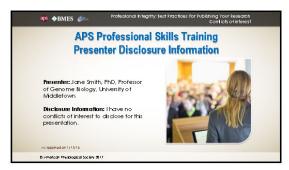
Definitions & Resources to Remember		
ICMJE definition of conflict of interest	"A conflict of interest exists when professional judgment concerning a primary interest (such as patients' welfare or the validity of research) may be influenced by a secondary interest (such as financial gain). Perceptions of conflict of interest are as important as actual conflicts of interest." http://www.icmje.org/recommendations/browse/roles-and-responsibilities/author-responsibilitiesconflicts-of-interest.html	
ICMJE Form for Disclosure of Potential Conflict of Interest	http://www.icmje.org/conflicts-of-interest/	

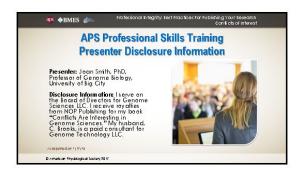
Guiding Questions

- What types of conflicts should I disclose as an author when submitting a manuscript?
- What types of conflicts indicate that I should NOT be a reviewer for a manuscript?
- 3. What types of things DO NOT indicate a potential COI for reviewing a manuscript?
- 4. PASS IT ON: How will I teach MY students about COI?

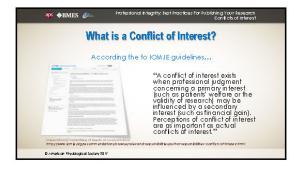
Presentation Slides

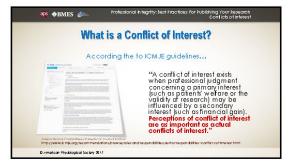






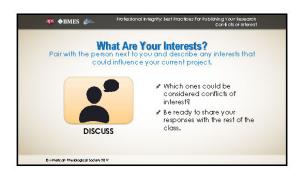






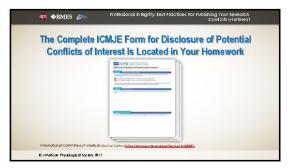




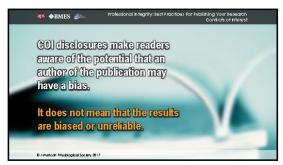






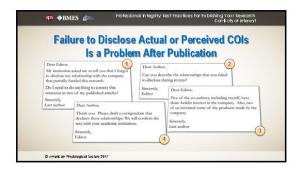






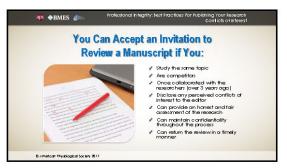




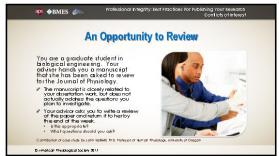






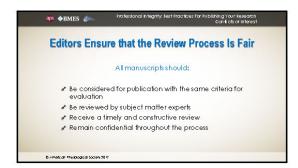


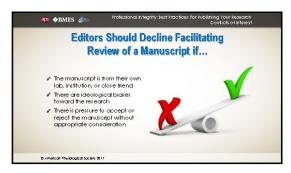


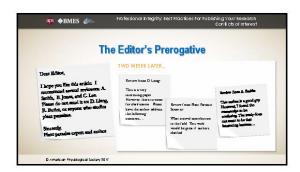






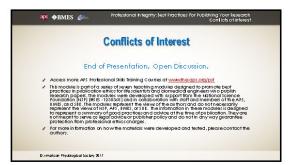












To download the PowerPoint (.ppt) slides, the MS Word (.doc) of the presentation slide text, and/or a video of the presentation, go to www.the-aps.org/pst/ethics.

