



University of Washington Biomedical Research Integrity Cases

Teaching Cases & Background Materials

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University of Washington Biomedical Research Integrity Cases

Teaching Cases & Background Materials

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UW BRI Cases

1. Faculty Guide to Ethics and Small Group Teaching

Faculty Guide

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In order to support your facilitation of the BRI Discussion Sessions, we have developed a few materials for your review.

1. **Strategies For Leading An Ethics Discussion**

This outline walks through a standard small group discussion, from set-up to wrap-up. We have added BRI specific notes throughout. For example, one issue that has come up for faculty is how to facilitate a discussion with trainees doing quite different kinds of research.

2. **Case-Study Approach**

One way to structure an ethics discussion can be to use a standardized process to working through a case. We suggest a decision-making process adapted from the Hastings Center. By using this approach to facilitate and guide discussion, you can move past a hasty ‘simple’ solution to a case. For example, break-out sessions of 2-3 students can be asked to explore different steps in the analytic process, followed by a group discussion of all steps. Our goal is to promote consideration of complexities in these case scenarios.

3. **Brief Overview of Ethical Frameworks and Principles**

Referring to specific approaches to ethical reasoning and to basic principles of biomedical research ethics can help to ground the discussion. These basic approaches can also help justify the best solutions to the cases.



Strategies For Leading An Ethics Discussion

Set The Context For Discussion

- Explain objectives and purpose of discussion
- Outline how the time will be spent
- Remind participants that this is a group discussion and not a didactic session (they are responsible for discussion, not you)

Facilitator's Role In Small Group Discussion

- Let the learners do the work to figure out how to resolve the case. The facilitators' job is to ask the questions to motivate the group to want to resolve the problem, and to focus them on the key issues. The *Case-Study Approach* (attached) can help with focus.
- Help learners see the complexity that exists in the case (some learners quickly jump to conclusions without appreciating other considerations).
- Help the learners acquire a systematic approach to dealing with difficult cases (which they can use to deal with future cases).
- Assist learners in making connections with other kinds of research (if it is an animal research case, when do similar issues arise in bench research or human subjects research?).

Working Through A Case

- Ask someone to read the case so that all are on the same page
- Ask the group if they have factual questions (emphasizes the importance of facts in resolving what are often a combination ethical, legal and psychosocial problems)
- An effective focusing tool is to ask the learner why he/she wants the information he/she is requesting.
- Use the Case-Study Approach to guide discussion. Consider different stakeholders (e.g. mentor, trainee, funder, subject) and what values each person seems to be holding. Are there values in conflict? Are there principles in conflict? What problems or issues are raised by the case?
- When considering multiple solutions, compare the options in terms of their capacity to serve key values. Justify the choice compared to alternatives.



Strategies For Leading An Ethics Discussion (continued)

Tips For Leading A Discussion

- Let participants do most of the talking.
- Help to *build the discussion* by introducing new questions or controversies. Use questions, probes, and *case variations* to focus the discussion.
- Where appropriate *provide your own experiences* or comments, but avoid acting as an expert. See if other participants can correct misconceptions first.
- Use strategies to prevent one person from dominating the conversation. “Thank you John, any thoughts from anyone ...”
- Invite everyone to participate. “John, do you have any thoughts or comments?”
- Make sure your goals and purposes are being met—if not, try to *redirect* the conversation.
- *Provide closure*. Summarize what was learned or discussed. Refer to other resources available on handout and BRI website



Case-Study Approach

This particular ethical decision making model was developed at the Hastings Center.¹ The six-steps to be completed either individually or collaboratively within a group are:

Step 1: Gathering and assessing relevant facts

The second step in the decision making process involves assessing the facts that are available to decision-makers. At this step it is important to address the non-ethical issues raised within the case. For example, one may need to know the legal constraints of the decision. Since it is impossible to include all facts in a case-study, frequently students will have to make assumptions based on the information that they do have. If students have longer than one class period to work on the case-study, they can identify research areas to find out more information at this point.

Step 2: Identifying the Stakeholders

At this step, all stakeholders in the decision should be identified. As with Step 1, think broadly and generate a list of all possible individuals, groups, or entities (e.g. the environment) who will be affected by the decisions to be made. In the next 2 steps, students will be able to weigh the stakeholders' positions and assign priorities to the various groups.

Step 3: Identifying the values that are at stake

Identifying the values at stake in the decision can be challenging, as this language is more often foreign to students. Values are concepts, goals, or standards that are important to consider when choosing between competing courses of action. These include, but are not limited to, beneficence, justice, autonomy, truth telling, integrity, and preserving relationships. Some stakeholder values may include supporting a family (self-preservation), or winning an election (self-interest). While each of the values identified should be considered, they will vary in their importance depending upon the circumstances and the facts of the case at hand. It can help at this step to identify values that work together or values that conflict.

Step 4: Identifying the ethical issues raised in the case

The first step involves identification of the ethical problems the case raises. It can help to start with an exhaustive list and then focus attention on specific issues that should be considered from there. Many issues will arise, not all of which will be ethical issues. Certain key terms may suggest when a question is an ethical question (e.g. "right," "responsibility," "duty," "ought," and "should.") A common element to

¹ The model and notes can be accessed as part of the ELSI module under Teacher Resources from the University of Washington High School Human Genome Program: <http://hshgp.genome.washington.edu/>



Case-Study Approach (continued)

ethical questions is that they raise concerns about what is appropriate conduct in a given situation and/or directly refer to the rights or interests of others.

Step 5: Identifying possible solutions

At this stage, students should develop and assess multiple ways to resolve the issues involved with the decision. They should consider “what *could* be done”. This list can be open-ended and include solutions that are not possible (thinking about the reasons why something is not possible, or is ethically unacceptable, can be very useful).

Step 6: Choose and justify the better solution

In step 6, students should consider “what *should* be done”. Alternative solutions from Step 5 can be identified and justified in terms of the values that the solutions support.



Brief Overview of Ethical Frameworks and Principles

What is the right act? And what makes it so?

Principles of Bioethics

Since Hippocratic times, the profession of medicine has identified a version of these four primary principles as guides in their practice. The biomedical research community has also adopted these principles in the Belmont Report (1979).

- Beneficence: How can I be of benefit?
- Nonmaleficence: How can I minimize harm?
- Respect for Persons: How can I treat people as if they matter?
- Justice: How can I act fairly?

Frameworks for Ethics

These three approaches are used in most arguments. It can help to be explicit about which framework is being used, otherwise the argument will not go anywhere (if rules are being countered with consequences, for example). Each framework is valid. It can be useful to review justifications for alternative solutions from each perspective:

- **Principle or Rule-Based**
An action is right if it follows fundamental moral rules. The reasoning process here involves identifying the appropriate moral rule for the situation. Rules and principles may come from multiple sources, including one's profession, society, religion, or an institution. Rules or principles, even from within the same system, may come into conflict at any one time. Justifying why one principle might be privileged over another in a given situation is much of the work of ethics in this model.
- **Consequence-Based**
An action is right if the good outweigh bad consequences. The reasoning process here involves identifying specific anticipated, as well as unintended, outcomes of various options. Deciding which consequences to consider, and how to 'weigh' them against one another, is the challenge of this approach.
- **Virtue-Based**
An action is right if it enacts a core purpose. The reasoning process in this approach involves identifying what role the decision maker will take in the situation (is it one of citizen? Policymaker? Scientist? Teacher? Mother?). From there, one must decide what the core values are for that



Brief Overview of Ethical Frameworks and Principles (continued)

What is the right act? And what makes it so?

position. These core values should capture the core purpose (e.g. as a mother, my core purpose is to protect my children from harm). The challenge of this approach is negotiating competing interpretations of core purpose and resolving conflicts between roles.

Skills to Teach in Ethics Education

Ethics is a skill-based activity. Four components must be addressed:

- **SENSITIVITY:** Can you recognize the issues?
- **REASONING:** Can you reason through the dilemma?
- **MOTIVATION:** What is your responsibility? (As a trainee? As a scientist?)
- **ACTION:** What will you do?



UW BRI Cases

2. Primary Discussion Topic: Collaborative Science

**Additional Discussion Topics: Publication/Authorship, Data Acquisition, Management, Sharing and Ownership.
Cases & Notes for Faculty Facilitators**

Collaborative Science

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Objectives for case discussion:

1. Understand that good collaborative relationships are the result of *developing* the relationship, addressing issues as they arise, and clearly defining expectations regarding the research project and the collaboration.
2. Distinguish different kinds of “data” and “ownership”.
3. Understand the guidelines for data ownership within team relationships.
4. Understand the guidelines for data ownership for projects involving external funding.
5. Develop strategies for establishing authorship.

Resources:

NIH Grants Policy Statement (2001).

http://grants1.nih.gov/grants/policy/nihgps_2001/part_ii_a_6.htm

Ownership of Data. UW Attorney General Office (2002).

<http://depts.washington.edu/or/dataownership.html>

University of California, San Diego *Collaboration and Mentoring*

<http://ethics.ucsd.edu/courses/integrity/assignments/collaboration.html>

American Academy of Microbiology *Dynamic Issues in Scientific Integrity:*

Collaborative Research <http://www.asmusa.org/acasrc/pdfs/research.pdf>

<http://www.washington.edu/medical/som/research/ethics.html>



Case 1: Multi-Site Research Collaboration

As a result of a paper you've just published, you are approached by some researchers at Swell University. You have been doing developing a new drug which shows some promise for patients with Parkinson's disease. The work has been supported by an NIH training grant. The researchers at Swell want to collaborate with you and foresee setting up a multi-site clinical trial.

- What do you need to consider prior to agreeing to collaboration with the researchers from Swell?
- How will you determine issues such as ownership, and use of data and authorship on publications?



Case 1: Variations

Multi-Site Research Collaboration

The following variations of this case can be used to discuss the issues further.

- What if you were approached by a for-profit company rather than a University?
- What if the folks from Swell just want use of some of the compounds you've developed?
- You've not yet finished your research nor published your results. Rather the researchers from Swell were at a conference at which you presented some preliminary data.
 - o Are there different considerations regarding the potential collaboration due to the research being in early stages?



Case 2: Continuation of a Previous Student's Work

A graduate student in Professor Jones' laboratory recently completed a series of ten experiments designed to test a model proposed by the Professor. The model was originally proposed to explain an unpublished experimental result generated by a former graduate student.

The current graduate student wrote up her results and submitted the manuscript for publication, with the Professor as a co-author. The reviewers recommend the paper be published, but only if the original experimental data are included. The original data can be obtained from the old notebooks of the former graduate student, which are still in the laboratory.

The former student left after a year of conflict with the Professor and is currently enrolled in medical school. Both authors believe the former student would refuse to have his data used in the paper, as he would like to make things as difficult for them as possible. They decide to include the data without contacting the former student for permission.

- Was this the appropriate action on the part of the co-authors? Why or why not?



Case 2: Variations

Continuation of a Previous Student's Work

The following variations of this case can be used to discuss the issues further.

- What if the departed student refused on the grounds that he feels that his work is somehow misrepresented, perhaps selective results were omitted?
- What if two graduate students, one not affiliated with the lab but with needed expertise, write up some results from an experiment, but the Mentor/Professor refuses to give the unaffiliated student authorship?
- What if the departing student had taken his notebooks with him?



