

# Office of Research Integrity

## NEWSLETTER

The *ORI Newsletter* is published quarterly by the Office of Research Integrity, Office of the Assistant Secretary for Health, Department of Health and Human Services, and distributed to applicant or awardee institutions and PHS agencies to facilitate pursuit of a common interest in handling allegations of misconduct and promoting integrity in PHS-supported research. Please duplicate and circulate this newsletter freely. An electronic copy is available on the ORI home page at <http://ori.hhs.gov>.



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### Keeping RCR Relevant

In this edition, we introduce two new RCR tools that were developed to provide new teaching options on real-life responsible conduct of research (RCR) issues. In addition, ORI invited several RCR educators, who have been working in the RCR field for 25 years, to provide their thoughts on the future directions they are pursuing in their efforts to keep RCR relevant. They describe why their RCR curriculum has changed over time and how they involve students in the current process and, we hope, in lifelong learning. We also have a perspective from

a scientist on how he prepared to teach RCR to researchers who had no RCR training and were from a different science field.

We appreciate the contributors' efforts and willingness to share their thoughts with us. Specifically, we thank the following:

- James M. DuBois, Ph.D.
- Michael Kalichman, Ph.D.
- John E. Kaplan, Ph.D.
- Zubin Master, Ph.D.
- Camille Nebeker, Ph.D.

### New RCR Tool: “The Research Clinic”

*New interactive video aims to better protect research subjects and reduce research misconduct in clinical research*

The Research Clinic, a Web-based interactive training video aimed at teaching clinical and social researchers how to better protect research subjects and avoid research misconduct, was released April 1, 2014, by the U.S. Department of Health and Human Services' Office of Research Integrity (ORI) and Office for Human Research Protections (OHRP).

The video lets the viewer assume the role of one of four characters and determine the outcome of the storyline by selecting decision-making choices for each playable character. The characters are:

- A principal investigator (PI), a busy oncologist who must balance doing what he thinks is best for his patients and his research;
- A clinical research coordinator, an overworked nurse who works for a PI who pressures her to falsify data and violate study protocols;
- A research assistant who has difficulties obtaining informed consent and following research protocols; and
- An Institutional Review Board (IRB) chair who is tasked with (See Research Clinic, page 2)

### The RCR Casebook with Stories about Researchers Worth Discussing: A Resource for Face-to-Face Instruction Sessions

James M. DuBois, D.Sc., Ph.D., Washington University

I had the privilege of editing the Office of Research Integrity's (ORI's) recently published *RCR Casebook: Stories about Researchers Worth Discussing*. The collection contains fictionalized cases based on real stories. About half of the stories were gathered in the context of interviews conducted by Joan Sieber with the National Institutes of Health (NIH) investigators focused on observed wrongdoing in research.

#### Research Clinic (from page 1)

ensuring that research subjects and the integrity of the research enterprise are protected while dealing with a culture resistant to change.

The viewer is presented with various scenarios. For each scenario, the viewer is asked to choose from among courses of action, each of which leads to a different outcome. The video can be used to teach researchers how to avoid research misconduct and violating regulations enacted to protect human subjects in research studies.

About one-third of ORI's research misconduct findings relate to clinical research studies. The unique pressures in a clinical research setting may lead to falsification, fabrication or plagiarism of data by members of a research team. When serious violations of human subject protections occur, it is possible that falsification and fabrica-

Some of the *Casebook* stories involve classic ethical dilemmas in which it is difficult to determine what the right thing to do is. For example, should you grant community members the right to approve the dissemination of potentially controversial study findings? Is this an appropriate form of respect for community members who may have been wronged in the past and who serve as gatekeepers? Or is it acquiescing to censorship that

tion of data may go unidentified. The video highlights scenarios to help identify research misconduct in the clinical setting and provides solutions to help researchers avoid such missteps.

"We suspect research misconduct in clinical research may be underreported because review of clinical research data often focuses on issues other than falsification, fabrication or plagiarism," said Don Wright, M.D., M.P.H., ORI acting director.

Every year, OHRP receives about 400 reports alleging violations of regulations enacted to protect human subjects who participate in research studies. Examples of violations include the enrollment of ineligible subjects who may be harmed by research interventions, failure to obtain or to properly document informed consent, and

could lead to the publication of incomplete or misleading findings? A thoughtful small-group discussion could focus on how to balance both the scientist and the community perspectives.

Other stories contain dilemmas of an entirely different kind. In these stories, the protagonist knows what is the right thing to do, but finds it difficult to do. Given the (See *RCR Casebook*, page 3)

the conduct of research without IRB review and approval.

"This training video has the potential to greatly reduce compliance violations by providing an engaging method to teach researchers how to properly protect the people who generously volunteer to participate in clinical trials," said Jerry Menikoff, M.D., OHRP director.

The Research Clinic is available free on the ORI and OHRP websites. In 2011, ORI released a similar product focusing on biomedical research, [The Lab: Avoiding Research Misconduct](#). Since its release, The Lab has been integrated into research training programs at many universities and research institutions. ORI and OHRP anticipate that The Research Clinic will have the same success with research hospitals and other clinical research organizations.

## RCR Casebook (from page 2)

power structures in a lab, as a post-doc, how should you react or what can you say when a senior colleague puts her or his name on your paper after doing nothing more than correcting your English style? In still other stories, the protagonist thinks he or she knows what is the right thing to do—but may indeed suffer from “unwarranted certainty.” These stories encourage trainees to find additional information as they seek ways to resolve the dilemmas.

