Responsibility in the Conduct of Quantitative Sciences: Preparing Future Practitioners and Certifying Professionals

Rochelle E. Tractenberg¹ and Kevin T. FitzGerald²

 ¹ Collaborative for Research on Outcomes and –Metrics; and Departments of Neurology; Biostatistics, Bioinformatics & Biomathematics; and Psychiatry, Georgetown University Medical Center, Washington, D.C.
² Pellegrino Center for Clinical Bioethics; Department of Oncology, Georgetown University Medical Center, Washington, D.C.

Abstract

The American Statistical Association (ASA) Ethical Guidelines (ASA, 1999, http://www.amstat.org/committees/ethics/) address eight general topic areas: Professionalism; Responsibilities to Funders, Clients, and Employers; Responsibilities in Publications and Testimony; Responsibilities to Research Subjects; Responsibilities to Research Team Colleagues; Responsibilities to Other Statisticians or Statistical Practitioners; Responsibilities Regarding Allegations of Misconduct; and Responsibilities of (those) Employing Statistical Practitioners. The National Institutes of Health (NIH) has a very similar list with nine topics (NIH NOT-OD-10-019; NIH, 2009).

Both are lists of factual information with which trainees should become familiar. However, both are also static - they neither support nor suggest increasing or changing responsibility over a career. That is, mentors and instructors in the responsible conduct of research are indistinguishable from trainees; technically at the end of a course (whether it is 1 hour, week or semester long) the trainee has as much information as the instructor. Moreover, as new areas of concern arise, additional topical training is required –but rarely completed.

Although the NIH requires that all trainees who receive NIH funding also receive training in the responsible conduct of research, to integrate the ASA Guidelines for Ethical Statistical Practice into training, two things are needed: 1. A semester course syllabus; and, 2. A method of documenting the qualifications of instructors to serve as mentors for such training. We describe both in this paper.

Key Words: ethics training, mentorship, professional practice, ASA ethical guidelines for professional practice

1. Introduction

The American Statistical Association (ASA) Ethical Guidelines for Professional Practice (ASA, 1999) address eight general topic areas: Professionalism; Responsibilities to Funders, Clients, and Employers; Responsibilities in Publications and Testimony; Responsibilities to Research Subjects; Responsibilities to Research Team Colleagues; Responsibilities to Other Statisticians or Statistical Practitioners; Responsibilities Regarding Allegations of Misconduct; and Responsibilities of (those) Employing Statistical Practitioners. The National Institutes of Health (NIH) has a very similar list with nine topics: conflict of interest – personal, professional, and financial; policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices; mentor/mentee responsibilities and relationships; collaborative research including collaborations with industry; peer review; data acquisition and laboratory tools; management, sharing and ownership; research misconduct and policies for handling misconduct; responsible authorship and publication; the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research (NIH, 2009).

Both of these can be characterized as lists of factual information with which trainees should become familiar. However, both are also static: they do not support increasing or changing responsibility over a career; they do not suggest that such changes are possible (or sometimes even unavoidable). Neither one supports the development of any ability to prioritize the topics, nor to resolve challenges that may arise where more than one of these topics is actually in play. Individuals who are identified as "mentors" and/or "instructors in the responsible conduct of research" are actually indistinguishable from trainees who complete this (same) training: the assessment of learning in courses in "research" or "professional" ethics do not differ depending on career stage. While the 2009 NIH rules stipulate that "the instruction (in RCR) should ... span the investigators' careers", this is almost universally implemented as repeating the same training quadrennially, or giving the same lecture on the NIH topics list every year. Moreover, the proliferation of training opportunities to teach the NIH topics list for "responsible conduct of research" has unfortunately been accompanied by a proliferation in the number of cases of research misconduct (see e.g., Antes et al. 2010 or Schmaling & Blume, 2009).

It is possible that the failures widely observed for the NIH initiatives in "training in responsible conduct of research" to actually promote responsibility are perceived as evidence that formal training "in ethics" is not as useful as intended. Although the NIH published new rules describing requirements for RCR training for federally-funded research trainees (NOT-OD-10-019, 2009), there is little evidence that these new rules can or will increase the utility (whether real or perceived) of this type of training. The NIH rules outline five features of formal instruction in RCR: *format* must be face-to-face (but <u>can</u> include online "instruction"); *subject matter* should include at least some of the nine dimensions articulated in NOT-OD-10-019; *faculty* must contribute to the training in RCR, either in their own research groups or for the institution; the *instruction* must be substantive (which is defined as having a duration of at least 8 hours); and the instruction should both span the investigators' careers and must occur at least once per *career stage and* not less than once every four years (frequency). "RCR Training" that is designed to meet the letter of these criteria is unlikely to support <u>lifelong learning in responsible</u>

<u>conduct of research</u> (which represents the spirit of the criteria and their promulgation). Further, adapting this model in order to design training in the ASA Ethical Guidelines (or the code of conduct of any discipline) is unlikely to lead to more interest in, or willingness to, either teach or enroll in such courses among quantitative scientists.

