



Research Regulator

Promoting Responsible Conduct in Research



Volume 2, Issue 2

Office of Research Compliance

Spring 2008

New NIH Publications Policy

~Starting April 7, 2008, journal articles resulting from NIH-funded research must be deposited to PubMed Central within 12 months of the publication of the article.

~Beginning May 25, 2008, applications, proposals or progress reports submitted to NIH and referencing an article that arose from NIH-funded research, must include that article's PubMed Central reference number.

In January, NIH announced the "Revised Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research" to become effective on the dates listed above. The purpose of the policy is to ensure that the public has access to the peer-reviewed, published results of NIH-funded research in order to

advance science and improve human health. The new policy applies to peer-reviewed manuscripts resulting either fully or partially from NIH-funded research. It does not apply to book chapters, correspondence or editorials.

Case's Approach to the Publications Policy

Case's Cleveland Health Sciences Library has prepared a [Tip Sheet](#) to assist researchers with navigating the process. To ensure compliance, investigators should follow these steps:

Step 1: Researchers need to ensure that when negotiating publication copyrights, they retain the ability to comply with the NIH mandate. Case has prepared a letter that should be downloaded and submitted along with each NIH-funded manuscript that is sent to a journal. The standard letter requests that the publisher submit the article to PubMed Central within 12 months of acceptance or include in the contract specific language that allows Case to submit the manuscript. The letter, which has been signed by the Provost and VP for Research and Technology Management, can be accessed at the following link: <http://www.case.edu/chsl/PMClletter.pdf>

Step 2: Ensure that the peer-reviewed manuscript is submitted to the NIH Manuscript Submission system by Case or the publisher. A list of journals that submit for researchers may be found at: http://publicaccess.nih.gov/submit_process_journals.htm.

Step 3: Beginning with May 25 submissions, ensure that when preparing an NIH application, proposal or progress report, that you include the PubMed Central reference number (PMCID) for any article you cite that arose from NIH-funded research that is covered by this policy. See the [Tip Sheet](#) for examples.

Need Help?

Locally, investigators can Contact the Cleveland Health Sciences Library at hclref@case.edu.

NIH has prepared a series of web pages to address questions and issues with the new policy: <http://publicaccess.nih.gov/index.htm>. The site includes a useful list of Frequently Asked Questions, as well as additional information about the policy and submission process. ❖

Inside this issue:

Research with Animals	2
Research Misconduct	3
Discussion Starters...	4



NIH Requests Community Input on Public Access Policy

Through May 31, 2008, the NIH is accepting public comment on the new publications policy. Several large organizations have already responded, including the Council on Governmental Relations (COGR) and the Association of American Universities (AAU). Both organizations support the policy. Some publishers, however soundly disagree with the requirements.

The NIH is particularly interested in information about the following:

- Do you have recommendations for alternative implementation approaches to those already reflected in the NIH Public Access Policy?
- In light of the change in law that makes NIH's public access policy mandatory, do you have recommendations for monitoring and ensuring compliance with the NIH Public Access Policy?
- What additional information, training or communications related to the NIH Public Access Policy would be helpful to you?

Responses to this request for information can be submitted at: <http://publicaccess.nih.gov/comments.htm>. Responses, including identifying information about the respondent, will be publicly accessible on the internet.

RCR Core Areas

Covered in January 2008 issue:

- ~ Peer Review
- ~ Collaborative Science
- ~ Conflict of Interest

Covered in this issue:

- ~ Animal Research
- ~ Research Misconduct

Look for in upcoming issues later this year:

- ~ Human Subjects
- ~ Mentoring
- ~ Authorship Issues
- ~ Data Management



Animal Research ~by W. John Durfee, DVM, DACLAM, Director, Case Animal Resource Center

The use of animals for research is a privilege vested in Case Western University by the federal government through the Public Health Service (PHS) and the United States Department of Agriculture (USDA). The primary documents governing animal research are set forth in the [Animal Welfare Act](#) and the [Guide for the Care of Use of Laboratory Animals](#). These Animal Welfare Regulations describe institutional requirements for establishing personnel qualifications and training.

