Research Integrity | Case Study 1
Were These Slides Falsified?

Helen, a professor of cell biology, found herself mentoring a young woman named Julie. Julie had sought work in Helen’s lab as a technician. She had to drop out of the graduate program because of health and family issues. She felt stuck in the role of lab technician and complained a lot. Even though Helen gave Julie a lot of support and encouraged her to resume her PhD work in the near future, Julie became bitter and uncooperative.

A problem arose in connection with an autoradiography process Julie used to detect proteins. Julie presented the data she had gathered using that process at one of the weekly lab meetings in which researchers, research assistants, and students bring their lab notebooks and present their data in its raw form. After the first part of her presentation, Julie said she had repeated the experiment and had gotten the same result. She showed her slide (a PowerPoint slide of a film from an autoradiogram) from Experiment 1, in which proteins were transferred to a membrane and an X-ray film then laid on top of the membrane, and then showed another slide from Experiment 2 showing the same thing.

Helen didn’t spend a lot of time looking at the raw data of her lab staff, but liked to keep track of questions she had from the presentations at lab meetings. She often followed up later, asking any questions she might have about people’s data. She had noted that the two slides Julie had shown looked more than similar—they seemed identical. After the presentation, Helen asked Julie whether she might have shown the same image twice, in error. Julie said no—she had done two separate experiments, had labeled the images correctly, and had noted that the experiments yielded the exact same result. Julie’s unable to repeat the experiments since the original membranes were accidently destroyed in the lab.

Helen was still troubled. After everyone had left the lab, Helen went to Julie’s notebook and looked at the films much more closely. Helen held the two films over each other, and they matched exactly. Clearly, this was a duplication of the same film since ordinarily, in this type of analysis, each membrane inevitably produces idiosyncratic artifacts.

Helen consulted with others who used this technique. All of the senior scientists and post docs she talked to agreed that the film looked like a duplicate. The following day, Helen called Julie into her office and said, “Julie, I’ve looked at these two films carefully, and all the imperfections in the film indicate that it is the same sample.”

To her dismay, Julie again insisted that she had done two individual experiments and obtained identical results.

What should Helen do?

LaToya Johnson and Sandra Rajeev are first-year graduate students in social work at a major research institution in New York City. They are working with Dr. Francine Lockheart, who specializes in studying the effects of homelessness on children. Dr. Lockheart has received a major federal grant to study the education of homeless children in New York City compared with children who are poor but have more steady housing. The study will follow children over a five-year period, from the fifth to the tenth grade.

A significant part of the grant involves fieldwork, in which investigators must go to homeless shelters and obtain informed consent from parents so that they and their children can participate in the research project for the duration of the study. Researchers must get permission to review the educational records of the children, and also must get the same informed consent and approvals from the parents of the children who have homes. Part of the study involves parents filling out a survey of information about themselves and the children with an interviewer. Another part involves an educational test of the children, to validate the school records. Both the survey and the test are specifically designed to be performed in the field.

Besides LaToya and Sandra, Dr. Lockheart has a staff of five paid surveyors and five paid testers, to make it easier to obtain a cross section of children from the five boroughs of New York City. Dr. Lockheart holds a training session for the 12 people involved, explaining to them the research tools and the importance of accuracy and honesty in reporting the results of the surveys and tests. Each of the surveyors and testers is given a wireless laptop computer, which allows them to input the data and transmit it to a main computer as soon as the surveys and tests are performed.

Each interviewer or tester is expected to handle 25 children in one year, for a total of 300 children. LaToya is an interviewer and Sandra is a tester. Dr. Lockheart had hoped to remove the potential for tester bias by separating the surveying aspect of the study from the educational testing part. The testers, who do not know whether a child is homeless or not, meet the children at a school after the surveyors get the demographic information. Dr. Lockheart also tells the surveyors and testers that their work will be monitored or verified, to serve as a deterrent to falsification.

LaToya is assigned a section in Queens and Sandra is assigned Staten Island. The two young women are excited about participating in such an important study. After the first month on the job, they talk to each other about the experience, and are saddened by the circumstances of the children in both groups. Sandra also says that she feels guilty about exploiting the children, since the results of the study will come out only after it would be possible to help them. Sandra discusses her feelings with Dr. Lockheart, who is sympathetic, but she explains that the only way society can know whether there needs to be more resources for these children is to do these kinds of studies.
Sandra agrees, but she still feels that she needs to do more to help. So although she knows that her work might be validated by someone else and that she is not supposed to ask the child she is testing whether he or she is homeless, she does so anyway. She decides to change a few of the right answers from the homeless group to wrong answers and a few of the wrong answers from the children from homes to right answers. She figures that her minor changes really won't make a difference in the overall study results, because she thinks that the homeless children probably will fare more poorly, educationally, than the children who come from homes. After another tester repeats the test with the same children, the results of the two are averaged.