The ASA Ethical Guidelines for Professional Practice have not been integrated formally into undergraduate or graduate training programs (although their inclusion is being considered for the 2014 undergraduate ASA curriculum guidelines revisions, see http://www.amstat.org/education/pdfs/guidelines2014-08-30.pdf). Here we describe a new training paradigm for responsibility in the practice of science - including the quantitative sciences – which could be used to support the integration of this sort of training for graduate or undergraduate students. This paper describes a semester course syllabus (or, a series of 13 meetings that can be completed over a longer period) that is contextualized within a method of documenting ongoing growth and development in the knowledge, skills, and abilities required to practice (all) science ethically. The method is a training paradigm that includes qualifications for individuals at different career stages, such that growth is both explicitly encouraged and also feasible as self-motivated learning (rather than requiring additional formal coursework over time). The paradigm (published in 2012) includes a separate level to qualify individuals to serve as instructors and mentors for such training. As outlined below, this paradigm supports the purposeful integration of "ethical guidelines" from the ASA and from the NIH topics lists (topics lists of other associations, institutions and agencies could easily be included instead of the NIH topics we have used) - into the training and mentorship of quantitative scientists. The paradigm includes an articulated developmental trajectory, and uses a portfolio (rather than an exam) for assessment. In this paradigm, mentors can be "certified", while mentees at all levels can obtain (whether it is a requirement or their choice) a more standard mentorship experience than is currently available.

2. Methods

2.1 Syllabus and course development

The Mastery Rubric for Ethical Reasoning (MR-ER, Tractenberg & FitzGerald, 2012) treats <u>ethical reasoning</u> as a learnable, improvable skill set: (identification and assessment of one's) prerequisite knowledge; recognition of a moral issue; identification of relevant decision-making frameworks; identification and evaluation of alternative actions; making & justifying a decision (about the moral issue); reflection on the decision. These KSAs were derived from compendia of scholarly work reflecting ethical decision-making (e.g., <u>http://www.scu.edu/ethics/practicing/decision/framework.html</u> - initially published in 1996). Tractenberg (2013) discussed how to integrate the MR-ER and the ASA Ethical Guidelines for Professional Practice to support the initiation of new students into the habits of mind that characterize the developing quantitative scientist. Here, we discuss a course (Syllabus, Table 1) and discuss how this could be adapted to promote the qualification of instructors for such a course, or for mentorship, in order to support and sustain ongoing growth and development in the professional identity these guidelines were developed (in part) to promote.

The course and assessments were designed using principles of <u>assessment validity</u> (Messick, 1994) reflecting answers to these questions:

1. What is/are the knowledge, skills, and abilities (KSAs) that students should possess (at the end of the curriculum)?

- 2. What actions/behaviours by the students will reveal these KSAs?
- 3. What tasks will elicit these specific actions or behaviours?

We applied these principles, combined with the MR-ER and the ASA Ethical Guidelines topical areas (all of which are included), to develop the syllabus shown in Table 1 (Results). The course was designed to provide two meetings for addressing each of the ethical reasoning KSAs, to promote instruction, practice, feedback (from instructors and peers), and also to ensure that current, topical materials (cases, vignettes) are discussed to integrate information from the NIH topics list (all of which are included).

2.2 Portfolio supporting ongoing professional growth and development

A portfolio can be compiled, similar to the one used to apply for ASA PStat Accreditation (<u>http://www.amstat.org/accreditation/index.cfm</u>), to certify that quantitative scientists and professional practitioners are "qualified" to mentor new statisticians in the ASA professional practice guidelines. Students completing the course outlined in Table 1 would be able to compose a portfolio on which they could build over time (see Tractenberg, 2013). Using this method to qualify mentors in the ASA program, for example, would specify a minimum level and type of mentorship for all mentees. Table 2 shows descriptions of the performance levels of the KSAs that would be taught in the course, at the level that would be required to qualify an individual to teach that course or mentor statisticians (if such a qualification model were to be accepted/implemented).

The satisfaction of the 2009 NIH rule that "instruction (in RCR) should... span the investigators' careers", is almost universally implemented as completing some training (which is focused on topics, and not on skills or their development; see https://www.citiprogram.org/index.cfm?pageID=22) every four years throughout the career, or either giving one lecture within a course, or teaching a course over time. By contrast, the Mastery Rubric for Ethical Reasoning (MR-ER, Tractenberg & FitzGerald, 2012) treats ethical reasoning as a learnable, improvable skill set, with different KSA performance levels expected for individuals who operate independently ("journeyman" level) and those who are qualified to teach and mentor others ("master" level). These are described in detail in Tractenberg & FitzGerald (2012) and Tractenberg (2013) for the ASA Ethical Guidelines for Professional Practice, and instantiated in Table 2 for instructors and mentors of those in the quantitative sciences.