In addition to cases, each chapter of the *Casebook* contains a role play. Role plays are particularly well suited to exploring situations that promote the examination of a strong interpersonal or political issue. They allow instructors to explore interpersonal and problem-solving skills and model a behavior that has not been considered.

The *Casebook* Introduction identifies several reasons why RCR instructors might use the cases through face-to-face training sessions:

- To comply with a recently updated NIH policy requiring a minimum of eight hours of face-to-face instruction in the responsible conduct of research (RCR).<sup>1</sup> By providing case studies, role plays, and reflection questions, this book offers valuable ways of engaging learners in face-to-face discussion, debate, and enactment of important RCR issues.
- To foster ethical problem-solving skills, including (1) identifying

stakeholders, morally relevant facts, pertinent ethical norms or principles, and viable options, and (2) activating strategies for balancing competing principles.<sup>2,3</sup>

- To promote the development of sense-making skills, including “(1) recognizing the complexities of your circumstances, (2) seeking outside help, (3) questioning your own and others’ judgment, (4) dealing with emotions, (5) anticipating the consequences of actions, (6) assessing personal motivations, and (7) considering the effects of actions on others.”<sup>4</sup>
- To increase ethical sensitivity, that is, to heighten a researcher’s awareness of many important dimensions of an ethical decision rather than concentrating on one primary point of interest.<sup>5</sup>

These broad aims were supported by a previous project supported by ORI: The development of a consensus on the appropriate overarching aims of RCR instruction using Delphi survey methods.<sup>6</sup> In that project, we asked a team of RCR instructors, researchers, trainees, administrators, and journal editors to identify goals that extended well beyond knowledge of regulatory requirements and institutional rules.

The *Casebook* does not aim to replace standard RCR textbooks; rather, it is meant to supplement them. I would strongly encourage participants to complete a short RCR training program—whether an online program or textbook reading—before participating in the

case-based or role-play component of RCR instruction.

An Instructor’s Manual accompanies the *Casebook*. It contains brief essays on facilitation of small groups, adult learning, and various techniques for using the cases to:

- Focus questions for discussion questions,
- Promote problem-solving frameworks,
- Examine sense-making processes,
- Encourage group debate,
- Facilitate role plays, and
- Suggest ways of responding to observed wrongdoing.

Each essay provides references to additional information for instructors who wish to adopt a specific approach.

The *Casebook* is freely available online at <http://ori.hhs.gov/rcr-casebook-stories-about-researchers-worth-discussing>

### Endnotes

<sup>1</sup> National Institutes of Health. Update on the Requirement for Instruction in the Responsible Conduct of Research In: Health NIH, ed. *NOT-OD-10-019*. Bethesda, MD: National Institutes of Health; 2009.

<sup>2</sup> DuBois JM. *Ethics in mental health research: Principles, guidance, and cases*. Oxford; New York: Oxford University Press; 2008.

<sup>3</sup> Bulger RE, Heitman E, Reiser SJ. *The Ethical Dimensions of the Biological and Health Sciences*. 2nd ed. New York: Cambridge University Press; 2002.

(See RCR Casebook, page 4)

### Lessons Learned over 25 years in Developing an RCR Curriculum in a Basic Science Graduate Studies Program in a Medical School

John E. Kaplan, Ph.D., Alden March Bioethics Institute, Albany Medical College (AMC)

The Graduate Studies Program of AMC has provided education and training in research integrity and the responsible conduct of research (RCR) since the early 1990s. This program has been directed to graduate students in the basic sciences working toward master's and doctoral degrees and to post-doctoral fellows in the basic sciences. The impetus for initiation of such education and training was the mandate issued by the National Institutes of Health that required a description of activities related to instruction in RCR in institutional training grant applications. We will describe the initiation, development, evolution, and current status of our curriculum.

The individual training grant directors were responsible for the initial activities of this endeavor, which were sporadic, inconsistent, and undocumented. Subsequently, in 1994, the Dean of AMC charged the Associate Dean for Graduate

#### RCR Casebook (from page 3)

<sup>4</sup> Mumford MD, Connelly S, Brown RP, et al. A Sensemaking Approach to Ethics Training for Scientists: Preliminary Evidence of Training Effectiveness. *Ethics & behavior*. Oct 1 2008;18(4):315-339.

<sup>5</sup> Gibbs JC, Basinger KS, Fuller D. *Moral maturity: Measuring the development of sociomoral reflection*. Hillsdale, NJ: Lawrence Erlbaum; 1999.

<sup>6</sup> DuBois JM, Dueker JM. Teaching and assessing the responsible conduct of research: A delphi consensus panel report. *The Journal of Research Administration*. 2009;XL(1):49-70.

Studies, who happened to be me, with the task of developing a formal graduate course to address this mandate.

This task was initially addressed by identifying faculty who would develop and teach this course, create curriculum plans and objectives, and identify materials useful in teaching. This process also included self-education because this area had not been previously taught here. It also involved a good deal of public relations because most students and faculty resisted the implementation of training in RCR as an intrusion upon time that should be most profitably spent in the laboratory.

Solicitations were sent to basic science faculty for volunteers to lead the development effort and teach the course. No one volunteered, so I became course director by default. That is how I became an RCR instructor two decades ago. My background was in science, so an additional instructor, a clinical ethicist, was identified and recruited to participate in this venture. This was a successful pairing. As we taught the course, I learned a great deal about the ethical basis for RCR and became conversant on the subject. The clinical ethicist learned to apply ethical principles in the research context. We retained this model until the next decade when I became adequately versed in bioethics to play both roles and the bioethicist stepped away. Eventually we added two more faculty members to the

course, who were trained initially in basic science and became familiar with RCR through both training and experience. We have retained this model to the current time.

