Learning Theories and Principles Applied to Responsible

Conduct of Research Instruction

by

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ABSTRACT

Academic research institutions provide the formal training ground for developing reasoning and critical thinking skills embedded within the application of the scientific method. For many, this training includes instruction in the Responsible Conduct of Research (RCR) where trainees become acquainted with rules, regulations, professional codes, and standards of practice that influence research integrity. This qualitative case study examined an RCR instructional model developed for science graduate students preparing for cross-sector science professions (e.g., business, government, and nonprofit). The research questions explored how instructional content and process contribute to developing knowledge of practices that influence research integrity in the academic and corporate settings. The model was field tested in conjunction with a student internship experience involving a student intern, faculty member, and employer as participants. The How People Learn (HPL) principles for design of effective learning environments and Malcolm Knowles’ original four assumptions on andragogy formed the theoretical frameworks to guide examination of the course.

Results indicate that core content typically associated with RCR (e.g., data management, conflict of interest, collaboration), combined with instruction that actively engages participants in the learning process through inquiry, discussion, and case based reasoning can facilitate learning about RCR and its application to a corporate setting. To advance this model for adoption within science graduate programs, research is needed to assess employer perceived value of ethics education as a component of employee professional development. The broader implications for RCR educators suggest adoption
of the HPL framework as a tool to guide examination of existing RCR instruction for alignment with theories of human learning supported by research.
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CHAPTER 1—INTRODUCTION

A deep commitment to scientific integrity is best achieved by providing sound training in scientific practices and the ethical conduct of science, and by creating institutional and professional environments that reinforce the high standards addressed in that training. Ideally, this educational process should begin early in the training of future scientists and continue through the most senior career stages. (Commission on Research Integrity, 1995, p. 19)

Individuals navigate personal and professional challenges daily and routinely face difficult choices with ethical implications, prompting the question “What should I do?” (Shamoo & Resnik, 2009). This question is central and distinct to a practitioner, be it a physician, scientist, or educator, engaged in ethical decision-making (Schrag, 2005).

Consider the following scenario:

Biomeca, Inc. developed a drug that mitigates the effects of multiple sclerosis. Most of the company’s revenues are derived from this drug and the drug will be the primary contributor to revenues for quite some time. Dr. David Biltmore, a biostatistician with the company, recently completed a meta-analysis of the clinical data. His findings suggest that the drug causes birth defects. However, the meta-analysis was based on data from relatively small patient populations and the results, while significant in the meta-analysis, could not confidently be extrapolated to the much larger population of actual drug users. Dr. Biltmore presented his findings to upper management in a meeting in which his results are discussed in great detail. At the end of the meeting, the company executive team decides that Biltmore’s findings should be shelved. The users of the drug have
realized substantial quality of life benefits from taking the drug, and any potential negative publicity relative to the drug would compromise the company’s sole revenue stream. This executive decision, though, is counter to Biltmore’s better judgement. What does Dr. Biltmore do now?

This instructional case presents a plausible ethical dilemma that a science professional might encounter in the corporate world and was developed by participants in a course designed to promote understanding about the responsible conduct of research (RCR) in the workplace. In research, as in many professions, there are values, traditions, and standards to guide one’s work and ethical decision-making (Bebeau, 1995). There are also norms and conventions, which are broad and less formal than rules and reflect a community’s fundamental principles (e.g., honesty, objectivity) and deeply held values, which guide appropriate behaviors within groups and organizations, including scientific research (Anderson, 2000; Shamoo & Resnik, 2009). Knowing the rules and regulations that govern the conduct of research are important; however, as Bebeau (1995) argues, reflecting on the underlying rationale that supports the standards and norms guiding the science profession is essential for ethical reasoning.

How to educate scientists and engineers about responsible and ethical research practices and foster the critical thinking skills needed to navigate complex ethical dilemmas is a focus of this study. Specifically, this study examined an educational model developed to facilitate understanding about RCR as practiced in academic and industry professional sectors. In this chapter, I introduce the (a) Background to the Problem; (b) Problem Statement; (c) Study Purpose; (d) Research Questions; (e) Study
Significance; (f) Conceptual Framework; (g) Role of the Researcher; (h) Limitations and Delimitations; (i) Definition of Terms; and (j) Organization of the Study.

**Statement of the Problem**

Research is carried out to advance knowledge and contribute to the betterment of humanity through a system grounded in integrity and trust (Anderson, 2011). Academic research institutions provide the formal training ground for science trainees to learn the reasoning and critical thinking skills embedded within the practice of the scientific method. During this apprenticeship, junior scientists are indoctrinated by senior researchers/mentors who are expected to pass on the discipline’s code of ethics, as well as the standards and norms of the research community (Anderson, 2000; Bulger, 1994; Kalichman, 2007). The rigor and integrity of the scientific method combined with the core values of honesty and objectivity of scientists forms the foundation of the public’s trust that research will be carried out ethically and responsibly (Anderson, 2000; Shamoo & Resnik, 2009).

Science, as a profession, is characterized by self-regulation and professional autonomy (Anderson, 2000). Unfortunately, the ability for scientists to self-regulate was called to question during the early 1980s. At that time, several prominent cases of research misconduct involving fabrication, falsification, and/or plagiarism came to the public’s attention (i.e., William Summerlin [Sloan-Memorial Cancer Center], John Darsee [Harvard], Vijay Soman [Yale], and Elias Alsabati [various U.S. research institutions]) prompting Congressional hearings that eventually led to increased federal oversight of research (Steneck, 1994, 2006; Steneck & Bulger, 2007). Specifically, Congress passed the Health Research Extension Act in 1985 and later published the Final
Rule, “Responsibilities of Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science” (Steneck & Bulger, 2007). The regulations required academic research institutions to develop policies and procedures to manage allegations, investigations, and reports of research misconduct and foster a climate of research integrity.

Much of the initial work in the 1980s focused on developing policy, defining research misconduct, and establishing procedures to respond to allegations of misconduct with little attention paid to RCR education (Steneck & Bulger, 2007). However, reports published by the Institute of Medicine (IOM) entitled *The Responsible Conduct of Research in the Health Sciences* (Rubenstein, 1989) and *Integrity in Scientific Research* (Rubenstein, 2002) assessed the roles and responsibilities of various stakeholders specific to research integrity (e.g., government, university, professional associations) and made recommendations to promote research integrity through formal instruction (Bulger & Heitman, 2007; Rubenstein, 1989, 2002; Steneck & Bulger, 2007). Shortly following the initial IOM report, the National Institutes of Health (NIH) mandated training in RCR as a condition of funding for students and trainees supported by NIH National Research Service Awards (NIH and Alcohol, Drug Abuse, and Mental Health Administration [ADAMHA], 1989). The National Science Foundation (NSF) followed suit with similar training requirements in 1997 that applied to trainees receiving the Integrative Graduate Education and Research Traineeship (IGERT) award (Steneck & Bulger, 2007). The IOM reports combined with the NIH training mandate are credited with establishing the foundation for RCR education within academic institutions (Bulger & Heitman, 2007).
Universities responded to RCR training mandates in a variety of ways since the NIH policy did not have a set curriculum or established standards for what would be an appropriate training plan (Steneck & Bulger, 2007). Mastrionni and Kahn (1998) conducted a study in 1996 to learn how academic research institutions complied with the RCR training requirements and found responses were quite diverse regarding who was trained (e.g., trainees covered by mandates or all trainees), who was responsible for teaching (e.g., principal investigator, ethics faculty), what content was covered (e.g., conflict of interest, data management), what instructional methods were used (e.g., lecture, seminars, discussion forums) and whether instruction was discipline specific or general. Mastrionni and Kahn identified a number of obstacles to implementing RCR, including the need for resources, program evaluation, and culture change. Likewise, they noted actions to mediate these obstacles (e.g., sharing of resources, tailoring teaching to disciplinary interests, and identifying competencies) stating that widespread and effective RCR training would foster “integrity of the research process and a solid future for the research enterprise” (Mastrionni & Kahn, 1998, p. 1249).

To manage reports of research misconduct and guide RCR education, the federal Office of Research Integrity (ORI) was created in 1992 and in 2000 published a “Policy on Instruction in the Responsible Conduct of Research” (Steneck & Bulger, 2007, p. 831). This policy would have expanded the NIH RCR training requirement to all research staff involved in Public Health Service (PHS) supported research; however, the policy was suspended shortly after publication in response to widespread university concerns around the objectives, scope, timeline, and costs of the policy (Steneck & Bulger, 2007). Regardless, aspects of the policy have influenced RCR education over the
past decade including the core instructional areas and educational objectives proposed by ORI. Specifically, ORI proposed that instruction address: (a) data acquisition, management, sharing and ownership; (b) mentor/trainee relationships; (c) publication practices and responsible authorship; (d) peer review; (e) collaborative science; (f) protection of human research subjects; (g) use of animals in research; (h) research misconduct; and (i) conflict of interest and commitment (ORI, 2000, p. 4). Likewise, ORI training objectives identified the desirable skills, knowledge, and attitudes as:

- Increase knowledge of, and sensitivity to, issues surrounding the responsible conduct of research.
- Improve the ability of participants to make ethical and legal choices in the face of conflicts involving scientific research.
- Develop appreciation for the range of accepted scientific practices for conducting research.
- Provide information about the regulations, policies, statutes, and guidelines that govern the conduct of PHS-funded research.
- Develop positive attitudes toward lifelong learning in matters involving RCR.

(Steneck & Bulger, 2007, pp. 831-832)

In the 20 years that followed passage of the federal regulations and training mandates, RCR education developed haphazardly, largely because of meager institutional support, poorly articulated goals (e.g., is RCR education intended to avoid misconduct or foster research integrity?) and lack of coordinated educational initiatives (Kalichman, 2007; Kalichman & Plemmons, 2007; Steneck & Bulger, 2007). Recent studies to evaluate the effectiveness of RCR education have documented little positive change in
knowledge and attitudes and, in some cases, have reported a detrimental impact on knowledge and attitudes (Anderson, 2007; Antes et al., 2010; DuBois & Dueker, 2009; Peiffer, Hugenschmidt & Laurienti, 2010; Powell, Allison, & Kalichman, 2007). Concerns about the progress of RCR education prompted both the NIH and NSF to publish updates to their training requirements in 2009. The National Institute of Health (NIH) provided additional guidance on expectations of RCR instruction including expanding requirements for training beyond the original training grants and added detail regarding format, duration, content, and involvement of faculty (NIH, 2009). The NSF update required institutions to have an RCR plan in place to train all students and postdoctoral trainees supported by NSF funds (NSF, 2009). These revised training mandates have increased focus on research ethics education and have prompted research on RCR pedagogy.

Research on education designed to improve knowledge, attitudes, and skills needed to practice RCR suggests instructional methods may be a contributing factor in disappointing student-learning outcomes (Anderson, 2007; Antes et al., 2009). The majority of RCR educators report using the lecture/discussion format and case studies to convey relevant material with some integration of interactive methods (e.g., small group discussion, collaborative case analysis, simulations via role play; Antes et al., 2009; Bulger & Heitman, 2007; DeBruin et al., 2007). A few RCR educators have endorsed the use of active learning techniques to promote discussion, questioning, and development of problem solving skills (DeBruin et al., 2007; Kalichman, 2007), and the literature is growing with documentation of interactive learning strategies to teach RCR which are presented in Chapter 2. Additional research on RCR education is needed to identify
teaching methods that can accommodate differences in research orientation (e.g., social sciences, bench sciences, behavioral sciences), lack of RCR subject matter expertise among faculty within the discipline and differences in standards and norms across disciplines (Antes et al., 2009; Antes et al., 2010; Bulger & Heitman, 2007).

**Purpose of the Study**

The purpose of this qualitative case study was to examine how instructional process and content can facilitate understanding of cross-sector standards of professional and research ethics, and to what extent instruction is aligned with research about how humans think and learn. The existing literature on RCR education confirmed that traditional teacher-centered strategies have had limited success on student learning about RCR and suggest interactive instructional techniques advance learning about RCR (Antes et al., 2009; Antes et al., 2010). Educators recognize that the inconsistency across disciplines specific to standards and norms of research practice present challenges to curricular development (Bulger & Heitman, 2007; Kalichman, 2007). Moreover, variance in organizational values and norms extend into the workplace setting where a science graduates will be employed (Shamoo & Resnik, 2009). An assumption of this study is that teaching about research integrity may be improved through curricular design and use of instructional strategies that align with what is known about human learning.

For this case study, data were obtained from an RCR course field tested with participants in a Professional Science Master’s (PSM) degree program in computational sciences at San Diego State University (SDSU). A goal of the RCR course examined for this case study was to increase participant knowledge of standards and norms across RCR core instruction areas (e.g., publication practice, research subject protections) applied to
both the academic (e.g., computational sciences) and business (e.g., biotechnology) setting. The objectives of the course were to:

• Develop awareness of the ethical dimensions of research or practice within the context of the profession and discipline.
• Develop/refine skills to question, analyze, and recommend ethical action.
• Improve understanding of relevant legal, institutional, and professional resources and standards.
• Foster research integrity in the workplace as science professionals within commercial, nonprofit and/or government employment sector.

The instructional strategies and course format are described in Chapter 4.

**Significance of the Study**

This study is significant because it introduces a model for teaching RCR that is informed by theory and research on human learning. The science and industry integrated training provided through the Professional Science Masters degree programs in combination with education in ethics will have a broader impact on society by moving concerns of ethics and integrity in scientific research outside of the academy and into business/industry sectors that create technologies which directly impact society.

Addressing ethics in the PSM curriculum is important, as advances in science and technology often lead to discoveries that have ethical implications that must be recognized and discussed. The three main areas of significance emerging from this study focus on teaching RCR to graduate students who will pursue science professions in business, industry and/or nonprofit employment sectors and include: (a) identification of instructional process and content that facilitate learning about rules, codes, and standards...
that influence research integrity across employment sectors; (b) understanding of factors that support or hinder participation of faculty, employers, and students in collaborative learning of research integrity, and (c) development and dissemination of teaching guidance to support faculty capacity for teaching RCR.

While it is difficult to establish whether RCR instruction impacts actual behavior and ethical decision making skills, it is possible to assess course objectives and outcomes for alignment with principles of learning. Once tested and refined, effective methods of RCR instruction can be shared with educators. Developing an ethics education model that addresses cross sector application of content will contribute greatly to graduate degree programs that are preparing scientists for professional positions in industry, business, and nonprofit employment sectors. In addition, this study examined the feasibility of introducing discussion of ethics through internship experience involving faculty, students, and employers to explore ethical dimensions of research. Determining how to deliver a course that involves engagement of key stakeholders in ethics education will be an important contribution.

Finally, recommendations from this study will inform revisions to the Teaching Resource Guide to enhance adoption by PSM programs. In addition to the teaching guidance, related resources for teaching RCR can be disseminated through the PSM national professional associations and through national repositories for research ethics teaching resources.

**Theoretical Framework**

This study was informed by the National Research Council report entitled, *How People Learn: Brain, Mind, Experience and School*, which emphasized the importance of
“learning with understanding” and connected the science of learning to instructional practices that assist learners to become “self-sustaining, lifelong learners” (Bransford, Brown, & Cocking, 2000, p. 5). In the HPL framework, Bransford et al. (2000) illustrate a theory of learning built upon 30 plus years of scientific research on the study of the mind. The framework is influenced by research in anthropology, social and behavioral sciences, neuroscience, developmental and cognitive psychology, with an emphasis on “learning with understanding” (Bransford et al., 2000, p. 8). The HPL framework identifies four areas of importance thought to “improve significantly people’s ability to become active learners who seek to understand complex subject matter and are better prepared to transfer what they have learned to new problems and settings” (Bransford et al., 2000, p. 13). The HPL theory suggests educators must rethink course content, the teaching and learning process, and the context of assessment in order to enhance transfer of learning. The HPL model includes four interrelated perspectives to guide the design of optimal learning environments informed by research on human learning (Bransford et al., 2000):

- **Learner-centered**—Environments attend to the knowledge, skills, attitudes, and beliefs that students bring, and which influence learning.

- **Knowledge-centered**—Environments articulate what information and subject matter is taught, why it’s taught and what competency or mastery is desired.

- **Assessment-centered**—Environments integrate ongoing assessment to make student thinking more visible to monitor progress of learning.

- **Community-centered**—Environments promote a sense of community and contextualize learning for transfer to other settings. Conceptually, the model is
depicted in Figure 1 as a “system of interconnected components that mutually support one another” (Bransford et al., 2000, p. 133).


Given this model is supported by the data on human learning, Bransford et al. (2000) recommend educational researchers begin to examine existing curricula and instructional techniques for alignment with the principles described. In addition, they suggest the curricula review consider:

- depth over breadth of coverage;
- effectiveness of opportunities provided to grasp key concepts related to the subject matter;
• extent to which the curriculum provides opportunities to explore preconceptions about the subject matter;
• adequacy of the factual knowledge base provided by the curriculum;
• extent to which formative assessment procedures are built into the curriculum;
• extent to which accompanying summative assessment procedures measure understanding and ability to transfer rather than memory of fact. (Bransford et al., 2000, p. 255)

The four interrelated components of the HPL framework, including the review criteria noted above, were selected to provide a lens for analyzing data for this case study.

In the HPL model, Bransford et al. (2000) emphasize the “importance of helping people take control of their own learning” (p. 12). Theories that support development of self-directed and lifelong learning skills are often tied to humanist and social constructivist orientations. The social constructivist theory stems from the work of Candy, Dewey, Lave, Piaget, and Vygotsky (Merriam, Caffarella, & Baumgartner, 2007). Vygotsky (1978) is credited with influencing the foundational perspectives of social constructivism through his beliefs that learning is socially mediated through interactions with others, and that knowledge is created when individuals engage in conversations and bring their understanding to share in making meaning of reality. This theory supports active learning methods and recognizes the socio-cultural influences of learning. Pedagogy, using a social constructivist orientation, encourages the learner to make meaning from experience and contextualize knowledge within a social setting or with members of a group who share common interests (Lave & Wenger, 1991; Vygotsky, 1978). The role of the teacher shifts from the traditional paradigm of content delivery to
one of a facilitator who negotiates meaning-making with the learner and involves opportunities for experiential learning, reflective practice, recognition of communities of practice, and situated learning (Merriam et al., 2007).

Humanism as a learning theory “emphasizes that perceptions are centered in experience” and values the self-directedness of adults and their experiences in the learning process (Merriam et al., 2007, p. 282). Malcolm Knowles, an influential scholar in adult education, championed the movement of learner-centered instruction by contrasting assumptions of pedagogy with andragogy (Merriam et al., 2007). Knowles’ assumptions of adult learners and self-directedness maintained that the learner needs to be empowered and have some control over his/her learning process and, as a result, the educator becomes a facilitator rather than a deliverer of facts (Merriam, 2001).

While Bransford et al. (2000) acknowledge that the HPL framework assumes learners are children, they argue that the four domains apply to adult learning. In many ways, the HPL framework resonates with Malcolm Knowles’ principles of andragogy. These principles include self-directedness, consideration of the learner’s experience, relevance of learning to work, and use of problem-centered approaches. Knowles’ principles were considered critical factors of adult learning contrasting the need to be directed (e.g., teacher-centered) with being guided (e.g., learner-centered; Knowles, 1970; Merriam, 2001). Knowles’ assumptions of adult learners complement the HPL goals of developing self-directed and lifelong learners and were considered in the analysis.

The Research Design

A qualitative case study research methodology was selected for this study with the case being the initial field test of an RCR training designed for a Professional Science
Master’s degree in computational sciences. The source documents included an overview of the course instructions, pre- and postassessment, self-study assignment narratives, transcripts from face-to-face sessions, mid-course narrative, and instructional cases developed as a culminating experience. Study findings will further inform the utility and scalability of this RCR training for broad distribution.

**Research Questions**

The following research questions were developed for this study.

1. What instructional strategies are used in the course and how do they facilitate learning about RCR generally and, more specifically, to cross-sector application?

2. How are commonly accepted RCR instructional topics used to understand standards, conventions, and practices in an industry setting?

3. What are the implications to advancing RCR pedagogy?

**Study Limitations and Delimitations**

This research is limited by the nature of the case study as a research methodology. The case study limits analysis to one demonstration of the RCR module applied to a computational sciences graduate internship with a local biotech company. Consequently, results may be limited in generalizability to other disciplines or business settings until additional demonstrations are conducted. Delimitations are that the protocol for implementation of the course was carefully planned with data collection instruments designed to elicit formative data within an actual internship experience carried out over the course of two semesters. The transcripts reflect authentic discussion about the
relevance and application of RCR topics to computational sciences and a biotechnology company.

**Role of the Researcher**

Since 1995, I have developed educational programs to promote responsible and ethical research practices targeting both academic (students and faculty) and nontraditional trainees (e.g., lay research staff). I have been involved in research regulatory compliance and research administration for over 17 years and currently serve on national associations to advance education on responsible conduct of research.

I contributed to the design and demonstration of the RCR course examined in this study and participated in the demonstration that produced the data used for this study as an observer and co-facilitator. This study represented the first of four field tests to explore the feasibility of incorporating RCR education into a PSM internship experience. The outcome from this field test informed revisions to the model for future implementation.

At the time this course was field tested, I was not enrolled in the doctoral program and had planned to use the data collected for the sole purpose of advancing the project goals. During my doctoral studies, I learned about educational research and the science behind teaching and learning and became interested in assessing RCR instruction for alignment with principles of learning. The PSM RCR course provided an opportunity to apply techniques of discipline based educational research to RCR instruction.