Case 1 Supplement: Teaching Materials

Teaching Points:

- Collaboration is an important part of the scientific process. Nevertheless, collaborative research can be difficult, due to the bringing together of different personalities and agendas. The University of California, San Diego lists the following as questions to be considered when working in collaboration?:
 - What are the goals of the collaboration?
 - Who are the participants?
 - What are the responsibilities of everyone involved?
 - What is the intended pace of the proposed collaboration? How long should the collaboration last?
 - What are the plans for authorship and credit?
 - What are the obligations to the private and/or public funding agencies of the research?
 - What are the conflicts of interest for each of the participants?
 - What are the plans for sharing and ownership of all products of the collaboration?
 - Under what circumstances, and how, can participants withdraw from the collaboration?
- The “data” that can be owned is broadly defined by most scientific agencies. For example, the *NIH Grants Policy Statement* reads: “. . . 'data' means recorded information, regardless of the form or media on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other research data.”
- "Ownership" of data usually refers to a particular way in which information might be controlled, such as control over access, disclosure, use, or distribution.

² <http://ethics.ucsd.edu/courses/integrity/assignments/collaboration.html>



Case 1 Supplement: Teaching Materials (continued)

Guiding Principles:

- Federal rules typically declare that the institution owns data developed under federal funding and that the federal government has non-exclusive, royalty free rights with respect to that data. Federal rules also require the institution to maintain data for a minimum of three years.
 - The institution must own all data in order to be able to acquire and protect associated intellectual property rights.
 - The evaluation and/or confirmation of research results and the analysis of allegations of scientific misconduct support ultimate institutional ownership and control of data.
 - Protection of the privacy of human subjects requires institutional control and ownership.
 - The institution may be called upon to arbitrate rights in data after a falling out among the investigators, as where a Principal Investigator refuses to allow a no-longer trusted colleague to access data for publication purposes, or where there is a dispute among investigators regarding authorship or inventorship.
- The PI is the “steward” of the data and is responsible for every aspect of the study, including decisions about access to data, even while the Institution has “ownership”. For this reason, Institutions are often highly cautious about signing any agreements with commercial or other entities that give control over data to an external party.



CASE 2 Supplement: Teaching Materials

Teaching Point:

- Learners should know they can discuss issues of authorship and use of data/animals/genes/ reagents/etc., at the time the work begins. The student can write a letter or email outlining the agreement and give a copy to the advisor or PI.

Guiding Principle:

- Collaborative authorship should be encouraged, and involves rights and responsibilities for both mentors and students. If the PI decides to use results that were produced by the former student, s/he should inform him that they will be used and invite co-authorship up until the time of publication. The departed student does not have grounds to refuse, unless he feels the data are being misrepresented in the paper.



UW BRI Cases

3. Primary Discussion Topic: Conflict of Interest

**Additional Discussion Topics: Publication/Authorship, Data Acquisition and Ownership.
Cases & Notes for Faculty Facilitators**

Conflict of Interest

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Case 1 Answers 18
Case 2 19
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Case 1 Teaching Supplements 21
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Objectives for case discussion:

1. Understand institutional rules governing financial conflict of interest
2. Understand the complexities involved in working with commercial sponsors of research and identify steps that can be taken to avoid problems these complexities can generate.
3. Understand that financial conflict of interest is one of many types of conflict of interest.
4. Become familiar with local and international statements on requirements for authorship of scientific publications.

Resources:

Grants Information Memorandum 10 of the University of Washington's Significant Financial Interest Disclosure Policy.

<http://www.washington.edu/research/gcs/gim/gim10.html>

The International Committee of Medical Journal Editors "Uniform Requirements for Manuscripts Submitted to Biomedical Journals"

<http://www.icmje.org/>

Fred Hutchinson Cancer Research Center Conflict of Interest Policy.

http://www.fhcrc.org/admin/general_counsel/conflict_interest_2002.pdf

Fred Hutchison Cancer Research Center Requirements for Authorship Policy. <http://www.fhcrc.org/admin/hr/pppm/p0912.htm#Principles>



Case 1: Conflict of Interest and Disclosure

Dr. M is a cancer researcher and is submitting a grant application seeking support for a randomized clinical trial evaluating the safety and efficacy of Newblockbusteron, a drug manufactured by Newbigpharma Inc., compared to Oldblockbusteron, a drug which is the current standard of care and is manufactured by Oldbigpharma Inc.

For each of the questions below, answer “yes” or “no” with regard to whether the financial interest must be disclosed and reviewed under the policy for your primary institution. Also consider whether or not the investigator should be prohibited from conducting the research in any of the scenarios.

1. Dr. M. gives after-dinner talks on cancer research for Newbigpharma that are completely unrelated to either Newblockbusteron or Oldblockbusteron, for which he receives \$15,000 annually.
2. Same as question 1, except that the annual income is \$2,000.
3. Same as question 1, except that the talks are for Oldbigpharma.
4. Dr. M is also engaged in outside consulting for Anotherbigpharma, Inc. which pays him over \$10,000 per year to provide strategic advice on promising directions in the field of arthritis therapy, which are unrelated to the Newblockbusteron clinical trial.
5. Dr. M's wife owns \$1,000 worth of stock in Oldbigpharma.
6. Dr. M's brother-in-law is an employee of Newbigpharma.
7. Dr. M is a co-inventor of Newblockbusteron and receives annual distributions of royalty payments for the inventions through the university.
8. The Chair of Dr. M's department has indicated that if the grant application is awarded and he publishes the results of the study, he will be promoted to full professor, receive a 20% salary increase, and be given a share of indirect costs from the study that will go into a discretionary account that Dr. M can use for professional and other university business purposes.
9. Part of the grant funds will be used to pay for Dr. M to travel to Newbigpharma headquarters located in the Great Caymans to review certain aspects of the clinical trial.
10. Same question as 9, except Newbigpharma agrees to reimburse the University for Dr. M's travel costs.



Case 1: Answers

Conflict of Interest and Disclosure

Case 1 Answers:

Disclosure requirements for policies in effect at University of Washington, Seattle WA (UW) and Fred Hutchinson Cancer Research Center (FHCRC).

Institution	Yes	No	Not Covered By Institutional Conflict of Interest Policy
UW	1,2,3,5,7	4,6,8,9,10	N/A
FHCRC	1, 2, 3, 4, 5, 7, 10 <i>(see note below)</i>	6	8, 9

Note: FHCRC researchers, as well as their spouses, domestic partners, and dependent children, must disclose for review any interest in, payments from, or relationship with for-profit companies that are engaged in business that might relate to research at FHCRC.



Case 2: Multi-Institutional Involvement

Dr. G., a newly appointed assistant professor, is pursuing research on genotypes associated with adverse reactions to a class of drugs used in the management of congestive heart failure. She has been approached by a pharmaceutical company interested in supporting her research. After a very productive conversation with a scientific representative of the company, Dr. Y, in which the general plan for the research has been agreed upon, she receives a copy of the proposed contract. The contract will provide 40% salary support for three years, as well as support for other costs of the research, including a full-time technician. Data will be reported to the company on a semi-annual basis, and Dr. Y will participate as a consultant on the project and co-author on any publications derived from the project. No work can be published without Dr. Y's concurrence.

- Are these arrangements appropriate? Why or why not?



Case 2: Variations

Multi-Institutional Involvement

- Same case as Case 2 but rather than the requiring that all publications include Dr. Y, the pharmaceutical company wants all references to its company and employees omitted from publication.
- Dr. G. has had two research projects fail. In order to advance her career she needs to obtain this grant. Her department chair has mentioned that if she were to get this grant, consideration for her tenure would be improved and she will be able to keep the indirect costs in a discretionary account



Case 1 Supplement: Teaching Materials

Teaching Suggestion:

Ask the participants to serve as the conflict of interest review board for the institution. If the group is large, you may ask them to work in smaller groups of 4-5 in this capacity. Charge them with making decisions for each of the 10 scenarios (or breaking them up between small groups). Ask the group to consider why they would make a particular ruling (as being a conflict of interest or not) beyond simply referring to the regulations. The regulations have room for interpretation on many of these points.

Note: Faculty may wish to include a review of their own institutional policies a part of this case.

Discussion Questions:

- Why do institutions have conflict of interest policies?
- Are they effective at limiting conflicts of interest?
- Why does \$10,000 seem to be the cut point for many policies? Is a moral distinction being drawn?
- What other potential conflicts of interest exist, other than financial considerations?

Teaching Points:

- The potential for conflicts of interest is a reality in the field of biomedical research.
- Conflicts of interest take a variety of forms. Current regulatory practice focuses on financial conflict of interest, but other conflicts may affect research integrity as well.
- Learners should understand what constitutes a conflict of interest. The University of Washington defines a conflict of interest as “...when there is a divergence between an individual's private interest and his/her professional obligations to the University such that an independent observer might reasonably question whether the individual's professional actions or decisions are distorted by considerations of personal gain³.”

³ <http://www.washington.edu/research/gcs/gim/gim10.html#definitions>



Case 1 Supplement: Teaching Materials (continued)

- Many institutions have review and reporting requirements outlined in policies that define financial conflicts of interest and the disclosure they require. The primary purpose of institutional review is to determine the appropriate level of action for a given financial conflict of interest. Efforts to address conflict of interest may take several forms: (1) management of conflict, e.g., by limiting an investigator's role on a project; (2) barring certain activities, e.g., barring an investigator from performing certain kinds of research when significant financial conflicts are present; and (3) disclosure, e.g., disclosing relevant financial relationships at the time of publication.
- Non-financial conflicts of interest are more difficult to identify and are less frequently and less clearly addressed by policy guidelines. They might include authorship, career advancement, or primacy of discovery. Policies about conflict of interest may differ within an institution dependent on the circumstances of the research (e.g. a clinical trial versus non-clinical research.)

Guiding Principles:

- Concern for conflicts of interest stem from the ethical responsibility of researchers to preserve the integrity of the research process and protect research subjects.
- Even if an individual does not believe that he or she is compromised by certain circumstances the possibility that a reasonable person might perceive a conflict of interest needs to be considered in determining the appropriate actions.
- If a situation suggests conflict of interest, public trust in the institution and the research enterprise may be at stake.



CASE 2 Supplement: Teaching Materials

Teaching Points:

- Learners should know that institutions have policies governing contracts with outside companies/institutions. Generally, an individual researcher cannot sign a contract with an outside company without review of the contract by the primary institution. Policies of the primary institution can serve to protect the researcher from unfavorable or restrictive contracts.
- Learners should understand that conflict of interest is generally brought about by a situation, not the behavior of individuals. Making the situation transparent to research participants, reviewers and institutional monitors can avoid compromising the research, results and reception of the data.
- The criteria for consideration of authorship according to the International Committee of Medical Journal Editors (ICMJE) Uniform Guidelines for Manuscript Submission⁴, is as follows:
 - All individuals listed as authors ought to qualify for authorship under the below listed qualifications. Likewise everyone who meets the qualifications ought to be listed as an author. The qualifications for authorship credit are based solely on meeting all three of the following criteria:
 - ◆ Substantial contributions to conception and design, or acquisition of data or analysis and interpretation of data;
 - ◆ Drafting the article or revising it critically for important intellectual content; and
 - ◆ Final approval of the version to be published.
 - Authorship is not justified solely due to the acquisition of funding, collection of data or general supervision.
- Fred Hutchison Cancer Research Center states the requirements for authorship as follows:
 - “Authorship shall not be accepted on papers or abstracts unless the investigator has had a genuine involvement in the conduct of the research. Any investigator accepting authorship formally accepts responsibility for the quality of the work being reported in the publication. All individuals who qualify as authors shall be included as such⁵.”

