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ETHICS INSTRUCTION INCREASES GRADUATE STUDENTS' RESPONSIBLE CONDUCT OF RESEARCH KNOWLEDGE BUT NOT MORAL REASONING

KAREN B. SCHMALING and ARTHUR W. BLUME
University of North Carolina at Charlotte, Charlotte, North Carolina, USA

The purpose of this study was to assess the short-term effectiveness of ethics courses in enhancing responsible conduct of research (RCR) knowledge and moral judgment among graduate students in health-related disciplines. Forty-eight graduate students completed a questionnaire about research experience, knowledge and judgments about appropriate research practices, and a standardized test of moral judgment at the beginning and end of a semester-long ethics course. Knowledge about RCR but not moral judgment increased significantly in some areas. The results are discussed in terms of implications for RCR instruction and of future research designed to improve RCR instruction.

Keywords: *ethics, moral reasoning, responsible conduct of research*

Introduction

The 2000 Public Health Service (PHS) policy on instruction in the responsible conduct of research (RCR) requires all National Research Service Award Institutional Training Grant applications provide RCR instruction. The 2007 America COMPETES act also requires mentoring plans, including RCR instruction, in applications to the National Science Foundation for postdoctoral support (NSF, 2008). The PHS policy defined nine areas for instruction, noting that there would likely be some variability in the extent of focus on each area depending on the trainees' discipline, and was not prescriptive in the method or length of instruction. The nine areas are: data acquisition, management, sharing, and ownership; mentor/trainee responsibilities; publication practices and responsible authorship; peer review; collaborative

Address correspondence to Karen B. Schmaling, Ph.D., Dean and Professor, UNC Charlotte, College of Health and Human Services, 9201 University City Blvd., Charlotte, NC 28223, USA. E-mail: kbschmal@uncc.edu

science; human subjects; research involving animals; research misconduct; and conflict of interest and commitment.

RCR instruction has short- and long-term goals. Examples of the former would be improvements in participants' knowledge, skills, and positive attitudes toward RCR, and an example of the latter would be less research misconduct (Plemmons et al., 2006). The assessment of changes in the frequency of research misconduct is challenging because the majority appears to go undetected and unreported. An anonymous survey of scientists funded by the National Institutes of Health conducted by Martinson, Anderson, and de Vries (Martinson et al., 2005) found that 33% of respondents (1,072 of 3,247) reported engaging in at least one of ten serious and sanctionable behaviors in the three years prior to the survey. By comparison, fewer than 300 research misconduct allegations are reported to the Office of Research Integrity each year (Office of Research Integrity, 2008).

There has been relatively little examination of the short-term effectiveness of RCR instruction. Instruments that could be used to evaluate the effectiveness of RCR knowledge include the Scientific Misconduct Questionnaire-Revised (SMQ-R) (Broome et al., 2005) or the Responsible Conduct of Research Measure (RCRM) (Wester et al., 2008), which consist of 80 and 42 items, respectively. The SMQ-R and RCRM have demonstrated internal consistency and construct validity, but their predictive validity does not appear to have been investigated.

One way to assess the effects of RCR instruction would be to compare trainees longitudinally, before and after RCR instruction. Medical students' knowledge but not attitudes about RCR increased significantly after a research ethics course (Powell et al., 2007). Funk et al. (2007) found that RCR instruction did not increase the number of ethically appropriate responses to vignettes about authorship and publication practices among a sample of postdoctoral fellows. There is little support that RCR instruction results in enhanced knowledge, attitudes, and ethically appropriate judgment.

Another way to assess the effects of RCR instruction would be to compare groups cross-sectionally, for example, by grouping trainees with and without prior RCR instruction. Some studies have found negative or weak evidence of positive outcomes associated with RCR instruction: Anderson et al. (2007) found

that early-career NIH-funded scientists with prior research ethics coursework had a *greater* likelihood of engaging in questionable research practices related to data than those without such coursework. Macrina et al. (2004) found few differences between postdoctoral fellows with and without RCR instruction in terms of their responses to vignettes about authorship and publication practices.