Presentation Slide Text

Slide #	Text
1	This presentation is part of the professional skills training series on professional integrity
	best practices for publishing your research.
	Today we will review best practices for Conflicts of Interest. This presentation will help
	you to:
	 Identify different types of interests and potential conflicts of interest (or "COIs")in publishing
	 Design effective ways to manage potential COI situations in the role of author, reviewer, and editor
	Describe and apply good practices for dealing with conflicts of interest in publishing
2	At conferences and other public meetings you may see a disclosure statement on the screen before a talk begins. It is there to inform the audience about the relationships that the speaker has outside of his or her academic job. Our hypothetical presenter, Dr. Jane Smith, has nothing to disclose to the audience.
3	Jane's sister Joan is also a professor of Genome Biology and her disclosure statement declares her involvement on the Board of Directors for a Genome company. She also is a consultant for a Genome Technology firm, and she has written a book about Genome Science.
	Which person would you consider to be more of an expert, Jane who has no disclosures or Joan who has reported a number of activities? It is highly likely that both investigators are experts in their field of research since both were invited to speak at a meeting. However, to some, Dr. Joan Smith's activities suggest that she is more involved in the Genome biology community and may have more expertise than Dr. Jane Smith. And to others, it may alert them to consider Dr. Joan Smith's presentation with more caution considering that she has a number of interests that may, in some way, bias her interpretation of her own genomics research.
4	The same holds true for publishing. Journals will ask you to disclose activities and relationships, or interests, that could be considered to be related to, and possibly influence, the results reported in the publication. If you performed research alone in your own personal environment, your own bubble, perhaps your only interests would be to ask questions, produce results, and determine whether it supports or disproves your hypotheses.
	In reality, however, we all have other interests that actively, or peripherally, influence our work. Not all interests are bad. And not all interests cause conflict with how we do research. Those activities that could give the appearance of conflicting with research

	1
	interests are called potential conflicts of interests.
5	So what is a conflict of interest?
	According to the International Committee of Medical Journal Editors (ICMJE) guidelines, "A conflict of interest exists when professional judgment concerning a primary interest (such as patients' welfare or the validity of research) may be influenced by a secondary interest (such as financial gain). Perceptions of conflict of interest are as important as actual conflicts of interest."
6	I repeat, perceptions of conflict of interest are as important as actual conflicts of interest. That is, it may be that you have NO conflict of interest between your research activities and your non-research activities, BUT if the public is left with the impression that you have a conflict of interest, then you should treat it as a real conflict of interest when it comes to presenting your work in publications, at meetings, and elsewhere and disclose your outside activities when asked. We'll talk more about how to do that later.
7	Possible conflicts of interest include financial relationships with sponsors. Sponsors could include pharmaceutical companies, bio-tech companies, and other private firms who may have an interest in the specific outcomes of the research. Sponsors are not funding bodies like NIH and NSF. Personal relationships can be considered conflicts of interest. Would you be able to review your spouse's manuscript in the same manner that you reviewed a stranger's manuscript? What about manuscripts written by your mentor or your lab-mates? Even agreements between authors and sponsors may be considered a conflict of interest, such as when a sponsor does not provide all of the data necessary for an author to fully analyze the findings or interpret the data. Or when a sponsor restricts the author's ability to share all or part of the findings in publications. Other conflicts of interest may arise with those that are in competition with you, either intellectually or academically.
8	 Before you give a talk to a particular audience, or a write a paper on your lab's work or work performed with collaborators, you must honestly ask yourself if your financial or personal relationships (or those of your spouse or immediate family members) were public knowledge: Would the public read your scholarly work with any concern about conflict of interest? Would they trust that you performed the experiments correctly and analyzed the data appropriately? Would they think that your work was credible, that is, would they think that the work was honest and that you were not influenced consciously or unconsciously by other factors?