**Definition of Terms**

The following definitions are provided to assist the reader with terminology used throughout the document.
How People Learn (HPL) Model: The HPL model includes four interrelated perspectives to guide the design of optimal learning environments informed by research on human learning (Bransford et al., 2000).

National Institutes of Health: The National Institutes of Health (NIH) is located within the U.S. Department of Health and Human Services and functions as the research agency to advance medical discovery (NIH, 2012a).

National Science Foundation (NSF): The National Science Foundation (NSF) is the federal agency that supports research and teaching in all fields of fundamental science and engineering (NSF, 2012).

Office of Research Integrity (ORI): “The Office of Research Integrity (ORI) oversees and directs Public Health Service (PHS) research integrity activities on behalf of the Secretary of Health and Human Services with the exception of the regulatory research integrity activities of the Food and Drug Administration” (ORI, 2012, para. 1).

Professional Science Master’s Degree (PSM): The PSM is a graduate degree program designed to train scientists for careers in business, industry, nonprofit and government economic sectors. Presently, the Keck Graduate School determines whether a degree program meets criteria to be designated as a PSM.

Questionable Research Practices (QRP): Behaviors that obscure the truth of research findings are considered questionable research practices (e.g., reporting data that conflicts with previous findings or not including all data within the analyses). These behaviors may not reach the level of criminal behavior as defined in federal regulations; however, they remain a threat to the integrity of research.
Research Ethics: Steneck (2006) defines research ethics as “the critical study of
the moral problems associated with or that arise in the course of pursuing research”
(p. 55). Shamoo and Resnik (2009) considers research ethics as an applied discipline
involving ethical principles and practices for conducting research. Teaching in research
ethics includes concepts, tools, principles, and methods useful in identifying and
responding to ethical challenges in the research setting (Shamoo & Resnik, 2009).
Kalichman (2009) defines research ethics as “the ethics of the planning, conduct, and
reporting of research . . . . The domain of research ethics is intended to include nothing
less than the fostering of research that protects the interests of the public, the subjects of
research, and the researchers themselves” (p. 86).

Research Integrity: Steneck (2006) qualifies research integrity as “a
characterization or presents an evaluation of research behavior” (p. 55).

Research Misconduct: Research misconduct is defined by policy within the
Federal Register (Public Health Service Policies on Research Misconduct, 2005) as
“fabrication, falsification, or plagiarism in proposing, performing, or reviewing research,
or in reporting research results.” Fabrication is “making up data or results and recording
or reporting them” whereas, falsification is “manipulating research materials, equipment,
process, or changing or omitting data or results such that the research is not accurately
represented in the research records” (Public Health Service Policies on Research
Misconduct, 2005). Plagiarism is taking another persons words, ideas, or results without
proper attribution or credit. These behaviors, often referred to as “FFP,” are what define
research misconduct.
Responsible Conduct of Research: The term Responsible Conduct of Research is defined by Steneck (2006) as “conducting research in ways that fulfill the professional responsibilities of researchers, as defined by their professional organizations, the institutions for which they work and, when relevant, the government and public” (p. 55).

Organization of the Study

This dissertation is presented in five chapters with Chapter 1 providing a summary of the study to set the context. Chapter 2 presents a review of the relevant literature on responsible conduct of research education including pedagogy and evaluation. Chapter 3 (Research Design and Methodology) includes a description of the research design employed in this study. Chapter 3 also includes a review of the research questions, subject selection process, ethical considerations, a description of source documentation and data analysis methods.

Chapter 4 (Findings) presents an analysis of the instructional strategies used in the course demonstration and outcomes associated with implementation. Chapter 4 also includes an analysis of how RCR core instructional topics were applied in a biotechnology business setting. These findings inform conclusions and recommendations reported in Chapter 5.

Chapter 5 (Discussion, Conclusions, Recommendations and Summary) presents a discussion of the results and implications. This includes an overview of the findings, review of the limitations, recommendations for further research, and implications for practices.
CHAPTER 2—LITERATURE REVIEW

Chapter 2 provides background about research misconduct and requirements for responsible conduct of research (RCR) education. Relevant literature on RCR education is presented including the goals, objectives, teaching strategies, and evaluation. This chapter addresses challenges in teaching RCR across disciplines and economic sectors, as well as gaps in the literature.

Introduction

Scientists create knowledge and with that knowledge come social responsibilities and an obligation to the public to provide expertise and intellectual authority (Shamoo & Resnik, 2009). The integrity of the scientific method is of utmost importance to consumers given the findings and recommendations of scholarly research and subsequent contributions to the scientific record result in recommendations that influence the collective health and well-being of the public (Bird, 2006; Whitbeck, 2004). To ensure that the best science is supported, developed, and fostered, scientists carry out their work in a self-regulating environment with ethical standards and accepted conventions defining culturally appropriate behaviors (Anderson, 2000; Anderson, Ronning, De Vries, & Martinson, 2010; Shamoo & Resnik, 2009).

Unfortunately, cases of research misconduct, defined as fabrication, falsification, and plagiarism, as well as less serious, yet more prevalent incidents of questionable research practices (QRP), have occurred in both academic and industry research environments threatening the integrity of science and the public’s trust in the scientific process (Anderson, Ronning, De Vries, & Martinson, 2007; Fanelli, 2009; Heitman, Anestidou, Olsen, & Bulger, 2005; Martinson, Anderson, & De Vries, 2005; Resnik,
2003, 2011; Steneck, 1994, 2000). The actual number of cases of research misconduct remains unknown since incidents go unreported and the investigative process may introduce bias; however, estimated cases range from 1 in 100,000 to 1 in 100 (Steneck, 2000). In response to the growing concerns of research misconduct, the federal government published regulations (42 CFR 50 and 93; Public Health Service Policies on Research Misconduct, 2005) and research sponsors mandated education in RCR (NIH and ADAMHA, 1989).

To manage claims of research misconduct and guide RCR education, the federal Office of Research Integrity (ORI) was created in 1992. As part of its charge to advance RCR education, the ORI and other federal agencies (i.e., NIH and NSF) identified topics for RCR instruction and published guidance and requirements for institutions that accepted federal funding to conduct research. These agencies also funded educational initiatives to develop RCR instruction related to responsible and ethical research practices. A year prior to initiating this research project, both the NIH and NSF updated their respective training requirements. The NSF (2009) stated that institutions must have a written plan in place to provide RCR training to all students and postdoctoral trainees supported by the NSF. Shortly thereafter, the NIH updated its requirements for RCR education by publishing an announcement that addressed much of the past confusion around expectations for training and provided guidance about format, structure, faculty participation and content, duration, and frequency of instruction (NIH, 2009). While there is consensus that RCR education is of value, questions remain as to the overarching goals, how those goals will be achieved, and what methods of RCR teaching are most effective to enhancing responsible and ethical research practices (Kalichman, 2007).
**RCR Goals**

When the NIH published its requirement for Responsible Conduct of Research, it acknowledged that institutions already had practices and procedures in place to promote the responsible conduct of research, including:

- Informal seminars and presentations on conflict of interest, data recording and retention, professional standards and codes of conduct, responsible authorship, institutional policies and procedures for handling allegations of misconduct, policies regarding the use of human and animal subjects, etc. or formal courses on bioethics, research conduct, the ideals of science, etc. (NIH and ADAMHA, 1989, p. 1)

The NIH and ADAMHA (1989) instructed those requesting support to include a “description of the formal or informal activities related to the instruction about the responsible conduct of research” (p. 1). The NIH language was intentionally nonprescriptive to permit flexibility and encourage education responsive to the needs of the trainee and the program. For much of the 1990s, RCR was “more or less left to grow on its own under the guidance of a small but growing corps of largely volunteer RCR instructors” (Steneck & Bulger, 2007, p. 831). While the lack of guidance was intended to respect the autonomy of institutions and researchers, it left those responsible for compliance without clear direction. A study conducted by Kalichman and Plemmons (2007), nearly 20 years after the training mandate was published, revealed that educational goals varied widely among RCR instructors, noting 50 distinct objectives were voiced by participants touching on knowledge, skills, attitudes, and behavior to reduce misconduct and foster research integrity. While the variation in RCR scope,
content and approach to education is not necessarily a problem, it presents a challenge for determining best practices and assessing whether institutional resources are adequate (DuBois, Schilling, Heitman, Steneck, & Kon, 2010).

**RCR Objectives and Instructional Content**

To reach consensus in identifying relevant goals and instructional content for RCR education, two studies are included in this literature review that critically examined core content and RCR educational objectives. Heitman and Bulger (2005) designed a study to assess textbooks, anthologies, case collections, monographs, and on-line educational materials developed for RCR to identify a consensus of topics. Their analysis produced a list of content areas they identified as “core educational concepts and standards of responsible conduct of research” (p. 222). For the most part, the list built upon the nine core instructional areas published by the Office of Research Integrity in 2000 with expanded categories detailing content to address within each category. For example, relabeling “research misconduct” to “research integrity” was recommended with more detailed subcategories/topics that address “ethical safeguards of the scientific method” and “the role of trust and honesty in the growth of scientific knowledge (ORI, 2000, p. 222).

A few years later, DuBois and Dueker (2009) convened a Delphi Panel to acquire consensus on RCR goals and content. The project enlisted a diverse panel of experts to inform RCR objectives starting with core content areas using seven (excluding human and animal subjects since those topics are covered extensively) of the nine ORI core instructional topics as a framework for guiding discussion of the overarching objectives of RCR training (e.g., knowledge, attitudes, skills). The experts represented researchers
who published, taught, and/or conducted research on responsible conduct of research.

Through a process of consensus building, the panel identified two new core areas of instruction, namely “social responsibilities of researcher” and “current issues in RCR” and nine educational objectives (see Figure 2; DuBois & Dueker, 2009, p. 58).

| 1. Understand the importance of RCR. |
| 2. Identify source of RCR regulations and policies. |
| 3. Examine limitations of RCR regulation and policies and variations in standards across fields, institutions and labs. |
| 4. Understand key distinctions within the field of RCR |
| 5. Foster research integrity or professional character. |
| 6. Foster ethical sensitivity or the ability to identify ethical issues in the conduct of research. |
| 7. Develop ethical problem solving skills. |
| 8. Examine ways of preventing ethical problems in research. |
| 9. Provide an open forum for discussion of individual RCR concerns and challenges. |

*Figure 2. Nine educational objectives identified by the Delphi Panel for RCR education.*


In addition to achieving consensus on RCR objectives, the panel agreed upon 43 content areas to guide RCR instructional content. For example, within the topic area of “Data Acquisition, Management, Sharing and Ownership,” 10 major content areas were identified as important for instruction by the panel (see Figure 3).
Data Sharing

a. How and when data should be shared, advantages and disadvantages.
b. Transferring data
c. Acceptable and unacceptable uses for shared data.


Findings from both studies contributed to clarifying goals and instructional content and validated Kalichman’s (2007) observation regarding the extensive and complex objectives associated with RCR education. Specifically, Kalichman stated the difficulty in defining the scope of RCR education is that it is not one thing. RCR has come to include a wide-ranging mix of knowing and following rules, being a moral person, having good character, exhibiting good ethical judgment, and acting with integrity and responsibility. (p. 870)

Because of the broad scope of RCR education, most agree that no one educational strategy will meet the needs of all and, as such, we will likely continue to see a variety of approaches used in RCR education (DuBois & Dueker, 2009; Kalichman, 2007).

**RCR Pedagogy**

Teaching RCR requires consideration of the learning outcomes and pedagogical objectives with respect to developing and/or changing behaviors, knowledge, attitudes, and skills (Pritchard, 2005; Schrag, 2005). Recently, interactive and problem-oriented
instructional strategies have been reported in RCR education; however, evaluation studies reveal the traditional teacher-centered format of lecture and discussion are reported most frequently (Antes et al., 2009; Antes et al., 2010; DeBruin et al., 2007; Plemmons, Brody, & Kalichman, 2006; Powell et al., 2007). Studies that examine RCR instruction are described in this section.

Antes et al. (2010) published a nationwide study assessing the effectiveness of RCR instruction where they enrolled 40 instructors and their students as study subjects. Instructors indicated courses were conducted over a semester time frame, targeted graduate students, generally covered the nine core instructional topics identified by ORI using “moderately complex cases and both individual and group activities” and “reported discussing, to a moderate extent, approaches for solving ethical problems or making ethical decisions” (p. 521). Another study to assess effectiveness conducted by Plemmons et al. (2006) recruited 268 students from 11 courses at 10 institutions. Instructors characterized the course format as a combination of lecture and discussion in all but one course, which identified as “discussion” only. The number of sessions reported ranged from 7 to 17, with each session being 1-2 hours long. Powell et al.’s (2007) study on RCR course effectiveness also described the course as using a lecture/discussion format conducted over four sessions of 90 minutes each. This literature suggests that most RCR educators rely on lectures and discussions and may include discussion of instructional cases to depict ethical dilemmas in research settings.

**RCR Evaluation Studies**

Several studies have been conducted to assess whether RCR instruction influences student learning finding either no change or documenting a negative impact of RCR
education with graduate students and trainees (Antes et al., 2009; Antes et al., 2010; Plemmons et al., 2006; Powell et al., 2007). Antes et al. (2010) examined the effect of RCR instruction on ethical decision making, meta-cognitive reasoning strategies, and social dimensions of ethical problem solving. Study subjects included faculty teaching RCR courses at academic institutions around the country and students enrolled in those courses. Instructors completed a 68-item course content survey which revealed that RCR courses were typically held over a semester and targeted graduate students in life sciences. Course content was described as “moderately time intensive,” and topics taught included the nine core RCR topics recommended by the ORI. Methods used by instructors included lecture, case analysis, and discussion, with the author concluding that the RCR courses included in the assessment were similar in content and strategy. Findings were disturbing in that one would expect RCR instruction to lead to improved ethical decision making yet, to the contrary, analyses revealed the “ethicality of decisions made with respect to data management, study conduct, and professional practices did not improve or decline after instruction” and “course participants were more deceptive, retaliatory, closed, and neglectful of personal responsibility in their responses following instruction” (Antes et al., 2010, p. 523). Furthermore, findings revealed that while students were more skilled in the social elements of ethical problem solving following the RCR course, they were also more closed off and internally focused (Antes et al., 2010).

Findings that RCR instruction produces undesirable results calls to question the premise that instruction will improve ethical decision making or at least, do no harm. If RCR instruction produces undesirable results, it follows that further research is needed to evaluate what may contribute to these findings. Antes and colleagues (2010) speculate
that learning about the serious consequences of research misconduct (e.g., criminal charges, loss of career) and awareness that other researchers are unethical leads to a desire to protect oneself from those who might engage in misconduct. Another factor the authors suggest contributes to instructional effectiveness of RCR is student motivation and assessment of relevance to their work (i.e., if the students do not believe training is valued, they will be less likely to find it meaningful). Antes et al. (2010) suggest student perception of RCR training may be negative, due to it being a compliance requirement of the institution to participate in research and competes with time they could be spending more productively. The authors acknowledge some of the challenges associated with RCR instruction, namely RCR content involves learning rules, principles, strategies, and processes, which are typically learned through lecture, discussion, and case study analysis. They also acknowledge the social factors of ethics instruction and science as a discipline and suggest research on unique social elements of ethics instruction. Conclusions invite the need for research to understand what promotes and/or hinders effective instruction and explore educational strategies that integrate the social aspects of the research setting.

Another study involving a meta-analysis of RCR instructional effectiveness found that ethics instruction is moderately effective as presently conducted (lecture and case-discussion) with a cognitive decision-making approach to instruction being deemed the most effective (Antes et al., 2009). The authors also found that case-base instruction was more effective than lectures. Instruction that was highly interactive with a number of different learning and practice opportunities enhanced effectiveness. While they acknowledge the complexity of RCR education and the need to conduct more extensive
research, they confirm that instructional methods that actively engage the student will favorably influence student-learning outcomes (Antes et al., 2009).

Anderson, Horn, et al. (2007) conducted a national survey of early and mid career biomedical and social scientists selected from NIH records of postdoctoral fellows and R01 awards. They survey measured exposure to formal RCR training (e.g., stand alone course, integrated with coursework, both or neither) and perceptions of help that respondents received from a mentor in their graduate education or through related professional experience. Behavior was measured by asking respondents to self-report whether that had engaged in any of 33 behaviors thought to damage the integrity of science over the preceding 3 years. The behaviors were organized conceptually into eight categories including “data, methods, policy, use of funds, outside influence, peer review, credit and cutting corners” (p. 854). Examples of the behaviors included “publishing the same data or results in two or more publications,” “withholding details of methodology or results in papers or proposals,” and “falsifying or cooking research data” (p. 857).

Respondents qualified mentor behavior by the type of guidance received including: assessing ethics (discussion on ethics), research (instruction in good research practices), financial (instruction in grant proposal writing), survival (developing professional relationships), and personal (emotional support). Anderson, Horn, et al. reported little difference in frequency of problem behaviors between those who received training and those who did not receive training. Respondents also reported the mentoring had “more significant associations with questionable behavior than did training in research integrity” (p. 858) leading to concern about what messages are being communicated about the conduct of research. While the authors note limitation to their findings, they suggest
further research on differences in RCR pedagogy, course content, and mode of delivery is needed (Anderson, Horn, et al., 2007).

In a study reported by Plemmons and colleagues (2006), participants who completed RCR training through 11 separate courses at 10 different institutions were surveyed about course effectiveness and how the course would influence their future behavior and thoughts. The majority of respondents ($n = 268$) were graduate students and took the course in response to a training requirement. Findings reveal that participants found their RCR course to be beneficial in learning to recognize, avoid, and respond to potential misconduct, and reported increasing time spent thinking about and discussing research ethics. Respondents identified authorship, conflict of interest, and intellectual property as most important to their careers. The two principle findings of this study were that respondents generally reported positive outcomes from their RCR courses and that information learned was greater than impact on skills or attitudes. The authors recommend future research look more closely at influence of RCR instruction on student knowledge, attitudes, and skills. Other than noting that the courses were taught using discussion and lecture, specific information on course content or format was not presented.

**Experiential and Problem-Based Learning Strategies**

**Applied to RCR Education**

In a survey conducted by DeBruin and colleagues (2007) to study educational approaches to RCR in a clinical setting, the majority of those surveyed (85%) used lecture and discussion as primary instructional strategies; however, 21% reported using problem based and experiential learning strategies in which students are actively engaged in the
learning process (e.g., case analysis, field observation, role-play, and simulation).

Experiential learning strategies are associated with constructivist learning theory that anchors learning to experience (e.g., Dewey, Piaget, Vygotsky). In the constructivist paradigm, learner constructs knowledge based on a personal interpretation of an experience (Bednar, Cunningham, Duffy & Perry, 1995). Problem based learning PBL is a method of experiential learning with a long history in teaching and has become more common across disciplines as more is known about learning (McKeachie, 2002).

Hmelo-Silver (2004) provides the following description of problem-based learning:

Psychological research and theory suggests that by having students learn through the experience of solving problems, they can learn both content and thinking strategies. Problem-based learning (PBL) is an instructional method in which students learn through facilitated problem solving. In PBL, student learning centers on a complex problem that does not have a single correct answer. Students work in collaborative groups to identify what they need to learn in order to solve a problem. They engage in self-directed learning (SDL) and then apply their new knowledge to the problem and reflect on what they learned and the effectiveness of the strategies employed. The teacher acts to facilitate the learning process rather than to provide knowledge. The goals of PBL include helping students develop 1) flexible knowledge, 2) effective problem-solving skills, 3) self-directed learning skills, 4) effective collaboration skills, and 5) intrinsic motivation. (p. 235)

Strategies for introducing problem-based learning in RCR instruction typically involve review and analysis of case studies and, more recently, simulation through
role-play. Case analysis involves engaging students in ethical decision-making by identifying a problem and considering choices based on lessons learned from a similar past experience and reflecting on what information and principles about that situation can apply to solve a new problem (Aamodt & Plaza, 1994; Jonsen, 1988). When using the case method to develop problem solving and critical thinking skills, hypothetical or real events are used to depict an ethical dilemma, and inductive reasoning is used to guide analyses (Allen, Otto, & Hoffman, 2000; Shamoo & Resnik, 2009). The use of instructional cases for teaching RCR is considered an effective method because it engages students in discussing authentic situations in their academic environment (Eisen & Parker, 2004; Pimple, 2007). Professional communities are more often using instructional cases to capture and organize circumstances that depict the community culture and institutional practice and can be used to introduce new members to the community values, missions, and goals (Allen et al., 2000).

Using role-play is another technique that has been reported within the RCR teaching literature (Brummel, Gunsalus, Anderson, & Loui, 2010). Role-play is a socially situated experiential learning strategy that is used to engage the student in learning a subject matter (Joyce & Weil, 2000; Poorman, 2002). There are a number of advantages, including elevated interest in the topic, active participation of the student, and an opportunity to understand different perspective (Poorman, 2002). Several examples of how experiential and/or problem based learning is being incorporated in RCR education follow.

Barry, Borenstein, and Butera (2012) created a team-taught, stand-alone course on engineering macro-ethics with a goal of preparing future engineers to understand and
resolve fractious problems using problem-based learning. Barry et al. (2012) applied PBL to a course in engineering ethics by grouping students into teams who were then asked to solve a “fractious” problem. For example, a team was asked to consider the use of neuroimaging for screening students (elementary and postsecondary) who had demonstrated anti-social behavior to determine treatment decisions, as well as the appropriate educational setting. Students worked collaboratively to analyze the issue and develop policy recommendations. This example offers a collaborative method of problem solving as a learning activity using real issues that are relevant to the learner. The authors are encouraged by the outcomes and note concerns about scalability and sustainability due to the time and effort needed to deliver the course.