The results of other cross-sectional studies had more positive outcomes: Heitman et al. (2007) found that graduate students with previous RCR instruction scored significantly higher on a test of RCR principles, regulations, and standards than graduate students without prior RCR instruction. Mundy (2008) found that graduate students in allied health disciplines that had taken at least one ethics course scored higher on scientific integrity related to the use of human subjects than graduate students that had not taken an ethics course, but there were no significant differences in other domains of RCR, including authorship, conflict of interest, and publication. However, only two of the nine scales on the survey instrument achieved adequate internal consistency ($\alpha \geq .70$), and the human subjects scale was not among the two. To the extent that graduate students spent more time in RCR or ethics instruction and in discussions with others about RCR or ethics, they rated themselves as significantly more knowledgeable about the options available to them to deal with nine research ethics problems (Brown and Kalichman, 1998).

The development of moral reasoning and judgment is an alternate way to frame the goals of RCR (Bebeau, 2002), and there is mixed evidence that RCR instruction positively affects moral reasoning. The original and revised versions of the Defining Issues Test (DIT2) (Rest et al., 1999) have been used to evaluate pre-to-post changes in moral judgment as a function of ethics and RCR instruction. Both favorable (Bebeau and Thoma, 1994) and unfavorable change (Heitman et al., 2002) on Defining Issues Test scores have been reported among dental and graduate students, respectively, after RCR instruction. Using another measure of moral reasoning, graduate students in an ethics course demonstrated increased moral reasoning scores compared to graduate students in a human resources course, controlling for pre-instruction scores (Hull et al., 2002).

The extant literature suggests that RCR instruction is widely regarded as a necessary and important component of scientists' training, but positive outcomes are not consistently associated with the completion of RCR instruction. The goal of this study was to assess the short-term effectiveness of ethics courses in enhancing RCR knowledge and moral judgment among graduate students in health-related disciplines. As reflected in the review above, previous studies have typically assessed either RCR knowledge or moral judgment, but not both. A secondary goal of the study was to examine the associations between change in RCR knowledge and moral judgment.

Methods

Sample

Potential participants were psychology and health services research (HSR) graduate students enrolled in ethics courses related to their respective disciplines. A total of 49 students were enrolled in these courses: the HSR course was offered in fall 2005 and spring 2008, and the psychology course was offered in fall 2005, 2006, and 2007.

Measures

Participants provided information on their gender and age range, which was collected separately from the other measures for the purposes of anonymity, and then completed two questionnaires.

The first questionnaire consisted of nine questions related to the students' level of previous research experience; 11 questions about RCR knowledge; 10 brief research scenarios that were rated as ethical or unethical; and 11 questions about authorship that were adapted from the survey used by Eastwood et al. (1996) (with permission: personal communication from Dr. Susan Eastwood, July 28, 2005). (See Appendix 1, which includes the first three questions in each section.) The 11 RCR knowledge items were rated on a 1 (always or almost always true) to 4 (always or almost always false) scale. The 10 brief research scenarios were rated on a 1 (always or almost always

ethical) to 4 (always or almost always unethical) scale, and summed across items. The 11 authorship items were rated in terms of sufficiency of the contribution to warrant authorship on a research paper on a 1 (always or almost always sufficient) to 4 (always or almost always insufficient) scale. Ten of these items described singular contributions (e.g., collected the data), with the intention that the final item, "several of the above," would be the most appropriate choice to select as "always or almost always sufficient." Thus, the 10 items were summed, with higher scores reflecting less awareness of the multiple contributions needed to warrant authorship. The first 10 items also were recoded as either 1 (more sufficient than insufficient) or 2 (more insufficient than sufficient).

The second questionnaire was the DIT2, including three dilemmas ("famine," "reporter," and "cancer" dilemmas) that were subsequently scored by the Center for the Study of Ethical Development (Minneapolis, MN) for the P (postconventional) index, and the N2 index, after purging participants' scores that failed the reliability check algorithms (Rest et al., 1999), which included 5 students at the first assessment, and 6 students at the second assessment. Rest et al. (1999) argue that the N2 index is a superior measure of moral judgment to the P index, but the P index also was retained for analysis because of its longer history of use. The P index reflects the extent to which the participant engaged in higher-order, principled reasoning, and the N2 index reflects both the P index and the extent to which items that reflected higher moral development stages are endorsed compared to lower stage (e.g., self-interest) items.

Procedure

The study was reviewed and approved by the Institutional Review Board at the authors' institution. The authors were the ethics course instructors; therefore, at the first class meeting, prior to any instruction, the instructor introduced a colleague to the class, saying that the colleague would describe a study to the class, and left. The colleague described the purposes of the study to include becoming familiar with the research process as a participant, to prompt thinking about the course and its topic, and to assess change as a function of time and being in the

course. It was emphasized that participation was voluntary, and that the surveys would be completed anonymously as participants would construct an identification code known only to them that would allow the measures to be linked and compared from the beginning and end of the class. The measures took approximately 20 minutes to complete. This procedure was repeated at the end of the final class meeting of the semester.

