

Workshop Cases

Authorship Case 1

Jay Akash, a new assistant professor, is getting ready to submit his first paper since joining the faculty. He reviews one of the figures for his paper, which is an image of an ethidium bromide-stained agarose gel. The gel contains the products of PCR-amplified whole-cell DNA. The photograph displays the predicted 3-kb DNA fragment. Jay comments that a second, minor signal was also evident on the original gel. Based on its size, Jay believes that this second fragment represents a very exciting discovery, but it needs considerable additional work. This second fragment cannot be seen in the image. Jay discloses that this is because he has deliberately adjusted the contrast of the image using a computer editing program to obscure the second fragment. He says he did this because he is worried that competing groups in larger, more established labs will recognize the potential of the second fragment and will "scoop" him. He has prepared a figure legend that says: "a second, minor signal of unexplained origin was present in this experiment but is not visible in the photograph." But the figure legend does not indicate the size of the unexplained fragment. Thus, he argues he will be telling the truth while protecting himself from his competition. Are Jay's actions appropriate? Is he (i) simply playing fairly in the hotly competitive arena of biomedical research, (ii) falling victim to self-deception, or (iii) perpetrating scientific fraud?

Authorship Case 2

A computer scientist and a radiologist, both faculty at an research university, have enjoyed a productive collaboration involving the development of a software program to evaluate abdominal tumors that have been visualized using magnetic resonance imaging (MRI). The computer scientist authored all of the computer source code and tested it using archived MRI files. The radiologist designed and carried out the clinical trial, and also provided guidance in this testing phase, allowing the computer scientist to refine and to ultimately perfect the program. Although both collaborators are elated by the fruits of their labors, they have become perplexed over how to publish their results. They recognize that the prime thrust of the manuscript will be the design and creation of the software, and this is not likely to be of interest to clinicians and physician-scientists. Such individuals will be mainly concerned with the application of the program and the clinical results. But these collaborators are well aware of the publication guidelines of journals in their disciplines: most strictly prohibit the publication of the same material in two different journals. The collaborators agree there is no single journal that gives them the necessary coverage to both the computing scientist and the clinician researcher. They also believe that splitting the data into two papers aimed at two different audiences will diminish the impact and possibly the utility of their work. They come to you for advice. What do you tell them?

Authorship Case 3

Dr. Mary Travers, a well-funded scientist, leaves Medium University to take a position at Large Medical Center University. Dr. Levi Stubbs, the department chair assigns another faculty member, Dr. Carl Wilson, to Travers' former office and lab. A few months later Wilson comes across some of Dr. Travers' files in a cabinet drawer. In looking through these materials, he discovers what looks to be a completed draft of a manuscript written by Dr. Travers. What attracts Dr. Wilson's attention is that the title page lists Travers' address as Large Medical Center University. No mention of or acknowledgement of Medium University is noted in the manuscript. Dr. Wilson is puzzled by this but does not take any action. Several months later, a paper authored by Dr. Travers appears in the *Journal of Biological Chemistry*. Dr. Wilson notes the published paper is virtually identical to the manuscript he discovered in Travers' former office. He has a good appreciation of the science involved, and believes that she could not have accomplished the work reported in the few months that she has been at Large Medical Center University. What's more, the acknowledgements in the printed-paper thank a technician who Dr. Travers supervised at Medium University. Dr. Wilson believes that Dr. Travers is attempting to demonstrate her research prowess by convincing her supervisors at Large Medical Center University that her research program is up and running at full throttle. Dr. Wilson brings departmental chair Stubbs the manuscript and a copy of the published paper. He suggests Dr. Travers has committed scientific misconduct by deliberately falsifying information in the manuscript. Commenting, "so Levi, the ball's in your court" Wilson gracefully exits the chair's office. Stubbs comes to you, the department's resident expert in research ethics, and asks what he should do. What's your advice for him?

Conflict of Interest Case 1

Boris Pickett is a bioengineering graduate student at Upscale University. Under the supervision of his predoctoral mentor, Dr. Norman Bates, Boris has developed a novel feedback control loop and software implementation for image-guided radiotherapy. The study has been funded in part by the National Cancer Institute. Bates and Pickett have co-authored 2 published papers on the subject. They are now preparing to launch a clinical trial to evaluate their system. Unbeknownst to Dr. Bates, Boris' father, a physicist, is an inventor on the patent that covers the feedback algorithm in the most widely used image-guided frameless stereotactic radiosurgery delivery system. The patent is held by a small company and Boris' father earns about \$70,000 a year in royalties. In addition, Boris' father was given founder's stock in the company and these equity shares are now worth about 4 million dollars. These shares were placed in a trust fund for Boris several years ago, a fact that Boris is aware of. Boris is agonizing over whether to tell Dr. Bates about these issues. Are there any conflict of interest issues looming if Boris engages in the clinical testing of the new system? If so, discuss what are they and how they can be ethically and legally managed.

