The American Occupational Therapy Foundation & American Occupational Therapy Association’s

Promoting Integrity in the Next Generation of Researchers: A Curriculum for Responsible Conduct of Research in Occupational Therapy

Part 1

2005
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Promoting Integrity in the Next Generation of Researchers

BACKGROUND AND USE OF THE CURRICULUM

What is responsible conduct of research?
Responsible conduct of research (RCR) is the goal of a broad effort to promote integrity in the design, conduct, management, dissemination, and review of research. The federal Office of Research Integrity, in collaboration with the American Association of Medical Colleges (AAMC), funded this curriculum to provide information about RCR to current and future occupational therapy researchers. As a secondary benefit, the curriculum may spur conversation among faculty, encouraging a broader culture of responsible research.

Why should occupational therapy instructors teach RCR?
At its best, research involves a “highly skilled, meticulous, and dispassionate search for the truth in an atmosphere of scrupulous honesty” (Korenman & Shipp, 1994, p. 1). Each occupational therapy curriculum requires that its students learn and apply rigorous scientific research skills. This RCR curriculum, like most, assumes that those skills are in place or under development, and focuses on developing students’ sense of research responsibility and knowledge of strategies to prevent or address ethical research issues. Many funders require that researchers have RCR training.

There are undoubtedly cases of intentional research misconduct, but the curriculum assumes that most research misconduct occurs because researchers are no different from other people and are therefore “vulnerable to inadequate training, poor judgment, weakness of character, and other factors that may lead to inappropriate behaviors” (Korenman & Shipp, 1994, p. 1). A recent study of NIH funded researchers indicates very little serious misconduct, but widespread incidence of lesser research misbehaviors (Martinson, Anderson, & deVries, 2005).

The curriculum’s case studies describe research scenarios that are ripe for misconduct or in which misconduct has occurred. The case studies can be used to clarify the likely outcomes of responsible and irresponsible choices and to model the occupational therapy profession’s expectations for RCR.

What are the components of the RCR curriculum?
The Promoting Integrity in the Next Generation Researchers curriculum consists of PowerPoint lectures, independent readings for students, case studies, and a PowerPoint summary of the cases. The curriculum has been designed for flexible use as a classroom presentation, an independent assignment, or a combination of the two.

PowerPoint lecture: Each unit is presented as a PowerPoint slide series. PowerPoint slides are most effective when simple visuals are used. Instructors
who are teaching an RCR curriculum for the first time will want to review the student readings to better understand the topic.

In their form in this curriculum, the PowerPoint lectures are suitable for use as regular class-length lectures. Instructors are encouraged to edit them (by removing slides, adding slides, combining lectures, etc.) to:
1. Adjust to more limited class time
2. Form shorter, independent presentations
3. Broaden the lectures

Student handouts can be printed using the standard PowerPoint options.

Each lecture includes a list of resources (e.g., Web sites, texts, articles) that offer additional information on the topic. These resources are likely to become outdated quickly. Occupational therapy instructors are urged to update the sources yearly.

Student readings: The student readings contain the content of the PowerPoint lectures. They are intended to be used as independent reading assignments when in-class time is limited and is therefore best spent in case discussion. It is suggested that students review the readings after the cases have been discussed in class. This way, the cases can pique student interest in the topic.

Case studies: The case studies were developed expressly for occupational therapy student researchers and represent occupational therapy’s range of research types, settings, and populations. Each case presents a research dilemma and affords an opportunity to convey several messages to students. These are:

1. It is harder to solve a problem than to avoid it. No one is astute enough to avoid all errors. In spite of good planning, ethical problems surface and need to be addressed. Students usually are quick to see that a case problem could have been prevented with better foresight and more responsible decision making. They often want to start the discussion by describing the types of responsible actions that would have avoided the problem. This should be avoided. Instead, discussion should assume that the case is a fait accompli and initially focus on what can be done to resolve the case dilemma. In addition, when discussing problem resolution, instructors should ask students to brainstorm several options, even if they are imperfect. This can help students recognize the range of decision options to every situation.

Each case presents an existing problem with existing ramifications. In many of the cases (as in life), students must choose the least bad alternative from a series of generally unsatisfying options. In the process, students learn that solving a problem rarely provides as good an outcome as avoiding it. This insight may encourage them to commit themselves to avoiding similar problems in their own research.
2. There are others who may help them resolve issues. Students often recommend that the case characters consult with ethical experts for help in deciding on an appropriate action. They may suggest consultation with institutional review board staff, ethics faculty, or the case character’s thesis advisor, or the department chairperson. If reasonable, all of these consultations should be encouraged, but they are not in themselves the answer. The curriculum is trying to prepare occupational therapy students to understand and problem-solve ethical dilemmas. Thus, students should be encouraged to consider what these individuals might suggest, and to recognize that not all such consultations will lead to a responsible action. Students are responsible for their choices, even when they consult another person.

3. There may be many acceptable solutions, but not all solutions are equally acceptable. Most of the case studies in the curriculum are complicated and are intentionally open to more than one analysis, interpretation, and alternative. Some include a series of “what if” questions that incrementally complicate the case. Cases may have many acceptable solutions, but these are likely to range in their degree of acceptability. Even acceptable solutions may have unfortunate or unsatisfactory consequences. As with all research decisions, a researcher is ethically bound to seek a solution that affords justice, beneficence, and autonomy to participants and stewardship to funders, over solutions that meet the needs of the researcher at the expense of participants or funders. The fact that most students struggle with the cases before recommending solutions that disadvantage the researcher is evidence of the students’ immersion in the reality of the case problem.

4. There are unacceptable solutions. Students should be encouraged to approach the case studies realistically. Realistically there are unacceptable options. Although it is “plausible that blind adherence to accepted rules or standards would sometimes be an unacceptable course of action” (Burke & Kalichman, 2003), options that violate known rules and regulations of an institution or a government, or require unethical acts of omission or commission, are unlikely to be responsible and are likely to have their own consequences if chosen. Both professional ethics and the concrete consequences of irresponsible acts should be discussed.

5. Prevention is better than treatment. After students have dealt with the messiness and the frustration of a number of imperfect solutions to a case, instructors should allow them to discuss how the problem could have been avoided by prevention. Insights gained from the discussion about prevention are more powerful if students can apply them to their own research. Thus, instructors should encourage students to examine their own studies and research situations for similar weak spots and to recognize the actions and the values needed to prevent similar issues in their real-life experiences.
PowerPoint abbreviations of the cases: A PowerPoint summary of the cases provides a brief synthesis of the major points of each case, stripped to expose the major ethical issue. These summaries can be cut and pasted into a PowerPoint lecture and used to help lead class discussion.

How can the RCR curriculum be used?
The curriculum is designed to be flexible. In our pilot use, the strongest reaction to the curriculum was seen when students were asked to read and respond to the case studies before the class or as an instructional set to introduce the lecture. In each situation, the class’s case discussion established a need to learn.

The PowerPoint lectures or the student readings can be used after the class discussion, or be left unused if the points are adequately made via the discussion. In occupational therapy curricula with little RCR class time, the most efficient learning is likely to come by using independent pre-class reading of the case studies, in-class discussion of the case, and then independent responsibility for the student reading outside class.

If the curriculum is to be used as an independent study, instructors may want to combine the cases, with the student readings and student run discussions at real or virtual meetings (i.e., using Internet or telephone conference links).

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How to go beyond the intuitive when discussing cases?
Bebeau, Pimple, Muskavitch, Borden and Smith (1995) detail an ethical decision-making process for students to use when analyzing RCR case studies. Burke and Kalichman (2003) summarize the key questions that Bebeau et al. recommends as follows:

1. “Who are the affected parties (individuals, institutions, a field, society) in this situation?
2. What interest(s) (material, financial, ethical, other) does each party have in the situation? Which interests are in conflict?
3. Were the actions taken by each of the affected parties acceptable (ethical, legal, moral, or common sense)? If not, are there circumstances under which those actions would have been acceptable? Who should impose what sanction(s)?
4. What other courses of action are open to each of the affected parties? What is the likely outcome of each course of action?
5. For each party involved, what course of action would you take, and why?
6. What actions could have been taken to avoid the conflict?”

Bebeau et al.’s (1995) method of analysis helps introduce students to the decision-making process and reduces their reliance on ethical intuition, instead offering a structure to support students’ analyses of issues. The process may become internalized once a class has used it once or twice, allowing subsequent case analyses to progress efficiently and effectively, independent of the formal questions. Both Burke and Kalichman (2003) and Bebeau et al. offer samples of the process in use.

References
Promoting Integrity in the Next Generation of Researchers

PROTECTION OF HUMAN SUBJECTS*

Student Reading Notice

The other units of this curriculum include student readings that can be used in place of the PowerPoint lectures. Because nearly all research texts now include information on the protection of research participants, this unit does not provide such a reading. If readers wish some strong, in-depth reading on this topic, they are directed to the on-line tutorial offered by the National Institutes of Health (NIH, 2000) to learn about participant issues, and to the Code of Federal Regulations to learn about the parts required in a consent form (Elements of Informed Consent, 2000).

Faculty and students may establish free accounts allowing them to access the NIH tutorial. Once checked in, they may complete the tutorial and have the results sent to their institution.

The tutorial is somewhat long, and many students may learn better if they have a printed copy to supplement their online interaction. The faculty members who are responsible for instruction in protection of research participants may wish to log on to the NIH Web site, download the materials, and print them for student use.

References

* Although this curriculum uses the term participant to describe a person who participates in research, the title reflects the more common, older term subject.

Additional Resources
Promoting Integrity in the Next Generation of Researchers

PROTECTION OF HUMAN SUBJECTS

Participant Recruitment 1

Kissima Martin is an entry-level occupational therapy student interested in the effects of health behavior interventions in adolescents battling chemical dependency. He has received Institutional Review Board (IRB) approval for a 30-person study of the effects of an eclectic approach using Social Cognitive Theory (emphasizing self-efficacy), Transtheoretical Theory (emphasizing stages of change), and Relapse Theory (emphasizing planning for and sensitizing to high-risk situations). The approach uses group interaction and motivational interviewing to gain participant investment and action. Each group has 6-10 participants, ranging from 15-17 years old. All participants must be enrolled in high school. All participants must have parental consent and give their own permission to be part of the study.

Kissima stated in his IRB application that he would solicit participants using flyers posted at local psychologists’ offices, presentations to schizophrenia support groups, and by health care professionals giving his study information card to individuals who might be interested. Kissima hoped to get similar numbers of males and females, as well as a mix of races, but he recognized that he was likely to get more women than men, and little diversity among participants. By chance, Kissima’s 3 groups (n= 21) thus far were composed entirely of teenage women, all of whom self-reported as “white/Caucasian”. Kissima has one more group to run. He has 6 teenage women already accepted into the group when he receives a voice mail message from Zeke (a 16 year-old man who describes himself as Asian/Hispanic). Zeke is interested in joining the study. From the information left on the voicemail, Kissima believes that Zeke is likely to fit the study’s criteria. On the same voice mail, colleagues who are recruiting for Kissima inform him that they have given his cards to 5 additional young women.

Last month, during a statistical consultation, Kissima was told that a homogenous sample would simplify his data analysis and strengthen his results. Kissima knows that one or two males in his sample will not make his results applicable to both men and women. Further, his experience facilitating the groups leads him to think that teenage women may be more comfortable with an all-women’s group.

Kissima’s flyers and information cards indicate that he is seeking both male and female participants. There is no indication whether treatment groups are mixed or single-sex.

Kissima wonders if it is ethical to refuse Zeke’s participation or to at least strongly discourage his participation by describing the issues that he sees (e.g., “You’d be the only guy”, “I’m not sure that the women will be comfortable with you.”).
Student Questions
1. Describe Kissima’s dilemma in terms of the beneficence, autonomy, and justice required in research?
2. Can Kissima side step the situation by filling the group with the waiting women?
3. Some have suggested that Kissima allow Zeke to attend the sessions, but not include his data or report his participation in the study. What do you think of this alternative?
4. Kissima views his dilemma as a conflict between scientific rigor and human participants requirements. Is there anything he can do in his next study to control or prevent this dilemma?

Discussion Points
It is unfortunate that Kissima did not strongly recruit the populations that he knew he’d have trouble entering for his study, but his poor planning and poor “luck” does not reduce his responsibility to be just and honest with his participants. It would be irresponsible for Kissima to keep an appropriate participant from the benefits of participation just because it is statistically inconvenient. Kissima owes all potential participants that meet his inclusion and exclusion criteria the same access to the study. Although addition of a single male to his study makes the study “messy”, justice requires that he abide by his set criteria. In addition, any change in inclusion/exclusion criteria requires IRB approval.

To allow Zeke to attend the sessions, but not include his data in the study or to fail to report his participation in the study would be irresponsible in two ways. First, it would be a disservice to Zeke, who reasonably believes that when he volunteers he is offering something to the community as well as helping himself. Second, it would be irresponsible to those who read Kissima’s research and would incorrectly assume that the groups were single-sex since there would be no data reported for men. It is especially important that Kissima not obscure the sex of group members since he himself believes that it may be important to the program’s success. It is better to run the group and test to see if the mixed group is an outlier when compared to the single sex groups.

In the future, Kissima could plan a more homogenous study, but would have to strongly defend his rules for exclusion. IRBs are sensitive to the justice of a study, and believe all who might benefit from treatment should have access to research on the treatment. Historically, IRBs were less sensitive to this issue and permitted many drugs to be studied on only men. Researchers considered women’s hormonal shifts and their possibility of becoming pregnant as unnecessary complications to be avoided. Unfortunately, this meant that for many of the drugs developed during these years, only the side effects on men and only the drug dosages for men were known. Men have significant physical differences from women in terms of body fat, height/weight, and hormones. Many drugs were later found to have special risks and actions when used by women. Realizing this, most IRBs will advocate for mixed studies.
Promoting Integrity in the Next Generation of Researchers

PROTECTION OF HUMAN SUBJECTS

Participant Recruitment 2

Rodney Manoweh is an occupational therapy graduate student working part-time on a study of parental stress. The Principal Investigator (PI) on the project, Dr. Allison Cross, is his boss and his thesis advisor. Dr. Cross has agreed that after Rodney recruits all of the parents needed for her study, he can invite a subset to participate in his thesis research.

It has been difficult finding parents who will agree to participate in Dr. Cross’s research. Rodney has already recruited through local schools and community agencies that provide services to disabled children and their families. These parents are very busy and have many work and family priorities. Rodney finds they are not easily convinced to participate in research like theirs that involve lengthy interviews. As a result, Rodney has fallen behind on his monthly recruitment targets. He is anxious about his low productivity and concerned that if he does not boost recruitment he may be fired. Even if he is not fired, he fears that poor performance on the research project may make it difficult to get a strong letter of recommendation from Dr. Cross to support an upcoming scholarship application.

Rodney believes that he might find participants at a nearby children’s hospital that is active in biomedical research. He contacts his friend and fellow graduate student, Sherry, a staff occupational therapist who works there. Rodney tells Sherry about his recruitment problems and asks for help. Sherry agrees to speak with other therapists. She also promises to talk to the parents of the children that she treats. She takes 50 copies of the recruitment flyer (previously approved by the university’s Institutional Review Board (IRB), placing some in the occupational therapy waiting room, and giving others to parents as they schedule their child’s next appointment. Two weeks later, Sherry surprises Rodney with a list of 14 parents’ names and phone numbers, all of whom are ostensibly interested in the parental stress study. None of the names are familiar to Rodney and he is hopeful that all might become study participants! Although he wonders why no parents phoned him directly to volunteer (his office number was on each flyer) he quickly forgets this concern in his excitement at finally having potential participants. Thrilled with his good fortune, Rodney begins calling the names on the list. The first few parents he speaks to are very interested and eager to participate. At the next team meeting, Rodney announces he has successfully recruited all 14 of these parents to the study, a result which delights Dr. Cross.

Student Questions
1. Rodney has his participants and Sherry has helped a friend. Are there any procedural or ethical problems with the recruitment? If so, what?
2. What conflicts of interest are possible in Rodney being both a student and employee of Dr. Cross?