Results

Participant Characteristics and Research Experience

Of the 49 students enrolled in the courses, 48 students (98%) completed the measures described above at the beginning of the courses, and 44 students completed the measures at the end of the courses. The majority of the participants were female (82.6%) and 30 years old or less (56.5%) ($N = 46$; demographic data were not provided by two participants).

In terms of students' level of research experience, at the beginning of the ethics courses, a minority had taken a previous research ethics or RCR course (22.9%), or had led the writing and submission of an IRB proposal (33.3%), although half had participated in writing and submitting a proposal led by another investigator. The majority of students reported prior experience in working with human subjects (recruiting, consenting, enrolling, etc. in a research study) (70.8%), been responsible for the secure and confidential organization and storage of subjects' data (54.2%), and having been in a research lab or team where ethical issues were discussed in lab/team meetings (56.3%). A minority reported that they knew someone who had engaged in plagiarism, falsification, or fabrication (14.6%).

RCR Knowledge

Eleven items of RCR knowledge demonstrated moderate internal consistency when assessed at the beginning of the ethics courses, $\alpha = 0.62$. Table 1 shows that compared to the beginning of the ethics courses, students became more certain in their rating of unethical practices such as submitting the same article to several

TABLE 1 Students' RCR Knowledge at the Beginning and End of Ethics Courses

	Beginning	End	t^1
Consequences of research misconduct can be serious	1.33 (.57)	1.37 (.54)	–.53
Address misconduct to higher authority when a power differential exists	1.56 (.59)	1.42 (.54)	1.23
Honest data errors are not misconduct	1.86 (.84)	2.29 (1.11)	2.41*
Do not address RCR concerns when power differential exists	3.81 (.66)	3.67 (.64)	1.36
Scientists responsible for RCR for the community	1.40 (.58)	1.26 (.54)	1.23
Determine authorship when the paper is done	2.81 (1.11)	3.45 (.97)	–3.45*
Submit article to two journals simultaneously	3.31 (.90)	3.81 (.55)	–3.53*
Put identifying information in dataset with study data	3.58 (.82)	3.70 (.80)	–.78
Anonymity = participants cannot be identified; confidentiality = participants only known to researcher	1.26 (.66)	1.72 (1.12)	–2.11*
Study PI is the best person to determine if subject with AEs should continue or discontinue	2.37 (1.09)	2.63 (1.22)	–1.21
Need placebo condition to test a new drug for a common condition (depression, hypertension)	1.63 (.98)	1.88 (.96)	–1.40

[1]df = 42 except df = 41 for 'honest data errors' and 'authorship' items; standard deviations are in parentheses.

*$p < .05$; AEs = adverse events; lower scores indicate the item is judged as true and higher scores as false.

journals at the same time to share the information with the scientific community "as soon as possible."

Ethical Judgments

Ten items were brief scenarios that were rated on a 1 (always or almost always ethical) to 4 (always or almost always unethical) scale. These items demonstrated moderate internal consistency when assessed at the beginning of the ethics courses, $\alpha = 0.61$. Students reliably rated these items as more unethical at the end of their

TABLE 2 Students' Ethical Judgments of Brief Scenarios at the Beginning and End of Ethics Courses

	Beginning	End	t^1
Delete outlier based on 'gut sense'	3.40 (.85)	3.21 (.86)	1.43
Professor delays students' progress out of self-interest	3.16 (.78)	3.53 (.74)	–2.28*
Professor is romantically involved with a graduate student	3.64 (.53)	3.64 (.79)	0
Nonresponsiveness to data sharing request	3.16 (.65)	3.40 (.69)	–1.81
Leave out methods details to decrease manuscript length	2.86 (.80)	3.07 (.80)	–1.30
Clinician recruits his/her own patients for research	2.53 (.85)	3.09 (.95)	–4.03*
Subject signs consent form without reading	3.30 (.71)	3.70 (.67)	–2.65*
Recruitment is slow, professor says 'be persuasive'	3.21 (.89)	3.60 (.73)	–2.53*
Ask son to translate consent form for mother	2.81 (1.02)	3.12 (.83)	–2.11*
Add questionnaire to study without IRB approval	3.98 (.15)	3.95 (.21)	1.00

[1]df = 42 except df = 41 for 'romantic involvement' and 'translation' items; standard deviations are in parentheses; higher scores indicate the item is judged as being more unethical.