3. Results

The challenges for integrating formal training in either the ASA or NIH descriptions of ethical conduct as a member of the scientific community include:

- A. Practitioners of quantitative sciences are not, or do not consider themselves to be, "ethicists", and so may defer the training in this domain to ethicists on their campus or refer students to online resources.
- B. If training in ethics is not required, programs and instructors prefer to dedicate their training hours to methodologies and domain-specific skills such as communication, consulting, or writing.
- C. Because of A. and B., and since the ASA Ethical Guidelines for Professional Practice have not been integrated into graduate training programs for quantitative sciences, faculty in these programs may be unaware of the Guidelines or may be unprepared to

teach, provide formative feedback on, and encourage growth in, student work involving either the Guidelines or the KSAs for ethical reasoning.

These challenges also exist for the mentors that are chosen to participate in institutional mentorship programs or the ASA's new mentorship program. As described in the Introduction, neither the ASA nor NIH information on ethical professional practice suggests that the requisite KSAs should or even *could* change over a career. Also, case analysis (the recommended method for teaching ethics for scientists) is only rarely assessed beyond determining that it has or has not been done. This has the unintended consequence that instructors in the responsible conduct of research, or mentors, often have no more training in ethics than the typical trainee who has recently completed this training. By integrating the ASA Ethical Guidelines for Professional Practice and the knowledge, skills and abilities required for ethical reasoning, we have created a syllabus that any practitioner can utilize to incorporate the Guidelines (and ethical reasoning) into training for statistical consulting, or professional preparation for quantitative science (**3.1**). Additionally, we have outlined descriptions (**3.2**) of Master-level performance for instructors or mentors.

3.1 Syllabus

The MR-ER treats ethical reasoning as a learnable, improvable skill set: (identification and assessment of one's) prerequisite knowledge; recognition of a moral issue; identification of relevant decision-making frameworks; identification and evaluation of alternative actions; making & justifying a decision (about the moral issue); reflection on the decision. These KSAs were derived from compendia of scholarly work reflecting ethical decision-making (e.g., http://www.scu.edu/ethics/practicing/decision/framework.html - initially published in 1996). This ethical reasoning KSAs constitute a process worked through whenever an issue arises. The structure of the course is to present the KSAs, and have students step through the process repeatedly each week. Table 1 shows how a specific KSA is emphasized each week, while the students continue to practice the entire reasoning process. We have used the NIH topics list as "context" for the Guidelines and KSA practice, so a course based on this syllabus would fulfill federal requirements for "RCR training" of students with grant support from any federal agency.

Table 1: Syllabus for either a 13-meeting (semester) course, or a series of 13 meetings over a year.

Course Objectives and Topics

NOTES: *Italics* = MR-ER KSA (2 sessions on each). <u>Underline</u> =NIH topics. **Bold** =ASA Ethical Guidelines for Professional Practice topic.

- 1. Orientation meeting: introduction to the KSAs, case study approach, and portfolio assessment. Begin discussion of *prerequisite knowledge*, and its role in developing a sense of responsibility for the conduct of research and the practice of quantitative science.
- 2. Discuss the utility of *prerequisite knowledge* and how/whether augmenting this with formal ethical reasoning can serve as a basis for adequate reasoning and case study discussions. Is it ever OK not to use the **highest possible levels of competence**, **judgment**, and diligence in the design and execution of an analysis?
- 3. Definitions of unprofessional conduct, <u>research misconduct</u>, and policies for handling **misconduct** in the workplace and/or from funders' perspectives. Whistle-blowing,

what promotes and what prevents it, and policies around whistleblowing and whistleblower protections. Discuss *recognition of ethical or moral dilemmas* in these contexts.

- 4. Discuss *recognition of ethical or moral dilemmas* in the <u>confidentiality and privacy</u> interact/intersect in data science and quantitative applications, and how **confidentiality and intellectual property** interact/intersect generally.
- 5. Identify and articulate obligations to protect fundamental human rights and respect diversity in all cultures. Describe <u>"socially-responsible use"</u> of the efforts of data scientists. Discuss *decision-making frameworks* and their application(s) in protecting fundamental rights, ensuring social responsibility, and respect for <u>diversity</u>.
- 6. Describe *decision-making frameworks* and their applications in cases involving the design of **ethical** <u>clinical or animal research</u>, <u>participant recruitment</u>, <u>and the concept of "informed" consent</u>.
- 7. *Identify and evaluate alternative actions* with respect to current developments in **animal research/models** (e.g., translational research; power/sample size; genetics).
- 8. Discuss **responsibilities to funders, clients & employers**: identifying and avoiding conflicts of interest personal, professional, and financial in <u>collaborative work</u> <u>and/or research</u>. *Identify and evaluate alternative actions* in the identification, management and/or removal of <u>conflicts of interest</u>.
- 9. Discuss the use and interpretation of data analysis within and outside of work teams (collaborative work); responsibilities for *making and justifying decisions* with **due consideration of the employer or funder and funding structure** in <u>data management</u>, sharing, and ownership.
- 10. Whether or not quantitative work will be <u>published</u> or shared, **what are our responsibilities to our professional community**? Discuss *making and justifying decisions* around ethical dilemmas arising from the professional community perspectives including **publication, testimony**, and **peer review**.
- 11. *Reflecting* on the <u>environmental and societal impacts of quantitative sciences</u> in scientific research (academic or lay consumers). Discussion of the *decision-making processes* every data scientist engages in, whether in research or applied settings; and sole and team science contexts.
- 12. *Reflecting* on the <u>quantitative scientist as a responsible member of society</u>, and larger impacts of *decisions* made by the quantitative scientist throughout design and execution of analyses and simulations, and reporting of results.
- 13. Final meeting: final project/paper (to assemble a portfolio with a 1000 word essay outlining how each completed assignment represents the learner's growth and development in each KSA, and how the evidence represents their achievement of the "beginner" level –or how it does not); plans for future/continued growth by students/learners.