Federal Assurance

In order to secure funding from PHS, Case has provided assurance of compliance with the regulations to the Office for Laboratory Animal Welfare (OLAW) in the NIH Office of Extramural Research. PHS policy requires that the Animal Welfare Assurance includes "a synopsis of training or instruction in **the humane practice of animal care and use**, as well as training or instruction in research or testing methods that **minimize the number of animals** required to obtain valid results and **minimize animal distress**, offered to scientists, animal technicians, and other personnel involved in animal care, treatment, or use" (PHS, 1986, p. 4). The policy set forth by the PHS is echoed in the Animal Welfare Act which states that "It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel." The requirement for training is an integral part of the ongoing program of Animal Care and Use at Case Western Reserve University.

Training at Case Western Reserve University

Training strategies focus on formal web-based instruction supplemented by direct hands-on learning experiences to provide sufficient exposure to impart the required information to animal researchers. At Case, the Animal Care and Use Training Program is administered by the Institutional Animal Care and Use Committee (IACUC) (<http://casemed.case.edu/ora/iacuc/>). All personnel listed on approved **IACUC Protocol Forms must receive some training. The principal investigator (PI) is ultimately responsible to ensure that personnel under his or her supervision are qualified to perform the specific procedures in the laboratory involving live animals. The PI is assisted in this effort through the program of animal care and use training.**

A variety of training modules are made available through the [Animal Resource Center's web site](#). Following the web training, investigators are given a tour of the appropriate animal facility and specific hands-on training is scheduled to provide

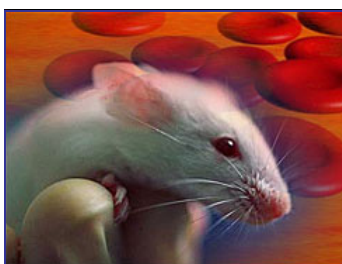
instruction tailored to the needs of each individual. Once all training requirements are completed, access is granted to animal facilities to begin working with animals.

Training requirements are determined for each individual by the IACUC Training and Compliance Supervisor, Tami McCourt (txm9@case.edu). The training for each individual

at minimum includes:

- 1) Orientation to Facilities
- 2) Occupational Health and Safety Training
- 3) Basic Animal Handling for the species being used

Other specific training given as needed, includes surgery, mouse and rat microisolator technique, use of controlled substances and biohazardous agent use in animals. ❖



Internet Resources

Local laboratory animal training resources are augmented by a wide range of internet sites designed to acquaint investigators with current animal use issues and methods.

The Johns Hopkins Center for Alternatives to Animal Testing (CAAT) <http://caat.jhsph.edu/> provides web services like Altweb, an international gateway to animal testing alternatives and training resources: <http://altweb.jhsph.edu/>

Also at Altweb, "**The Principles of Humane Experimental Technique**", the first published description of three principles known as the "3Rs", namely; **Reduction, Refinement and Replacement**, which provide guidance to refine and improve experiments to minimize the number of animals used and to drive experimental design to protect animals from unnecessary suffering.

The National Agricultural Library sponsors the Animal Welfare Information Center (AWIC) and provides resources to search for alternatives to reduce the use of live animals in research: http://awic.nal.usda.gov/nal_display/index.php?info_center=3&tax_level=1&tax_subject=169

The Institute for Laboratory Animal Welfare (ILAR) maintains an online reading room where publications like [Recognition and Alleviation of Distress in Laboratory Animals](#) are available to help investigators refine experimental techniques: http://dels.nas.edu/ilar_n/ilarhome/reports.shtml

The Laboratory Animal Welfare Training Exchange provides a clearing house for the distribution of shared training materials: <http://www.lawte.org/>

The ILAR Journal (Volume 48(2)) provides a detailed description of current practices: http://dels.nas.edu/ilar_n/ilarjournal/48_2/html ❖



Research Misconduct – What You Want to Know...