*$p < .05$.

ethics courses, compared to the beginning of their ethics courses (t (42) = –3.44, $p < .001$). An inspection of Table 2 shows that most students recognized the unethical nature of these hypothetical behaviors as the averages at the beginning of the course were all greater than 2.5, and that in particular, students rated items reflecting conflicts of interest as more unethical at the end of the courses.

Authorship

The total authorship scores did not change significantly from the beginning (mean (M) = 22.26, SD = 4.40) to the end of the class (M = 23.02, SD = 5.22) (t (42) = –1.01, ns). McNemar tests for changes in proportions were calculated to examine students' judgments of singular contributions as sufficient or insufficient to warrant authorship at the beginning vs. the end of the course (Table 3). Students judged collecting data as less sufficient to

TABLE 3 Contributions Sufficient to Warrant Authorship at the Beginning and End of Ethics Courses

	% Sufficient beginning	% Sufficient end	McNemar test exact *p*
Collected the data	52.4	28.6	.01*
Designed the study	93.0	81.4	.06
Analyzed and interpreted data	95.3	86.0	.22
Wrote the first draft of a paper from the study	100.0	100.0	N/A
Read draft and made substantial comments	50.0	40.5	.39
Referred participants to the study	2.4	.0	1.00
Obtained funding for the study	37.2	46.5	.34
Head of the lab in which the study was conducted	38.1	45.2	.61
Developed hypotheses for the study	79.1	79.1	1.00
Analyzed the data for the study	83.7	76.7	.58
Several of the above	97.7	95.3	1.00

warrant authorship at the end of the ethics courses compared to the beginning.

Moral Judgment

Due to missing and unreliable responding (Rest et al., 1999), only 33 participants had complete pairs of DIT2 data. Neither the P nor N2 indices increased significantly from the beginning to the end of the courses (beginning Ms = 39.91 (*SD* = 16.93) and 40.86 (*SD* = 17.68), and end Ms = 41.64 (*SD* = 13.42) and 42.79 (*SD* = 13.87) t (32) = –0.58 and –0.70, ns, for P and N2, respectively).

Associations between Moral Judgment and Ethics Knowledge

Partial correlations of moral judgment scores with judgments related to ethical situations or authorship total scores from the end of the ethics courses, after controlling for moral judgment scores from the beginning of the courses, were nonsignificant (all coefficients < .20, ns).

Discussion

Previous research on the value of ethics instruction on the RCR has led to ambiguous results, and in that way, the results of the current study are consistent. There were significant changes in scores for some items of the RCR knowledge (Table 1). Unlike the study of post-doctoral fellows (Funk et al., 2007), the present study found that ethics instruction was associated with improved scores for appropriate ethical responses for items related to publication and authorship. Further inspection of Table 1 suggests that some items did not change significantly because of ceiling or floor effects. That is, students rated some items as appropriately true (e.g., consequences of research misconduct can be serious) or appropriately false, both the beginning and end of the courses (e.g., put identifying data in a dataset next to study data; not address RCR concerns when there is a power differential). Ethics instruction was not associated with appropriate ratings or changes in beliefs about other areas of research conduct (e.g., that the lack of clinical equipoise with demonstrably effective drugs for common conditions implies a placebo control design is probably not ethical with a new drug, or that the PI is unlikely to be the best person to determine if subjects with adverse events should continue due to conflict of interest) possibly because these issues are relatively more complex and the appropriate actions are less clear.

With regard to the ethical scenarios (Table 2), results indicated that students were increasingly convinced of the inappropriateness of specific behaviors after participation in ethics instruction. The average scores at the beginning of the courses for each scenario tended toward disagreement (> 2.5), so instruction may not necessarily have changed beliefs but rather may have enhanced and reinforced already held beliefs or at least resolved ambivalence. These results are potentially consistent with the results of a study by McGee and his colleagues (McGee et al., 2008), which found that RCR instructions enhanced trainees' prior attitudes when they agreed with what was being taught.

Nearly all students knew that multiple forms of contribution were needed to warrant authorship and that a sole form of contribution, such as referring patients to a study, was insufficient to warrant authorship. These judgments did not change from the

beginning to the end of the ethics courses (see Table 3). Although overall judgments of contributions warranting authorship did not change significantly from the beginning to the end of the class, students appropriately judged collecting data as insufficient to warrant authorship over time.