Jones et al. (2010) developed RCR curriculum at Wake Forest University for biomedical graduate students. The model employed learner-centered strategies using case-based instruction to “engage, explain, explore, elaborate and evaluate” (Jones et al., 2010, p. 614), a 5-step model developed by Roger Bybee and colleagues. Students were assigned to small groups of 6-8 with two problem based learning trained faculty facilitators. The facilitators were responsible for guiding acquisition of PBL skills and discussion about professional norms during the case analysis process. The small group design is intended to create a safe place to practice interpersonal dialogue and develop confidence in defending decisions. The authors note an advantage of the PBL format is that it does not require the facilitators to be content experts; however, facilitators participating in their program were given notes to assist in guiding discussion around the case objectives specific to RCR content. Another observation made by the authors was that student familiarity learning in a didactic format were initially challenged with the
PBL process as it requires them to become self-directed and responsible for learning. Jones et al. noted challenges to scalability and sustainability due to the “significant logistical support to coordinate multiple groups and scheduled” (p. 618).

Brummel et al. (2010) describe the process of developing RCR role-plays and with students reporting that role-plays were more “engaging and promoted deeper understanding than a lecture or case study covering the same topic” (p. 573). This formative work resulted in development of nine role-play scenarios that cover topics commonly associated with RCR. Each role-play, based on an actual incident, was pilot-tested with preparation time of 5-10 minutes incorporated, during which time the actor reviews the case and his/her role and considers various perspectives of the problem. The role-play is then performed and runs for approximately 5-10 minutes followed by discussion and a debriefing. The pilot-test of the model informed role-play scenarios, which were further refined and demonstrated with 576 students over the course of one year. Evaluations revealed that a majority of participants rated the role-play methods to be either “good” or “neutral” and “worthwhile” (p. 579). Qualitative results were organized by advantages and disadvantages. An example of an advantage was having actual interactions about “real life situations” and disadvantages focused on feeling awkward participating, length of time needed to cover the material, and lack of adequate knowledge to play the role (p. 580). Participants in this study reported that a goal of RCR education should focus on communication skill development rather than rules and regulations, given the concerns that arise are often attributed to being able to set expectations and communicate concerns and disagreements. The authors have additional
research planned to measure whether role-play, as an active learning strategy, is more effective when compared to lecture in learning RCR principles.

An article by DuBois, Dueker, Anderson, and Campbell (2008) describes the development and assessment of an NIH-funded RCR training program utilizing a train-the-trainer model focused on mental health research. Development of the program was derived from Rest, Navarez, Bebeau, and Toma’s four component model of moral development with a goal being to “facilitate ethical behavior: moral sensitivity, moral judgment, moral motivation, and moral character” (DuBois et al., 2008, p. 596). The content of the course addressed human research protections as opposed to RCR more broadly defined. Instructional strategies included slide presentations on ethical and regulatory issues followed by case discussion and analysis. The instruction was conducted face-to-face and to remote attendees in real time using an Internet-based video-streaming format, which allowed distance learners to watch a live Internet broadcast and email or call during the session discuss and/or pose questions. The course took place over nine 2-hour sessions held every other week, which was labeled “time intensive” by DuBois et al. (2008, p. 601). Participants were health professionals (e.g., psychologists, epidemiologists, research coordinators) who planned to use the course for training others.

In another study, McGee, Almquist, Keller, and Jacobsen (2008) addressed the importance of “viewing RCR training from the perspective of learning theory and how prior knowledge influences what people learn” (p. 30). McGee et al. (2008) acknowledged the lack of evidence for RCR educational impact and questioned whether to attribute lack of demonstrated efficacy on “a failure of course design, delivery, or other
interfering influences on learning” (p. 31). A limitation they noted regarding prior research on RCR education is the perspective of the student in the learning process, specifically, the process of learning and the import of the student’s prior experiences in filtering information, noting if the information is consistent with existing knowledge, the student is more likely to accept and, otherwise, may dismiss or ignore the information. The authors assumed that “RCR training occurs within a constantly changing context” (p. 32) and proceeded to study influences of the trainee’s prior knowledge and belief that what is learned in a course will change behavior. The study targeted students enrolled in RCR training at the Mayo Clinic who were PhD and MD postdoctoral fellows. The course format was face-to-face with topics including scientific fraud, data management, authorship, conflict of interest, and research subject protections. The material was covered through a combination of lecture and case study analysis and discussion. The authors developed interview questions using results from focus groups and subsequently interviewed 30 students about the conflict of interest and authorship sessions. Those sessions were selected because the participants disclosed little prior understanding of the topic and general confusion about the related principles and practices. Data were analyzed to compare participant pre and postsession responses across knowledge, attitudes, and potential to influence behaviors across prior exposure to the topics.

While the authors found that the qualitative approach produced valuable data that has not been previously collected using survey methods, McGee et al. (2008) confirmed that “learning occurs within the context of what an individual knows or thinks they know” (p. 57) and that learning is more challenging when the information conflicts or opposes what is known. Not surprisingly, several participants disclosed what they were
learning in the course about accepted standards and norms were not observed in practice which supports instruction that facilitates “group mentoring” suggested by Anderson (2007, p. 390) to bring the norms and expectations to an open communication between RCR educators and trainees in the context of practice. The authors concluded that RCR educators be aware that prior experience matters, especially when topics or practice are not held in common.

A few business and research ethics scholars have taken experiential learning a step further by engaging students more directly through creative writing and case construction related to a current event or work experience (Atkinson, 2008; Laditka & Houck, 2006; McWilliams & Nahavandi, 2006). Specifically, Atkinson (2008) used creative writing assignments to enhance development of instructional cases. McWilliams and Nahavandi (2006) asked students to identify a current event that involved an ethical issue and write their own case based on a lived ethical challenge. Students then presented and discussed their respective cases to explore the problem and consider possible solutions. Laditka and Houck (2006) asked students to reflect upon their workplace experiences to inform an instructional case applying a framework to consider relevant value system, resources, organizational setting, and decision-making process. Students were surveyed following the assignment and reported an increased awareness of ethical decision-making in the workplace and concluded that the case construction approach is effective in facilitating student exploration of their attitudes and skills needed to navigate ethical dilemmas in the workplace.
Application of Cross Sector RCR Education

Trainees learn about regulations, standards, and conventions through academic mentors, RCR instructors, and/or automated on-line instruction (Anderson, 2007). A challenge addressed in this study was how to educate scientists who are preparing for science careers in nonprofit, industry, and/or government sectors where the culture and expectations may be different and standards of practice may conflict to some extent with academic norms. While many standards and conventions for ethical conduct are shared across all scientific fields (i.e. do not fabricate data), some standards many be contextual and nuanced or special to a discipline (Bulger & Heitman, 2007). For example, the convention in many life science disciplines is to identify the senior author as the last author, whereas, within the social sciences, the first author is typically the senior author. Differences in conventions, values, and norms within and between the academic environment and the commercial industry/business environment are discussed more often as a result of the Bayh-Dole Act of 1980, which incentivized academic researchers to advance commercialization of intellectual property (Shamoo & Resnik, 2009).

The tensions associated with cultural differences between business and academia have become more evident as scientists pursue the entrepreneurial spirit and test the waters of turning a concept into a commercially viable and competitive product. Understanding organizational values and their influence on the culture is important to consider when learning how RCR may present in the professional setting versus the academic setting. With a growing number of graduate students seeking employment in the nonacademic employment sectors (NIH, 2012b), RCR education will need to address knowledge and skills necessary for those preparing for careers as science professionals to
understand distinctions between the academic and commercial/industrial cultures. For the purpose of this discussion, Shamoo and Resnik (2009, p. 88) capture the essence of how organizational values differ between the academic and commercial sectors in Table 1.

Table 1

*Academic Values Versus Business Values*

<table>
<thead>
<tr>
<th>Academic values</th>
<th>Business values</th>
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</thead>
<tbody>
<tr>
<td>Goals: Educate students, advance human knowledge through research, scholarship, and creative activities, conduct public service.</td>
<td>Goals: Knowledge for the sake of profit, maximize profits, and produce goods and services.</td>
</tr>
<tr>
<td>Communications: Free speech, free thought, emphasis on academic freedom, exploration.</td>
<td>Communications: Protect interests of the corporation, nondisclosure, business model driving decisions.</td>
</tr>
<tr>
<td>Free Trade: No obvious interest in corporate competition; commercialization a lesser priority than advancing knowledge.</td>
<td>Free Trade: Produce high quality goods/services, invest in human, financial, and technical resources. Control over local markets.</td>
</tr>
<tr>
<td>Obligation to: Students, faculty, alumni, staff, community, research sponsors (government/state/foundations).</td>
<td>Obligation to: Stockholders, consumers, <em>employees</em>, society.</td>
</tr>
</tbody>
</table>


**RCR in Professional Science Master’s Degree Programs—**

**Cross-Sector Training**

The Professional Science Master’s degree is a terminal graduate degree initiated in 1997 to prepare scientists for careers in business, government, and nonprofit sectors.
The degree includes interdisciplinary and multidisciplinary courses called *Plus* courses taken in conjunction with traditional science master’s degree courses. Professional Science Master’s *Plus* courses provide professional skills development in, for example, entrepreneurial management, international business, ethics, regulatory compliance, communications, and business administration to enhance graduates’ responsiveness in the workplace.

The *Plus* component of the PSM is a distinguishing factor of these degree programs; however, development of *Plus* courses has also proved challenging (Lynch, Babco, & Vincent, 2009). The PSM faculty within the discipline may not have the subject matter expertise in the *Plus* area of interest (e.g., business management, regulatory issues, ethics, and intellectual property). To develop the *Plus* courses, PSM directors have turned to departments within their respective institutions for subject matter expertise using courses within these departments or enlisting colleagues from those departments to teach workshops in the requisite *Plus* categories (Lynch et al., 2009). The *Plus* courses are unique in that they are tailored to apply the content/discipline to the specific field of study and link the relevance to the industry in which students will pursue professional careers. *Plus* courses are generally integrated as stand-alone courses or as a thread in existing curriculum or via workshops or web-based or hybrid courses. The RCR course examined in this case study was developed to facilitate cross-sector understanding of practices that enhance research integrity and could be adopted for use as a *Plus* course.

**Gaps in the Literature**

This study was initiated to examine an RCR course tailored to science graduate students who plan to seek careers in the private, public, or government sectors of the
economy. In my review of the literature, there are resources that describe ethical dilemmas and concerns that arise when private industry and institutes of higher education form relationships. For example, Shamoo and Resnik (2009) acknowledge the potential for “conflicts of interest, research bias, suppression of research and secrecy” in collaborations between academia and private industry (p. 81). In my review of the literature, I did not come across reports of RCR instruction designed to address cross-sector science professions.

Summary

The literature reviewed for this study documents the variation in scope, content, and approaches used in RCR education. Evaluation of existing RCR courses indicates that traditional teacher-centered instruction has had limited influence on learning. There is growing evidence from educational research supporting interactive instruction as an alternative to teacher centered methods of lecture and discussion. Those studies that involved interactive pedagogies produced encouraging outcomes; however, the authors also expressed concerns about scalability and sustainability due to the time and effort required for course delivery. There is growing consensus that more research is needed to determine what is effective RCR instruction.
CHAPTER 3—METHODOLOGY

Introduction

Chapter 3 describes the research methodology and data collection strategies used to answer the research questions developed for this study. Included is a description of the (a) research design, (b) an introduction to the Professional Science Master’s degree program which serves as the vehicle for testing the responsible conduct of research (RCR) model, (c) an overview of the data management process including data collection and analysis, (d) procedures to address validity and reliability, and (e) study limitations.

This study examined the initial field test of an RCR training model for science graduate students seeking employment in industry. The educational model prompted exploration of cross-sector application of the RCR domains and examined a delivery option for teaching students preparing for careers in business and industry. The research questions prompted examination of instructional strategies for understanding of RCR generally and, more specifically, cross-sector relevance of core content, in this case a biotechnology company. The results of this study will inform the field of RCR education by identifying methods of instruction that mitigate challenges associated with discipline variability (e.g., experience, rules, community standards, professional norms) and RCR transfer to nonacademic employment sectors.

Research Design

A case study methodology was chosen to examine implementation of the course within a PSM program in computational sciences. The case study method is a form of empirical inquiry that can be used to study real-life phenomena (e.g., decisions, programs, implementation process, organizational change, etc.) at an individual or group level (Yin,
Gerring (2004) considers a case study as “an intensive study of a single unit for the purpose of understanding a larger class of (similar) units” (p. 342). A case study can employ mixed methods; however, the case study is traditionally considered a qualitative strategy to study a program, activity, or process in depth (Creswell, 2009). As Yin (2009) notes, case studies allow for a holistic investigation of group behavior and processes and is useful in describing an intervention in real-life context. For these reasons, the case study methodology was deemed appropriate for examining this model of instruction.

A case study is defined by the unit of analysis (Yin, 2009) and, for this study, the course represented the unit of analysis. Yin (2009) advises to distinguish those within the group from those on the periphery when defining the context of the case study. For this study, the small group involved in the field test was composed of: (a) a graduate student/intern affiliated with a Professional Science Master’s degree program in computational sciences; (b) the intern’s mentor/supervisor; and (c) a faculty member affiliated with the program. Those external to the immediate group were the two co-facilitators who guided the field test over the course of this study. Yin recommends that the case study “define a specific real-life ‘case’ to represent the abstraction” (p. 32). The participants included in this demonstration formed the learning community used for this demonstration and represent a real life case to evaluate the RCR instructional methods applied to an internship experience. Field test of this model occurred within a controlled setting and permitted the instructional process to be documented and analyzed to uncover strengths and weaknesses of the model to inform future iterations and adaptation within Professional Science Master’s degree programs.
Propositions and Research Questions

In designing case studies, Yin (2009) recommends that, in addition to the research questions, the investigator identify propositions to be examined within the scope of the study. Informed by the literature on human learning, the following three propositions are examined as core elements of the theoretical frameworks of Bransford et al. (2000) and Knowles (1980):

- Learning with others who share a common interest will promote understanding about the ethical conventions within a particular profession and workplace (Lave & Wenger, 1991).
- Dialogue between participants about RCR topics will facilitate construction of meaning regarding how and/or whether RCR topics transfer to the workplace setting (Mezirow, 1991).
- Principles of adult learning theory, when applied to RCR education, will complement goals of learner-centered instruction. Specifically, students and trainees need to be involved in planning and assessing their instruction; trainees will be most interested in learning subjects that are relevant to their jobs or personal lives; and, problem-centered learning is preferred to content oriented approaches; trainees are capable of self-directed and autonomous learning (Knowles, 1980).

The following research questions guided analysis:

1. What instructional strategies are used in this course, and how do they facilitate learning about Responsible Conduct of Research generally and, more specifically, to cross-sector application?
2. How are the Responsible Conduct of Research instructional topics (e.g.,
authorship, data management, etc.) used to understand standards, conventions,
and practices in an industry setting?

3. What are the implications to advancing Responsible Conduct of Research
pedagogy?

**Setting—Professional Science Master’s Degree**

The setting for this study is a Professional Science Master’s (PSM) degree
program in computational sciences. The Professional Science Master’s degree is a 2-year
terminal graduate degree designed to prepare scientists for cross-sector professional
positions in industry, government, and nonprofit organization. The PSM augments
traditional science coursework with interdisciplinary and multidisciplinary courses called
*Plus* courses to develop business skills (e.g., management, policy, law, and ethics) with
an emphasis on communication skills and project management (National Professional
Science Master’s Association [NPSMA], 2012). Initiation of the PSM degree is
associated with reform in graduate education which began to percolate in the mid 1990s
with advocates noting that PhD trained scientists were pursuing careers outside of the
academy (National Research Council, 1998). At that time, master’s degree production in
the science, technology, engineering and mathematics (STEM) had been flat for nearly
10 years (National Research Council, 1998). Investing in the workforce was becoming a
priority and experiments in master’s level programs, as found with the PSM, were finding
success in preparing science and engineering students to be competitive in the global
market, with business skills and knowledge necessary to perform in nonacademic
economic sectors as productive science professionals (Musante, 2009; Wendler et al., 2010).

The Professional Science Master’s degree programs were initiated in 1997 as an alternative to traditional graduate education, with funding through the Alfred P. Sloan Foundation and the William M. Keck Foundation (Lynch, 2011). Initially, PSM programs focused on math and science degree programs and later expanded to including biotechnology, physics, environmental sciences, and informatics. Professional Science Master’s degree programs have steadily expanded over the past decade and now exceed 244 programs at 114 institutions nationally, with programs developing internationally (Professional Science Masters (PSM), 2011). A unique feature of the PSM degree programs is prioritizing team oriented learning methods and completion of an internship as an alternative to the research thesis. The internship provides an opportunity for students to apply the coursework directly to the professional environment and work in teams to relate concepts to practice. Since the internship experience provides an opportunity for PSM students to engage with leaders in the professional community, as well as an academic mentor, the initial demonstration of the PSM RCR model was situated within a student internship experience.

**PSM Ethics Education**

Ethics education emerged as an important focus of PSM education, in part due to the America COMPETES Act (2010) and its stated requirements for education in RCR. In 2009, funding was obtained from the National Science Foundation (NSF) to create an RCR educational model for the PSM to prepare science graduate students to learn about the standards and conventions of science in the professional setting. The initial field test
of the RCR course developed for the computational sciences was the source of data used for this study.

**Local Setting**

San Diego State University was the local setting for this RCR course field test. The PSM in Computational Sciences at SDSU was identified as one of three PSM disciplines to participate in field tests. Dr. Jose Castillo, the director of the PSM in Computational Sciences, agreed to assist in recruitment of participants for the demonstration.

**Recruitment**

To initiate recruitment, Dr. Castillo recommended potential participants who met the inclusion criteria. For this demonstration, we requested involvement of a faculty member affiliated with the PSM program, a PSM student who was beginning an internship with a local company, and the intern supervisor who was an employee of the company. These individuals were provided with a brief summary of the project and invited to contact the project investigator if interested in participating.

**Ethical Principles and Practices**

To invite participation, an overview of the project was presented to each person by the investigator via email (see Appendix A). In advance of initiating the project, approval from the SDSU Institutional Review Board was secured on August 10, 2009 (Appendix B). The project was considered to be educational research and verified as exempt from 45CFR Part 46 (Protection of Human Subjects, 2012).

Individuals initially recommended by the PSM director all agreed to participate in an information session and, at that time, the project investigator recapped the overview
and asked each individual to review a consent statement (Appendix B) that explained the purpose of the study, described what participation involved, expected duration of participation, potential benefits, and possible risks, as well as a description of how audio tape recordings would be handled to protect their privacy and confidentiality of data collected. To ensure voluntary participation, each individual was told that participation could be stopped at any time without penalty. Prior to confirming the agreement to participate in the project, an open dialogue allowed for points to be clarified, and questions were answered. Each participant was paid an honorarium for participation in this study to recognize their time and contributions to informing the direction of the project. Since participation involved the discussion of practices associated with ethical and responsible research, pseudonyms were given to each participant, as well as to the biotechnology company to protect their privacy. Likewise, participants were told that their identities would not be revealed in publications or materials developed in association with this project to encourage open disclosure without concern of retribution.

The project was initiated in September 2009 and completed in April 2010.

**Process and Data Collection**

This initial field test was conducted over the fall 2009 and spring 2010 semesters. The purpose was to test the instructional strategies, use of RCR core content, and feasibility of integrating RCR education within a PSM internship experience. The field test objectives were to:

- Understand whether RCR domains common in academia could be used as a starting point to explore how rules, standards, and norms of the academic environment transfer to the private biotechnology sector.
• Identify what elements of instructional design fostered understanding about RCR and connection of topics to the workplace.

• Develop instructional case studies that depict ethical challenges unique to the biotechnology setting.

• Assess the feasibility of integrating RCR within an internship experience.

The process of how the course was implemented for this demonstration is detailed in Chapter 4. Also included is a description of the syllabus, which includes data collection processes and procedures (see Table 2, p. 57).

**Data Sources, Management, and Analysis**

The primary sources of data collected for this study are the course instructional strategies, pre- and postassessment survey, narratives, digital audio recordings, and instructional cases developed by the group members. These sources are described in detail as part of the document analysis in Chapter 4. All data were stored securely in hard copy in a locked file cabinet and electronically on a password protected personal computer.

A descriptive case study approach was used to document implementation of the module and describe outcomes associated with application of the instructional strategies. Saturate software was used in combination with hand coding to analyze data obtained from narratives and face-to-face (F2F) discussion sessions for both process and content. A description of the analysis strategy for each data source follows.

**Responsible Conduct of Research—Instructional Strategies**

• Process/Document Analysis. Instructional strategies and procedures for implementation were assessed though an analysis of the instructional content
and transcripts of recordings and/or narratives produced from implementing instruction. Instructional strategies were examined for alignment with Knowles’ (1980) principles of adult learning (e.g., engaging learners in the learning process, soliciting examples of experiences, inviting inquiry, collaborative learning projects, etc.).

The course was also examined for alignment with the principles of the optimal learning environment (e.g., learner, knowledge, assessment, and community) using the review criteria recommended by Bransford et al. (2000). Specifically, does the training provide opportunities for the learner to understand key concepts of RCR? To what extent are preconceptions about RCR areas explored? Is the factual knowledge provided adequate? Is formative assessment integrated into the model? And are summative assessments incorporated to assess transfer of understanding as opposed to memory of facts? (Bransford et al., 2000).