The development of the curricula and the selection of educational materials were linked in many senses. The process was meaningfully facilitated by the release by the American Association of Medical Colleges of *Teaching the Responsible Conduct of Research through a Case Study Approach, A Handbook for Instructors*, prepared by Stanley Korenman and Allan Shipp. This volume provided well-designed cases and appropriate discussion (See Lessons Learned, page 5)

*“Those people who develop the ability to continuously acquire new and better forms of knowledge that they can apply to their work and to their lives will be the movers and shakers in our society for the indefinite future.”*

**Brian Tracy**  
(1944- )

## Lessons Learned (from page 4)

questions to launch our additional offering. It provided a wealth of advice for instructors, nearly all of whom, at that time, were new to the field. It included cases focused on the conduct of research; reporting of research; peer reviews; handling of research data, materials, and proprietary information; mentoring and laboratory supervision; misconduct, conflicts of interest, humans and animal research, and genetic research. We still use many of these cases and have replaced some that became outdated. Although other sources of cases are available, those from this original volume stand out as extremely well developed, allowing students to relate easily to the described scenarios and participants. The ensuing decade saw the development of many other excellent resources for RCR education, an effort facilitated by a grant program for this purpose sponsored by the Office of Research Integrity.

Three considerations guided placement of the class in the curriculum: providing early exposure to students who were just beginning their research careers, allowing time for students to gain some familiarity with working in the laboratory, and fitting the class into the existing schedule for students in six different basic science departments. This original class, which was 12 contact hours and entitled *Discussions in Scientific Integrity*, was placed in the fall term of the second year to allow students to have gained research experience to relate to the cases. After several years, we added an *Introduction to Research Integ-*

*riety* during the fall of the first year to provide earlier exposures and more skills. This component added six more contact hours and addressed current topics in scientific integrity, introduction to ethical thinking, a workshop on case analysis by moral reasoning, and considerations in selecting a research mentor. These two courses are taught as a continuum and provide a research ethics curriculum as opposed to a single course. Ultimately, to achieve even earlier exposure and to emphasize the importance of this material, programming was added to our new student orientation. Additional opportunities, including pursuit of a master's degree in Bioethics, are available to students wishing more exposure to the field.

These educational opportunities were designed to utilize principles of adult learning and are largely student led and interactive. There are no lectures. Most classes have included 10 to 25 students. These courses are required of all master's and doctoral students in basic science regardless of their source of support. Before the first two-hour session in the first year, students are assigned to find articles on research ethics and scientific integrity in the current media. Students provide short reports to the rest of the class, and these current topics are utilized to develop ethical principles through both student participation and faculty moderation. During the second two-hour session, students learn moral reasoning and case analysis from a faculty-led workshop through adaptation of

the methods described by Bebeau and co-workers at [http://depts.washington.edu/uwbri/PDF%20Files/Moral\\_Reasoning\\_in\\_Scific\\_Res.pdf](http://depts.washington.edu/uwbri/PDF%20Files/Moral_Reasoning_in_Scific_Res.pdf). The students apply this knowledge during the remainder of the scientific integrity curriculum. The third two-hour session consists of a case-based discussion of the consideration students might use for the selection of a laboratory and research mentor. At the end of these first-year sessions, students are told that the first session of the second year will consist of their verbal reports of when they have utilized lessons and principles of scientific integrity. These reports include how they selected their mentors, conflict with others in the lab, data ownership (since these students "inherited" projects from other students who have graduated), and cases of others absconding with their reagents or monopolizing their equipment. They also frequently describe their difficulty and often frustration in developing techniques utilized by others. They are candid in describing people who they do not believe have acted honorably, although these generally refer to experiences before they joined our graduate program.

After this first session of the second year, the additional sessions are case-based discussions of specific topics led by students. Each session is led by one student or a pair of students working as a team. Students are responsible for a short PowerPoint type of introduction to the topic and applicable policies. (See **Lessons Learned**, page 6)

### Relevance of Case-Based Studies in Workshops on RCR for Diverse Audiences

Zubin Master, Ph.D., Alden March Bioethics Institute, Albany Medical College (AMC)

By sharing a recent experience in which I delivered a lecture and case at a responsible conduct of research (RCR) workshop for biomedical science trainees, I will comment on why I believe that pedagogy on the RCR, specifically for biomedical scientists, needs two essential

ingredients: delivering knowledge/information and providing case-based learning. The art is to determine how much of each element is needed and how to most effectively deliver information on an RCR topic and ensure trainees get the most from the ethical analysis of cases.

#### ***Ethics Workshop: Responsible Research Conduct & Misconduct in Stem Cell Research***

As part of Canada's Stem Cell Network at <http://www.stemcellnetwork.ca>, I had the unique opportunity to organize and present an Ethics Workshop as part of the Network's annual Till & McCulloch Meetings in October 2013. The workshop was a lecture followed by an interactive ethical case using "The Lab: Avoiding Research Misconduct" video hosted by the Office of Research Integrity (ORI) at <https://ori.hhs.gov/thelab>. The 50 to 60 workshop attendees were primarily master's, doctoral, and post-doctoral trainees, and almost all were biomedical researchers working with stem cells. Most attendees had never heard of RCR. Thus, the goals of the workshop were modest and involved introducing attendees to the following: RCR, research misconduct (fabrication, falsification, and plagiarism), the RCR link to scientific retractions, issues of authorship and publication ethics, and Canada's RCR framework.