⁴ <http://www.icmje.org/>

⁵ <http://www.fhcrc.org/admin/hr/pppm/p0912.htm#Principles>



CASE 2 Supplement: Teaching Materials (continued)

Guiding Principles:

- Restrictions on freedom to publish results represent a threat to scientific integrity.
- Conflicts of interest (and potential conflicts of interest) ought to be disclosed and appropriately managed in the interest of preserving the integrity of scientific research. Disclosure of potential conflict of interests can help preserve public trust in science.

UW BRI Cases

4. Primary Discussion Topic: Mentor/Trainee Responsibilities

Additional Discussion Topics: Collaborative Science, Publication/Authorship, Peer Review



Mentor/Trainee Responsibilities

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Objectives for case discussion:

1. Develop an awareness of the importance of working to develop good collaborative mentor/trainee relationship.
2. Understand the roles and responsibilities that are a part of mentor-trainee relationships as well as the other relationships that are a part of collaborative science.
3. Become familiar with structures, policies and other resources that can help trainees negotiate difficult mentor-trainee situations.
4. Develop an appreciation for changing roles – current trainees will become mentors and should think about what kind of mentors they want to be.
- 5.

Resources:

A Guide to Training and Mentoring in the Intramural Research Program at NIH <http://www1.od.nih.gov/oir/sourcebook/ethic-conduct/mentor-guide.htm>

National Academy of Sciences. Advisor, Teacher, Role Model, Friend: On Being a Mentor to Students in Science and Engineering. <http://www.nap.edu/readingroom/books/mentor/>

Office of Research Integrity. Silence is not Golden: Making Collaborations Work. http://ori.dhhs.gov/html/programs/science_is_not_golden.asp



Case 1: Inappropriate Use of a Trainee's Work

You are a graduate student preparing the protocol for the research that will be the foundation of your doctoral dissertation. Your advisor, Dr. Flanders, will also serve as your PI. Throughout the process of developing the research topic and preparing the protocol he has been involved only casually. Prior to submitting your proposal for approval you ask him to review it, which he does, providing a handful of helpful comments. At a later date, you discover that Dr. Flanders wrote his own research proposal, using sections of the proposal he reviewed for you. At the time you were preparing the protocol, you understood his research to be going in a different direction from your own.

- How do you respond?
- What are your concerns?
- Does it matter if Dr. Flanders' proposal is regarding research that is merely similar to your own, rather than being virtually the same?



Case 1: Variations Inappropriate Use of a Trainee's Work

After the first version, you can offer the following variations to help the discussion participants appreciate the issues.

- The research proposal Dr. Flanders submitted was to the same funding agency you submitted it to.
- Rather than a research proposal, you are preparing an abstract for an article you hope to publish on research Dr. Flanders was involved with. He uses sections of the abstract in a presentation he gives at a convention without attributing your contribution.
- Rather than including your work in a proposal of his own, Dr. Flanders offers a copy of your research proposal to another student who came to him for help developing a research protocol of his own. Although Dr. Flanders intended the proposal only to be read as an example, the student lifted several sections of your proposal, making minor alterations, and submitted the protocol as his own research project.
- Dr. Flanders did not in any way use your research proposal for his own benefit. Rather, after you have completed the experiments and are in the process of writing up the results, Dr. Flanders suggests you ought to carry out several additional experiments. Without them, he says, your research is insufficient to serve as the basis for your dissertation.



Case 2: Collaboration

Bill, a graduate student, seeks advice about a problem with his thesis advisor from Professor John Smith, who is a member of his thesis committee. As John knows, Bill and his thesis advisor have a difficult relationship. The causes are not entirely clear, but Bill is a very independent student, and the thesis advisor is known for his monumental lack of tact in dealing with students. Nevertheless, the work done in the thesis advisor's lab is exciting and innovative, and Bill's project, in particular, has been highly successful.

Bill's question is this: He is preparing a paper reporting part of his thesis work. His good friend, Kim, who is a graduate student in a lab doing related work, has helped him a lot with the paper. She has critiqued it from the initial draft, suggested an additional control experiment that Bill considers very helpful in presenting the results, and helped Bill to draft the discussion section. Because of these contributions, Bill has offered her co-authorship. However, this offer has been rescinded by his thesis advisor, who states Kim has no claim to authorship, and, further, that he objects to her having been involved in this way, "behind his back" without his knowledge or permission. Bill feels that to deny her authorship is tantamount to plagiarism.

- He asks what he should do.



Case 2: Variations Collaboration

The following variations of this case can be used to explore the issues further.

- Early on, Bill had mentioned to his advisor that his friend Kim had suggested a technique that had been helpful in performing some difficult experiments. Without her suggestion Bill wasn't sure he would have been able to get the necessary data. His advisor had responded saying "Well, that's what science is about. We become better scientists through sharing ideas with other scientists." By this comment, Bill understood his advisor to be encouraging collaboration.
- The scenario is the same as the first variation except that Bill was unable to perform the technique Kim had suggested. Kim offered to show Bill how to do it and together the two of them completed the series of experiments. The authorship Bill wishes to extend to Kim recognizes her contribution to the production of the data as well as her methodological suggestions.
- Bill's advisor reminds Bill that Hank R. has been helpful by supplying necessary materials for the experiments, materials without which Bill would not have been able to complete his work. Hank also has some materials that Bill's advisor would like for another set of experiments a different student in his lab wants to begin. He puts Hank's name on the paper as an author despite Bill's protests that Hank has not contributed intellectually to the paper.
- English is Bill's second language and at times he has difficulty polishing his writing. Having been chastised by his advisor for the "unprofessional" writing of some early drafts he asks Kim for her help in writing this paper. The help Bill needs goes beyond copy-editing and Kim really composes the majority of the paper for Bill.



Case 1 Supplement: Teaching Materials

Teaching Points:

- Most institutions require departmental policies to be established that include policies for review of student grievances. Learners ought to familiarize themselves with these policies early on, to use such policies as a reference throughout their training, and seek guidance from appropriate departmental personnel if something is unclear or appears to be a problem.
- Learners bear part of the responsibility for making sure expectations regarding their work are clear from the outset. They also share in the responsibility for practicing good communication.
- Learners have a responsibility to address issues they believe are unjust or inappropriate. Understanding the justification a mentor may have for certain actions can help to inform learners of the broader picture.
- Mentors have a responsibility to set clear guidelines regarding the work expected. Other members of the thesis committee may also play a role in this process.

Guiding Principles:

- All members of a research team have responsibilities to ensure effective teamwork, through personal integrity, good communication and a respectful attitude toward others.
- Mentors have a special responsibility to foster the learning and professional growth of trainees.
- As part of their guarantee of research integrity, universities and research institutions have an obligation to promote productive interactions between trainees and mentors.



CASE 2 Supplement: Teaching Materials

Teaching Points:

- The structure of most labs is hierarchical. Trainees may feel powerless to address concerns related to conflict with a faculty member. It is important that learners know that there are often institutional structures in place to help them address concerns and conflict. It is important to identify what these structures are at one's institution and what kind of help they offer. In this case, it may be appropriate for Bill to ask for departmental review of decisions concerning authorship. However, the legitimate interests of the PI in the work of his lab need to be taken into account in this review.
- Learners share in the responsibility for developing collaborative relationships. In this case, the PI has a legitimate interest in knowing what research the graduate student is performing, and the nature of any collaborative work with other students. In retrospect, Bill should have informed his mentor of Kim's potential participation in the research, before it occurred.
- The PI carries responsibility for the functioning and productivity of the lab, and as a result has significant authority to make decisions about authorship. Learners are encouraged to start conversations about authorship early in the process of research, even if no potential for conflict is apparent. These conversations should continue as needed during the research process.



CASE 2 Supplement: Teaching Materials (continued)

Guiding Principles:

- Core elements of research integrity include collegiality in scientific interactions, adherence to mutual responsibilities among members of a research team, and accuracy in representing individual contributions to scientific reports.
- The criteria for consideration of authorship according to the International Committee of Medical Journal Editors (ICMJE) Uniform Guidelines for Manuscript Submission⁶, is as follows:
 - All individuals listed as authors ought to qualify for authorship under the below listed qualifications. Likewise everyone who meets the qualifications ought to be listed as an author. The qualifications for authorship credit are based solely on meeting all three of the following criteria:
 - ◆ Substantial contributions to conception and design, or acquisition of data or analysis and interpretation of data;
 - ◆ Drafting the article or revising it critically for important intellectual content; and
 - ◆ Final approval of the version to be published.
 - Authorship is not justified solely due to the acquisition of funding, collection of data or general supervision.
 - The authors of a paper ought to provide a description of what each contributor has contributed to the paper.
 - There is a recognized way to acknowledge those who have made important contributions to a paper but who do not qualify for authorship. Guidelines for acknowledgements can be found at <http://www.icmje.org/Acknowledge2>.
- Fred Hutchison Cancer Research Center, Seattle, WA, states the requirements for authorship as follows:
 - “Authorship shall not be accepted on papers or abstracts unless the investigator has had a genuine involvement in the conduct of the research. Any investigator accepting authorship formally accepts responsibility for the quality of the work being reported in the publication. All individuals who qualify as authors shall be included as such⁷.”

⁶ <http://www.icmje.org/>

⁷ <http://www.fhcrc.org/admin/hr/pppm/p0912.htm#Principles>

You are a new faculty member, at University X, which is in a different state from University Y where you recently completed a post-doctoral fellowship. Your senior faculty mentor meets with you to discuss your research work. Your mentor suggests a new series of experiments that will hopefully clear up a problem you have encountered. The new series of experiments involves surgical manipulations. However, your IACUC protocol for the project did not include any potential surgical procedures. You note that there will need to be a delay before starting the new experiments, while you submit an amended protocol. Your mentor advises says that he wouldn't want you to go through the trouble of an amended application if the technique is not going to be useful. He suggests that you first try a few experiments and, if the procedure looks like it is going to work and you will continue performing it, you can submit an amended protocol at that time.

- What do you do?
- And why?



UW BRI Cases

5. Primary Discussion Topic: Animal Subjects Research

Additional Discussion Topics: Mentor/Trainee Responsibilities Cases & Notes for Faculty Facilitators

Animal Subjects Research

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Objectives for case discussion:

1. Consider both ethical and practical considerations when working with animal subjects.
2. Appreciate the regulatory framework that exists for animal subjects in research.
3. Understand the variety of views and concerns regarding the use of animal subjects in research.
4. Understand that there is an evaluative process by which the need for animal subjects and the use of specific species is ascertained.