Discussion Points
This case study highlights the ethical issues involved in identifying “difficult to recruit” populations for research. Particularly when there is pressure to recruit, there may be a tendency to use ‘informal channels’ rather than secure the necessary ethical approvals. One question raised by this case is whether research staff can ever ethically share lists of names and contact information of potential recruits. Accepting a list of recruits, even from a trusted colleague, is of questionable ethics because there is no way to ascertain whether the individuals on the list were coerced into giving their contact information. In an effort to help her friend, Sherry may have unintentionally coerced some of the parents into permitting her to take their contact information. Even if Sherry intended to act as a firewall of sorts by approaching these parents, it would have been more appropriate to use the established recruitment procedure approved by their university IRB.

Recruitment at a new institution, as in this case, may also require approvals and permissions from that institution. Thus, at minimum, Dr. Cross must file an IRB amendment to her university, requesting permission to use this new recruitment source (and strategy). Second, since recruitment at a site implies that site’s endorsement of the research, Dr. Cross must ascertain whether the biomedical hospital has its own IRB and if so, submit her research proposal to them. In the event that a hospital does not have an IRB, it is still necessary to work with appropriate personnel to ensure that the hospital understands the recruitment activities that will be used and can confirm that they are willing to allow these activities to occur on their premises with patients and families and perhaps even staff affiliated with their institution.

The second major issue in this case study is that of power relationships and coercion, both real and perceived. At least in theory, Dr. Cross was in a position to influence Rodney inappropriately. For example, if Rodney’s job performance was poor it could cost him in terms of his degree progress. Reciprocally, if Rodney had problems in his graduate work, it could adversely affect his employment. Student-employees and advisor-employers must discuss these dual roles beforehand and develop policies for action. Proper training and an atmosphere of respect are also key factors in ensuring a constructive working environment.
Promoting Integrity in the Next Generation of Researchers

PROTECTION OF HUMAN SUBJECTS

Data Collection

Anita Manosaen, OTR/L, is in the thesis stage of her post-professional master’s occupational therapy program. Her research examines the patterns of upper quadrant and trunk motion in children with cerebral palsy during functional reach while engaged in a standing play activity. Anita has been independently collecting data since her study’s approval by the university and hospital Institutional Review Boards (IRBs), two months ago. Anita is employed as a part-time occupational therapist in the hospital where she is collecting her data. Anita has gathered data on the 50 participants, the maximum that were approved by the IRBs.

As Anita begins processing her data, she and her advisor realize that the participant demographics form used in the study neglected to ask for participants’ height and weight. The IRBs had approved a form that originally included that data, but the questions disappeared from the final form. Height and weight are critical variables that are used to account for surface slippage of markers during the study, and the community standard is to accept parent reports of these data. Anita must have height and weight data to complete her thesis and publish her findings.

Anita has the master list connecting participants’ names with study numbers, but has destroyed the list of participants’ telephone numbers and addresses. Realizing that she is in trouble, Anita turns to a student colleague with a personal history of finding ways around problems. This colleague suggests that Anita can get the critical height/weight data several ways:

1) Anita can look up each participant’s data in their current medical charts, since all but one or two of the child participants are treated in Anita’s clinic.
2) Anita can look up each participant’s telephone number (using the Internet or telephone book), telephone the parents, and ask them to report the child’s height and weight.
3) Anita can find each participant’s address, and write the parents requesting that they send the child’s height and weight in an enclosed pre-stamped envelope.

The colleague believes that option 1 is the quickest and surest way to get the data. She argues that the data isn’t sensitive, that Anita has access to these charts as a clinic occupational therapist, and that the IRB already gave Anita permission to include this data in her study so there is nothing inappropriate about getting it from this accessible and highly accurate source.
The colleague also likes option 2 or a combination of options 2 and 3. She reasons that anyone with a public telephone number can be freely contacted; and since participants voluntarily gave Anita their telephone numbers they have implicitly indicated that they are willing to be contacted using that method. She also notes that people can refuse to give Anita the information if they choose, but that a telephone call would have the highest and quickest rate of return.

The colleague likes the 3rd option least, because it is slower, more time consuming, more costly, and has an increased likelihood of parents failing to return the information. She notes that in her experience, people often forget to return a card or envelope (even one with return address and postage). This option will therefore have poorer return rates than the options that require telephone contact.

As a last resort, the colleague suggests that Anita could gather an additional 50 participants’ data (an estimated 70 hours of work).

**Student Questions**
1. Can you think of any options that the colleague has not outlined? Which options are/aren’t ethically sound? Why?
2. Does Anita need to contact anyone for permission or approval before she moves forward with her decision?
3. Does Anita owe it to her participants to gather this additional information rather than ‘throw-away’ the data already collected.
4. Assuming that Anita finds a way to get the needed height and weight information, does she need to inform her article readers that these data were collected after the fact?

**Discussion Points**
1. Can you think of any options that the colleague has not outlined? Which options are/aren’t ethically sound? Why?
   This case touches on several of the ethical requirements in research:
   - **Beneficence** – Participants have a right to expect that their effort and time will be put to good use. A researcher should dispose of data only if there is no legitimate way to use it.
   - **Autonomy** – Participants have the individual and independent right to give information, but it cannot be taken without their permission. Therefore, it is unethical to use clients’ charts when they did not explicitly give permission for this access. In addition to being unethical, it is illegal to use medical charts in this manner. There is nothing in the case indicating that patients/parents have given permission for Anita to use their charts for her research. Just because she has a job at the clinic does not mean that she can capitalize on that job to assist her research.
**Justice** – All participants must be treated equally. As long as all are contacted in the same way – telephone or mail or a combination – the two remaining solutions (or combination) would be ethical.

2. **Does Anita need to contact anyone for permission or approval before she moves forward with her decision?**
   Anita should run, not walk, to her advisor. The advisor needs to part of the decision making. In addition, because all options are a deviation from the protocol that the IRBs initially approved, these same IRBs need to be consulted and must approve any new plan of action. Since this is a case of an error needing correction, it is probably best for the advisor or Anita to discuss the situation and get an idea of how the IRB wishes the problem to be handled. It is likely that an IRB will consider unannounced telephone calls intrusive, and that the Boards are more likely to approve contact via the mail, with a follow-up telephone call as a reminder. Anyone who chose not to share the information, by returning the declining letter or by verbal refusal in the telephone call, could not be solicited further.

3. **Does Anita owe it to her participants to gather this additional information rather than ‘throw-away’ the data already collected?**
   Anita does owe her participants a good faith effort to ensure that their time and energy is not wasted. Because the IRBs approved only 50 participants, if Anita and her advisor decide that she should continue data collection, an increase in numbers would need to be approved before any data collection took place.

4. **Assuming that Anita finds a way to get the needed height and weight information, does she need to inform her article readers that these data were collected after the fact?**
   If the measures were likely to be significantly different (e.g., self-report vs. actual measure of height and weight), then Anita would need to inform readers that her data were atypical. If the time between data collection and height/weight collection introduces a significant variable, then readers should be informed of the delay. However, if the data are not likely to be materially affected, there is no need to inform a reader of the atypical circumstances of data collection.

   Anita cannot state that she gathered the height and weight demographics at the lab session, since this is categorically untrue.
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PROTECTION OF HUMAN SUBJECTS

Unexpected Event

Julie White is a licensed occupational therapist who has returned to school to complete a PhD. She is working as a research assistant on a large study investigating the experiences of adults (age 20-30) who have completed a job placement program offered through City College. The study is based on telephone interviews. Participants often have complicated histories (e.g., high school dropouts, runaways, substance abuse, teenage pregnancy, etc.). The job placement program has helped many of these individuals get their lives on track, and the interviews are trying to uncover how and why the program works from the perspective of the participants.

Although the interview is focused on the program and the job experience, data collectors have been encouraged to create a respectful and encouraging tone in the interview. Julie soon discovers that the participants often disclose more information than is necessary to answer the interview questions. In a work review last week, Julie’s supervisor urged Julie to maintain greater emotional distance during her interviews, reminding her that her “role is as a researcher not a counselor”.

Yesterday, during an interview, a participant (Amy) disclosed to Julie that she was being physically abused by her partner. Julie was taken off guard and was uncertain of what to do or say. She continued the interview, and the woman mentioned the abuse two more times, providing details about the injuries she recently incurred, and reporting that she did not feel safe going to the hospital for care. Amy stated that she felt trapped in her situation and her home, and asked Julie to do something to help her. Julie was uncertain of what to do, and asked permission to call Amy back after consulting with her supervisor. Amy became angry, accused Julie of caring only about the research, and hung up without giving permission.

Student Questions
1. Is there anything Julie could or should have done differently?
2. What are the options now?
3. What are the potential positive and negative consequences of the actions you suggested in #2?
4. How would Julie’s actions differ if Amy had made this same disclosure in the context of an occupational therapy intervention session rather than a research interview? Why?
5. Did Julie err in her interview, if it opened discussion of Amy’s abuse?
6. What could a principal investigator do to reduce the likelihood that another interviewer is unprepared when facing an unexpected situation?
**Discussion Points**

1. **Is there anything Julie could or should have done differently?**
   
   Given that Julie didn’t know what to do, her decision to talk to her supervisor was appropriate.

2. **What are the options now?**
   
   a. Check what to do, and then call Amy back. This is not a great alternative since Amy hung up, but it is an option.

   b. Do nothing. This is also not a great option, given Amy’s cry for help.

   c. Report the abuse to the authorities. Amy is not a vulnerable adult, and this would mean disclosing that Amy was a research participant, and therefore breaching her confidentiality.

3. **What are the potential consequences of these options?**
   
   a. By checking what to do and calling Amy back, Julie will get guidance from her supervisor, find out about the rules/laws that apply to the situation, and make sure that she is making an informed decision. Amy may initially be angry, but the call will be clear evidence to Amy that she is believed and that someone is watching out for her. It may increase her trust, and would give an opportunity for Amy to be encouraged to contact help herself. Such contact must be handled carefully as it could increase abuse if the abusers discover it before they are eliminated.

   b. By doing nothing, there is a risk that Amy may experience further and more severe abuse, and she may incur serious injuries that Julie could have prevented by acting.

   c. By reporting to the authorities, Julie must disclose personal information about Amy, and her confidentiality as a research participant will be breached. Basically, the decision is: what is worse – breaching confidentiality or doing nothing to prevent future abuse? From an IRB perspective, if Amy is not a vulnerable individual she has the right to report or not report her condition. However, an IRB is likely to advise that Amy be discontinued from the study as her relationship with the researchers appears to have gone beyond that expected for a participant.

4. **How would Julie’s actions be different if Amy had made this same disclosure in the context of an occupational therapy intervention session rather than a research interview? Why?**
   
   In a clinical situation, depending on the laws, you may be obligated to report the abuse.
5. Did Julie err in her interview, if it opened discussion of Amy’s abuse?
   Not necessarily. Often research participants disclose information to an interviewer simply because the interviewer is listening to them. There is little that can be done to prevent this type of disclosure, particularly when the study is addressing complex social issues. The key is ensuring that interviewers are prepared for such potential disclosures, and know how to respond correctly.

6. What could a principal investigator (PI) do to reduce the likelihood that another interviewer is not placed in a similar situation, that is, not knowing how to address a situation of abuse with a participant?
   It is the responsibility of the PI to anticipate situations that may arise in interviewing situations and ensure that staff members are trained to know what to do. Written protocols with guidelines should be available for interviewers.
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DATA MANAGEMENT

Student Reading

OBJECTIVES
1. Discuss why data management is an issue of both scientific rigor and ethics.
2. Describe what constitutes data.
3. Discuss who is responsible for the accuracy of data collection, recording, and storage.
4. Discuss the policies that determine how long data must be kept, who may access data, and in what contexts data may or must be withheld.

READING
Responsible management of research data addresses data collection, record keeping, data analysis, data ownership, data storage and retention, and data sharing (Magnus & Kalichman, 2002). The most extreme examples of misconduct in the management of research data are intentional fabrication (creation), falsification (alteration), or misanalysis or misrepresentation of data. People performing such acts generally understand that they are acting irresponsibly, but may feel justified to do so by pressure from a sponsoring or funding entity, a need to find something publishable for their own advancement, shame or guilt because of poor efforts, or as a cover-up of errors. In most academic settings, students may have their degrees revoked for intentionally engaging in these behaviors, and faculty may be suspended from grant activities or fired. Fortunately such intentional misconduct is rare (Martinson, Anderson, & deVries, 2005).

Most misconduct in data management begins as an error. Irresponsible choices may appear clear-cut when researchers consider the ramifications, but researchers may err because they do not clearly see the ramifications. This unit will discuss the range of RCR issues related to data management.

Responsible Data Collection
Data should be broadly construed. Raw data come in many forms. Notes recorded by a behavioral observer, questionnaires completed by a participant, tapes or notes from focus groups or interviews, and recordings via instrumented devices are all data. Data also can be secondary, such as reports gathered from institutional files or records, or notes recording a process of theory development as part of the research.

All who gather, handle, or use a study’s data are responsible for its protection. The PI designs the study and selects or creates the means for data collection, data recording, and data storage. Data collection and storage systems can easily become obsolete as new forms or devices replace earlier versions. The PI is, therefore, responsible to ensure that the data can be reviewed in spite of changes in computer programs or electronic collection devices.
Although the PI is responsible for training, supervising, and periodically rechecking data collectors, data collectors themselves must be consistent in their day-to-day methods to ensure that they record only accurate data. In addition, they must know to seek supervisory input when faced with unusual circumstances, and to report problems that arise.

It is unethical for a PI or data collectors to fabricate data, to falsify data, or knowingly to collect data in a biased manner. It also is unethical for them intentionally to fail to gather data on a side effect that is likely to be negative. Whether data collection is biased by acts of commission or omission, bias in data collection is not only bad science, it is unethical.

**Responsible Record Keeping**

It can take years to gather and analyze study data and additional years to disseminate findings fully. Something that is vividly remembered during data collection may be only fuzzily recalled 12 months later. Sketchy records can become confusing, and an absence of records can leave a researcher unable to retrace events. Therefore, all records of a study should be thorough, complete, and organized.

Record keeping systems should include not only the study outcome and sample descriptors, but also the records that report methodological choices and actions. Indeed, records should be made on all decisions, including “what was done by whom and when” (Magnus & Kalichman, 2002).

Research notebooks can be important tools for both quantitative and qualitative research. In quantitative studies, deviations from protocol are considered problematic, so researchers are generally expected to record all actions, incidents, and variations from protocol in a research notebook (University of Minnesota, n.d.). In qualitative studies, researchers often alter questions to focus on specific information as themes emerge. Therefore, qualitative studies also require a written record of the researcher's reasoning and decisions. This record is called a decision trail. It allows an auditor to follow the reasoning behind each of the investigator’s decisions throughout the study. In both forms of research, records also should document the intellectual processes used in the analysis of the data.

It is generally recommended that research notebooks be written in ink, have continuous pages, and be used exclusively for their research purpose. Post-Its or other added memos should not be used. If notes are kept electronically, each electronic version of the study data and analyses should be separately saved so that an audit can verify that no changes were made to the data.

Occasionally, data are recorded incorrectly. The error may be as simple as someone recording “40” instead of “80,” or misspelling a name. Such errors should be treated in the same way that they would in clinical practice. They should *not* be erased or
obiterated. Instead errors should be struck through, dated, and initialed. If it is not obvious from the correction, the researcher also should note his or her reasons for the changes. Anyone auditing the data should be able to understand which data are correct and whether protocol was changed for a participant (University of Minnesota, n.d.).

**Responsible Data Analysis**
As noted earlier, it is unethical to change, add, or exclude data to intentionally bias findings or produce a desired result. Indeed, most researchers include all data collected for a study, excluding only those that fail logic checks (e.g., a score of 20 on a measure that ranges from 0 to 11).

Excluding or correcting data is sometimes called *data cleaning*. Because researchers want to put the best light on their data, it is easy for bias to sneak into data cleaning. For example, researchers might be more likely to include an unexpectedly high functional measure if they found it in a treatment group than if they found it in the control group. To protect against unperceived and unintended bias, decisions to include or exclude data should be based on objective criteria established before cleaning.

In qualitative research, divergent, conflicting, or disconfirming themes should be reflected in the findings. Qualitative research uses triangulation, peer review, and member checking to help ensure that findings accurately reflect all of the study’s data.

