Research Integrity | Case Study 1

After his medical residency, Miguel decides to go into academic research. Although medical school was exciting, and he enjoyed the challenge of applying what he had learned in clinical practice to his specialty area of pain disorders, what he really likes is the idea of working in science. He is especially attracted to the notion of interacting with other researchers in his field, sharing ideas, and benefiting from the intellectual interplay of the research world…brown bag seminars, conferences, internet exchanges, and a helpful mentor.

Miguel decides that he had better pursue his research interests while he is still young, single, full of new ideas, and brave enough to see if he can become a successful medical researcher. He rationalizes that he can always return to the more secure world of clinical medicine if research doesn’t work out, but that he probably cannot go the other direction—from many years as a clinician to becoming a researcher. His main interest, pain management, is a field that is really taking off, and he has a lot of ideas that he wants to pursue as a researcher.

Miguel receives some startup funds from Dr. Jones, his advisor and clinical liaison, and begins to delve deeply into the literature to formulate his own ideas around some novel uses of a drug that is currently on the market. He writes a complex investigator protocol which he thinks is very good. He asks Dr. Jones and another colleague, Dr. Harpin, to read and critique his full proposal.

A month later, Dr. Harpin, calls Miguel. “Hate to tell you, but Dr. Jones just submitted a research proposal identical to yours as part of a large federal grant that the institution is tendering,” he says. “I know it is yours because I edited it.” Miguel can’t believe his ears. His colleague says, “Unfortunately, I’m afraid the administration will pull your protocol and say it’s in the best interests of the organization to have someone of his stature submit the protocol, not you.”

Miguel is flabbergasted. He’d done all the hard work of devising the protocol, not Dr. Jones. When he tells his friend and junior researcher, Erika, she responds, “Oh, you stupid idiot. Why did you send the entire protocol to anyone?”

Miguel explains that he thought that academic medicine provided a place where he could and should share his ideas. Now he is angry with himself for losing control of his protocol.

At this point, Miguel feels so discouraged, powerless, and defeated that he wishes he were back in clinical practice. He wishes he were anywhere except where he is.

What should Miguel do?
**Research Integrity | Case Study 2**

Richard is a young Associate Professor of biochemistry at a major research university. He is unmarried, lives with his parents, and devotes all his time to establishing his scientific career and develop his lab into a highly successful scientific enterprise that is turning out world class publications. He has remained in close touch with John, his PhD advisor, and thinks of their relationship as a warm mutual friendship.

John tells Richard that one of his former PhD students, Allan, had fallen on hard times. He’d lost his first academic appointment and was now driving a cab in the city where Richard lives. John suggests that Richard hire the down-and-out guy who is 15 years his senior and practically homeless.

Richard hires Allen as a favor to his old mentor. He has Allan work with some research assistants in his lab. For the first six months, Allan’s work is poor, and he resents Richard’s supervision. Allan not only insists that his work is superior to that of others, he also makes unacceptable personal remarks to female graduate students.

Richard becomes totally fed up with Allan’s attitude and upset at himself for taking Allan in. Richard begins thinking about the steps he needs to take with Human Resources to fire Allen but feels somewhat immobilized at how he has let Allen manipulate him and get away with his poor performance.

Richard becomes more assertive, laying down the law and stating what he expects of Allan, specifically, some decent data on the experiments they’re running. In response, Allan produces a dataset that fits Richard’s hypotheses a little too perfectly. Richard questions him, and has a student gather some more data, which do not resemble Allan’s data at all. When Richard confronts him with this discrepancy, Allan leaves the lab in a huff.

The next morning he bristles with hostility as he hands a copy of a letter to Richard, saying “You thought you could cross me, didn’t you? I just sent this.”

Allan’s letter was to the Dean of Academic Affairs. In it he claimed that Richard had required him to falsify data and that much of the data Richard had published in the last two years was falsified.

In a way, Richard is not surprised, but in another he is incredulous that Allan would do such a thing. Richard is sure the Dean will not take the accusation seriously since Allan lacks standing. Nevertheless, Richard is troubled that this alleged complaint may come down to his word against Allen’s.

How should Richard respond?

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Mentor and Trainee Relationships | Case Study 1

Kara is a pre-doctoral student who works for a very demanding principal investigator (PI) in psychology. Dr. Srichaphan considers himself her mentor even though he seems to offer no constructive guidance.

She considers herself an expert problem solver. The trouble is, she can’t figure out how to solve her problems with her mentor. Not only is he exacting and demanding, but he also is exploitative and intolerant—finding fault with her for not being able to keep up with the rigors of academic and clinical studies even though he’s the one who’s overloading her with too much work.

The last straw is an invitation to be a “guest lecturer” in a section of her mentor’s undergraduate cognitive processes class. She can’t very well say no. It would only make her look inept. Still, it couldn’t come at a worse time. The research study that Kara is primary coordinator of has just been halted—it turns out one of the protocols needs many changes, and some of the changes will have to go through the IRB again. They are complex and require careful thought. All the protocol forms will need to be filled out again, the consent forms revised, and the study procedures redone. These changes will have to be made quickly since the study cannot resume until the IRB approves of the new modifications.