9	Let's stop for a moment and think about what types of interests you may have in your research.
	At this time, pause the presentation and write down any interests that could influence, or could be perceived to influence, your current project. Which ones would be considered conflicts of interest? If you have specific questions about potential conflicts of interest, be sure to discuss them with your advisor or a more senior colleague.
10	In many journals, authors are asked to disclose perceived conflicts of interest at submission so that the editor and reviewers are aware of the relationships and can assess the contents of the article with the information in mind.
11	 Did you or your institution receive payments or services from a third party for any part of the submitted work? This includes: research funding, consulting fees or honoraria, travel money to attend meetings, fees to participate in review activities, payment to write or review a manuscript, or providing support services to help facilitate the progress of the study. Have you had a financial relationship with sponsors within the past 3 years? This includes: Board membership, consultancy, employment, expert testimony, grants, payment for lectures, payment for manuscript preparation, patents, royalties, stock, travel expenses, or other financial support. Do you have other relationships that could appear to influence your work?
	 This includes: Family members working for companies with a financial relationship.
12	 The form on the screen, produced by ICMJE, is used by a number of journals to query authors for potential conflicts of interest. This document is in your course workbook. Let's take a moment to see what is included on the form: Section 3 asks for disclosure of financial relationships. Section 4 asks for declaration of patents or royalties from the work. Section 5 asks about other relationships that are not listed but could be perceived to be a COI.
	This form should be answered fully and honestly.
13	The conflict of interest statements or Disclosure statements are provided at submission and reported in the published manuscript. Here are three examples: • Disclosures No conflicts of interest, financial or otherwise, are declared by the author(s).
	securities of interest, interest, interest of other wise, are decided by the dutilon(s).

Disclosures

A patent has been filed for the REM-monitoring system to authors DG and MK.

Competing interests

The author has completed the ICMJE unified disclosure form and declares no support from any organization for the submitted work; no financial relationships with any organization that might have an interest in the submitted work in the previous three years; and no other relationships or activities that could appear to have influenced the submitted work.

Funding provided by granting agencies like NIH and NSF are usually listed in the Acknowledgments section of a manuscript, not the Disclosures section.

Remember: COI disclosures give the readers all the information they need to evaluate the validity of the conclusions. It does not mean that the results are unreliable.

Be transparent in your work. Let readers know about your related activities and let them decide whether any additional caution is warranted.

Likewise, merely disclosing Conflicts of interest does not satisfy YOUR responsibility of publishing your work honestly and truthfully. You should only publish work that you can publicly support and defend.

You have an ethical responsibility to publish honest research!

Likewise, failing to report a perceived COI may raise serious concerns by a reviewer or reader about the integrity of the work.

For example, a reviewer for a research journal alerted the Editor to a possible COI. The reviewer saw the first author featured on the website for the company that produced the drug used in the paper. The website described the author as their lead scientific expert.

The authors had reported to the journal that the company funded part of the research BUT there was no disclosure regarding relationships between the authors and the company.

The journal suspended peer review and contacted the author. The author explained that he has visited the facility and his work is the basis for some of their products. However, he is not and was never employed by the company nor received any compensation. He was unaware that the company posted pictures of the visit on their website. Moreover, he said that the findings he reported in the paper did not support all of the claims made by the company.

What was the outcome? The Editor asked him to revise the manuscript to disclose all relationships between the authors and the company in the manuscript. Then, the editor asked the reviewers to assess the corrected manuscript with the potential COI in mind.

Likewise, failure to disclose actual or perceived conflicts of interest is a problem if it is discovered after publication as it may be perceived to reflect poorly on the author, the home institution, and even the publisher. For example, a journal and an author had the following exchange:

The last author wrote to the journal, "My institution asked me to tell you that I forgot to disclose my relationship with the company that partially funded this research. Do I need to do anything to correct this omission in two of my published articles?"

The editor of the journal replied, "Can you describe the relationships that you failed to disclose during review?"

The author then explained: "Five of the co-authors, including myself, have share-holder interest in the company. Also, two of us invented some of the products made by the company." The editor agreed that the authors should draft a corrigendum to declare the COI. The editor also noted that they would "confirm the text with the academic institution."

What was the outcome? The author submitted the corrigendum to the journal and the journal submitted the draft to the authors' University for review because if an author writes to a journal at the request of the University, you know there is a reason why the University wants the journal to be informed.

The University responded and asked the journal to add. "Last author is the President and Chair of the company's Board."