All decisions to drop or alter data points, and all ways in which missing or aberrant data were handled, should be fully reported and explained. Researchers should describe how they reviewed data, how they selected data for exclusion or alteration, which data they excluded from the analysis, and how the exclusion or the alteration changed findings.

Because they recognize that data analysis can be unintentionally biased, many federal funders now require that researchers analyze data while they are still in *masked* form—that is, before the researchers know which data represent the control group, and which, the treatment group.

**Responsible Data Ownership**
Regardless of a study’s funding, its data and any materials produced for or by it typically belong to the institutions under whose auspices it is being performed, not to the students, faculty members or collaborative groups performing the research (Columbia University, 2003–2004). Thus, ownership accrues to the academic or medical institutions that are sponsoring the study and are ultimately responsible for protecting participants’ rights and complying with legal and financial requirements. If an institution chooses not to exercise its rights of ownership, it may allow the students, the faculty members, or the collaborative groups to use the materials and data as they see fit.
Student researchers are generally permitted to own a copy of their data as long as participant identifiers have been removed. Funders are generally not given copies of data.

**Responsible Data Storage**

Researchers are responsible for protecting stored data and other records from being lost, taken, or damaged. Data storage is so important that consent forms often promise participants that their data will be securely stored in a locked office.

Unfortunately, storing data in a car is common and risky. Thieves are unlikely to steal data forms, data disks, or data stored on a laptop computer, but they are likely to take a gym bag, a briefcase, or a computer that contains data without sorting through its contents to determine what is and is not of value. In the end the thieves may acquire unwanted papers rather than money or credit cards, but the researchers will still have lost the data that were in their trust. Houses or apartments may be slightly more secure than cars, but even they should be used only as a last resort or a temporary alternative.

Storage organization should ensure the confidentiality of the participants. Consent forms and master code sheets should be stored separately from each other and from the data. Master code sheets that link participants’ names to participants’ numbers should be kept only as long as required for the protection of participants.

With the exception of the master code sheet, the copying of which is generally not permitted, it is wise to keep copies of vital data. To avoid being overwhelmed by paper, researchers may scan data (including research notebooks) into electronic form. It is especially prudent for students to store one copy of their critical data with their advisors.

**Responsible Data Retention**

As stated earlier, data should be retained in a form that is retrievable regardless of changes in the technology used to collect data or the technology (e.g., software and hardware) used to store data. Federally funded data must be retained and accessible for at least three years after a final report is made to the funder. The American Psychological Association (APA, 2001) recommends that data be kept for five years following publication of an article based on them.

**Responsible Data Sharing**

Responsible data sharing is the final aspect of responsible data management. The term *data sharing* refers to one researcher’s allowing another to have access to his or her raw data or database. Researchers may share data under several circumstances. They may share data to respond to questions about their study’s validity or honesty (e.g., during an audit by an institutional review board or an RCR audit. The National Institutes of Health encourages researchers to share data as long as they preserve participant confidentiality (National Institutes of Health, 2003).
Unless proprietary agreements specifically prohibit distribution, commercial or other groups with a vested interest may access any data that were gathered with public funding or at public institutions. Tobacco companies have used this rule to examine and criticize research on tobacco’s addictive properties, and political organizations have used it to access data examining sensitive political issues.

As stated earlier, when data are shared, they must be stripped of all identifiers or variables that would enable identification of individual participants. One way to test whether the proper identifiers have been removed is to ask a participant to select his or her data from a field of other data. If the participant is unable to recognize himself or herself in the data field, then others are unlikely to be able to identify individuals.

Data may not be shared if the researcher is unable to strip identifiers or otherwise protect the confidentiality of data and the anonymity of participants. Similarly, data may not be shared if doing so compromises proprietary information or if temporary restrictions specified by contractual agreement with sponsors are in effect.

References


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DATA MANAGEMENT

Data Collection

Laura Schmidt is an occupational therapist working on her dissertation, a longitudinal qualitative research study. The study includes men and women (n=15) living independently in the community with a variety of mild physical disabilities. The main goal of the study is to identify and describe the employment experience of this cohort over a year, with particular attention to discriminatory practices encountered in the job search and in the workplace. Each participant is interviewed five times during the year, and is paid $30 after each interview. Laura is the only interviewer on the project.

Laura interviewed Jay Higgens, a young man with visual impairment, for the first time three months ago. The interview went well and Laura felt that Jay enjoyed it too. Shortly after the interview, Jay called Laura to ask for some tips on appropriate dress for an upcoming job interview. Laura provided a few suggestions and wished him luck. One week later he called to tell Laura that he got the job. Three months after that, at the second research interview, Laura learned that Jay’s new computer job ‘was going really great’ and it had given Jay a greater confidence about the future. At the conclusion of the interview, Jay asked Laura if she’d like to celebrate his job success by joining him for coffee that Saturday. Laura agreed and the two of them shared a pleasant afternoon. Two weeks later Jay called Laura again and asked if she would join him for dinner. He said he really liked talking with her the other day and hoped she might like to see him again socially. Knowing that she enjoyed his company, and finding him very attractive, Laura said, “Yes”. At the end of their date, Jay gave Laura a warm hug and said they should do this again soon. Laura agreed.

Laura drove home realizing she had feelings for Jay and that she wanted to explore the possibilities of a real relationship with him. Laura and Jay started seeing each other. Their relationship strengthened and deepened. Jay and Laura discussed Jay’s continuation in the study and decided that there was no reason to discriminate against him, just because they were now dating. Jay met all the criteria for continued participation in the study, gave valuable data for the project, and was paid the same as all other participants. Laura conducted two more research interviews with Jay over the following months. Laura, a naturally private person, saw no reason to bring up their relationship with her dissertation advisor. In fact, the first time Laura mentioned her relationship with Jay to her advisor was a year after first meeting Jay; it was the day she announced her engagement to Jay.

Student Questions
1. Laura and Jay are both adults and neither is considered vulnerable. Has Laura done anything wrong? If so, what?
2. Once Laura’s dissertation advisor becomes aware of Jay and Laura’s personal relationship, what are her ethical obligations?
3. Should Laura be permitted to interview Jay for his final interview? If not, what should happen?
4. What should become of Jay’s data? Can it be retained in the study?
5. Are there any oversight agencies (e.g., Institutional Review Board (IRB), funder) that need to be informed about Jay and Laura’s actions?
6. Would your response to this case be different if Jay and Laura broke-up after the first 3 months of dating?
7. Assuming that this case indicates inappropriate actions, what could have prevented or short-circuited the problem?

**Discussion Points**

Qualitative research puts research staff in closer emotional proximity to research participants than does quantitative research. This is a direct result of the nature of the research process itself. Qualitative researchers ask their participants to share feelings, attitudes, and opinions on a wide array of topics, and sometimes these topics are of a private and even intimate nature. Qualitative researchers also tend to use face-to-face interviews, and conduct their data collection in participants’ homes. This too lends a more personal quality to the interaction. Of course, good interviewers possess strong interpersonal and observational skills and are sensitive, intuitive, and empathetic listeners, all of which places participants at ease and are likely to create a real or perceived relationship. In addition, much of qualitative research is longitudinal. This increases the chances for familiarity between researchers and participants by bringing researchers into repeated contact with their participants. In summary, qualitative research provides the conditions where relationships may go beyond the ‘professional’ to the ‘personal’. The central ethical issue in the case study above is whether Laura’s personal relationship with Jay ‘crossed the line’, presenting an opportunity for coercion or for misrepresentation of findings. For example, if Jay was thinking of quitting the study because he was too busy with his new employment, he might reconsider quitting, knowing that doing so may cause trouble for Laura. Coercion could also occur if Jay felt ‘forced’ by Laura to continue in the study so she would not have to recruit another participant. In the current case, Jay does not feel coerced in his personal relationship with Laura, but that could become an issue should he want to discontinue that relationship and feel that his action would also require that he leave the study.

Methodologically speaking, Jay’s data may suffer from social desirability bias. Specifically, Jay may no longer feel as comfortable revealing his true feelings about his workplace experiences, especially feelings that ran counter to what he knew the study was hoping to find or that might make Laura think less of him as her future mate. Laura and Jay’s relationship represents a personal conflict of interest, and as such Laura should have disclosed and sought external input rather than believing that she and Jay were the parties who had authority to decide this issue. Laura should have notified her dissertation advisor of the situation when it first arose. It is not wrong that Laura became involved with Jay, but it is wrong to have kept it secret.
If Laura’s advisor was informed of the situation earlier, she may have asked Laura to either discontinue Jay from the study or suggest she wait to date him until after the study was concluded. In a study with multiple interviewers, the advisor might have felt it was reasonable to assign Jay to a different interviewer. Now, Laura and her dissertation advisor need to report this unexpected turn of events to their university IRB, using an “Unexpected Event” form or its equivalent, since there was a breach of the IRB approved protocol. As far as using the data already collected, the right thing to do would be to remove all of Jay’s data from the dataset because it cannot be ascertained whether or not coercion occurred. This, as with notification of the IRB, is an ethical responsibility irrespective of how the relationship ended.

References

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DATA MANAGEMENT

Data Storage

Elena Jevehirjian is an occupational therapy master’s student, working as an interviewer for a qualitative study of community integration after spinal cord injury. Interview questions focus on environmental and social barriers that limit community participation for people using wheelchairs. Elena audiotapes interviews in people’s homes. Each interview lasts about 3 hours. Study participants are widely dispersed, living anywhere within a 50 mile radius of the city’s metropolitan area. Because of the distance she must travel to interview these participants, Elena typically goes directly home after a day of interviewing and brings her data into the office on the next work day.

On Friday, Elena has an extra-long day, interviewing 3 participants. The interviews go very well, and Elena obtains excellent data. She knows her boss will be pleased with the depth and richness of the participants’ answers to the interview questions. Elena returns to the city at approximately 8 pm and carefully locks the research bag in the trunk of her car in the apartment garage.

When Elena returns on Sunday from a weekend trip, a neighbor informs her that the garage was burglarized on Friday night saying, “The thieves didn’t have long, but they took my bicycle and they broke into 2 cars – yours and mine.” Elena is shocked to find that her car’s rear passenger window is smashed, CDs and gas/toll money is missing from the front seat, and one of her interview tapes is lying in a puddle of water near her open trunk. Also gone is her leather research bag containing a) the 3 participant screening forms from Friday with participants’ demographic and health information; b) the tape recorder, the other 2 interview tapes, all of Elena’s interview notes, backup tapes, batteries and interview materials; and c) the Mapquest search and driving directions to the research participants’ homes. Elena is devastated and keeps asking “Why would anyone take research data?”

Student Questions
1. What went wrong? Is there a policy of behavior that would have protected against this?
2. Under what conditions is it acceptable to keep data outside of a research clinic or office?
3. Do Elena and the principal investigator need to inform any persons or agencies of this theft? If so – who?
4. Can Elena re-interview these 3 participants or re-constitute the data from her memory, so that the information is not lost?
Discussion Points
The primary issue in this case study is data storage and security. What protocols could be put in place to prevent something like this from happening again? For example, should the PI mandate that all study data be returned to the project office each night? What standard of data security is reasonable?

A second issue is what level of reporting is required when an event like this occurs. What must the principal investigator disclose to the university and the agency that funded the research?

Another issue is research staff training. How could the likelihood of this event be minimized? What policies and procedures could be put in place to heighten security of study data – both outside of the project office and inside the project office?

Finally, what about the actual content of the stolen research data? In this study, data were mainly thoughts and opinions about barriers to community integration after spinal cord injury. Whoever stole this data now knows the address of individuals who require wheelchairs for mobility. What if this information was used to rob or otherwise harm them?

The current study’s questions are not tremendously personal, but what if the survey asked questions about more private or sensitive topics where disclosure of study data to others (whether by theft or loss) could have devastating personal consequences (e.g., alcoholism, sexual abuse, HIV status, etc.). Information like this, linkable to the participant and disclosed to inappropriate persons (e.g., a family member, an insurance company, one’s employer, the media, etc.) could have potentially disastrous consequences. What extra steps must be taken by researchers to secure data and ensure participant anonymity?
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DATA MANAGEMENT

Data Cleaning

Michael Marshall is an OTD student who is completing a fieldwork experience at a not-for-profit agency. The agency provides information about assistive technology (AT) to consumers with disabilities, and recently evaluated their information services by interviewing consumers 3 months after their contact with the agency. The agency wanted to determine if consumers were satisfied with the information received, if they would refer a friend to the agency for AT information, and if they actually made AT purchases after consulting with the agency. Among those who did make a purchase, the agency wanted to know what type of AT was purchased and its cost.

Ten volunteers collected data from 100 consumers and entered these data into a computerized database. None of the agency personnel have research experience, so the agency asked Michael to complete the project and write the final report as part of his practicum.

In the process of reviewing the database, Michael uncovers 3 problems:

1. In 8 cases the cost of the AT is listed as $25,000. All other technology in the database ranges from $100.00 to $12,000.00. Michael reviews the data collection sheets and finds that those responses are recorded as $25000. Michael also finds that the single interviewer for all 8 cases is inconsistent in using dollar signs, decimals, and commas in her handwritten notations. Michael decides that although it is possible that the AT purchases were truly twenty-five thousand dollars, it is more likely that the classified technology (mobility adaptations) would cost far less, since all other recordings in that category are less than $5,000.00. Michael changes the figures in the database to $250, assuming that the interviewer forgot the decimal point.

2. The satisfaction questions were left blank in 15 cases in the database. Some of these cases are the same ones for which Michael already changed the AT costs. When he checks the data collection sheets, Michael finds that they were completed in pencil and are smudged and illegible. Michael decides to complete the database satisfaction variables using the “neutral” option. He makes a similar decision for 4 other variables in the database, using the neutral option when information is missing.

3. In five cases, raw data collection sheets indicate that participants characterized themselves as ‘very unsatisfied’ but reported that they “would definitely” refer others to the agency for information on AT. Michael views these paired responses as illogical and believes that it is likely that the “very unsatisfied” rating is erroneous. He sees that many of the data collection sheets have corrections on this item. He notes that the scale for the satisfaction question
progressed from positive to negative, while all other scales in the interview progressed from negative to positive. Michael believes that it is highly likely that the interviewer checked the wrong box for this question. Consequently, for these 5 cases, Michael alters the response to “very satisfied” in the database.

Student Questions:
1. What do you think of Michael’s approach to data cleaning? Why?
2. Are any of Michael’s choices more or less responsible than the others?
3. What other options were available to Michael to address the questionable items (i.e., costs and satisfaction ratings)?

AN ADDED ISSUE: A semester later, Michael and one of the interviewers are discussing their experiences on the project. The interviewer remarks, “I hope that the agency improved their information on adapted vans. I interviewed a bunch of people who had purchased really expensive van modifications and were very dissatisfied with the quality of the agency’s information, although they liked the agency on the whole. It’s too bad! Those clients spent so much money to get the wrong thing, and now they are stuck with it.” Michael feels sick. He knows that the agency made no changes because the study results indicated no problem in satisfaction. In addition, nothing in the database indicated that people were spending more than $12,000 on AT.

4. Is there any action that Michael should take now?
5. Besides Michael, what other people hold responsibility for what happened in this situation? What actions should they take now?
6. What actions could Michael or others have taken to avoid the problem?

Discussion Points
One of the major problems with Michael’s approach to data cleaning is that he did it independently, and based on personal assumptions. He did not consider other options, which could have included:

- Notifying his supervisors of the discrepant information to seek their input in the process.

- Going back to the original interviewers to see if they remembered the interview. In unusual cases (e.g., very dissatisfied but willing to refer others), interviewers will often remember the discussion with the participant.

- Analyzing the satisfaction data in different ways to see how his decision to impute “neutral” influenced the results. Multiple analyses is a common approach when imputing. If each analysis results in the same conclusion/interpretation, then the researcher can be confident in the findings; if each analysis produces a different conclusion/interpretation, then the researcher cannot be confident and must make a decision about how to address the problem of missing or changed data.
Michael’s data cleaning challenges could have been easily avoided by better documentation and training of the interviewers, and emphasis on consistency.

