



Cornell University

2018 Responsible Conduct of Research (RCR) Symposium: Maintaining Public Trust in Industry-Funded Research

Monday January 22, 2018
Warren Hall, B25 Auditorium

Program Schedule

10:30–11:00 AM

Auditorium (Warren B25)

Registration

11:00 AM–11:45 PM

Auditorium

Welcome and introductory lecture

*Patrick Stover, Professor and Division Director of Nutritional Sciences,
of Human Ecology*

11:45 AM–12:15 PM

Assigned Rooms

Lunch

*Note: Discussion room assignments are included in your
registration packet*

12:15PM – 1:30PM

Assigned Rooms

Small-group case study discussions

*Note: Case study documents are included in your
registration packet*

1:30PM –1:45 PM

Break

Reassemble in Warren B25 Auditorium

1:45PM–3:00 PM

Auditorium

Panel Discussion, Q&A & closing remarks

*Patrick Stover, Professor, Nutritional Sciences
Marie Caudill, Professor, Nutritional Sciences
David Erickson, Professor, Mechanical & Aerospace Engineering
Mary-Margaret Klempa, Office of Sponsored Programs
Frank Schroeder, Associate Professor, Chemistry & Chemical Biology
Bettina Wagner, Professor, Population Medicine & Diagnostic Sciences*

CASE STUDIES

Case 1: Barking Up the Wrong Tree? Industry Funding of Academic Research¹

Brian Schrag, Gloria Ferrell, Vivian Weil, Tristan J. Fiedler

Association for Practical and Professional Ethics, Duke University, Illinois Institute of Technology, University of Miami

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Nellie Shepherd is a graduate student at a large Midwestern university working with a group of graduate students and postdoctoral fellows in the lab of Dr. Thomas Katz. The primary focus of the lab group's research is various aspects of the fate, transport and biological effects of 1, 3, 5-trimethyltriazinetrione (TTT) in aquatic systems. TTT is a by-product of several chemical manufacturing processes and is extremely difficult to remove from wastewater. Katz, a well-established scientist, is internationally known for his work on TTT. Much of his current research is funded on an annual basis by a consortium of chemical companies that generate wastewater containing TTT. Katz has the highest funding level and best equipped laboratory in the department; however, his students find him distant and communication difficult.

For her dissertation research, Nellie is attempting to determine what environmental factors have contributed to the decline of native fish species downstream from the point at which wastewater from several chemical companies is released into the Missouri River. In addition to TTT, the wastewater contains numerous other substances, including dipropyl phthalate (DPP). At present, no regulatory levels have been established for TTT or DPP; for a variety of reasons, there is much public interest in TTT whereas DPP has been largely ignored.

In a field survey, Nellie found large differences between enzyme levels in fish collected upstream and downstream from the area where wastewater enters the river, with the lowest levels in fish collected closest to the source of wastewater. Short-term experiments conducted by Katz's lab several years earlier did not indicate that native fish species were adversely affected by exposure to TTT, although enzyme levels were not analyzed. An extensive literature search yielded a series of papers indicating that exposure to DPP decreased enzyme levels in several European fish species and linking low enzyme levels to increased susceptibility to disease. Nellie is concerned that DPP, rather than TTT, is the cause of the biochemical changes she has observed and designs a series of simple lab experiments to determine whether exposure to DPP decreases enzyme levels in native fish species.

Nellie arranges a meeting with Katz in which she summarizes the papers she has found showing effects of DPP similar to those she has observed. She also describes the experiments she feels are needed to determine if DPP decreases enzyme levels. Katz tells her that she is barking up the wrong tree and insists that she limit her research to the effects of TTT because that is what the lab's funding is designated for. Nellie is surprised by Katz's response to her proposed experiments. When she tries to pursue the issue, she is abruptly dismissed.

¹ The complete six-volume set *Research Ethics: Cases and Commentaries* can be obtained from the Association for Practical and Professional Ethics, Indiana University, Bloomington, Indiana. Individual cases can also be found on-line at <http://www.onlineethics.org/reseth/scenarios.html>. The scenario, 'Barking Up the Wrong Tree? Industry Funding of Academic Research' is published by permission of the Association for Practical and Professional Ethics.

Nellie discusses her meeting with Katz with several members of the lab group. Everyone she talks to feels that her concerns about DPP are valid. Several weeks later, one of the postdocs tells her that Katz confided in him that he didn't want Nellie to "open up another can of worms for the chemical industry." Nellie knows that loss of the chemical industry funding would be devastating to the lab. She realizes that she can probably complete her dissertation without addressing DPP. However, if DPP has caused the decline of native fish species, this issue needs to be addressed quickly because several of the fish species are considered to be on the verge of extinction. Nellie has the materials and reagents she needs to conduct the experiments evaluating DPP.