The workshop began with a discussion of several high-profile cases of stem cell fraud, including the 2009 Hwang cloning scandal. The discussion also included more recent cases involving research misbehaviors uncovered at The New York Stem Cell Foundation meeting and the case of misconduct in Amy Wagers' lab at the Harvard Stem Cell Institute. The purpose was to make the audience (See Case-Based Studies, page 7)

#### **Lessons Learned** (from page 5)

These are compiled on an online course management site (we use Sakai, but any will work) so they can be accessed later. The remainder of the session consists of student-led discussions of cases pertinent to the session topic. The final session is a faculty-led wrap-up of the two-year curriculum, a discussion of how students will use these lessons going forward. Students receive one hour of credit for the first- and second-year course combined. The courses are graded on a pass/fail basis based on participation. Any missed sessions require make-up assignments.

Additional opportunities are available to revisit and expand on these experiences. Some departments have asked me to provide questions for their students' written preliminary examinations. These have consisted of cases for students to apply their background in ethics case development by moral reasoning. Students wishing greater exposure to this and related topics have entered a dual degree program in which they can pursue a Master's of Science in Bioethics simultaneously with their Ph.D. studies in their chosen field. This degree includes a comprehen-

sive three-credit hour course entitled *Fundamentals of Research Ethics*.

This story describes both the development and the evolution of our scientific integrity curriculum. From a personal point of view, it also describes a 25-year period in which my primary area of emphasis has evolved from physiology and cell biology to bioethics with a focus on scientific integrity. I hope that these reflections will be useful to others engaged in education on this essential topic.

*"We now accept the fact that learning is a lifelong process of keeping abreast of change. And the most pressing task is to teach people how to learn."*

**Peter Drucker**  
(1909-2005)

## Case-Based Studies (from page 6)

aware that research misbehavior does occur in the stem cell field and in other areas of biomedicine.

I chose to focus on research misconduct and authorship because our workshop was 1.5 hours. I focused on misconduct because it is perhaps one of the most dishonest behaviors in the ethics of science. I also focused on authorship because most students are likely to encounter situations in which they disagree on it. I began with a broad picture of science and society and explained why scientists have moral obligations to conduct research upholding the highest integrity standards. I next offered a big-picture overview of the range of ethical violations in research. I then delved into the ethics, policies, and practices related to research misconduct and to authorship and publication ethics. To convey an ethical case that had elements of misconduct and authorship, I decided to use The Lab interactive video. The ORI video was ideal for use with a large audience. It permits attendees to choose responses and allows me to pause the video and ask why some chose one response over another before moving forward to the next segment. For smaller classroom settings, a more intimate discussion would be better suited to get into the crux of the case. We chose to examine the role of Kim Park, the graduate student who questions how another researcher used her data. I made sure that not all the best choices were selected so participants could understand why some choices are better than others. From the continuous discussion and laughter, it seemed the video was a

hit, and a follow-up survey showed that students were very satisfied.

I was quite happy with the results of the workshop, and while flying back home, I reflected on some of my experiences teaching RCR to different audiences. Since 2009, I have given guest lectures on RCR to government scientists and academic audiences, primarily students in science, medicine, and law. In the past two years, I have co-instructed the two RCR courses offered at AMC, which my colleague John E. Kaplan, Ph.D., describes in his commentary. The focus of the course will inform the tools you decide to use in class. For example, lectures I have given to law students in a *Biotechnology Policy and the Law* course at the University of Alberta focused on the ethics of science and the governing laws and policies in Canada and internationally. The lectures could have incorporated an analysis of legal cases if the focus were on legal practice and I were trained as a lawyer. As scientists are not trying to be legal or bioethics scholars in RCR, both the RCR workshop and our AMC courses on scientific integrity take on a more practical bent, and the emphasis is placed on cases. As I will go on to discuss, cases with nearly no background information on an RCR topic paint a partial picture. Courses designed to teach RCR to scientists require both knowledge components and case-based teaching.

### *The Importance of Including Both*

Case-based learning has a place in bioethics and moral analysis. Past

cases of scandals and tragedies in human research have established ethical norms and practices and have spurred the creation of international codes of conduct. Today, case-based ethics pedagogy is also the foundation of most training programs in clinical ethics and clinical ethics consultation. Cases are effective in RCR training because they engage scientists in thinking about ethical situations that occur in the lab. These are situations that they can relate to, and some may be more commonplace (e.g., the stress of results not working out, favoritism, or authorship disputes), whereas others may be scenarios they heard about (e.g., a questionable retraction or possible contamination of solutions). Most of the second-year AMC course on scientific integrity is to analyze and discuss cases. Similarly, the interactive video at the RCR workshop was successful in getting trainees to think about the ethical situation encountered by the graduate student. Although there is little data on whether case-based training actually results in better ethical decision making, intuitively it seems a critical component if scientists are to be ethically aware of their practice in relation to others.

