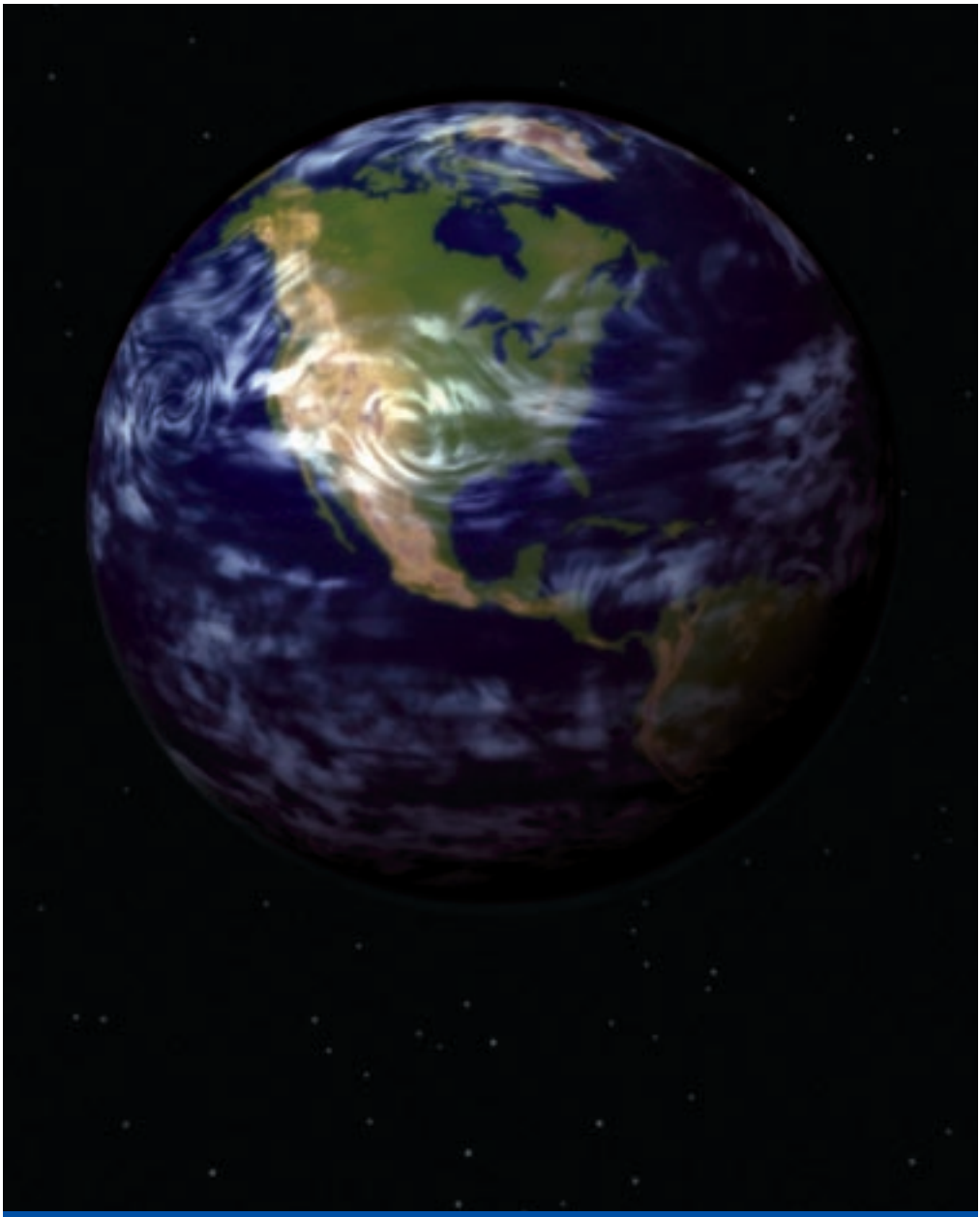

A Guidebook for Teaching Selected Responsible Conduct of Research Topics to a Culturally Diverse Trainee Group

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Chapter 1
Introduction and Background

Chapter 1: Introduction and Background

Of the 52,000 postdoctoral fellows (postdocs) at U.S. institutions, more than 50% hold temporary resident status in the U.S[1]. Because the 1990 PHS requirement for Responsible Conduct of Research (RCR) education does not extend to foreign national postdocs (who are not eligible for training grants), and a significant percentage of institutions do not provide RCR training beyond this NIH trainee group[2], it is reasonable to assume that foreign postdocs are not obtaining adequate instruction in this area. The National Academy of Science has called on institutions to begin addressing the needs of this group[3]. At the same time, Swazye and Bird suggest that social and cultural factors be considered in the teaching of research ethics[4]. Interestingly, several highly publicized incidents of scientific misconduct involved foreign nationals[5,6]. Recognizing that attitudes and behaviors which are culturally based might contribute to such cases, the Japanese government has been sponsoring seminars to educate U.S.-bound trainees on how to navigate U.S. laws on intellectual property, conflicts of interest, data management and authorship[7].

The rationale for developing this guidebook was to address the training needs of this large subgroup of international postdocs, making use of information gathered from focus groups comprised of postdocs from various countries. It was anticipated that the focus group method would be particularly well-suited to:

- exploring ethical ambiguities from a cultural perspective and identifying beliefs, attitudes, values and behaviors that could impact interpretation or acceptance of institutional standards and guidelines;
- stimulating discussion about patterns of scientific practice across cultures and increasing sensitivity to cultural differences;
- using the case-study approach and setting institutional norms and best practices for selected RCR topics (data management and ownership, intellectual property and research misconduct);
- achieving consensus on institutional guidelines for responsible research behavior.

With these goals in mind, we developed materials for these group sessions that could serve as model process and content for RCR instruction of international trainees. We then conducted eight focus group sessions at our institution [The Joseph Stokes Jr. Research Institute at Children's Hospital of Philadelphia (CHOP)] with the help of consultants expert in both diversity and focus group methodology. The groups allowed us to simultaneously pilot the materials, collect valuable information, and educate the postdocs on an RCR topic. Based on our experiences conducting the groups and the feedback from the participants, we then improved the teaching materials. This guidebook includes a summary of themes that emerged during the groups (Chapter 2); a script for facilitation of small group discussion and teaching points distilled from the focus group sessions (Chapter 3); and the final teaching materials (surveys, cases, discussion questions, suggested hand-outs) for the topics of data management, intellectual property, and research misconduct (Chapter 4-6).

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Chapter 2
Summary of Results from RCR Focus Groups

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Focus Group Methodology

The Children's Hospital of Philadelphia (CHOP) has over 100 Ph.D.-trained postdoctoral fellows working in clinical and basic science research. Of these, approximately 20 were supported by NIH training grants at the time of this project and were already participating in a mandatory program of RCR instruction along with their NIH supported M.D.-trained counterparts. In the winter of 2003, the 84 postdocs that were supported by PI grants (R01s, etc.) and not receiving any formal RCR instruction were asked to attend a single, two-hour group discussion on responsible research behavior. The scheduling process yielded eight groups with eight to thirteen participants per group, for a total of 79 participants. Each group discussed one of three topics: Data Management and Ownership (3 groups), Intellectual Property (2 groups), and Research Misconduct (3 groups). The topic to be discussed was not made known to group members in advance.

Sixty-nine percent of the participants were in their first or second years as postdocs at CHOP, with the remainder in years three or four. The majority of the participants (68%) were foreign nationals holding a visa; 23 countries were represented. Over half of the participants received their doctoral training outside of the U.S.: Western or Eastern Europe (11); Asia, non-Indian (20); India (5); South America (4); Middle East (4); Canada (2) and Australia (1).

