

Analyzing Everyday Compliance Issues: Case Studies

Case Study #1

Dr. Jack Smith (PI) owns IsozyPharma LLC. IsozyPharma is co-owned by Dr. Smith and the EF Research Foundation, which is a technology transfer agency for AB University. Dr. Smith asked his staff, a postdoctoral fellow and two graduate students to work on projects to test and improve two enzymes' stabilities from IsozyPharma. Dr. Smith's lab currently has two NIH R01 projects, and there is a Small Business Innovation Research (SBIR) grant between the lab and the company. Two graduate students received compensation from Isozypharma for two summers. Dr. Smith submitted his outside activity report. He disclosed his ownership of Isozypharma, but didn't mention the activities related to IsozyPharma in his lab. Dr. Smith promised the postdoc a job at IsozyPharma. The postdoc delayed his publication, which affected the thesis defense for two graduate students. The two students discussed the situation with Dr. Smith and the postdoc without any resolution. The students informed and explained the situation to the AB University Graduate School.

Case Study #2

Dr. Valentine is an established and well-respected Principal Investigator at XYZ University, a top tier research institution. She's had ongoing projects funded by multiple Federal sponsors, including NIH and CDC, for several years. Her previous results suggest potential in using techniques and materials described in a recent issue of A Scholarly Journal. She has an approved IACUC protocol that expires in two months for which she has submitted renewal paperwork. Her biosafety approval expires next month. Dr. Valentine has submitted renewal paperwork for it, which is in the process of being reviewed. She's certain that the new materials and uses are justified, and that she will receive approvals for both revised protocols without needing further review. She knows that a colleague of hers in another department was recently approved for similar materials and uses.

Ever a busy woman, Dr. Valentine has a large lab with several postdocs and graduate students. She is in the process of preparing a renewal proposal for one of her NIH awards, but has yet to achieve certain results that she would like to include in the proposal. Because of the current budget situation, she's anxious to make her renewal proposal as competitive as possible.

Howard, a postdoc in Dr. Valentine's lab, is a good friend of Sharon, the departmental administrator who covers Dr. Valentine's department and one other department. One morning over coffee, Howard mentions to Sharon that Dr. Valentine called him and Jayne, a grad student, into her office the previous day. The PI has asked Howard and Jayne to perform some experiments so that the data and results can go into her renewal proposal. Dr. Valentine has told Jayne that the renewal award will provide funding to allow her to continue her studies without interruption. Dr. Valentine has reminded Howard that the renewal will enable her to hire his partner, Jason, who is currently finishing his Ph.D. at a university in a neighboring state. Howard is aware that some of the experiments that Dr. Valentine is asking them to perform aren't really covered by the existing protocol approvals. Dr. Valentine assures them that the approvals will be easily obtained.

Case Study #3

Dr. Amy Smith (PI) is running a successful project with a NSF grant and a USDA grant, both of which are up for competitive renewal. The Federal budget situation has created a competitive proposal environment. Under this situation and pressure, Dr. Smith has pushed hard on her postdoctoral fellow and graduate student for data and results. In order to promote her research results and exchange ideas with other scientists in her field, Dr. Smith has spent significant time attending conferences and on travel and, consequently, has reduced her mentoring time with the postdoc and the graduate student. The postdoc artificially increased the numbers of experiments for the research project in order to save time and provide results to Dr. Smith when needed. The results were submitted for publication. Reviewers identified the fabricated results and reported them to University.