Ethics in Research
Review Session

Please review the following material and be prepared to discuss the cases within each of the following three areas:

Conducting Research
Cases A2 and A5

Reporting Research
Cases B1 and B3

Peer Review
Cases C2 and D3

Additional materials are provided for your information

Conducting Research

This section, "conducting research," covers activities that take place during the experimental phase of the research process. Thus, the cases in this section have been developed to draw the reader's attention to a few of the many dilemmas that may arise during formulation of a research protocol and the collection and selection of data. As is true of all the cases in the handbook, these are intended to present dilemmas and uncertainty and not present simple situations in which behaviors are blatantly wrong. For that reason, none of the cases describes a scenario in which data are simply fabricated or falsified.

Case A1, for example, illustrates the importance of selecting an appropriate experimental range, and how varying that range can dramatically influence the conclusions drawn from a research project. In addition, the case presents the dilemma of a trainee who must decide how important this variance is in her work and how to respond to her mentor, who dismisses her concerns.

Cases A2 and A3 explore the difficulty in determining when data points are truly outliers (data that are erroneous, stemming from extraneous causes) and when they reflect an actual experimental effect. The reader must also consider the appropriate way to handle outliers when compiling research results.

Although nonscientists in particular may think of data as only sets of numbers, data in fact come in many physical forms. Tissue samples, videotapes, sound recordings, and photographs may all serve as the sole tangible evidence of research findings. Yet, unlike numerical representations of a research phenomenon, which most trainees would know not to modify for the purposes of enhancing their results, the same might not be true of these other physical representations of experimental findings. These issues are dealt with in Cases A4 and A5.

The issues worth discussing in the context of the conduct of research are numerous. One salient issue, for example, relates to the objective of the research endeavor. Too often scientists set out to prove what they already believe to be true. However, in an objective search for truth – the essence of the scientific undertaking –- the scientist instead should test a hypothesis fairly and carefully and appreciate that a negative outcome can be just as fruitful and edifying as a positive one. The instructor may wish to develop new cases on this or other pertinent topics, which include:

- formulating a hypothesis,
- selecting appropriate controls,
- conducting and interpreting statistical analyses, and
- replicating experiments.

The suggested readings for this section deal with issues of experimental design, data selection, and data management. Readers may also wish to refer to the Selected Guidelines on the Conduct of Research found at the back of this handbook, as many of those references deal to some extent with topics pertinent to the experimental phase of research.

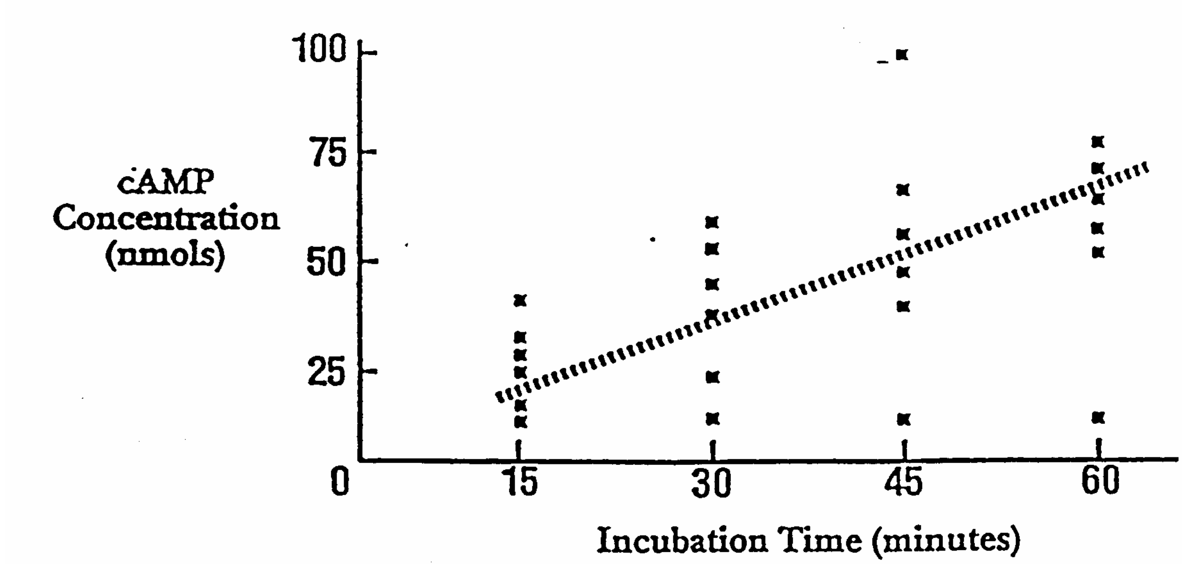
Data Selection and Retention

CASE A2

Alan Yeager has completed a series of experiments characterizing the receptor for a new class of hormones. During the course of his work, he studied binding characteristics and hormonal responses in tissue culture and in vitro, utilizing gels to characterize the molecular weights of receptor variants. This was exciting work for a second-year graduate student doing his first project. One day, Alan's laboratory chief asked him to prepare an abstract for an upcoming meeting and paper for publication, both to be based on the work Alan had been doing. The abstract was due in one week.