Now, Michael should notify the agency of his discovered error. They may wish to reconsider their data in light of the new information, or to seek follow-up information from the interviewers or participants.
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DATA MANAGEMENT

Data Reporting

Dr. Fred Grove is an occupational therapy professor and the lead investigator on a large epidemiological study examining the numbers, types, and contexts of falls that occur in school settings among children with cerebral palsy. This is his first time as a lead investigator. Jan Coulee and Bridget Dougherty are doctoral occupational therapy students who have been working on the project. The study had significant problems recruiting participants, and the original sampling plan had to be changed from a multi-stage random sample to a convenience sample. The Institutional Review Board (IRB) approved this change, and the needed sample (n=500) was ultimately recruited. The study, originally scheduled for a 2-year collection period, took 3½ years to complete. There have been several staff changes during that time.

At the end of the study, as the articles are being prepared for publication, Dr. Grove, Jan, Bridget, and Dr. Lou (the statistician) realize that they cannot identify how each participant came into the study because this information was not recorded. They estimate that approximately ¼ of their sample was randomly recruited; the other ¾ were from the convenience sample. The four collaborators are debating how to describe their sampling for an article that they are writing for a prestigious journal:

- Dr. Grove argues that they should characterize the entire sample as ‘convenience’ since that was the weakest methodology used, and the majority of the participants came from that method. He reasons that it is better to underestimate than to overestimate scientific rigor. He argues that this option does not claim anything better than was actually done. He thinks that ‘airing dirty linen in public’ by reporting their recruitment difficulties and inability to track participant recruitment would undermine the study’s findings.

- Dr. Lou argues that the change in the sampling strategy and their inability to fully describe their sample compromises the analysis and interpretation of the results. He argues that they should not disseminate the work.

- Jan suggests that the group could use the date that the IRB approved the change in recruitment to estimate which participants came into the study through random vs. convenience sampling. This estimate would be inexact, but at most would misclassify 30 to 50 participants.

- Bridget questions if the group needs to be arguing the issue. The journal to which they are submitting prefers brief methods sections and most of the journal’s articles give few details about their sampling plans. Bridget proposes that the
group avoid the problem by simply leaving this information out of their article, adding it only if journal reviewers specifically request it.

**Student Questions**
1. What do you think of each team member’s suggestion? Are any of the options more or less responsible? Why?
2. Assuming that you think that the study should be published, are there better alternatives for describing the study’s data sampling?
3. A responsible researcher is likely to be highly critical of his/her study’s methods. How should a researcher determine which research weaknesses or problems to disclose when disseminating?
4. In addition to responsible conduct of research, this case raises issues related to the scientific rigor of the project and its data management. How could the current problems have been avoided? Consider issues of project planning, as well as project and data management

**Discussion Points**
The problem experienced by this team is not unusual; the challenge is in disseminating the findings in a fair and just way and disclosing pertinent issues within the methods used for the study.

The statistician’s perspective is clearly the most conservative, but it ignores the team’s responsibility to share what they learned, however flawed it might be. If the team follows this perspective, it would not be meeting its obligation to the funders to share the study’s work.

Bridget’s plan is deceptive by omission. It risks having readers assume better quality methodology than really exists.

Jan’s plan is problematic as well, particularly if the samples are independent and not representative of the same population. It might be possible to do some comparative analyses across the two groups that can be identified, and determine if there really are significant differences between the samples.

Dr. Grove’s plan is also deceptive in that it does not acknowledge that the design of the study was altered midway, nor does it educate other researchers about the potential problems they may encounter with recruiting for a similar study or with a similar population. Dr. Grove is correct though in acknowledging that identifying a convenience sample does not claim the study as being more than it was – the convenience sample is the weakest approach used.

The main thing to consider when publishing is how readers will be evaluating and using the information presented, particularly given the push to evidence-based practice.
Writers need to be as honest as possible to ensure that readers are not evaluating the evidence as being stronger than it rightfully is.

One strategy to deal with this dilemma is to test for differences across the samples statistically. For example, there are individuals who are known to be recruited randomly and there are others known to be recruited conveniently. The characteristics of these two groups could be statistically compared to see if the method of recruitment fundamentally changed the nature of the sample. The researchers could report the problem, report the findings of the comparison, and then go from there. If there are no differences, then the change in recruitment becomes a non-issue. If there are differences between the samples, the researchers will have to decide if they should be reporting the results at all, or if they need to separate the samples into separate publications.
Promoting Integrity in the Next Generation of Researchers

DATAMANAGEMENT

Data Dissemination

Connie Friedland, an occupational therapy faculty member, used observation and in-depth interviews to gather data from six women with significant physical disabilities that were caused by their former partner’s violence. In all cases, the women’s partners were facing criminal charges and under restraining orders. Study data were gathered over a 12-month period in the shelter where the women lived. The study was approved by her institutional review board, and all six women consented to participate in Connie’s research, which was part of a larger study examining the shelter’s services.

Connie chose to disseminate her findings in a ‘case study’ format. This approach requires a full description of participants and factors relevant to their present and former lives. This rich description allows readers to judge the quality of the explanations and interpretations of study results advanced by the author. In her manuscript, Connie described the six women and the circumstances that brought them to the shelter. She also described the services that they received and how beneficial the women found the services. Cognizant of the importance of protecting the confidentiality of the women, and familiar with American Psychological Association’s guidelines, Connie used pseudonyms (false names) throughout the case study. Due to the severity of the violence and the threat that the women’s partners still posed, Connie also altered some details about the women. She changed their demographic data and other facts about their family situations and work histories. She also changed the name of the shelter and its location.

Connie submitted her manuscript to a prominent health journal that reached a broad range of administrators, physicians, and health care and policy decision-makers.

Eight weeks later, Connie received a letter rejecting her manuscript. In his letter, the editor acknowledged the importance of the research and even characterized the work as “innovative” and “promising”. But the editor noted that Connie’s findings “did not ring true”. He wrote, “There seems to be a disconnect between the women you describe and the attitudes and views they hold.” Recognizing that her efforts to protect the women’s identities may have unintentionally muddled her study findings, Connie called the editor to discuss the issue. During their conversation, the editor was aghast to learn that Connie had deliberately falsified demographic facts about her research participants. Connie had not disclosed this in her submission letter or in her description of the study’s method of analysis or reporting.

The editor reminded Connie that his journal followed American Medical Association’s (AMA’s) style guidelines which state that “Authors and editors should not alter details in case descriptions to secure anonymity because doing so allows falsified data to enter the medical literature” (American Medical Association, 1998, pg.141). He reiterated that he could not accept a manuscript that falsified participant data. He suggested that Connie
either eliminate all identifying data and resubmit, or that she get written permission for publication from the participants to use their accurate but identifying demographic information in her paper. He then would be pleased to have the paper reconsidered for publication.

Connie fears that her participants are at risk for real physical harm if she does not take special measures to protect them. She also feels pressure to publish the work in this far-reaching journal that would bring her findings to a broad policy and decision-making audience. Connie believes that this audience is most likely to enact the successful interventions she identified in her research, and recognizes that publication in this prestigious journal would achieve greater recognition than would be achieved from a lesser forum. In addition, publication in the journal would assist her efforts to secure more stable and long-term funding for this important area of service provision.

References

Student Questions
1. It is likely that Connie’s participants would give her written permission to publish their accurate information, if asked. Is it ethical for Connie to seek this permission if she fears that it even slightly increases the chance that these women may be harmed by their partner?
2. Should Connie eliminate all fabricated descriptor data and resubmit a shorter manuscript even if this deadens the voice and potency of her findings?
3. Is it acceptable for Connie to withdraw her manuscript from the first journal and submit it unchanged to a non-AMA journal?
4. Is it responsible for Connie to withdraw the work (as described in #3, if this reduces the influence that her study is likely to have on policy?

Discussion Points
This case highlights the issue of protecting participants’ identities in situations and settings, especially when participants are vulnerable. Vulnerable participants include children, prisoners, pregnant women, or others whose unique circumstances present significant opportunity for coercion and harm. In qualitative studies, protecting vulnerable participants takes on additional complexity because oftentimes, the very details of the participants’ lives and the contexts they find themselves in are fundamental to the reporting of study results. Thus, these details must be revealed for the study findings to make sense. The challenge is to present research findings without placing participants at increased risk. In this case study, Connie’s actions to obscure her participants’ identities not only had the unintended effect of diminishing the comprehensibility of her manuscript, they also contravened an explicit journal policy.
Hence, Connie now must balance her desire to publish in this journal against her ethical responsibility to protect her participants.

Ethically, the primary concern of all researchers must be their participants. Anonymity is a critical aspect of this; so is the need to prevent a participant’s response from being linked to the participant who expressed it. One strategy that is sometimes useful is to write the results of qualitative research as a ‘composite case study’. In this strategy, the features of several participants are combined to create one or more fictitious, but still properly illustrative, cases. Of course, this strategy is not helpful if a journal expressly refuses that format, or if the goal is to protect the identity of an entire group, setting, or organization as in the case above. For example, while it may be possible to keep the real name and location of a women’s shelter secret in a city full of shelters, it will be much more difficult to do so, if not impossible, in a small rural town. Sometimes the best strategy is to obtain more comprehensive consent from the research participants at the outset. Or, as in the case above where concerns for participant safety abound, Connie could return to her participants, ask them to read the manuscript and listen to her concerns about their safety, and then ask them to decide for themselves if they will let their data stand or would prefer it withdrawn. Unless Connie decides to drop from her manuscript all of the data that was altered, she will have to obtain written consent from her participants to submit to the AMA journal. AMA journals would not have a problem with Connie dropping study data, but altering it (falsification) is not permissible.

Of course, by returning to her participants to ask for additional consents, Connie risks the withdrawal of one or more of her participants from the study. This could have an adverse practical impact, including making her study un-publishable due to inadequate data. Nonetheless, Connie must remember that participants have the right to withdraw from a study, or ask that their data be withdrawn, for any reason, at any time. Thus, it is recommended that investigators consider informed consent as a dynamic process and not a singular moment in time. Practically speaking, this means an investigator may need to return to her participants repeatedly over time, as the circumstances of the uses of the data change, and thus the potential risks to the participants change as well.

Lastly, we should consider whether Connie has an overriding obligation not to even seek the participants’ permission if she feels that these women are likely to make a poor choice, i.e., give consent, even if it increases their danger. Is it ethical to ask individuals to voluntarily take on increased risk, especially if one believes that they often make poor choices? Conversely, does such an authoritarian view by the investigator/author rob the research participant of their right to make an informed personal choice? In the current case, the women are competent adults so the question is “Can authoritative others (such as Connie) override their own autonomy?” Likely not. Indeed, participants have the right to expect that their data will be disseminated toward a larger goal; it may even have been part of the reason that they agreed to the research in the first place. This thinking would lean toward Connie informing participants of that choice, as well as the risks inherent to that choice, so that they can make this second informed decision.
There are no easy answers in this case, but investigators are reminded that they must always be guided by the principles of beneficence (i.e., “first, do no harm”), autonomy, and justice.

Connie should also remember that she need not make this decision alone. Investigators facing any ethical issue can always seek additional guidance from their institutional review boards (IRBs) or institutional ethicists.
Promoting Integrity in the Next Generation of Researchers

DATA MANAGEMENT

Data Retention

Two years ago, Nick Ramcharan completed a post-professional master’s degree in occupational therapy, and successfully defended his thesis research. He and his advisor, Dr. Johns, worked together to prepare the thesis for publication, and the article was published in a peer-reviewed journal 13 months ago. Nick was first author and Dr. Johns second.

Nick has recently started a PhD program in another city and took time to sort through his thesis papers before the move. Nick had given Dr. Johns the consent documents and data collection forms for the study as soon as their article was completed.

Dr. Johns called Nick yesterday asking for the set of draft diagrams that illustrate the development of the conceptual model that they published in their article. The final version of the diagram is part of their published article. Dr. Johns was recently contacted by the journal’s editor and asked to respond to an accusation that she and Nick “stole” another researcher’s model. Dr. Johns explains that this is a serious accusation, but that all they need to do is copy the diagrams that they drew of the developing model, and send them as evidence that they did not plagiarize the other researcher. Nick informs her that he threw out these diagrams and all of his other papers (e.g., committee meeting minutes, printed drafts of his thesis, a reflective journal of the work, a lab journal, diagrams of developing ideas, and email correspondence between himself and Dr. Johns). When she discovers that Nick destroyed these materials before his move, Dr. Johns becomes angry. She explains that maintenance of research data is critical to scholarly work and integrity. Nick is confused. He explains to Dr. Johns that he gave her all of the research data – the consent forms and the data collection forms. Nick states, “I would be drowning in paper if I kept everything from my thesis work!”

Student Questions
1. What constitutes data in research?
2. Nick and Dr. Johns published over a year ago. For how long should research materials be kept?
3. What responsibility do Nick and Dr. Johns each have for the materials that are missing?
4. What can Nick and Dr. Johns do now that the needed materials are not available?
5. What strategies could an investigator use to avoid this type of problem in the future and still avoid ‘drowning in paper’?
Discussion Points

1. What constitutes data in research?
   “Data can be defined as measurements, observations, or any other primary products of
   research activity. These provide a factual basis for inference, conclusions, and
   publication. If data are defined in this way as research products necessary to validate the
   integrity of published or reported work, then ‘data’ consist of much more than just
   measurements written in a lab notebook.”

   Reference: Magnus, P.D., & Kalichman, M. (September, 2002). Data
   Management. Retrieved August 20, 2005, from RCR Education Resources,
   Online Resource for RCR Instructors:

   “In the context of data management, data refer to all of the pieces of information that are
   collected from research participants to address a study’s questions, as well as all of the
   information that is gathered to monitor and manage study progress. Examples of this
   latter type of information include:
   • Recruitment processes, successes and costs;
   • Progress on data collection, coding, entry and cleaning;
   • Status of data storage and security;
   • Budget expenditures and changes; and
   • All other study decisions or processes that may inform a research team’s ability
     to explain what they did or their methodological decisions for future studies.”

   Reference: Finlayson, M., & Van Denend, T. (Under review). Data
   management. In: G. Kielhofner (Ed.). Scholarship in occupational therapy:
   Methods of inquiry for enhancing practice. F.A. Davis.

2. Nick and Dr. Johns published over a year ago. For how long should study materials
   be kept?
   Different organizations (e.g., National Institutes of Health, American Psychological
   Association) recommend different lengths of time that data should be maintained after
   publication. At minimum, data should be maintained for 3 years after publication,
   although 5 to 7 years is becoming a more common standard. One factor that should be
   considered is the extent to which the data influences thinking in the field or is
   controversial. The more influential or controversial, the more conservative the
   researchers should be in maintaining their data (i.e., longer).

3. What responsibility do Nick and Dr. Johns each have for the materials that are
   missing?
   Because they are co-authors, both hold responsibility for maintaining the data. At
   minimum, Dr. Johns was responsible for educating Nick on the responsibilities of
   authorship, the need to maintain data, and what “data” includes. The best case scenario
   would have been that they both had copies of the documents so that if one of them lost or
   destroyed the materials, the other had a copy.
4. What can Nick and Dr. Johns do now that the needed materials are not available?

They really do not have much recourse here, because their only option is to ‘recreate’ their work, which would be questionable from an ethical standpoint. Unfortunately Nick did not keep his reflective journal either, because going through this may have provided adequate evidence to support their work. If Nick kept the majority of his earlier drafts for the dissertation, these may also show the model’s development across time. It is wise to keep at least alternating drafts (e.g., draft 1, 3, 5) in hard copy and electronic form until the work has been in published form for many years (see question 2)

5. What strategies could an investigator use to avoid this type of problem in the future and still avoid ‘drowning in paper’?

Investigators can:

- Convert handwritten notes into electronic files (e.g., scan them) to facilitate backups;
- Set up files to clearly indicate materials that must be saved and for how long, or set up an ‘archive’ area or filing cabinet;
- Establish clear triage rules for discarding data, and train all staff in these procedures.
- Develop a technical report to summarize the activities, decisions and processes of a study.
Promoting Integrity in the Next Generation of Researchers

DATA MANAGEMENT

Data Sharing

Virginia Mathers is an occupational therapist who recently published her dissertation research on a wellness program designed to reduce falls in frail elderly living independently in the community. The study used a randomized control design.

Virginia was funded through a federal program supporting dissertations focused on community interventions. The intervention included education on wellness topics (e.g., exercise, nutrition, balance of rest/work, risk self-assessment, and modulation of activity); environmental changes to reduce risks; group strengthening sessions; and home exercise using a popular commercial tai chi DVD. The group that manufactured and distributes the DVD provided copies for the study at a reduced cost.