Resources:

Online Ethics Center. The Ethics of Using Animals in Research. (2003):
<http://www.onlineethics.org/reseth/mod/animalsres.htm>

University of California, San Diego (2003). Research Ethics Program:
Rules for Animal Subjects (includes links to key federal websites).
<http://ethics.ucsd.edu/rules/rules-animal.html>

Institutional Animal Care and Use Committee (IACUC). www.iacuc.org

University of Washington IACUC policy.
<http://www.hscer.washington.edu/iacuc/>

U.S. Government Principles for the Utilization and Care of Vertebrate
Animals Used in Testing, Research, and Training.
<http://grants1.nih.gov/grants/olaw/references/phspol.htm#U.S.%20Government%20Principles>

Auburn University. Personnel Training in Animal Care & Use (slide show).
<http://web6.duc.auburn.edu/research/vpr/animals/documents/PTUCA.pdf>



U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training⁸

The development of knowledge necessary for the improvement of the health and well-being of humans as well as other animals requires in vivo experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible Institutional Official shall ensure that these principles are adhered to:

- I. The transportation, care, and use of animals should be in accordance with the [Animal Welfare Act \(7 U.S.C. 2131 et. seq.\)](#) and other applicable Federal laws, guidelines, and policies.*
- II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.
- III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.
- IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.
- V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.
- VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

⁸ <http://grants1.nih.gov/grants/olaw/references/phspol.htm#U.S.%20Government%20Principles>



U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (continued)

- VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.
- VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.
- IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal care and use committee.



Case 1: If You Were an IACUC Committee Member

If you were on the Institutional Animal Care and Use Committee (IACUC) committee and the following proposals and protocol changes came up, what questions would you raise? What limits would you propose? What kinds of considerations would you like to see in the research design?

- a) An investigator has proposed experiments on learning and memory. In order to obtain rapid and efficient learning, she plans to use electric shock to the feet as a negative incentive. In order to test the generality of her results, the initial studies of rats will be repeated on cats and then on squirrel monkeys. Numbers of animals used: 60 rats, 12 cats, 8 monkeys. Surgical procedures: Implants of small cannulae in the hippocampus formation of the forebrain. Injections of drugs through these cannulae are used to disrupt the activity of the hippocampus. Financial support: grant from the NIH.
- b) An investigator plans a research project examining the effects of methamphetamine and related compounds – including illicit drugs – on brain activity. The study will monitor the brain activity of cats by hooking up electrodes, measuring brain activity before and after administration of the drug and finally sacrificing the animal to examine any physiological and anatomical changes in the brain tissue. The investigator notes that administering sedatives, anesthetics or analgesics to the animals has potential to alter brain chemistry and therefore the study results and therefore will not administer any such agents prior to sacrificing the animals.
- c) An investigator has been working on a research project comparing the efficacy and safety of two different types of bone implants with regard to their capacity to promote the healing of fractures. The literature regarding the implants indicates that both are nontoxic. The study has been carried out in dogs. The originally approved protocol called for assigning 20 dogs randomly to either Group 1 or Group 2 – each group being assigned to be implanted one of the two devices. After 8 weeks the dogs in both groups are to be sacrificed and the bones tested.

At 6 weeks the investigator has called the committee. Several animals in Group 2 have unexpectedly died and the cause of death is unexplained. The researcher reports that the animals appeared to be somewhat anxious and uncomfortable at the time of death. The researcher is debating between continuing the experiment in hope that some of the animals in Group 2 will survive and sacrificing all of the animals in both groups at 6 weeks.



Case 2: Amending the Protocol?

You are a new faculty member, at University X, which is in a different state from University Y where you recently completed a post-doctoral fellowship. Your senior faculty mentor meets with you to discuss your research work. Your mentor suggests a new series of experiments that will hopefully clear up a problem you have encountered. The new series of experiments involves surgical manipulations. However, your IACUC protocol for the project did not include any potential surgical procedures. You note that there will need to be a delay before starting the new experiments, while you submit an amended protocol. Your mentor advises says that he wouldn't want you to go through the trouble of an amended application if the technique is not going to be useful. He suggests that you first try a few experiments and, if the procedure looks like it is going to work and you will continue performing it, you can submit an amended protocol at that time.

- What do you do?
- And why?



Case 2 Variations: Amending the Protocol

After a discussion of the first version, you can offer the following variations to help the discussion participants appreciate the issues.

- The situation is the same, but instead of junior faculty member and senior mentor, the situation occurs between a graduate student and his/her thesis advisor.
- Rather than suggesting going forward with the surgical procedure without submitting an amended protocol, the advisor suggests finding a researcher at another institution with an IACUC more likely to approve the procedure.



Case 1 Supplement: Teaching Materials

Teaching Suggestion:

Divide the group into three smaller ones, each assigned to one of the cases. Ask the small groups to serve as an Animal Care and Use Committee, to make and justify their decision. Discuss rationale used by small groups and work to identify a policy statement. **NOTE:** Where details are sketchy in these vignettes, ask participants to focus on how their judgments change depending on the changing details. Asking the right questions is a skill of ethical sensitivity.

Teaching Points:

- IACUC's exist as a resource for scientists working with animal subjects. Though one function of IACUC's is to approve protocols and protocol changes, it can also serve to advise or provide resources to scientists when they find themselves in a difficult situation or need to talk through an issue regarding animal care.
- Research with animal subjects is based on the principle that it will contribute to finding solutions to human medical problems. It is not done for preliminary exploratory research or "fishing expeditions."
- Even when an important research question is being addressed, the decision to use animal subjects must be justified, as must the particular species of animal. Researchers may look at the anatomical suitability, similarity to human condition being modeled, the sentience and the relationship with humans of a species in making a decision as to the appropriateness of using the animal in an experiment
- Research with animal subjects is monitored by veterinarians. If in the course of an experiment there are unanticipated adverse effects for the animal subject, the protocol needs to be re-visited, to determine whether modifications to alleviate the adverse effects are needed. Changes in protocol need to be approved by the IACUC.



Case 1 Supplement: Teaching Materials (continued)

Guiding Principles:

- Research on animals requires humane care of the animals in order to produce “sound science and social benefit (*Integrity in Scientific Research*).” Humane care of animals requires researchers to:
 - Evaluate the need for animals in any particular protocol.
 - To ensure the basic needs of the animals are met prior to research
 - To weigh the benefits and likely harms for the animal and society
 - To implement procedures to minimize pain, suffering and distress of the animals.
- The scientific rationale for the use of animals in scientific research is that animal subjects provide a system which can be observed and manipulated so as to better understand the mechanisms of normal function and illness. This information provides greater understanding of living systems and can be generalized to humans and other animals.
- The ethical rationale for the use of animals in scientific research is that the information gained through the use of animal subjects can be used to develop therapies which can alleviate pain and suffering caused by illness, thus benefiting society. This supposes that the research can be done with minimal to no distress or discomfort to the animal subject. Any distress of the animal must be mitigated by the benefit it provides society.
- Both scientists and lay individuals are a part of the society which stands to benefit from information obtained through research on animal subjects and which funds the research. As members of that society, each needs to be informed about the ethical and scientific reasons for the use of animal subjects as well as the range of views and concerns about such research practices.



CASE 2 Supplement: Teaching Materials

Teaching Points:

- Trainees should understand that they may confront different standards of compliance with regulatory oversight at different institutions.
- They have a responsibility to be informed about regulatory requirements for oversight of animal research (as well as the principles informing them), and to comply even if encouraged to do otherwise.
- IACUC approval is only for procedures specified in the research protocol. Even pilot studies need IACUC review and approval.

Guiding Principles:

- Animal research requires oversight by an IACUC (Institutional Animal Care and Use Committee). The committee reviews details of the protocol and needs to be consulted regarding significant changes to the approved protocol.
- “Significant changes” of protocol is difficult for some research institutions to define. According to the University of Washington IACUC significant changes include the following:
(www.bsccer.washington.edu/iacuc/policies/signifch.html)
 - Results in increased mortality over levels that were either specified or presumed to occur when the protocol was originally reviewed.
 - Results in increased morbidity or pain.
 - Results in using a method of anesthesia or euthanasia different from that specified in the protocol.
 - Results in using a different species.
 - Results in using more animals than the number specified in the approved protocol.
 - Results in a change in the overall aims or objectives of the study.
 - Results in changing a study.
 - ◆ from not requiring surgery to one involving surgery;
 - ◆ from requiring only minor surgery to major surgery;
 - ◆ from requiring non-survival to survival surgery; or
 - ◆ from requiring a single surgical procedure to one that requires multiple surgical procedures.
 - Changes personnel performing animal use procedures.



UW BRI Cases

6. Primary Discussion Topic: Data Acquisition

Additional Discussion Topics: Publication/Authorship, Human Subjects Research, Mentor-trainee Responsibilities

Data Acquisition

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Objectives for case discussion:

5. Understand the importance of proper management and protection of data and the on-going responsibility to maintain such protection.
6. Recognize that different institutions and funding agencies have different policies regarding data ownership and use. Researchers have a responsibility to learn about these policies prior to entering into relationship with these entities.
7. Appreciate the complexities and responsibilities involved in collaborative science when an established relationship changes and the ownership of data, materials and information is called into question.
8. Recognize the importance of discussing expectations regarding mentoring, individual rights to collaborative work, and authorship.

Resources:

USDHHS HIPAA Privacy Rule Information for Researchers:
http://privacyruleandresearch.nih.gov/pr_02.asp

NIH Office of Extramural Research: Availability of Research Results
http://grants1.nih.gov/grants/policy/nihgps_2001/part_ii_a_6.htm

University of Pennsylvania RCR Resources for Data Acquisition, Management, Sharing and Ownership.
<http://www.upenn.edu/research/rcr/data.htm>

Case Western University Online Ethics Center Background on Responsible Management of Data
<http://onlineethics.org/reseth/mod/data.html#background>



Case 1: Confidentiality and Data Access

A clinical psychologist-investigator, whom you know, did a pilot study of psychiatric patients with certain characteristics. This work suggested interesting implications for your own studies, and you approached him about being a co-investigator on a new study. His role was to interview a certain population of patients and score them for certain characteristics. Your work involved analysis of biological samples taken from the research subjects. You agreed that you would be first author on any publications in your field, and he would be first author on any publications in clinical psychology.

The work was completed several years ago and you published two articles in your field with yourself as first author. Your colleague has since taken on heavy administrative responsibilities and has yet not written anything. He was only able to participate in writing one of the two articles you drafted, and so was listed as an author only on that one. You are aware that, as PI for the grant that funded the work, you have responsibility to ensure confidentiality of patient data and are concerned that your collaborator has data of a sensitive nature. Although your collaborator removed names, addresses and patient record numbers from the data, the interviews paint a detailed picture of the physical and mental conditions of each patient, details that the psychologist says he needs in writing up his own articles.

Your colleague says that he does intend to publish based on his pilot study and your joint work, but he does not know when.

- What do you do?