As Alan examined his accumulated data, he noted that a number of cell culture plates failed to respond to the hormonal stimulus and that there was considerable variability in the dose-response relationship. His data are represented in Figure 1.

Figure 1



Furthermore, on reexamination, he noted that a number of his gels were not very aesthetic in appearance, yet he was sure that they demonstrated the molecular weight, agonist binding, and subunit characteristics of the receptor.

Alan mentioned his distress to Pam Alden, a fifth-year graduate student, who said, "Why don't you clean up your data? You'll never get the paper published unless you do. We always clean up the data around here." She then suggested that the four culture points failing to show a response (along the X-axis at the 0 nanomolar concentration) be dropped because the cells were probably dead. She also pointed out that he might eliminate the top data point at the 45 minute interval as an outlier. She examined the gels and suggested retouching the negatives from which the prints were to be made, including the duplication of one of the nicer gel lanes to replace another that turned out poorly, but showed essentially the same result. "That will greatly improve your chances of publication," she said. Alan replied, "Maybe I should repeat a few of the experiments or try to improve the culture conditions?" "No," said Pam, "If you're convinced of your results, why go through the time, expense, and uncertainty of more repetitions? You'll never complete an experiment in time for the abstract, anyhow." Somewhat dismayed, Alan thanked her and turned back to his work.

CASE A2

Questions

1. What do you think about Pam's comments on publication practices and her suggestions for "cleaning up" the data?

2. How should Alan go about determining which points to include and which to exclude?

3. What other course(s) of action would you recommend to Alan?

4. Pam's perception about improving the chances of publication by "cleaning up" the data is not uncommon. How might journal editors and reviewers work toward correcting this perception?

Data Selection and Retention

CASE A5

John Sato, a young technician in an immunology laboratory, is anxious to read a paper recently published in a national scientific journal by Michelle Greer, one of the postdoctoral fellows in his lab. John assisted Michelle in preparing the electron micrographs that provided the empirical support needed for Michelle's central thesis concerning the surface characteristics of a certain class of lymphocytes. John was supposed to receive photo credits and he was excited about seeing his name in print.

On Friday, when the journal arrived in the lab, John noticed that the electron micrographs were not quite as he remembered them. He recalled that he and Michelle had some difficulty in interpreting which of the surface structures visible in the micrographs were of the type that interested Michelle, and which were irrelevant to the thesis of Michelle's research. In the published images, the differences in the structures seemed greatly exaggerated and more uniformly corresponded to their description in the text than John recalled being the case. Knowing that Michelle had the original photographic materials, he began to wonder if Michelle hadn't done something artificial to enhance them.

Initially, John was reluctant to challenge Michelle on this point. Nonetheless, the electron micrographs were credited to John and he believed it was unfair for Michelle to alter his work without consultation. After mustering his nerve, John did question Michelle, who admitted rather unabashedly that she had employed some "enhancement techniques" to improve the clarity of the images. These micrographs were for publication, after all, Michelle said, and needed to be of the best quality and clarity they could obtain. There was nothing wrong with this, Michelle asserted, as long as the images were merely, "enhanced" but not altered to change their fundamental characteristics.

CASE A5

Questions

1. Is it acceptable to enhance visual presentations submitted for publication in the manner described in the case? What are acceptable ways to enhance photographic illustrations? Is there a difference between "enhancing" visual presentations and "altering" them?

2. After turning over to Michelle the electron micrographs and the negatives that he prepared, to what extent does John bear responsibility in monitoring or ensuring what happens to those materials when prepared for submission to a journal?

3. John is a technician and has limited responsibility for the final product of this research effort. Would this responsibility be different if he were a postdoctoral fellow or a senior scientist himself? What if he were listed as a coauthor?

4. Now that the electron micrographs are in print, should John do anything further? Assume that John continues to feel unsettled about having his name associated with images that do not reflect his original work. How might he address those concerns?