- Implementation/Outcome Analysis. Qualitative analysis of data sources obtained during implementation (e.g., pre/post, narratives, face-to-face session transcripts) were used to evaluate application of the learning strategies on achieving instructional goals (e.g., discussion, connection of topic to work, and identify ethical dilemmas that form the basis of an instructional case).

**Pre/Post and Midpoint Assessments (Process and Content Analysis)**

- Process Evaluation (see Process/Document Analysis above). Each preassessment was hand scored and results were compared across participants to assess equivalence of knowledge between the student/intern, faculty
member, and intern supervisor at baseline. The pre- and postassessment scores were compared within and across participants to examine influence of baseline RCR training on understanding of RCR topics.

- Process Evaluation (reference 1a above). The self-study and mid-point written narratives were analyzed using qualitative methods to assess application of self-assessment as a learning strategy in developing understanding of RCR topics and relevance to discipline and profession.

- Content Evaluation. The self-study and mid-point narratives were coded across and RCR topics to identify patterns and connections between academic and industry practices, standards, and relevance for training.

**Face-to-Face (F2F) Discussion Sessions (Process and Content)**

- Process (see Process/Document analysis above). All F2F sessions were audio recorded using a digital recording device. Each audio recording was professionally transcribed. The transcripts were reviewed to identify how instructional strategies (e.g., guided dialogue and case analysis) were used and whether those strategies were effective in achieving the instructional goals of fostering dialogue about RCR, connecting content to the discipline and profession, and identifying topics for case construction.

- Content. Transcripts were initially coded by paragraph to identify properties and discover patterns followed by focused coding to determine adequacy of the codes and categories (Charmaz, 2006). Analytic memos were used to note code definitions, characteristics of themes, and document patterns emerging as transcripts were compared across topics of discussion (Charmaz, 2006).
**Constructed Instructional Cases (Process)**

Instructional cases constructed by the participants were reviewed to assess whether the collaborative project assignment produced plausible examples of ethical challenges found in industry.

**Validity and Reliability**

Several procedures were implemented to ensure study findings were consistent and reliable. Creswell (2009) suggests checking transcripts for accuracy to ensure they do not contain mistakes and using the constant comparative analysis to enhance reliability of coding and interpretation. Focus group audio recordings were professionally transcribed. To verify accuracy, I selected sections of the transcript where the professional transcriptionist identified over-talking or garbled to check the audio recording against the transcript. While verifying select sections of the transcripts, I continued to listen to several minutes of each recording and compared the written text to the audio recording.

Yin (2009) identifies three principles that increase construct validity and reliability of the evidence used to support a case study and recommends using multiple sources of data, creation of a database, and maintaining a chain of evidence. Each principle and associated methods was applied to this case study to increase reliability and validity of findings associated with the analyses.

When discussing multiple sources of data, Yin (2009) describes triangulation as occurring when the facts of the case are supported by “more than a single source of evidence” which also contributes to construct validity (p. 116). This case study used multiple sources of data consisting primarily of materials collected from study participants augmented by literature on human learning and observations made during the
data collection and analysis process. The primary data included the participant pre/post assessment survey, written self-study and mid-point reflections, transcripts of recordings made to document face-to-face focus group sessions, and artifacts in the form of instructional cases. These data sources reflect examples of multiple measures used to support study findings.

The purpose of a case study database is to demonstrate that the data/evidence collected for the case study are retrievable for verification of conclusions drawn from the analyses, as well as to facilitate further study (Yin, 2009). Yin distinguishes the database from the actual case report noting the report will contain the data necessary to allow the reader to draw conclusions about the case; however, Yin emphasized the need to maintain the evidence (e.g., notes, documents, recordings) relevant to the case for storage and retrieval. For this study, a database was constructed that includes all evidence drawn upon for the report (e.g., completed pre- and postassessments, survey key, self-study journal format, etc.), which are stored electronically and in hard copy.

The final principle Yin (2009) suggests to increase reliability is to maintain a chain of evidence so that one can follow the “derivation of any evidence from the initial research to ultimate case study conclusion” (p. 122). The importance of rigor in collection and maintenance of evidence is stressed by Yin who recommends that researchers provide sufficient citation of materials used to draw conclusions within the report, create access to documentation of original source data, and confirm that the data collection procedures followed the research protocol. This study was carried out in accordance with a protocol approved by the SDSU Institutional Review Board. Data
were collected and stored in keeping with this approved protocol to ensure privacy of participant information and confidentiality of data.

In qualitative research, researcher bias can influence study validity and Creswell (2009) recommends that researchers clarify how their interpretations may be influenced by background and experiences. For that reason, I now provide information about my background and experience to inform those reading this case study.

For nearly 20 years, I have worked in university research administration developing policy, procedures, and programs to address research regulatory compliance, as well as research promotion/development for students and faculty. During that time, I have developed research ethics education for students and lay research staff. I am interested in learning how to empower students and/or employees to gain knowledge and understanding about federal regulations, professional codes of ethical conduct, organizational policies, and personal standards that influence research and professional ethical practices within the workplace setting. My review of the literature confirms my intuitive belief that RCR instruction will be most effective if the aims are to: (a) develop self-directed and lifelong learning skills through inquiry, discussion, reflection, and practice and (b) provide opportunities to apply learning to authentic situations of practice. Through awareness of this bias, I have been cautious in my interpretations of the data analyzed for this study to be as objective as possible. Regardless, readers should be aware of my background in RCR education and possible bias that is introduced through my experiences.
Confidentiality

Participants in this case study agreed to allow their materials to be used for research purposes. All data sources were coded to protect the participant privacy and kept in a locked file. The position each participant represented (i.e., student, faculty, employer) was used in lieu of individual names when reporting results to protect participant privacy and confidentiality of data. The biotech company that hosted this internship is not referred to by name. Both the academic program and institution are noted.

Summary

This chapter described the research design, research questions, the setting of the study, subject recruitment, ethical considerations, data sources, data management, data analysis, limitations, and methods to ensure validity and reliability of the data. Qualitative data collected from discussion meetings and participant reflections are analyzed and reported in Chapter 4.
CHAPTER 4—FINDINGS

Introduction

A challenge when developing responsible conduct of research (RCR) education for students seeking professional careers in the public and private sectors is in establishing cross sector relevance. Standards of practice in a professional setting (e.g., business, industry, government, and/or a nonprofit organization) may vary from those within an academic discipline and can also differ across employment sectors. Ethics education that speaks to these differences is needed to prepare science professionals for the workplace. With that in mind, a plan was developed to introduce RCR training within a student internship experience so that topic relevance and application to practice could be learned on the job, so to speak. The plan was written as the course was developed and documented in a draft teaching guidance manual that would be the basis of further field testing. The instructional elements were field tested with participants involved in a PSM internship in computational sciences, specifically a graduate student/intern, intern supervisor, and program faculty member. The participants served in an advisory capacity and as study subjects. The data gathered for this study were analyzed using qualitative analytical techniques discussed in Chapter 3. Chapter 4 describes the findings from analysis of data collection during field-testing of this training.

The study findings are organized and presented in two parts. Part 1 focuses specifically on the instructional techniques used, application of the instruction, and outcomes to answer the first research question. Data sources include the instructional steps, assignments, response to assignments, and transcripts of face-to-face discussion sessions. To answer the second research question, Part 2 describes the RCR content
covered and how participants connected RCR topics to practice in the academic and workplace settings. The content analysis in Part 2 relied on data obtained through face-to-face sessions, written narratives, and observations. Part 2 describes (a) RCR Content and Cross Sector Transfer; (b) Influence on Behavior, and (c) Feasibility of Implementation.

The agenda and schedule for implementation of the project is depicted in Table 2.

Table 2

_Agenda and Schedule_

<table>
<thead>
<tr>
<th>Phase</th>
<th>Initial phase trial of RCR internship model</th>
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</thead>
<tbody>
<tr>
<td><strong>Phase 1</strong></td>
<td>Phase 1—Preparation</td>
</tr>
<tr>
<td>August-September</td>
<td>Project Overview Meeting (1 hour)</td>
</tr>
<tr>
<td>• Planning</td>
<td>• Review goals, format, content, and process</td>
</tr>
<tr>
<td>• Preassessment</td>
<td>• Informed Consent Process</td>
</tr>
<tr>
<td>• Self-study</td>
<td>• Preassessment Administration</td>
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<tr>
<td></td>
<td>• Instructions for guided review (self-study) of research ethics.net</td>
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<tr>
<td></td>
<td><strong>Homework Assignment:</strong> Independent self-study of RCR materials (approximately 12 hours over 2 weeks)</td>
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<tr>
<td><strong>Phase 2</strong></td>
<td>Phase 2</td>
</tr>
<tr>
<td>October-March</td>
<td>Face-to-face Dialogue Sessions 1-6: (1.5-2.0 hours each)</td>
</tr>
<tr>
<td>• Postassessment</td>
<td>• Postassessment Administration (Session 1)</td>
</tr>
<tr>
<td>• RCR content discussion</td>
<td>• Review and discuss RCR topics</td>
</tr>
<tr>
<td>• Reflection narrative</td>
<td>• Guided Dialogue Prompts</td>
</tr>
<tr>
<td>• Capstone</td>
<td>• Case Analysis</td>
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<tr>
<td></td>
<td>• Homework assignment</td>
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<tr>
<td></td>
<td>• Reflection on Learning (Session 5)</td>
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<tr>
<td></td>
<td>• Instructional Case Capstone (Group Collaborative Project)</td>
</tr>
</tbody>
</table>
Format

This field test was implemented with a group composed of a graduate student, industry supervisor, and faculty member. The rationale for convening the intern/student, intern supervisor, and faculty member was to model a learning community whereby participants could converse about RCR within the context of the discipline and the work place and to explore whether it was feasible to incorporate this model within an internship. Both the concept of creating a learning community and building knowledge from collective experiences is consistent with instruction designed to promote lifelong learning aligns with the “Knowledge” and “Community” frames of the How People Learn framework and the “Experience” and “Relevance” principles of andragogy.

Participants

Pseudonyms are used in lieu of the names to protect participant privacy. The intern supervisor is referred to as P1, the faculty member is P2, and the graduate student is P3. The company is called Absorb, Inc. These three formed the learning team for this initial field test and were joined by two project facilitators, referred to as F1 and F2, who guided the process, recorded sessions, and took notes during the process. Implementation of the RCR Intern model in this group setting allowed for the process to be carried out in a controlled environment.

The intern supervisor/mentor, Participant 1 (P1) holds a doctorate in chemistry and is the head of Absorb, Inc. Absorb, Inc. is a biotechnology company specializing in research and development of pain management products. At the beginning of this project, the company was awaiting approval of a new drug by the Food and Drug Administration. P1 is an accomplished scholar, scientist, and business entrepreneur and is internationally
recognized in his field. Participant 2 (P2) is a university professor specializing in bioinformatics whose goal is to work with his lab toward solving unsolved computational problems. P2 is originally from the United Kingdom and came to the United States for postdoctoral studies and to pursue a career in academia. Participant 3 (P3) is a graduate student enrolled in a professional sciences master’s degree program in computational sciences. P3 worked in the private sector for several years for a data security systems company. Working as an intern with a local drug delivery device biotechnology company presented the opportunity to learn about intellectual property and technology transfer practices.

Part 1—Instructional Process and Outcomes

This section describes the instructional strategies used during this field test, including objectives of the instructional process and steps for implementation. The process is depicted in Table 2 and included Phase 1: an initial planning session, administration of a preassessment, and instructions for an independent self-study followed by a homework assignment to develop baseline knowledge and Phase 2: post-assessment, initiation of face-to-face (F2F) discussion sessions, guidance for analyzing and construction instructional cases, and a homework assignment consisting of a reflection assessment narrative. Part 1 of this chapter describes the instructional technique, process of implementation, and associated outcomes. Findings are reported to answer the first research question on what instructional strategies were used and how they contributed to developing understanding of RCR generally and application to computational sciences and a biotechnology company specifically. Each step of the process is described beginning with the planning session.
Phase 1—Preparation

Phase 1 involved the preparatory process for initiating the field test. Included was a 1-hour planning meeting where project goals, format, course content, and process were explained and discussed. In addition, the informed consent process was conducted, preassessment data collected, and instructions were provided for the independent study assignment.

Planning session. The two co-facilitators (including this investigator) led the initial planning session. During this session, the participants introduced themselves and the project was discussed including an overview of objectives, expectations, and format for future meetings. Participants were informed that their respective experience in the academic and industry settings was important for developing an understanding about how RCR topics present within the discipline of computational sciences (academic) and in a biotechnology company (industry). Recognizing the value of participant prior experience is consistent with Knowles’ principle of “Experience.” They were also informed that they were not expected to be subject matter experts in RCR content aside from knowledge they had obtained from prior experiences in academic or industry settings. Informed consent to participate in the project was discussed, and each participant agreed to participate.

In advance of initiating future face-to-face discussion sessions, participants agreed to review preselected RCR materials independently to acquire foundational understanding of core content. For each F2F session, participants agreed to share responsibility for facilitating discussion sessions, share their experiences around each topic, and develop instructional cases that reflected ethical dilemmas in the professional setting. All sessions
were held on the SDSU campus at times and dates convenient to the participants. The participants received a monetary stipend as compensation for their contributions to the planning process.

**Preassessment.** A preassessment was administered during the planning session to assess participant knowledge prior to beginning the independent self-study process. Providing an opportunity for learners and facilitators to understand existing knowledge and preconceptions is consistent with the HPL principles of knowledge and assessment. An excerpt of the assessment is found in Figure 4, and the entire assessment is in Appendix C. While status in the group (e.g., faculty, student, or employer) or prior experience may influence knowledge of RCR, the expectation was that participants would enter the training with a similar understanding of RCR topics generally. The 30-item measure included questions that reflect research integrity broadly (e.g., research misconduct, conflict of interest, mentoring, data management). The items included both forced choice and open-ended response options. The results indicate that at the preassessment, P3 (student) scored 8 correct answers, P1 (industry) scored 11 correct answers, and P2 (faculty) scored 15 correct answers. For practical purposes, these data support the premise that these participants started the project with limited knowledge about RCR. Stating that participants began the project with a similar understanding of the topics was not supported given the faculty member was most familiar with 50% correct responses; however, these scores suggest that all could benefit from increasing their understanding of topics related to RCR. The HPL knowledge centered domain suggests a goal of instruction is to move participants from a novice status to an expert
6. Please list three reasons why collaborations are increasing in science.

7. Which of the following are primary ethical principles that form the basis for conducting human research in this country? [Circle all that apply]
   - A. Community need
   - B. Justice
   - C. Beneficence
   - D. Quality of science
   - E. Respect for persons

8. According to the International Committee of Medical journal Editors (ICMJE) guidelines, which of the following does not count toward an authorship credit?
   - A. Providing lab space
   - B. Substantial contribution to research conception and design
   - C. Final approval of the manuscript to be published

**Figure 4.** Excerpt of pre/post survey.

status. Using the pre was a useful tool to assess baseline subject matter knowledge; however, it did not measure conceptual understanding.

**Self-study process and outcomes.** Following the pretest, group members were instructed to independently review a web-based resource on research ethics to acquire introductory information about RCR topics. The purpose of reviewing this tutorial was for participants to obtain foundational information about RCR (e.g., topics, definitions, goals) that would inform future face-to-face discussion sessions. The website selected for this field test is called Resources for Research Ethics Education (RREE). This website was developed by Michael Kalichman, director of the research ethics program at University of California, San Diego along with other contributors with the purpose of “providing resources and tools for teachers of research ethics” and a goal to “promote best practices and evidence-based research ethics education” (Resources for Research Ethics Education, 2012, para. 1). The website includes 14 topics relevant to research
integrity instruction, including the nine core instructional topics recommended by the Office of Research Integrity. Within each RCR topic area is a summary, background information, regulations and guidance, instructional cases, and resources.

Participants were instructed to review materials within the RREE website over a 2-week period (see Appendix D for detailed instructions). To guide this self-study process, participants were given instructions for reviewing the modules and directions for keeping a journal throughout their review of the materials (see Figure 5). Briefly, the participants were instructed to review the “Introduction” which included distinctions, purpose for teaching research integrity, related goals, knowledge, attitudes, behaviors, and skills. Following the introduction, participants were asked to review sections within the module to become familiar with the background, regulations, considerations, and resources. In addition, participants were asked to review instructional cases for each topic and consider how the case might be reframed to represent the realities of the professional setting, in this case, a biotechnology company. To guide reflection about these topics questions/writing prompts (see Figure 5) were used with participants being instructed to answer the questions in a written journal for each topic covered in the RREE.

Participant journal entries were analyzed to assess whether the instructional strategies of self-directed learning and reflective writing were carried out. Completed journals were submitted by P1 and P3. When reviewing the narrative entries for the two participants who completed journals, it was evident that each participant had engaged in guided self-study to become familiar with the RCR topics. One participant provided handwritten notes organized by topic that included thoughts on module review questions,
1. Based on your experience and what you already know about this topic, what is left unaddressed in the material presented in this module?

2. What additional questions does this reading raise for you?

3. Based on your experiences in academia, what seems unrealistic or impractical in the information/approaches presented in this module?

4. Based on your experiences in business/industry, what seems unrealistic or impractical in the information/approaches presented in this module?

5. What information presented in this module is specific to the academy/academic research environment and not relevant to business/industry?

6. What did you learn about this topic that you did not know prior to reading the module?

7. What would you want your colleagues to know that they probably do not know about this topic?

Figure 5. Reflective writing prompts for self-study activity.

case studies and assignment questions (see Figure 5) totaling 30 pages. The other participant used a type written format to answer the assignment questions; however, it did not include reflections on the cases nor module review questions.

To reiterate, the purpose of utilizing the self-study materials was to develop baseline knowledge of RCR content and to begin thinking about discipline and cross sector application and relevance to industry. The participant narratives provided evidence confirming that self-study of RCR materials can be useful in developing knowledge and assessing relevance to one’s work. Several examples follow:

- Animal Research

  P3: Working in the field of computational science, I have had very little exposure to animal subjects. The background reading does a great job at introducing the topic but raises more questions than answers.
- Research Misconduct

P3: Outside of academia, people working in science do not all necessarily consider themselves scientists. Should they feel the obligation to act?

- Social Responsibility

P1: Who is responsible for clinical dimensions of scientific discoveries?

Scientists play a role, but not a determining one.

- Authorship

P3: Authorship is a very difficult subject to discuss and one that I have come across in my work. It would have truly helped me to read this article before discussing the subject with my advisor. I liked that it brings up other forms and levels of credit and acknowledgment. While not all authors reviewed the final version in my experience, they reviewed and approved their section of expertise.

- Publication

P1: Only a small proportion of industry research is published and guidelines for patent texts are different.

Likewise, participants were in agreement that RCR topics were relevant in both the academic and business environments. However, they recognized the conventions of practice varied. For example, collaborative relationships within the academic setting are viewed as more casual than in the business setting. One respondent noted, “Business collaborations are drawn out explicitly by legal documents with discussion of credit, work, acknowledgments, etc. hashed out by the lawyers and not the scientists.” Another difference noted was with regard to data ownership with industry being very clear that
“all data and records belong to the company,” whereas in the academic setting, data ownership is negotiated between the institution, faculty, and/or student and may be handled differently if external funding is involved.

The self-study instruction prompted participants to reflect on questions that remained following their review of the materials. It was anticipated that learning about RCR would raise a number of questions for participants. Documenting questions about the material demonstrates a form of self-assessment, which is consistent with learner-centered instructional practices to assess understanding (Bransford et al., 2000). A few examples of questions posed by the participants included: “How much animal testing is being done in research today?” “To what degree does mentoring at the level recommended actually happen in research?” “Are there comparable ‘dual use’ concerns in domains outside of the biological sciences?” “Whether a collaborative framework between, say, two academic groups can be formalized in writing ahead of commencement or, whether such would stifle the prospect of the collaboration being established?” “Are record keeping practices more rigorous in business when compared to academic laboratories?” “Can an individual be held responsible for the quality of data after they have left an institution?” It was expected that thinking about questions in advance of face-to-face meetings would prepare participants for ongoing discussion and facilitate dialogue.

**Postassessment.** The postassessment was used as an additional assessment of the self-study process to identify if the number of correct answers changed as a result of completing the RREE and was administered in advance of beginning the face-to-face sessions. The postassessment was identical to the preassessment and can be found in
Appendix C. For the two participants who completed the written narrative, pre- to posttest scores increased substantially, with one participant increasing the number of correct answers from 11 of 30 to 23 of 30 and the other participant improving from 8 of 30 to 27 of 30. One participant, P2, who did not submit a written narrative of self-study, showed a slight increase with 17 correct answers compared to 15 of 30 at pretest.

As previously stated, the purpose of the pre- and postassessments was to see whether participants were entering the project with similar understanding of RCR content and if guided self-study of introductory materials on RCR content would improve participant knowledge, which may then contribute to informed discussion. The pre-post test scores indicated that guided review of materials on RREE resulted in increased knowledge of RCR topics for the two participants who provided documentation of completing the assignment. The participant who did not provide documentation of his review also did not improve his scores to the same degree. While it is not possible to generalize these findings, the data suggest that the guided self-study approach is useful in increasing understanding of RCR core content areas and is congruent with the learner-centered domain of the HPL framework, which encourages instructors to attend to what the learners bring at onset so that knowledge can be developed with consideration to prior conception (Bransford et al., 2000). Additional testing of this method is recommended for future research.