Although cases are essential elements to training practitioners, they have finite value if they are not integrated with knowledge-based components. As a trained scientist, I can't imagine being given a case about ethical authorship practices without having some background (See **Case-Based Studies**, page 8)

### RCR at UC San Diego: Lessons Learned and Steps to Foster Lifelong Learning

Camille Nebeker, M.S., Ed.D., and Michael Kalichman, Ph.D., University of California, San Diego (UCSD)

Over the past 25 years, we have learned a great deal about teaching responsible conduct of research (RCR) (Kalichman, 2013a). More recently, RCR scholars have connected the research on human learning and have suggested how

we might think about and improve RCR teaching (McGee, Almquist, Keller, & Jacobsen, 2008; Nebeker, 2013; Nebeker, 2014). Considering what we (the authors) have learned from the relevant literature, our combined experience, and our

independent research on research ethics instruction, we conclude that developing lifelong learning skills on matters affecting RCR should be a primary goal of instruction. Such strategies are designed to increase (See **Lifelong Learning**, page 9)

#### Case-Based Studies (from page 7)

on what is ethical authorship and why it is important. For example, mentioning that authorship is based on giving someone due credit and that scientists are required to be honest and fair and to provide others with opportunities are important aspects to convey. Some elements must be mentioned if the cases are to make sense. One is reporting some interesting facts, such as a study showing that about 10 percent of scientists said they have engaged in unethical authorship. Another is pointing out that most science and medical journals have authorship policies and explaining what those policies mean. Moreover, providing such information gives scientists the tools they need to further look up policies and information if they should ever encounter a similar case. A discussion about norms, practices, and policies needs to be incorporated in some manner into RCR pedagogy directed to scientists to provide a thorough picture.

Having a lecture followed by one or more cases is certainly one way to teach individual RCR topics, and a way that worked in the RCR workshop. But knowledge-based instruction can be incorporated in

different ways. In our second-year *Discussions in Scientific Integrity* course at AMC, we have students lead each class with a synopsis of the topic, and we choose to fill in gaps as we deal with cases. How you deliver information in RCR classes can take on many forms. It can be through introductions of topics led by students, a lecture beginning each class, or integration of information into the cases. Similarly, delivery of cases can be done in different ways, including role playing, having class break out into smaller groups to later convene and discuss findings, or using an interactive video or written cases.

Together, knowledge-based material needs to be integrated with case-based learning as the necessary two ingredients for effective RCR education for biomedical scientists. Case-based ethics training in RCR is valuable because it promotes ethical awareness of situations that might occur in a lab and provides knowledge and skills on how to best handle them. This training also engages scientists because they can relate to the cases, which causes them to reflect on ethical situations by putting themselves into the roles of the dif-

ferent actors to better understand their values, motives, and reasons. And certainly, providing some important background facts on a topic and drawing them to resources are absolutely necessary for researchers to get an overview of the topic. Incorporating developments from research on research integrity into lectures and workshops will provide current information and demonstrate the evolving nature of the field. This training format incorporating important knowledge-based information and cases for biomedical scientists will help students realize that ethical situations in research are unlikely to be black and white. Students will also realize that how situations are handled is a key part of ensuring they don't escalate and in preserving lab morale and collegiality.

More work on the effectiveness of RCR training is needed, especially in understanding whether training improves ethical behavior. It should be noted, though, that providing RCR training is intrinsically important. It raises awareness and highlights the importance of the ethical conduct of research and the role of scientists in society.

## Lifelong Learning *(from page 8)*

student and trainee familiarity with issues that arise in their day-to-day work and infuse confidence leading to conversing about the ethical dimensions of research when questions arise.

To do this, we design RCR instruction that involves learning by doing for both individual and collaborative models. Ideally, these experiential or hands-on methods empower individuals to develop skills that translate to being self-sufficient, capable, and sophisticated thinkers and learners on matters that influence RCR practice and ethical research. In this article, we describe the transitions we have made and are making to improve RCR instruction at UCSD.

**Emphasis on RCR:** In preparation of a course in RCR while still working full time in the neurosciences, Dr. Kalichman was aware of multiple allegations of research misconduct (e.g., summarized in Engler, Covell, Friedman, Kitcher, & Peters, 1987; Kevles, 1998; Crewdson, 2002). These cases were becoming known not only to scientists, but to our federal legislators and regulators as well as to

the general public. For this reason, the 18-hour course included a final lecture on research misconduct. The focus of that lecture was to tell the adult trainees that they shouldn't lie, cheat, and steal (i.e., don't commit research misconduct). It wasn't until later that it became clear how unrealistic it was to focus on such an admonition in a single brief course. The conclusion to focus on RCR, not research misconduct, is explained in more detail in Kalichman (2011).

In later years, a scientific ethics (SE) course was developed at UCSD and evolved to focus on promoting RCR. A prominent feature of our courses was to select instructional strategies that foster a collaborative environment in which the ethical dimensions of research are discussed. It became apparent in the early years of teaching that some students were knowledgeable about some, if not all, of the course topics. Similarly, some students were clearly proficient with respect to interpersonal skills, problem solving, critical thinking skills, and ethical decision-making skills. It is a National Institutes of Health (NIH, 2009) expectation that trainees should take an RCR course at each career stage, and at least every four years. Along with NIH's expectation, a reasonable conclusion is that participation in an RCR course is not defined by reaching a particular level of proficiency, but more by expecting that everyone should be part of the discussion. Our course goals are now defined by creating an environment in which students

from diverse backgrounds, and with variable competencies, speak with one another. We hope they return to their research groups and projects to promote an ethical culture by asking questions, seeking out conversations, and exhibiting responsible research behavior.

**Course goals:** The shift in the course emphasis to promote ethical and responsible research contributed to the development of three course goals:

1. To know rules, issues, options, and resources for research ethics
2. To understand the purpose and value of ethical decision making
3. To have a positive disposition toward continued learning about research ethics

To achieve these goals, we offer a 14-hour course conducted over seven 2-hour sessions to 20 students and use teaching strategies that actively engage students in the learning process.