University of Pittsburgh

Provost and Senior Vice Chancellor

MEMORANDUM

To: Members of the University Research Community

From: James V. Maher James V. Maher

Date: August 29, 1997

RE: Guidelines on Data Retention and Access

In anticipation of federal requirements, a University team developed the enclosed *Guidelines on Data Retention and Access* to define data and provide researchers with methods and a timeline to follow for data retention. These guidelines have been reviewed by the Council of Deans and approved by the University Research Council and the Chancellor. They are to be used in conjunction with the *Guidelines for Ethical Practices in Research* which were distributed previously under separate cover.

Any questions regarding this document should be directed to Dr. George E. Klinzing, Vice Provost for Research, x4-0784.

Enclosure

UNIVERSITY OF PITTSBURGH
GUIDELINES ON DATA RETENTION AND ACCESS
February 3, 1997

Introduction

The University of Pittsburgh has both rights and responsibilities toward scientific data generated by research at the University. Data produced from federally sponsored research are increasingly subject to requirements of the Federal Freedom of Information Act (FOLA) and private sponsorships often generate potential conflicts of interest and litigation over ownership of research data. In addition, increased mobility of University researches on recent years has changed the continuity of scientific research necessitating the development of institutional policies on data access, retention, and transfer.

Definition of data

Data means recorded information, regardless of form or the media on which it may be recorded. The term includes computer software (computer programs, computer databases, and documentation thereof), and records of scientific or technical nature. The term does not include information incidental to award administration, such as financial, administrative, cost or pricing, or management information. In practice, scientific data include both intangible data (statistics, findings, conclusions, etc.) and tangible data. Tangible data include, but are not limited to notebooks, printouts, computer disks, photographs, slides, negatives, films, scans, images, autoradiograms, eclectrophysiological recordings, gels, blots, spectra, samples, specimens, IRB consent forms, and other materials that are relevant to the research project.

Data Retention

The retention of accurately recorded and retrievable research data is of utmost importance for the progress of scientific integrity. The investigator must have clearly defined responsibility for recording, retaining, and storing research data. These records should include sufficient detail to permit examination for the purpose of replicating the research, responding to questions that may result from unintentional error or misinterpretation, establishing authenticity of the records, and confirming the validity of the conclusions.

The experimental notebook is the most common medium for documentation of experiments and its proper maintenance is of utmost importance. In addition to the study title, the investigators' names, and the study hypothesis, the experimental notebook should include detailed information on the materials used, sources of the materials, experimental methodology, statistical treatments, results and conclusions so as to enable replication of the experiments by others at any time. Bound notebooks with consecutively numbered pages are recommended for the data recording and maintenance. Whenever possible, raw data should be stored together with the experimental notebook. In the event that this is not possible, explicit instructions as to where the data can be found (e.g., location of disks, samples, specimens, etc.) should be included in the notebook. For studies involving several investigators/collaborators, possibly in more than one laboratory, it is recommended that the principal investigator maintain a master log that catalogues the experiments of the whole study and provides the location of the experimental notebooks, data, and relevant materials stored in other laboratories or locations.

There are some governmental guidelines prescribing the length of time researchers must maintain the original data. The times required to retain data vary from <u>three to seven years</u> depending on the governmental organization. In accordance with these guidelines, the University of Pittsburgh requires that research records be archived for <u>a minimum of five years</u> after final reporting or publication of a project. The archived records should be the originals whenever possible. In addition, the records should be kept for as long as may be required to <u>protect any patients resulting from this work</u> or as required by an external funding source. If any questions regarding the research are raised during the five-year retention period, the records should be kept until such questions are fully resolved.

Data Ownership and Access to Data

Both the principal investigator and the University have responsibilities, and hence, rights concerning access to, use of, and maintenance of original research data. Research data belongs to the University of Pittsburgh, which can be held accountable for the integrity of the data even after the researches have left the University. Although the primary data should remain in the laboratory where it originated (and hence at the University), consistent with precepts of academic freedom and intellectual integrity, the investigator may be allowed to retain the research records and materials created by him/her. In the event that the investigator leaves the University, an Agreement on Disposition of Research Data may be negotiated by the investigator and the Department Chair or Dean to allow transfer of research records. However, consistent with the same precepts, it should be specified in the agreement that the University has the right of access to all research records and materials for a reasonable cause after reasonable prior notice regardless of the location of the responsible investigator. The University is ultimately responsible for producing original records in case of allegations of misconduct or fraud against its researchers and protecting research integrity.

