Case #1 - Whistleblowers

Dr. Florence Chase was a prominent geneticist working in a well-funded Midwestern University. When one of her students, Betsy Turner, was given a few pages of one of Dr. Chase's grant applications to help her get started on a new research project, she recognized data from a previous lab publication that was identified as unpublished in the proposal. She mentioned this worry to another more advanced student in the lab, Tom Kennedy, who was already working in the area described by the grant application. Looking at the proposal, Tom noticed that there was one experiment describing his work that had never actually been done!

The students then sought advice from other scientists from outside the department who counseled them to bring their concerns to Dr. Chase and document their actions. Tom Kennedy brought his concerns to Dr. Chase who denied wrongdoing and said the data included were probably just "placeholders" she had forgotten to remove before submission. She mentioned that she would take corrective actions to inform the funding agency.

Questions

1. Did the students act appropriately in confronting Dr. Chase about the issue?

    A. What were Betsy Turner's options before going to Tom Kennedy for advice?

    B. What other options did the students have other than confronting Dr. Chase?

2. Given Dr. Chase's claim that an innocent error was made, what are the student's responsibilities to the funding agencies involved?

    A. Should the students follow-up on Dr. Chase's assurance that she would contact the funding agency? Who might they consult to make sure that she corrects the situation?

    B. What other actions might the students pursue if they are unsatisfied with Dr. Chase's response?

What are the responsibilities of the Department to protect the interests of the students in this case?

If the lab is closed because of the incident, students risk losing years of graduate work. Should a graduate program alter its criteria for granting a Ph.D. if the student's graduate advisor is proven to be guilty of misconduct?

Resources

Science Article:
http://www.sciencemag.org/content/313/5791/1222.full

ORI ruling:
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-130.html

Related content:

http://www.uwalumni.com/home/alumniandfriends/onwisconsin/owspring2008/worms.aspx

http://scienceblogs.com/ethicsandscience/2007/06/06/whistleblowing-the-communitys/

http://www.biotechniques.com/news/biotechniquesNews/biotechniques-302891.html

C.K. Gunsalus, “How to Blow the Whistle and Still Have a Career Afterwards,” *Science and Engineering Ethics*, Vol. 4 (1998), 51-64.

Case #2 - CLUES: Research Misconduct or Sloppy Science?

Professor Plum has taken on a new graduate student, Rose Scarlett, as part of an overseas exchange program. Her graduate program mandates attending their extensive training in research ethics and record keeping. She integrates easily into the lab culture, making friends, but seems very secretive, almost protective of her data. Her project is part of a collaboration with another exchange student, Grey Pu Pon, and a Research Fellow, Dr. Byrdie Peacock, who oversees the project for Professor Plum.

As the work progresses, Dr. Peacock believes the three should meet regularly to go through their data. At first, Rose brings in her results, usually in the form of finished tables or graphs, but gradually finds excuses to miss the meetings. Rose also never discusses her work with Grey. When Byrdie goes to Rose directly to go over the original data for one of her figures, Rose cannot produce the data. She claims that because the figure was finished, she deleted the original files from the lab computer associated with the image processer. Byrdie cannot find it in Rose's file on the lab's back-up server. When pressed to look at her notebook, Rose sends Byrdie the data she was unable to produce, claiming she had it on a memory stick but had forgotten about it.

Several months later, Dr. Peacock believes they have enough information and a good story to begin assembling figures and data for a manuscript. By now, Byrdie has seen several versions of a figure with Western blots that Rose had been working on. They appear similar, but have subtle differences. Rose provides yet another figure of the blots, again different from the previous versions. Byrdie insists that Rose produce her lab notebook.

Byrdie finds that experiments and data in most cases are not dated and that data sheet printouts for other assays are minimally labeled or have nothing at all by way of documentation. They are just stuffed in randomly. Of greater concern is the fact that the lanes of the original gel images for the Westerns have no labels for treatment conditions. When pressed for an explanation, Rose claims that she felt rushed to produce a final product. The last figure has been labeled directly and represents the primary data. She apologizes but maintains that the final figure she provided is the correct representation of the experiment.