All focus groups were held in a conference room at CHOP and facilitated by an external consultant who was completing her Masters degree in Law and Diplomacy (with a thesis on the Chinese Diaspora). A note-taker was present at each group, as was one representative from our Research Education Department. At the beginning of the session, each participant was asked to complete a very brief (4-8 item) anonymous questionnaire on the discussion topic. The format and facilitation process used for all sessions is described in full in Chapter 3. Each session generated approximately 15 pages of typed notes.

Themes

The content of each session was first analyzed for themes pertaining to postdoctoral fellows and RCR generally. These themes, presented below, emerged across groups and are therefore not specific to any one of the three RCR topics selected for discussion (i.e., data management, intellectual property or research misconduct). For the purpose of this summary, content that overlapped themes was placed into one category only. If not otherwise indicated, a statement reflects consensus opinion/sentiment in that the group as a whole endorsed it. An opinion expressed by one or only a few of the participants is identified as such. *It is important to note that in the course of the discussion, group members reflected on their entire postdoc experience.*

A second review of the session content focused on themes that were specific to the RCR topic under discussion. These are presented as teaching points in Chapters 4-6.

International issues

- Some European countries have a culture of more casual sharing and scientists rely on their relationship with colleagues, rather than contracts, to facilitate collaboration; to individuals from these cultures, U.S. research institutions have a corporate feel.
- Laboratory roles differ from country to country (e.g., Ph.D.s in China do not rely on technicians to assist them; postdocs in Europe are not as autonomous as those in the U.S.).
- The apprenticeship role is embraced in Europe, and there is less pressure to publish and obtain own grants.
- Some international postdocs find it hard to adapt to working in the U.S., but feel that they are here to learn and must be open to new ideas.

- International postdocs face significant language barriers, especially in written expression, but also in communicating with mentors. For example, a number of postdocs prefer to record in their native languages in lab notebooks. While few have received guidance about this, there was consensus that they should be recording in English, even at the cost of efficiency. They thought about whether day-to-day communication within the lab setting should always be conducted in English and generally agreed that it should.
- Postdocs do not observe many inconsistencies in research practice between U.S. and native countries related to data management, intellectual property, and research misconduct (e.g., most countries have rules surrounding transfer of technologies).
- They wonder what rights they have to their ideas and research results if they need to return home – will they be able to continue their work?
- Good Laboratory Practices (GLPs) are followed in some countries, and not others.
- Some international postdocs find it hard to challenge or question their mentor or certain practices within the lab and this stems, in part, from worries about their citizenship status – would they have the courage to act as a whistleblower if the situation demanded it?
- International postdocs feel somewhat intimidated by the legal and corporate environment with an emphasis on the bottom line, and express some resentment. They ask: Do countries that have more written laws or more clearly defined concepts of property actually have more rights than countries without such laws? Do the latter countries forfeit their rights simply because they have a different culture?

- They do not support separate training sessions for international postdocs, stating that one cannot assume that American postdocs understand the rules any better than international postdocs…they need the same information and need to follow the same guidelines.
- They believe that there are issues that pertain specifically to international postdocs, but RCR is not one of those issues. There is strong consensus that, for many reasons, U.S. postdocs need to be made aware of the issues facing international postdocs, not the least of which is that they may one day be mentors to postdocs from other countries.
- Some foreign-trained mentors are viewed as having a better understanding of local rules than U.S.-trained mentors, because they "had to learn it themselves"; they are also viewed as more sensitive to the needs of international postdocs.

Mentoring

- Postdocs rely on their mentors to establish rules, set expectations, standards and practices, and to teach anything relevant to responsible research behavior.
- Postdocs understand the importance of full and honest communication with their mentors about a wide range of concerns related to RCR, but find it difficult to speak with them about certain issues.
- Mentors typically assume and expect that postdocs have had prior RCR instruction and do not always provide it, even informally (e.g., no one recalled receiving guidance specifically about omitting data in presentations or publications).
- Mentors need training in RCR and need to know all the institutional guidelines so that they convey them to their postdocs and other members of the research group.

- Postdocs believe that it is the responsibility of the mentor to ensure that the research group acts responsibly and that the data has integrity.
- Mentors should lead by example; they are trusted to do the right thing, yet postdocs also realize that mentors might not have the necessary training in RCR.
- Postdocs see themselves as future mentors.

Having institutional guidelines

- Neither the U.S. nor non-U.S. trained groups had much prior exposure to guidelines for RCR.
- Postdocs like the idea of having guidelines and can see their potential value, but wonder about the practical implications, (i.e., would they be "rules" or "guidelines"; how would they be enforced; would they set an unachievable standard; and what if one is caught between a guideline and a mentor practice?)
- They observe that practices and norms differ from lab to lab, discipline to discipline, institution to institution, and question whether it was possible to develop uniform standards.
- Postdocs identify the following potential benefits of guidelines:
  - ✓ Increase awareness of institutional rules and help navigate local systems
  - ✓ Serve to confirm or validate the wisdom they have received from their mentor
  - ✓ Can promote collegiality by establishing norms – "can help people get along"

- ✓ Would be very useful for postdocs who act in a mentor capacity to technicians, graduate students, etc.
- ✓ Can help to resolve ambiguity
  It was pointed out that written guidelines might be most beneficial to international postdocs, where communication barriers and/or cultural interpretations create the potential for misunderstanding.

- Postdocs suggest that any guidelines developed should:
  - ✓ Be based on common sense and a standard of reasonableness.
  - ✓ Be discussed between colleagues/peers; they emphasized the difference between *knowing* the rules and *interpreting* the rules.

Written vs. "unwritten" rules and practice

- The typical experience is for postdocs to learn about RCR related issues on the job and from prior work experience, without formal instruction.
- They rely on common sense and good judgment to tackle ethically difficult or ambiguous situations.
- Practices should be based on the principles of reasonableness, courtesy and common sense.
- A few countries require postdocs to sign contracts referencing their rights (of ownership, etc.) and rules, but most do not.
- There are definitely lab traditions and a process of socialization into these traditions; policies are inferred from the way one works in the lab; guidelines may be taught informally.

Training the incoming postdoc

- The preferred training method for RCR is small group discussion using cases. It allows for each member of the group to contribute and be heard.
- Discussion groups are important for uniform interpretation of any existing rules and policies.
- There is some difference of opinion as to whether there should be distinct and separate training for clinical and basic researchers; some feel it would be more effective, while others disagree.
- Written guidelines can be an important resource and should be distributed or available on-line as a supplement to group discussion.
- RCR training can be incorporated into an orientation, but this should only occur after the postdoc has spent time in the lab; it is important to connect RCR topics to daily real-life experience.
- Mentor training is critical since mentors are responsible for communicating guidelines/standards/practices to postdocs; institutions should not expect that a knowledgeable mentor will communicate this knowledge to their postdoc.
- Mentors should also have case-based training to facilitate their own subsequent discussions of responsible research behavior with their postdocs.
- Mentor training should occur separately from postdoc training: a few postdocs mention that they would value instruction from a non-mentor perspective, while most of them feel that postdoc-only training would increase active participation on the part of postdocs.

- The optimal format might vary by topic or content. For example, the postdocs had little prior exposure to technology transfer but feel that it is pretty "cut-and-dry" and that a handbook or on-line material would be sufficient.
- One postdoc stated that the type of training should mirror the organization's culture, i.e., a top-down organization might provide very formal, structured training conducted by top faculty and administrators.

Challenges

- In almost all the groups, one or more postdocs express some difficulty reconciling their interest in science and advancement of humankind with the need for restrictions in sharing (tech transfer), limitations on collaborations, the politics of funding (especially in hot fields), and the hassles of negotiating system hierarchies.
- The position of postdoc as neither a student nor independent researcher leads to some uncertainties regarding responsible research behavior: Just how far does the responsibility of the postdoc extend? It is often difficult to determine roles and responsibilities in the lab. For example, are senior postdocs responsible for the behavior of junior postdocs?