Some circumstances may warrant an exception, requiring that the primary data be retained by the University. In the case of the multi-institutional studies, the institution of the primary study director is responsible for retention and access to original data. Extramural sponsors providing support for research may also have the right to review the data and records resulting from that extramural support. When the data are used for a patent application filed by the University, it may be necessary for the original data to be kept at the University. Patient medical records also may not be removed from the University. Primary research data and unique materials (such as DNA, cell lines and genetic mapping information) developed with funds from the Public Service (PHS, of which the National Institutes of Health form a component) would be accessible to the research community after publication.

Split of collaborative team:

When a collaborative team is dissolved, University of Pittsburgh policy states that each member of the team should have continuing access to the data and materials with which he/she had been working, unless some other agreement was established at the outset. The unique materials prepared in the course of the research should be available/accessible under negotiated terms of a transfer agreement.

Co-investigators, trainees, and students:

The original data must be retained by the senior investigator and co-investigators. Trainees and students who are an integral part of the research project should be allowed continued access to all records and data which pertain to their part of that project.

Note: These guidelines have been developed based on similar policies now being implemented at other universities.

Reviewed and approved by: [signature] **Mark A. Nordenberg, Chancellor of the University** — 8/4/97 **Date**

LABORATORY NOTEBOOKS

Each research group should establish a policy on laboratory notebooks. This is a sample of one such policy.

1. Purpose and disposition of lab notebooks.

Individual lab notebooks, when taken together with the lab's group notebooks, should provide a complete and permanent record of all aspects of all experiments. Thus, with the information contained within these notebooks it should be possible at any time in the future to reconstruct exactly what was done in any given experiment. This information will be of particular importance to others who wish in the future to explore an issue related in some way to previous work within the lab.

All lab notebooks should be available to other members of the lab and remain with the lab if and when you leave for another position. Many of people will want their own copies of some or all of the material contained in these notebooks. In such cases they should either (a) use a type of lab notebook that has carbon paper and second, perforated sheets, or (b) make photocopies of pages of interest.

2. Style of Notebook

The basic lab notebook should have three characteristics: (1) it should be bound, (2) the pages should be numbered, and (3) it should be reasonably sturdy. There are a wide range of notebooks that meet these criteria.

3. Individual Lab Notebooks

Each member of a lab should maintain at least one individual lab notebook at all times. In this notebook they should record most of the information of relevance to their research, making use of other specialized group notebooks as appropriate (see below). Lab members may wish to maintain separate lab notebooks for different types of experiments or to combine all their research in a single notebook, using an index to help locate different experiments.

Keep in mind that these notebooks are not designed to be works of art accurate records of all you did (and *most* of what you thought). Thus, use it as a moment-to-moment log rather than a report written after the fact. Strenuously avoid writing bits of information on scraps of paper for later inclusion into your notebook. This leads to errors and to missing information.

For each experiment, your entry should include the following:

a. *Numerical designation.* This will permit you and others to find the right book and page for this experiment

b. *Date of Entry*.

c. *Purpose*. A few sentences summarizing what you hope to accomplish with this experiment. Best written *before* you do the work.

d. Methods. Rule of thumb: include *all* details needed to replicate your procedure precisely, including which reagent bottles (company, lot number) and solutions (date made person making it).
[Note: In some cases you will be able to indicate that additional details can be found in previous experimental write-ups.)

e. *Results.* Same rule of thumb: *all* data, *all* calculations, and *all* incidental observations go directly into your lab notebook.

There are several special cases in which it is not practical to place the actual raw data in your bound notebook (see "Special Case" below). However, even in those circumstances it is essential to provide an indication of where the data can be found and to enter the transformed data (either by hand or by attaching a computer print-out)

f. *Conclusions*. A short paragraph indicating your conclusions and, in some cases, a discussion of possible future experiments can be very helpful a year from now when you or someone else is trying to reconstruct your thoughts.

In addition to the above information required for each experiment, each notebook should have a table of contents. If different types of experiments are contained in the same notebook, an index grouping experiments by type also is useful.