Definition

Federal regulations and University policy define Research Misconduct as “fabrication, falsification, or plagiarism in proposing, performing or reviewing research, or in reporting research results.” *Fabrication* is making up data or results and recording or reporting them. *Falsification* is manipulating research materials, equipment or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. *Plagiarism* is the appropriation of another person’s ideas, processes, results or words without giving appropriate credit. Research misconduct does not include honest error or differences of opinion.

Research misconduct, on the surface, seems clearly defined. However, as projects progress, the line may become blurry between what is sound, ethical research and what may be considered a questionable research practice. The purpose of focusing on each of the core Responsible Conduct in Research (RCR) areas is to promote awareness and foster good decision-making should an ethical quandary arise. Below are answers to some common questions about research misconduct.



What policies apply? Locally, Case’s “[University Policy for Responding to Allegations of Research Misconduct](#)” describes the procedures followed when an allegation is made. In addition, where Public Health Service (PHS) funding is involved, Federal Regulations at [42 CFR 50 and 93](#) apply. Other agencies, such as the [National Science Foundation](#), also have research misconduct policies.

Who decides if research misconduct has occurred? Allegations of research misconduct should be reported to the Case Office of Research Compliance (ORC). A faculty committee of five members is then appointed by the ORC to review allegations. Committee members are screened for conflicts of interest, and should possess the scientific expertise to evaluate the research in question.

Who will know about the allegation? The misconduct procedures are designed to protect both the accused and the accuser. The ORC operates under strict confidentiality guidelines, and therefore, only those necessary to carry out the process will be informed of the identities of involved parties.

What can happen if someone is found guilty? Depending upon the severity of the misconduct and the individual’s position at the University, sanctions will vary. In the most severe

cases, students may have their academic degrees revoked, staff may have their employment terminated, and faculty can lose tenure. In less serious cases, journal retractions and thesis or dissertation re-writes may be necessary. Recommendations for sanctions are made by the faculty committee and referred to appropriate University officials.

How often does this happen at Case? The ORC generally consults with between five and ten individuals each year regarding suspected misconduct. Cases that do not have the potential to meet the definition of research misconduct (i.e. authorship disputes or interpersonal differences) are referred to the appropriate University department or office, such as human resources, the office of general counsel, the academic integrity board, or deans or department chairs. Typically, one to three cases can be reviewed under the research misconduct policy, resulting in an average of less than one finding per year.

What are the most common allegations made? According to recent statistics from the Department of Health and Human Services’ Office of Research Integrity (ORI), up to forty percent of misconduct cases have involved questioned images. With the availability of photo-altering computer software, some investigators have attempted to mislead readers with falsified images. Dr. John Krueger from the Division of Investigative Oversight at ORI has developed some effective techniques to spot altered images. The Forensic Tools section of the ORI website shows examples of altered images and methods to “de-authenticate” them. Krueger warns that it is as easy to recognize an altered image as it is to create one! Check out ORI’s Forensic Tools at: http://ori.dhhs.gov/tools/data_imaging.shtml

Why would someone commit misconduct? In a [letter to the Judge](#) who sentenced him to 366 days in a Federal prison, researcher Eric T. Poehlman described the reasons why he fabricated and falsified data repeatedly on federal grant applications that awarded him \$2.9 million dollars:

“...I believed that because the research questions...were legitimate...it was okay to misrepresent “minor” pieces of data...”
“I saw my job and my laboratory as expendable if I were not able to produce.”
“I cannot deny that I was also motivated by my own desire to advance as a respected scientist...”

Who to contact at Case? The research misconduct policy is administered by the ORC’s research integrity team:

[Christian LaMantia](#)
368-4513

[Tracy Wilson-Holden](#)
368-6131

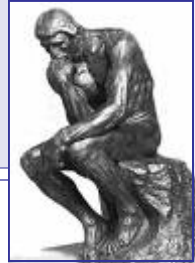


Discussion Starters: things that make you go hmm

How to use the Discussion Starters:

Case Western Reserve University encourages faculty to be actively involved in the Responsible Conduct of Research (RCR) education of those whom they teach, mentor and supervise. To facilitate meaningful discussion of ethical issues related to research, **Research Regulator** will include short case studies in each issue.