When Dr. Lockheart analyzes the data from the first year of the study, she finds that homeless children in Manhattan and Queens actually do a little better on their educational tests than their counterparts from homes, and that homeless children in the Bronx, Staten Island, and Brooklyn don't do as well. Dr. Lockheart said she was surprised by the findings in Staten Island, because the amount of money spent per capita on providing educational services for homeless children is the same as in Manhattan and Queens, and more than the amount spent in the Bronx and Brooklyn. Other demographic factors and results from other studies also seem to suggest that the homeless children in Staten Island should have done better than the study found.

Although the results are preliminary, politicians have begun to discuss the results in the press and are asking that more money be spent in Staten Island, Brooklyn, and the Bronx. Sandra realizes that her actions probably contributed to the brouhaha and tells Dr. Lockheart what she did. They redo the testing of the Staten Island homeless children and find, in fact, that the Staten Island homeless children fare as well as the Manhattan and Queens homeless children. When the truth comes out, a furor erupts within the university, in the press, and at the federal funding agency.

Pamela is a geneticist at a major research university. Her department, Biology, is very large and includes a wide variety of sub-disciplines. It attracts a diverse array of graduate students, including many from outside the U.S.

Pamela has a PhD student, Hua, who comes to the program after finishing medical school in her native country. Hua plans to return after receiving her PhD and because she plans to practice genetic medicine, she is not too concerned at her poor ability to write in English. At Pamela’s urging, Hua signed up for an English as a Second Language (ESL) program on their campus to improve her communication skills.

Pamela was particularly concerned about Hua’s writing because Hua would have to take a preliminary examination prior to beginning her dissertation research. Their department’s preliminary exam has two parts: (1) write a proposal in NIH style format, and (2) write a review article on a topic outside of the student’s area of interest.

For her exam, Hua submitted a review paper on gene duplication as a cause of disease. Her review had a title which sounded familiar to Pamela. And the English was far better than Hua’s usual writing.

Pamela asked Hua if she had used any review articles in preparation of her own review article. Hua replied that she had, and so Pamela responded that Hua must cite those articles. Because of the very rapid development of a black market in review articles, Pamela knew that students found it easy to lift part or even whole reviews that have been published. To her relief, even if it was at the last minute before the deadline, Hua came back with some citations added to her review article. Pamela let Hua hand it out to the Committee, but the title of Hua’s paper still bothered her. She went to the library and did a search. She found an article with the same title, but the university did not subscribe to the journal so Pamela ordered it through interlibrary loan.

In the meantime, Hua barely passed her preliminary exam. A week later, Pamela got a copy of the journal article – 80% of Hua’s paper had been copied verbatim.

Pamela reported her finding to the Committee. A debate ensued as to whether to report this to the Dean of Students, or to make a departmental determination of how to respond to Hua’s plagiarism.

**How should the committee respond to Hua’s alleged plagiarism?**

Conflicts of Interest | Case Study 1
Age-Old Conflicts

Dr. Bobby Bill was an undergraduate in the lab of one of the first researchers to successfully demonstrate the existence of a “longevity gene” in c. elegans, and since then his passion has been the search for the expression of genes uniquely present in genetic variants of organisms that live significantly longer than the mean. He has turned the attention of his NIH-funded lab to drosophila as a model organism, and his research group at a very good Midwestern school in the US has successfully isolated a handful of genes that are highly expressed in fruit flies that live significantly longer than typical.

Dr. Bill was contacted by a large pharmaceutical company, also interested in longevity, to be a professional consultant. Initially, they were interested in establishing a drosophila colony that would include an aged population, and asked Dr. Bill’s help in the husbandry of the aged fruit flies. They invited Dr. Bill to their corporate research labs about three times a year, each time paying his travel and a $2,000 honorarium. However, the relationship has evolved and now Dr. Bill is serving a role more like a scientific collaborator than a consultant. He has now been asked to serve on their Scientific Advisory Board and as compensation will be getting some shares in the company stock currently worth about $12,000. Furthermore, they have “gifted” $180,000 to his lab to cover a postdoctoral fellow for three years to work on a few collaborative projects. Dr. Bill now spends about 15% of his effort on the collaboration and 60% of his effort on his NIH project. The remainder of his time is spent on teaching and committee service. The trips to the company have increased, and sometimes Dr. Bill has to get other faculty members to cover his lectures because of his travel schedule.