**Phase 2—Discussion Sessions**

This section describes instructional strategies used within the face-to-face discussion sessions and documents examples of how the strategies contributed to discussion about RCR in computational sciences and a biotechnology company.
**Face-to-face (F2F) discussion.** The purpose of the face-to-face sessions was for participants to (a) share their knowledge and understanding of RCR content and practice; (b) connect the application of these topics to their work; and (c) develop instructional cases that depict ethical challenges that a science professional may experience in a company setting. The findings reported in this section describe the instructional process including examples of how those strategies prompted participants to share knowledge, connect RCR to their work experience, and produce awareness of challenging situations in the workplace that would provide source material for instructional cases.

Face-to-face sessions were held in a conference room on the San Diego State University campus. The campus location was identified by the participants as convenient and was selected solely for that purpose. The room is approximately 15x25 feet, with a rectangular conference table that seats 8 to 10 people. The conference room is accessed from the office lobby and has a large screen monitor at one end of the room. The monitor was used to project case studies that were used during group discussion. The sessions were scheduled at the convenience of the participants and typically occurred either early in the morning or early evening.

The first session was unique in format when compared with sessions that followed in that it was facilitated by the co-facilitators with the goal being to gather information from participants about their self-study process and to generally discuss RCR content to identify areas that were most and least relevant to their work. Sessions 2-6 involved more focused discussion on animal research, data management (documentation, retention, and sharing), authorship, publication, peer review, human subjects and social responsibility and were facilitated, primarily, by participants. The final face-to-face session included
Guidance on instructional case writing, topics to consider, and responsibilities for writing. Each session lasted approximately 90 minutes.

**Guided dialogue.** With the exception of the first session, participants identified two topics (e.g., human subjects, authorship standards, etc.) to discuss. Having participants involved in decision making about the course reflected Knowles principles of andragogy and the HPL learner-centered domain. To prompt discussion, each member of the group was asked to review their self-study written notes and case studies in advance of face-to-face meetings. After the initial meeting, group members alternated responsibility for facilitating each session. The designated facilitator used prompts to guide reflections and open discussion during the session (see Figure 6).

1. From your experience, how does this topic present in the academy or business/industry?

2. In what ways does this topic need to be re-defined/re-conceptualized to take into account business/industry realities?

3. What are the specifics of this topic in industry that aren’t found in academic research setting?

4. Elaborate on whether the ethical dilemmas presented in these research case studies are relevant to PSM students in your industry? How might they need to be presented differently to capture industry concerns?

5. What do you think would work best to increase awareness of ethical issues in industry?

**Figure 6.** Prompts to guide discussion.

Analysis of the transcripts and observation of conversations during F2F sessions indicated these questions were useful in guiding discussion and engaging the participants in talking about their understanding and experiences, connecting the topic to their work, and considering cross sector implications. Not only did the questions prove useful in
initiating conversation among participants, they also prompted additional inquiry and
dialogue between group members about the topics. Several examples are provided to
demonstrate how the process of guided dialogue resulted in participant discussion of their
experiences and understanding of the RCR content as practiced in an academic discipline
and a business setting.

Example 1: In this first example, Participant 1 is assigned the role of facilitator
and initiates conversation about the RCR topics of human subjects by asking the first
prompt question.

P1: Prompt: OK, so we’re doing human subjects and the first question is from
your experience, how does this topic present in your work?

P2: So what I’ve run into is much more from the pharmaceutical line I’ve
worked; I’ve had some internships when I was much younger at
pharmaceutical companies that were doing late stage clinical trials and those
kinds of things, so how do they document the trial process and working with
doctors to recruit patients and those kind of areas, and then I guess also a
little bit of just local bio-techs hearing stories but not really being directly
involved.

P1: I’ve never directly worked with human subjects in an academic context, but
like here is there or in your past experience, P2, where clinical studies of
some form were pursued by the academic institution. How do the
participants sign up to take part in the study? I mean what’s the process that
they have to go through? Are they encouraged by a professor to do so or?
P2: So, one good example is how we’re here, so this study is controlled by an institutional review board, so actually anything you do, even if you stop people in the street and ask them questions or if you watch people using computer software.

P1: It has to go through the IRB?

P2: Yeah, any time you interact with a person it has to go through the IRB.

P3: So, what do they decide though?

P2: So, for most of it there’s an exemption that just says they just kind of look at it and you know are the questions appropriate, are you asking anything that you shouldn’t be asking, are you trying to find out information that you shouldn’t be trying to find out.

This example demonstrates how the initial question prompted a participant to reflect on his prior experience and then connect knowledge about human subjects protections to this actual project. The session facilitator, P1, also prompted further discussion by sharing his lack of direct experience, which stimulated participant interaction about how human subjects research is treated in the academic environment. An interesting observation in this example is that each participant contributed to the dialogue without needing to seek guidance from the project facilitators. The level of facilitator dependence is an important consideration in development of the practicum and in determining whether the instruction and guidance can stand alone or will require an RCR subject matter expert in some capacity.
Example 2: In example 2, Participant 3 was charged with leading the group discussion on conflicts of interest. The guided dialogue prompt is used to initiate the conversation, which results in discussion between participants about nonfiscal conflicts.

P3: Alright, so I guess we’ll start with the conflicts of interest module and so from the reading, I mean from your experience, how does the topic present in business and industry? P1, would you like to start?

P1: Absolutely. Well, in industry some of the thoughts that came to mind on conflicts of interest is where the possibilities of advancement promotion, possibility for funding, well I’m thinking there for funding if the outcome is positive.

P3: I mean I kind of thought from the reading that the possibility of advancement/promotion was kind of along the same lines and not necessarily a conflict I mean.

P1: Well, I know, but it’s where you’re not fully being objective because the outcome, you know, the outcome may benefit you in what you know.

P2: Whether you’re going to promote your wife or husband?

P3: Well, that’s . . . .

P2: Nepotism.

These examples are generally reflective of conversations that occurred over the course of the F2F sessions and across the various topics discussed. The prompts were not used prescriptively and the conversations flowed freely among participants providing opportunities to practice having conversation about RCR in the workplace. Discussion of instructional cases was another strategy that influenced conversation during the F2F
session. A description of how case analysis was introduced is described in the following section.

**Case analysis.** Case studies were discussed to prompt reflection about ethical issues that may occur within the professional setting and consider how that particular issue may transfer to industry practices. Case-based reasoning is considered a problem-based learning approach used to develop critical thinking skills and falls within the constructivist theoretical paradigm. This instructional method resonates with Knowles principles of andragogy and learner-centered instruction in that connecting content directly to what the learner finds relevant in their personal and professional interests will facilitate learning. Likewise, problem based learning is used to connect relevance of the instruction to the participants’ actual work setting. The practice of case analysis was also used to increase familiarity of how cases are constructed so that participants could develop instructional cases following the discussion of the topics. Cases reviewed during the F2F discussion session included those reviewed during the self-study process, as well as cases obtained from other public sources. When assessing the various case studies reviewed during the discussion sessions, participants were asked to consider: (a) what aspects of the problem presented an ethical concern; (b) the facts of the circumstance and what laws, regulations and/or codes may be in questions; (c) parties or stakeholders who may have an interest in the case and, (d) possible courses of action that could be taken and consequences of those choices. Several examples of conversation prompted by cases analysis show how participants examined the situation and practiced problem-solving strategies:
Example 1: In the following example, a case is discussed that depicts a problem in a laboratory setting between a graduate student and a faculty mentor. The case analysis process prompts the participants to discuss the issues from various perspectives and to strategize problem solving.

P3: Does she have responsibility for two of the lab mates to kind of stand up to Holtzer and kind of not let it go down?

F1: Well, I think she has that responsibility. I’m not sure I would say that’s responsibility to her lab mates, more of her own responsibility if she’s going to be a colleague eventually.

P2: To scientific integrity?

F1: Right, yeah, she needs to say what she needs to say for her own sense of integrity and her own sense of how science works and works well; although the benefits would accrue to the lab, yeah. So this one hinges on being a rock and a hard place and then trying to figure what realistically a graduate student could do in this instance, right? So that’s where you would be helpful in sort of thinking through in a case the relative powerless of a grad student, it’s relative powerlessness; you’re not completely without power, you do still have some agency and so?

P1: So, what would you do P3?

P3: What would I do? I’d probably try to seek approval, I mean if it gets done faster right?

F1: So, you’d right an amendment and submit it to the IACUC?

P3: Yeah. Well, how long does IACUC approval take?
P3: If I thought it would be short, relatively short I’d probably go that route, maybe I’d go talk to someone else and figure out, all right what other options you have.

This example shows how the case analysis process presented opportunities for participants to explore how they might handle an ethical dilemma, which is demonstrated in the example when both F1 and P1 prompted P3 to explore how he would address this conflict. It also depicts an example of ethical dilemmas that have few good options from which to choose.

Example 2: Example 2 demonstrates how discussion around case analysis can prompt reflection of the participant’s direct experiences with an ethical challenge. This example was taken from the session when authorship was discussed, and the participant describes how he thinks about authorship in practice.

P3: It is under the topic of authorship and it’s case number one . . . so there’s no agreed upon definition of what it means to be an author at all. So is, is there [a definition] for [an] inventor are there certain . . . .

P1: Well there is, but I mean in principle there is, but in practice it’s a little bit fuzzy as well.

P2: Yeah, I think I’m in the boat, the more the merrier for authorship.

P3: It’s path of least resistance, right?

P2: There’s no impact.

F1: Unless they haven’t done actually anything on the paper.

P2: But it doesn’t matter. It makes no impact to me.
F1: Well, it makes no impact to you but, it is, again it depends on what we want authorship to mean. Both ourselves individually and what we want it to mean in the academy, and what we want it to mean in the larger world, to the public.

P2: Yeah, but quite frankly I can’t care about those three things. Because I have to deal with the reality of talking to the people that say, I think I made a contribution to that paper. I should be on the paper, and I say well, what did you do? And they said well, I read that paragraph. And then I say well, that’s not enough and they say, ohhhh, usually. And then there’s tears and stuff.

It is evident from this dialogue that the case analysis process can provoke discussion of real, as well as hypothetical, ethical challenges and also demonstrates the difficulties in making decisions when the guidelines are not black or white. Areas lacking in guidance or firm rules were those eliciting the most discussion from participants. The industry perspective, with respect to authorship, was a much lesser problem area since publication is not prioritized nor encouraged.

Example 3: Example 3 provides evidence of how the use of case analysis prompted a discussion of differences between the academy and business with respect to data management practices.

F1: How does that work in industry?

P1: The notebooks are owned by the company, and any self-respecting company would have a fairly tightly controlled check-in check-out so you know who’s got it at any one time in our case would be.
F2: So, this would never be a question in industry?

P1: We back them up, well I mean it’s a pain in the butt to do right.

F2: So, if P2 is working for your company and he now wants to go to another company, there’s no way he’s going to ever think that he can take any of it with him?

P1: There’s no question.

P2: Yeah, but at the same token as this case study, then I might think well I’ve had all these brilliant ideas while I’ve been working for P1 if I just photocopy them I can take them with me, and I’m not going to be working on the same thing when I go to my new company, but at least I’d get a record of all my brilliant ideas that I had.

P1: Yeah, but even that would be in the [contract] language.

F2: But I think he already had you sign something that said you don’t own any of your brilliant ideas the minute you put something on that document it belongs to them, that’s part of your employment contract, right?

P1: Yeah, I mean you know we, you tend to sweat that a bit to make sure the language is all encompassing, yeah. But I’m still intrigued by this issue about the professor being able to walk off with the notebooks, I mean why, we think the students can’t, why can the professor?

P2: So, it’s also a little bit not so black and white. So, one of the problems with this case is that it’s also a mentoring case because typically when I, especially when people that are going to get jobs, and if I haven’t had the conversation beforehand, you know sometimes it hasn’t happened to me but I know at
least in one where somebody went straight from Ph.D. to a faculty position, which is unusual typically, people don’t do that right? And, so I actually counseled my friend who did this that she should sit down with her advisor and discuss what are you going to work on? what am I going to work on? And, that’s a conversation that you need to have openly, and before you just kind of say, “I want my books,” you need to have it be very clear about that and to think about it and it’s a mentoring issue.

This example demonstrates that discussing a case study can prompt dialogue about how RCR domains present in practice. In this case, the group discussed data ownership, intellectual property rights, consulting agreements, and responsibilities of mentors and mentees to discuss expectations. In this discussion, the norms and practice within the academic setting are clearly different than the business environment, which is not unexpected given the different goals and values. These examples provide some evidence that the case analysis instructional strategy is effective in facilitating dialogue about RCR and relevance to a discipline or business setting.

Example 4: This passage presents an example of how case analysis discussion was an effective instructional strategy for prompted ideas to inform an instructional case that the participants would write for a final project. The concept was to identify content areas that were particularly challenging in determining an appropriate ethical course of action and consider how that situation could be developed into an instructional case. In this example, the participants are discussing the differences between academic and business expectation around publication practices.
P1: Well, in any company that’s doing research, there is a dynamic that is arguing the case for publication. On behalf of, as P2 said, the people, the credibility, the presence of the company. But there are several other forces that are arguing against, and it’s an interesting dynamic. Easy answer is, we never publish anything. That’s the simple, you know, really is, because you end up kind of often being a lone voice, saying we should do this. And it’s a hard argument because the benefit of the publication is intangible. And the potential cost is often not. But it’s another interesting dimension if we know, let’s say we came up with a way of oh, just trying to think of predicting who’s going to get aggressive melanoma. And we, we somehow use that in the development of new products, that you know, that protect the skin from sun irradiation, which contributes to that. Are we are ethically obligated to disclose that we have this, you know, this diagnostic test?

F1: Keep that in mind, because that would make an excellent case . . . would allow you to bring in all sorts of public versus private knowledge, profit versus, knowledge generation, social responsibility and the limits of, and expectations of. If you have more expectation of a public servant being socially responsible than you do of a capitalist, basically so, that, that might be interesting as well.

Learning about the cultural difference between the academy and business setting was possible because participants came to the discussion with adequate knowledge to engage in meaningful discussion. The semi-structured guided dialogue process combined with case study analysis provided opportunities for participants to share their experiences,
knowledge, and understanding of core RCR instructional content, as well as examine their misconceptions. Likewise, the face-to-face interactions enabled participants to connect content to practice within the workplace, be it the academic lab or the business setting. The discussion also contributed to material for instructional cases that participants would use to depict ethical challenges that a science professional may experience in a company setting. The F2F meetings produced extensive discussion covering a variety of issues associated RCR including mentoring, training of mentors, conflicts, data ownership, inventorship, consulting agreements, social responsibility, organizational culture, authorship, theft, espionage, and collaboration that are discussed further in Part 2 of this chapter. The broad range of topic areas discussed by participants supports using traditional RCR instructional domains as a starting point for learning about how RCR is practiced within a discipline, as well as how content transfers to practice in a biotech business environment. In that regard, the instructional methods of guided dialogue and cases analysis around RCR topics appears to be an effective strategy in creating a forum for participants to share their knowledge and understanding of RCR topics and to connect the application of these topics to their work.

The concept of forming a small group to discuss RCR from both an academic and business perspective was valuable for learning how RCR topics present and transfer, as well as the unique challenges that arise. Assigning responsibility to participants for guiding F2F discussions worked well with this group, as demonstrated through the examples. Overall, these face-to-face instructional elements were effective and aligned with elements of both Knowles’ principles of andragogy and the Bransford et al. (2000) How People Learn framework.
Regardless of the valuable learning opportunities, there were challenges raised by the participants when queried about whether these conversations could realistically happen in an internship placement. Participants noted that employers may not value or prioritize ethics education, or may assume students should receive this education elsewhere. There were also concerns whether coordinating schedules to carry out 12-15 hour of F2F time would pose a barrier and suggested alternative approaches. These challenges along with recommendations are discussed later in this chapter.

**Midpoint assessment narrative.** Before completing the face-to-face sessions and beginning the instructional case construction phase of the module, each participant was asked to independently reflect on their learning and the learning process by answering statement/questions about each of the topics discussed in the sessions (see Figure 7). This homework assignment was completed outside of the scheduled F2F meetings. The purpose of this reflective writing assignment was for participants to assess their understanding of the topic and for the co-investigators to have additional feedback regarding the process of learning through dialogue and self-study methods. This method of instruction is congruent with the metacognitive approach to learning within the HPL assessment-centered domain and integration of metacognitive approaches to promote “sense-making, self-assessment, and reflection” (Bransford et al., 2000, p. 12).

Narratives were analyzed to understand how participants considered the topics, whether they were using what they had learned and how they perceived their responsibilities as a result of participating in the module. In their narratives, participants reiterated some of the complexities associated with the topics disclosed during the
1. Briefly describe what you think was the most important point of information about this topic for your work.

2. Do you think it is important to talk about this topic with others (e.g., faculty, interns, students, employees)? Why or why not?

3. In the time since we talked about this topic, have you had discussions with others about this topic/the ethical dimensions of this topic? Why or why not?

4. Are you more comfortable talking about this topic/the ethical dimensions of this topic as a result of these discussions?

5. Do you have a better sense of how this topic fits in with your industry/teaching/PSM program work as a result of these discussions?

6. How much responsibility do you think you should take in initiating conversations about the ethical dimensions of this topic as a student/intern, faculty mentor or intern supervisor?

Figure 7. Midpoint reflection prompts.

discussion session. The narratives also provided added detail about the participant’s attitudes and behaviors about ethical dimensions of their work.

The topics addressed included authorship, data management, collaboration, conflict of interest and animal research, as those were the RCR domains discussed up to that point in time. Consistent with the discussion sessions, the topics were all considered important to both computational science as a discipline and to the biotechnology company. Authorship and collaboration were areas noted by participants to be most important for frequent discussion when compared to data management, conflict of interest, and animal research. The rationale provided by respondents points to authorship and collaboration as being areas that are not as clearly defined by rules and regulations; however, they have the potential to significantly impact one’s career and require clear communications about expectations and roles on a project.
For example, with respect to authorship, participants each confirmed the importance of this topic from both an academic and business perspective and acknowledged the differences between how authorship is valued in both settings. As to responsibility participants assumed for discussing authorship, all agreed it was important to talk about authorship with colleagues early in the relationship and appreciated knowing of guidelines and standards (e.g., contributorship model and ICMJE guidelines) for considering authorship. When asked if they had actual discussion about authorship with colleagues since discussing the topic as a group, both P2 and P3 affirmed they had engaged in dialogue to clarify their role regarding authorship. For example:

P3: During this time, I have written several papers and have had several discussions on authorship. The reading has helped me build a platform with which to build my arguments. This is a topic I had never discussed before these sessions and I’m glad to have covered this topic.

Participants also acknowledged feeling more comfortable discussing authorship. For example, when asked directly if the discussions resulted in increased comfort talking, participants stated:

P1: Yes, I am—the availability of an independent, objective set of guidelines, that people who are faced with authorship issues have put substantial time and thought into developing is certainly a help.

P2: Yes. I didn’t know about either the contributorship model (although I have used it) or the ICMJE guidelines. I can use these in discussions with colleagues and collaborators.
P3: Definitely. The reading/discussion on this topic has given me a basic understanding and the general consensus of who should receive authorship credit. It has also introduced some of the dilemmas about the topic (e.g., should authorship be granted to technicians who supervise the work?)

When asked about responsibility in initiating conversations about authorship, all believed they needed to take responsibility for initiating discussions. This responsibility to formalize authorship and/or collaborative work was put to practice by P1, who disclosed how he planned to increase discussion and documentation of expectations in the workplace now that he was more aware of differences in expectations and value of authorship from an academic perspective.

P1: I am primed to bring up the subject for discussion in interactions with University students, where a suitable forum presents itself. I’ll think further as to how I might bring up this topic in discussions with, for example, new entrants into our company, or at those times when external presentations or papers are being discussed. I do anticipate raising the topic should I again supervise or co-supervise a graduate or postgraduate student and, potentially, when next establishing a collaboration with a third party academic.

Independent of our work here, I have moved in the direction of more discussion and documentation of expectations and treatment of the outcomes of research (note, though, business research not scientific research) with undergraduate interns that I am now engaging to work with me.

These responses provide evidence in support of introducing reflection activities as an instructional strategy for formative learning assessment. The participant reflection
narratives suggest an increased appreciation and understanding of the ethical dimensions across each topic considered, and the increase in knowledge appears to influence attitudes and behaviors. A more detailed analysis of cross sector relevance of RCR topics is reported in Part 2.

**Instructional case construction.** Case analysis during the F2F sessions was used to advance discussion about ethical aspects of research in practice and connect the RCR domain to the work environment. Responsible conduct of research cases that reflect academic biomedical settings were used to provoke discussion of how the situation might present in industry. In some cases, the instructional case could be adapted to reflect the industry environment, and with several the participants found there was no connection or relevance to their discipline or business setting. The practice of instructional case construction was incorporated as an instructional strategy for the purpose of having participants work collaboratively to create a case. The idea for the case development project would initiate a bank of instructional cases that could be used by a PSM educator as a resource for teaching about ethics in the workplace. The F2F sessions included time to practice analyzing case studies and guidance for how to write a case study.

The outcome of the case building instructional strategy was the creation of four instructional cases (see Appendix E). The subject matter of each case reflected a few of the complex ethical issues raised during the F2F discussions and depicts authentic ethical challenges that intersect academy and industry concerns. The case topics cover intellectual property ownership rights, data integrity, animal protections, and consulting conflicts. With each case, the participants included an analysis that addressed the parties involved, actions taken, consequences to the parties and obligations (see Figure 8 and
Andrew Kulpa just finished his second year as a master’s student at the College of Saint Remos and has taken a summer internship at a software startup. This startup, Zing, is working on a new search technology focusing on images. The company was started recently by two former graduate students from Saint Remos who had been researching machine learning; they dropped out to pursue this business venture.