Like any NIH course, one meeting is allotted per NIH topic, and also per ASA topic area. The focus of the course is actually the development of the set of KSAs involved in ethical reasoning, so that trainees will be equipped to engage with topic areas from both lists, and cases of increasing complexity, as they move through their training and careers. The topics are not changing over time, so can be revisited; it is the skills to comprehend and to prioritize challenges – particularly those that arise involving multiple topical areas – that this course is focused on initiating and developing.

3.2 Assessment/qualification of Mentors or instructors.

During the course, or as the meetings outlined in Table 1 are scheduled, instructors and mentors must be prepared to introduce each of the KSAs as well as the ASA Ethical Guidelines for Professional Practice, and also to monitor and provide formative feedback to participants and mentees. That is, the learning goals for the course go beyond familiarity with the topical material, and so the instruction must also go beyond what is typical. Instructors must be qualified to teach, but also to diagnose and remediate, the KSA performance of less-sophisticated reasoners, to foster their metacognition around their own KSAs and how their work does/does not reflect the target level of achievement. Self-assessment, and student revision of their own work to be more representative of the ethical reasoning KSAs, must be nurtured and supported by targeted input from instructors, and this type of input is notoriously difficult to provide (e.g., Keefer & Davis. 2012), but is most useful in ethical development (e.g., Dunlosky et al. 2013). Table 2 describes the evidence that an instructor or mentor would have, or should seek to establish for qualification. The ASA Ethical Guidelines for Professional Practice outline eight general characteristics which are integrated in the expert practitioner. Table 2 instantiates the intersections between these ethical reasoning KSAs and the Guideline areas; the NIH topics (representing any relevant topics list) are simply superimposed and could be aligned differently.

JSM2014

Table 2: From: <u>http://www.amstat.org/committees/ethics/index.html</u> after Tractenberg & FitzGerald (2012, Table 1) and Tractenberg (2013, Table 1); describing the KSA levels MENTORS should have attained before being certified as ASA mentors. *Italics* = MR-ER KSA. <u>Underline</u> =NIH topics. **Bold** =ASA Ethical Guidelines for Professional Practice topic.

	Knowledge, skills and abilities (KSAs) of Ethical Reasoning					
Ethical Reasoning KSAs: ASA Ethical Guideline Areas:	Prerequisite knowledge: Instruction on NIH RCR domain and its relevance to the ASA ethical area	Recognize a Moral issue: what are the implicit and explicit issues being considered when choices to act any given way are made? What are the responsibilities, and to whom? Are any goals or guidelines in conflict, and how can these conflicts be best resolved?	<i>Identify decision- making frameworks:</i> Focus on Stewardship, virtue ethics, "accepted practice", and utilitarianism frameworks.	Identify and evaluate alternative actions: Delineate the various alternatives available to choose. Actions must support both the profession and the scientific domain under study or policy and decision-making they are intended to facilitate.	Make & justify decision: Articulating how and why actions chosen represent professionalism and competence. Consideration of the balance of stakeholder interests and guidelines.	Reflect on decision: Automatizing and internalizing decision- making and considering how to promote greater reasoning and justification in future actions. Acknowledging limitations of chosen action, and possible future remediation.
Professionalism competence, judgment, diligence	Participation in discussion over time on fundamental (foundational) ethical issues, including <u>peer</u> <u>review</u> ; active membership on editorial boards for journals; mentoring as a peer reviewer.	Identify subtle conflicts relating to self or others' professional competence (in quantitative sciences) at the personal, interpersonal, institutional or societal level. Articulate questions arising either at the level of thought or feeling. Identify moral and ethical components. Analysis of how moral/ethical question arises. Coherent synthesis of perspectives of all relevant individuals involved for full recognition of moral issues and distinction between moral and ethical issues.	Judge among frameworks for: Relevance to problem; internal consistency and broader applicability, including consideration of transparency, informativeness, precision, accuracy, and groundedness. Capacity to create vignettes for eliciting decision-making frameworks from less- proficient RCR trainees.	Create and evaluate a relatively comprehensive list of alternative actions from the perspectives of those ethical points of view that are specifically relevant to the problem. Capacity to create vignettes for eliciting lists or evaluations from less-proficient RCR trainees.	Identify the 'best' alternatives from the perspective of each stakeholder as well as overall. Critique these classifications from the perspectives of experts in the field. Capacity to create vignettes for assisting less- proficient RCR trainees in perceiving the perspectives, alternatives, and justifications.	Facilitating the reflection of others on ethical decision- making; taking a leadership role in pursuing contextual changes that could be made to avoid, adapt, or facilitate, similar decision-making in the future. Drawing attention to the ways in which conflicts arise among
Responsibilities to funders, clients & employers assuring that statistical work is suitable, and that the stakeholders' expectations are not in conflict with each other or with ASA guidelines.	Participation in discussion over time on fundamental (foundational) ethical issues of <u>data acquisition</u> <u>and laboratory tools;</u> <u>management, sharing and</u> <u>ownership</u> . Consideration of greater and lesser levels of sophistication of participants in these discussions (e.g., by trainees and mentees).	Identify and discuss competence and professionalism, as they inform choices made by employers (e.g., to NOT share data); coherent synthesis of perspectives of all relevant stakeholders with guidelines for professional practice.	Use of frameworks to describe ethical challenges and how they arise (e.g., from each stakeholder's perspective), and to prioritize expectations with guidelines so as to identify alternative solutions the ethical issue defensibly. Capacity to elicit this sort of prioritization	Considering practitioner responsibilities to stakeholders (and guidelines), formulate and prioritize alternative actions around data management and sharing. Capacity to create or identify vignettes and case studies that highlight the potential for conflicts among stakeholders, for eliciting	Justification of decisions about resolving ethical challenges relating to data, its management and sharing. Elicitation and formative assessment of the justifications by less- sophisticated reasoners; supporting their relating justifications to alternative actions and the affected stakeholders.	stakeholders – with their different decision- making frameworks- and how these must be prioritized by the quantitative scientist to arrive at justifiable decisions.