1. Create a schedule to devote time on a regular basis (i.e. once a month at a lab meeting) to discussing RCR.
2. Focus on one core area for each session.
3. Use the scenarios suggested, or create your own scenario that relates more directly to the research you do.
4. Foster an open forum to elicit input from others and encourage discussion and debate.
5. Present alternate circumstances and see how that changes opinions.
6. Send us your scenarios for use in future issues!



Research Misconduct

- ~ After several costly mishaps in previous attempts at running an experiment, researchers finally successfully run the experiment and are able to substantiate their hypothesis. Later, they become aware that the labels from two samples fell off and a technician replaced the labels. The technician is unsure if the labels were put back on the correct samples. Results, with the labels now in place show the expected results. If the labels are reversed or the two samples are omitted from the analysis, the results do not reach statistical significance. (Adapted from a case study written by Dr. Michael Kalichman, UCSD, 1998)
- ~ Two phlebotomists working on a research protocol in a hospital are required to get just two more participants' blood samples to finish their specimen collections for a study. They are having difficulty getting participants to agree, it is Friday afternoon, and they want to finish so they can leave for the weekend. They decide to take each others' blood and make up enrollment information for two fictitious patients. They reason that they have already collected enough specimens and these last two will not significantly alter the interpretation of the data acquired. (Adapted from a misconduct case summary posted on [ORI's website](#))
- ~ In an alcoholism study, a nurse coordinator is sure that a study participant is not being truthful in reporting his alcohol consumption on the self-report survey form given as part of the study session. He has responded that he has not consumed any alcohol in the past 24 hours, but she can smell it on his breath. At the completion of his appointment, she changes his survey response. She knows that it is important that the principle investigator have accurate information when evaluating the rest of the data from the session.
- ~ A researcher is finishing an abstract that is due in the morning. She is exhausted and feels that her writing is less clear than usual. She is using an article that is outside of her direct field of study, and one that those who read her abstract are unlikely to have read before. To make sure that she presents the information clearly, she copies two sentences directly from the other paper, but does not use quotation marks. She does include the article in the references. ❖

Animal Research

- ~ Researchers are using an animal model to study the effects of severe trauma and abuse in children. Their protocol calls for subjecting rats to different levels of pain and suffering, including administering mild electric shocks, forcing the animals to swim until they reach exhaustion, and subjecting them to other traumatic treatments. (Adapted from The ORI Introduction to RCR, Chapter 4f, The Welfare of Laboratory Animals, [Broader Responsibilities](#))
- ~ "Unexpected Adverse Events"—Several weeks into a study comparing different bone implants' effect on healing in dogs, some of the animals begin to die unexpectedly. Read more about this case by following this link: <http://www.onlineethics.diamax.com/cms/16226.aspx>
- ~ A study is planned using 50 pigs. An endoscope will be used to access abdominal cavities by passing it down to the stomach and out through an endoscopically created hole made in the stomach wall. This study will investigate the feasibility of more complex surgical maneuvers utilizing a specific method of endoscopic surgery. Multiple goals are included in this protocol including (1) attempting a full thickness resection of a small portion of the stomach, (2) evaluating multiple closure devices for the stomach and colon, (3) removing a small section of the colon through the hole made in the stomach, and (4) constructing a connection from the small intestine to the stomach for alternate emptying purposes. Is this a good example of the principle of reduction, or too great a burden for these animals? ❖

Questions or suggestions?

We welcome your input and suggestions for future issues of **Research Regulator**. Let us know what you think and how you use the newsletter. Contact Tracy Wilson-Holden at 368-6131 or tjw18@case.edu.

Look for the expanded Human Subjects issue in the early fall, including a 4 CREC quiz!!