Andrew is working specifically on a variation of the current grouping algorithm. The Zing founders originally created the algorithm during their time at Saint Remos. They decided to keep their algorithm a trade secret, not wanting to teach their competitors their key advantage.

Andrew was given a desktop computer in which to do his work at Zing, but would often bring his work home on a flash drive. At the end of the summer, Andrew was asked to continue his internship during the school year, where he is done with his classes and is solely working on his master’s thesis.

Because the Zing founders are Saint Remos alumni, they receive invites to the department’s thesis defenses. Reading of Andrew’s defense the next week, they think it would be a good opportunity to support their employee and mingle with old cohorts. Upon arriving for the defense, the Zing founders notice the title of Andrew’s work—“Grouping Images via Content Determination.” There is a real possibility that Andrew is about to divulge key Zing company secrets. What do they do?

Analysis

Parties
- College of Saint Remos
- Zing and its founders
- Andrew Kulpa
- Andrew’s advisor

Actions
- The Zing founders agitate to immediately stop the thesis defense.
- The Zing founders can let the thesis defense continue.
- The Zing founders approach Andrew quietly and ask about his research, something they had not done previously.

Consequences
- The Zing founders protect their company secrets. This ruins Andrew’s thesis and Andrew is not allowed to graduate.
- The Zing founders possibly lose their business. Andrew is allowed to defend his work and graduate.

Obligations
- The Zing founders have an obligation to their shareholders to protect the company interests.
- Andrew had an obligation to seek permission to use Zing’s material and time to apply to his thesis project.

Figure 8. Case of intern dissertation and intellectual property.
Appendix E). Integrating a collaborative project assignment within this RCR education demonstration proved to be an effective instructional strategy. Interestingly, further field-testing of this module resulted in a range of styles of case studies suggesting the need for more detailed guidance for the case development project, if there is a desire for style consistency.

**Part 2—Cross Sector Relevance of RCR Domains**

Through discussions and written narratives, participants commented on how RCR content pertained to standards of practice within the discipline of computational sciences, as well as transfer of practice to the biotechnology industry. Topics discussed included, but were not limited to, authorship, data management, research subjects, collaboration, conflict of interest, mentoring, and social responsibility. These domains of research ethics were described in terms of relevance, regulatory oversight, expectations within the domain, and experiences of participants with both industry and academic settings. The transcripts and narratives provided examples of relevance to the field and similarities and difference in values and conventions. In many cases, participants identified clear distinctions between expectations within the business environment and the academic setting. The data also showed that traditional instructional RCR content can be used effectively to explore differences in the conventions and standards between the academic and business setting. For example, data management raised extensive discussion on issues around standards for documentation, intellectual property, consulting agreements, trade secrets, and publication practices. Likewise, discussion about publication and peer review raised issues around organizational goals (openness versus proprietary) and the
valuation of patents being greater than the sharing of knowledge through publications.

Additional examples follow.

The area of authorship was used to generate a discussion about data ownership, patents, and value of credit in academic and business settings. All participants identified authorship as an important aspect of their work and recognized similarities; however, the practice of authorship was clearly distinct between industry and academic settings.

Authorship, within the academy, is a method of documenting one’s contribution of new knowledge to a particular field of study and is encouraged and valued. Within the culture of industry, authorship is also valued; however, the practice of publication can conflict with the need to protect proprietary information in the patenting process. Within the narrative summary, P1 stated:

Publication is not something we currently have as a priority. We do sometimes have issues of researchers being concerned about credit for research advances made, but these are all internal management issues, at least at this stage, and not tied to any external publication.

Organizationally, the business culture is perceived by participants to be very structured with firm positions on who owns the data and how it can be used that are negotiated formally through legal agreements. The practice of formalizing agreements was contrasted with the academic environment, where agreements are often informally constructed. The discussion of authorship also prompted dialogue on consulting agreements, nondisclosure agreements, collaborative science projects, and patents. The following passage is an example of discussion around the ethics of consulting with industry and ethical challenges of intellectual property rights:
P2: But I think one of the things that I think probably needs to be discussed at PSM’s relative to ethics and consulting agreements and those kinds of things is you know what’s an appropriate consulting agreement, what’s appropriate behavior for a consultant that’s consulting at different places you know, so if you’re really, you start consulting and you go to two or three different companies, is it ethical to take the paperwork from one company and use it for another company?

P1: Take the paperwork, stuff that you’ve written?

P2: Yeah. Right and sort of reformulate it right, or should you really start from scratch? Is it ethical to I’m not saying you know photocopying stuff and stealing it and giving it to the competitors which is clearly not, but if I, you pay me to write some code, you know, develop some computer program and then somebody down the street pays me to develop a computer program, how much of what I develop for you can I use for them? How much can I double dip?

P1: Well, then the simple answer is none.

P2: Yeah, that’s the simple answer, but I’m sure . . . .

P1: It’s hard to enforce because typically the agreement would say that whatever you do while working for us is owned by us and cannot be copied or disseminated.

P2: And the other thing I was thinking about, somebody was telling me that you know you have to do a whole bunch of paperwork to get a drug approved or to do something right, so you’ve kind of got the templates because you’ve
already written them, so then the next company you go to now you have to
deal with all the paperwork again, so you kind of take the templates as
opposed to just re-writing all the documents.

P1: Yeah, that’s a tough one, but again I would say that you know we’ve sort of
gone through that over the last 9 months, so the fact is that developing the
template is a significant cost.

P2: Yeah, absolutely.

P1: And so you know you shouldn’t copy template because something of real
value, you’ve contributed to that company and being paid for, you know, it’s
not reasonable that you take it somewhere else because there may be a
competitor of the company or whatever that you’re helping so, unless its in
public domain somehow. You know if you had it beforehand that would be
different. If you pulled it off the web that would be different but . . . .

P2: But so that’s, yes, I agree with you 100% if I write a piece of code that you’re
paying for I should not use that code again, but you know what if I change
50% of the code right; what if I start with that idea and I’ve changed all of the
code, I mean, it’s like there’s another joke about isn’t there about somebody
buying a car and he buys like a wheel and then.

P1: Oh yeah.

P2: When is it ethically appropriate? What is ethically appropriate? Is it just to
say if you are doing consulting for different companies, and you write a piece
of code for them, you should never touch that code again, you should give it
to the company and destroy it from your computer and not think about it?
This passage denotes the complex issues of intellectual property and ethical challenges in using work developed when consulting or work for hire and gave participants an opportunity to converse about these issues and examine the standards and expectations. This example also supports using commonly accepted RCR instructional content as starting point for learning about similarities and differences in conventions. However, these discussions suggest that additional topics be added if they are identified consistently during field testing.

Mentoring was a subject that also had different connotations between how it is practiced in business versus the academy, as well as how ethics is considered within mentoring. Mentoring, from the industry perspective, was viewed as a prevalent, yet an informal process, with the motivation being to get guidance on career direction. The formal process within a company was equated to an orientation process for employees where they would be introduced to the company values and co-workers. Within the academy, the mentoring process was described as a substantial commitment and investment of time requiring a selective process. For example:

P2: There’s a lot of filtering that goes on between the big pool of students and the ones that end up in my research group. And then, over time I start making an investment in them, right? When they get into my lab, I’m making an investment of both, you know, my time and resources and other things. And then, the mentoring process changes as they’re in the lab, and they start working more closely with me. Whereas, if I think in a company, you’ve already done the selection so you have a few people that come in and that process then is for you to try and get the best out of them. For me, that
doesn’t happen until a little bit later on in the process, so there’s a difference there.

Integration of ethics into mentoring was thought to be one of a number of dimensions covered under mentoring, but not necessarily a priority of a mentoring relationship. For example:

P1: I don’t think I’ve ever gone to someone else for guidance on an ethical issue, but I have gone to a lot of other people just to talk generally about directions, research directions, and career directions.

From an academic perspective, the ethical issue associated with mentoring focused on navigating difficult relationships between a mentor and mentees and appears to be more of a concern within the academic environment. Generally, the participants considered mentoring to be informal, with a primary purpose of career advisement and up to the mentee to seek out a mentor. Participants also commented on a lack of formal training in mentoring requiring on-the-job testing of different practices.

F2: So how did then, how do faculty become educated in advance if they haven’t had a mentor that has helped them learn what’s expected?

P2: We do it by trial and error.

Lack of formal training in mentoring has the potential for developing desirable behaviors as well as fostering less desirable and questionable practices (Anderson, 2007). Given the potential negative impact of poor mentoring on an organization, elevating the formality of mentoring may be an important goal.

Collaboration was another area where participants identified differences in conventions between business and academic practices. Within the business setting,
participant 2 expressed an important aspect of collaboration for him was recognition of the “different levels of collaboration, from friendly chats in a bar to organized collaborative efforts.” The “different levels” experienced in the academic setting reflect a casual or informal approach to collaboration that is not as common within the business setting. P3 noted a lack of standard practice within the academic setting stating:

P3: In industry, collaborations are clearly defined by contracts and lawyers.

However, in academy, these collaborations are more vague. They tend to be more verbal and should be discussed early to define expectation much like authorship.

P1 confirmed that collaborations are important but do require extensive legal review and agreements in place in advance of embarking on a partnership, as noted in the following passage:

P1: The concept of a discussion, potentially even some form of written agreement, ahead of launch of an effort that articulates expectations on both sides. Based on experience, developing such documentation can be tedious and time consuming; it can also lead to multiply iterated discussions between the parties involved. But this is largely because each has a different understanding of expectations, commitments, and responsibilities. It is much easier, provided one is reasonably adept at such discussions, to have these up front, before challenging issues have arrived. By then there is much more at stake and emotions may be running high.

The casual and informal aspect of the academic model of collaboration was also attributed to difficult relationships that occurred from not communicating expectations in
advance; however, a formal agreement was not considered as important from the academic perspective, P2 noted in this response when asking about the importance of communication in collaborative relationships:

P2: Yes, [talking is important] but not necessarily in formal terms. Often, it is a “what do you expect out of this collaboration” approach.

These examples demonstrate the different expectations with regard to collaboration within the academic setting and business setting. All participants agreed that a strategy for managing these challenges is to have frequent and ongoing communication, and all reported feeling more comfortable about initiating these conversations as evidenced by the following comments:

P1: Yes, our sessions helped strengthen the sense that the directions I had already proceeded along made good sense and evidenced that similar approaches might also be taken in, for example, academic collaborations.

P2: The discussion definitely left me more prepared, and also more able to see their side of things a little clearer.

P3: Yes, I have had several topics with my advisor about collaborating with other labs. These collaborations are mutually beneficial, and we clearly defined much of the work to be done and what we will do with this work.

These disclosures provide evidence demonstrating that RCR domains or topical areas common to the academy can be used to generate conversation to develop and connect understanding to cross sector application. Another important finding was the influence of the course on participant behavior and how they applied knowledge gained or were thinking about what they had learned.
Does Talking About Ethics Influence Behavior?

When asked to reflect on what they had learned and whether learning had influenced practice, participants indicated that they were talking more about the ethical aspects of their work, feeling increased comfort in initiating these discussions and were taking responsibility for implementing practices consistent with responsible conduct of research. In this section, I provide examples of what participant’s disclosed about how they used the course in actual practice.

Intellectual property rights expressed through documenting credit and ownership, as well as collaborative relationships were areas that participants discussed in detail. The interest focused mostly on things that can go wrong if there are not clear communications of expectations between those involved in the relationship. Authorship was a good example, and as previously noted, was less relevant to the industry representative as their priorities were not around publishing new findings, but in protection of inventions via the patent process. As a result of discussion and increased awareness of differences between academic and industry values with respect to authorship P1 identified a need to invite discussions with students interning with the company as depicted in the following passage:

P1: I am primed to bring up the subject for discussion in interactions with University students, where a suitable forum presents itself. I’ll think further as to how I might bring up this topic in discussions with, for example, new entrants into our company, or at those times when external presentations or papers are being discussed. I do anticipate raising the topic should I again
supervise or co-supervise a graduate or postgraduate student and, potentially, when next establishing a collaboration with a third party academic. Likewise, both the student and faculty participants reported integrating what they had learned about authorship standards into recent discussions with colleagues. For example, the following disclosure from the student participant demonstrates the apparent value of learning about authorship standards and how to negotiate decisions around authorship:

P3: During this time, I have written several papers and have had several discussions on authorship. The reading has helped me build a platform with which to build my arguments. This is a topic I had never discussed before these sessions, and I’m glad to have covered this topic.

Because these conversations can be uncomfortable to initiate, it appears that having opportunities to practice talking about the ethical dimensions during group discussion meetings also contributed to an increased comfort in talking about authorship. Each participant affirmed an increased comfort in initiating conversations about authorship. The following two examples confirm this value:

P2: Yes. I didn’t know about either the contributorship model (although I have used it) or the ICMJE guidelines. I can use these in discussions with colleagues and collaborators.

P3: Definitely. The reading/discussion on this topic has given me a basic understanding and the general consensus of who should receive authorship credit. It has also introduced some of the dilemmas about the topic (e.g., should authorship be granted to technicians who supervise the work?).
Similar to authorship, all participants believed it was essential to talk about collaborative relationships early and often to spell out expectations and avoid misunderstandings. Likewise, they each disclosed feeling increased comfort in talking about the ethical dimensions of collaboration as a result of reviewing readings and having discussions in class. As with authorship, participants were more aware of their responsibility for initiating discussions and had acted on this responsibility since participating in the course. An example of how the student viewed his responsibility for communicating is noted in this passage taken from the midpoint reflection:

P3: I believe it is the responsibility of each participant in a collaboration to initiate conversation about what each wants out of the collaboration and what each will bring to the table. After these discussions, I feel like I have more responsibility in a collaboration, even as a student or employee, than I had previously.

This increased awareness was also demonstrated by actions the industry participant was taking to ensure that new student interns understood the policies and expectations as an intern. Recognizing that the conventions between academia and industry are different with respect to intellectual property and data use, P1 had modified the language in the internship agreement as noted in the following example:

P1: Yes, I have executed internship agreements with four interns that delineate my expectations on each of them and their expectations on me, including objectives for the work they are doing and a clear statement of who owns and can make decisions relative to the outcome of their work.
When talking about conflict of interests, data management, and research subject protections, participants expressed appreciation for learning about the standards, regulations, and discussing the ethical dimensions. Similar to authorship and collaboration, the participants reported that reviewing cases and group discussions increased understanding of the issues as indicated in the students disclosure about conflict of interest.

P2: Yes, I see how conflicts of interest might lead to falsification of data or bias in an experiment, etc. This can be a very abstract topic for me and don’t necessarily see ulterior motives. Reading the case studies and discussing live scenarios really helped bring this topic to the real world for me.

One participant observed that because some of the RCR domains are covered by regulations, there are fewer potential ethical problems to navigate. That may be true for those who are familiar with the rules; however, having adequate knowledge about the various areas was recognized as important. Developing the ability to know how to identify, question, and discuss a potential ethical issue is a skill that is desirable and typically a goal of RCR instruction. The following example provides some evidence that participation in this course may facilitate those behaviors:

P3: I discussed this topic briefly with my advisor about a conflict of interest on another project I am working with for [employer name]. There is no monetary conflict, but her thoughts were that of leaked code. After some discussion, she realized the projects were very much different and my time at [company] is voluntary.
Another example of increasing communication about ethical dimensions of research was noted by P1 who indicated a plan to increase conversations about research and professional ethics at his company. Specifically, he was considering how to incorporate discussion of ethics through a “lunch and learn” series.

These examples provide encouraging support for the instructional approaches used in the initial draft of the RCR practicum. The opportunity to access materials that clarify the regulations, rules, and standards of practice combined with guided discussion and case based reasoning were effective strategies for learning about cross sector application of responsible and ethical practices. The data from this case study suggest that participant comfort in talking about the ethical dimensions of research is connected to understanding of the regulations, standards, and conventions of responsible conduct of research domains. Confidence in discussing RCR might be related in willingness to talk about associated RCR areas with colleagues. Additional educational research is needed to learn about how education can influence practices that affect research integrity.

**Feasibility of Incorporating This Model**

In addition to assessing the instructional design, participants assessed the feasibility of integrating the face-to-face sessions within an internship experience. The major points raised that would influence the likelihood of RCR education being implemented into an internship were employer expectations, time and scheduling, and value of ethics education. Participants who contributed to this demonstration noted the following:

1. **Employer Expectations.** The interest of the employer and faculty mentor in prioritizing research ethics education for preparing a PSM student would need
to be established. P1 believed that the employer expects the PSM student to be knowledgeable about the industry setting and culture in advance of accepting employment. However, P1 also acknowledged the challenges in conveying the accepted standards of business and industry given the cultural practices and norms of industry can change across employers.

2. Time and Scheduling. Time needed for face-to-face discussions was valuable, but may not be realistic in a business setting. Likewise, coordinating time for the triad members to meet is challenging and other methods for dialogue (e.g., electronic discussion, guest speakers) should be explored.

3. Value of Ethics Education. Branding the PSM ethics education would be important to elevate understanding of the value added to the company and student for having knowledge about and critical thinking skills needed to identify and discuss the ethical challenges found in the workplace.

Through narratives and discussion, participants believed all core RCR instructional topics were important for discussion. All were in agreement that while face-to-face discussion is important, the group meetings may not be efficient suggesting instructional methods used in this module be adapted to a course where possible. In summary, findings support the use of the instructional design for teaching responsible conduct of research; however, the format of instruction will require adaptation to focus on only essential content and require fewer in person meetings.

**Summary**

Chapter 4 provided a report of findings found in analyzing data collected during the field testing of the instructional strategies and content used to develop understanding
of cross sector application of RCR content. In Chapter 5, these findings are discussed and the curriculum is examined for alignment with the How People Learn principles, as well as Knowles’ principles of andragogy. In addition, implications for practice and recommendations for future research are presented.
CHAPTER 5—DISCUSSION AND RECOMMENDATIONS

This qualitative case study was conducted to examine an instructional approach developed to support learning about disciplinary and cross sector practices in the responsible conduct of research (RCR). The previous chapters provide an introduction to the study and theoretical framework (Chapter 1), a review of the literature (Chapter 2), a description of the research design (Chapter 3), and findings from a qualitative analysis of data (Chapter 4). This final chapter presents a discussion of key findings, the significance of these findings, and conclusions. This chapter also addresses study limitations, recommendations based on the study findings, and implications for future research.

To briefly summarize, graduate students training for careers in business, industry, government, and nonprofit sectors must be able to identify, comprehend, navigate, and respond to ethical dilemmas that are present in the workplace. Both the National Science Foundation and National Institutes of Health require training in the responsible conduct of research for the researchers who receive their support (NIH, 2009; NSF, 2009). Many universities have extended RCR training requirements to all students and trainees regardless of the fiscal support for the research. The emphasis of this study on cross sector application of ethics education was in response to the growing number of Professional Science Master’s degree programs that are preparing science graduate students for careers outside of the academy.

The process of planning, conducting, and reporting research is guided by a number of regulations, professional codes, and institutional policies. In combination, these regulations, codes, and policies inform accepted standards for responsible conduct of research. However, while there are accepted standards for RCR, practices can vary
between disciplines and employment sectors. Educators now recognize the inconsistency across disciplines specific to standards, and norms of research practice present challenges to curricular development (Bulger & Heitman, 2007; Kalichman, 2007). Existing methods of teaching RCR through lectures, discussions, and case analyses have shown limited success in improving knowledge and attitudes and, in some cases, have identified less desirable outcomes (Anderson, 2000; Antes et al., 2009). Evaluative studies suggest that RCR instruction will be enhanced through active learning techniques that promote the discussion, questioning, and development of problem solving skills (Antes et al., 2010; DeBruin et al., 2007; Kalichman, 2007; McGee et al., 2008). This study examined an approach to RCR instruction that employed active learning strategies.

For the theoretical framework, this study used the Bransford et al. (2000) How People Learn model that includes four interrelated perspectives to guide the design of the learning environments. The model focuses on the learner’s preconceptions, organization of knowledge that supports understanding, ongoing assessment that makes thinking visible, and connection to the community in which learning is applied (Branford et al., 2000). In addition to using the HPL model to examine curricular alignment with principles of learning, Knowles’ original four principles of andragogy were included to consider the curriculum in relation to adult learning (Knowles, 1980). Specifically, the curriculum was examined for alignment with the principles of self-directedness, consideration of the learner’s experiences, relevance of learning to work, and use of problem-centered approaches.

An assumption of this study is that teaching professional and research integrity may be improved through curricular design and use of instructional strategies that
promote self-directed and lifelong learning skills. For this case study of RCR instruction, the following research questions were addressed:

1. What instructional strategies are used in the course and how do they facilitate learning about RCR generally and, more specifically, to cross-sector application?
2. How are commonly accepted RCR instructional topics used to understand standards, conventions, and practices in an industry setting?
3. What are the implications to advancing RCR pedagogy?

**Key Findings**

The theoretical framework and analysis of data sources produced key findings that have significant implications for teaching of the responsible conduct of research. These findings are briefly introduced under the following three points followed by a more detailed explanation of implications for RCR instruction.

1. *Alignment With Theoretical Framework*: This study examined the alignment with the How People Learn framework and Knowles’ principles of adult learning to examine existing RCR curriculum. Applying principles associated with the science of learning and consideration of adult learning can influence effective RCR education.