4. Special Cases:

There are a number of special cases in which it is not practical to rely entirely on a bound notebook. Here are some examples:

a. Chromatograms (paper, disk): It is no longer practical to print out all HPLC chromatograms and paste them into a notebook. Moreover, even if you could do this it would not be sufficient since it would obscure data that might eventually become important (e.g., because the gain was too high or too low). Thus, it is acceptable to store chromatograms in a loose-leaf notebook and original data on a disk. However, be sure that information in your notebook is adequate to permit a reader to find these data and (in the case of a disk) to display the data. In addition, it is useful to store a sample chromatogram in your notebook and/or in the Equipment Notebook for the HPLC system that you used. This is especially true when you are working near the sensitivity of the method. Include a standard as well as samples at the extremes of concentration for the compound being measured.

b. Output from liquid scintillation counter: As in the case of HPLC output it may not always be practical to include all output from scintillation counters in your notebook. If not use the approach outlined above (4a).

c. Histology: Slides should be stored in slide boxes coded so as to permit retrieving them as necessary.

d. Work done in collaboration with another lab: When another lab is involved in an experiment it may be necessary to work out a compromise that suits both labs. This should be done on case by case basis.

5. Other Types of Lab Notebooks

There are several common lab notebooks. When entering information in any of these notebooks remember to indicate your name and the date.

a. Equipment Notebooks: Each major piece of equipment will have its own notebook. This is the place to indicate information of general interest such as (a) standard curves (along with chromatograms), (b) inspections, changes, repairs, and (c) problems in equipment functioning.

b. Solution Notebook: Each time you make a solution that will be used by anyone other than yourself (e.g., a buffer or a stock solution of acid or base), *all* the information needed to make that solution must be available in the lab's Solution Notebook. This includes al the information needed to find the particular reagent bottle you used, the amounts you measured out, and the calculations you deed to determine those amounts. If you are making a solution that has already been entered into the Solution Notebook you can refer back to the page on which the information exists. However, be sure to also record and deviations from the previous information (e.g., a different bottle of a reagent).

c. Methods Notebook: The Methods Notebook should contain all methods that have been used the lab and all subsequent modifications. It is important to retain all methods while also continually updating the notebook by adding new versions. In this way it is possible to determine how a given procedure was carried out at any time in the past and at the present time.

The Methods Notebook should contain a complete description of all methods used in the lab, including surgical procedures, the construction of probes, and the preparation of reagents. These methods should be prepared with sufficient care to permit someone in another lab to reproduce out method without any additional information. Thus, all the little tricks should be including – heating, stirring, adding in a particular order, using a particular order, using a particular brand, and so forth.

d. Drug Solution Notebook: This notebook should contain all the vital information needed to use any specialized compound, including (a) source, (b) structure, (c) molecular weight, (d) solubility, and (e) people within the group with experience in its usage.

MJ Zigmond
October 4, 1991
November 1, 1993 (minor revision)

Reporting Research

"Reporting research" relates to the communication of research results, whether through publication of peer-reviewed articles, abstracts, presentations at meetings, or some less conventional means. There are five issues pertinent to this topic that are dealt with in this section:

- Communicating preliminary research results,
- making significant and complete contributions to the literature, rather than fragmenting work into less meaningful reports,
- providing full and appropriate credit to those whose work substantially benefited the research in question,
- avoiding plagiarism, which encompasses the theft of ideas, words or other forms of communication, and
- conveying sufficient methodological detail to permit subsequent replication of work by others.

Case B1 deals with the question of when research findings may be considered "ripe" for presentation in a public setting. Results that are presented too early may not be confirmed by subsequent work, leading to misinformation or false conclusions. Research by others may then be erroneously influenced by building on incorrect assumptions. Thus, the case also raises the issue of how to retract or withdraw mistaken conclusions once presented publicly.

Often, a single project of research yields a number of interesting or important findings that can be published together in a single paper or broken up into separate reports. The concern over the latter practice relates to a cluttering of the literature with a greater number of papers of less significance. Thus, researchers must determine the point at which findings are significant enough and sufficiently developed for publication. Some scientists would argue that an inordinate emphasis is given to numbers of publications in decisions related to promotion or tenure, and thus they feel significant pressure to publish prolifically. These issues are dealt with in Case B2.

Researchers rarely work in isolation and, indeed, collaboration is essential in the scientific endeavor. Individuals contribute to the work of colleagues in diverse ways and significant contributions need to be recognized when writing up research for publication. Case B3, therefore, presents a scenario in which a number of individuals have made contributions both to the design and conduct of a research protocol, and to the paper in which the research results are presented. The protagonist must determine which contributions are important enough to merit recognition in his paper, and what form of recognition is most appropriate (by acknowledgment or authorship).

Although more widely recognized today as inappropriate than several years ago, gift or courtesy authorship – according authorship status on any basis other than one's actual contribution to the research – continues to be a problem. Thus, Case B4 deals with this matter, drawing out through the questions additional issues related to the rights and responsibilities of coauthors.