			from mentees and	lists or evaluations from		
			trainees.	trainees		
Responsibilities in Publications and	Participation in discussion over time on	Identify and discuss competence and	Use of frameworks to describe ethical	Considering practitioner responsibilities to	Justification of decisions about resolving ethical	Taking a leadership role in pursuing contextual
Testimony	fundamental	professionalism, as they	challenges and how	stakeholders (and	challenges relating to	changes that could be
	(foundational) ethical	inform choices made by the	they arise (e.g., from	guidelines), formulate	publication and	made to avoid, adapt, or
	issues of <u>responsible</u>	practitioner to ensure that	each stakeholder's	and prioritize alternative	testimony. Elicitation and	facilitate, decision-
	authorship and publication - including	stakeholders – i e reviewers	quantitative scientists	and readers (or heaters) –	the justifications by less-	scientists around
	with peers, editors, and	readers/hearers, and decision-	seeks to maintain	and decision-makers.	sophisticated reasoners:	publications and
	students/mentees.	makers, have been met.	transparency,	Demonstrated ability to	supporting their relating	testimony in the future.
			informativeness,	engage trainees/mentees	justifications to	-
		Identify case studies for	precision, accuracy,	in the identification of	alternative actions and	
		supporting the development	and groundedness of	the potential for conflicts	the affected stakeholders.	
		of situation where these	publication and	identifying alternative		
		responsibilities might need to	testimony.	actions.		
		be prioritized.	, and the grade of the second s			
Responsibilities to	Participation in	Identify and discuss the role	Use the frameworks to	Considering practitioner	Justification of decisions	Facilitating the reflection
Research Subjects	discussion over time on	of a quantitative scientist in	highlight how conflicts	responsibilities to	about resolving ethical	of others on ethical
	fundamental	the alignment of a research	either arise or are	stakeholders (and	challenges relating to	decision- making with
	(foundational) ethical	relevant governing policies	internally consistent	and prioritize alternative	sample size,	design sample size and
	regarding human	regarding study subjects and	decision is identified.	actions around the	and/or analytic method.	analysis planning (in
	subjects, live vertebrate	ASA guidelines. Analyze and	Consideration of the	research participants,	Encouraging	proposals, posters,
	animal subjects in	synthesize the	applicability of the	(using professional	mentees/trainees to	manuscripts,
	research, and safe	positions/actions that	frameworks to the	competence and	consider by what	dissertations, and/or IRB
	laboratory practices, as	prioritize sample size and	quantitative scientists'	judgment, without solely	authority the justification	submissions).
	relevant for	halance of risk and	role(s) with respect to	practice' for that	situation	
	practice/context.	knowledge-value.	Create vignettes for	domain). Elicit and	situation.	
		6	eliciting decision-	provide formative		
			making frameworks	feedback on alternatives		
			from trainees for	identified and evaluated		
			prioritizing research	by mentees/trainees.		
			responsibilities			
Responsibilities to	Participation in	Identify and discuss the	Consider relevant	Considering practitioner	Justification of decisions	Facilitating the reflection
Research Team	discussion over time on	potential(s) for conflicts of	decision-making	responsibilities to	about resolving ethical	of others on ethical
Colleagues	fundamental	interest for a quantitative	frameworks to support	stakeholders (and	challenges relating to	decision- making with
	(foundational) ethical	scientist. Analyze the	the identification and	guidelines), formulate	conflicts of interest and	respect to conflicts of
	interest – personal	with respect to students and	management of	actions around conflicts	declaration and	declaration/management
	professional, and	academic vs. industry or	conflicts of interest	of interest and their	management? Diagnose	Taking a leadership role
	financial; and of	government based	from the quantitative	identification,	and remediate decisions	in pursuing contextual
	collaborative research	collaborators/projects.	scientists' role(s) in	declaration, and	that fail to prioritize or	changes that could be
	and work, including	Synthesize perspectives of all	projects. Create	management. Create	consider all stakeholders	made to avoid, adapt, or