Discussion Questions:

- Should Nellie proceed with the experiments evaluating DPP? Why or Why not?

[Scenario 1]

Nellie decides to obey Katz's instructions. She does not include an evaluation of DPP in her work. She refocuses her dissertation topic, limiting it to the effects of exposure to TTT. Results of her work support the preliminary experiments and indicate that TTT has no major adverse effect on the fish species studied. Katz asks Nellie to include an evaluation of the effects of elevated water temperature on fish enzyme levels.

Discharge of water used for cooling by an electrical power plant has caused a 3o C increase in the average annual water temperature of the Missouri River in Nellie's study area.

Discussion Questions:

- Has Nellie compromised her integrity by omitting DPP from her research?
- In what way is the analysis of this case changed by Katz's request that temperature be evaluated?

[Scenario 2]

Nellie proceeds with the experiments evaluating the effects of DPP on two fish species. Her results indicate that exposure to DPP results in decreased enzyme levels.

Now that she has the additional data, Nellie recalls Katz's irritation when she initially suggested evaluating DPP. Because of her apprehension, she decides not to tell Dr. Katz about these experiments and proceeds with her dissertation research as described in Scenario 1.

Discussion Questions:

- By conducting the experiments and not divulging the results, has Nellie compromised her integrity more than in Scenario 1?
- Was she wrong to have conducted these experiments using resources obtained from chemical consortium funds earmarked for research on TTT?

[Scenario 3]

Nellie decides to tell Katz the results of the experiments with DPP. He becomes irritated when she admits that she has conducted the experiments, and he informs her that if she wishes to continue her investigation of DPP, she will need to find another source of funding and another laboratory to work in.

Discussion Questions:

- Is Katz's behavior appropriate? Note: The research of some of the other graduate students in the lab group involves compounds other than TTT.
- Would Nellie's behavior be considered differently if she were working for a consulting firm with Katz as her supervisor rather than as a graduate student? How might public perception of her work change in this setting?

Case 2: What's in an agreement?

Amita Verma, Mary-Margaret Klempa, Cornell University

Andrew Smith is an Assistant Professor of Nutrition at Great Western University (GWU). He studies the effect of infant nutrition on cognitive development, particularly on attention, learning, and retention through childhood, adolescence and early adulthood. His research program is growing, he has a couple of PhD students and funding from the NIH and USDA, however, he thinks that he needs one major project to clearly distinguish his research.

One day Andrew receives an email from Cindy Melford, asking for a phone call to discuss a collaboration. Cindy and he were Ph.D. students together 20 years ago. Cindy works at NutriScience, which produces formula and food supplements for infants and young children. Andrew has followed her career on LinkedIn and knows that she has steadily moved up in the company and now heads up their R&D division.

A week later during their call, after catching up about families and careers, Cindy gets serious. "Andrew, I am sitting on a gold mine of data that we don't have the expertise in-house to analyze, and I would love for you to help us make sense out of it." About 15 years ago, Cindy tells him, NutriScience launched a program where they offered customers who had bought their infant formula a decent amount of compensation to enroll in a study. Each month the families would receive a questionnaire about foods that their infants and children were eating, feeding schedules, and food related traditions and practices in their families. The surveys had a battery of questions on demographics, family history, housing and family income, the physical development of the children, school performance and several standard cognitive measures. Families were compensated as long as they continued to participate in the program.

Data from this program continued to come in over the years. The person who started the program had left a long time ago, however, the R&D department continued to send questionnaires, maintain the study database, and compensate the participants. When Cindy learned of the study, and the significant past and continuing cost, she was astounded to find that the data, which spanned 15 years, was incredibly complete and of excellent quality Cindy is hoping that Andrew would be willing to consider collaborating with NutriScience on this project.

Andrew can't believe what he is hearing. This type of data would indeed be a gold mine, and is unprecedented in its longitudinal nature, breadth, and completeness. This would be an incredible enhancement to his research program and he is certain it would assure a successful tenure review. Cindy and Andrew set up two more meetings later that week to talk about the data and the possible approaches to analysis, hypothesis and angles that this research could take. The more they talk, the more excited they both become. They agree on the research approach and a rough estimate of costs. Cindy tells him that her people will set up the agreement and be in touch.