Research Misconduct or Sloppy Science?

- Are there problems regarding data management, and if so, what are they?
- Who is at fault? Was there a role for Professor Plum?
- What is your opinion of Rose's explanation?
    - Is pressure-internal or in relation to a job application- ever a legitimate excuse for being sloppy?
    - What is an appropriate response to pressure?
    - Would your opinion change if Rose had had previous training in ethics and record keeping?
- How could this situation have been prevented?
- Can you show all of the primary data for each experiment you performed a year ago?
- Can your experiments be reproduced by someone else from your lab notebook?

Review the elements of a good record keeping and contents for a lab notebook
http://sourcebook.od.nih.gov/ethic-conduct/RECORDKEEPING.pdf

Case #3 - Data Management in Clinical Studies

Scene 1: Dr. Abadayo, a post-doctoral fellow in Dr. Hidalgo's section, is reviewing clinical data for the Results section of a manuscript the two are preparing. She notes that data for 60 of the 180 research participants in the study data base are not fully consistent with the primary source data in the participants' electronic medical records. Data for the remaining 120 participants are accurate. Dr. Abadayo is concerned that these discrepancies may jeopardize publication of the manuscript.

What should she do next?

Check the data again?

Review the data collection and data entry procedures with clinical staff?

Bring her concerns to Dr. Hidalgo, the principal investigator of the clinical study?

Scene 2: Dr. Abadayo presents her concerns to Dr. Hidalgo. He downplays the significance, given that two-thirds of the data are clearly correct. He suggests that Dr. Abadayo review the data collection and data entry procedures with clinical staff to identify possible sources of error.

Does the proportion of questionable data influence the seriousness of the matter and the response?

Who has responsibility for investigating this situation?

Scene 3: Dr. Abadayo finds that clinical staff used different procedures for abstracting study data from the electronic medical records and for entering it into the study data base for statistical analysis. She believes that this variability accounts for the inconsistencies that she discovered.

Do the procedures of this study reflect good clinical practice?

How can one distinguish sloppy clinical practice from research misconduct in this type of situation?

Does this distinction matter?

What steps could the investigators have taken before the start of the study to avoid this problem?

Scene 4: Dr. Hidalgo is pressing Dr. Abadayo to complete the Results section of the manuscript so that it can be submitted for publication. Dr. Abadayo is hesitant because the data discrepancies she observed make her question the validity of her initial statistical analyses.

What steps can Dr. Abadayo take to ensure the validity of the findings?

If Dr. Abadayo cannot fully resolve her doubts about the data from the 60 participants, what should she do?

Re-analyze using only data from the 120 participants whose data she is confident about?

Use all the data, reconstructing the questionable data as best she can?

Take another approach?

What role might the study Sponsor (if any) or approving IRB play in this situation?

Source: Adapted from a case in Shamoo, A., & Resnik, D. (2003). *Responsible Conduct of Research*. New York: Oxford University Press.

Case #4 – Nepotism in the Training and Research Setting

Dr. Julie Brand is a Section Chief in NCI's Intramural Research Program. Her daughter, Sally, is just finishing college and very interested in a medical career, but wants a year off to help her decide her next steps. Dr. Brand suggests that she apply for a post-bacc IRTA position at the NIH in an area of research that interests her. (Dr. Brand has post-bacc IRTA students in her own lab, and views the position as an important stepping-stone for talented students to become successful scientists.) Sally submits her application, and after two weeks mentions to her mother that the reference letters haven't arrived. In order to help Sally, Dr. Brand begins checking on the status of her application at the OITE Online Application System website, and when it is complete, she suggests a few good laboratories that Sally might focus on.

Questions

1. Is it proper for Dr. Brand as an NIH scientist to, a) encourage her daughter to pursue a biomedical career? b) review her daughter's online OITE IRTA application? (What if Brand was an A.O.?)