JSM2014

	collaborations with industry and/or academia	relevant stakeholders, and elicit this synthesis from less experienced reasoners.	vignettes for eliciting decision-making frameworks from trainees for prioritizing research objectives and team relationships to avoid, minimize or manage conflicts of	(realistic) vignettes in which multiple conflicts must be managed simultaneously.	and perspectives in conflict of interest identification, declaration and management.	facilitate, decision- making by quantitative scientists around conflicts of interest.
Responsibilities to Other Statisticians or Statistical Practitioners	Participation in discussion over time on fundamental (foundational) ethical issues of the quantitative <u>scientist as a responsible</u> <u>member of society,</u> <u>contemporary ethical</u> <u>issues in scientific &/or</u> <u>quantitative work and</u> <u>research, and the</u> <u>environmental and</u> <u>societal impacts of</u> <u>quantitative sciences in</u> <u>scientific research</u> – whether this affects academic or lay consumers. Helping scientists be responsible; and policy makers make supportable decisions.	Identify and discuss the potential(s) for scientific, societal, legal or ethical issues arising from what is written/presented, published, or taught. Recognize ethical conflicts that arise for career, institutional, funding, and societal considerations, and also consider the specific communities of scientists and practitioners who may be most directly affected, or who may remain unaware of these challenges. Specific attention to the differences in and for ethical, legal and societal issues that can arise when academic work is "translated" for other purposes.	Consider relevant decision-making frameworks to support the quantitative scientists' role(s) with respect to <i>other</i> quantitative scientists in terms of the impacts of the work of each, under each of these frameworks. Create vignettes for eliciting decision-making frameworks from trainees for prioritizing these responsibilities around realistically complex situations.	Create and evaluate a relatively comprehensive list of alternative actions that accommodate, or prioritize, the perspectives of other statistical practitioners. Consider how some alternatives may be in conflict with those that prioritize the perspective(s) of a funder or to the public or a/the scientific community. Capacity to create vignettes for eliciting these lists and evaluations from less- proficient RCR trainees.	Justification of decisions about resolving ethical challenges relating to the quantitative scientists' role in society, more broadly and also relating specifically to interactions with other statisticians and quantitative practitioners. Consideration of the community of science, the public and/or private funders of research, and the institutional or departmental context.	Facilitating the reflection of others on ethical decision- making with respect to how I portray myself to other statistical and quantitative practitioners. Taking a leadership role in pursuing contextual changes that could be made to avoid, adapt, or facilitate, decision- making by quantitative scientists around recognizing and acting on their responsibilities to others in the same field.