Other Opinions

- Postdocs learn over time that a big part of science is establishing networks.
- They realize that the relationship with one's mentor and lab colleagues is critical to a good postdoctoral experience.

Facilitator observations of group process

Group facilitators and note-takers (six in all) provided their observations of the group process. The primary facilitator was present at all group sessions and a second facilitator was present for two of those sessions. Each notetaker attended at least two sessions.

- The participation level of each group varied, depending on the personalities in the group, and whether group members knew each other. It appeared that the greater the number of international postdocs relative to the number of U.S. post-docs, the greater the participation – perhaps they felt more comfortable. And foreign postdocs who had trained in the U.S. seemed more comfortable sharing their experiences, as did those who had been postdocs for a longer period.
- The presentation of draft guidelines was effective in facilitating discussion. Group members seemed to feel more comfortable sharing once the guidelines were in hand and they had something to which they could react.
- Facilitators were surprised that postdocs felt so dependent on their mentors for information and instruction; at times, they detected a sense of powerlessness.
- An on-going (i.e., semester or year-long) small discussion group would be a very effective teaching method; membership in the groups does not have to be the same from session to session; it is the experience of being in such a group that matters, not familiarity with other members.
- If a larger group is more feasible, smaller breakout groups could be used to discuss cases after presentation of institutional guidelines or standards.
- Sessions two hours in duration may not be long enough for in-depth discussion of any one topic, but it seemed to be the right amount of time from the participant perspective.

- Groups ranged in number from 8-13; within that range, the size of the group did not seem to matter.
- Cases do not have to be lengthy to be useful – they can be as brief as two sentences.
- Total number of cases per session: two (plus mini-cases) seemed to be just right.
- Though a script had been developed for each session, the facilitators did not feel constrained by it; they were able to adapt it to the needs of each group.

Conclusions from Focus Group Process

Many and varied opinions were expressed during the eight focus group discussions, but there were more points of consensus than disagreement, within and across groups and topics. It appears that though international postdocs face many special challenges in research institutions in this country, their RCR training needs are identical to those of their U.S. citizen counterparts. Both groups have depended largely on individual guidance from their mentors on these matters, and both have found this guidance wanting. Perhaps as a response to this situation, postdocs tend to look favorably on the concept of written RCR guidelines, but question the logistics of their development and implementation. The groups endorsed small group discussion as the preferred format for RCR instruction.

Group dialogue sometimes took unanticipated but welcomed turns, usually toward more abstract consideration of personal and professional values. The topics of intellectual property and data ownership, for example, stimulated lively discussion about the tension between science and commerce, and about the potential for infringement of academic freedoms. There was also concern about the exportation of Western values to international collaborators: would it be forced, and could or should it be resisted by non-Western or third world countries? Questions of global responsibility in a global research environment were raised. Though the groups sometimes meandered off topic, (thus borrowing group time from more mundane matters), exploration of these issues served to enrich and enliven the discussion.

Regardless of topic, there was much focus on mentorship and the quality of the relationship between mentor and postdocs. The two facets of this relationship, the intellectual and the social-emotional, can each impact the practice of responsible research behavior. First, mentors are the source of information, of content knowledge that must be transmitted to the postdocs. Any effective RCR instruction needs to ensure that the mentors themselves have this knowledge and can transmit it, either directly through teaching, or indirectly through role-modeling. Second, most postdocs expend quite a bit of psychic energy trying to manage the relationship with their mentor. A certain comfort level is required on the

part of postdocs to be able to approach a mentor about an ethically ambiguous (or not so ambiguous) situation that is occurring in the research environment, and then to proceed to address it through an open, problem-solving type of discussion. The subtext of the discussions was, in fact, this search for ways to establish a quality working relationship with a mentor. The teaching of strategies to achieve this might, therefore, be a critical component of an RCR program.

Chapter 3
Small Culturally Diverse Groups for Case-based RCR Instruction: Format and Script

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This chapter describes a format for leading case-based RCR instruction in small, culturally diverse groups. This format includes a set of the teaching materials; a generic script for facilitation of small group discussion; and general teaching points that emerged from our experience conducting the RCR focus groups. Subsequent chapters will present teaching materials and teaching points that are specific to each of three RCR topics.

Teaching Materials

✓ Script

A script was created to provide a uniform framework for discussion across the three selected RCR topics; it includes queries designed to facilitate in-depth case analysis, with an integration of the international perspective. This generic script was then tailored to the topic content.

✓ Mini-surveys

Brief surveys administered at the start of the session can reveal gaps in knowledge to the participants, and are also intended to provoke thought and discussion. With small groups, the responses can be tallied during the session and presented back to the group at a meaningful point during discussion. The surveys consist of original items and items used by other RCR educators.

✓ Cases

The cases were designed to resonate with a predominantly international group of postdoctoral fellows -- to reflect their day-to-day experiences while addressing themes important to all scientists. They are similar in format and style to many of the cases that appear in the RCR literature, and each have a set of questions to facilitate the discussion and analysis of the scenario.

✓ Institutional Guidelines

RCR Guidelines should contain definitions of key terms, examples, exceptions, recommended procedures and/or behaviors, clarification of responsibilities, and resources (e.g., federal and institutional policy). Ours were developed *in draft form (and not yet codified as policy or standard operating procedure)* in collaboration with institutional offices involved with a particular area (e.g., Technology Transfer for intellectual property; Biostatistics and Data Management Core for data management, IRB for human subjects). Many examples of institutional guidelines can be found in "Creating Effective Research Guidelines" (See Appendix), a draft resource document produced by the Office of Research Integrity. A set of generic questions designed to facilitate discussion of guidelines is provided in the script.

✓ Tip Sheet

A tip-sheet is a single page, simply worded distillation of key points or take-home messages from the institutional guidelines -- the "Do's and Don'ts" pertaining to a particular area.

✓ Mini-cases

So-called because they are briefer than the cases presented early on in the session, mini-cases address one or at most two issues. In our sessions, the mini-cases served a very specific purpose: to elucidate the institutional guidelines and demonstrate how they can be applied in problem-solving common RCR scenarios. The mini-case discussion questions, therefore, refer directly back to guidelines developed for a particular topic. A set of generic mini-case questions is provided in the script.

✓ Teaching/Dissemination/Adoption Questions

These questions were designed to elicit feedback from trainees on preferred teaching methods, possible methods of disseminating the RCR message, and perceived obstacles to adoption of guidelines or recommended research practices. The more well-developed RCR programs that have already assessed training needs and evaluated teaching strategies may be interested in using this time to inquire about elements of the institutional culture that promote or impede research integrity.

✓ News Item Hand-outs

This is a two-page summary of recent real cases that appeared either in the media or on the Office of Research Integrity (ORI) Web site.

✓ Teaching Points

RCR topic-specific teaching points were generated from the focus group sessions with postdoctoral fellows at CHOP and from our experience designing and delivering a mandatory RCR training program for NIH-supported trainees.

Session flow with sample script

I. Introduction: Mini-survey, welcome and agenda (15 minutes)

Distribute mini-survey as part of the welcoming and arrival process.

> *Please take a few minutes to fill out this questionnaire. It is completely anonymous, and will only be used to help us get a clearer picture of how responsible conduct of research is understood.*

Introduce faculty and/or other facilitators. Have the participants introduce themselves by name and indicate area of specialty and place of doctoral training.