Virginia’s first article compared the outcomes of the experimental and control groups’ strength, flexibility, balance, incidence of falls, patterns of mobility inside and outside of the home, and sense of self-efficacy in controlling falls. Virginia had also used focus groups to gather the experimental participants’ subjective responses to the program, asking them to discuss the aspects of the program that they found especially helpful or challenging, and to clarify their perceived life changes since the beginning of the study. These data were mentioned but not presented in the first article.

Two groups have contacted Virginia asking to share her database. The first group is comprised of researchers who want to compare Virginia’s data to their own study of a more costly intervention, to compare the cost-benefits of the two programs. The second group produces a competing tai chi DVD that they want to market for home use by the elderly. They asked that Virginia send a copy of the focus group transcriptions. Their letter states that they plan to use this information to improve their product and to market it more competitively.

Student Questions

1. What should Virginia do? Is she under any obligation to share her data with either or both of these requesting groups?
2. Is Virginia under any obligation not to share this data with the DVD company in competition with the one used in the study?

Discussion Points

In either request – the first issue would be maintaining the participants’ confidentiality and their anonymity. Assuming that Virginia’s database could be stripped of identifiers, Virginia should indeed share her data with these other researchers. This means more than
simply removing names, contact information or other clear identifiers. Virginia would want to ensure that a combination of data such as age, sex, race, past-occupation, living situation, social-economic class, and co-morbidities, could not also identify participants. This sharing is especially reasonable given the federal government’s financial support of the study.

The other request may be more emotionally difficult for Virginia. Her initial response may be to protect the study’s tai chi DVD producer by refusing the request. But just because the DVD was commercial does not mean that the study’s data is proprietary. It is unlikely that Virginia entered into a proprietary agreement with the company before gathering the focus group data. In addition, she probably intends to analyze and publish the results of her focus group data. After such publication, she could be required to produce the data if the results or methods are questioned. Thus the more pertinent issue is whether participant identifiers or variables that permit identification of individual participants can be stripped from the focus group transcripts. If identifiers can be removed so that participants are unable to recognize themselves from the transcripts, then these stripped transcripts can be shared with the requesting company. Virginia should probably also share these data with the company that makes the DVD used in the study, so that both parties can judge whether statements are being misrepresented, presented out of context, or otherwise manipulated.
Promoting Integrity in the Next Generation of Researchers

CONFLICTS OF INTEREST

Student Reading

OBJECTIVES
1. Define conflict of interest, and discuss how it applies to personal, financial, political, and other perceived or real influences.
2. Recognize situations in which protections should be established to control the appearance of conflicts of interest or true conflicts of interest.
3. Discuss how professionals and institutions can avoid or minimize the impact of conflicts of interest.
4. Differentiate between conflicts of interest and conflicts of commitment.
5. Feel empowered to prevent or address conflicts of interest.

READING
A conflict of interest is a situation in which a person’s or an institution’s objectivity, ethics, or responsibility is compromised or appears to be compromised by a “competing financial, personal, or political obligation, gain, desire, loyalty, or bias” (Shamoo & Resnik, 2003, p. 141). Although this reading focuses on conflicts of interest as they pertain to research, Shamoo and Resnik (2003) suggest that understanding common, non-research examples can help clarify the issues. So, consider:

**Financial:** A governor who owns 20 recreational vehicles proposes elimination of the state tax on these vehicles. Is he taking care of himself or the state?

**Personal:** A mother judges a beauty contest in which her daughter is an entrant, and her daughter wins. Is this the result of the mother’s bias?

**Political:** A doctoral student in occupational therapy who teaches part-time in the occupational therapy master’s degree program gets permission to take a doctoral-class exam three days after her peers take theirs, without any penalty. Are the faculty treating this doctoral student the same way that they would treat doctoral students who are not faculty colleagues?

Do these situations demonstrate conflicts of interest? The answer in each case is maybe. The tax on vehicles may be unjust or unwise, the daughter may have been the best looking, and the graduate student may have received no more than the usual courtesy offered to all students. But in each case, an uninvolved outsider might reasonably question the situation, and the external world is likely to perceive the possibility of biased behavior. It is that perception of a conflict of interest that needs to be addressed.

Research conflicts of interest can be considered across the same categories:
Financial: A researcher is studying the effects of a new device. She holds stock in the company that manufactures the device and accepts funding for trips from the manufacturer. The external world, knowing about the stock ownership and the trip funding, may suspect that her research has a positive bias.

Personal: A researcher studies the effects of a treatment developed and strongly endorsed by a friend. He reports glowing results. The external world, knowing the relationship between the two people, may wonder if the study was biased in that direction or if the data were appropriately analyzed.

Political: A researcher reviewing a journal article recommends against its publication. He is currently researching the same question and hopes to publish results soon. The rejected author, discovering who reviewed the article and knowing the pressure to disseminate, may perceive that he was the victim of a negative bias.

None of these examples demonstrate proven bias. Possibly, even probably, the researchers performed their work without bias. But with conflict of interest, perception is nearly as critical as reality. Indeed, “it is often difficult to determine (or know) whether a person has a conflict of interest, because we may not know how their personal, financial, or political interests are affecting . . . their judgment, reasoning, motivation, or behavior” (Shamoo & Resnik, 2003, p. 141).

Some conflicts of interest are unavoidable, but because even the appearance of conflicts of interest can damage public trust, rules have been established to control them and ensure that behaviors are as unbiased as possible. Indeed, in its Report on Individual and Institutional Financial Conflict of Interest, the Task Force on Research Accountability of the Association of American Universities (2001) notes, “The problem is rarely a particular conflict itself—rather it is the question about what is done with the conflict. In most cases, problems arise when the conflict is not made apparent, or when it is not assessed or managed” (p. i).

Controlling Conflicts of Interest
Shamoo and Resnick (2003) suggest three strategies to control conflicts of interest: disclosure, management, and avoidance.

**Disclosure:** Faced with a real or apparent conflict of interest, a researcher or an institution should always disclose it to an objective party who is independent, but interested. For example:

- Reviewers should disclose it to the journal editor or the funder.
- Authors should disclose it to the journal’s readers as part of their author information.
- Researchers should disclose it to their institution’s institutional review board.
Management: Once informed of a possible conflict of interest, an independent but interested party such as an editor or administrator can use rules and policies to control the conflicting interests. These rules and policies often rely on special oversight, safeguards, or added vigilance. For example:

- External review of a study’s design by uninvolved persons
- Analysis of data before unmasking of group assignments
- Review of the article or the grant proposal by an additional person

Financial limits are sometimes used to manage financial conflicts of interest. This management technique establishes a dollar limit at which a reasonable person or institution may feel beholden. The U.S. government has established a limit of $10,000 in salary, gifts, or services (National Institutes of Health, 1999). Beyond this amount, salary, gifts or services to individual researchers, their spouses, or their children represent a potential conflict of interest. (NOTE: The $10,000 does not include payments from public or nonprofit agencies for work such as lectures or performing reviews, or from private practice income, or from royalties as long as the researcher has no other financial or research ties to the source granting the royalties.)

A set financial limit is based on two assumptions:
1. Financial issues are the major concern in conflicts of interest.
2. A reasonable person is unlikely to be biased by less than the set financial limit. Some researchers refuse to accept personal gifts or payments of any size, paying for their own meals at meetings and for their own travel to disseminate results. Other researchers see no problem with such financial support as long as the sponsor is disclosed to the audience. It is likely that some people can be biased by far less than $10,000 and others could not be biased by twice that amount. The issue, as with most things surrounding conflict of interest, is whether others might believe that gifts, payments, or services worth $25, 1,000, $5,000, or $10,000 would bias researchers’ objective study of an issue.

Avoidance/prohibition: It makes sense that conflicts of interest should be avoided (Magnus & Kalichman, 2002), but not at the expense of conducting needed research or performing necessary service. If a conflict of interest cannot be controlled the person with the conflict can be removed, but this would come as a last resort. For example, although the professional service of article or grant reviewing exposes a researcher to potential conflicts of interest, it is unethical to avoid this professional service by hiding behind a claim of conflict of interest. Researchers may reasonably excuse themselves from a specific review, but not from the professional responsibility of reviewing. Researchers may ethically avoid potential conflicts of interest only when other options are not strong enough to control the real or apparent risk.
Conflicts of Commitment
The term conflict of commitment is used when resources (including time and efforts) inappropriately distributed (Shamoo & Resnick, 2003). For example, a researcher who has numerous consultative activities and is therefore inadequately supervising a research assistant is demonstrating not a conflict of interest but a conflict of commitment.

Resolving conflicts of commitment usually requires that individuals or institutions (1) determine the required commitments, (2) set clear goals and priorities related to those commitments, and (3) limit or remove additional commitments that are optional and not within their capabilities (Shamoo & Resnick, 2003).

The coining of the term conflict of commitment appears to acknowledge that researchers are overstrecthing their quantitative limits and that research quality may be suffering.

References
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CONFLICTS OF INTEREST

Industry-based Research

Marlene Manella is working in her first job as a school-based occupational therapist. Before graduating, Marlene completed a fieldwork at a wheelchair clinic and studied user satisfaction with custom wheelchairs for her thesis. At a recent conference, Marlene sees a new wheelchair that hooks on staircase banisters, permitting quick stair-climbing. She is impressed by the wheelchair’s engineering, and is pleased by the manufacturer’s interest in pursuing research to test the advantages of the wheelchair.

After the conference, Marlene suggests that the manufacturer fund a study to document how well their stair-climbing wheelchair improves things that are associated with mobility in high school students. Over the next several months, Marlene develops the research protocol and negotiates funding with the manufacturer. During her efforts, she develops a close collegial relationship with the company’s wheelchair designers and marketing executives. Ultimately, Marlene suggests studying students in three local high schools for one semester, measuring the effects that use of the new wheelchair have on 1) accessibility to the schools’ physical environments (e.g., counseling offices, gym, cafeteria, and informal space), 2) frequency of peer interactions, 3) sense of belonging, and 4) participation in out-of-class activities.

The wheelchair manufacturer is impressed with Marlene’s proposal and awards her a $45,000 contract to fund her research time, an occupational therapy graduate student research assistant for data collection and compiling, and payments to student participants.

While the study is in process, Marlene, her research assistant, the high school administrators, and the executives of the wheelchair company meet biweekly to coordinate the project. The team works well together and the study’s data collection proceeds on schedule.

After the data are collected, the manufacturer’s Research and Development Department runs the statistical analyses that Marlene had proposed for the project. The results reveal that students rarely use the stair-climbing feature of the wheelchair. Instead, they rely on the schools’ elevators to move from floor to floor. According to the data, the stair-climbing feature has no effect on accessibility to physical environments, frequency of human interactions, or participation in out-of-class activities. Participants using the stair-climbing wheelchairs, however, do show a slightly stronger sense of ‘belonging’ (effect size d=.25) significant at p=.05.

The research team is very disappointed and feels blindsided by the powerful effects of the elevators. Marlene is sensitive to the impact that the study’s findings could have on the wheelchair sales. She writes an article reporting the findings about belonging, and publishes it in an obscure architecture trade magazine. The article emphasizes the
positive effect of the wheelchair on this important aspect in teen development. At the manufacturer’s suggestion, Marlene surveys the peers of the wheelchair users, asking what they thought of the wheelchair. The peers are impressed by the wheelchair, and comment that it allows students to continue discussions and be part of the group between classes.

The manufacturer offers to pay for Marlene and her graduate student to present the combined findings on belonging and peer response at a national conference on school therapy. Marlene accepts the offer, feeling that the research group has “salvaged success from the jaws of defeat”. She reasons that the group should have foreseen that the elevators would interfere with the wheelchairs’ effects on access and participation and, therefore, that data on those outcomes should never have been collected.

**Student Questions**
1. Everyone seems happy with the way things have ended. What actions do you question in this case?
2. What would have happened if Marlene had published all of the study data in the highest profile journal that was willing to accept it?
3. How do the different missions and cultures of the manufacturer and Marlene-as-researcher mesh? Where do you see potential conflicts? How would you deal with agencies that have different missions from your own?
4. This case involved both personal and financial conflicts. In what way did they relate? How would you handle the friendships that naturally develop when individuals in industry and research interact?
5. Would the case have been different if the manufacturer had shown the same support, but Marlene had performed the study on her own time, without funding? With funding from a government or non-profit research agency?
6. Would the need for disclosure have been satisfied if Marlene had noted that there were other study data that were not being reported in the article or presentation?

**Discussion Points**
Several factors are involved in this case study’s dilemma. Perhaps the funding and relationships Marlene developed with the manufacturer actually affected the research. Conflict of interest may have actually suppressed scientific discovery. For example, it is plausible that the conflict of interest quashed the highly significant finding, that stair-climbing wheelchairs do interact with the availability of elevators, and that the outcomes of wheelchairs are specific to architecture and available facilities. Such a finding could have substantial implications on cost-benefit and policy related to assistive technology.

This case reveals the potential conflict between profit-based industry and science. Changes in governmental laws and policies, funding of universities, and social expectations have encouraged academic research to move closer to industry to secure needed funding for scientific research. This case needs to be discussed on both the level
of the researcher (Marlene) and what should have been done differently, and the larger ramifications on research financing and research partnerships with industry in general.

In this case study, students should recognize that it is not personal connections or financial relationship that led to Marlene’s bias in data analysis and reporting. It is her failure to establish an intellectual firewall separating her goals (discovering and sharing new knowledge) from those of the manufacturer. Marlene failed to retain her role identity. Had she retained her independent viewpoint, her friendship or her financial dependence would be less at issue. Students should also recognize the signs that indicate Marlene’s perception of the funders as a partner on the project, for instance, their presence at meetings and processing of the data. Although a funder should receive regular reports, it is inappropriate for a funder who has a vested interest in a specific outcome to participate as part of the collaborative team for what is meant to be an independent study. By the time that Marlene willingly spins the study’s data to favor the manufacturer, we are no longer terribly surprised at her irresponsible actions.
Dr. Charlotte Guthrie serves on the editorial board of the journal *Occupational Science and Technology*. She was asked to review a paper titled, “Effects of an Acceleration Strategy for Augmentative Communication Devices Used in Conversation”. Only two research groups in the country have strong lines of published research on this topic. Dr. Guthrie belongs to one. Although Dr. Guthrie is reviewing a blinded copy of the paper, she believe that the manuscript’s references show that it was by a person or persons from the other research group. These two groups view the research on augmentative communication very differently. In fact, at last year’s national conference, a dialogue during a question and answer session reflected the vehement disagreement of opinions between Dr. Guthrie and the other research group.

Reasoning that the editor trusts her to be impartial, and knowing that she and her research group are one of the only two expert sources in this research area, Dr. Guthrie decides that she is obliged to provide the review for the editor.

Dr. Guthrie performs the review and returns it to the editor without noting any potential conflict of interest.

Dr. Guthrie’s review is scientific, objective, and non-confrontational. But, Dr. Guthrie does suggest substantial revisions, including that the original author propose alternate explanations for the data that conform more consistently to Dr. Guthrie’s perspective.

A few weeks after reviewing the work, Dr. Guthrie receives a letter from the journal editor. The editor writes that the article’s author contacted him, and that the editor informed the author that a person from Dr. Guthrie’s institution had performed the review. The author (correctly) assumed that this person was Dr. Guthrie, and severely criticized the editor for allowing such a biased individual to serve as the primary reviewer, informing the editor of the heated exchange at the conference. The editor chastises Dr. Guthrie for behavior that the editor characterizes as “unethical”, pointing out that Dr. Guthrie was obligated to disclose that her situation was likely to be perceived as a conflict of interest.

Dr. Guthrie is hurt and angered by the letter. She believes that she provided a sound and impartial review, and does not believe that the editor was warranted in his concern. Dr. Guthrie is considering refusing to perform other review service.
Student Questions
1. What are the turning points in this story? Where could a different action have resulted in a more reasonable outcome?
2. Does holding a strong opinion inherently make a reviewer inappropriate for a task? If Dr. Guthrie held the same antithetical view of augmentative communication devices, but had never publicly disagreed, would conflict of interest still be an issue?
3. If Dr. Guthrie’s review was objective and empirically based, was there really a reason for worrying about the conflict of interest?
4. How much of this conflict of interest is due to the players and the actions of the players in the case and how much is due to the protocol that the journal uses in reviewing manuscripts? Does the editor, reviewer, or author have any responsibility to future reviewers, authors, and editors who might find themselves in similar situations?
5. What do you think of Dr. Guthrie’s plan to avoid problems by not reviewing again? In parallel, what would you think if the author decided to avoid submitting manuscripts to this journal?