Clearly, these authors were not forthcoming with their relationships. These relationships matter because the interpretation of the data may be skewed by having direct interest in the company doing well. For instance, if the products do not work well, would these authors be eager to report it? Maybe not.

Conflicts of interest associated with publishing research articles are not solely associated with the author. Reviewers can have actual or perceived conflicts of interest as well.

Can you think of an instance when a reviewer might have a conflict of interest?

- 19 It is recommended, perhaps even an obligation, to decline an invitation to review a manuscript if:
 - The authors are close friends
 - There is a professional conflict
 - There are ideological biases toward the research
 - You recently collaborated with the researchers, that is, within 3 yrs.
 - The authors are from the same institution, or
 - You have a relationship with a company that sponsored the studies

Editors would much prefer you to decline their invitation to review the manuscript

rather than receive a review that is not constructive or appropriate to send to the authors.

- On the other hand, one should feel comfortable accepting an invitation to review a manuscript if you:
 - study the same topic
 - are friendly competitors
 - once collaborated with the researchers, at least 3 years ago
 - disclose any perceived conflicts of interest to the editor
 - can provide an honest and fair assessment of the research
 - can maintain confidentiality throughout the process; and
 - can return the review in a timely manner

You should feel free to review work submitted by former colleagues, even your mentor, if you have not worked with them for more than 3 years as long as you feel sufficiently separated from their work to be able to review the work without personal bias.

One of the biggest complaints from authors is not receiving reviews in a timely manner and receiving reviews that are not constructive. Both waste authors' time to get their work published and some see it as a way for reviewers to delay publication of a competitor's work. If you cannot provide an honest, constructive and timely review, then you should decline the invitation.

Many journals are amenable to reviewers sharing their duties with a junior colleague. Such activities help to train the next generation of researchers on how to be a good reviewer. Journals may require the reviewer to declare that the review was performed by a colleague under their mentorship. And as with any review, information about the manuscript and the review must remain confidential.

If your advisor has not asked you to review an article, then ask to participate. It is a great way to gain proficiency in reviewing articles as well as to develop your expertise in your research area.

22 Consider the following scenario:

You are a graduate student in biological engineering. Your advisor hands you a manuscript that she has been asked to review for the Journal of Physiology. The manuscript is closely related to your dissertation work, but does not actually address the questions you plan to investigate. Your advisor asks you to write a review of the paper and return it to her by the end of the week.

Is this appropriate? What questions, if any, should you ask?

The answer is yes. However, it may be good to confirm that she will inform the journal that the review was done by a junior colleague. Also, it would be good to confirm that she plans to discuss the findings of your review with you before returning it to the journal.

23	Continuing with the scenario: Despite your great insights, the paper you helped review has been rejected by the Journal of Physiology.
	As you further develop plans for your dissertation work, you remember the article, and it gives you an idea for a new study that could build on their work and your work in a very positive way.
	Do you revise your dissertation plan to include the new idea?
	The answer is: If the data are not published, then you cannot "build" on their work. One must wait until the work is published to use the findings to support your study and incorporate it into your dissertation plan.
	One possible way to build upon the idea is to see if the data reported in the manuscript have been presented at a national meeting. Perhaps, then you may have enough information to contact the author and discuss some type of collaboration. However, one must not disclose that you reviewed their article.
24	We have discussed possible conflicts of interest as an author and reviewer. The other roles in publishing that must consider potential conflicts of interest are the Editor and Associate Editor.
	Editors are responsible for managing the review process. Usually they perform an initial assessment of the manuscript to determine whether the work is a good fit for their journal. Then they ask experts in the field to review the manuscript. Once the reviews are returned, the editor makes the decision as to whether the manuscript should be accepted, rejected, or invited to submit revisions.
	Can you describe an instance when an editor might have a conflict of interest?
25	Editors must ensure that every manuscript submitted to the journal is evaluated with the same criteria and is reviewed by appropriate subject matter experts. They also must be certain that manuscripts go through the peer review process in a timely and confidential manner.
26	Editors should not facilitate the review of manuscripts from their own labs or institutions, or by authors with whom they have close relationships. Likewise, editors should not make decisions on manuscripts that may be influenced by personal biases or external pressure to accept or reject the work without appropriate consideration.
	It is important for journals to have processes in place to address potential conflicts of interest between editors and authors.
27	The editor's job is to facilitate a fair review. If an author asks the editor to exclude every expert and possible rival, in the field then the editor is left with very few options for reviewers. Pause the recording for a minute and read the emails and reviews. As shown here, the reviews from Dr. Liang and the Plant Parasite expert show that they