> *This is the most I will talk today because the purpose of this meeting is to provide you with an opportunity to learn from each other. With that in mind, I'd like to quickly go around the room. Introduce yourself with your name, where you did your graduate school training, and your area of specialty.*
> *(Go around room.)*
> *Great, thanks. I can see we have an extraordinarily diverse group here today, and I look forward to hearing from each one of you about your perspectives and experiences.*

Describe purpose and goals of the discussion (including background on RCR), the agenda and any "ground rules".

Explanation and example of ground rules:

> *Let's set up some ground rules first. I'm going to write these down and if at any point, you feel like something should be added or we're not following one of the rules, speak up. The first ground rule I would like to set is that of confidentiality. Nothing that is said here will be used to judge your performance or opinions. Although we are taking notes, it is for our purposes only to help us create the most effective program. No one person will be quoted that can be identified. Our goal is for everyone to feel comfortable speaking openly and honestly. Are there other ground rules you feel would help us achieve that?*

I'm interested in hearing what you think, not what you think I want to hear. The second ground rule is that I will strive to be unbiased. I will make sure everyone has a chance to talk. I am here not to express any personal opinion or judgment. My role is simply to listen and help guide the conversation along. If at any point you feel I have violated my role as unbiased facilitator, please call me on it.

Address the cultural diversity of the group directly.

I want to stress that one of the most valuable assets that [your institution] has is the diversity of its postdoc community. Part of why you are so important as a thinking partner in the development of this program is because of your past experiences and what you bring to this community. Don't feel when you speak that you speak for "your people." Goodness knows how many times people assume I'm speaking on behalf of [example: women, Asians, etc.] when it's just my opinion, so I can empathize. But your cultural experiences are exactly what makes this community rich and can contribute a lot today.

II. Case Studies (45 minutes)

Instruct group to read and reflect on Case 1. This is a good opportunity to record, on a flip board, any relevant survey results.

Please take a few minutes to read this case, think about it a bit, and then we'll jump into conversation. There are a few reflection questions that you may want to consider after you read the case. Please look up when you're finished.

Discuss Case 1 using a prepared set of questions.

Remember that as we discuss the issues that come up, we're not here to resolve these cases in any definitive way. The idea is to get your perspectives, so let's try not to get caught up on any particular point.

Instruct group to read and reflect on Case 2.

> *I'm sure we could go on for longer, but I'd like to move on to the second case, which I don't doubt will generate as many comments. Again, take a look at the reflection questions, and be prepared to share your experiences and perspectives.*

Discuss Case 2 using a prepared set of questions.

III. Institutional Guidelines and Mini-cases (45 minutes)

Distribute Institutional Guidelines pertaining to RCR topic.

> *For the next forty-five minutes or so, we will be focusing on [draft] guidelines that the Department of Research Education has put together. Keep in mind that this is a draft, and so we want to get your perspectives on it. We want these guidelines to be practical and helpful, not just a bunch of words on a piece of paper that no one will read. To do this, I'll be asking several questions to get you thinking about your own understanding, past experiences, cultural beliefs, and current practices. Depending on how much time we have, we may get to a few mini-cases to illustrate these guidelines. Please take about 5 minutes to look over these guidelines.*

Use Tip Sheet and RCR Guideline Discussion Questions to facilitate discussion of guidelines.

> *Don't worry if you don't remember every detail. The point of this discussion is not to get caught up in word-smithing the document, but to get at your understanding and experiences, and to see how these guidelines might be similar to or different from what you've experienced in other places. The key take-aways are noted on the Tip Sheet. Let's quickly walk through a few highlights. (Summarize highlights). Now let's talk about them:*

RCR Guideline Discussion Questions

1. *Think back to your own experiences. Were you exposed to information about these practices prior to coming to this institution?*
    a. *Where? How were they different? What was different about them? Can you give examples?*

2. *Some of you have been trained outside the U.S. Were these issues addressed there?*
    a. *How do these practices differ from what you were taught or experienced?*
    b. *Are there any parts that are contrary to or inconsistent with what you were taught in another country, or the standards held there? What was different there? Can you give an example?*

3. *Let's talk about these guidelines "in practice." Do these guidelines fit with the practices you or your colleagues use? If not, which parts are different, or don't seem to fit?*

4. *Do these guidelines seem realistic and practical for you to follow here at [your institution]?*
    a. *Are there areas missing that you would add or clarify?*

5. *Do these guidelines make sense to you? What parts seem most confusing or unclear?*

6. *What barriers or obstacles do you feel exist that would prevent compliance with these guidelines? What are some of the things that would stop you or other researchers you know from following some of these guidelines? (what's the barrier, to which guideline, why?)*
    a. *Are there cultural assumptions we should be aware of that may affect this?*

7. *How would you respond to problems in this area? What if it happened to you? What if you witnessed it?*

8. *What are the steps that you feel need to be taken to ensure these guidelines are followed? How would you encourage others to practice them?*

Mini-cases

Instruct group to read and reflect on one or two mini-cases, focusing specifically on how the guidelines might help to resolve the case.

Let's look at one mini-case in light of these guidelines.

1. *Do the guidelines help you to understand the facts of this case, or its implications?*
2. *Do the guidelines tell you something different about this situation than your previous training or experience would suggest?*
3. *How would the guidelines help you recommend a course of action to the key players?*
4. *Has this happened to you before? What did you do? How do the guidelines suggest that you change your behavior or beliefs about that situation?*
5. *Using the guidelines, would you know how to respond?*

IV. Solicitation of Feedback and Wrap-up (15 minutes)

Solicit feedback from group on perceived obstacles to promotion of research integrity in your institution.

I'd like to take the next ten minutes to find out from you what you think is the best way to teach and adopt these guidelines, to promote these practices here at this research institution.

Questions:

1. *What are the best teaching strategies: on-line, small groups, one-on-one?*
2. *Should training be tailored or held separately for different subgroups? For example, for U.S. citizens or foreign nationals, clinical or basic researchers, mentors or fellows?*
3. *How should mentors be trained?*

4. *Which cases did you find to be most useful?*

5. *When during the postdoc experience should training occur?*

6. *Are there obstacles that might prevent adoption of these practices/guidelines, anything that would make it difficult for you to adhere to these?*

7. *What steps can you take to make sure these are practiced?*

8. *How can you encourage others to do so?*

Distribute hand-outs (“Data Management/IP/Research Misconduct In The News”)

In these final moments, I wanted to thank you for coming, sharing, and contributing. Honest discussions are not easy, and so I appreciate hearing from you about your different background and experiences.

I'm going to hand out a sheet that has some news clips of actual cases involving alleged irresponsible research behavior. The point is not to scare you, but to help you to understand that the cases you discussed today can and do occur in real-life research settings.

General Pointers

- ✓ Since RCR is a relatively new and evolving area of instruction, it is appropriate to indicate to students/trainees that they are instrumental in shaping the local RCR program.
- ✓ Do not presume that the level of prior knowledge differs for those trained inside v. outside the U.S.
- ✓ Make an effort to know what kinds of research projects are being conducted by the audience (e.g., basic, clinical, behavioral), and to understand the implications of their specialty for the RCR topics. Use cases and examples from these research areas.
- ✓ Begin each new area of discussion with open-ended questions and try to follow a dialogue to its natural end. Balance a focus on an individual (as in "what do you think?") with a focus on the group as a whole ("what does the group think about this?") in order to build consensus.
- ✓ If quality of group discussion is compromised by the size of the group, provide the opportunity for smaller breakout groups to discuss cases or do other exercises.
- ✓ Use institutional guidelines if possible (even in draft form) to facilitate discussion and achieve consensus on standards for research behaviors.
- ✓ If such guidelines exist, apply them to specific cases as a group exercise.
- ✓ Provide name and contact information of a local resource person or persons and provide references to any local policies and procedures.
- ✓ Know that cases do not have to be long or complex to be effective.
- ✓ Use the groups as an opportunity for community building.