Discussion Points
1. What are the turning points in this story? Where could a different action have resulted in a more reasonable outcome?
   a. The editor could have requested that all reviewers provide written indication of potential conflicts information. It is rare for editors to do so. Instead they typically expect reviewers to contact them if there is a conflict of interest situation. Other review processes, such as grant reviews (e.g., those for the National Institutes of Health Center) require overt identification of conflicts by all reviewers.

   b. Dr. Guthrie could have consulted with the editor before reviewing the study. Dr. Guthrie made her decision based on the false assumption that the editor was aware of the two research groups and the controversy. Once Dr. Guthrie disclosed the possible conflict of interest, she would have more than just the two options that she originally saw (i.e., recusing herself from the review or providing the review). Disclosing the potential conflict of interest could have allowed the editor to manage the conflict by examining Dr. Guthrie’s review more closely for bias or getting a second independent reviewer from an associated area (even if not as fully expert on this area).

2. Does holding a strong opinion inherently make a reviewer inappropriate for a task? If Dr. Guthrie held the same antithetical view of augmentative communication devices, but had never publicly disagreed, would conflict of interest still be an issue?
   Holding a strong view makes it more likely that others could perceive a conflict of interest, and therefore requires more thought regarding management. If this had never been publicly expressed, there might be fewer people who know about it,
but there is still a potential perception of this conflict of interest – and the reviewer should still have informed the editor.

3. If Dr. Guthrie’s review was objective and empirically based, was there really a reason for worrying about the conflict of interest?
Conflict of interest involves the presence of conflict and the perception of conflict. This case represents issues around both.

4. How much of this conflict of interest is due to the players and the actions of the players in the case and how much is due to the protocol that the journal uses in reviewing manuscripts? Does the editor, reviewer, or author have any responsibility to future reviewers, authors, and editors who might find themselves in similar situations?
Conflict of interest cases usually emerge due to a historical incident, but resolutions fall into two domains. Administering satisfactory resolutions often require both handling the current issue and creating mechanisms to prevent future incidents.

5. What do you think of Dr. Guthrie’s plan to avoid problems by not reviewing again? In parallel, what would you think if the author decided to avoid submitting manuscripts to this journal?
While we all make decisions based on current events, we also need to step back and view the larger context. Perhaps being able to view and appreciate the larger context in this conflict becomes a responsibility and serves as an indicator of maturity. Of course, this also reveals the need for taking consequences of the incident seriously and the review system may need to accept some of this responsibility as discussed above.
Classroom Peer Review

Carla LeBeck is an entry-level master’s occupational therapy student enrolled in a prominent occupational therapy program in a research university. She is enjoying her final year in the program and is actively working on her thesis. At this university, the occupational therapy students who are working on their master’s theses meet regularly in a research seminar class to share their progress and problems. Students’ grades in the seminar are based on class participation and a non-masked peer review of another student’s thesis progress (i.e., peer reviewers sign their reviews in case the reviewed student needs clarification).

Carla has been assigned to serve as the peer reviewer for Dan Claven, a very good friend of hers. Dan is an excellent student, but he does not always accept criticism well. Over past semesters, Dan has often complained to Carla about faculty critiques and harsh grading of his work. Dan has characterized these critiques as unfair, disrespectful, and subjective.

There are two types of peer review in the seminar. First, during class presentations, students are required to ask questions of all thesis presenters to probe their understanding and prompt an in-depth discussion about the theoretical basis and methodology proposed for the thesis. Second, students prepare written critiques of their assigned colleague’s work and give one copy of these to the instructor (for a grade) and one to the colleague for their use.

Dan’s thesis topic is, “Occupational Interventions for Manic Depression Bipolar Illness”. As with many students, Dan’s topic is too broad and needs focus. This was noted early in the research seminar, but Dan has resisted revising his topic, not wanting to “give up anything valuable”. Thus, Dan has been presenting more and more detail about his research plan, compounding and failing to address his main problem of poor focus. Dan’s adverse initial reaction to his thesis advisor’s suggestions have left that faculty member less willing to challenge Dan to bring the topic under control. In addition, the advisor has been less available for consultation during this particular semester due to a recurring illness. This has increased Dan’s dependence on his peers’ input in the research seminar.

In spite of the fairly obvious problems in Dan’s thesis work, Carla has been hesitant to critique, question, or provide ideas, fearing that these would be interpreted negatively by Dan. Her input inside of class, outside of class, and on the official critique forms has been mild and deferred to Dan’s own opinion of his work. In fact, Carla’s critiques are so weak that the seminar instructor believes that Carla is not participating appropriately in the course and that she demonstrates a shallow understanding of research. At the midterm evaluation, the instructor indicates that unless there are significant changes, Carla will receive a “C” for her peer work. Carla has historically been an “A” student.
The potential for a “C” grade upsets Carla, who feels that she is in a bind. She does not feel that she deserves a “C”, but with half of the semester already completed and several reviews performed, she believes that Dan would be very upset if she was to begin being critical of his thesis plans at this stage of the seminar.

**Student Questions**

1. What conflicts of interest do you see in this case?
2. What is the role of the instructor in this conflict? Does the occupational therapy faculty member have a responsibility to have prevented this conflict or to help resolve it?
3. What role does Dan have in the conflict? In what ways could he help resolve the issue? How would he know that there is a problem and should he be informed?
4. How much of this case’s conflict of interest is due to the individual players in this scenario versus the actual protocol in use (i.e., the mechanism of the assignment and the peer review).
5. Conflicts of interest may be prevented in different ways at different points in time. When might the conflicts that you described in #1 have been avoided, and how?

**Discussion Points**

This conflict of interest case has many elements. Changing one or a combination of elements could radically change the ethical dilemma. For example, in this scenario conflicts of interest exist between the peer reviewers who may have many reasons to make more or less rigorous reviews due to friendships, peer competition, perceived expectations or opinions of the instructor, or other baggage. Requiring that students sign the reviews unmask the process and may influence the potency of the review.

A number of actions could reduce the conflicts of interest in the scenario. The instructor could:

1) avoid peer reviews entirely, removing the conflicts but also losing the students’ critical thinking experience

2) establish mechanisms for blind reviews; vetting the signed review before it is turned over to the student, thus instructing students on reasonable phrasing, while retaining the element of peer critique

3) create a rubric for reviewing that helps guide feedback and removes some of the subjective emphasis

By educating students about the potentials for conflict of interest the instructor could create an environment where students model the same behaviors expected of journal and grant reviewers, and one where individuals learn the issues and resolutions of conflicts of interest. In such an environment, if Carla had disclosed her close friendship with Dan the teacher might have assigned a second reviewer, thus managing the conflict; or removed Carla as a reviewer, thus avoiding the conflict of interest.

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In the current conflict, the instructor could take a major role in dealing with the issue. He might have mentioned something to Dan about the disparities across the reviews or advise Carla on reasonable approaches that she might take when approaching Dan. In any action, we should not consider Dan as either victim or villain in this case. Dan needs to be informed of the ways in which his actions are interfering with his research progress, and finally to receive the feedback that he deserves to hear even if he chooses to ignore it and reap the results.
Promoting Integrity in the Next Generation of Researchers

PEER REVIEW

Student Reading

OBJECTIVES
1. Describe types of peer review.
2. Describe principles and policies that guide peer review.
3. Given cases, discuss the dilemmas, problems, solutions, and preventive actions associated with peer review issues.
4. Commit yourself to being honorable in the peer reviews that you may perform.

READING
The term peer review refers to a process in which one or more experts judge and comment on another’s work. Peer review is considered the highest form of research review.

Peer review is used to decide which grant proposals are funded, which articles are published, and which papers or posters are presented at professional conferences. Also, students are commonly asked to peer-review colleagues’ work.

Not all journals use peer review. The American Journal of Occupational Therapy and the Occupational Therapy Journal of Research are both peer-reviewed journals. In contrast, OT Practice does not use peer review. Articles written by its own staff and manuscripts written by others are reviewed only by the editor.

Peer review serves two purposes. First, it determines if a work is good enough to fund, publish, or present. Second, it offers the authors suggestions for improving a work toward future funding, publication, or presentation. To decide if a work is good enough, a peer reviewer considers the work’s importance and its quality. Its importance is judged by asking whether the research presents or is likely to create new information or ideas, and whether it advances the science, theory, practice, or philosophy of the profession (American Medical Association, 1998). Its quality is judged by asking whether a work is grounded in theory; uses rigorous, reliable, and valid design and techniques; is responsible in its interpretation of findings; is critical in its acknowledgment of limitations; and is reflective in its conclusions (Magnus & Kalichman, 2002; Shamoo & Resnik, 2003). These are the goals against which the peer reviewer assesses the work.

Students whose work is peer-reviewed have the right to expect the same sort of critical analysis.
Types of Peer Review
There are three types of peer reviews, each with advantages and disadvantages:

**Open review:** An open review is the most transparent type. In an open review, the reviewer knows the identity of the author, and the author knows the identity of the reviewer. This type is rarely used in professional reviews because identifying reviewers is thought to make it difficult for them to be frank regarding a work.

**Single-masked review:** In a single-masked review, the reviewer knows the author’s identity, but the author does not know the reviewer’s identity. Concealing a person’s identity is called *masking or blinding*. Because single-masked review protects reviewers’ anonymity, it encourages reviewers to be frank in their assessments. This is generally a benefit of masking, but it can be a flaw if reviewers use their anonymity to be brutal rather than frank. Because the reviewer knows who the author is, a single-masked review does not control for positive or negative reviewer bias. For this reason, single-masked reviews are used only when an author’s identity or institutional affiliation is critical to the decision being made. For example, most grant proposals are reviewed using the single-masked process. This permits the funding decision to be based, in part, on the individual’s and the institution’s record of prior activity and success.

**Double-masked review:** In double-masked reviews, neither the reviewer nor the author knows the other’s identity. Double-masked reviews are the surest way to reduce the risk of bias, but are as likely as single-masked reviews to encourage unnecessarily harsh reviews. Most peer-reviewed journals use a double-masked model.

Guidelines for Reviews
Responsible reviewers follow six guidelines. An individual should:

1. Decline to review a work if they are not expert in the topic. Reviewers are expected to provide informed opinion, not just personal opinion.

2. Bring any real or apparent conflicts of interest to the attention of the editor or the funder. Such a disclosure is the first control on conflict of interest and is mandated by many organizations, including the International Committee of Medical Journal Editors (2004). The disclosure should take place before the reviewer provides a review to the decision maker, allowing enough time for the decision maker to devise a management strategy or to remove the reviewer. Removal, termed *avoidance* because it avoids the conflict of interest, generally is used only when other options are not strong enough to control the conflict. It is unethical to avoiding the professional responsibility of review by hiding behind a conflict of interest.
3. Provide a prompt review. Reviewers often are very busy with their own research, but delays in submitting reviews can unfairly disadvantage those who are eagerly awaiting a decision about publication or funding. At their worst such delays can become conscious efforts to time the reviewer’s own research better or even to “pocket-veto” (reject by inaction) another researcher’s work.

Some publications now ask that reviewers “hand off” a work if they are unable to review it in a timely fashion. In such a case, the reviewer is given implicit responsibility to ensure that the new reviewer understands the rules of confidentiality (see item 4).

4. Keep all information confidential. Researchers who submit papers and grant proposals trust that their work will be confidentially reviewed. This means that their ideas will be kept confidential and that the fact that their work has been reviewed also will be kept confidential. A reviewer should not share a review grant proposal or manuscript or any part of the information contained within it with students, colleagues, or other people. Such sharing, even to help educate a student about the review process, is acceptable only if the editor, the funder, or another supervising agent approves the action before the work is shared.

Researchers entrust their reputations to a reviewer. Occupational therapy is a small profession. Even a positive comment about a work, made to someone uninvolved in the review, shares something that the reviewer has no right to share.

Students also must recognize the need for confidentiality in peer review. In the small world of the classroom, disclosure of review details is close to gossip and therefore must be avoided.

To help maintain a review’s confidentiality, reviewers are generally directed to destroy all materials once a review is complete. Keeping materials after agreeing to destroy them constitutes misconduct.

5. Not use a reviewed work as a private source of information. Reviewers have private access to other researchers’ work. This access exposes them to ideas, methods, and findings that may not yet be public knowledge. Reviewers are not allowed to use this insider information until it is publicly available. Indeed, the federal Office of Research Integrity considers unauthorized use of nonpublic ideas, methods, or findings obtained in review of grant proposals or manuscripts to be theft of intellectual property (Magnus & Kalichman, 2002b).

There is one exception to this rule: “If reviewers become aware on the basis of work under review that a line of their own research is likely to be unprofitable or a waste of resources, then they may ethically discontinue that work [American Chemical Society, 1996; Society for Neuroscience, 1999]. In such cases, this decision should be communicated to the parties requesting the review” (Magnus & Kalichman, 2002). Thus a reviewer is allowed, even encouraged, to stop work
that is clearly on the wrong track. However, the reviewer is not allowed to follow the new direction proposed in the grant proposal or the manuscript until that information becomes public.

6. Offer constructive criticism. A reviewer is committed to improve as well as judge a work. It is often said, “Even when a reviewer is wrong, he or she is right.” This does not mean that every comment offered by a reviewer is accurate. Rather, each comment gives insight about a problem in the work. For example, a comment expressing concern over a study’s use of x-rays may indicate that additional safety information or clarification of risk is needed in the grant proposal or the manuscript. A review helps ensure that the next version of the work will be clearer and stronger. In the best case, the next version of the work should be so improved that it can be funded, published, or accepted for presentation.

References
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PEER REVIEW

Learning by Doing

Kayla Thomas, OTR/L, is a doctoral student in the final stages of designing her research project on habit formation in adults with stable cognitive disability from head trauma. Kayla and her advisor (Professor Sandy Cefalu) work well together. Indeed, Dr. Cefalu is not just Kayla’s advisor, she is truly her mentor. Dr. Cefalu frequently provides Kayla with opportunities to develop her scholarly and academic professional skills. Many of Kayla’s peers envy her relationship with Dr. Cefalu.

Today, when Kayla drops by Dr. Cefalu’s office her mentor has just received a manuscript asking for her blind peer review of a manuscript toward publication in a peer-reviewed journal. The article is on habit formation in teens with brain injury. After Dr. Cefalu skims the abstract, she suggests that Kayla write her own critique of the research article. “After all,” notes Dr. Cefalu, “you’ll be asked to perform peer reviews once your own work is known.”

Kayla is excited about this new challenge. That same day, she forwards an electronic copy of the manuscript to her dissertation discussion/support group and suggests that they might all enjoy discussing the manuscript. The group agrees. Although the document is blinded, several group members believe that they can identify the researcher from her distinctive writing style and extensive citations to her own prior work. They are excited to review such timely and prestigious work.

In a few days, Kayla sends her critical review to Dr. Cefalu. Included within it, without attribute, are several insights offered by her group. A few days later, Dr. Cefalu sends her own review to the journal, including several of Kayla’s observations that Dr. Cefalu found insightful and with which she agreed.

Student Questions
1. Is there an issue here?
2. What do you think of Dr. Cefalu’s handling of the review? Why?
3. What do you think of Kayla’s handling of the review? Why?
4. Are there variations that would make everyone’s actions more appropriate?

Discussion Points
It is relatively common for student discussions to focus on the possible plagiarism of Kayla’s critique by Dr. Cefalu and the general lack of attribution within this case. If the review were being published, this sort of citation would be required. But, authors rarely credit verbal or written suggestions for a non-disseminated work such as a peer review.
Furthermore, this is not the key issue in the case! The issue is one of confidentiality of peer review.