The theft of ideas and words – plagiarism – is nor nearly as straightforward as some might believe. Of course, some cases involve copying long passages of text verbatim and are self-evident. In other circumstances, however, text can be modified in sophisticated ways to render it not immediately recognizable from the source material. Even when one set of text is clearly derivative of another, it may not be clear which of the disputed authors had primacy in the formulation of the ideas or text, or proprietary rights to the final product. Repeated publication of a single set of results, failing to cite properly one's own previous work, and reanalysis of prior data are important facets of this issue that may not be widely recognized as inappropriate practices. Also, failure to attribute the contributions of colleagues or collaborators, whether deliberate or not, may be viewed as a form of plagiarism. All of these issues are examined in Cases B5 through B8.

Finally, the significance of scientific observations is predicated on their reproducibility. Thus, investigators have a responsibility to convey as completely as possible all important information concerning how their research projects were carried out. Omitting an arcane, yet critical, detail can impede the ability of other scientists to replicate the reported work, and delay the progress of science. Instructors may wish to develop their own case on this topic.

The suggested readings in this section include various guidelines that define the responsibilities of authorship, as well as works that alert the reader to the broad implications or plagiarism.

Reporting Preliminary Results

CASE B1

Lauren Janss is a bright, hard-working postdoctoral fellow. She is carrying out important research on dopamine receptors in the brain that may yield a better understanding of Parkinson's disease. When the abstract deadline for the national neurosciences meeting approached, each trainee in the lab, including Lauren, was asked what he or she planned to submit. Lauren hesitated to respond. Dr. Jim Cummings, her postdoctoral advisor, urged her to utilize data presented at a recent lab conference because it made a good story and she would have plenty of time to confirm and extend the results before the meeting. Lauren preferred to hold off because, as she explained to Dr. Cummings, she recently has been unable to confirm the main result fully. Dr. Cummings insisted, saying that Lauren was being too timid and that the others would get the credit if she delayed. He added that Lauren should not be concerned, as the experimental results were consistent with theory. Dr. Cummings said, " Lauren, you must be more aggressive with your data if you are to succeed in the cutthroat world of contemporary science. After all, it's publish or perish! Why don't you take first authorship on this abstract?"

Reluctantly, Lauren submitted the abstract and to her surprise and Dr. Cummings's delight it was selected for a plenary slide presentation.

Despite an enormous effort, Lauren could not replicate or extend the results and announced to Dr. Cummings that she wished to withdraw the abstract. Visibly irritated by Lauren's request, Dr. Cummings told her harshly that this was not an option and pressed her to do more experiments.

CASE B1

Questions

1. What are the research requirements for submitting an abstract to a meeting?

2. If you were Lauren, how would you have responded to the initial request for an abstract?

3. If you were Dr. Cummings, how would you have approached Lauren?

4. To what extent does a presentation at a meeting resemble a publication? To what extent does it differ from a publication?

5. As first author on the abstract, does Lauren have different responsibilities from those she would have had if Dr. Cummings's had assumed primary authorship?

6. In light of her ability to replicate or extend the results, what should Lauren do to correct the record concerning the apparently erroneous results presented in her abstract? How should she respond to Dr. Cummings's refusal to consider withdrawal of the abstract?

7. Not all submitted abstracts become full papers. If you were Lauren, would you have felt differently if the abstract were accepted for a poster session?

Criteria for Authorship and Attribution

CASE B3

Bob Powell, a postdoctoral fellow in biochemistry, has just completed a manuscript detailing the results from the first project in which he had taken a leading role. The focus of his project has been to discern the ways in which humans metabolize sulfites, a class of chemicals commonly used to preserve wines and dried fruits. Although he had developed the rough outlines of the project on his own, he owes much to individuals both inside and outside his lab. The assistance he received from others includes the following:

- A colleague at another university, a toxicologist specializing in food additives, shared with Bob his previous work on the *in vito* activity of sulfites, information that allowed Bob to choose the ideal animal model for the experiment – the Abyssinian field mouse.

- A friend of his, who happened to be a wildlife specialist, provided Bob with much advice on rearing and maintaining a colony of Abyssinian field mice such that he would have a stable pool of animal subjects.

- A highly experienced technician in the lab gave Bob advice on modifying an assay he had been using, which finally allowed him to measure successfully sulfite metabolites in mouse urine. This technician also assisted in writing up the methods section of the paper.

- The number of assays that Bob had to conduct was quite sizable and more than he could manage on his own, given other demands of the project. Thus, an undergraduate college student collected most of the urine samples and conducted the assays yielding the data.

