



Erica Aitken

## Unintentional fraud

### An oxymoron?

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I almost engaged in fraudulent medical research. As a third-year pulmonary fellow, I conceived of a study while taking a research methods course. The design was flawless, accounting for all possible sources of bias. The experiment was randomized, controlled, and double-blind by natural design. Randomized controlled trials, especially blinded ones, are revered in the ivory tower of academia as the highest level of experimentation. Results are trusted and considered least subject to bias and mistakes.



Data dripping in like honey  
from a cold fridge

Using statistical tables and newly-learned epidemiologic concepts, I realized that my sample size was going to be in the thousands. I needed help—a lot of it. I recruited twenty undergraduate students from various colleges in the area, whose primary responsibility would be subject recruitment. Soon, I had an army of eager pre-meds, willing to do my bidding. This came with a lot of unexpected heartache. Not only did I have to collect and interpret my data, I had to manage and contain a group of busy, pre-medical, pre-occupied, and over-committed kids. As the study gained momentum, I expended enormous amounts of energy motivating, organizing, and inspiring my research assistants to continue to collect reams of data, usually from uninterested, unwilling subjects. Qualified subjects were few and far between. It was grueling work. The data dripped in like honey from a cold fridge.

Although I praised each of the research assistants when they brought in their daily kill, they quickly became discouraged and unenthusiastic.

Even with our focus on team effort, it was hard not to notice who the “stars” were. My most productive research assistant was a pre-med student from a local high-tier university, who was hoping to be accepted to the medical school where I worked. He seemed always to be willing, even eager, to take the least desirable and largest number of shifts, and his data collection rate was significantly higher than all of the other research assistants put together. Over spring break, he enlisted his brother, home from an East Coast prep school, for data collection. The brother’s subject response rate was similarly impressive.

One night, about nine months into data collection, I was making follow-up calls for some of the research assistants who were on spring break. I went through a pile of The Star’s questionnaires and noticed some irregularities. Most telephone numbers were not in working order, and the occasional subject I did reach had no idea who I was and why I was calling. Shaking, with my husband at my side, I began a random audit of The Star’s subjects: Thirty out of thirty of his latest batch of questionnaires had been fabricated. They were fraudulent. This type of situation had not been covered in my textbooks.

I was devastated, enraged, panicked. My study had been violated, to what degree I did not know. Two years of painstaking work, my first attempt as a researcher, and nineteen young people’s commitments potentially wasted. I called the culprit, who initially denied my accusations, but then blurted out his confession with tears and threats of suicide. I remained on the phone with him for several hours until he finally agreed to go to the student health center. After hanging up with him, I was left with my binders of three thousand subject questionnaires. My husband and I stayed up much of the night trying to chart next steps. I alternated between deciding to abandon

any attempts for a career in academic medicine, to blaming the pre-med student, to blaming myself for my naivete and inexperience.



One bad apple did not ruin  
the entire basket

Over the next six months, I completed large random audits of all of the other researchers' work, telephoning hundreds of subjects to ensure that they had truly participated. Luckily, there had only been one bad apple. I discarded all of The Star's "subjects," and filed a complaint with his university's ethics committee. I called his brother's school on the East Coast and alerted them to his behavior. We continued data collection and ended up with an exciting study that was later published in *JAMA*.

Who's to blame? The student for his unethical, amoral behavior? Me for my naivete and inexperience? My training program for focusing on study design and methodology before data management and ethics? Society for over-trusting the word of science and physicians? Medical journals for not performing their own quality assurance and accepting manuscripts on the honor system?

This student clearly had an underdeveloped ethical foundation, which allowed him to cross the line of professionalism. His goals were purely opportunistic and he put his own advancement above the goal of discovering truth through science. This type of person can be found in all walks of life, taking advantage of weaknesses in systems for self-advancement. However, we need to make sure that our systems are designed to prevent this type of practice. We need to discourage and punish this type of behavior in all academic institutions, from elementary school through masters programs. If The Star and his brother had known that they could be prevented from graduating or that their records would be forever blighted by this behavior, they might have been deterred.

They both graduated with honors several months after these events, the ethics committees of both schools claiming that these projects were not under their purview for oversight.

Training programs for new investigators must teach data management and quality assurance techniques alongside strategies for sample size and power calculations. If I had planned and publicized weekly random audits into the protocol, or had required subject signatures at the bottom of the questionnaires, this disaster might have been avoided. If I had required that all data collection sessions be attended by at least two researchers, it might have been nipped

in the bud. There are countless other safeguards I would have taken if I'd been prepared for the possibility of fraud.



The unprofessional Star gets an  
MBA

The story does have a happy ending. The study was published. The Star, although allowed to graduate from college, was apparently dissuaded from pursuing his dream of being a cardiac surgeon. He got an MBA instead. I've continued a career in academic medicine and have learned firsthand how to provide real quality control for my data. I have taken a personal interest in ethical conductance of research, and I talk to residents and medical students about my experience

Fraudulent research, although hopefully rare, weakens the institution as a whole. We can and should hold individual researchers accountable for their lack of morals, but we bear a responsibility as an academic community to make sure that systems are in place to discourage fraud at all levels. Although I obtained an MPH and took a series of advanced courses on research design and epidemiology, I received no formal training regarding data management and ethics in research. Managing a lab or research assistants complicates matters, because you have other people's motivations, organization, and ethics to account for. External review and audits of data should be built into every research protocol, for everyone's protection, but mostly for maintaining the integrity of our research compendium.

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