Neither Dr. Cefalu nor Kayla had the right to disseminate a manuscript before its publication. There is no indication that Dr. Cefalu asked permission of the journal editor to share the manuscript with Kayla. Likewise, Kayla did not have permission to share the manuscript with her discussion group. Once confidentiality is breached, the possibility of wider dissemination increases exponentially. Imagine to how many additional people the discussion group members might send the article or how often they may refer to it in discussion. Imagine that each keeps the electronic copy of the article, rather than deleting it as reviewers are nearly always required to do.

Dr. Cefalu failed in her responsibilities as a peer reviewer in three ways:
1) she failed to maintain the confidentiality of the work,
2) she failed to get permission to distribute the article to another individual, and
3) she failed to inform or educate Kayla, whose actions then further breach the confidentiality of review.

Dr. Cefalu could have gotten permission from the journal’s editor to share the work, and then instructed Kayla on the appropriate handling and disposal of the work. As things stand, the copy that Kayla forwarded to her peers now has a life of its own.

Until a work is published it is not open for discussion or distribution. Reviewers are prohibited from making any public comment about a work that is in review. There are many reasons for this. Chief among these is that silence protects the authors’ ideas from others until they are published and available for all and their professional reputations should the work be declined for publication or withdrawn from consideration.

The confidentiality of peer review is the same regardless of the type of work being peer reviewed (e.g., course efforts, grant, manuscript) and regardless of whether the work is or is not blinded.
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**PEER REVIEW**

A Well-Timed Peer Review

As an assignment in a research course, Sherry White, an entry-level master’s occupational therapy student, reviewed a manuscript for an important journal on home care. The review was *single-masked*, which means that Sherry was given the author’s name and institution, but the author was not told Sherry’s identity. The journal editor gave permission for the articles to be assigned to students for review, as long as the students “understood and observed the rules of confidentiality commonly required in review situations”.

Sherry was impressed by the manuscript that she reviewed. Indeed, she adopted the author’s theoretical model for her own master’s thesis, and used one of the questions in the manuscript’s *Future Research* section as the focus of her own thesis study. Because Sherry did not know whether the original manuscript was accepted for publication, she used the American Psychological Association’s format for unpublished works with limited circulation when citing the manuscript.

Sherry’s committee was impressed by Sherry’s sophisticated model and the complex nature of her thesis proposal. They approved Sherry’s thesis proposal and encouraged Sherry to apply for funding for the study from her university’s student fund. Sherry was approved for this funding, and her original summary explaining the theory and the project was published without references on the fund’s Web site.

**Student Questions**
1. Did Sherry behave responsibly? If yes, what supports that perspective? If no, where did Sherry deviate from acceptable peer-review behavior?
2. Have Sherry’s actions caused any harm to the author of the original manuscript? To the journal to which that manuscript was sent for review?

**Discussion Points**
Authors share cutting edge ideas and findings in their manuscripts, and they rely on the confidentiality of reviews to guarantee that their work is not appropriated before it is placed into public review. In the current case Sherry had no right to use the materials she reviewed until it the manuscript was published or its ideas made public in some other forum such as a conference. Once publicly discussed, ideas may be freely integrated into new works. Until that time the reviewer is not allowed to act on the information or to use the ideas. It is sometimes difficult not to act on a great idea discovered during review, but that is exactly the commitment that a reviewer makes when agreeing to review.
From her actions, one can assume a second irresponsible act. It appears that Sherry has retained her copy of the manuscript. Most journals require that works be destroyed after review. So, Sherry has been irresponsible in retaining a copy of the manuscript and in her use of the information within the manuscript. Sherry appears to be unaware that she is breaking the rules of peer review. She does not try to hide her use of the manuscript, indeed she makes sure that she cites it. But, Sherry’s actions are still wrong.

Because the fund has posted an abstract of Sherry’s proposal, Sherry’s work could erroneously now be considered the first work, unintentionally ‘stealing’ that right from the manuscript’s authors.

If Sherry was informed of the issues, she might be able to correct the situation a bit. First, she could apologize to the original author and journal editor, committing herself to confidential review in the future. She could also ask that a notice be added to the Web page, acknowledging the original source of the model.

While it is not required, it is generally considered polite to contact authors whose work you wish to use as fundamental portions of your own research. Had she planned to offer this courtesy, Sherry would have realized that she could not do so until the work was published, and would have realized that she needed to delay or defer her use of this work. As things stand, she could apologize to the original author and journal editor, committing herself to confidential review in the future. She could also ask that a notice be added to the Web page, acknowledging the original source of the model.
Promoting Integrity in the Next Generation of Researchers

COLLABORATIVE SCIENCE

Student Reading

OBJECTIVES
1. Describe four types of collaborative research.
2. Discuss potential issues associated with each form of collaboration.
3. Describe how collaborative research can be enhanced.

READING
It is often said that “research is a social act.” Indeed, collaboration is becoming an increasingly common research model. There are several types of research collaborations. These include collaborations:

Within a field (intradisciplinary) when professionals from a single field work together on a research project. For example, a group of academic and clinical occupational therapists collaborating to study the short- and long-term effects of thumb splints on osteoarthritis pain.

Across two or more fields (interdisciplinary) when professionals from different fields work together, bringing their separate perspectives to a study. For example, an engineer, an occupational therapist, and a driving rehabilitation specialist collaborating to study the effects of simulated driving practice on sitting and standing balance in people with Parkinson’s disease.

With industry when researchers from industry and academia research the clinical clinical potential of commercial products. For example, an occupational therapist working with a company that manufactures glucometers to research how to improve long-term adherence to self-management regimens of teenagers with diabetes.

With communities when representatives of local communities and researchers from academia investigate grass-root questions originating from and endorsed by the community. For example, a community and an occupational therapy researcher collaborating to provide and assess a program to encourage adults with disabilities to participate in local, state, and federal elections.

Research Collaboration is Increasingly Common
Several factors are contributing to the increase in collaborative research:
1. Research questions are increasingly complex, requiring several persons with complementary skills.
2. Funding sources, especially federal ones, encourage collaboration by providing special monies for collaborative studies or by assigning extra points for interdisciplinary studies during competition for funding.

3. Inexpensive and universally available communication via e-mail and teleconferencing encourages people to collaborate across great distances.

4. Federal laws and financial considerations make industry collaborations more attractive to academic institutions.

5. Communities are increasingly recognizing that research funding can help support program development.

**Potential Issues in Collaboration**

Research collaborations have all the issues associated with a multiperson group, as well as some specific issues brought to a collaboration by the nature of the research process.

**Individual issues:** As with any group activity, collaboration may mix persons with differing communication, thinking, and leadership styles. This may be complicated by the presence of both formal and informal leadership, by competition among collaborators who are used to being the leader, and by each person’s emotional response to differing forms of leadership.

**Interdisciplinary issues:** Interdisciplinary collaboration is complicated by turf issues and by professional disciplines’ differing cultures and rules (Magnus & Kalichman, 2002). Professions often have distinct languages and terms. Even more confusing, terms used by the collaborating members may have different meanings across the professions. In addition, professionals may differ in their assumptions about and views on group process, their expectations of consensus versus autocratic decision making, their timelines, their ways of resolving problems, and their expectations about dissemination and authorship.

For example, some professions or disciplines draw a collaborative group together to *implement* an established plan, whereas others draw a group together to *create* a plan. Collaborators who expect to be told their part in the research may interpret a process-oriented phase as lack of leadership or direction. Collaborators who expect a process phase may feel that their contributions are not being respected if the group skips that phase.

Different disciplines also may vary in their comfort with and understanding of qualitative and quantitative methods. An interdisciplinary group may need more thorough discussion of methodology and analyses to inform all parties about the rigor of the work being performed and to help frame the reasonable uses of the findings.
Professions can have radically different work habits and timelines. A person from a profession that typically works from loosely sketched principles may find it difficult to collaborate with a group member from a profession that traditionally makes detailed plans (Magnus & Kalichman, 2002). Further, some professions may be flexible in their ability to shift dedicated time when needed, whereas others may be grounded in a fixed schedule and be reliable in their productivity, but less able to dedicate time on short notice.

Finally, authorship and presentation conventions, rules, and policies differ across professions and disciplines. This topic is covered in greater depth in the Publications and Authorship units of this curriculum, but it bears mention here. At the extremes some professions or disciplines think that each participant owns an individual research question, whereas others see all questions as owned by the group. Members of professions or disciplines that believe in individually owned questions may expect to publish or present independently and on their own schedule. Members of professions or disciplines at the opposite extreme may expect the group to work as a whole and all collaborators to participate in shared decision making regarding dissemination, and shared authorship in the work.

Cultural issues between industry and academia: These collaborations typically involve people from differing disciplines and are therefore likely to have all of the problems already noted under interdisciplinary issues. In addition, these collaborations involve at least two differing cultural perspectives on information. Academic research (that is, research by faculty and students) is grounded in the assumption that information should be broadly shared, whereas industrial research historically is grounded in the understanding that information is proprietary, to be kept for the specific manufacturer’s private use and benefit. Thus, academics are likely to value transparency and disclosure of study methodology and outcomes, whereas industry participants may be uninterested in or even prohibit these disclosures, to ensure secrecy of the details about their products.

Neither of these views is more ethical than the other. They simply represent a difference in cultures. Historically, academic research has examined a phenomenon or a question without a plan for a practical product, whereas industry has been more likely to expect research to translate into a product or a product improvement. With the Bayh-Dole Act of 1980, academic institutions are allowed greater control of intellectual property produced by their faculty. They are therefore able to benefit financially from patents and licenses (Columbia University, 2003–2004). This financial benefit, accompanied by reductions in other academic financing, has encouraged America’s universities and colleges not only to participate in collaborations with industry, but also to seek them actively.

Cultural issues between communities and academia: In addition to raising the issues already discussed under the other types of collaborations, community research collaborations bring special issues. They often involve communities that are underserved, feel unempowered, and have a history of abuse by society’s
powerful elements (Community-Campus Partnerships for Health, 2004). Therefore, it is crucial that collaborators identify and address issues of privilege and power (Community-Campus Partnerships for Health, 2004). For example, titles and status commonplace at the university (researcher, professor, etc.) may contribute to a perception of an unequal relationship, impairing a collaborative effort. Experienced community collaborators suggest that all members of community research collaborations be addressed using titles of equal status (e.g., Mr., Miss, Ms., or Mrs., or first names) (Catherine Jordan, personal communication, April 14, 2005).

There are also likely differences of culture between academia and the collaborating community. Experienced community collaborators emphasize the need to talk openly about each culture and to discuss explicitly the different norms of emotions, timelines, and tolerance for or valuing of storytelling. True community collaboration requires extensive discussion and shared experiences. Thus, experts in the field suggest months and perhaps years of connected and shared experiences, including those that form more personal bonds, such as storytelling, meals, and celebrations (Catherine Jordan, personal communication, April 14, 2005).

**Enhancing Collaborations**

Clear and open communication is a critical element in any research collaboration. As a group develops a common language, all members should clarify and validate the meanings of the terms being used. Communication is especially key if the collaborators have a history of turf battles, as may be present in interdisciplinary research, or oppression, as is commonly present in community research.

Communication is complicated when it relies on telephone or e-mail, media in which language subtleties and lack of visual cues can lead to misinterpretations. Special efforts should be made to encourage the use of best-practices in these contexts. For example, the collaboration might wish to agree to use a set of previously agreed upon terms, to never use special formatting that could be misunderstood in email, and to forego sarcasm or jest when communicating in writing.

Methods for decision making and conflict resolution should not be left to chance. Each collaborative group should develop explicit guidelines before problems arise. Once established, these should not be altered without group discussion. A collaboration that uses majority rule for its first few decisions is not likely to do well if the principal investigator arbitrarily replaces it with autocratic decision making the first time there is a split-vote across options.

Many community research collaborations require consensus decision making. This requires that all partners must agree to an action before it can be taken (Community-Campus Partnerships for Health, 2004). This effectively gives veto power to any single member and can create long discussions and periods of inaction. But it also expresses a
philosophy of shared leadership and ensures that all actions are supported by the collaborative group as a whole (Catherine Jordan, personal communication, April 14, 2005).

As soon as the research is designed, collaborators should discuss who will do what, when they will do it, and how it will be assessed. Each time the research tasks change or collaborators enter or leave the group, group members should reexamine and discuss their current understanding of tasks, roles, and responsibilities, and explain the reasons for their self-interest (Columbia University, 2003–2004; Shamoo & Resnik, 2003). This process goes beyond simply disclosing conflicts of interest. In community collaborations, academic and community members may have different cultural requirements and motivators. For example, academic members may expect the research project to assist them in their yearly salary review and toward tenure or promotion. Understanding these self-interests can clarify the reasons for participation and ensure that the collaborative group works as a whole to meet both the group’s and individual members’ goals (Catherine Jordan, personal communication, April 14, 2005).

At the start of any collaboration, the participants should establish the methods of data storage, management, and ownership, as well as ownership of the final products (if there are to be any). This is especially important in collaborations with industry. Funded studies should have a written contracts clarifying ownership of the study data and the product (Columbia University, 2003–2004; Shamoo & Resnik, 2003).

It also is wise for all members of a group to understand and agree on the ways in which information and materials (e.g., methods, data, and products) may be shared with outsiders (Macrina, 1995, Shamoo & Resnik, 2003). Some groups put formal agreements in writing to ensure that there is no confusion on this issue. This is especially important in industry-academia collaborations, in which sharing materials for noncommercial purposes may be acceptable whereas sharing them for commercial purposes may not be. In most cases, when materials are shared, the person or the institution receiving them must formally agree to make no further distribution.

Authorship can be a particularly thorny issue, and it is wise for a collaborative group to discuss authorship early in its efforts. To ensure prompt analysis and dissemination, some collaborations vote on who will have first authorship as data become ready for analysis (Bob DeVellis, personal communication, n.d.). That group member then has a specific amount of time to distribute a draft to all. If he or she is unable to do this, first authorship is brought back to the table, and the group either awards it to another member or allows it to be retained by the original collaborator for a newly specified amount of time. Other collaborative groups assign authorship or acknowledgment at the start of the project and reassess these assignments as people leave or join the group or as the research changes. In interdisciplinary collaborations, members should discuss and clarify professions’ customs for determining authorship and agree on the rules that will guide their mix of disciplines.
In community-academia collaborations, the whole group should share credit for all accomplishments. Academics tend to be sought out as public authorities on a project, and university and college public relations offices may emphasize the academic contribution over the community one. Community-Campus Partnerships for Health (2004) suggests that “community partners . . . be involved in developing the publicity, as well as in sharing the credit” (p. 65). This means that at each point in the wide range of dissemination, the community collaborators should be part of the authorship team. Involving all partners in this way ensures that all collaboration members share credit and responsibility and that the interpretation of findings reflects community as well as academic viewpoints. This requires that all dissemination from press announcements to formal papers, be reviewed and approved by all group members.

Finally, collaborations have some inherent risks. In most collaborations, researchers are treated with trust and supervision is rare. Thus “collaboration can leave a scientist vulnerable to the actions, or inaction, of his or her collaborators” (Magnus & Kalichman, 2002). Institutional oversight usually focuses on assuring financial obligations. These measures, such as verification of paid time (i.e., investigator effort surveys) and reports to contracts and grants offices, do not provide enough detail to establish whether a collaborative partner is meeting obligations for productive work. To avoid problems, collaborative groups should establish internal methods of review and hold members to timelines, proof of action, and standards of quality.

References
Promoting Integrity in the Next Generation of Researchers

COLLABORATIVE SCIENCE

Community-based Participatory Research

Large Lake County is a rural environment with a single high school serving four townships. The county recently had three fatal teen automobile accidents. The accidents all involved risky driving and alcohol. Five students died.

Chenoa Bo is an occupational therapist earning a PhD in rehabilitation sciences. She originally lived in this community and sees her research interest (risk taking in driving) as a way to help the community gather data on this issue. She asks the school board to work with her to develop a research project measuring county teenagers’ risk taking levels and behaviors, to see if these general risk taking measures can predict sober risk taking driving behaviors in driving simulation. The school board sees Chenoa’s offer as an opportunity to gain a clearer idea on all risk taking, and to help them design a risk management curriculum. In collaboration, they form a school research group composed of Chenoa, three members of the school board (all drawn from the largest town in the county), the superintendent of the school district, the principal of the high school, and two high school teachers (one health teacher and one biology teacher).