- Finally, a senior researcher in a neighboring lab who took an interest in Bob's career offered to review the initial drafts of Bob's paper. By the end of the writing process, this researcher had helped Bob outline the paper, suggested a few additional experiments that strengthened the paper's conclusions, and made a number of editing changes in the penultimate draft that enhanced the paper's clarity.

CASE B3

Questions

1. What kind of attribution should be given to each of these individuals who contributed in one way or another to Bob's project? For example, who should be recognized as an author and who should receive an acknowledgment in the paper? Who does not merit formal recognition?

2. What criteria should be applied when determining whether

   a) to list someone as an author?
   b) to note someone's contributions in the acknowledgment?

3. What are the responsibilities of authors in representing the contributions of others?

4. At what point in the process of conducting and reporting on one's research should decisions concerning authorship and acknowledgments be made?

5. Are decisions concerning attribution entirely Bob's responsibility? Should he consult with others? Why or why not?

Peer Review

Peer review, the process by which the quality of work is assessed, encompasses multiple activities. This portion of the handbook is concerned with two types of peer review that researchers encounter in the extra-institutional setting. First, there is the peer review of research proposals, the system by which the NIH and other federal and nonfederal supporters of research assess the scientific merit of grant applications. Second, journals and other publishers utilize a form of peer review to assess the quality of articles and other written works describing scientific findings.

These forms of peer review are based on the premise that skilled scientists in the same or similar field of research as that being considered are best equipped to evaluate the merits of a proposal or the quality of a written work. It is a sound premise that has worked well for many years and one that most individuals in the research community vigorously support.

This is not to say that the system is without problems. For peer review to function as it should, reviewers must be acknowledgeable, objective, and impartial. This can be a particular challenge in both arcane and fast-moving fields of research where it may be difficult to find a sufficient number of reviewers who are both intimately familiar with the area of research in question, yet neither personally associated nor in competition with the investigator or a competitor.

Case C1, for example, points to just that problem in the context of reviewing a grant application. The protagonist has clearly gleaned information from a proposal that proved useful to his own work. He is thus beset with the problem of balancing his desire to correct the course of his own work against retaining confidentiality and respecting the work of others.

Confidentiality is another aspect of peer review that, while frequently debated, is generally considered essential if peer review is to operate effectively. Yet, in case of assessing submissions to journals, reviewers may be tempted to solicit the opinions of friends and colleagues with expertise in a particular area. This practice, which may pose breaches of confidentiality, is described in Case C2. Readers interested in the topic of confidentiality as it relates to peer review may also wish to refer to case D3 in the following section on Handling Research Data, Materials, and Proprietary Information.

The suggested reading list includes the confidentiality statement that is read by all NIH study section members in the review of grant applications, and other materials that should afford a better understanding of peer review in the federal contract and grant system. It also points to a number of statements that outline standards of integrity for journal reviewers and discusses dealing with conflicts of interest in that context.

Handling Research Data, Materials, and Proprietary Information

This section deals with proprietary rights to the information and materials that serve as fundamental elements of research activity. Scientists have long assumed that they had proprietary rights over materials produced through their own labor and genius. It is not uncommon for scientists to take with them their notebooks and many of their original research materials when they move from one academic position to the next. Yet, most institutions assert that all laboratory materials developed on the institution's time with the institution's resources belong to the institution – not to the investigator. The federal funding agencies, too, support the position that primary research materials developed under federal grants belong to the awardee, which is almost always the institution, not the investigator.

Institutions have more than a proprietary interest in maintaining control over these materials. If a researcher's work is called into question, the institution will be expected to respond and will be held ultimately accountable. The institution clearly cannot fulfill its obligation to assess the integrity of the investigator's work if the original materials and notebooks are no longer accessible.

Another consideration is the desirability for openness and for sharing research materials. The free exchange of research materials and ideas, which is generally encouraged in the scientific culture, clearly benefits the scientific endeavor as a whole. Yet, in Case D1 a trainee learns that he may not freely transport his original materials to another lab. Through the questions, the reader understands that the trainee is trying to balance this policy of proprietary control against the need for access to materials. The discussion of this case can be enhanced by diverse participants (e.g., faculty, students, technicians) who may hold different ideas about this issue.