fully understood what the paper was trying to communicate and likely will provide a constructive review that will help the author improve the manuscript. However, the review from A. Smith does not convey an understanding of the information reported in the manuscript and likely will not provide useful comments for the author to address.

Think about what you want out of peer review. Ultimately, it is good to have reviewers and editors who: understand the studies performed, can suggest ways to improve the clarity and interpretation of the work, and acknowledge the strengths, and major weaknesses, of the study. It is not the time to have friends or "good guys" review your work.

- Consider the following scenario: The Journal of Applied Math is preparing a special issue on the topic "Wifi Wavelength and Health." The editor in chief is an expert on the topic and plans to contribute four articles to the issue.
 - Should the editor's articles undergo peer review?
 - Should the editor in chief facilitate the peer review process for her articles?
 - Are there other steps she should take to avoid the perception of a conflict of interest?

The answer to the first question is Yes. The editor's articles must undergo peer review just like all other articles in the special issue

The answer to the second question is No. It could be considered a conflict of interest for the editor to facilitate review of her own lab's articles.

The answer to the last question is Yes. Perhaps, the special issue could be managed by a "deputy" editor rather than the editor of the journal just to make it clear to the readers and other authors that all articles were considered with the same standards.

The remaining activities in this module will help you to APPLY what you have learned so far to common scenarios and to your own work.

BE SURE to add notes from this presentation to your "My Checklist" document.

Thank you for listening to this presentation. To access more information about APS Professional Skills Training Courses visit www.the-aps.org/pst.

References and Resources

- 1. ICMJE International Committee of Medical Journal Editors. ICMJE Form for Disclosure of Potential Conflicts of Interest. Retrieved from: http://www.icmje.org/coi/disclosure.pdf.
- 2. ICMJE International Committee of Medical Journal Editors. (Updated December 2016) Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals. Retrieved from: http://www.icmje.org/icmje-recommendations.pdf.

Course Resources

Each of the **Professional Skills Training Courses on Best Practices for Publishing Your Research** has multiple resources to accompany the Instructor Guide. All of the following resources are available at www.the-aps.org/pst/ethics.

- 1. PowerPoint (.ppt) files for the Interactive Lecture. These slides are editable.
- Instructor and Student Guides are available as editable .doc files.
- 3. Request form for assessment tools (quizzes and key).
- 4. Links to video versions of the Interactive Lecture on YouTube.
- 5. Links to online, on demand version of the module.

Publication Ethics Community

In addition, APS hosts a Publication Ethics Community on the Life Science Teaching Resource Community. The community posts ethics cases for comment by participants and experts. See www.lifescitrc.org and click on My Community.

Ethics CORE (Collaborative Online Resource Environment)

This website is coordinated by the National Center for Professional and Research Ethics. The site provides resources for Responsible Conduct of Research courses and seeks to create communities of responsible research and professional practice. It is an excellent source of case studies, simulations, role-play scenarios, videos, and lectures. See https://nationalethicscenter.org.

We welcome your questions and feedback on these materials. Email us at <u>education@the-aps.org</u>.

Student Handouts



These activities will help you:

- 1. Identify different types of interests in research and potential Conflicts of Interest (COIs) in publishing and to be able to provide examples of each.
- 2. Design effective and appropriate ways to manage potential COI situations as an author, a reviewer and an editor.
- 3. Describe and apply best practices for dealing with conflicts of interest in publishing to ensure full disclosure of research study intent and potential bias to editors, reviewers and readers.