Case 2: Data Ownership

You are a graduate student who has been working in a lab for several years. As graduation comes around, you prepare to leave the lab for employment at another university. You ask your advisor to write a recommendation and a summary of your work in her lab. She does this and adds a list of research materials that you may not take with you, as well as a list of research areas – some not yet under investigation – and a statement that you agree not to work in these areas. Your advisor asks you to sign a copy of this document

- Does the advisor have the authority to require this statement from you?
- If you disagree with what your advisor is doing, who do you talk to?
- What materials, notes, etc do you have rights to when you leave?
- How should you go about determining your relationship with the lab you are in and the research you have been a part of once you leave?



Case 2: Variations

Data Ownership

The following variations of this case can be used to explore the issues further.

- Although leaving for a position in another university, you will continue collaboration with your current lab, expanding the research you have been doing into a multi-institutional project.
 - Does this entitle you to greater access to the records and data in your current lab?
- Rather than having a position in another university, you have a position at a commercial institution.
 - Does this change anything?
- There is some research you are interested in pursuing in your new position that has its foundation in some work that you did in your current lab. It is not an area of research your advisor is interested in pursuing and it does not appear on the list of “off-limits” research topics your advisor wants you to sign. To facilitate further work:
 - Do you take your lab notebooks with you when you leave?
 - Do you make copies of them?



Case 1 Supplement: Teaching Materials

Teaching Points:

- There are regulations pertaining to the use and management of data. A researcher in this position has *at the very least* the responsibility to ensure pertinent regulations are complied with.
- Learners should understand the responsibilities involved in protecting sensitive data and the importance of eliminating the potential for identification of individuals when a study involves human subjects.
- Learners should appreciate the need for frank conversations regarding the timely and appropriate use of data they helped to obtain and toward which they have a responsibility.
- In this case, a consultation with the IRB is appropriate, to determine which elements of the data may be maintained in the dataset retained by the colleague, and the permissible timeframe for retaining the data.

Guiding principles:

- The NIH identifies the following topics as key issues to discuss in regard to data acquisition, management, sharing and ownership⁹:
 - Accepted practices for acquiring and maintaining research data.
 - Proper methods for record keeping and electronic data collection and storage in scientific research.
 - Defining what constitutes data.
 - The importance and process of keeping data notebooks, data selection, retention, sharing, ownership and analysis.
 - Understanding how legal issues such as those regarding intellectual property and copyright laws pertain to one's data and records.
- Researchers have an obligation to honor the privacy and contribution of the individuals who participated in their research. A part of this obligation is ensuring that identifiable information is appropriately protected and that the data obtained is not used beyond the scope of the research for which it was obtained.
- Questions about appropriate use or management of data should be evaluated in context of relevant regulation and institutional policies. Institutional resources, including the IRB, can help researchers when difficult situations occur.

⁹ <http://ori.dhhs.gov/html/programs/finalpolicy.asp#core>



CASE 2 Supplement: Teaching Materials

Teaching Points:

- Learners should seek out the policies that govern their working situation. What a trainee can and cannot take with him or her upon leaving a lab varies and is usually determined by the institution or individual PI. Addressing this issue well before one's planned departure can make the transition between labs go more smoothly and preserve collaborative relationships.
- Learners should recognize that the work they performed in a lab is usually part of a larger process, often begun prior to their arrival and continued after they depart. Ownership of the data generated typically belongs to the PI or the institution receiving research funding. If a trainee has concerns about receiving proper recognition, he or she should discuss this with the PI. Likewise, if there are concerns about what a trainee will be able to take with him upon leaving these should be addressed early on.
- Learners should know they can discuss issues of authorship and use of data/animals/genes/ reagents/etc., at the time the work begins. The student can write a letter or email outlining the agreement and give a copy to the advisor or PI.

Guiding principles:

- The issue of ownership of data is complex. Providing or obtaining funding does not alone justify ownership of the data generated though it is a significant part. Therefore a PI is clearly the primary steward of data. When a study is funded by the NIH, the data itself belongs to the institution in which the research was performed¹⁰
- While the PI has a major role in deciding what work the post-doctoral trainee can take from the lab when leaving, it is reasonable to expect that the trainee will continue to work in the same field. The PI should avoid placing unreasonable restrictions on the trainee's future work.
- The scope of a project and the circumstances, equipment, etc. necessary to making it possible may be much larger and involve more people than an individual trainee realizes. Helping trainees to see some of the complexity is an important part of their training and can help to avoid difficulties regarding issues of ownership and access to materials, data and other information.

¹⁰ <http://www.life.uiuc.edu/micro/ethics/data-ownership.html>



UW BRI Cases

7. Primary Discussion Topic: Human Subjects in Research

**Additional Discussion Topics: Conflict of Interest,
Collaborative Research
Cases & Notes for Faculty Facilitators**

Human Subjects in Research

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 Case 2 Teaching Supplements 57

Objectives for case discussion:

9. Understand factors that influence participation in research (for researchers and subjects) and the potential for coercion.
10. Be aware of federal and institutional regulations governing federally funded human subjects research and the underlying ethical principles.
11. Understand the relationship between subject and investigators and the rights and duties of the relationship.
12. Be aware that there are circumstances in which a waiver of consent may be an appropriate substitution for actual consent by study participants.

Resources:

Belmont Report (1979).

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm>

U.S. Food and Drug Administration *Guidance for Institutional Review Boards and Clinical Investigators: A Guide to Informed Consent* (1998):
www.fda.gov/oc/ohrt/irbs/informedconsent.html.

University of Washington policy of informed consent:

<http://depts.washington.edu/hsd/INFO/MANUAL/99-IV.htm>

University of Washington policy on the use of waivers of consent:

<http://depts.washington.edu/hsd/INFO/MANUAL/99-IV.htm#IV-d4>

University of Washington Human Subjects Division. Statement and Policy on Conflict of Interest for Researchers.

<http://depts.washington.edu/hsd/INFO/c-of-i.htm>

University of Washington Policy on Enrollment Incentives (March 2002)

<http://depts.washington.edu/or/Policy/EnrollmentIncentive.htm>

University of Washington School of Medicine. Office of Research and Graduate Education. Ethics in Science Resources, including links to University and Federal Policies.

<http://www.washington.edu/medical/som/research/ethics.html>



Ethical Principles from the Belmont Report

(Excerpted, see link on preceding page for full text). It may be helpful to use these principles as sources of justification within the group discussion. The principles will sometimes be in conflict and will need to be interpreted given the specific context of each case, but they serve to ground the discussion in an established ethical basis for research with human subjects.

1. ***Respect for Persons.*** Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.
2. ***Beneficence.*** Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.
3. ***Justice.*** Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Possible responses include:
 - (a) to each person an equal share,
 - (b) to each person according to individual need,
 - (c) to each person according to individual effort,
 - (d) to each person according to societal contribution, and
 - (e) to each person according to merit.



Case 1: Informed Consent

You are a researcher working with a team developing a new drug that shows promise in reducing tumor loads in animals with experimental hematological malignancies. The drug has the side effect of nausea, based on data from preliminary human subject safety (Phase 1) trials. About 60% of patients experience nausea and a small percent suffer severe vomiting. Additionally, some peripheral nerve dysfunction was noted in experimental animals exposed to the drug, and in the phase 1 human subject studies about 10% of subjects reported mild tingling sensations in hands or feet. The plan is now to test the drug in patients who have failed conventional therapy for certain leukemias; the goal of the trial is to determine whether reductions in tumor load similar to those observed in experimental animals will occur. In the doses used in this trial, the drug is unlikely to change life expectancy of these terminal patients. You are charged with developing:

11. an appropriate consent form for use in this trial
12. a plan for recruitment of subjects.
 - What are the key elements you must include in order to guarantee informed consent?
 - What are your considerations regarding who you want to recruit and how you plan to recruit them?
 - If you are going to offer an incentive to participants, how will you determine whether or not the incentive is appropriate and not unintentionally coercive?



Case 1: Variations Informed Consent

The following variations in this case can be used to further explore the issues.

- What if it were a study focusing on teenagers?
- What if you wanted to include a colleague in the study, who will recruit patients from a clinic?
- Would you develop the consent form or recruitment plan differently for a study of participants in a weight loss clinic who would be receiving free care and a new obesity drug?
- Do your responses change if a certain racial or ethnic group were the subjects of study?
- What if you wanted to retain blood or tissue samples for future studies?



Case 2: Incentives and Coercion for Researchers

A biotechnology company approaches a researcher with a proposal for a Phase II drug study. The drug in question has been found to reverse obesity in animals (mice and rats) and has proved safe in humans at comparable serum levels in two small Phase I studies. The company now seeks larger populations for efficacy studies and has approached the researcher because of his previous work on risk factors for obesity among a primary care population. The biotechnology company offers 20% salary support and the assistance of a research manager. To maintain this support, the researcher will need to recruit 20 subjects per month for the first year of the study, randomize them to treatment/non-treatment and then follow them monthly for 24 months.

- Is this an appropriate arrangement for this researcher?
- Is there a conflict of interest? Why or why not?

Two months into the recruitment phase, the company notifies the researcher that it would like to speed up the study because of information about a competitor drug. It requests recruitment of 40 subjects per month, and will increase the researchers' support to 50% FTE for the duration of the recruitment process. The researcher has been recruiting subjects through a general notice to patients in a primary care plan; he thinks he can increase recruitment to the new target level if he personally recruits patients from his own primary care practice.

- Is this an appropriate arrangement for this researcher?
- Is there a conflict of interest? Why or why not?



Case 2: Variations Incentives and Coercion for Researchers

The following variations in this case can be used to explore issues further.

- Researcher receives cash for each participant recruited.
- Researcher is a key investor in the device/pharmaceutical/genetic company for which the product/drug is being researched.
- Researcher needs preliminary data in order to have a competitive grant renewal.



Case 1 Supplement: Teaching Materials

Teaching Suggestion:

Break participants into smaller groups to work on key elements of the consent form and recruitment plan. You could also discuss the first variation as a large group, then break into smaller groups to discuss each of the variations (you will have to present the variations). When you come back together as a large group you can compare notes as to plans and rationale.

Teaching Points:

- Some populations are more “vulnerable;” incentives that are appropriate in one population may be coercive in another.
- Evaluating the potential for coerciveness for any given study requires knowledge of the context in which recruitment will occur, and the population among which subjects will be sought.
- Coercion is not solely an issue of payment, e.g. offers of free care, or personal relationships, may be coercive.
- Learners should understand what the elements of informed consent for participation in clinical trials are and appreciate the importance of helping participants fully understand them. These elements include:
 - That participation in the study is fully voluntary and patients have a right to withdraw from the study at any time they wish regardless of having previously consented to participate and despite any perceived or real inconvenience to researchers.
 - What will happen during the course of the trial? This includes the procedural elements of the trial as well as foreseen side effects.
 - Although participants may have failed conventional therapies, palliative care is a viable alternative therapy to that which is being offered through the study. Helping a participant to understand what palliative care might look like in his or her circumstances is a part of informing him or her about alternative therapies.
 - A clear understanding of what the possible side effects of the experimental therapies could be.
 - An explanation of the limits of research and that although therapeutic outcomes might be achieved, the likelihood of such an outcome is very low.