Conflict of Interest Case 2

Dr. John Quinn is the chief of internal medicine at a large community hospital. He frequently participates as a co-investigator in clinical research with faculty at a nearby academic medical center. Presently he is involved in two clinical trials, both of which are registered on *clinicaltrials.gov*. Recently, he was been contacted by Neils Smith, the head of a financial planning group in Boston. Smith has invited Dr. Quinn to participate in a teleconference with 4 financial analysts in the Boston area. As part of this 1 hour teleconference, Dr. Quinn would be asked to give a brief professional overview of the two registered trials. He would then answer any questions the analysts might have. Smith stresses that Dr. Quinn is not being asked to disclose anything confidential about the study or its results in his remarks. And he can decline to answer questions that he feels are inappropriate or might compromise the trial. Dr. Quinn will be paid \$1,500 for participating in the teleconference. Before giving his decision to Mr. Smith, Dr. Quinn comes to you for advice. What do you tell him? Why?

Conflict of Interest Case 3

Dr. Wilkins has a modest research program supported by a grant from a local foundation. Dr. Wilkins brings a personal check for \$3,000 into the office of Mr. Cole, the departmental administrator, and says that it is a gift that may be used by the department at the discretion of the chair. When Mr. Cole consults with the chair, Dr. Vaughn, he learns that Dr. Vaughn and Dr. Wilkins have already discussed this arrangement. Dr. Vaughn says she has agreed to let Dr. Wilkins spend this money, as it will help him strengthen his research program to the point where he will be able to compete successfully for federal grants. Over the course of the next several months, Dr. Wilkins uses some of the money to purchase a new computer and printer, which he installs in his home. He uses the remainder of the money to attend a meeting in his research field. At the end of the year Dr. Wilkins donates \$5,000 to the department. Over the next several months he uses this money to attend two other meetings and to pay for several subscriptions to scientific journals and an electronic database. Comment on any conflict-of-interest considerations of this scenario. The issue is brought to your for resolution. Who is affected by this action and how? What are the potential benefits or negative consequences of this transaction?

Record Keeping Case 1

Donna Adkins has collected blood samples from 100 human patient volunteers to test antibody levels against two different viruses. Relevant clinical histories of these patients, corresponding to the individual samples, are noted in her data book. She has carefully tagged the tubes with self-adhesive labels and stored them in racks of 20 in the freezer. She assays the samples in three of the five racks and obtains interesting results. She records her results meticulously in her lab data book, cross-referencing the antibody values to the clinical patient data. Donna asks you to witness these data book pages because the results have implications for the development of an important diagnostic test. You sign her data book pages as requested. When she opens the freezer to retrieve the sera in the fourth rack, she makes a disturbing discovery. All the labels have fallen off the

tubes in racks 1 and 2. (She later finds out she used the wrong kind of self-sticking labels on these tubes, resulting in their failure to adhere at –C.) Donna proceeds to number all the tubes in racks 1 and 2 by order of their rack location. Then she repeats the antibody assays on these samples. She arranges her resulting data into a summary table that she compares with her original assays of these samples. She is relieved that the data compare favorably, and she re-labels the tubes consistent with their original designations. She comes to you for advice on her actions and asks how, if at all, she should record these events in her data book. What do you tell her?

Record Keeping Case 2

Dr. Brown's research group recently published an important paper in a leading physiology journal. Four months after the publication of the manuscript, Dr. Brown is contacted by a European colleague who has been unable to reproduce the results presented in two figures of the paper. Dr. Brown faxes copies of the pertinent laboratory protocols and recipes to his colleague and thinks no more of the discrepancy. Two months later, a graduate student in a competitor's laboratory contacts Dr. Brown and reports that he too was unable to reproduce the results. After this second call, Dr. Brown meets with Adam Green, the postdoctoral fellow who did the experiments in question. He asks Adam to bring his data book to the meeting so they can review the results together. Once in Dr. Brown's office, Adam confesses that he has been remiss in keeping his data book. He says that all of his electrophysiology experiments were recorded on VHS tapes with a live microphone into which he reported the experimental proceedings and observations. Adam transcribed these observations into his data book. However, there was a period of several days when his microphone was not working properly. Although Adam replaced the microphone as soon as he found that it was not working, he relied on his memory to transcribe the results of those particular experiments. After completing the figures for the manuscript, Adam was pleased to find that his data supported Dr. Brown's hypothesis. Dr. Brown comes to you for advice on how to handle this situation. What do you suggest?

Record Keeping Case 3

Al Dunn, a fifth-year PhD student, was in the process of re-running some analyses for a revised manuscript submission. This publication is the remaining hurdle between Al and his dissertation defense. Al's research has involved analysis of survey items. In preparing his data for analysis, he has been careful to document all of the variables and their codes (i.e., 1=strongly disagree, 2=somewhat disagree, 3=somewhat agree, 4=agree, 5=strongly agree) in a codebook. Now as he looks at the raw data prior to analysis, he sees one variable's responses include several "0"s. This is unexpected because the range of responses should have been from 1 to 5. He now realizes that the "0"s actually represent missing data. Instead of being considered "missing", his initial analysis had included the "0"s as real values. This erroneous analysis was used for the original submission. In a slight panic, Al deletes all of the "0"s from the database, and re-runs the analysis. He breathes a sigh of relief because his results are still significant, though somewhat different ($p=0.048$ compared to a previously reported $p=0.011$). Al is

concerned that if he makes public his error, this could cast doubt on the integrity of his analyses; this could delay or even preclude publication. He decides that, since the results are still significant, he will erase all evidence of the previous “0”s and the earlier analyses. He also plans simply to report “ $p < 0.05$ ”. As the senior postdoctoral in the lab Al runs his plan by you and asks your advice. What do you tell him?