Another fundamental element of research that can be shared voluntarily or involuntarily is information. A description of a novel assay technique or newly discovered biochemical pathway can permit a researcher to leap a seemingly insurmountable roadblock. Of course, a researcher who has struggled long and hard to develop this information may feel disinclined to share it openly, at least not without being fully credited with the finding. In Case D2, a trainee discusses the work of one lab with the head of another lab in same field. After exchanging a fair amount of information, the specter of competition occurs to the individual and he feels suddenly conflicted. Case D3 deals with the responsibility of two individuals with regard to valued, possibly confidential information. One individual is perhaps indiscreet in sharing the information, while another, who inadvertently becomes privy to it, treats the development as an opportunity to be capitalized upon.

The suggested reading list points to references that relate to the ethical and legal aspects of data sharing and ownership.

Reviewing Submissions to Journals

CASE C2

Anne Baldwin is a postdoctoral fellow working in a highly specialized area of research on lentiviruses and prions. Her boss, Dr. Sam Richardson, recognizes Anne's talents and believes that she is the most promising postdoctoral fellow in his lab.

Anne's contributions have included aiding Dr. Richardson identifying a rather obscure pathway by which the prion responsible for Creutzfeldt-Jacob disease, a degenerative brain disorder, emerges from years of latency to initiate active infection.

When Dr. Richardson is asked by a leading neurobiology journal to review an article on the pathology of Creutzfeldt-Jacob disease, he decides to involve Anne Because of her skills and specialized experience. He makes a copy of the manuscript and asks Anne to write her own critical review of the piece, just as if she were the actual reviewer. This exercise, he reasons, would afford Anne a good opportunity for exposure to the process of peer review, while putting her in touch with the latest literature on her primary field of research.

CASE C2

Questions

1. Is Dr. Richardson's idea a good one? Why or why not? Are there other ways for him to involve Anne in reviewing the article?

2. Dr. Richardson's motives for having Anne participate in this manner seem well-intended. What might be some negative reasons for involving Anne in this way?

3. What concerns might Dr. Richardson's approach pose for the author of the article? What issues are posed for the journal in which the article may appear?

4. If Anne feels uncomfortable about Dr. Richardson's request, how might she respond?

5. Assume that rather than sharing the paper with Anne, Dr. Richardson distributed it to the laboratory's "journal club" for discussion. What kinds of problems does this scenario pose?

Use of Confidential or Proprietary Information

CASE D3

While quietly sipping a soda and looking over the landscape at his departmental retreat, Professor Aaron Chen inadvertently focuses in on the conversation at the next bench. Joe, a young faculty member, is talking to his graduate student, Yolanda.

Joe — I know that reviewing papers for publication is part of our job, but this steady influx is exhausting me. The only saving grace is that I get to learn about some pretty exciting science.

Yolanda — That's a pretty desirable burden compared with what I have to put up with as a teaching assistant. At least you get to learn something in the process. Come across anything particularly interesting?

Joe — Well, since we don't work in this immediate area, I guess it's okay to talk about it. There's report of a new cellular transcription factor that plays a powerful role in expression in virus-infected cells. It's been messing up everyone's *in-vitro* transcription systems. It's easy to purify because it binds to the DNA binding region of the estrogen receptor and can be affinity-purified from columns containing that region specifically. The paper is well-written and I am recommending publication with only minor corrections so it should be out soon.

Yolanda — Fascinating! I can't wait until I see that in print.

Prof. Chen has been having great difficulty carrying out *in vitro* transcription with DNA from virus infected cells and has been wondering where to turn next. The overhead remark is like a gift from heaven. He then unexpectedly runs into his graduate student Paul Louden.

Prof. Chen — Paul, have you been thinking how to get our *in vitro* transcription process to work better? Maybe the viruses induce new cellular transcription factors that are not present in normal cells.

Paul — That's a great idea. We've been looking for technical problems for much too long. Why don't we try and find out.

Prof. Chen — Let me tell you about what I overheard. I think we could get this project done in time to submit it just about when the other group publishes their finding. It surely makes science more efficient for us to get on the right track, and our study will validate their result if we can confirm its validity in our system.

CASE D3

Questions

1. How would you assess the behavior of the following individuals in this case (where appropriate, explain what was troublesome or unethical about behavior of the individual identified):

    a. Yolanda?
    b. Joe?
    c. Professor Chen?
    d. Paul?

2. If you were an author of the paper under discussion, with whom would you be upset?

3. How should Professor Chen have reacted to Joe's conversation with Yolanda?

4. What is an appropriate way for Joe to respond when he learns that Professor Chen has overheard and acted on the information that Joe and Yolanda exchanged informally? If Yolanda were to learn of Professor Chen's actions, how might she respond?