JSM2014

Responsibilities Regarding Allegations of Misconduct	Participation in discussion over time on fundamental (foundational) ethical issues of <u>definitions of</u> <u>research misconduct and</u> <u>policies for handling</u> <u>misconduct</u> by mentees/trainees, collaborators, and employers	Identify and discuss the potential(s) for scientific, societal, legal or ethical issues arising from differing definitions of misconduct. Consider whether government agency (e.g., NSF, NIH), institutional, or professional society definitions confer greater confidence or only stronger implications. greater confidence? Discuss the situation(s) where actions marginally avoid a label or charge of "misconduct" while failing to maintain professional standards.	Consider relevant decision-making frameworks to support the quantitative scientists' role(s) with respect to misconduct by <i>non</i> quantitative scientist colleagues. Create vignettes for eliciting decision- making frameworks from trainees for considering responsibilities relating to misconduct as defined from different groups and with different interests.	Create and evaluate a relatively comprehensive list of alternative actions that accommodate the community of science, the public and/or private funders of research, and the institutional or departmental context; elicit similar lists from trainees that also include the perspectives of other statistical practitioners.	Justification of decisions about resolving ethical challenges relating to the identification of misconduct. Consideration of the community of science, the public and/or private funders of research, and the institutional or departmental context; creation of vignettes to promote trainees' prioritization of these stakeholders and possibly their respective perspectives on misconduct.	Justification of decisions about identifying and/or reporting ethical challenges and particularly, formulating allegations of misconduct when necessary. Elicitation and formative assessment of the justifications by less- sophisticated reasoners on these decisions, with specific attention to the obligation to report and respond to allegations of misconduct owed to the practice and other practitioners.
Responsibilities of Employers	Participation in discussion over time on fundamental (foundational) ethical issues arising from <u>mentor/mentee</u> <u>responsibilities and</u> <u>relationships</u> Consideration of the responsibilities of both mentor and mentee to promote excellence, competence and professionalism for professional practitioners.	Identify and discuss training mentees to a standard of competence and professionalism. Consider ethical issues that arise from choices that are made around selection and preparation/support of mentors as well as mentees. as they inform choices made by the practitioner to ensure that their responsibilities to stakeholders have been met. Identify case studies for supporting the development of trainee/mentee awareness of situation where these responsibilities might need to be prioritized.	Consider relevant decision-making frameworks to support the quantitative scientists' role(s) with respect to training and mentorship of <i>non</i> quantitative as well as quantitative scientist colleagues. Create vignettes for eliciting decision-making frameworks from trainees for considering responsibilities relating to mentorship (from the mentee, mentor, and employer perspectives.	Create and evaluate a comprehensive list of alternative actions that accommodate the community of science, the public and/or private funders of research, and the institutional or departmental context; elicit similar lists from trainees that also include the perspectives of other statistical practitioners. Consider whether and how responsibilities to have or provide mentorship vary throughout a career, across different contexts (academia, industry, government).	Justification of decisions to resolve ethical challenges relating to being, becoming or seeking a mentor. Consideration of the relative positions of the community of science, the public and/or private funders of research, and the institutional or departmental context on whether or not employers should support formal mentorship programs; creation of vignettes to promote trainees' prioritization of mentorship for optimizing professional competence.	Reflection on whether the independent (or sole) quantitative scientist has different responsibilities to mentor/be mentored than collaborative or "supportive" quantitative scientists (possibly in other contexts). Taking a leadership role in pursuing contextual changes that could be made to facilitate choices that are made around selection and preparation/support of mentors as well as mentees.

As described in Tractenberg & FitzGerald (2012), the overall description of "Master" level performance on the KSAs of ethical reasoning is that it "... is characterized by consistent exemplification of all RCR dimensions; proficient mentoring of less senior/proficient investigators; active and competent participation in RCR training activities, including their development and evaluation. (Performance) includes understanding, analysis and synthesis, and mechanisms by which these cognitive skills can be elicited by less-proficient scientists and RCR trainees." In this case, mentors in the ASA program might be chosen because they have consistently exemplified the ASA Ethical Guidelines for Professional Practice *and* have documented their abilities to encourage, instruct, diagnose and remediate the KSAs required for ethical reasoning around the challenging, and often conflicting, topics and areas in new and developing professionals in the quantitative sciences.

4. Discussion

4.1 Quantitative scientist *ownership* of the preparation of their students for professional practice

The dominant institutional culture around ethics education for doctoral students (about whom our research and work in this area is focused) in the basic, biomedical, and quantitative sciences tends to emphasize compliance or outsourcing over *inculcation*. By "compliance" we mean that "only what is required" is done and supported; this includes programs that offer no ethics education because none is required. By "outsourcing" we mean that students are sent to be trained outside their programs of study (e.g., institutionwide "training in the responsible conduct of research"). The domination of these characteristics is understandable, given that most basic, biomedical and quantitative scientists and practitioners are not incentivized to spend their own teaching time and effort *teaching ethics*. However, compliance and outsourcing do **not** contribute to the establishment and maintenance of ethical cultures in science or the communities within which quantitative scientists practice. They also tend to treat "responsible conduct of research" (RCR) as if it were a vaccine requiring a single dose, with intermittent boosters containing the exact same material (National Academy of Engineering, 2009). Quantitative scientists, including those practicing outside of science or policy (e.g., in business and industry), should instead be inculcated into the habits of mind that characterize professional practitioners. More than directing their attention to the ASA Ethical Guidelines for Professional Practice, we advocate a formal integration of these Guidelines into the preparation and instruction of these future practitioners (e.g., Table 1; and Tractenberg, 2013); and the integration of these Guidelines into the ASA mentorship program and other informal mentoring activities for quantitative scientists.

Thus we *discourage* simply "making students of quantitative sciences aware of" the ASA ethical guidelines for professional practice (we are similarly critical of the identical approach to "making students in other disciplines aware of statistics"). Like the single required training experience for "ethics" in research, the typical single "required course" may be perceived by students (and faculty) as extraneous to the main objectives of a course of study, and of the profession. Professional statisticians, and those who practice quantitative sciences, can take ownership of the training of their students by formally and explicitly integrating the ASA Ethical Guidelines for Professional Practice into the required course for research ethics or integrity, to promote the perception of the

Guidelines and this training as central and integral to students' development into professionals practicing the quantitative sciences.