2. *Discipline and Cross Sector Application*: The core content combined with the instructional strategies used in this RCR curriculum are successful in facilitating learning about research regulations, expectations, and standards of practice in both the academic discipline and biotechnology business setting.
Identifying methods to learn cross sector application of RCR will inform the development of ethics education for Professional Science Master’s programs.

3. **Delivery:** This study informed the feasibility for delivery of the instructional format described in the RCR practicum within a PSM internship. Alternative methods of course delivery are examined as a result of this study.

**Alignment With the How People Learn Framework**

Bransford et al. (2000) identified four principles that contribute to an optimal learning environment labeled as learner-centered, knowledge-centered, assessment-centered, and community-centered. Bransford et al. (2000) recommended that research be carried out through the four lens of the HPL model across seven project areas. One of the seven areas focuses on evaluating existing curriculum, instruction, and assessment for alignment with HPL principles. Guidance for review of existing curricula suggested six main points to assess, which are described below in relation to the review of the RCR practicum guide.

- **Depth over breadth of coverage.** The HPL model suggests that to develop competence in an area, learners must have adequate depth of understanding of a subject (Bransford et al., 2000). In this initial field test of the Guide, participants were asked to independently review the subject matter typically associated with the instruction of RCR. The point of this exercise was to expose participants broadly to background, regulations, guidelines, and resources for planning, conducting, and reporting research to acquire knowledge of the subject matter generally. The practice proved successful for the purpose of the field test. Asking participants to reflect on their
experiences, consider relevance of the content to their academic or work setting, and to consider questions that remained unanswered stimulated greater depth of coverage. The face-to-face discussion sessions were an effective method of studying the content area and discussing practices in a discipline and the workplace. Engaging participants with experiences in the academic discipline and professional setting contributed to exploring the topics in greater detail. For these reasons, the RCR course is responsive to criteria for depth over breadth of coverage.

- *Effectiveness of opportunities provided to grasp key concepts related to the subject matter.* The idea of the knowledge-centered domain is to bring learners from novice to expert in a subject. In this field test, each participant independently acquired factual knowledge about key concepts through materials presented in an established RCR educational resource called Research Resources for Ethics Education. This self-study assignment guided participants to obtain foundational RCR knowledge to prepare for the discussion during the face-to-face discussion sessions. The two participants who provided evidence of completing the self-study assignment demonstrated improved knowledge about key concepts associated with RCR domains, while the third participant, who did not submit documentation, showed little change in correct responses at postassessment. Through discussion sessions, participants were able to talk about concepts in greater depth. Guided discussion in the group sessions combined with practicing case analysis permitted the subject to be discussed in greater depth and contextualized to the
workplace setting. For these reasons, the RCR instruction provided opportunities for participants to grasp key concepts and understand how the content transferred within the academic and business settings.

- **Extent to which the curriculum provides opportunities to explore preconceptions about the subject matter.** The HPL model emphasizes knowing what preconceived understanding the learner has of the subject matter and suggests metacognitive approaches that focus on sense-making and self-assessment. Strategies that encourage reflection of what is known and what remains in question are recommended. The initial preassessment provided participants with information about content covered during the course. Completing the postassessment following the self-study review of RCR materials gave participants additional feedback about what they learned and areas where additional information would be needed. The open discussion forums presented participants with ample opportunity to discuss core content, their prior experiences, expectations, observations of practice, and gain understanding from other perspectives. The group process modeled a learning community and situated learning within the context of practice.

While staged for this field test, the learning community model proved effective in stimulating dialogue that pertained specifically to ethics in the discipline and the work place. The Guide provided opportunities to explore preconceptions. More attention could be placed on the importance of exploring preconceptions to ensure present understanding does not conflict with developing new knowledge and understanding of research ethics in
practice. This would be especially important in research ethics education as a learner’s prior experiences or observations may not align with accepted standards of practice.

- *Adequacy of the factual knowledge base provided by the curriculum.* The curriculum used an established reliable resource for participants to gain factual information about RCR content and engaged two subject matter experts to guide implementation of the course. Knowledge of RCR content was further developed during face-to-face discussion sessions through contributions of the participants who brought forth their experiences and understanding of RCR applied to the discipline and cross sector setting. During each session, participants practiced problem solving through case analysis and discussed the transfer of knowledge to the academic and workplace settings. This curriculum relies on the expertise of the participants to contribute to the factual knowledge base by contributing their understanding of the regulations, expectations of their profession, and application of the standards to practice. This RCR instruction satisfies the criteria for adequacy of factual knowledge provided the participants are self-directed in their learning and motivated to obtain factual knowledge from existing sources.

- *Extent to which formative assessment procedures are built into the curriculum.* The HPL model emphasizes a metacognitive approach to learning whereby students attend to internal dialogue and have opportunities to explain what they are thinking and what they do not comprehend. Formative assessments used in the course combined with discussion sessions were useful
in learning about preconceptions and acknowledging what was understood, as well as where additional information was needed. These instructional methods supported the transfer of understanding to both the academic discipline and workplace setting, rather than simply memorizing of facts. The assessment tools (e.g., self-study pre/post, self-study review guidance questions, and midterm reflection narrative), combined with small group discussions, were effective in developing opportunities for participants to assess what they understood and what they continued to question. Bransford et al. (2000) stressed the importance of this type of assessment in helping learners take control of their learning.

- *Extent to which accompanying summative assessment procedures measure understanding and ability to transfer rather than memory of fact.* Summative assessment is used to identify whether participants learned what they were supposed to learn. The instructional case development assignment may be considered an assessment of understanding. This exercise demonstrated the participant’s ability to synthesize what was learned over the course and transfer content to practice through developing a creative instructional case study. This project resulted in four instructional cases depicting ethical challenges connected to a biotechnology industry setting. The instructional cases included a brief analysis, which could be expanded to include annotations that include additional details regarding laws or regulations in question, as well as a description of how the issues can be prevented and resolved. The mid-course narrative assessment provided data that confirmed
participants were thinking about and/or talking to others about RCR topics following discussion session. While mid course assessments were intended to gauge understanding, it was encouraging to see that participants also reported that they had incorporated knowledge gained into actions that influence research integrity. Generally speaking, the RCR module emphasized understanding of content and transfer of knowledge to practice satisfying this criterion for evaluating existing curriculum for alignment with the HPL framework.

Collectively, the instructional elements used in this RCR curriculum actively engaged participants with opportunities to talk about each topic, consider learning through assignments that prompt the reflection of knowledge and understanding, consider transfer of knowledge using discussion and case analysis, and demonstrate the synthesis of information through a case building project. These strategies are consistent with the data on human learning in that they encourage the learner to monitor how he/she makes sense of the material, incorporates ongoing assessment of content understanding, and considers application to the academic and business settings (Bransford et al., 2000). This review of the HPL criteria for examining existing curricula confirms that the instructional strategies in this RCR curriculum are in alignment with these principles.

**Alignment With Knowles’ Principles of Andragogy**

When examining instructional strategies in this curriculum, it was important to consider the theory that supports learning in adults since graduate students are those who typically enroll in RCR education, and the HPL framework was developed with elementary education in mind. Knowles’ (1980) identified four principles to consider
when designing instruction for adult learners. The four principles were later expanded to six suggesting that learners need to be internally motivated and need to know why they are learning something to actively engage in the learning process (Merriam et al., 2007). For the purpose of this study, alignment with this curriculum was limited to Knowles’ initial four principles. Specifically, Knowles’ assumptions consider adult learners to:
(a) be self-directed as a result of their maturity, (b) have experiences that can be drawn upon for learning, (c) be motivated to learn when content is relevant to their lives, and (d) benefit from problem centered approaches that have direct application.

- **Self-directedness.** The assumption of self-directed learning is that adults are independent and can be autonomous in their learning because, as an adult, one is responsible for their learning and are generally motivated to learn. Because RCR training is mandated for many students, completion of the course may be viewed as an intrusion to time they would normally spend advancing their research (Antes et al., 2009). There are a number of ways that training can be accomplished for the purpose of achieving compliance with mandates. The curriculum analyzed in this study approaches RCR education as a valuable aspect of good scientific practice and professionalism rather than as a compliance requirement. As such, self-directedness of the participant is an expectation.
- **Experience.** The reference to experience within Knowles’ concept is that experience is seen as a valuable resource from which to draw upon during the learning process, both during discussion, as well as during case analysis and construction. Contrary to HPL, the emphasis on experience is not to explore
prior conceptions that may complicate the acquisition of new knowledge. In this curriculum, experience is explored during the self-study process and is used to direct the learner to self-assess how learning about the subject matter has developed and under what circumstances, so that information can contribute to group discussion. Likewise, participants were expected to disclose their experiences with the subject matter to bring depth of conceptual understanding within the academic and/or nonacademic work setting. Understanding and engagement of participant experience is an important element of this RCR instruction and takes into account both Knowles’ (1980) and Bransford et al.’s (2000) perspectives.

- **Relevance.** The Guide includes a number of methods to engage the learners by prompting reflection, via narrative assessments and discussion session, to connect the RCR content to their work. Relevance is a key aspect for learning about RCR, as it needs to be contextualized to circumstances in which the participant can understand why they need to know and how knowing can be of benefit to their professional competence and ability to foster a climate of research integrity. During the self-study process, participants were instructed to respond to questions during review of each topic to reflect upon their prior experiences in both the academic and business/industry settings. Likewise, during case analysis, participants were asked to consider how the concepts presented in the cases study would transfer to their discipline or workplace. These activities were intended to stimulate discussion of direct relevance in the discipline and workplace for both the purpose of understanding why the
information was needed, as well as the benefit for contextualizing that knowledge. As such, relevance of content and application is a theme throughout this RCR course and is consistent with both Knowles (1980) and Bransford et al. (2000).

- **Problem centered.** Problem centered learning in Knowles’ assumptions is considered with regard to differences between child and adult learning. In this context, problem centered is viewed as needing to have direct application to one’s current life circumstances, rather than acquiring knowledge for use at a future time. The problem-centered principle is congruent with the interactive learning aspects of HPL and the need to actively engage in the learning process to enhance transfer of learning to new problems and settings. The RCR instructional strategies are aligned with active learning strategies, which include problem-centered learning.

Knowles’ principles of adult learning are evident in the instructional strategies used in this RCR practicum. Likewise, there are commonalities between the adult learning literature and the HPL framework given they have similar aims to develop self-directed and lifelong learning skills. While the HPL principles clearly complements the adult learning literature, the design framework “assumes that the learners are children” (Bransford et al., 2000, p. 26). As such, educators should consider applying Knowles’ principles in addition to the HPL model when designing RCR curricula.

**Discipline and Cross Sector Application**

The findings demonstrate that the instructional strategies used in the curriculum were successful in facilitating learning about ethical practices in both the academic
discipline and biotechnology business setting. Likewise, the core instructional content traditionally used in RCR courses stimulated extensive discussion about cross sector standards of practice and expectations. These findings are important, as they inform how RCR can be adapted for students preparing for science careers in business, industry, government, and nonprofit sectors. In addition to informing curriculum for cross sector application, these findings support the use of the HPL framework to guide RCR curriculum development broadly.

The propositions or assumptions of this study developed from the literature in adult learning suggest learning will be enhanced when it (a) takes place among those who share a common interest (Lave & Wenger, 1991); (b) encourages dialogue between members of the group to facilitate construction of meaning and understanding of practice (Mezirow, 1991); and (c) connects content to professional interests (Knowles, 1980). The findings show that the small group composed of a graduate student/intern, faculty member, and intern supervisor identified common interests associated with RCR content. In addition, the use of self-study, guided dialogue, case analysis, and case construction projects resulted in important discussion about controversial, uncomfortable, and morally challenging issues. In review of narratives completed near the end of the course, participants acknowledged they had applied what they had learned in their day-to-day practice.

**Delivery**

In addition to learning that the content and process were successful in producing understanding about the cross sector application of RCR, another important aspect of the field test was to identify how to implement this model within a PSM internship.
Developing an ethics education model that engages faculty, interns, and employers in learning about research ethics is an important feature of this model. P1 provided representation of the employer perspective and stressed that attention must be paid to educating PSM employers about the importance of having students trained to be familiar with the organizational culture, regulations, expectations, and standards of practice as they pertain to scientific integrity. To do this, P1 suggested a memorandum of understanding be developed that addresses the expectation for ethics education as part of the internship agreement. A modified version of this RCR model would be used to guide the learning process at the site of the internship. P1 also suggested a certification process would be important for branding the training and favorably acknowledging those who had completed the ethics module as part of the internship. P1 acknowledged he had a greater appreciation of the complex issues surrounding research integrity and an increased understanding of differences in practice between academia and business. As such, his value of this training was elevated and he would consider a resume more favorably if it included completion of this training.

P2 provided the faculty perspective and stated that he found the meetings and conversations to be “important as they ensure that the participants think about the work.” However P2 questioned whether the triad group meeting approach was the most effective method. He suggested a model whereby group discussions could take place in conjunction with a class with both faculty and industry representatives involved in discussions. P2’s comment suggests that introducing RCR during a regularly convened course may accomplish the similar goals and be more conducive to scheduling given the students and faculty are committed to a schedule, and industry representatives could
confirm availability in advance. Likewise, several employers could be included as guest participants to offer a wide range of perspectives regarding application of RCR topics in their respective fields. This concept was later field tested at CSU Channel Islands with favorable results.

Limitations

The limitations of this study were presented in Chapter 1 and are worth noting again. The data collected during the initial field test of this practicum represent one administration of the course with three participants. While the data collected from this field test was valuable for examining both the instructional content and process, additional data are needed to inform how RCR can be introduced within a PSM internship. Since this initial field test was conducted, the practicum has been tested in three additional PSM disciplines with encouraging outcomes. These data are contributing to an understanding of how the course can be adapted for PSM programs to engage faculty, students, internship supervisors, and employers as participants.

Recommendations

The recommendations informed by this study involve (a) adapting the HPL framework for assessment and development of RCR education to assist RCR educators, and (b) considering methods to improve delivery of RCR education within PSM internships.

Adapting the HPL Framework for RCR

Educators can examine existing RCR courses against the HPL framework and consider instructional strategies that align with the framework when developing RCR instruction. To orient faculty who may teach RCR to the science that supports human
learning, the following recommendations are made for each frame of the Bransford et al. (2000) HPL model. These frames are learner-centered, knowledge-centered, assessment-centered, and community-centered.

**Learner-centered.** Responsible conduct of research instruction should promote an environment that fosters awareness of knowledge, attitudes, beliefs, cultural practices, and skills that participants bring to the setting. An important reason for acknowledging prior experience in RCR instruction is to understand existing perceptions and misconceptions may compete with new knowledge and make learning more challenging (Bransford et al., 2000; McGee et al., 2008). The implication for teaching RCR suggests incorporating opportunities to understand knowledge about key concepts and identify preconceptions that may conflict with desired practices. This can occur by inviting active discussion throughout the course about core content (e.g., determining authorship, establishing ownership of intellectual property, disclosing conflict of interest, recruiting research subjects, etc.), and examining perceptions and understanding that have shaped the participant’s current perspectives. Instructional strategies that present opportunities for connecting theory to practice (e.g., debate, case analysis, etc.) and reflection (e.g., Have you had similar experiences? How have you responded? What have you learned?) represent methods of creating a learner-centered experience.

The course tested in this study included several strategies to enable the learners to explore existing knowledge and to examine various perspectives and practices for learning about key concepts.

**Knowledge-centered.** Responsible conduct of research instruction should attend to what is taught, why it is important, and how competence is defined and measured.
the knowledge domain, research suggests that instructors place priority on developing an understanding of the subject matter, rather than just an awareness of associated facts. The evidence supports connecting content (e.g., collaboration, social responsibility, etc.) through “meaningful problem-solving activities,” with the facilitator fostering interaction as to “why, when and how those facts and skills are relevant” for learning to be enhanced (Bransford et al., 2000, p. 23). The implication for RCR teaching supports learning generally about topics associated with ethical and responsible research practices with a more in-depth focus on topic areas most relevant to the learner’s discipline. Likewise, instructional strategies that engage the participant through problem solving and modeling to construct the understanding of RCR topics facilitates learning of core content and connecting concepts to practice. This domain also stresses the importance of having a knowledgeable facilitator who is able to assist students in understanding and contextualizing the subject matter.

During the administration of this field trial, the instructional strategies were effective in developing knowledge about RCR and transferring concepts to practice. For example, throughout the discussion sessions, topics explored during the self-study were examined from the perspectives of the computational sciences discipline and a drug delivery biotechnology company. During these discussions, organizational expectations, interpretation of regulations, and standards of practice were continually compared and contrasted. To further connect content to practice, case studies were analyzed and reconstructed to resemble issues that might be more familiar to the biotechnology setting. As a culminating project, instructional cases were created to demonstrate understanding of the issues and perspectives that are reflective of the discipline and workplace.
**Assessment-centered.** Responsible conduct of research instruction should integrate ongoing formative assessment to make the learning process more visible for both the student and instructor. “Learner-friendly” assessment is an integral component and involves ongoing reflection and dialogue (Bransford et al., 2000, p. 24). Both knowledge and assessment domains suggest the application of meta-cognitive strategies that promote sense-making through self-assessment and reflection about what is understood, what is not understood, and how the student/trainee is contextualizing the information to be meaningful (Bransford et al., 2000). The implication for RCR teaching is to create opportunities for students to think about and discuss their understanding of a topic, as well as how that understanding transfers to settings outside of the course.

Assessment is easily incorporated within inquiry and skill based instructional strategies (e.g., case analysis, problem solving, role-play) that prompt analysis and discussion among group members. Mezirow (1991), in his writing about transformative education, strongly advocates for reflective practices stating it is “crucial that the individual learn to negotiate meanings, purposes, and values critically, reflectively, and rationally instead of passively accepting the social realities defined by others” (p. 3). Reflection and self-assessment strategies are particularly important when teaching RCR, since the accepted rules and/or standards and norms being discussed during the course may conflict with realities within the student/trainees work environment.

In this field trial, assessment occurred through the pre- and posttesting, as well as through reflective writing and case analysis. Including an assignment for learners to develop instructional cases was also a method of assessing understanding of knowledge and transfer.
**Community-centered.** Responsible conduct of research instruction should include opportunities to connect learning contextually to enhance the transfer of what is being learned to practice in the field. A goal of the HPL model is to create an environment for students and trainees to practice skills within an authentic context. Lave and Wegner (1991) emphasize the importance of connecting content to practice by situating learning within the community to enhance the successful transfer of knowledge and skills. The implications for RCR education is to involve instructional strategies grounded in the learner’s actual professional setting and/or through modeling an authentic/realistic experience where participants can practice solving the ill-defined, complex, or new problems that are, for many, daily experiences that prompt one to question an appropriate solution. Case analysis, debate, and role-play are instructional tools used to connect RCR content to the research setting. Likewise, integrating questions to prompt reflection provide further opportunities to connect knowledge to practice by asking the participant to consider the issues in relation to their personal experiences. Instructors may also consider asking participants to draw upon their own personal experiences and write an instructional case that illustrates an ethical challenge they have encountered and/or to interview a scientist/practitioner in their field to gather firsthand understanding of how a topic (e.g., intellectual property rights, authorship) is considered within the academic discipline or a cross sector professional setting.

During this field test, engaging the faculty member, industry partner, and student in a learning community model created the ability for learners to consider the concepts in the context of the work environment through their experiences and understanding of the organization culture.
**Recommendations for Delivery—Internship Application**

This field trial informed whether implementation of a model within an internship experience was feasible. This model is considered moderately time-intensive and requires involving a faculty member, student intern, and industry supervisor in independent and collaborative assignments and face-to-face discussion meetings. In addition to testing instructional strategies, participants were asked to provide candid feedback regarding the delivery format and provide recommendations that would make adoption within a PSM internship feasible. Recommendations made by the participants in this field test included:

- **Develop a Memorandum of Understanding.** If this module is introduced within an internship, a memorandum of understanding is needed to ensure the employer recognizes her/his responsibility as a participant in the learning process. This agreement could be appended to the internship agreement. The agreement would specify the expectations to learn about ethics in the workplace setting. Employers play a critical role in ethics education and will need to be educated about how they should be involved and the value added of having new employees knowledgeable in industry relevant ethics.

- **Essential Content.** While participants in this study found value in reviewing all RCR topics during the self-study assignment, in depth discussion should be limited to three to four areas selected by the employer and intern as most pertinent to the employing unit. The practicum would be used, as in this study, to guide discussion and case analysis on those specific topics.
• Certification. Participants recommended that students who complete the RCR module receive a certification. Branding of the certificate as the “gold seal” of completion of ethics education was recommended, so that students completing the module would stand out and be considered more favorably in recruitment and employment.

• Time Commitment. Scheduling face-to-face meetings was the greatest challenge. Triangulating with the faculty mentor may need to be reconsidered unless the faculty member can meet at the intern’s employment placement. Incorporating a distance-learning element in the course is recommended so that faculty members, employers, and students can interact in virtual discussion.

Further Research

Results of this field test suggest opportunities for further research that focus on employer expectations, adaptation of the model for classroom and distance delivery, and broadening application of RCR educational research.

Employer Perspectives

Research to gain a better understanding of employer expectations regarding ethics education for science professionals is needed. Implementation of this RCR model will result in the gradual education of employers as participants; however, more direct inquiry may serve to advance partnerships with organizations whose leadership views ethics education as a core value.

As science trainees become more aware of how science is practiced in business, industry, government, and nonprofit sectors, as well as similarities and differences in
responsible conduct of research, it will be important to know whether this training is valued by employers, and whether students believe they are better prepared for knowing how to identify and navigate ethical dilemmas in the workplace. In addition to gaining a better understanding of PSM employer expectation of future employees specific to ethics education offered by the PSM program, research could inform whether PSM employers would value ethics education as an area of professional development training for all employees.