**Teaching strategies:** Lectures were a frequently used teaching option in the past; however, we now limit a lecture to about 15 percent of in-class time. We believe that student participation in the learning process is essential to meeting our goals, and although lectures may be effective for some settings, we use other techniques. UCSD RCR courses have been taught using diverse tools and strategies to encourage class discussion. These tools and strategies include, but are not limited to: (See *Lifelong Learning*, page 10)

*“Education is the  
kindling of a flame,  
not the filling of  
a vessel.”*

**Socrates**  
(469-399 B.C.)

### Lifelong Learning *(from page 9)*

case studies, video cases, debates, case-based lectures, question-based lectures, role play, student-led instruction, current events, surveys, books (e.g., Lewis, 1925; Macrina, 1995; Goodman, 2007), and at least one short story (Hawthorne, 1837, 1851). On the basis of these experiences, as well as a randomized comparison of three different discussion strategies (Kalichman & Plemmons, unpublished), it is clear that almost any approach can be a catalyst for excellent and useful discussion. Also, although it is important to have relevant topics to discuss, it is not as important *which* topics are discussed as it is *how* those topics are discussed. An experienced instructor/facilitator, well versed in the subject (e.g., knowledgeable about the practice of science, the variation in standards for much of what is discussed in an RCR course, and relevant standards, guidelines, and regulations) and able to facilitate group interaction, can guide and develop the value and depth of the discussion.

For example, we use a teaching strategy that we call “student-led

instruction.” Students are assigned a topic (e.g., data management) and design and deliver a presentation to the class. Student-led instruction can involve a number of teaching strategies (e.g., role play, case analysis, or debate) that actively involve the class members. Students review their plans with the course instructor and receive feedback and guidance. Student-led instruction is an exercise to practice gathering relevant data, synthesizing information, and facilitating conversations about the ethical dimensions of research. Students are not formally evaluated on their presentation content or delivery skills. However, the process is informally evaluated by the interest and enthusiasm generated during class discussions.

**Class size:** During the early years, class size gradually increased to more than 90 students. For several reasons, we decided to cap course enrollment to 20 students. We also decided to use various techniques (e.g., small-group discussion) to increase the likelihood that students will have opportunities to listen, reflect on the content, and engage in conversation about the ethical dimensions of their work. The small course size supports our desire to create a collaborative learning environment, in which those with more or less expertise and experience can both benefit from collective conversations.

#### *Next Steps to Support Lifelong Learning*

**Student Learning Outcomes (SLOs):** Research on learning re-

veals that students are more motivated to learn when they know what they need to know, why they need to know it, and what competencies are expected (Ambrose, Bridges, DiPietro, Lovett, & Norman, 2010; Bransford, Brown, & Cocking, 2000). As a result, it is important to have clearly defined course objectives and learning outcomes that are shared with the trainees, for example, in writing through a syllabus, during the course introduction, and during class discussions. One can then identify instructional techniques that facilitate achieving the SLOs and can develop assessment tools that measure whether the strategy works. In addition, we’d like to know whether we are effective teachers by using these course objectives and SLOs to assess our teaching strategies.

**Formative assessment:** We have conducted a pilot test to get a sense of student change over time with respect to the course goals. Students complete a written self-assessment in Sessions 1, 4, and 7. The assessment data gives us information about (1) students’ prior RCR experience, preconceptions, and questions; (2) personal RCR-related goals and professional interests; and (3) frequency of RCR-related conversations outside of class. Gathering these data provides valuable information that can help to more clearly define course objectives, develop effective teaching strategies, and improve learning outcomes. We are considering administering a follow-up survey to the 2013 fall (See *Lifelong Learning*, page 11)

*“The more I live,  
the more I learn.  
The more I learn,  
the more I realize,  
the less I know.”*

**Michel Legrand**  
(1932- )

## Lifelong Learning (from page 10)

cohort to learn the extent to which these students are thinking and continuing to learn about responsible and ethical research practices.

**New goal—assess lifelong learning:** The evidence for effectiveness of RCR teaching has been, at best, disappointing (Kalichman, 2013b). However, the field has two qualitative studies (McGee et al., 2008; Plemmons, Brody, & Kalichman, 2006) that have shown an overwhelming majority of students receive substantial benefit from RCR courses. But those benefits varied among the students. This variation in self-reported outcomes should not be surprising given that students arrive with diverse backgrounds and preparations. It also emphasizes the value for creating an appreciation of the need for continuous learning about RCR. No one has measured continuous learning in the RCR field. However, the literature on lifelong learning is growing in both post-secondary and professional education (e.g., for physicians [Hojat, Veloski, Nasca, Erdmann, & Gonnella, 2006] and for engineers [Courter, Anderson, McGlamery, Nathans-Kelly, & Nicometo, 2012]). We believe that it is important to see whether RCR training influences the application of learning to promote responsible research behaviors that are fundamental to students' professional practice. Therefore, we are evaluating this growing literature, plan to adapt or develop methods to assess constructs of lifelong learning in RCR, and are hopeful that these approaches can be adapted to RCR education.

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### Case Summaries

#### **Dong-Pyou Han, Ph.D.** **Iowa State University of Science and Technology**

Based on the report of an inquiry conducted by the Iowa State University of Science and Technology (ISU), a detailed admission by the Respondent, and additional analysis conducted by ORI, ORI and ISU found that Dr. Dong-Pyou Han, former Research Assistant Professor, Department of Biomedical Services, ISU, engaged in research misconduct in research supported by National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grants P01 AI074286, R33 AI076083, and U19 AI091031.