Case 1 Supplement: Teaching Materials (continued)

Guiding Principles:

- Any payment to subjects needs to be justified carefully, in terms of the burdens and costs the study imposes for participants.
- In addition to payment, it is important to consider how the offer to participate is made, and in particular, how voluntariness of participation is emphasized.
- Researchers are required to obtain informed consent in order to ensure the understanding and safety of research subjects. The requirement of informed consent also acknowledges the rights and dignity of human subjects by recognizing research subjects cannot make independent decisions regarding their participation in a study unless they are fully informed.



CASE 2 Supplement: Teaching Materials

Teaching Points:

- Transition from acceptable incentive to coercion is dependent on context. Incentives always carry the potential for coercion.
- Enrolling one's own patients is a particularly problematic recruitment strategy. Patients may be motivated to please the doctor, or may not understand their right to refuse participation, or may fear their health care may suffer if they refuse. It may be appropriate to exclude the patient's physician from the recruitment process, taking into account study risks and other contextual features.

Guiding Principles:

- Incentives to investigators can create conflicts of interest.
- Careful scrutiny should be applied to any study in which a health care provider enrolls his/her own patients



UW BRI Cases

8. Primary Discussion Topic: Peer Review

Additional Discussion Topics: Mentor/Trainee Responsibilities, Data Acquisition, Research Misconduct, Conflict of Interest

Peer Review

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Objectives for case discussion:

13. Recognize that identifying where and when one gets an idea can be difficult. Researchers need to be conscientious about attribution and respect the confidentiality of privileged information.
14. Understand appropriate and inappropriate use of information obtained through the peer review process.
15. Recognize pressures that may provide disincentives for acting responsibly.
16. Acknowledge that many non-financial conflicts of interest can occur and may be more difficult to recognize and manage than financial conflicts.

Resources:

NIH Office of Extramural Research Peer Review Policy:
<http://grants1.nih.gov/grants/peer/peer.htm>

NIH Center for Scientific Review. Policy, Procedure, and Review Guidelines. <http://www.csr.nih.gov/review/policy.asp>

University of Washington Attorney General Office (2002)
http://depts.washington.edu/ventures/resources/scvpres/autm_02_data_rights.pdf



Case 1: A Problematic Site Visit

Frank R. is a post-doc working in Dr. K's lab. After Dr. K participates in a site visit to another lab, she comments to Frank "You'll need to stay on top of things and get your work done so you don't get scooped!"

Frank infers that the other lab is working in the same area he is. Over the next few days Frank feels growing concern about the situation. He is concerned not only that the other lab might scoop him, but that when he and Dr. K write up their work, they might be open to the allegations that they stole the idea for the experiments from the lab Dr. K. visited.

- What should Frank do?



Case 1: Variations A Problematic Site Visit

After the first version, you can offer the following variations to help the discussion participants appreciate the issues.

- Same case as above only Frank learns about other lab doing the same research concurrently from a friend who was at a local presentation given by the other lab.
- Dr. K mentions the name of the lead investigator at the lab she visited. This person is someone with whom Frank worked closely in graduate school and with whom Frank shared some of his ideas for the experiments in question. Frank believes that this person has appropriated his ideas.



Case 2: Peer Review of a Scientific Publication

You are a graduate student in Dr. Luke's lab. Dr. Luke has been asked to review an article for a journal. She asks you to read it and to prepare a 1-page critique of the article. You read it and prepare the page of comments. When you submit the comments to Dr. Luke, the two of you have an hour-long meeting discussing the article and your critiques of it in detail. When the review comes out, you notice that Dr. Luke has used your written and verbal comments extensively as the basis of the review.

- Was this inappropriate?



Case 2: Variations

Peer Review of a Scientific Publication

The following variations can be used to further explore the issues.

- You were impressed with the article you read and excited about having had the opportunity to help review it. Thinking that the article could be of interest later on, you keep a copy of the manuscript in your files.
- After reviewing the manuscript you have lunch with one of your friends. During the conversation you realize that the work your friend is interested in is very similar to the work proposed in the manuscript you just reviewed. Without giving any details, you suggest your friend contact the researcher who wrote the manuscript you just reviewed and you provide your friend with his name and contact information.
- The material reviewed is a grant application rather than a manuscript. A few years later another student in Dr. Luke's lab proposes a series of experiments that seem familiar to her. Going back through her files she realizes that the experiments are very similar to those proposed in the grant the first grad student reviewed. Talking to the second student Dr. Luke finds out that the student got the idea from the first student who had not identified that the source of the ideas was the grant proposal.



Case 1 Supplement: Teaching Materials

Teaching Points:

- Learners should recognize that the discovery of ideas often happens concurrently and that overlapping research will likely occur.
- In some situations, as in this case, an appearance of scientific misconduct could occur as a result of participating in a peer review process. For this reason, it is important to make one's interests and undertakings transparent when potential conflicts arise.
- Learners should understand that there are guidelines to determine appropriate conduct as a member of a study section or site visit team. The NIH has outlined guidelines for peer reviewers¹¹:
 - The Scientific Review Administrator (SRA) and the Chair of the study section work together to lead the peer-review process and are valuable sources of information when you have questions.
 - **Conflict of Interest:** The SRA will identify conflicts of interest involving you and any application. Your assistance is necessary. Consider the following as potential conflicts: investigators are listed with whom you have a financial and/or professional relationship; the funding decision on any application would benefit you directly; you feel there may be a perception of conflict. Notify the SRA in such cases. The SRA will make the final determination. Supplying a reagent or service that is available to anyone in the scientific community does not, by itself, constitute a conflict of interest.
 - **Confidentiality:** The applications are to be considered confidential and it is important to respect the privacy of the investigators' ideas. If consultation with an expert is appropriate, contact the SRA who can recruit an outside opinion and secure a signed conflict of interest form.
 - **Scientific Misconduct:** It is vital that you not make allegations of potential misconduct at the study section meeting or in the critique. Such concerns must be brought to the attention of the SRA in a confidential manner, preferably before the study section meets.

¹¹ <http://www.csr.nih.gov/Guidelines/revguide.htm>



Case 1 Supplement: Teaching Materials (continued)

Teaching Points (cont'd):

- In this case, Frank may have misinterpreted Dr. K's comment, which may have had nothing to do with the site visit. However, it is appropriate for him to discuss his concerns with Dr. K. If the lab at which the site visit occurred is in fact pursuing the same work that Frank is doing, it may be appropriate for Dr. K to discuss this overlap with the SRA or chair of the site visit team, and potentially arrange for the PI of the lab to be notified of the parallel work. It is also important to note that Dr. K should not have discussed any information concerning the site visit with Frank.

Guiding principle:

- Peer review contributes to the integrity and quality of scientific research, but creates the potential for conflicts of interest and/or misuse of information. Researchers need to take great care in undertaking this responsibility



CASE 2 Supplement: Teaching Materials

Teaching Points:

- Learners should understand the peer-review process, including the obligation of peer reviewers to maintain confidentiality and respect the intellectual property of the investigator and understand the processes by which apparent instances of inappropriate conduct can be addressed.
- Learning first hand about the peer review process is an excellent opportunity for a trainee. However it ought to be recognized as a learning experience, requiring mentors to explore the issues of confidentiality, appropriate use and elements of the review process with trainees, so as to avoid inappropriate use of the information. Most journals require the reviewer to notify the journal prior to sharing the review with any other colleague.
- In this case, the student should not have been offered the opportunity to participate in the review process without the concurrence of the journal, and should have been instructed in his or her obligation to respect the confidentiality of the material reviewed, including the usual requirement to return or destroy the material.

Guiding principle:

- Peer review contributes to the integrity and quality of scientific research, but creates the potential for conflicts of interest and/or misuse of information. Researchers need to take great care in undertaking this responsibility.
- Manuscript and grant proposal reviews are inappropriate sources from which to develop one's own research ideas.

UW BRI Cases

9. Primary Discussion Topic: Publication Practices and Responsible Authorship

Additional Discussion Topics: Mentor/Trainee Responsibilities, Collaborative Research, Research Misconduct Cases & Notes for Faculty Facilitators



Publication Practices

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Case 2 Teaching Supplements	73

Objectives for case discussion:

4. Understand the complexities involved in working in collaboration with others and identify steps that can be taken to avoid problems these complexities can generate.
5. Realize that there are local and international statements on requirements for authorship of scientific publications.
6. Discuss the responsibilities to colleagues, the scientific community and society generally that publication and authorship carry.
7. Discuss the variety of issues that come up regarding publication and potential ways for navigating them. Identify resources that may be able to help trainees through the process of publication.

Resources:

The International Committee of Medical Journal Editors “Uniform Requirements for Manuscripts Submitted to Biomedical Journals”
<http://www.icmje.org/>

American Physical Society Ethics and Values Statements on Guidelines for Professional Conduct. <http://www.aps.org/statements/02.2.html>

University of Washington Copyright Connection
<http://depts.washington.edu/uwcopy/create/ownershipfactors/1.shtml>

American Psychologist “Reflections on Determining Authorship Credit and Authorship Order on Faculty–Student Collaborations”
<http://www.apa.org/journals/amp/kurdek.html>

Fred Hutchison Cancer Research Center Requirements for Authorship Policy <http://www.fhcr.org/admin/hr/pppm/p0912.htm#Principles>



Case 1: Who is an Author?

You are a part of a lab that has just concluded research on the efficacy of a new drug treatment for childhood asthma. At the next lab meeting you are to discuss authorship for the resulting publication. Please **consider the appropriateness** of each of the the individuals listed below in the authorship listing; where in the listing each might be; and what the responsibilities resulting from inclusion as an author might be:

- a) The lab manager who has contributed to the research by offering a few suggestions from time to time but who has not been a part of the research process other than in his role of maintaining the laboratory.
- b) A representative from the drug manufacturer. She has offered substantial contributions. (Consider this individual under two circumstance: (1) the drug manufacturer is requiring her to be listed as an author (2) the drug manufacturer is requiring there to be no mention of the company in any publication.)
- c) A post-doc who is no longer a part of the lab but who had facilitated the partnership between the lab and the drug company, written much of the protocol and obtained significant funding for the project.
- d) You and several other graduate students who did the majority of the work and analysis.
- e) Another graduate student who was assigned a portion of the work. His portion did not yield any results that could be included in the publication but was instructive to the work the rest of you were doing.
- f) The lab technician who brought up several key points from some literature she had been reading on related work.
- g) The biostatistician who has helped the lab with the finer points of various analyses.
- h) The PI who has been rather “hands off” on this project.
- i) A post-doc who joined the lab about a year ago, has made some contributions to the research project and who has a lot of pressure to publish something soon.

With your decisions in mind, draft a policy (or suggest elements for a policy) on authorship that would be used by your lab in the future (either now, or when you are PI).



Case 2: Data Clean Up and Publication Delay

You are a senior graduate student in Dr. Matthews' lab. You have recently completed a series of experiments of primarily your own design characterizing the receptor for a new class of hormones. Part of the work you have done has been to study the binding characteristics and hormonal responses in tissue culture and in vitro, utilizing gels to character the molecular weights of receptor variants. You are now ready to prepare an abstract for an upcoming meeting and a paper for publication based on the work you have done. The abstract is due in one week.