Sally emails several NIH P.I.s and indicates her interest in their work. However, despite initial positive replies, no offers are forthcoming. The situation leaves Sally defensive and Dr. Brand puzzled based on Sally's strong academic record and honors in science. Being a concerned parent and a scientist who knows what makes an application stand out, Brand decides to review Sally's online application and notices that one of the recommendation letters is a carelessly written draft version.

Questions

2. Why is it important that OITE applications (including reference letters) be kept confidential?

3. If Dr. Brand is contacted by an NIH colleague who is considering Sally for a post-bacc IRTA position, may Brand offer an opinion about Sally's strengths and weaknesses? May she mention anything about Sally's recommendation letters?

Over lunch one day, Dr. Brand bemoans Sally's situation to an NIH colleague she is close to, suggesting that the poor recommendation letter was an innocent mistake that could easily be corrected. Dr. Brand's friend points out that the NIH post-bacc IRTA website clearly states that access for the purpose of inspecting applications of relatives or friends is strictly forbidden. Dr. Brand is surprised to hear this, re-visits the OITE Online Application System website (appended below), and verifies that such use is indeed strictly prohibited. She resolves never to violate the rule again. In the end, however, Sally gets no offers, after which Dr. Brand approaches her NIH colleague and asks him if he would take her on in his lab.

Questions

4. Has Dr. Brand engaged in nepotism? If so, when?

5. Who is harmed by violations of nepotism policies in place on the NIH campus?

6. If you are approached by a close friend or relative seeking employment for themselves or their own children at the NIH, how should you respond?

The NIH has formulated specific guidelines for the conduct of employees in supervisory or administrative positions with respect to the employment of relatives and friends. It can be found at http://oma.od.nih.gov/manualchapters/person/2300-310-1/2300-310-1.pdf.

NIH OITE Online Application System - Terms of Use Agreement

Important: Clicking the "I accept" button below constitutes your acknowledgment that you have read and agree to follow the Terms of Use.

Warning Notice

This is a U.S. Government computer system, which may be accessed and used only for authorized Government business by authorized personnel. Unauthorized access or use of this system may subject violators to criminal, civil, and/or administrative action.

All information on this system may be intercepted, recorded, read, copied, and disclosed by and to authorized personnel for official purposes, including criminal investigations. Such information includes sensitive data encrypted to comply with confidentiality and privacy requirements.

Authorized Use

Collection of the information in this system is authorized under 42 USC 282(b)(10), 282(b)(13), 241, 242l, 284(b)(1)(C), 284(b)(1)(K), 42 CFR Part 63, and 42 CFR Part 61, Subpart A. The primary use of this information is to evaluate applicants' qualifications for research training at the NIH.

The information collected is subject to the Privacy Act, and is collected and maintained in accordance with the following Privacy Act Systems of Records Notices: 09-25-0158, "Administration Records of Applicants and Awardees of the Intramural Research Training Awards Program;" 09-25-0014, "Clinical Research: Student Records;" and 09-25-0108, "Personnel: Guest Researchers, Special Volunteers, and Scientists Emeriti."

You are responsible for safeguarding the data in this system in accordance with the above notices. For more information regarding your responsibilities, see the NIH IT Rules of Behavior, the NIH Information Technology (IT) Privacy Program, and the Secure One HHS Web site.

Examples of ***unauthorized*** access or use of this system include:

- Disclosing your login credentials to a colleague.
- Accessing the application of a relative, friend, or child of a friend for any reason. Please refer to the NIH Manual Chapter on Nepotism; 2300-310-1.
- Sharing system data, including letters of recommendation, with individuals who are not authorized personnel.
- Sending applicant data via unencrypted e-mail.
- Storing system data on portable devices such as laptops, PDAs, or USB drives.

This list is not exhaustive. If you have questions regarding authorized access or use of this system, contact OITE at 301.496.2427.

Refer any FOIA requests to the NIH Freedom of Information Act Office. You can find Privacy Awareness Training at both the NIH and HHS Web sites.

I accept | I decline