ORI and ISU found that the Respondent falsified results in research to develop a vaccine against human immunodeficiency virus-1 (HIV-1) by intentionally spiking samples of rabbit sera with antibodies to provide the desired results. The falsification made it appear that rabbits immunized with the gp41-54 moiety of the HIV gp41 glycoprotein induced

antibodies capable of neutralizing a broad range of HIV-1 strains, when the original sera were weakly or non-reactive in neutralization assays. Falsified neutralization assay results were widely reported in laboratory meetings, seven (7) national and international symposia between 2010 and 2012, and in grant applications and progress reports P01 AI074286-03, -04, -05, and -06; R33 AI076083-04; U19 AI091031-01 and -03; and R01 AI090921-01. Specifically:

- a. Respondent falsified research materials when he provided collaborators with sera for neutralization assays from (i) rabbits immunized with peptides from HIV gp41-54Q (and related antigens HR1-54Q, gp41-54Q-OG, gp41-54Q-GHC, gp41-54Q-Cys and Cys-gp41-54Q) to assay HIV neutralizing activity, when Respondent had spiked the samples with human IgG known to contain broadly neutralizing antibodies to HIV-1; and (ii) rabbits immunized with HIV gp41-54Q to assay HIV neutralizing activity, when Respondent had spiked the samples with sera from rabbits immunized with HIV-1 gp120 that neutralized HIV.
- b. Respondent falsified data files for neutralization assays, and provided false data to his laboratory colleagues, to make it appear that rabbits immunized with gp41-54Q and recombinant *Lactobacillus* expressing gp41-64 (LAB gp41-64) produced broadly reactive neutralizing

antibodies, by changing the numbers to show that samples with little or no neutralizing activity had high activity.

Dr. Han has entered into a Voluntary Exclusion Agreement and has voluntarily agreed for a period of three (3) years, beginning on November 25, 2013:

(1) to exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as “covered transactions” pursuant to HHS’ Implementation (2 C.F.R. Part 376 *et seq.*) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 C.F.R. Part 180 (collectively the “Debarment Regulations”); and

(2) to exclude himself voluntarily from serving in any advisory capacity to the U.S. Public Health Service (PHS) including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

#### **Parag Patel, D.O.** **Advocate Health Care Network d/b/a Advocate Health Care**

Based on an investigation conducted by Advocate Health Care Network d/b/a Advocate Health Care (Advocate Health Care) and additional analysis conducted by ORI in its oversight review, ORI and Advocate Health Care found (See Case Summaries, page 13)

*“Self-education is, I firmly believe, the only kind of education there is.”*

**Isaac Asimov**  
(1920-1992)

## Case Summaries *(continued)*

that Dr. Parag Patel, Cardiologist, Department of Medicine, Advocate Health and Hospitals Corporation d/b/a Advocate Lutheran General Hospital, Park Ridge, Illinois, engaged in research misconduct in research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grant U01 HL089458.

ORI and Advocate Health Care found that the Respondent engaged in research misconduct by directing or intimidating fellows and others to influence left ventricular ejection fraction (LVEF) scores of  $\leq 35\%$  and requesting attending physicians to reassess scores of LVEF to be reported as  $\leq 35\%$  for research subjects after being diagnosed with acute myocardial infarction, thereby causing and being responsible for falsification of research records. These falsifications made subjects eligible for enrollment into the “Vest Prevention of Early Sudden Death Trial” (VEST) when they otherwise may not have been eligible.

The Respondent, Advocate Health Care, and the U.S. Department of Health and Human Services (HHS) want to conclude this matter without further expenditure of time or other resources and have entered into a Voluntary Settlement Agreement (Agreement) to resolve this matter. Respondent neither admits nor denies ORI’s and Advocate Health Care’s findings of research misconduct. This settlement does not constitute an admission of liability on the part of the Respondent.

Dr. Patel has voluntarily agreed for a period of two (2) years, beginning on February 21, 2014:

(1) to have any U.S. Public Health Service (PHS)-supported research in which he is involved be supervised; Respondent agreed that prior to the submission of an application for PHS support for a research project on which the Respondent’s participation is proposed and prior to Respondent’s participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent’s duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent’s research contribution as outlined below; Respondent agreed that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed-upon supervision plan;

(2) that the requirements for Respondent’s supervision plan are as follows:

- a committee of two to three qualified physicians at the institution’s discretion, who are familiar with Respondent’s field of research, but not including Respondent’s supervisor or collaborators, will provide oversight and guidance; the committee will review primary data from Respondent’s participation in PHS-supported research on a quarterly basis and submit a report to ORI at six

(6) month intervals setting forth the committee’s meeting dates, Respondent’s compliance with appropriate research standards, and confirming the integrity of Respondent’s research contribution; and

- the committee will conduct an advance review of any PHS grant applications (including supplements, resubmissions, etc.), manuscripts reporting PHS-funded research submitted for publication, and abstracts; the review will include a discussion with Respondent of the primary data represented in those documents and will include a certification to ORI that the data presented in the proposed application/publication are supported by the research record;

(3) that any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(4) to exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant. **(See Case Summaries, page 14)**

### Case Summaries *(continued)*

#### **Timothy Sheehy, B.A., BSc. SAIC-Frederick, Inc.**

Based on the report of an investigation conducted by SAIC-Frederick, Inc., and additional analysis conducted by ORI in its oversight review, ORI found that Mr. Timothy Sheehy, former Manager, DNA Extraction and Staging Laboratory (DESL), SAIC-Frederick, Inc., the Operations and Technical Services (OTC) Contractor for the Frederick National Laboratory for Cancer Research (FNLCR), Frederick, MD, engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), contract HHSN2612008000001E awarded by FNLCR/NCI, NIH, to SAIC-Frederick, Inc., and the intramural program at the Occupational and Environmental Epidemiology

Branch, Division of Cancer Epidemiology and Genetics, NCI.