Meanwhile, the undergraduate section of the class Kara’s been given to lead is so large that it’s fast becoming like a full teaching load. The course is not going well because the syllabus that her mentor developed was not well thought out, and many students are coming to Kara’s office to complain. One of the complaints is that there is a cheating ring among some of the students. When she tells her mentor, Dr. Srichaphan blames it on her teaching. She is so taken aback that all she can do is splutter that it’s not her fault—the cheating ring extends to other study sections as well and may even have begun there. Ignoring her protests, he informs her that she needs to provide assistance at a clinical rotation site.

Kara can’t believe her ears. She feels like she will crack under the strain if one more thing is added to her load of duties. Just the thought of arguing with her mentor makes her queasy, but she does her best to remind him that she has her own coursework as a doctoral student and has two term papers due in the next three weeks. She begs him to assign someone else to the clinical rotation. He frowns. “It’s gotten to the point where you cannot handle your research and teaching responsibilities, evidently,” he goads her. Kara, who prides herself on her “can do” style, finds she simply cannot do all that is required of her. She’s on the verge of retching from nerves. Her mentor is not impressed. He shakes his head and tells her that science is not for the faint of heart.

What should Kara do?

Multidisciplinary research is a form of collaborative research that involves researchers working across disciplines, within an institution or in different institutions. Interactions among collaborators require various modes of communication to ensure that expectations and goals are met.

-Nicholas H Steneck, PhD

Dr. Ho’s lab is like a little United Nations. The scientists working there are from all over the world where everyone speaks English but mostly as a second language. They bring multiple cultures and perspectives, and, while interesting, the results of all of this cultural diversity are not always easy for Dr. Ho’s lab manager, Nick.

Nick’s current challenge is a scientist named Mohamed who works in Dr. Ho’s lab as a research technician. Mohamed is eager to move up in the scientific world, or at least in Dr. Ho’s lab, but he feels he is doing all the work for Dr. Ho and getting no credit. He is burning with resentment and is already working on moving to a better research position somewhere else.

Dr. Ho has no interest in patting people on the back or rewarding them for work they should be doing anyway. He makes it clear that he is in charge and that those below work for him, not with him. When Dr. Ho describes the experiments he wants done, he gives a clear description of what the results are likely to be and why he has advanced that hypothesis. He doesn’t expect anything less than success, and Mohamed isn’t sure how to please him.

Nick, the lab manager, tells Mohamed that it’s in his best interests to do whatever Dr. Ho asks. Mohamed interprets this to mean something else entirely. It seems to him that, in order to prove his boss’s intuition correct, he must make the data conform to what he thinks Dr. Ho wants to appear.

When Nick and Dr. Ho realize that Mohammed is reporting questionable positive results, they condemn Mohamed for falsifying data. Mohamed is outraged at their insinuation that he is committing fraud, and he soon leaves the organization in a huff for his new job, muttering a few threats to anyone who will listen.

At first, Nick feels justice has been done, so he simply destroys the paperwork that partially documented what had happened. But then Nick gets a call from someone at another university wanting a reference for Mohamed. Nick is asked if he would employ Mohamed again. Nick is unsure what to say.

How should Nick respond?
In the absence of human trials it's impossible to know about the safety of drugs in humans that were found to be safe in other animals. Phase I clinical trials involve the dosing of new drugs to tolerance in control subjects and doing pharmacokinetics to determine blood levels, binding, and disposal rates of the drug.

Years ago, a large drug company advertised for volunteers for Phase I clinical trials of new agents. They noticed as the weather turned cold, middle-aged persons who were dirty and poorly dressed volunteered, and that the number of volunteers increased yearly. The volunteers were housed in a metabolic unit for 6 months and were given a number of agents in sequence during the winter. Each trial was approved by an "in house" IRB. When it became known that many of the volunteers were homeless alcoholics, screening tests were done to ensure that chemistries were normal or near normal. Each volunteer signed a consent indicating that their compensation would be provided to them at the end of the period of being a control and that they would refrain from alcohol for the duration of their stay.

The company believed sincerely that it was helping these individuals. The process was revealed in the media after some years.

Aortic tissue samples from patients undergoing cardiac transplantation have been collected and stored for many years. Permission for the sampling was granted under the blanket research approval in the surgical consent form. Previously, investigations were permitted under waiver of IRB review because the samples were used completely without identifiers. The samples (n=2000) were dated and stored untouched in liquid nitrogen.

The medical team gave permission to Dr. Gomez, a geneticist, to sample all 2000 specimens to study the prevalence of a number of gene polymorphisms proposed to relate to development of dilational cardiomyopathy. The genetic findings were to be related to a specific patient by identifying the tissue donor by correlating the sample date to the operative schedule. Dr. Gomez claims that no IRB approval or new consent forms were required for this study because the study did not utilize individuals, only stored tissue.