While examining the accumulated data you notice that a number of cell culture plates failed to respond to the hormonal stimulus and that there was considerable variability in the dose-response relationship. Additionally, several of the gels are not as clear as you would like although they do demonstrate molecular weight, agonist binding and subunit characteristics of the receptor. Despite these issues, you're very confident that your results are correct and that your research is ready to be presented. Nevertheless, you hesitate.

Dr. Matthews is out of the lab and unavailable for consultation until after the deadline. You wonder if you should omit some of the data points and clean up the negatives for the gels, repeat some of the experiments (delaying publication and possibly missing the meeting) or go ahead with the data as is.

- What are the arguments for each of these courses of action (or any other course of action)?
- Why would you go ahead with or refrain from any particular option?
- What is the most appropriate course of action?



Case 2 Variations: Data Clean Up and Publication Delay

The following variations of this case can be used to further explore the issues.

- You talk to a post-doc who is in the same lab, familiar with the work you have been doing and has offered helpful suggestions in the past. She tells you that as long as you're confident with your results you can "clean up" the data for a more aesthetically pleasing publication. Doing so will probably positively impact how your work is received and is something that "every other research out there does, all the time."
- Same case as Case 2 except that your data is publishable only in a second or third tier journal. Dr. Matthews believes with a few additional experiments your paper could make publication in a first tier journal. She asks you to hold off on publication until those experiments are completed.
- Dr. Matthews has asked you to hold off publishing your paper until the additional experiments are completed however you have finished your degree and will be leaving the lab prior to those experiments being done. Dr. Matthews tells you that Sally, another student in the lab will take over your work. You have concerns that after you leave, the experiments could be indefinitely protracted, leaving the possibility that you will either "get scooped" or that your work will become background to the subsequent experiments Sally will do and that you will lose your place as first author. As a recent graduate, you also have an interest in having a paper with your name on it published sooner rather than later.
- Dr. Matthews contacts you with the paper she intends to publish based on both your and Sally's research. Reading the paper you are concerned about the integrity of the research and analysis and you disagree with the conclusion the paper has drawn. Because of these concerns, you are not sure you want to be included as an author on this paper.



Case 1 Supplement: Teaching Materials

Teaching Suggestion:

We suggest breaking the participants into groups of 3-4 depending on group size to work through the first part of this case. You can assign 2-3 scenarios per group. Once the groups have made their determinations, you can re-group as a whole and discuss decisions made, then work on defining the elements of a good research team policy based on the sub-group decisions.

Teaching Points:

- Learners should be aware that there are differences in the way that authorship decisions are made. Although many journals and institutions are trying to create unified guidelines by which to identify authors and their contributions to the paper, there is some leeway for the individual (usually the PI) who is making the final decision.
- There are responsibilities that accompany authorship. These responsibilities include being knowledgeable of about the content of what the paper and able to verify that the paper accurately represents the work that was done. When a paper has multiple authors, individuals have a responsibility to make sure the work they have contributed is accurate and verifiable.
- In some cases, co-authors may not share responsibility for the accuracy of the entire paper. However they are responsible for the material they have contributed and should be able to affirm that to their knowledge the paper does not contain any misrepresentations of the research.
- Authorship is a form of currency within the scientific community. As such it can be abused. Misrepresenting an individual's work either by exclusion or improper inclusion on an author list ought to be avoided. Learners who find themselves in an authorship situation that they feel is not an accurate reflection of the research project have a responsibility to bring this to the attention of appropriate individuals. Although there is an imbalance in power between trainees and faculty that may make such discussions difficult, trainees should make such the attempt, utilizing committees or advising processes available for such purposes.
- For some contributions, other methods to acknowledge an individual's contribution may be more appropriate than authorship, for example, in an acknowledgements section.



Case 1 Supplement: Teaching Materials (continued)

Guiding Principles:

The criteria for consideration of authorship according to the International Committee of Medical Journal Editors (ICMJE) Uniform Guidelines for Manuscript Submission¹², is as follows:

- All individuals listed as authors ought to qualify for authorship under the below listed qualifications. Likewise everyone who meets the qualifications ought to be listed as an author. The qualifications for authorship credit are based solely on meeting all three of the following criteria:
 - Substantial contributions to conception and design, or acquisition of data or analysis and interpretation of data;
 - Drafting the article or revising it critically for important intellectual content; and
 - Final approval of the version to be published.
- Authorship is not justified solely due to the acquisition of funding, collection of data or general supervision.
- The authors of a paper ought to provide a description of what each contributor has contributed to the paper.
- There is a recognized way to acknowledge those who have made important contributions to a paper but who do not qualify for authorship. Guidelines for acknowledgements can be found at <http://www.icmje.org/Acknowledge2>.

Fred Hutchison Cancer Research Center, Seattle, WA, states the requirements for authorship as follows:

- “Authorship shall not be accepted on papers or abstracts unless the investigator has had a genuine involvement in the conduct of the research. Any investigator accepting authorship formally accepts responsibility for the quality of the work being reported in the publication. All individuals who qualify as authors shall be included as such.”¹³

¹² <http://www.icmje.org/>

¹³ <http://www.fhcrc.org/admin/hr/pppm/p0912.htm#Principles>



Case 1 Supplement: Teaching Materials (continued)

Although all collaborators on a research project have a responsibility to ensure it is accurately reported, the levels of responsibility may be different for different contributors. The American Physical Society has illustrated different levels of responsibility co-authors may have in the following way¹⁴:

- “All collaborators share some degree of responsibility for any paper they coauthor.”
- “Some coauthors have responsibility for the entire paper as an accurate, verifiable, report of the research. These include, for example, coauthors who are accountable for the integrity of the critical data reported in the paper, carry out the analysis, write the manuscript, present major findings at conferences or provide scientific leadership for junior colleagues.”
- Some coauthors may have more limited responsibilities. “Coauthors who make specific, limited contributions to a paper are responsible for them, but may have only limited responsibility for other results. While not all coauthors may be familiar with all aspects of the research present in their paper, all collaborations should have in place an appropriate process for reviewing and ensuring the accuracy and validity of the reported results, and all coauthors should be aware of this process.”
- Regarding reviewing the manuscript, “every coauthor should have the opportunity to review the manuscript before its submission. All coauthors have an obligation to provide prompt retractions or corrections of errors in published works.”
- Additionally, “any individual unwilling or unable to accept appropriate responsibility for a paper should not be a coauthor.”

¹⁴ http://www.aps.org/statements/02.2.html#supplementary_guidelines1



CASE 2 Supplement: Teaching Materials

Teaching Points:

- It is the responsibility of the individual publishing a paper to make sure the information published is a fair representation of the research that was done. There are plenty of ways to clean up data or images, some of which are within the scope of what is acceptable and some of which are not. Learners ought to determine those which might obscure or misrepresent ones research and those which present and accurate yet clarified account.
- Different individuals involved with a research project and/or publication can have different goals, or different methods for achieving similar goals, either of which can cause misunderstandings and difficulties within the collaborative relationship. Discussion in the developmental stages of the project can clarify goals, identify potential issues and create solutions. Although this kind of discussion may be ideal, it does not always happen. Learners should recognize that there may be conflicts during the process of bringing a paper to publication and try to resolve them cooperatively.
- While there are limits to what an individual can do to resolve conflicts, it is the responsibility of every individual to attempt collaborative solutions. The power differential between a trainee and a PI should be recognized as a potential source of difficulty when faced an authorship conflict. A PI has experience and perspectives that trainees have not yet developed but may not always propose the best solution. If a trainee has concerns about a decision made by his or her PI, he or she ought to seek to understand what is informing the decision before considering whether to seek additional help.
- The scientific process of reproducibility will identify mistakes, fabrication or falsification of data or analysis over time. However this process alone should not be relied upon to identify research misconduct or irresponsible publication. It is the responsibility of the individuals involved in the research to present accurate, timely and appropriate information to the scientific community.



Case 2 Supplement: Teaching Materials (continued)

Guiding Principles:

- Although publication of one's research results represents the culmination of a particular body of work it is also the point at which the larger scientific community can assess that work and apply it to further research. As such, it is important that researchers contribute honestly and carefully to this larger collaborative research relationship. It is important that other influential motivations – making a name for oneself, promotions, and similar gains – do not compromise the integrity of the research or researcher.
- Mentors are instrumental in establishing responsible publication practices in trainees. Senior researcher ought to be aware of their actions and how they might influence more junior researchers. Nevertheless, trainees have a responsibility to question practices that seem irresponsible or contradictory to the goal of furthering scientific advancement.
- It is generally impossible to include every facet of a research project in the culminating paper. Trainees must learn what ought to be included and that which can be omitted. Eastern Michigan University identifies the following three “likely self-evident” standards for publication¹⁵:
 - “Published data should accurately represent the data collected during the research.
 - Data should not be excluded from a publication for the sole reason that they do not agree with a particular model.
 - Techniques used to analyze data should be compatible with the techniques used to collect the data and should not be selected because they skew the results in favor of a particular model.”

¹⁵ http://www.rcr.emich.edu/module6/f5_1_data.html



UW BRI Cases

10. Primary Discussion Topic: Research Misconduct

Additional Discussion Topics: Publication Practices and Responsible Authorship, Mentor/Trainee Responsibilities Cases & Notes for Faculty Facilitators

Research Misconduct

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Objectives for case discussion:

17. Understand what constitutes research misconduct.
18. Develop strategies for avoiding and addressing possible instances of plagiarism or fabrication and falsification of data.
19. Identify the responsibilities researchers have when presenting research findings.
20. Realize that there can be difficulty determining whether research misconduct has occurred.

Resources:

National Science Foundation Misconduct In Science And Engineering: Final Rule http://ogsr.ucsd.edu/ethics/policy/nsf_policy.htm

University of California, San Diego Course on Scientific Integrity <http://ethics.ucsd.edu/courses/integrity/assignments/misconduct.html#intro-what-is>

University of Indiana. *Plagiarism: What it is and How to Avoid and Recognize it.* www.indiana.edu/~wts/wts/plagiarism.html

University of Washington *Procedural Guidelines Addressing Allegations of Scientific and Scholarly Misconduct.* <http://www.washington.edu/faculty/facsenate/handbook/04-09-01.html>

Office of Research Integrity. *Federal Policy on Research Misconduct* http://ori.dhhs.gov/html/policies/fed_research_misconduct.asp

American Physical Society: Guidelines for Professional Conduct <http://www.aps.org/statements/02.2.html>

International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals (Updated October 2001): <http://www.icmje.org/>



Case 1: Expedience, Misrepresentation, or Falsification

Dr. Leyos is a senior scientist in an internationally respected cancer research institute. His research group has recently been studying the regulation of a novel gene that may be a primary factor in allowing tumors to metastasize. Three pilot (preliminary) experiments have shown positive results consistent with the hypothesized role, but none of these studies are publishable. In the first case, investigators were not blinded to the origins of the samples for data collection and analyses. In a second case, adequate controls were not included and in the third case, the freezer thawed resulting in some sample degradation. However, despite these limitations, all three pilot experiments were consistent with a hypothesis. Based on these results, a definitive experiment was designed and carried out. Because of long incubation periods and assay times, the experiment required six months to complete. Because demonstration of the effect required pooling of 20 mice for each data point, the experiment was extremely costly both in lives of animals and dollars spent.