Chapter 4
Teaching Materials for Data Management, Sharing and Ownership

Chapter 4: Teaching Materials for Data Management, Sharing and Ownership

In this chapter, you will find teaching materials and teaching points designed to facilitate instruction of postdoctoral fellows in the RCR topic of data management, sharing and ownership.

Mini-Survey

1. How much do you think about standards of conduct relating to each of the following areas? Use the following scale:

   1 Never
   2 Rarely
   3 Sometimes
   4 Often

   a. Record-keeping practices (lab notebooks or research charts) _____
   b. Storing and retaining data _____
   c. Data ownership _____
   d. Sharing data _____
   e. Confidentiality of data with identifying information _____

2. If faced with problems in the following areas, how would you rate your knowledge of the options available to you? Use the following scale:

   1 Low
   2 Average
   3 High
   4 Very high

   a. Record-keeping practices (lab notebooks or research charts) _____
   b. Storing and retaining data _____
   c. Data ownership _____
   d. Sharing data _____
   e. Confidentiality of data with identifying information _____

3. Have you ever been advised that sharing of research data is not in your best interest?

   _____Yes _____No

4. Have you ever been advised that sharing of research data constitutes good science?

   _____Yes _____No

5. With whom would you be willing to share your data prior to its publication? (check all that apply)

   _____a colleague from your department
   _____a member of another department/division at your institution
   _____a researcher from another institution
   _____a friend working in your field of research
   _____a competitor in your field of research

6. When do you think research data should be made available to anyone who requests it? (check all that apply)

   _____while the project is in progress
   _____when data collection is complete
   _____when data analysis is complete
   _____when the manuscript is written
   _____when the manuscript has been accepted for publication
   _____when the paper is published

7. Who has the final approval as to what will be done with your data (research notebooks, details of methods, raw data)?

   _____you
   _____your mentor, PI
   _____granting agency
   _____your institution
   _____don't know

Case DM-1

Antonio, a senior postdoc at a U.S. academic institution, has developed a transgenic mouse model to study Alzheimer's disease. For the last four years of his postdoctoral fellowship, Antonio has faithfully recorded every detail of his experiments into a lab notebook. His mentor has commented several times about his meticulous notes and has even asked Antonio to coach other lab members on how to maintain a lab notebook. Antonio was taught previously to keep two notebooks. One notebook contains all of the details of his experiments and the second notebook contains his thoughts about future experiments and directions; some thoughts are recorded in his native language. Antonio understands that the first notebook must stay in the lab when he leaves but he plans to take the second notebook with him to his new position in industry. Antonio is training a Ph.D. student and encourages her to also keep two notebooks. The student mentions this practice to the mentor who seems surprised to learn of this. He calls Antonio into his office and tells him and the grad student that members of his lab are to keep only one notebook and that EVERYTHING should be recorded in that one notebook. This upsets Antonio, especially since this was a common practice in the country where he was trained. He feels that the thoughts and ideas written in that notebook belong to him. Besides, his mentor has never given any guidance on lab notebooks.

Discussion of Case DM-1

1. What are the issues or problems in this case? Who or what is affected?

2. What do you think about the mentor's comments? Were they reasonable? Does the mentor have the right to be upset?

3. Is it appropriate for Antonio to keep two notebooks? Did Antonio record appropriate things in the second notebook? Does it matter that some things were recorded in another language?

4. Who owns the ideas written in Antonio's notebooks?

5. Should Antonio be offended by the mentor's dismissal of his previously learned practices?

6. Has keeping two notebooks been standard practice anywhere you have worked before? Do you or someone you know at this institution maintain two notebooks? Is the mentor aware of this practice?

7. Imagine that you left this institution and went to another research institution, could you use the information you gathered at your new place of employment?

8. Is there anything in your previous experience that would tell you what to do if you were Antonio? Have you received any training about this issue that would help you know what to do? If so, what was it? Where did you receive this information?

9. What can be done to prevent this situation from occurring in the future?

10. What is a mentor's responsibility to provide guidance on this issue?

Case DM-2

Nyla was grateful for the opportunity to do a research project with Dr. Ricardo Moreno, a prominent protein biochemist in the United States. Nyla came to the Moreno lab 3 years ago from overseas. Now that her fellowship is ending, Nyla is planning to return to her home country. In fact, she's successfully negotiated a faculty position at a top university there. She's looking forward to reuniting with her family and has already begun to ship her personal belongings. She has promised the new university that she will continue her work on HIV-associated proteins. Nyla has even discussed this with Dr. Moreno, but one evening, he notices a list of materials that Nyla plans to ship to her new lab. He is angered to find that the list includes some cell lines developed by Nyla and a graduate student in the lab. He confronts Nyla and tells her that she cannot steal materials from his lab and threatens her with legal action if she tries to do so. Nyla assumes they are collaborators and will share these materials. She worries about future sharing with this lab and what this means for her research career.

Discussion of Case DM-2

1. What are the problems or issues in this case? Who or what is affected?

2. Is Dr. Moreno's reaction justified?

3. Should Nyla be permitted to remove the materials? Who owns the cell lines? Does it matter that Nyla developed them?

4. What options does Nyla have? After Dr. Moreno's reaction, how can she approach the subject of future collaborative efforts? Should she consider setting up a data sharing agreement?

5. What have you learned previously about the sharing of both information and research materials? Have you been given guidelines on sharing?

6. Has a situation like this ever happened to you? If so, what did you do?

7. Are there differences between what you learned before and what you've experienced at this institution regarding sharing and ownership of data? What are those differences?

8. What can be done to prevent situations like this one from happening?

9. When should you discuss these issues with your mentor?

Guidelines for Data Management and Ownership

Distribute institutional guidelines.

Tip Sheet for Data Management and Ownership

Distribute a page of tips derived from institutional guidelines.

Example:

"Share data through publications, archives, and repositories….while protecting privacy of subjects and proprietary data."

Mini-Case DM-A

Janet Smith has joined a lab at a pediatric hospital as a postdoctoral fellow. Janet's lab members use their own style of record-keeping because no formal practices exist. Janet is working on a promising project that often requires her to work late in the evenings and on weekends when she records her data and results on paper towels. After months of hard work and good results, Janet is pleased to write up her results in a manuscript to be submitted for publication. While reviewing the manuscript, Janet's faculty mentor has questions about a specific experiment and asks to review her data. Janet is horrified to discover that she has misplaced the paper towel on which the relevant data was written.

Questions:

1. Would these guidelines help you know whether or not this data can be used? Can the data be used? Which guidelines address this dilemma?
2. Do the guidelines tell you something different about this situation than your previous training or experience would suggest?
3. What should Janet have done? What is her responsibility in this case? Would these guidelines help you to recommend a course of action to Janet?
4. Will the guidelines change your behavior with respect to record-keeping?

Mini-Case DM- B

A postdoc in his third year of training is conducting research in a fast-paced, productive laboratory under a well-respected faculty member. One evening he returns to change the media on his transfected tissue culture cells and finds his faculty mentor and another postdoc reading his lab notebooks. He is immediately angry and confronts the two.

Questions:

In this situation:

1. Who has access to the data generated by the postdoc? The mentor? Institutional officials? Sponsors? Other lab members?
2. How would you respond if this happened to you?
3. Would the guidelines be of any help in this situation?

Mini-Case DM-C

Results published three years ago established a connection between maternal diet and the development of a common childhood disease. Results of a study just released refute this previous finding and have sparked debate as to the validity of the maternal diet model as a cause of the disease. The principal investigator, whose postdoc conducted the previous study 5 years ago and has since left the lab, decides to reevaluate the data. He learns that the hard copies of the data and the computer files containing the data were discarded when the group moved offices last year.