At a recent research meeting at the company, Dr. Bill and the Board could clearly see a potentially patentable product emerging from their joint line of inquiry. This product, which stimulates expression of the longevity genes, has the potential of providing a therapy to slow the onset of aging in humans, which is extremely exciting and could be quite lucrative. However, the Scientific Advisory Board would need to decide whether or not to publish their findings, and how to protect the intellectual property rights emerging from this research. The Board asks which parties need to be represented legally as the push to commercialize the product moves forward: Dr. Bill, his postdoctoral fellow, his institution? Dr. Bill feels that, while his research group contributed to the success of the project, direct experiments related to the product were not performed by any NIH-funded personnel. And, he has spent much effort at night and on weekends on the company’s project. Therefore, he feels that it is fair that his intellectual property (IP) interests be represented, but not necessarily the school’s interests. Dr. Bill feels as though, since he fulfilled his teaching, service, and research efforts at the school during this time period, all additional efforts he may have made were on his own behalf. Further, Dr. Bill feels that since the postdoctoral fellow was getting his training on this project, he has not really earned any additional benefit for his participation in the project.

How should Dr. Bill answer the Board’s questions about who should be listed on the potential patent?

Mary Smith is a department administrator at Flat Plains College working in the Chemistry Department for twenty years. During that time, she has worked closely with and has developed a highly professional and trusting relationship with Professor Thomas. Three years ago, the College signed a research agreement with ApeX Chemicals Inc. At the end of the third year, ApeX Chemicals Inc. decided not to continue the sponsored project agreement, and the agreement was terminated. Professor Thomas had other contacts at Zeta Inc., and the College was able to execute a sponsored project agreement to fund the research for another three years. Professor Thomas, being very busy, told Mary that Zeta Inc. also wanted him to sign a consulting agreement. Because he trusted her implicitly, he wanted Mary to negotiate the personal consulting agreement for him. When Mary looked at the agreement she found that the statement of work was identical to the statement of work contained in the Zeta’s sponsored project agreement with the College. While the sponsored project agreement signed by the College preserved intellectual property rights for the university, the consulting agreement would give all intellectual property rights to the Zeta Inc.

In addition, in the consulting agreement, Professor Thomas would agree to use his graduate students to perform the research at no cost to the company since this would be a "learning experience" for them and would give them exposure to valuable experience. Finally, Professor Thomas told Mary Smith that it would be very helpful to him if she would collect payments under the consulting contract and administer the funds through a private bank account he would establish. Mary felt uneasy but was not sure what was causing this gut reaction. She believed in doing the right thing, but she also felt that if she refused to help Professor Thomas, she was betraying their longstanding trust and professional relationship.
Conflicts of Interest  |  Case Study 3
It Slipped My Mind...

William is a Professor of Cardiology who has found evidence in his practice that, Dilox, an approved drug used to treat erectile dysfunction appears to be effective in lowering cholesterol. He decides to conduct a randomized controlled clinical trial to determine how effective Dilox (being used off-label) is for lowering cholesterol compared to currently used statins. William submits his research protocol to the IRB and receives approval; however, the study is subject to an annual IRB audit.

As the research gets underway, the drug-maker of Dilox, Restall, learns of William’s study and offers to provide him with financial support to complete the study more quickly. Restall says it will pay William $200 per participant recruited into the study; it will also pay for the Dilox, key personnel, and any study-related procedures required to evaluate the drug’s effectiveness. William agrees to accept the conditions proposed by the company, including sharing the results of the study with Restall prior to publishing.

Since the collaboration with Restall happened after the IRB approved the protocol, William makes a mental note to submit a disclosure to them and the institution soon. The trial progresses so rapidly, enrolling participants and easily meeting recruitment deadlines that combined with his busy clinical schedule, it slips his mind that he didn’t fill out the financial disclosure form regarding his relationship with Restall.

Before he knows it, the first annual audit takes place. The IRB chair has reviewed all documents related to the study. Thus far, it has a total of 120 participants: 60 in each study arm. There is no financial disclosure form. However, a research nurse coordinator who works for William at the university called the IRB office, worried that some participants may have been enrolled in studies who do not meet inclusion criteria as indicated by certain lab values and previous procedures. She refused to identify herself and hung up before sharing anything more. The IRB chair also notes that nearly a dozen participants were withdrawn from the study by the Principal Investigator in the last two months but no rationale was provided. In addition, he notices that some side effects identified as adverse events seem to meet the criteria for serious adverse events related to the research. In fact, there are only 10 serious adverse events listed while there are about 80 adverse events listed. Yet the IRB was only made aware of half (5) of the serious adverse events listed.

As the one conducting the annual audit, the IRB chair decides more information is needed to examine if the trial is being conducted ethically. William is asked to explain how the study staff is categorizing side effects as well as the reporting of adverse events.

What should the IRB Chair do?