ORI found that the Respondent engaged in research misconduct by fabricating and/or falsifying U.S. Public Health Service (PHS)-supported data in Table 1 included in *Cancer Epidemiol Biomarkers Prev* 19(4):973-977, 2010 (hereafter referred to as the “CEBP paper”).

Specifically, ORI found that Respondent fabricated the quantitative and qualitative data for RNA and DNA purportedly extracted from 900 formalin-fixed, paraffin-embedded (FFPE) colorectal tissue samples presented in Table 1 of the CEBP paper and falsely reported successful methodology to simultaneously recover nucleic acids from FFPE tissue specimens, when nei-

ther the extractions nor analyses of the FFPE samples were done. Thus, the main conclusions of the CEBP paper are based on fabricated data and are false.

Mr. Sheehy has entered into a Voluntary Settlement Agreement and has voluntarily agreed for a period of three (3) years, beginning on November 8, 2013:

(1) to have his research supervised; Respondent agreed that prior to the submission of an application for U.S. Public Health Service (PHS) support for a research project on which the Respondent’s participation is proposed and prior to Respondent’s participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of his duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent’s research contribution; Respondent agreed that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed-upon supervision plan;

(2) that any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by (See Case Summaries, page 15)

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## Case Summaries *(continued)*

Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract;

(3) to exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(4) that a letter will be submitted to the editors of *CEBP* requesting that the journal retract the publication.

### **Baoyan Xu, M.D., Ph.D. National Heart, Lung, and Blood Institute, National Institutes of Health**

Based on allegations made by readers of a published paper,<sup>1</sup> additional review by the National Institutes of Health (NIH) and ORI, and a limited admission by the Respondent that “some better looking strips were repeatedly used as representatives for several times [sic],” ORI found that Dr. Baoyan Xu, formerly a Postdoctoral Fellow, Hematology Branch, Systems Biology Center, National Heart, Lung, and Blood Institute (NHLBI), NIH, and currently at the Institute of Infectious Diseases, Southwest Hospital, Third Military Medical University, Chongqing, China, engaged in research misconduct in research supported by intramural research at NHLBI, NIH.

The questioned research involves a Western blot analysis of IgM and IgG antibodies from Chinese subjects in patients with non-A-E hepatitis and control subjects to test reactivity towards a newly discovered virus. Analysis of Figure 6 of the published paper and Figure S4 of the online supplemental information identified thirteen pairs of Western blot bands which had a common origin yet were labeled as from different subjects and usually as detecting a different class of immunoglobulin. Specifically the following pairs were shown to match using forensically useful tools in Photoshop. Each represent a falsification in one or both of the figures as indicated in the table:

<i>Identity of Strips</i>	<i>Located in</i>
A1 IgM/F1 IgG	Fig. 6 & Fig. S4
B6 IgM/E1 IgM	Fig. 6 & Fig. S4
D7 IgM/A11 IgG	Fig. 6 & Fig. S4
G3 IgM/H4IgG	Fig. S4
H9 IgM/F4 IgG	Fig. S4
A4 IgM/E2 IgG	Fig. S4
A5 IgM/B9 IgM	Fig. S4
C9 IgG/C6 IgM	Fig. S4
D11 IgM/H11 IgG	Fig. S4
D5 IgM/A1 IgG	Fig. S4
A10 1GM/F7 IgG	Fig. S4
C11 1gM/E9 IgG	Fig. 6
F3 IgG/E9 IgM	F3 in S4/E9 in Fig. 6

The Respondent agreed to correction of Figures 6 and S4 of the *PNAS* paper.

Dr. Xu has entered into a Voluntary Settlement Agreement and has voluntarily agreed for a period of three (3) years, beginning on December 6, 2013:

(1) that prior to the submission of an application for U.S. Public Health Service (PHS) support (including NIH support) for a research project on which the Respondent’s participation is proposed, and prior to Respondent’s participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of her duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent’s research contribution; Respondent agrees that she shall not participate in any PHS-supported research until such a supervision plan is submitted to

*“We learn more  
by looking for  
the answer to a  
question and not  
finding it than we  
do from learning the  
answer itself.”*

**Lloyd Alexander**  
(1924-2007)

### Case Summaries *(continued)*

and approved by ORI; Respondent agrees to maintain responsibility for compliance with the agreed-upon supervision plan;

(2) that any institution employing her shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived, that the data procedures, and methodology are accurately reported in the application, report, manuscript, or abstract, and that the text in such

submission is her own or properly cites the source of copied language and ideas; and

(3) to exclude herself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

### Endnote

<sup>1</sup> Xu, B., Zhi, N., Hu, G., Wan, Z., Zheng, X., Liu, X., Wong, S., Kajigaya, S., Zhao, K., Mao, Q., & Young, N.S. “Hybrid DNA virus in Chinese patients with seronegative hepatitis discovered by deep sequencing.” *Proc. Natl. Acad. Sci. (US)* 110(25):10264-10269; hereafter referred to as the “*PNAS* paper.”

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