Questions:

1. Do the guidelines help you understand the mentor's responsibility to retain this data? What is his responsibility?
2. Do these guidelines tell you how long data should be retained?
3. What should a postdoc do if no data retention and storage requirements exist in the lab? Do the guidelines help you in that situation?
4. Do the guidelines tell you something different about this situation than your previous training or experience would suggest?

Hand-out: Data Management in the News

Cases that recently appeared in the news media or in professional newsletters and Web sites.

Teaching Points for Data Management

- ✓ Expect that postdocs, whether U.S. or foreign-trained, have little understanding of standards and practices of data sharing (what, when, with whom) or of data ownership, and that their need to know this information, given current and future roles, is enormous.
- ✓ Determine whether some postdocs record in their native language in their lab notebooks and, if so, whether an institutional standard should be communicated.
- ✓ Understand that some cultures encourage more casual sharing among academic colleagues (compared to the U.S.), and limits on sharing can be viewed as at odds with academic freedoms.
- ✓ Attempt to make explicit the implicit, unwritten rules of lab groups pertaining to data sharing, management, and ownership; determine which of these reflect broader (across-group) standards.
- ✓ Take advantage of the cultural diversity of your group by using it to examine the practical and ethical implications of global collaborations for data management, sharing and ownership.

Chapter 5
Teaching Materials for Intellectual Property

Chapter 5: Teaching Materials for Intellectual Property

This chapter describes teaching materials and teaching points designed to facilitate instruction of postdoctoral fellows in issues related to intellectual property.

Mini-Survey

1. If faced with problems in the following areas, how would you rate your knowledge of the options available to you? Use the following scale:

   1 Low
   2 Average
   3 High
   4 Very high

   a. Data ownership _____
   b. Intellectual property _____
   c. Securing a patent for an invention _____
   d. Creator rights for software applications _____
   e. Obtaining a copyright _____

2. Who has the final approval as to what will be done with your data (research notebooks, details of methods, raw data)?

   _____you
   _____your mentor, PI
   _____granting agency
   _____your institution
   _____don't know

3. If a researcher at an institution patents an invention, who owns the rights to that invention?

_____you
_____your mentor, PI
_____granting agency
_____the institution
_____don't know

4. If a researcher at an institution designs a software application, who owns the rights to that software?

_____you
_____your mentor, PI
_____granting agency
_____the institution
_____don't know

Case IP-1

Justin is excited about being chosen to give a talk at the National Oncology meeting in a couple of days. He has spent hours on his presentation and believes that each slide is perfect. He is proud of his accomplishments and feels honored to represent his lab and institution. In just two years as a postdoc, Justin has perfected an imaging technique that could drastically improve current procedures for the early detection of prostate cancer. Dr. Stephens, Justin's mentor, has reviewed Justin's presentation and seems pleased at the final product. To get some practice presenting his talk, Justin presents it at the weekly departmental seminar. Justin gets a good response from his division colleagues and as he is packing up to leave the conference room, he is approached by someone who introduces himself as the institution's intellectual property specialist. This person tells Justin that he cannot present his talk in its existing form because the methods are described in too much detail. The intellectual property specialist goes on to tell Justin that he must be careful not to disclose too much information without protecting it first. This incenses Justin. His graduate school mentor instilled in him the importance of sharing in science and is annoyed that the technology transfer office is approaching him especially on the day before he is due to leave for his meeting.

Discussion of Case IP-1

1. What are the issues in this case? Who or what is affected?

2. Is the intellectual property specialist's request reasonable? How would you react in this situation?

3. Should Justin be concerned that he has revealed too much in his presentation? What are the consequences if he shares too much information? Does anyone benefit?

4. What is the role of the technology transfer office? Should Justin have to discuss each presentation with them?

5. What constitutes a disclosure? What factors determine this?

6. Has it been standard practice in your previous places of work to protect information presented outside of the institution?

7. What is Justin's responsibility to the institution? What is your responsibility to share data with other investigators for the sake of open scientific inquiry?

8. How can situations like these be prevented?

9. How should this situation be resolved?

Case IP-2

Natalia joined Research University in the U.S. a few years ago. She thought she had developed a pretty good relationship with her mentor, Dr. Newman, so she was surprised when he commented on her recent annual evaluation that "Natalia is a good worker but her oral and written communication skills need improvement." Natalia was hurt by this, especially since she's been working so hard to improve her writing skills. Natalia believes that Dr. Newman favors the U.S. postdocs in the lab but feels it best to keep her suspicions to herself. Nonetheless, with the help of Dr. Newman, Natalia has managed to publish two papers in good journals and is ready to move on to a career position. Natalia has developed a process for screening transgenic mice for certain genes and has discussed submitting a patent application with the technology transfer office. Natalia shares her excitement about the prospect of obtaining a patent during the weekly lab meeting and is surprised to hear from John Smith, a fellow postdoc in the lab, who says that he should be a co-inventor on the patent application. Natalia appreciates John's contributions to the project. She had several conversations about the project with him but feels that she conceived the idea and worked out all of the details on her own. She's not willing to share it with anyone. She fears that Dr. Newman will support John.

Discussion of Case IP-2

1. What are the issues or problems in this case? Who or what is affected?
2. What are the criteria for inventorship? Should she share "inventorship" with John?
3. How do you know if you have something patentable? Who owns the rights to a patent at this institution?
4. What are Natalia's options?
5. What were you taught previously about who has the right to patent? How does it differ from what you were taught here?
6. Should Natalia address with her mentor the issue of favoritism in the lab?
7. What is Dr. Newman's role in all of this? What are his responsibilities as a mentor?
8. How can this situation be resolved?
9. How can situations like these be prevented in the future?

Guidelines for Intellectual Property

Distribute institutional guidelines on intellectual property.

Tip Sheet for Intellectual Property

Distribute a page of tips derived from institutional guidelines.

Example:

"Authorship is not inventorship."

Mini-Case IP-A

Ron is a postdoctoral fellow who develops a powerful algorithm using a commercially available software program purchased with the mentor's grant funds. Ron's algorithm works completely within the spreadsheet application software. The system takes raw data, statistically analyzes it and presents the results in multiple graphic formats. The application software used for this project was purchased under an agreement with the institution and is copyrighted by the manufacturer. Ron is considering protecting his algorithm as intellectual property before he distributes it to anyone outside of the lab.

Questions:

1. What are the key issues that Ron faces?
2. Based on the guidelines, what options does Ron have? Can he copyright the algorithm? Can he patent it? Can he do both?
3. Would these guidelines help you to know what to do?
4. Do the guidelines tell you something different about this situation than your previous training or experience would suggest?

Mini-Case IP-B

Mary has become increasingly bitter about the way she has been treated as a graduate student in Dr. Smith's lab. Their relationship has become more and more strained over the years, but Mary writes and successfully defends her dissertation and is excited about moving on to her new position as a postdoctoral fellow. Just before she leaves Dr. Smith's lab, Mary informs him that she has decided not to publish any more of her dissertation work and that she has copyrighted the dissertation so he will not be able to publish any of the work either. Dr. Smith has received federal funds to do this work and needs to publish it to prove that the work was done, however, he is worried that he will face a legal battle if he uses any of the data from Mary's dissertation.

Questions:

1. Would these guidelines help you know what copyright issues and data ownership issues are relevant here? Who owns the data? Who owns the copyright?
2. Do the guidelines tell you something different about this situation than your previous training or experience would suggest?
3. What should the faculty member do? What are his rights in this case? Would these guidelines help you to know what to recommend to him?
4. How do these guidelines change your behavior or attitude about data ownership and copyrights?