Interestingly, the DIT2 indices (N2 and P) did not change significantly between the beginning and end of the ethics courses, although the small sample for the DIT2 results makes interpretation difficult. We also found that moral reasoning and RCR judgment and authorship variables were not significantly associated, which may suggest that RCR knowledge and moral reasoning are distinct and complementary components of RCR. Other research studies using the DIT2 have found mixed results about whether RCR instruction reliably modifies moral reasoning among scientists in training (Bebeau and Thoma, 1994; Heitman et al., 2002). Changes in moral reasoning tend to be defined within a developmental process (e.g., Kohlberg and Hersh, 1977) that assumes gradual change. Such changes may not reliably occur within the short time frame of a single semester: there could be a delayed response that a test at the end of the semester may not capture. On the other hand, there is some evidence that other factors, such as executive cognitive function (e.g., Cottone et al., 2007) and personality traits (e.g., Mudrack, 2006), may not be easily modifiable, could impact learning, and may be related to levels of moral reasoning. Although Bebeau (2002) reported increasing moral reasoning scores by level of formal education and by discipline (e.g., philosophy graduate students), further work is needed to demonstrate that graduate education, including RCR instruction, results in both knowledge and moral reasoning abilities that sufficiently prepare students to function as ethical scientists.

The small sample size, especially for the DIT2 results, warrants caution when interpreting the results of the study. The study also utilized a volunteer sample that was drawn from ethics courses and is potentially limited because of the non-randomized design. In addition, the modest internal consistency values indicate that the psychometric properties of the study's measures could be improved. However, given the limited number of longitudinal studies evaluating the efficacy of ethics instruction to modify the ethical beliefs and practices of scientists in training,

the study extends the knowledge base in this area of inquiry and provides new directions for future research efforts. These results potentially imply that more effective teaching strategies and longer term instruction and evaluation may be needed to prepare students in the knowledge, skills, and moral judgment abilities needed for RCR.

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Appendix 1

Sample Questions

In this section about your experience with conducting research, mark an 'X' over False or True for each item:

I have *taken the lead* on writing up and submitting one or more research protocols to an IRB.	False	True
I have *participated* in writing and submitting a research protocol to an IRB.	False	True
I have taken one or more classes on research ethics and the responsible conduct of research.	False	True

In this section, mark how *true or false* you believe each statement to be with an 'X:'

Consequences of research misconduct can include being expelled from your professional organization, fired from your job, and disqualified from received federal research funding	Always or almost always true	Sometimes true, more often than false	Sometimes, false, more often than true	Always or almost always false
If you have a concern about someone's ethical behavior and there is a power differential (you are a student; s/he is a professor), you should take it to a higher authority	Always or almost always true	Sometimes true, more often than false	Sometimes false, more often than true	Always or almost always false
When you are involved with creating and analyzing a large dataset, some honest errors may occur, and honest errors are not research misconduct	Always or almost always true	Sometimes true, more often than false	Sometimes false, more often than true	Always or almost always false

In this section, mark how *ethical or unethical* you believe each action would be with an 'X:'

You are looking at the data you have collected and have a strong gut sense that the data from one subject is an outlier, so you decide to delete that subject's data and write up the paper with one less subject	Always or almost always ethical	Sometimes ethical, more often than unethical	Sometimes unethical, more often than ethical	Always or almost always unethical
Professor Delay encourages a senior graduate student to delay graduation to "beef up the CV," but the student already has several publications—you wonder if Professor Delay does not want to lose a good worker in the lab	Always or almost always ethical	Sometimes ethical, more often than unethical	Sometimes unethical, more often than ethical	Always or almost always unethical
You are a student in Professor L'Amour's lab, who appears to be having a romantic relationship with another graduate student	Always or almost always ethical	Sometimes ethical, more often than unethical	Sometimes unethical, more often than ethical	Always or almost always unethical

In this section, put an 'X' over if you believe the action *is a sufficient contribution to warrant authorship on a research paper*.

Collected the data	Always or almost always sufficient	Sometimes sufficient, more often than insufficient	Sometimes insufficient, more often than sufficient	Always or almost always insufficient
Designed or substantially helped design the study	Always or almost always sufficient	Sometimes sufficient, more often than insufficient	Sometimes insufficient, more often than sufficient	Always or almost always insufficient

Analyzed the data and interpreted the results	Always or almost always sufficient	Sometimes sufficient, more often than insufficient	Sometimes insufficient, more often than sufficient	Always or almost always insufficient