The school research group helps design the study and plans how results will inform curriculum development at the school. Chenoa chooses the study measures. Among the measures of risk taking behaviors and decision making, Chenoa plans to use a risk-assessment questionnaire developed on teens from urban, suburban, and rural settings in another region of the US. It asks participants to rate their likelihood of performing an act and the act’s level of risk to health or safety, regardless of whether they would or would not perform the act.

Chenoa spends a lot of time on the high school campus. She answers questions about the driving study at teacher meetings and student governance meetings. The project has great support. Over 80% of the students and students’ parents return signed consent forms agreeing to participation in the study as described above.

To ensure that the 50-item risk-taking questionnaire is understandable by these teenagers, Chenoa asks 6 students to review the survey and to write comments on the statements that are unclear or that they feel may not be understood by their peers. They are not asked to respond to the statements. The questionnaire includes multiple items under each of five categories: sex, drugs, alcohol, criminal behavior, driving. For example:

SEX: “Have genital sex without a condom.”
DRUGS: “Buy drugs from a stranger.”
ALCOHOL: “Buy alcohol using a false ID.”
CRIMINAL: “Take an item from a store without paying.”
DRIVING: “Drive your car while you are very tired from lack of sleep.”
Each student has written permission from his/her parents to participate in the original study, and would have encountered these items during that participation.

A week after this examination of the questionnaire, Chenoa receives an angry telephone call from the high school principal. He tells Chenoa that the school has received calls and visits from the parents of the 6 pilot students and from 22 other parents who have heard from their sons and daughters about Chenoa’s “obscene” test. Some of the 6 students were offended and confused by the survey’s graphic descriptions. They discussed their experience with their peers. One parent noted, “I don’t need my daughter getting the idea that these things are OK and done by her peers!” Another complained, “What does sex and stealing have to do with driving drunk?” The principal tells Chenoa that the study is over, that she cannot return to campus, and that he will inform the rest of the research group. Chenoa is devastated.

**Student Questions**
1. How would you describe the current problem facing this community-based participatory research project?
2. What actions should Chenoa take immediately? Who should these actions involve?
3. Community-based participatory research assumes community investment. Were there people or types of participation that were missing from this case that might have prevented the problem?

**Discussion Points**
Community-based participatory research is grounded in principles of trust (built on the foundation of a solid and well-tended relationship), shared mission and values, excellent two-way communication, meaningful inclusion of all stakeholders, and shared decision making. Chenoa did several things right. She invested time at the high school and tried to build relationships with administration, teachers, and students. Some aspects of decision making were shared among the members of the school research group, such as the overall design and potential application of the data. Some aspects of communication were good, for instance, Chenoa met with teachers and student governance and various important members of the school community.

However, the project fell short of the principles in ways that contributed to the study’s problem. The central ethical issue in this case study revolves around the risk-taking measure and its appropriateness for the community cultures. Chenoa failed to abide by the interrelated principles of communication, stakeholder representation, and shared decision making. If Chenoa had communicated her desire to use this risk-taking measure to a school research group with broader stakeholder representation, including parents and students, and had shared the task of deciding whether to use the measure, then the student and parent reaction to the risk taking measure might have been anticipated or avoided. It is unclear whether the research group reviewed the questionnaire or simply heard a description. Seeing the questionnaire would have helped the group give informed input, and would have ensured shared decision making. The group should also have
included a faculty advisor from Chenoa’s university. Someone with experience in working with communities may have helped anticipate and avoid potential problems.

At this point in the case, Chenoa should voluntarily stop her research, engage in serious reflection, and demonstrate insight. Her first step should be to inform her institution’s Institutional Review Board and consult with her faculty advisor. Chenoa should ask for the opportunity to speak with the school research group, and use that opportunity to admit her mistake and apologize. She should also apologize in writing to the parents and students. Chenoa might request permission to talk with all stakeholders to ask if they would be willing to continue a dialogue with her to help understand what went wrong and what could have been done differently.

Chenoa’s genuine display of regret, willingness to learn from community members, and concern for the teens in the community might begin to repair the broken trust. Chenoa might then be able to ask if stakeholders would reconsider working with her if the shortfalls described above are corrected. It is possible that Chenoa’s efforts to restart dialogue will fail, or that the dialogue will not repair the trust to the extent needed to reverse the principal’s decision. In that case, Chenoa needs to accept this decision and terminate the relationship with the school community respectfully. This will leave the door open for future collaborations between the community and the university.
Promoting Integrity in the Next Generation of Researchers

COLLABORATIVE SCIENCE

Participatory Action Research

Carmen Washington is a new graduate occupational therapist with a disability, who works in a large inpatient rehabilitation hospital program that actively encourages research. She frequently works with clients who are making decisions about their post-discharge living situation, including whether to live in the community, assisted living or a nursing home. As part of her professional education, Carmen worked as a research assistant in a participatory action research (PAR) project with disability and aging organizations that supported people who wanted to move out of institutions and into community settings.

Based on feedback from past clients, Carmen’s hospital starts a consumer advisory board (the Board) to help make the hospital’s services and research more consumer directed. Carmen serves on the Board as both a person with a disability and an occupational therapist, and is considered their Board consultant on research. The Board decides to conduct a small qualitative study examining past rehabilitation clients’ experiences in community integration. They hope that the study will outline strategies to improve consumer input and participation in community re-entry. The project receives a small amount of funding from a private foundation to pay data collectors.

Most of the Board members have never participated in research, so Carmen outlines the different roles in the research process, and discusses the need for community members to take active roles throughout the research process. The Board members are excited about the idea. This changes somewhat when Carmen informs them that the hospital requires that any person gathering, entering, or analyzing research data go through the Protection of Research Participants training offered by the hospital’s Institutional Review Board (IRB). Several Board members express their unwillingness to take this training. They characterize this training as “system bureaucracy” and argue that such training is unnecessary because their research is “by disabled people, about disabled people”. Other members of the Board are interested in the training, but view it as an obstacle to participation because the Board has representatives with cognitive impairments, and the training is specifically not adapted for them. They argue that anything that divides the group into “those able and those unable” to perform the research undermines the philosophy of the Board.

Attempts to gain compromise are unsuccessful. One Board member suggests that those who want to help gather data or review study data could have the training and those who do not could have access only to findings. This does not satisfy the majority of the Board who want all Board members to have access to both the data and to the paid employment associated with data collection. Some Board members suggest that the Board separate from the rehabilitation hospital and conduct the research independently, without the “bureaucratic oversight” of IRB or others.
Student Questions
1. The Board’s argument that they do not need IRB training is based on issues of power, control, solidarity/inclusion, and assumptions about the level of risk involved.
   a. How could Carmen respectfully strategize these issues without being perceived as trying to control the study?
   b. How might training be made more accessible and more acceptable for the Board?
   c. Should all Board members have an equal right to access to the data? Why?

2. What do you think of the suggestion that the Board withdraw from the auspices of the hospital? Does it resolve the problem? Create new problems?

3. Issues related to privacy and confidentiality are very likely to arise when working on a participatory action research project with community members. These are complicated by issues of cognition and ability to respect and maintain confidentiality. What protections could decrease or minimize these risks in the current case? What are the risks involved and what would represent reasonable risk, that is, risk defined as less than minimal? In what way, if any, is this different for PAR research than for other research studies?

Discussion Points
Action research in collaboration with or as led by people with disabilities, is complicated by the fact that these collaborators may or may not have research experience. This complex collaboration typically brings up a number of ethical issues, including:

Informed consent Students should be considering whether informed consent is needed and why it is important regardless of whether the community believes it as important or relevant. Looking at the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979) grounds this discussion and brings up issues such as do no harm, and ensure benefits outweigh risks and that research is done for the good of the participants, not the researchers, even when a researcher may come from within the community itself (in this case Carmen is also a person with a disability). Offering private IRB training specifically for the Board could allow the training to emphasize the most relevant issues to the research and to the Board members by highlighting past violations of participants’ rights involving persons with disabilities. This may help bring community members into the process more readily when they see the overlap with their own commitment to civil rights and justice.

Working closely with the local IRB review committee often helps to strategize how to make IRB training more accessible to people with cognitive disabilities. This includes improving the training access to meet different needs (physical,
sensory, cognitive, etc.). It may also include creating a separate version of data results that is easy to understand, a type of brief highlighted information guide that can be shared and easily discussed. It may also involve sharing data results in focus groups with members with cognitive impairments as member checks so the data is accessible, while at the same time confidentiality of the participants is respected.

**Privacy and confidentiality.** Frequent reiteration of clear ground rules related to privacy and confidentiality can help to decrease risk, as might discussions to gain greater insight of the risk of unintended disclosure of confidential information.

Risk to confidentiality can also be limited by sharing data after personal identifiers have been removed and IRB training completed. This gives the community access to original source data rather than just interpretations.

Issues of power, control, and ownership often arise in PAR. Discussing how action research is based upon premises of power and control from within the community, and how that may conflict with or challenge informed consent protections may bring to light the complexities of this type of research. Discussions will also bring up the grey areas of informed consent (e.g., no single correct answer, instead a reflective analysis of risk and benefit) and reinforce that the ultimate decision should be weighted toward the participants’ interests, not the researchers.

**References**
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COLLABORATIVE SCIENCE

Data Ownership

Camilo Montoya is a recent PhD occupational therapy graduate who is now teaching at a university far from the one where he did his doctoral work. Camilo conducted his doctoral research with Dr. Simcha Kim, studying the effects of volunteerism on the self-esteem and quality of life of elders with chronic physical disabilities, and the contributing constructs and contexts associated with their most meaningful experiences. The work was funded by a grant co-authored by Dr. Kim and Camilo. The project involved 50 participants and produced interesting outcome measures as well as an innovative model explaining those outcomes. Before Camilo left for his new job, he and Dr. Kim agreed that Dr. Kim would serve as second author when the dissertation was ready for publication.

Ten months after his defense, Camilo sends Dr. Kim the manuscript for the major article based on the dissertation. Dr. Kim tells Camilo that she and a “brilliant new master’s student” have continued gathering data and that the database now has 70 participants. Based on the enlarged database, the master’s student is working on a slightly different model than the one that Camilo and Dr. Kim initially proposed. Dr. Kim characterizes it as “premature and irresponsible” to publish Camilo’s findings from the smaller sample when a larger sample may offer slightly different findings and a “more refined model”. Camilo does not want to wait and believes that the original 50 participants afford a reasonable publication that contributes to the body of knowledge. He suggests that the work be described as “preliminary or pilot”, but that they continue with their original plan to publish the work.

The disagreement between Camilo and Dr. Kim becomes increasingly heated as they each assert and reassert their viewpoint. The final word from Dr. Kim is “The data is shared, and you can’t publish until we both agree that it’s ready.” The final word from Camilo is “It’s my database and my dissertation, and if you don’t want to be co-author I’ll publish it on my own.”

Camilo finishes the manuscript, and it is accepted for publication after two peer reviewers characterize it as “a strong, if preliminary, work”. Hearing of the acceptance, Dr. Kim contacts the journal and makes the following arguments to the editor:

- The work is collaborative, and therefore Camilo doesn’t have the right to publish it without the approval of the data’s second owner. She characterizes Camilo as having “gone behind her back”.
- The work is incomplete and could mislead the public. She argues that the journal should wait for a report on the complete dataset, with the “more interesting” model that the new student may propose.
• Even if she is not listed as an author on Camilo’s article, her colleagues will naturally associate it with her based on the topic and the institutional listing. To protect herself from this unwanted association, she should have the right to withdraw the paper from publication.

The editor doesn’t know what to do.

**Student Questions**
1. How can the editor act responsibly?
2. Do either of the parties (Camilo or Dr. Kim) have a more ethical claim to their viewpoint and behavior?
3. Were there turning points where different decisions or behaviors could have potentially avoided the problems in this case?

**Discussion Points**

*Note that as soon as we identify Camilo by his title, he takes on the same authority as Dr. Kim – a point not present when we refer to one by first name and the other with title.*

From the editor’s viewpoint, there are two questions that need to be addressed. The first is, “Is there a problem with the journal’s peer review?”; and the second is, “Does the article represent legitimate responsible research?” To determine the former, the editor must know if Dr. Kim heard about the article from one of the journal’s reviewers. If so, there’s a problem in the journal’s peer-review system. Let us assume that the peer-review process was confidential and that Dr. Kim learned of the article’s acceptance from a current colleague of Dr. Montoya/Camilo. The editor can therefore move to the second question and deal with the disposition of the article.

It would be inappropriate to suppress a legitimately researched, peer-reviewed work, based on the personal arguments of even a credible person. It would be similarly irresponsible to knowingly publish a work that violated rules of responsible research. This would include publishing a work in which:

- the human rights of the participants were not protected,
- the data were fabricated, falsified, or illegitimately accessed by the author,
- the analyses were intentionally misrepresented or seriously in error,
- the writing was plagiarized,
- the conflicts of interest were falsely reported,
- authors who should be listed were involuntarily excluded or those who should not be listed were inappropriately included, or
- conflicts of interest were falsely reported.

Dr. Kim’s major argument is that Dr. Montoya/Camilo doesn’t independently own the data and therefore cannot publish the results without Dr. Kim’s permission. In the current case, Dr. Kim is withholding permission because she believes there is better work to come. Does she have the right to place this roadblock for this reason? No.
It is typically stated that the university “owns” any study data gathered under its auspices. This rule is generally interpreted as meaning that the university has a right to keep a copy of the work, and that others who have made important contributions to the work may also keep a copy and continue to work with the data as appropriate. So, Dr. Montoya/Camilo has the right to see his dissertation work through to publication, in spite of Dr. Kim’s objections, and Dr. Kim has the right to expand the database and publish new findings off of the growing resource. Indeed, although both researchers would need to clarify how the databases overlap and how they diverge, both Dr. Montoya and Dr. Kim can continue to use and expand the database that they originally created together. The argument for shared ownership is strengthened by Drs. Kim and Montoya’s collaboration for funding, but even if Dr. Kim were the sole financial support of the work, it is still likely that a university would consider that Dr. Montoya’s work on the project was worthy of shared ownership of the original database.

Students may want to discuss potential reasons for each party’s position. Dr. Montoya/Camilo may need closure regarding his dissertation. He may feel that Dr. Kim’s choice of the expanded database and its new interpretation will deny him a reasonable right to first authorship for his doctoral work. His new job may place him under pressure to publish within his first year of work. In addition, perhaps Dr. Kim has a history of running good studies, but not following through on analysis and publication. If this were the case, it could Dr. Montoya/Camilo to question whether this new and improved work will ever even come to fruition. Although Dr. Kim was ill-advised to try to suppress the findings by going to the editor, it should be noted that she may be genuinely concerned about the confusion that could arise from several publications with progressively different results and models. In addition, she may also genuinely believe that the pragmatics of author order or even publication are secondary to rigorous search for answers.

Like so many issues in responsible research, much of both the emotional and ethical issues of this case could have been tempered by open communication and education. Dr. Kim should have informed Dr. Montoya that she planned to continue gathering data on the topic, and addressed the issues of other students’ involvement. Dr. Montoya should have informed Dr. Kim that he was in the process of readying the work for publication, to keep that investment active.

This case is based on a real occurrence in a non-health field. In that case, a post-graduate student left an institution after professional and personal conflict with his advisor. The ex-student kept a copy of the data that he’d gathered. No one continued his study. The ex-student wrote an article, and sent the article to his ex-advisor as co-author, and the ex-advisor refused to co-author, citing the preliminary nature of the work and the limitations of the evidence. The ex-student completed the article and it was accepted for publication, with the ex-student as sole author. The ex-advisor was then contacted by the journal (although the reason for that contact is not clear in the reports) and moved to suppress the article’s publication. Efforts at arbitration failed. Although the editor initially delayed publication hoping to resolve the issue, he or she ultimately decided that there were no grounds on which to suppress the article. The journal published the article along with an
addendum explaining that the advisor and his research group did not approve of the paper as published. This alternative allowed the ex-advisor to gain public distance from the ex-student’s work while allowing the readership to judge the research study’s merits. What do your students think of this real-life outcome? (To read current information about the case, search the Internet under the names of the post-doctoral student, Peter Schwartz (at California Polytechnic State University, San Luis Obispo at the time of this writing) or the advisor, Chad Mirkin (Northwestern University).