Mini-Case IP-C

Dr. Martin is an assistant professor at a university who develops a diagnostic test while working on a federally funded grant. She decides to start her own business on the side and plans to secure a license for and market the test. She is annoyed and angered when the technology transfer office informs her that this invention does not belong to her and that she must share any revenue earned from this test with the university.

Questions:

1. Based on the guidelines, was the request by technology transfer office reasonable?
2. Do the guidelines tell you something different about this situation than your previous training or experience would suggest?
3. Would these guidelines help you to know what to do? What would be your "next steps"?

Hand-out: Intellectual Property in the News

Cases that recently appeared in the news media or in professional newsletters and Web sites.

Teaching Points for Intellectual Property

- ✓ Start with the fundamentals. Postdocs are, by and large, unfamiliar with the language of intellectual property or the functions of a Technology Transfer Office.
- ✓ Written information on this topic (definition of terms, guidelines) will be well-received.
- ✓ International postdocs understand that they must conform to the Intellectual Property rules of their host country; some have had the experience, in their own countries, of being required to sign agreements or contracts upon hire specifying their rights and obligations.
- ✓ Be prepared to discuss IP issues facing postdocs who plan on returning to their own countries and would like to continue their research there.
- ✓ Know that this topic can arouse sentiments and stimulate debate on the tension between science and commerce, and on perceived restrictions on academic freedom.

Chapter 6
Teaching Materials for Research Misconduct

Chapter 6: Teaching Materials for Research Misconduct

In this chapter, you will find teaching materials and teaching points designed to facilitate instruction of postdoctoral fellows in the RCR topic of research misconduct.

Mini-Survey

1. How would you rate your understanding of the following concepts using the scale below:

   1 Low
   2 Average
   3 High
   4 Very high

   a. Fabrication of data ____
   b. Falsification of data ____
   c. Plagiarism ____

2. Is it "research misconduct" if a researcher omits data points when presenting results?

   ___Never
   ___Sometimes
   ___Always

3. Are disputes about authorship covered by the institution's policy on Research Misconduct?

   ___Yes
   ___No
   ___I don't know

4. Do you think you or your colleagues would know what do to if confronted with an incident of research misconduct at your institution?

   _____ Yes _____ No

Case RM-1

Tony has only been a postdoc for 6 months but already feels a lot of pressure to obtain independent funding. His mentor, Dr. Oliva, suggests that he apply on his own for a Young Investigator Award on the genetics of autism. Dr. Oliva provides Tony with all of the text of her previous (and successful) applications on the same topic, applications submitted prior to Tony's joining the lab. Tony does not have strong writing skills and he struggles to put her relevant content into his own words for this application. As the grant deadline approaches, however, he finds himself cutting and pasting long paragraphs from Dr. Oliva's application into his own, so much so that the five-page document begins to look like a mini version of a previous application. He also copies sentences verbatim out of one of Dr. Oliva's published manuscripts. Tony assumes that this is o.k. because he and his mentor will be working together on this project. Dr. Oliva reads the application, remarks that it is "great…extremely well-written!" and it is sent out that day.

Discussion of Case RM-1

1. What are the issues or problems in this case? Is this an example of plagiarism?

2. Should Tony have sent out the application?

3. What might have led Tony to copy Dr. Oliva's text? What can be done to address these factors?

4. What is Dr. Oliva's responsibility?

5. Does it make a difference whether the text came from a grant application or a published manuscript? Why do you think that? Does it matter whether the submitted document was a grant application or a final manuscript? Why?

6. What were you taught at your previous places of training about the appropriation of written material?

7. Has this ever happened to you or to someone you know? Think back…how did you handle it? Were you given particular guidelines to help you know what to do?

8. Are there circumstances in which it might have been fine to copy the text?

9. Should there be sanctions or consequences for Tony?

Case RM-2

Stefan and Marina are both postdocs in an immunology lab directed by Dr. Gary Fusilli. Stefan is in his 4th postdoc year and enjoys a particularly good relationship with Dr. Fusilli; in fact, they have become quite friendly and go running together at lunchtime. Marina is approaching the end of her first year in the lab and still feels like somewhat of an outsider. When Stefan and Marina began to combine their individual work on organ transplant rejection into a manuscript, Marina realizes that there is no way that Stefan could be doing the quantity or quality of work that he claims. He is careless about documenting his results and his lab notebook is crammed with slips of paper containing illegible notes. He is often absent from the lab for long periods of time without explanation. Furthermore, some of the critical experimental data provided by Stefan for the paper is dated 12/8/03 and Marina is almost 100% sure that she worked alone that Saturday. Marina is inclined to speak with Dr. Fusilli before the manuscript work proceeds, but she is due for her annual evaluation in one month and is reluctant to jeopardize her relatively good standing with her mentor before this milestone. After all, Marina tells herself, if she does not get a good evaluation, she could lose her immigration status, and Stefan has probably been engaging in dishonest behavior for a long time.

Discussion of Case RM-2

1. What are the issues or problems in this case? Who or what is affected?
2. Which, if any, of Stefan's behaviors might constitute research misconduct?
3. What might Marina's next steps be? Why?
4. What is Marina's responsibility to the lab? To Stefan as a colleague?
5. Can Marina justifiably wait to speak to Dr. Fusilli?
6. Has this ever happened to you or to someone you know? Think back…how did you handle it? Were you given particular guidelines to help you know what to do?
7. What is Dr. Fusilli's role in all of this? What is his responsibility as a mentor?
8. How can this situation be resolved?

Case RM-3 (for a predominantly clinical audience)

Henry is a third year postdoc who spends a small percentage of his time working with his mentor on a pharmaceutical company sponsored drug trial. It is his job to help recruit and assess subjects participating in a trial of a new cholesterol-lowering drug. At Henry's site, 14 patients successfully completed the trial and the data was submitted to the sponsor. When Henry reads the manuscript to be submitted to a journal, he notices that the number of subjects from his site is listed as 11. When he asks his mentor about this, his mentor says that further blood tests from the three patients indicated that they did not really meet eligibility criteria for the study so their data was omitted from the final analysis of results. With further examination of his own records, Henry begins to suspect that the patients were excluded because they did not have a very good response to the drug, but he doesn't know that for sure, so he does not do anything further.

Discussion of Case RM-3

1. Might this be an example of research misconduct? Why?
2. Who bears responsibility for reporting this misconduct?
3. Why might it go unreported?
4. Has this ever happened to you or to someone you know? Think back…how did you handle it? Were you given particular guidelines to help you know what to do?
5. What happens if it is true that they dropped the three patients because they didn't respond to the drug? What are the implications in terms of funding, future research, and the approval and marketing of this drug?

Guidelines for Research Misconduct

Distribute institutional guidelines.

Tip Sheet for Research Misconduct

Distribute a page of tips derived from institutional guidelines.

Example:

> "Misconduct is distinguishable from questionable research practices that weaken research but do not compromise the integrity of the research record. Sloppy or careless research, undeserved authorship, and failure to act collaboratively are examples of questionable research practices."

Mini-Case RM-A

Maria is a postdoctoral fellow in a cardiology lab at a major hospital where it is common practice for faculty members in this division to include the names of other faculty members as authors on manuscripts. Maria prepares a manuscript for publication and when her mentor reviews it, he asks that she add to the author list the name of one of his close friends who is new and needs publications. Maria is uncomfortable because she does not believe the other faculty member has contributed enough to be considered an author on her paper and wonders if this constitutes misconduct.

Questions:

1. Does this constitute research misconduct or is it a questionable research practice?
2. Would these guidelines apply to this case? Would they help you to know what to do?
3. How would you try to resolve this?

Mini-Case RM-B

Christina is a first year postdoc who learns that her faculty mentor has submitted a paper with her as first author. The mentor wrote the paper without her input and used some of her preliminary results that he read in her lab notebook. She is worried because the experiments are not complete and discusses her concerns with her mentor. He comments that he is sure the final results will support his new theory and that he just published the results a little early to help the chances that the lab will get funding.