On completion of the final assays, Dr. Leyos learned that labels fell off of two samples, one for a control group and the other from an experimental group. If the two samples are omitted from the analysis, the results just miss reaching the accepted level of statistical significance ($P < 0.05$). If the samples are assigned to control and experimental groups one way, the final analysis is also not statistically significant. However, if the samples are reversed, then the results are highly significant and consistent with the previous three experiments. Dr. Leyos is trying to decide among the following courses of action:

- j) Repeat the experiment (at a cost of approximately 6 months, 300 animals, and \$40,000)
 - k) Attempt to publish the findings without the questionable results (i.e. not quite statistically significant).
 - l) Assign the two samples to their likely groups and publish the statistically significant and convincing results.
- Which of these actions (a-c), if any, should Dr. Leyos take and why?
 - Which, if any, of these actions constitute data falsification and/or research misconduct?
 - Are there other courses of action available to Dr. Leyos?



Case 1: Variations

Expedience, Misrepresentation, or Falsification

The following variations of this case can be used to further explore the issues.

- You are a junior researcher in Dr. Leyos's lab and have done a significant amount of work on this particular project. You have been very excited about having your name listed prominently on the paper explaining the results of the research. Dr. Leyos has decided to publish the results without repeating the experiment or making mention in the paper of the labeling problem.
 - What do you do?
 - What are your concerns?
 - Do you have a responsibility to the journal or anyone else to make mention of the labeling mishap?
- Again, you are a junior researcher in Dr. Leyos's lab. You discover that another, more senior researcher in the lab, with whom Dr. Leyos is good friends and with whom he has published several papers, has been manipulating data in order to create greater significance in the statistical analysis of some of the experiments. You know that Dr. Leyos is planning on co-authoring a paper with this person and feel fairly sure Dr. Leyos does not know about the data manipulation.
 - What action might you take?
 - What do you need to consider before taking any course of action?



Case 2: Unintended Support by Way of Plagiarism

A senate committee has published a report in support of a controversial public health education policy. Upon publication, two individuals came forward indicating that documents they had previously written had been plagiarized in the writing of the report. One document is a student's recently published thesis, the others are articles written by a journalist. Substantial sections of the thesis were put into the report, including typing and grammatical errors. Additionally, both original authors have made allegations that figures they used have been altered.

The original authors take a different stance regarding the policy than the senate committee. The journalist has expressed his discomfort and concern regarding his work being used to encourage a policy he does not support.

- Is this an example of plagiarism?
- What limitations are there, or should there be, on the use of the work of other authors in one's own work?



Case 2: Variations

Unintended Support by Way of Plagiarism

The following variations in this case can be used to further explore the issues.

- Suppose the report was properly referenced. Do the authors have a legitimate claim that their work was misused?



Case 1 Supplement: Teaching Materials

Teaching Points:

- Learners should take into account that most researchers do not intend to fabricate or falsify data. Those who are found to have committed a form of research misconduct have often done so without meaning to. Technology that allows for “clean up” of images, etc. adds further difficulties in determining how far or how much is too much clean-up. While this does not absolve researchers who do engage in research misconduct it should increase learners awareness that such misconduct is not always intended and that they should take precautions so as not to inadvertently misrepresent their own research.
- Researchers should not rely solely on the reproducibility of results as the means of deterring research misconduct. Appropriate mentorship plays a role in what trainees learn to consider suitable action. Both formal mentorship by official advisors and by more informal mentorship or observation of senior students, contributes greatly to the research practices of junior researchers. These individuals have a responsibility to conduct research responsibly thus setting an example for learners.

Guiding principles:

- ✓ The Federal definition of research misconduct is currently under review and revision (see http://ori.dhhs.gov/html/policies/fed_research_misconduct.asp for an update). An example of widely accepted definitions is:
 - “Fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the research community for proposing, conducting, or reporting research. Included is retaliation of any kind against a person who reported or provided information about suspected or alleged misconduct and who has not acted in bad faith. It does not include honest error or honest differences in interpretations or judgments of data (*Indiana University*).”
- By Federal law researchers must keep all relevant data (data which supports and verifies the findings of the research) for at least three years. Researchers must also keep records of how their work is proceeding with “sufficient detail” that their work can be accurately repeated at some point in the future.



Case 1 Supplement: Teaching Materials (continued)

- David Resnik in *The Ethics of Science* (1998) identifies twelve ethical principles associated with scientific research.¹⁶ Among these are:
 - **Honesty:** Scientists "should be objective, unbiased, and truthful in all aspects of the research process."
 - **Carefulness:** Scientists "should minimize experimental, methodological, and human errors and avoid self-deception, bias, and conflicts of interest."
 - **Credit:** "Credit should be given where credit is due but not where it is not due."

¹⁶ Summarized on the Eastern Michigan University website: http://www.rcr.emich.edu/module5/e4_respon_conduct.html



CASE 2 Supplement: Teaching Materials

Teaching Suggestion:

Encourage the participants to take a stand on this case and to justify their position. Discuss what steps a trainee can take if he/she suspects plagiarism of his/her own work

Teaching Points:

- If this situation were to occur in a medical journal, a legitimate claim of plagiarism could be made.
- It is the responsibility of researchers to make sure the information they present is a fair representation of the research they did. There are many ways to clean up data or images, some of which are within the scope of what is acceptable and some of which are not. Learners ought to determine those which might obscure or misrepresent ones research and those which present and accurate yet clarified account.
- The scientific process of reproducibility will identify mistakes, fabrication or falsification of data or analysis. However this process alone should not be relied upon to identify research misconduct or irresponsible publication. It is the responsibility of the individuals involved in the research to present accurate, timely and appropriate information to the scientific community.

Guiding principles:

- Plagiarism is the copying of ideas, images, concepts or text without proper citation and/or paraphrasing. An individual who commits plagiarism takes that which belongs to someone else and presents it as his own. This is akin to theft.
- In addition to attribution, authors should be cited in ways that do not distort their views or conclusions and which do not indicate endorsement of a view they do not hold. However data can be cited to argue against an author's original point.



UW BRI Cases

a. General Web Resources

1. Institute of Medicine National Research Council. *Integrity in Scientific Research* (2002): The National Academies Press, Washington, D.C. <http://www.nap.edu/books/0309084792/html/>
2. International Committee of Medical Journal Editors. *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*. <http://www.icmje.org/>
3. National Academy of Sciences. *On Being a Scientist: Responsible Conduct of Research*. (1995): <http://www.nap.edu/readingroom/books/obas/>
4. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Belmont Report, 1979). <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm>
5. National Institutes of Health. *Grants Policy Statement* (2001). http://grants1.nih.gov/grants/policy/nihgps_2001/nihgps_2001.pdf
6. Office of Research Integrity. *Responsible Conduct of Research Instructional Resources* <http://ori.dhhs.gov/html/programs/instructresource.asp>

ADDITIONAL WEB-BASED RCR PROGRAMS:

1. Case Western Reserve University. *Online Ethics Center for Engineering and Science*. www.onlineethics.org
2. Eastern Michigan State University. *Responsible Conduct in Research Instruction* <http://www.rcr.emich.edu/index.html>
3. *Ethical Dilemmas in Research Integrity*. <http://radio.weblogs.com/0116640/>
4. University of California, San Diego. Scientific Integrity: An Online Course in Responsible Conduct of Research. <http://ethics.ucsd.edu/courses/integrity/about.html>
5. Vanderbilt University. Responsible Conduct of Research and Certification Program. http://bret.mc.vanderbilt.edu/rcr/asp_files/RCR_course.asp



UW BRI Cases

b. Appendix: Case Sources and Credits

In developing this resource, we frequently began with cases from existing Responsible Conduct of Research educational materials to elicit discussion within focus groups. Focus group participants suggested variations and modifications that often improved the realism or raised complexities in the case. Other cases were contributed by members of our research team. To assure appropriate attribution, we provide a listing of the original case sources below.

1. Faculty Guide

PLANNING A RESEARCH STUDY

2. Collaborative Science

Case 1. Multi-Site Research Collaboration

Original case

Case 2. Continuation of a Previous Students Work

Original case

3. Conflict of Interest

Case 1. Conflict of Interest and Disclosure

Submitted by Michael Corn, Director of Regulatory Guidance, University of Washington

Case 2. Multi-Institutional Involvement

Original case

4. Mentor Trainee Responsibilities

Case 1. Inappropriate Use of a Trainee's Work?

Case based on *Advisor's Ownership of Mentored Work*.

<http://radio.weblogs.com/0116640/stories/2002/12/02/advisorsOwnershipOfMentoredWork.html>

Case 2. Collaboration

Original case



UW BRI Cases

b. Appendix: Case Sources and Credits (continued)

IMPLEMENTING A RESEARCH STUDY

5. Animal Subjects Research

Case 1. If You Were an LACUC Committee Member

Scenario a written by Gerald Schneider,

<http://www.onlineethics.org/>

Scenario b, “*A Question of Sacrifice*” <http://www.onlineethics.org/>

Scenario c, “*Unexpected Adverse Events*”

<http://www.onlineethics.org/>

Case 2. Amending the Protocol?

Adapted from a case by Francis L. Macrina, *Scientific Integrity: An Introductory Text with Cases*, First Edition (American Society for Microbiology, 1995), p. 128.

6. Data Acquisition, Management, Sharing and Ownership

Case 1. Confidentiality and Data Access

Case by Caroline Whitbeck, www.onlineethics.org

Case 2. Data Ownership

Case adapted from “*Rights to Mentored Research Concepts and Results,*”

<http://radio.weblogs.com/0116640/stories/2002/12/02/rightsToMentoredResearchConceptsAndResults.html>.

7. Human Subjects Research

Case 1. Informed Consent

Original case

Case 2. Incentives and Coercion for Researchers

Original case



UW BRI Cases

Appendix: Case Sources and Credits (continued)

REPORTING RESEARCH RESULTS

8. Peer Review

Case 1. A Problematic Site Visit

Original case

Case 2. Peer Review of a Scientific Publication

Case adapted from “Confidentiality of Material Being Reviewed,”

<http://radio.weblogs.com/0116640/stories/2002/12/07/confidentialityOfMaterialBeingReviewed.html>

9. Publication Practices and Responsible Authorship

Case 1. Who is an Author?

Original case

Case 2. Data Clean Up and Publication Delay

Based on the following cases found on

www.onlineethics.com: *Data Clean Up, Withholding or Misrepresentation of Data, Who is Where on the Author List?*

10. Research Misconduct

Case 1. Expedience, Misrepresentation, or Falsification

Case by Michael Kalichman,

<http://rcr.ucsd.edu/tools/cases/ucsd7.htm>©2000 The

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<http://rcr.ucsd.edu>

Case 2. Unintended Support by Way of Plagiarism

Originally the Tony Blair Iraq Dossier news paper article.

(www.mirrorco.uk/news/allnews 8 February 2003) changes made through meetings.