This module is part of the series, "Professional Integrity: Best Practices for Publishing Your Research" developed by:

American Physiological Society www.the-aps.org
Biomedical Engineering Society www.bmes.org
Society for Biological Engineering www.aiche.org/sbe

For information on the other modules or to take an online, interactive version of one or more modules, go to www.the-aps.org/pst.

About Your Publication Ethics Checklists

In these modules, you will be encouraged to create your OWN checklists for preparing manuscripts using ethical and professional standards of practice for researchers.



WRITE

Why do I need a checklist?

As your training progresses, your research and writing skills develop along with your knowledge of the field, your professional network, and your independence as a professional. This also means that understanding and following best practices for professional behavior, including research and publication ethics, increasingly rests on your shoulders. YOU become the person who is setting the standards for your laboratory group. YOU are the person who must establish protocols for assuring ethical behavior. And YOU are the person who has to teach standards and protocols to every trainee in your lab and, sometimes, to those with whom you collaborate. You cannot assume that they come with an understanding of best practice...you must inform, guide, and monitor their adherence to best practices.

What should I include in the checklist?

You are investing time and effort to learn best practice for publication ethics through this module (and possibly the other modules in this series). **This activity is the big "take away" from this module**. It is YOUR checklist of things to remember about publication ethics. In each module in this series, you will add a checklist of the things you want to remember from that module. You also will add notes on how you would teach this to your students in the future. For most modules, we encourage you to add three sections to your checklist:

- 1. Definitions to Remember Table: Consider adding the terms and definitions from the lecture. Also add the links for professional standards you want to access later (e.g., ICMJE criteria for authorship). Remember to add the source of your definition or text if you are copying it.
- 2. My Best Practices Checklist: What are the things you want to check as you develop or revise your manuscripts?
- **3.** PASS IT ON: How will you teach this to YOUR trainees in the future? How will you share this with those with whom you collaborate?

When you are done with these modules, we encourage you to make a copy of your checklists and keep them handy for use as you develop manuscripts in the future.

Activity A

Journal Conflicts of Interest Guidelines

Purpose This activity will help you to locate and compare conflict of interest (COI) policies in journals. After completing this activity, you will be able to identify best practices for COI as described by journals.

- Procedure 1. Select 2-4 journals in your field (e.g., you read it, you/your lab submits manuscripts to it, etc.).
 - 2. Go to the journal website and look for information on conflict of interest policies for authors, editors, and reviewers. You may need to browse around a bit. Try looking for sections such as "information for authors," "publication policies," "ethics policies," "research misconduct," or "editorial policies."
 - 3. Fill out the table below with as much information as you can find.
 - 4. Bring your completed table to class to share with your group/class.

Journal name	COI Policy for	Have policy? (Y/N)	URL	Describe policies for each
	Author			
	Editor			
	Reviewer			
	Author			
	Editor			
	Reviewer			
	Author			
	Editor			
	Reviewer			

Activity B

Using the ICMJE Conflicts of Interest Form

Purpose This activity can help you apply standard criteria for conflicts of interest (COI) to your collaborations and projects. After completing this activity, you will be able to generate an appropriate COI statement for your current work/papers based on standard criteria.

Procedure 1. You were asked to bring a recent abstract on which you are an author. Imagine that the abstract and research is now being translated into a journal manuscript.



- 2. Go to http://icmje.org/conflicts-of-interest/ and scroll down the page to download the ICMJE form.
- 3. Complete the form based on the work you did for the abstract.
- 4. If you have any questions about how to answer the form questions, bring them to class for the discussion. Bring a printout of your COI statement at the end of the form as well.

Activity C

Conflicts of Interest Case Studies

Purpose This activity can help you learn to apply best practices for conflict of interest issues in real life scenarios. After completing this activity, you will be able to identify different types of COI and how to deal with each.