Questions:

1. Is this a case of research misconduct?
2. Would these guidelines apply to this case? Would they help you to know what to do?
3. How will the guidelines change your data-reporting behavior?

Mini-Case RM-C

Philippe is finishing up his postdoctoral fellowship and is hoping to secure a scientist position at a pharmaceutical company right near his home. He is preparing to present his work at a national meeting where he's been told a representative from the company will attend. He includes measurements from his cellular assays in a graph on one slide but is concerned that some of the data points are questionable. He considers leaving the data points out. After all, he's not submitting a paper for publication and he's sure his conclusions are valid, plus he really wants to impress the company representative.

Questions:

1. Can Philippe leave the data out without compromising the integrity of his research?
2. Is this research misconduct according to the guidelines?
3. Has this happened to you or someone you know? What did you do?
4. How should guidelines regarding the omission of data be developed? At the level of the lab, the institution, the scientific discipline?
5. Would these guidelines apply to this case? Would these guidelines help you to know what to do?

Hand-out: Research Misconduct in the News

Cases that recently appeared in the news media or in professional newsletters and Web sites.

Teaching Points for Research Misconduct

- ✓ Begin by providing clear definitions and examples of fabrication, falsification, and plagiarism.
- ✓ Encourage postdocs to review their institutional policy on research misconduct so that procedures for reporting and handling allegations are widely understood.
- ✓ Understand that many postdocs do not feel comfortable addressing ethically ambiguous situations with their mentors, and that international postdocs have the added concern of protecting their visa status.
- ✓ Use an example to show how a seemingly minor act of research misbehavior (e.g., omission of data points) can reverberate outward, with effects on the science, on health care of individual patients, and even on health policy.
- ✓ Take advantage of the cultural diversity of your group to discuss how research misconduct might present itself in international collaborations.

Appendix:
Sources and Resources

Appendix: Sources and Resources

Sources and Credit

Chapter 4: Data Management, Sharing and Ownership

✓ Mini-survey

Several questions adapted from Macrina FL (2000): *Scientific Integrity: An Introductory Text With Cases, Second Edition* and used with permission of the American Society for Microbiology Press (ASM Press). Other questions developed by the Department of Research Education at The Children's Hospital of Philadelphia.

✓ Cases

DM-1: original case

DM-2: original case

DM-3: original case

✓ Mini-cases

DM-A: Used with permission of the Online Ethics Center for Engineering and Science at Case Western Reserve University. Case adapted from "Case Study 3" found at: http://www.research.umn.edu/ethics/curr_casestudy-03.html

DM-B: Used with permission of the Online Ethics Center for Engineering and Science at Case Western Reserve University. Case adapted from "Case Study 6" found at: http://www.research.umn.edu/ethics/curr_casestudy-06.html

DM-C: Used with permission of the FIRST Programs at the University of Minnesota. Case adapted from a case found on the University of Minnesota Ethics website: http://www.research.umn.edu/ethics/

Chapter 5: Intellectual Property

✓ Mini-survey

Several questions adapted from Macrina FL (2000): *Scientific Integrity: An Introductory Text With Cases, Second Edition* and used with permission of the American Society for Microbiology Press (ASM Press). Other questions developed by the Department of Research Education at The Children's Hospital of Philadelphia.

✓ Cases

IP-1: original case

IP-2: original case

IP-3: original case

✓ Mini-cases

IP-A: Used with permission of the American Society for Microbiology Press (ASM Press). Case adapted from Macrina FL (2000): Chapter 9, 9.10: Ownership of Data and Intellectual Property. In: *Scientific Integrity: An Introductory Text With Cases, Second Edition*.

IP-B: Used with permission of the American Society for Microbiology Press (ASM Press). Case adapted from Macrina FL (2000): Chapter 9, 9.1: Ownership of Data and Intellectual Property. In: *Scientific Integrity: An Introductory Text With Cases, Second Edition*.

IP-C: Used with permission of the Office of Research Integrity. Case adapted from *Creating Effective Research Guidelines*, Resource Document from the Office of Research Integrity, 2002.

Chapter 6: Research Misconduct

✓ Mini-survey

Questions developed by the Department of Research Education at the Children's Hospital of Philadelphia with assistance from consultants from the Center for Applied Research (CFAR).

✓ Cases

RM-1: original case

RM-2: original case

RM-3: original case

✓ Mini-cases

RM-A: original case

RM-B: original case

RM-C: original case

Resources

General

Creating Effective Research Guidelines, Resource Document from the Office of Research Integrity.

Macrina FL (2000): *Scientific Integrity: An Introductory Text With Cases, Second Edition*. Washington, DC: American Society for Microbiology Press.

National Institutes of Health http://www.nih.gov/

Office of Research Integrity http://www.ori.dhhs.gov/

Steneck NH (2003): *ORI Introduction to the Responsible Conduct of Research*. Washington, DC: Department of Health and Human Services.

Data Management, Sharing and Ownership

Do's and Don'ts for Keeping Lab Notebooks, Fasse and Beattie http://www.fr.com/practice/pdf/LABBOOK2.pdf

Freedom of Information Act http://www.usdoj.gov/04foia/

Harvard University Office for Technology and Trademark Licensing: Record-Keeping Procedures http://techtransfer.harvard.edu

HIPAA Privacy Rule http://www.hhs.gov/ocr/hipaa/

NIH Data Sharing Resources http://grants.nih.gov/grants/policy/data_sharing/data_sharing_resources.htm

NIH Policy on Data Sharing http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

PHS Policy on Sharing Unique Research Resources
http://grants1.nih.gov/grants/guide/notice-files/not96-184.html

Stanford University Office of Technology and Licensing: Suggestions for Keeping Laboratory Notebooks
http://otl.stanford.edu

University of Pennsylvania Center for Technology Transfer: Guidelines for Keeping Laboratory Notebooks
http://www.ctt.upenn.edu/

Intellectual Property

Bayh-Dole Act http://www.cogr.edu/docs/Bayh_Dole.pdf

Council on Governmental Relations: Technology Transfer in US Research Universities: Dispelling Common Myths
http://www.cogr.edu/

The Federal Technology Transfer Act of 1986
http://www.epa.gov/osp/ftta/fttafs.pdf

National Science Foundation Grant Policy Manual
http://www.nsf.gov/pubs/2002/nsf02151/gpm7.htm

NIH Intellectual Property Policy
http://grants1.nih.gov/grants/intell-property.htm

US Patent and Trademark Office http://www.uspto.gov/

US Copyright Office http://lcweb.loc.gov/copyright/

University of Pennsylvania Technology Transfer Programs FAQ's
http://www.finance.upenn.edu/ctt/about_tech/faq.shtml

Research Misconduct

National Science Foundation: Misconduct in Science and Engineering http://www.access.gpo.gov/nara/cfr/waisidx_00/45cfr689_00.html

Office of Research Integrity: Handling Research Misconduct http://ori.dhhs.gov/html/misconduct/introduction.asp

Office of Science and Technology Policy: Federal Policy of Research Misconduct http://www.ostp.gov/html/001207_3.html

Public Health Service: Code of Federal Regulations http://www.access.gpo.gov/nara/cfr/waisidx_00/42cfr50_00.html

Scientific Misconduct Regulations http://ori.dhhs.gov/html/misconduct/regulation_subpart_a.asp

Whistleblower Protection Act of 1989 http://thomas.loc.gov/cgi-bin/query/z?c101:S.20.ENR:

Whistleblower's Roles, Rights, and Protections http://ori.hhs.gov/html/misconduct/whistleblowers.asp