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?

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?

Authorship & Publication | Case Study 1

Ana holds a PhD from a prestigious American state university and specializes in the study of pain, its pathways and pain reduction interventions. Though trained in Taiwan, Ana thinks in English, which is her third language after the Khalkha dialect of Mongol kele and Mandarin. However, she has some difficulty writing scientific papers in appropriate and nuanced English; hence, she typically asks colleagues to review and help edit her writing.

Ana has taken a postdoctoral fellowship at a famous institution with a strong publish or perish culture. Researchers flaunt their publication record and look down on anyone who does not have as many published papers as they do. Ana enjoys giving people ideas and supporting them. In return, she sometimes asks for help with her writing and is happy to acknowledge their assistance in her papers. But when colleagues return her manuscripts with their names included in the list of authors, Ana is stunned. It seems they feel entitled to do this.

Although she feels that others are taking advantage of her, Ana refuses to change. She gains satisfaction by thinking that she is helping to improve science. She says her goal is to be a good scientist, not to fight over who gets to be an author of her work. She feels blessed with an opportunity to work on some of the most intellectually exciting projects and places in the world. She would never do anything to jeopardize this opportunity.

Yet Ana is upset when her lab boss not only puts his name on her work, but also takes a proposal she has prepared for funding by NIH and sends it off under his name—without even discussing that with her. She mentions it to him, and he just looks at her as though she were crazy. However, some administrators within the research institution who have seen the way people take her intellectual property are sufficiently disgusted and urge Ana to think about ways to stop people from stealing her work. Unfortunately, they have no power to intervene directly.

Ana is unsure what recourse she has. She values the opportunity to share ideas with others and get their responses, and is unwilling to do anything that will cut off that rich intellectual interaction. The theft of her ideas seems a minor price to pay for her scholarly environment.

What should Ana do?

Jeff is a professor who teaches advanced statistics courses and also does some outside consulting. When he makes important intellectual contributions in the projects on which he consults, he typically is listed as a co-author and always requests that his specific role be described. He is often brought in at various stages of research projects. Sometimes project leaders do it right by bringing him in at the beginning so that he can help them plan the design, procedures, data analysis, and presentation and perhaps help write the proposal. In other cases, project leaders wait until they are ready to analyze their data and then realize that they need help since they lack statistics expertise. Sometimes these projects are a bit of a mess, but most of the time Jeff can rescue them.

One day, Jeff’s institution was contacted by a journal editor to report that a reader is challenging the legitimacy of the data in a published paper and the journal is investigating the reader’s charges of potential research misconduct. Jeff had a hand in designing conducting the data analysis in the paper submitted for publication. However, the editor had deleted the part the authors’ detailed description of the roles authors played in producing the paper because the journal does not routinely include such material.

As a result, all three authors were investigated for misconduct. The first author, who was the Principal Investigator, had obtained the funding and designed the study. The second author, a post doc, had gathered the data and done the research. The third author, Jeff, had been brought in primarily to conduct the statistical analysis, which was difficult at times given flaws in their design. His job seemed pretty straightforward although the Principal Investigator and the post doc seemed edgy and defensive about their statistical naiveté.

What should Jeff do?

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?

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?

Plagiarism: the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit -45 CFR 93, 2005