- **Procedure 1.** In small groups, one student should read the scenarios to the group.
 - 2. The whole group should discuss the questions.



DISCUSS

Case Study I: Married to the Hypothesis

Rachel: I am so frustrated. My advisor wants me to prove that caffeine intake decreases expression of a family of neuromodulators. However, all of my results show either no change or a slight increase in expression. Based on prior studies, my findings make sense as someone has already shown that these proteins do not have caffeine receptors and thus there should be no direct interaction. Of course, the author of that work is my advisor's arch enemy and she does not believe anything that is reported from their lab. What I am supposed to do? She will not let me submit the paper until I show her the results she wants to see.

- 1. Is the advisor's request to Rachel appropriate? Explain.
- 2. Does the advisor have a conflict of interest? Justify your answer.
- 3. Rachel repeats the experiment four more times and one set of results shows a modest decrease. Should Rachel report just that particular result in the manuscript since it "fits" with the story her advisor wants to tell?



REMEMBER: Note ideas that you want to add to your My Conflicts of Interest Checklist.

Case Study II: Benefits to Being a Reviewer

Deepti: I helped my advisor review a research article for AJP-Cell Physiology and the findings were really interesting. I hope the editor agrees with our recommendation to accept it as some of their findings fit well with my work and may help explain why treatment B only causes an effect in a subset of animals. The manuscript also included a reference to a study that describes how to fractionate adipose tissue into various cellular components, a technique that I desperately need to use. I was thinking about calling the authors to ask them for more information about their results. Matt, I left the manuscript I reviewed on your desk. You may find the new results interesting to your thesis work, as well.

- Should Deepti have accepted the invitation to review the manuscript? Does she have a conflict of interest? Explain.
- 2. Is it appropriate for Deepti to contact the authors before the paper is published? Justify your answer.
- 3. Is it appropriate for Deepti to utilize the reference she discovered while reviewing the manuscript for her own work? Justify your answer.

4. Is it appropriate for her to share the unpublished manuscript with Matt? Justify your answer.



REMEMBER: Note ideas that you want to add to your My Conflicts of Interest Checklist.

Case Study III: My Studies Can't be Published

Diane (fellow postdoc): Hey Raj, you look a little frustrated, what's going on?

Raj: Remember when Dr. Smith gave me all those new reagents to test in our disease model cell line? Well, some of the reagents worked really well and others didn't work at all. I spoke with Dr. Smith last week about writing up the study. I spent half a year characterizing the effects of the reagents on the cell model, and I think the data are really interesting. Dr. Smith said that he would have to check with the biotech company that provided the reagents to see if we could publish it. I was a little confused when he said that, but I figured that there would be no reason why we couldn't publish it. Then today he said that the company does not want the data published. They just wanted to see what would happen in our model. Six months. I spent six months on a study and I can't even publish it! Dr. Smith went on to tell me about his most recent consulting trip for the company in Hawaii. It sounds to me like he is getting a lot of perks while I am just working with no consideration for my time and career.

1.	Who are the stakeholders	and what are their inte	rests in the research?

2. Should the data be reported? Justify your answers.

3. If the company did agree to allow the data to be published, what potential conflicts of interest should Raj and his advisor declare to the journal?



REMEMBER: Note ideas that you want to add to your My Conflicts of Interest Checklist.

Activity D

My Conflicts of Interest Checklist

Purpose In this activity, you will develop a checklist based on course material that you can use now and in the future to guide ethical text preparation in terms of conflicts of interest. You should use materials from the activities, readings, and Interactive Lecture. After completing the activity, you should have a checklist for conflicts of interest considerations AND a plan for teaching best practices to your students.

Procedure Review the previous activities and the Interactive Lecture notes. Use the guiding questions below to help you make a checklist of all the potential conflicts of interest that you should consider on research studies and professional activities in the future.



This checklist should be added to the other checklists you generate through the modules on publication ethics best practices.