**Classroom Adaptation**

This study, along with data obtained from additional field-testing, informed development of an instructor’s manual entitled, *Teaching Responsible Conduct of Research: A Resource Guide for Professional Science Master’s Degree Programs*. The Guide describes principles of the HPL theoretical framework adapted for RCR instruction and includes instructional guidance for classroom integration of RCR instruction, case studies developed during field-testing, and an extensive bibliography of relevant articles. The document will receive final review by collaborators involved in field-testing and will be distributed at meetings of the National Professional Science Master’s Association.

A follow up survey of PSM faculty who plan to use the Instructor’s Guide to introduce RCR into a course is needed to inform whether the Guide increases teaching of cross sector application of RCR. Likewise, collecting post course and follow-up data from students, employers, and faculty who participate in this RCR instruction could be conducted to identify whether there are changes in knowledge attitudes and behaviors and, if so, whether these changes are sustained over time.
Distance Learning

The instruction developed for this project has been adapted for delivery via distance education to facilitate access to students enrolled in PSM degree programs and interaction with employers and faculty through discussion forums. The distance learning application of this RCR model will be offered as a stand-alone practicum and pilot tested with students in 2013. This version of the RCR model involves the student as the primary conduit for initiating discussions about RCR with faculty members and practitioners in the field. While not directly tied to a PSM internship, this model involves faculty members and employer participants in the discussion forums so that students are able to learn about RCR, as applied to their discipline and the workplace. Research on implementation and outcomes associated with integration of ethics education using the distance-learning platform will continue to inform RCR training for science professionals.

RCR Educational Research

Bransford et al. (2000) suggest further research and development to achieve three goals of advancing education in alignment with HPL principles. The first goal is to look at existing curriculum, instruction, and assessment through the HPL framework. This case study is an example of examining existing RCR curricula and can be carried out on a larger scale by encouraging RCR educators to examine their courses for alignment with these principles. The second goal suggests facilitating alignment of the instructor training with the HPL principles of learning. Introducing the HPL framework as adapted for RCR instruction via a “train-the-trainer” format would be appropriate for educating those who teach RCR and could be carried out in conjunction with professional meetings that
address RCR pedagogy. The third goal is to make the findings of research using this framework more accessible and understood. These goals involve the RCR educational community broadly and can be introduced at upcoming meetings on RCR pedagogy.

**Summary**

In summary, the RCR practicum includes instructional strategies that align with scientific research on human learning. Educators responsible for the design and delivery of responsible conduct of research will likely see improved student learning outcomes if curriculum is considerate of the four perspectives of the How People Learn framework combined with Knowles’ principles of adult learning. While this study focused on a course designed for a Professional Science Master’s degree, the instructional design can be adapted to research ethics education irrespective of discipline or employment sector.
REFERENCES


America COMPETES Reauthorization Act, H.R. 5116 (111th Congress), §§ 6022, 7009 (2010).


doi:10.1007/s11948-010-9197-3


Thank you for your interest in the PSM Ethics Education project and willingness to participate as our industry partner. We are developing a research ethics education model for the Computational Sciences PSM and are engaging a team composed of a student/intern, faculty mentor, and an industry partner. We will meet as a team over the course of the semester at a convenient location and each session will about 2 hours.

The project involves facilitated discussion of commonly accepted instructional areas of research ethics to learn how those topics are handled in business/industry and science, what the similarities and differences might be and to identify and prioritize ethical challenges that would form the basis of an instructional case study that the student would construct with mentoring from the industry partner (you) and the faculty partner. The planning meeting and discussion sessions need to be in person, and we would like to schedule one meeting per week at a location convenient to those involved. We anticipate your time commitment to be approximately 20 hours over the next 4 months.

We have budgeted a stipend for participants to recognize the value of your contribution to developing this model. You will also have access to the materials developed upon conclusion of the project. Please contact me if you have any additional questions and/or to confirm whether you are able to participate. Once I hear from other potential participants, I will schedule a planning meeting to go over the objectives, process, and schedule in greater detail. Thanks again for your interest in this project.

Sincerely,

Camille
APPENDIX B

Institutional Review Board Approval and Informed Consent

August 10, 2009

Dear Camille Nebeker:

Project #364080 “Ethics Education for Professional Science Master's Programs” was reviewed and verified as exempt in accordance with SDSU's Assurance and federal requirements pertaining to human subjects protections within the Code of Federal Regulations (45 CFR 46.101). This review is valid to the conditions and procedures described in your protocol.

If any changes to your study are planned, please notify the IRB office. Additionally, notify the IRB office if your status as an SDSU-affiliate changes while conducting this research study (you are no longer an SDSU faculty member, staff member or student).

Please note the following for all exempt studies:

a) If this research involves the use of existing or secondary data sources, information obtained must be recorded so that subjects cannot be identified, either directly or through identifiers linked to the subjects.

b) If information will be obtained from an individual’s medical record, please check with the organization authorized to provide access to these records to determine whether regulations relating to the Health Insurance Portability and Accountability Act (HIPAA) pertain to your research. Likewise, if academic records are accessed, Federal Education Rights and Privacy Act (FERPA) requirements must be respected. Notify the SDSU IRB office if protocol revisions are necessary to comply with HIPAA regulations.

c) If recruitment will take place through an outside agency or organization, confirm with that institution that you have permission to conduct the study prior to initiation of any study activities. If this research involves the use of existing or secondary data sources, confirm with the data owner that you have permission to access the data.
d) Approval is contingent upon the completion of the SDSU human subjects tutorial (found at: http://www-rohan.sdsu.edu/~gra/login.php) by all members of the research team. This certification must be renewed every 2 years.

For questions related to this correspondence, please contact the IRB office ((619) 594-6622 or e-mail irb@mail.sdsu.edu). To access IRB review application materials, SDSU’s Assurance, the 45 CFR 46, the Belmont Report, and/or any other relevant policies and guidelines related to the involvement of human subjects in research, please visit the IRB web site at http://gra.sdsu.edu/research.php.

Sincerely,

Jeanne Nichols
Chair, Institutional Review Board
Informed Consent

Ethics Education for Professional Science Master’s Program

Consent Statement for PSM Team

You are invited to participate in the development of an educational model intended to introduce ethics education to Professional Science Master’s programs. The resulting ethics education training may be adapted for PSMs throughout the CSU system and may then be adopted by PSMs nationally. Three California State University sites have been selected for this project: SDSU, Channel Islands, and Chico. The three PSM fields include computational sciences, biological sciences, and environmental sciences.

Each site will involve a team composed of a faculty mentor, student intern, and industry partner. As a team member, you will participate in the following activities:

- Complete a pre-test to assess existing knowledge of accepted research ethics topics.
- Review a web-based training to increase understanding of accepted research ethics topics.
- Complete a post-test following the web-based training.
- Participate in up to 8 sessions. Each session will be 2 hours and will focus on two or three topics covered in the web-based training and relevance to the discipline and applicability in the profession (e.g., data management, conflict of interest, collaboration, authorship, etc.). Over the course of these discussions, the team will identify ethical problems that exist within the profession. The problems identified will form the basis of an instructional case(s) the team will develop as a culminating experience. The final two sessions will include training on how to develop a case study.
- Work with team members to develop two to three case studies.

Each session will be audiotape recorded so that we can review your comments and use your input to develop a teaching guide for other PSM programs. You will receive an honorarium for participating in the sessions and contributing to the ethics education model development process.

Your participation is voluntary. Your input during the development meetings will be incorporated into the program design and guidance materials that will later be tested with other PSM programs. We may also use the information collected in a manuscript to describe the process of developing this model; however, if that occurs, no information that is published will be attributed directly to you and your identity will be anonymous. If you have any questions about participating in the project, please contact the PSM director at your location or Camille Nebeker by email or telephone.

The National Science Foundation (NSF) is supporting this project.
APPENDIX C

Pre/Postassessment for Baseline Training

1. Which of the following are examples of research misconduct as defined in the federal regulations? [Circle all that apply]
   A. Altering research data
   B. Using other people’s written word or ideas without attribution
   C. Sexual harassment of colleague
   D. Cruelty to research animals
   E. Sloppy record keeping

2. Which of the following statements about conflicts of interest is true?
   A. Conflicts of interest are a type of research misconduct.
   B. The process of science is not enough to mitigate the consequences of conflicts in research
   C. Conflicts of interest are not a factor in unintentional bias

3. Which of the following should be your first priority if you believe that you have observed another researcher doing something inappropriate?
   A. Keep good records
   B. Get a lawyer
   C. Ask someone with more experience for perspective

4. Which of the following is not an aspect of effective mentoring?
   A. Teaching solely by example and modeling
   B. Helping trainees in their technical development as capable researchers
   C. Socializing trainees in the political, ethical, economic, and social dynamics of academia

5. Research data are the property of:
   A. The institution that employs those who are collecting the data
   B. The person(s) collecting the data
   C. The head of the research group that collects the data

6. Please list three reasons why collaborations are increasing in science.

7. Which of the following are primary ethical principles that form the basis for conducting human research in this country? [Circle all that apply]
   A. Community need
   B. Justice
   C. Beneficence
   D. Quality of science
   E. Respect for persons
8. According to the International Committee of Medical journal Editors (ICMJE) guidelines, which of the following does not count toward an authorship credit?
   A. Providing lab space
   B. Substantial contribution to research conception and design
   C. Final approval of the manuscript to be published

9. What is the institutional body with oversight of animal subjects research?

10. If you are unsure about expectations for peer reviewers in a particular journal, who would be most appropriate to answer your questions?
   A. Someone who has published in the journal
   B. The editor of the journal
   C. Someone who has previously reviewed for the journal

11. Which of the following statements about duplicate publication is true?
   A. In general, it is considered appropriate to duplicate entire paragraphs or even sections of a previously published paper, as long as the data being presented are new
   B. It is acceptable to submit a duplicate of a previously published manuscript to a new editor, as long as the editor of the previous journal is notified and the duplication is explained in the manuscript
   C. It is an accepted practice to publish some of the same data in two different publications even without citing the original publication

12. List the three prohibited behaviors found in the federal definition of research misconduct.

13. Which of the following describes a type of nonfinancial conflict of interest?
   A. Stocks or other holdings in company whose products you research
   B. Being on a study review section for animal research if you’re opposed to animal research
   C. Speakers fees from a company for conference presentations about that company’s products

14. If I have questions about how my mentor or one of my research colleagues is collecting or using research data, then I should:
   A. Submit an allegation of research misconduct to the Research Integrity Officer
   B. Confront her/him with my suspicion that they are doing something wrong
   C. Seek perspective from someone who is knowledgeable about research methods in my field

15. Mentoring is:
   A. An important part of the scientific enterprise
   B. Highly valued in the academy
   C. The same thing as supervision or advising
16. Under Public Health Service (PHS) requirements, how long are you required to keep your data?
   A. Until funding runs out
   B. Until all papers based on the data have been published
   C. Until 3 years after the last financial report on the grant

17. What kinds of collaborative arrangements are least likely to run into problems?
   A. Collaborations that have ongoing discussions about roles and expectations
   B. Collaborations between people with very different expertise and backgrounds
   C. Collaborations between people who have the same expertise and backgrounds

18. What is the institutional body with oversight of human subjects research?

19. State whether the following sentence is true or false:
    Early and frequent conversations about authorship can reduce the risk of misunderstanding and conflicts:
    T    F  [Circle]

20. The increase in regulations for research with animal subjects is most likely to have been directly caused by:
    A. Researchers asking for more regulations to keep other researchers from misusing animals
    B. Increased public awareness of cases of some researchers abusing animals
    C. Animal rights activists breaking into research facilities and releasing the caged animals

21. The primary responsibility of a peer reviewer for grant applications is to:
    A. Be critical, but be an advocate for the applicant
    B. To find the best possible arguments that the application should be funded
    C. To find what is wrong in the grant application

22. The focus of most conflict of interest regulations is:
    A. Academic/scholarship conflicts
    B. Conflicts of conscience
    C. Financial conflicts

23. Regarding mentoring, which of the following is not a responsibility of a trainee?
    A. Seeking out effective mentors
    B. Having an idea of their goals, strengths and weaknesses, and career plans
    C. Staying in a bad mentoring relationship because of the reputation of the mentor

24. To minimize problems during a collaborative relationship, which factors should be discussed at the earliest stages of collaboration?
    A. When the work should be done and who has responsibilities for completing the work?
B. When the work should be done?
C. Who has what responsibilities?

25. According to Public Health Services (PHS) and National Science Foundation (NSF) federal policies, disclosure is required when:
   A. Your equity interests exceed $10,000 in value or represent more than 5% ownership
   B. There is any personal, professional, or financial interest that might bias the research
   C. You have any relationship of any kind with a company whose products you are researching

26. The contributorship model of authorship:
   A. Is an attempt to more accurately reflect how research is done
   B. Is now the leading model for acknowledging authorship in most medical journals
   C. Is much more restrictive than the ICMJE model of authorship

27. Which of the following is not typically included as a guideline for notebook record keeping in the academy?
   A. Entries in the notebook should be written in ink
   B. All pages should be signed and notarized
   C. Pages should be numbered and dated

28. For federally funded research, raw data and other research records must be kept:
   A. Until the paper is submitted
   B. Until the paper is accepted for publication
   C. Until 3 years after the paper is published
   D. Until the grant is finished
   E. Until 3 years after the last expenditure report
   F. Indefinitely

29. In the absence of any other roles/contributions, which of the following most appropriately merits authorship?
   A. Editorial comments
   B. Writing of first draft of the paper
   C. Principal Investigator

30. Please state whether the following sentence is true or false:
   “Responsible collaborations are always defined by openness and early, on-going communication.
   T   F

Adapted from a survey develop by Michael Kalichman, Ph.D., UCSD Research Ethics Program.
APPENDIX D

Instructions for Review of Research Ethics.Net

Begin with the “Introduction,” and review the following modules:

- Distinctions
- Why Teach Research Ethics
- Goals
- Knowledge
- Skills
- Attitude
- Behavior

Following the introduction section, go through specific “Topics” modules. There are 12 areas/topics that are commonly associated with research ethics:

- Animal Subjects
- Authorship
- Collaboration
- Conflicts of Interest
- Data Management
- Human Subjects
- Mentoring
- Peer Review
- Publication
- Research Misconduct
- Social Responsibility
- Whistleblowing

Each “Topics” module has the following tabbed sections:

- Background
- Regulations and Guidelines
- Considerations
- Summary
- Resources

Self-study Written Narrative: Read the material in each tabbed section and consider the following questions:

- What is left unaddressed in the material presented in this module?
- What additional questions does this reading raise for you?
- Based on your experiences in academia, what seems unrealistic or impractical in the information/approaches presented in this module?
- Based on your experiences in business/industry, what seems unrealistic or impractical in the information/approaches presented in this module?
What information presented in this module is specific to the academy/academic research environment and not relevant to business/industry?

What did you learn about this topic that you did not know prior to reading the module?

In the Resources section of each module, review and answer the Discussion Questions to assess comprehension of the material. In addition, choose one of the three Case Studies to review and consider how the case might be relevant to the workplace.
APPENDIX E

Instructional Cases Developed by Participants

A Case of Restricted Access

Dr. Jay Maguire purchases transgenic rodents for laboratory research from a company that is accused of mistreating its animals and raising them in less than sanitary conditions. Dr. Maguire has had pleasant experiences with their employees and sales representative in the past. When asked about the accusations, the sales representative gives the corporate cookie cutter answer, claiming they are a “top-notch” facility with the utmost professionalism. Your requests to visit their facility are restricted to the times of pre-arranged appointments, and you can view only the sterile visiting area. The rodents and their cages seem okay, but you can never see the conditions beyond the “Employees Only” door. They claim that they cannot risk contaminating the other mice.

Three other suppliers have the same animals available, but they are all significantly more expensive than your current supplier. What might Dr. Maguire do?

Analysis

Parties
- Dr. Jay Maguire and his research colleagues
- The animal housing center and their staff

Actions
- Dr. Maguire can move animal housing centers.
- Dr. Maguire can file a complaint with regulatory committee.

Consequences
- Moving animal housing centers or filing a complaint may ruin his current experiments with the animals housed at the current center.

Obligations
- Dr. Maguire has an obligation to his test subjects and the science community to demand verifiable accountability.
Consulting Conflicts

Dr. Dorothy Felce leads a bioinformatics lab at the University of Nora with a particular interest in virus genomes. Her lab has had particular success in researching the severe acute respiratory syndrome (“SARS”) virus and the ACE2 receptor on cells that allows the virus to bind, enter, and then replicate.

Dr. Tom Duthie, a senior research scientist at Global Pharma Kingdom (“GPK”), visits the Biology department to present a talk at the weekly colloquium. During a post-talk discussion, Tom mentions that GPK is researching the binding area of the SARS protein. This quickly reveals commonalities with Dr. Felce’s research. Tom offers Dr. Felce and a graduate student in her lab consulting positions to aid GPK’s research. Dr. Felce, eager to pad her modest income and continue her research, jumps at the opportunity. The university policy states that a professor is allowed to pad his/her income up to 125%. The university does not need to realize administration costs from that money unless the work is being done on campus. This is a “win-win” situation in the eyes of Dr. Felce and GPK.

Dr. Felce proves to be a significant asset to GPK. Her work and guidance help steer GPK to creating a drug with the potential to prevent the spreading of SARS. GPK immediately files for patent protection. This move compromises the ability of Dr. Felce to continue work on SARS in her lab and, particularly, limits the extent to which researchers in her group can present their research results at upcoming meetings.

What does Dr. Felce do? Can the University do anything?

**Analysis**

**Parties**
- The University
- Dr. Dorothy Felce, the graduate student, and others in her research group
- Dr. Tom Duthie
- Global Pharma Kingdom

**Actions**
- University of Nora can review their employment contracts. In many cases, the employee is not entitled to give away rights to their inventions.
- GPK did not necessarily know the University’s intentions. The University could possibly negotiate some royalty fees.

**Consequences**
- The University may lose a large source of income.

**Obligations**
- Dr. Felce (and the graduate student) has an obligation to adhere to the terms of her employment agreement.
- GPK has an obligation to operate in a manner compliant with the University policy.
Intern Dissertation and Intellectual Property

Andrew Kulpa just finished his second year as a master’s student at the College of Saint Remos and has taken a summer internship at a software startup. This startup, Zing, is working on a new search technology focusing on images. The company was started recently by two former graduate students from Saint Remos. The graduate students had been researching machine learning, and they dropped out to pursue this business venture.

Andrew is working specifically on a variation of the current grouping algorithm. The Zing founders originally created the algorithm during their time at Saint Remos. They decided to keep their algorithm a trade secret, not wanting to teach their competitors their key advantage.

Andrew was given a desktop computer in which to do his work at Zing, but would often bring his work home on a flash drive. At the end of the summer, Andrew was asked to continue his internship during the school year, where he is done with his classes and is solely working on his master’s thesis.

Because the Zing founders are Saint Remos alumni, they receive invites to the department’s thesis defenses. Reading of Andrew’s defense the next week, they think it would be a good opportunity to support their employee and mingle with old cohorts. Upon arriving for the defense, the Zing founders notice the title of Andrew’s work—“Grouping Images via Content Determination.” There is a real possibility that Andrew is about to divulge key Zing company secrets.

What do they do?

Analysis

Parties
- College of Saint Remos
- Zing and its founders
- Andrew Kulpa
- Andrew’s advisor

Actions
- The Zing founders agitate to immediately stop the thesis defense.
- The Zing founders can let the thesis defense continue.
- The Zing founders approach Andrew quietly and ask about his research, something they had not done previously.

Consequences
- The Zing founders protect their company secrets. This ruins Andrew’s thesis and Andrew is not allowed to graduate.
- The Zing founders possibly lose their business. Andrew is allowed to defend his work and graduate.
Obligations

- The Zing founders have an obligation to their shareholders to protect the company interests.
- Andrew had an obligation to seek permission to use Zing’s material and time to apply to his thesis project.

A Meta-Analysis Prompts Data Integrity Concerns

Biomeca, Inc. has developed a drug that mitigates the effects of multiple sclerosis. Most of the company’s revenues are derived from this drug and the drug will be the primary contributor to revenues for quite some time. Dr. David Biltmore, a biostatistician with the company, recently completed a meta-analysis of the clinical data. His findings suggest that the drug causes birth defects. However, the meta-analysis was based on data from a relatively small patient population and the results, while significant in the meta-analysis, could not confidently be extrapolated to the much larger population of actual drug users. Dr. Biltmore presented his results to upper management in a meeting in which his results are discussed in great detail. At the end of the meeting, the company executive team decided that Biltmore’s findings should be shelved. The users of the drug have realized substantial quality of life benefits from taking the drug, and any potential negative publicity relative to the drug would compromise the company’s sole revenue stream. This executive decision, though, is counter to Biltmore’s better judgment. What does Dr. Biltmore do now?

Analysis

Parties

- Biomeca executive team and shareholders
- Dr. David Biltmore
- The users of the drugs and MS patients in general

Actions

- David again talks to the CSO and re-stresses his point.
- David becomes a whistleblower.
- David talks to one or more of his colleagues, perhaps including someone who might have more influence with the senior level executives.

Consequences

- David will probably lose his job regardless of the outcome.
- Biomeca may lose its sole source of revenues.
- A population of babies may needlessly live challenged lives

Obligations

- Biomeca has an obligation to society to improve peoples’ lives.
- David has an obligation to the science community.