A few days later Andrew receives a packet in the mail addressed to him with an agreement for a three year collaboration for \$1.2 million. His name is on the signature line for GWU and Cindy's name and signature are on the agreement for NutriScience. There is a sticky note with a personal message from Cindy, expressing her excitement about their collaboration and inviting him to Boston to visit the company headquarters at the company's expense to discuss the project.

Andrew is ecstatic. He has never signed an agreement before, so Andrew decides to consult with his Department Chair, Maria Lopez, (and also, to let her know of this amazing win!) just in case she needs to also sign something. Andrew likes Maria and trusts her counsel. Upon hearing about the

project, Maria congratulates him and asks to look at the agreement. As she reads the agreement, Maria becomes quiet and asks Andrew to contact Matt in the University's Office of Sponsored Programs to ask him to review it. Andrew is concerned that this additional bureaucracy will delay things, and Maria tells him that she understands, but must insist on following university processes. Andrew sends an email to Matt with the agreement attached, asking him to review it ASAP because he wants to book tickets so he and his student can visit the company in Boston right away, get the data and start the work.

The next morning Andrew receives an email from Matt asking to meet. When Matt arrives with the agreement, Andrew notices that several pages have post-its, red lines and comments. "Here we go", Andrew thinks, "mountains of paperwork, hours of nitpicking, and annoying jargon begin." Matt asks if Andrew sent a proposal to the company for the project, and Andrew explains that no proposal was necessary, because Cindy and he had agreed on the project over the phone and she had promised to provide the money to fully fund the project.

Matt goes on to say that according to the agreement, Nutriscience will provide selected data to GWU. This is surprising to Andrew, because his understanding was that Cindy would provide the entire dataset so that Andrew could understand it fully and decide what to do with it. The agreement also states that payment from NutriScience will be conditional on satisfactory results, and that analysis and results must be sent to Nutriscience for review prior to publication. Nutriscience will retain the right to require that the research results be kept confidential, and to approve manuscripts prior to their publication. The agreement further states that publications arising from the research may not reveal the name of the company as the data provider.

Andrew is puzzled by the terms, which seem to indicate a level of control that he had not expected. Although he trusts Cindy fully, Andrew is troubled by some of the terms.

Toward the end of the meeting, Matt informs Andrew that the terms are not acceptable to the University and will need to be revised. Matt tells Andrew that the project might need approval from the IRB, because there seems to be identifying information in the data. He also tells Andrew that Andrew cannot sign the agreement because only someone in the central office is allowed to do so. Inside, Andrew is seething about the paperwork and delays and worried that this immense opportunity might get lost in this bureaucratic mumbo jumbo.

Later that day, Andrew calls Cindy and tells her about the issues Matt raised, and she laughs. "Just as I thought, Andrew! These agreements and forms are just for the lawyers so that they can feel they have control. I would not dream of micromanaging your research. I have enough to do in my day job. Just sign the document, like I did. The two of us can figure this out once the lawyers are out of the picture. This will be such an amazing project. Aren't you excited? Don't you trust me?" "Yes, I do," Andrew says, but he lets Cindy know that the University will not sign the agreement with these terms. Cindy pauses and when she responds her voice is tense, "You know, Andrew, this is our standard R&D agreement. Making any changes at this point will definitely delay the project, and once our lawyers get involved, who knows if they will even agree to any changes. I suggest you sign the agreement as is."

"Why don't you want your company's name acknowledged in publications?" Andrew asks. Cindy replies "Because then you and I will both be on the defensive, trying to convince people that the company did not influence the study. You know how the media is: always twisting everything to make corporations look like the Big Bad Wolf. I don't need that kind of publicity. This is your work."

Plus I don't want the families to freak out. Some of them may not remember that we told them we are going to use the data for research." Andrew and Cindy agree to talk again the next day.

Andrew is really worried. On the one hand he completely understands that Cindy has no interest in manipulating his work and that she is in it for the research. On the other hand, the agreement just seems to want to tie his hands, although Cindy is clear that any changes could doom the project. He cannot let this opportunity slip by. This is the perfect project and exactly what he needs at this stage of his career. Andrew is not sure what to do, and he asks Matt to come and meet with him the next day.

Discussion Questions:

- Do you see problems in the terms that Matt highlighted for Andrew? What are they and why do you think they are problems?
- Should Andrew have the authority to sign the agreement on his own without the involvement of the Office of Sponsored Programs? Why or why not?
- Do you have concerns that Andrew will receive a limited set of data from the company? If so, why, and how can those concerns be mitigated?
- Would you have concerns about the company's hesitation to have its name associated with the study?
- What kind of issues might the IRB worry about in this project?
- What should Andrew do?