WRITE

Definitions and Resources to Remember			
ICMJE definition of conflict of interest			
ICMJE Form for Disclosure of Potential Conflict of Interest			

Guiding Questions

1. What types of conflicts should I disclose as an author when submitting a manuscript?

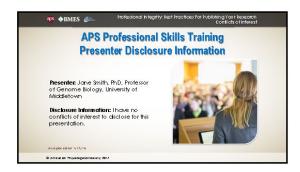
2. What types of conflicts indicate that I should NOT be a reviewer for a manuscript?

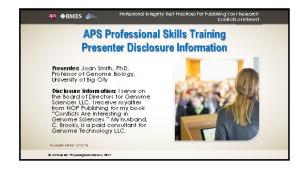
3. What types of things DO NOT indicate a potential COI for reviewing a manuscript?

4. PASS IT ON: How will I teach MY students about COI?

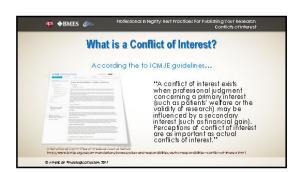
Student Slide Handout

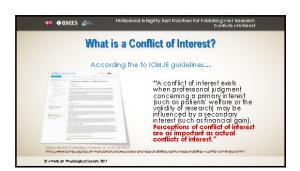














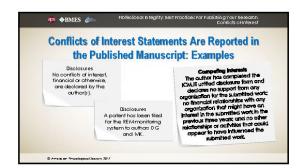


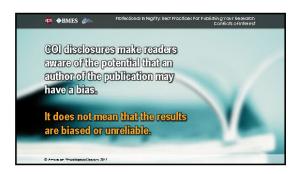




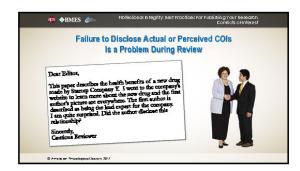


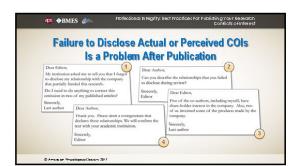
















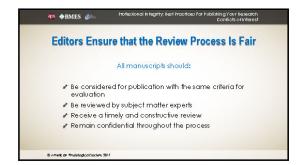




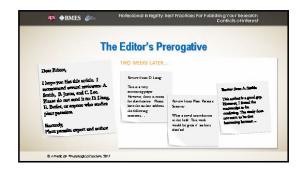


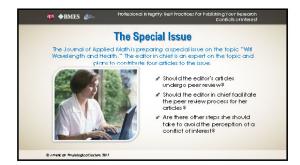




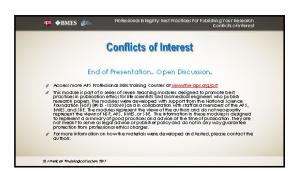












The time is always right to do the right thing.

-Martin Luther King Jr.

conflicts of interest is one of seven teaching modules designed to promote best practices in publication ethics for life scientists and biomedical engineers who publish research papers. Each module provides information on and principles of the most common publication ethics issues as well as the tools needed to integrate and apply professional standards of practice to real life situations. After finishing each module, students will have a personal checklist to use in the preparation of future manuscripts AND a plan for teaching module principles to their future trainees and collaborators.

Modules are designed to be used by higher education institutions, laboratory groups, individuals, and professional societies. The teaching paradigms used in the modules support various types of learners and were designed to integrate into current Responsible Conduct of Research (RCR) training courses/programs.

Modules were developed with support from the National Science Foundation (NSF) (#SES -1238368) and in collaboration with staff and members of the American Physiological Society, Biomedical Engineering Society, and the Society for Biological Engineers.

Handouts for instructor and students, audio and video resources, and online course links are available at www.the-aps.org/pst for all seven modules:

- Authorship
- Conflicts of Interest
- Considerations for Animal and Human Studies
- Data Fabrication and Falsification
- Data Management and Integrity
- Overlapping Publications
- Text Preparation and Avoiding Plagiarism