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Playing It Safe With Research Risk

If you fail to follow the rules, you could conduct an entire project and be forbidden to publish the results

By KAREN M. MARKIN

How is it that you can do human-subject research without ever seeing, touching, or talking to another human being? If you can't answer that riddle, you could conduct an entire research project and be forbidden to publish the results.

In the interest of safety, many research projects must undergo institutional review before you begin. Official approval is needed to work with human subjects, animals, dangerous biological materials, and radioactive materials. Each area is overseen by a different committee at your institution, and each committee has its own review process.

Young investigators may throw up their hands when faced by this maze of approval processes. How can an institution say it wants faculty members to conduct research and then erect so many hurdles?

Blame it on the federal government, which provides much of the money to conduct the research and therefore sets the rules. Institutions take those regulations seriously because failure to comply can hit them in the pocketbook through loss of grant dollars. It's important for you to take them seriously also, or your project could be delayed or terminated. Plus, any bad publicity resulting from an allegation of animal cruelty or carelessness with a dangerous microorganism could certainly dim your prospects for promotion and tenure.

Here is a rundown of the research-safety panels that exist at most institutions, along with a brief description of what they do. This article is not meant to be a definitive review of the myriad regulations governing research safety. The intent is to alert you to situations where you might need to gain official approval before beginning your work, so that you can plan ahead instead of getting caught short.

Human subjects. Regulations regarding the protection of human subjects in research first appeared about 30 years ago and have expanded ever since. Enforcement of such regulations was the subject of a congressional investigation following the death in 1999 of a young man involved in a gene-therapy trial supported by the National Institutes of Health. Today's researchers are working in an environment of heightened public concern for the safety of human subjects.

Even the most well-intentioned investigator can trip over the regulatory complexities of human-subjects research. For many of us, the term conjures up an image of a biomedical setting and procedures such as the collection of blood samples. But biomedical research is only one of the areas that require

consideration by your Institutional Review Board, commonly known as the IRB. Those other areas are the ones that tend to confuse Ph.D.'s.

For example, social- and behavioral-science research may require IRB approval, even when it involves what appear to be benign methodologies such as surveys, interviews, and observations. Analysis of an existing set of data may also require board approval, if it is possible to link the information to individuals, such as through names or Social Security numbers. In that way, you could conceivably conduct human-subjects research without ever coming into direct contact with a human subject.

Even minimal contact with another human, in the form of a specimen, can trigger IRB review. That includes working with blood samples or hair and nail clippings -- even when you did not collect the materials yourself. Privacy and confidentiality are the concerns here: A hair sample could reveal the use of illegal drugs, possibly exposing the subject to criminal charges if there is a link between the hair sample and the human subject.

Thus we have an environment in which a business professor conducting a telephone survey about attitudes toward the local economy could need IRB consideration.

Perhaps you are thinking that that is regulatory overkill. Answering survey questions about the economy poses no discernable risk to the participant. Surely that kind of study does not warrant the same scrutiny as a novel medical procedure?

In fact, the survey *does not* warrant the same level of scrutiny, but it is not up to you to make that determination.

Review boards use different levels of scrutiny for projects, depending on the risk they pose to humans. In some instances, the risk is minimal, and the project is eligible for "exempt review." Does that mean you don't have to bother with the IRB forms? To paraphrase Bill Clinton, it depends on what the meaning of the word "exempt" is. At most institutions, to say that a project qualifies for exempt review does not mean that no review is necessary. It means that, after you have submitted the necessary forms, an authorized official decides that no further review of your project is required.

Never the type to hold back, academics have forcefully voiced their feelings about the regulations. Some yell at the compliance officer, which has yet to result in quicker approval. Others have written scholarly articles about the First Amendment concerns that can arise.

Whatever your thoughts on the wisdom of current practices, be aware that these boards are powerful. They can prevent you from publishing data gathered for a project that was not submitted for consideration. They cannot grant retroactive approval for a project already under way. You might have to forfeit all data collected during your preapproval activities.

Animal care. Animal research is overseen by your university's Iacuc (pronounced "I-uh-kuck" at my institution, but I've also heard it pronounced "I-uh-kook"). That stands for Institutional Animal Care and Use Committee, but no one ever calls it that. It would be like referring to FM radio as frequency modulation.

Those panels, which were empowered more than 40 years ago by the federal Animal Welfare Act, ensure that researchers comply with complex federal regulations regarding animal care. Although that law empowers the secretary of the U.S. Department of Agriculture to set animal-care standards, the National Institutes of Health has its own, slightly different standards, and can require its grantees to meet

them. Things can get complicated. Your Iacuc can help you to meet the appropriate standard.

You must have your research plan of action, or "protocol," approved by your institution's Iacuc before you begin work. In addition to sticking with your approved protocol, you must follow proper rules for handling and caring for animals. Unlike assistant professors, lab animals are entitled under federal regulations to comfortable living quarters, with guidelines set for such details as the maximum temperature and minimum square footage. Don't begrudge a mouse the right cage because your office is in a broom closet. Government inspectors can and do pay surprise visits to university labs, and they can suspend your project if they find violations.

Biotechnology and biohazards. The NIH requires that organizations conducting recombinant-DNA research have an institutional biosafety committee to ensure that the work meets the safety requirements set forth in the agency's guidelines. Since the NIH is by far the largest federal supporter of scientific research, with \$28.7-billion in the current fiscal year, you can be sure that universities strive to follow those guidelines.

At many institutions, the biosafety panels, which were first established some 30 years ago, have taken on additional responsibility for overseeing research involving other potentially hazardous biological materials, such as infectious microorganisms, toxic biological substances, and biological allergens. Fear that those materials could be used by terrorists has intensified the oversight.

Federal law spells out strict controls over the use of so-called select agents -- that is, organisms and toxins that can pose a severe threat to human health, such as smallpox, botulism, and anthrax. Expect more government involvement with your biosafety committee regarding the review of "dual-use" studies -- projects with the potential for dangerous as well as beneficial applications.

Acquisition and possession of select agents is strictly controlled, reducing the likelihood that you may inadvertently breach the regulations.

Radioactive material. Here is another substance that the federal government requires universities to monitor for safety. Those regulations emanate from the Nuclear Regulatory Commission.

Your radiation-safety committee is responsible for the policies and procedures for acquiring and using such materials. Not surprisingly, their purchase is tightly controlled, reducing the chances that you will inadvertently run afoul of the regulations.

The bright side. The federal government recognizes the burden that some of these regulations place on researchers. Agencies realize that only a fraction of research proposals are financed, so they generally allow you to submit a grant proposal involving human subjects or animals before receiving the necessary safety approval. Should your proposal be selected, you will need the approval before the agency will release any money.

So play it safe in terms of both your own research agenda and the well-being of society. Don't wait until the last minute to begin the necessary approval process. IRBs and Iacucs have regularly scheduled meetings (usually monthly), as well as premeeting deadlines for receipt of your application. They won't convene a special meeting for you, no matter how much you beg, but they do meet throughout the summer. Biosafety and radiation-safety panels may meet less frequently. Contact them about their schedules and application requirements.

When in doubt, or for guidance about your particular circumstances, call your institution's compliance

officer. That officer and his or her staff are paid with recovered overhead dollars -- that faculty-disdained percentage of the grant that goes to your institution -- to serve you.

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