4.2 Supporting sustainable learning in professional conduct

The training paradigms for "training in ethics" suggest (or sometimes make explicit) that mastering the information associated with RCR topics (functioning at the "cognitive stage") will lead to the habits of mind that characterize real mastery of the key constructs in RCR (functioning at the "autonomous stage"; Anderson, 2005 pp. 281-2). This paradigm also signals to the community that passing a single module or course is sufficient as the start and end of training or preparation for ethical professional practice. This replaces the community value for integrity (e.g., Mayer et al. 2013; see also the ASA Ethical Guidelines for Professional Practice) with community value for "completing required training". We therefore encourage a formal introduction to reasoning with these Guidelines, applying them and considering how and when they conflict, and how to resolve complex ethical and professional situations in which they do. The current "RCR training" paradigm is simple to complete and administer. However, it is an inappropriate paradigm for adoption by domains (e.g., "training in big data") and disciplines (e.g., the practice of statistics). In particular, the current paradigm's many failures to achieve meaningful learning, and its emphasis on static topical knowledge instead of increasing sophistication, make this model especially poorly suited to adoption by the ASA or others seeking to integrate training in the ASA Ethical Guidelines for Professional Practice into graduate or even undergraduate curricula. Instead, we recommend a formal paradigm focusing on a learnable, improvable skill set in *ethical reasoning*.

If focused on professional practice, as our syllabus is (Table 1), the relevance of the training to preparing and mentoring future professionals in the discipline is much clearer and stronger; instructors may feel better prepared to integrate the training into their programs of study – even if this training is not mandated or required. The paradigm we have developed (Tractenberg & FitzGerald 2012; Tractenberg 2013) and described here explicitly has a developmental trajectory built in; performance of the ethical reasoning KSAs is described in a flexible manner so that any experiences can be reflected upon in order to demonstrate either the need for more development of a given reasoning skill, or the actual level at which that particular ethical reasoning element is possessed. Our work is based on the idea that ethics education should inculcate - seed and support the development of - a professional and ethical identity that can then grow over a *career* in science or practice (or both). We continue to develop materials for individuals who wish to implement the paradigm, so they can assess their own current functional level within the Mastery Rubric for Ethical Reasoning, and develop a feasible plan for achieving and documenting their Master level performance. Once their own metacognitive skills are developed and documented, they will be far better able to provide instruction and mentorship to others who are developing these skills for themselves.

Acknowledgements

This research is partly supported by the National Science Foundation, grant #1237590; and partly by a grant from the Mary Elizabeth Groff Surgical Medical Research and Education Charitable Trust.

References

- American Statistical Association (ASA) Ethical Guidelines for Professional Practice (ASA, 1999). Downloaded from <u>http://www.amstat.org/committees/ethics/index.html</u> June 2013.
- American Statistical Association (ASA) Professional Statistician Accreditation (PStat
Accreditation) portfolio (ASA, 2010). Downloaded from
http://www.amstat.org/accreditation/index.cfm June, 2011.
- Anderson JR (2005). *Cognitive Psychology and its Implications, 6E.* New York, NY: Worth Publishers.
- Antes AL, Wang X, Mumford MD, Brown RP, Connelly S, Devenport LD. (2010). Evaluating the effects that existing instruction on responsible conduct of research has on ethical decision making. *Academic Medicine* 85: 519-526.
- Dunlosky J, Rawson KA, Marsh EJ, Nathan MJ, Willingham DT. (2013). Improving Students' Learning With Effective Learning Techniques: Promising Directions From Cognitive and Educational Psychology. *Psychological Science in the Public Interest*, 14: 4-58. doi:10.1177/1529100612453266
- Accessed from: http://psi.sagepub.com/content/14/1/4.full.pdf+html 30 May 2014.
- Keefer M, Davis M. 2012. Curricular design, instruction, and assessment in professional ethics education: Some practical advice. *Teaching Ethics* 12:81–90.
- Mayer DM, Nurmohamed S, Treviño LK, Shapiro DL, Schminke M. (2013). Encouraging employees to report unethical conduct internally: It takes a village. Organizational Behavior and Human Decision Processes 121(1): 89-103.
- Messick S. (1994). The interplay of evidence and consequences in the validation of performance assessments. *Educational Researcher* 23(2): 13-23.
- National Academy of Engineering (NAE) (2009). *Ethics Education and Scientific and Engineering Research*. Washington, DC: National Academies Press
- National Institutes of Health (NIH). 2009. Update on the Requirement for Instruction in the Responsible Conduct of Research. November 24. Available online at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html.
- Schmaling KB, Blume AW. 2009. Ethics instruction increases graduate students' responsible conduct of research knowledge but not moral reasoning. *Accountability in Research* 16:268–283.
- Tractenberg, RE. (2013). Ethical Reasoning for Quantitative Scientists: A Mastery Rubric for Developmental Trajectories, Professional Identity, and Portfolios that Document Both. *Proceedings of the 2013 Joint Statistical Meetings*, Montreal, Quebec, Canada.
- Tractenberg RE & FitzGerald KT. (2012). A Mastery Rubric for the design and evaluation of an institutional curriculum in the responsible conduct of research. *Assessment and Evaluation in Higher Education*. 37(7-8): 1003-21. DOI 10.1080/02602938.2011.596923