HUMAN PARTICIPANTS AND ANIMAL SUBJECTS IN RESEARCH

Any scientist who conducts research with human participants needs to protect the interest of research subjects by complying with federal, state, and local regulations and with relevant codes established by professional groups. These provisions are designed to ensure that risks to human participants are minimized; that risks are reasonable given the expected benefits; that the participants or their authorized representatives provide informed consent; that the investigator has informed participants of key elements of the study protocol; and that the privacy of participants and the confidentiality of data are maintained.

U.S. federal regulations known as the Common Rule lay out requirements for research involving human participants. The Common Rule specifies which types of research fall under its jurisdiction, the provisions for obtaining informed consent, the procedures needed to gain approval of a project, and the training that researchers must undergo to use human participants in research. Federally funded research involving human participants also must be reviewed and approved by independent committees known as Institutional Review Boards (IRBs).[2] IRBs must approve all research covered by the Common Rule, must conduct regular reviews of such research, and must review and approve proposed changes in ongoing research. IRBs also have the authority to monitor informed consent procedures, gather information on adverse events, and examine conflicts of interest. These policies generally are observed for non-federally funded research as well and are followed in an increasing number of countries around the world.

The involvement of human participants in research can raise difficult questions. Should people be asked to participate in studies

[2]While IRBs are independent, they are local review committees that fall under the jurisdiction of the funded research institution.

Tests on Students

For his dissertation project in psychology, Antonio is studying new approaches to strengthen memory. He can apply these techniques to create interactive Web-based instructional modules. He plans to test these modules with students in a general psychology course for which he is a teaching assistant. He expects that student volunteers who use the modules will subsequently perform better on examinations than other students. He hopes to publish the results in a conference proceedings on research in learning, because he plans to apply for an academic position after he completes the doctorate.

1. Should Antonio seek IRB approval for his research project with human participants?
2. What do students need to be told about Antonio's project? Do they need to give formal informed consent?

that involve some risk to themselves with no prospect of benefits? How should consent provisions be modified for children, prisoners, the mentally ill, the undereducated, or other vulnerable populations? Should the same provisions apply to all research conducted everywhere in the world, or should standards be modified to reflect local conditions? Formal training in bioethics is sometimes needed to analyze the complex moral issues raised by human participation in research, and various bodies, such as the President's Council on Bioethics in the United States, are continuing to study these issues. At a minimum, anyone who engages in research that involves humans must be aware of all relevant regulations and have appropriate training.

The use of animals in research and research training is also subject to regulations and professional codes. The federal Animal Welfare Act seeks "to insure that animals intended for use in research facilities . . . are provided humane care and treatment." The U.S. Public Health Service's *Policy on the Humane Care and Use of Laboratory Ani-*

A Change of Protocol

Hua is doing a postdoctoral fellowship in a laboratory that studies cancer treatment. In the experiment she is overseeing, a cancer-prone strain of mice is allowed to develop visible tumors and then receives experimental drugs to observe the effects on the tumors.

Hua notices that the tumors are interfering with the ability of some of the mice to eat and drink. She also notices that some of the mice are weaker and more emaciated than the others, which she suspects is a consequence of their feeding difficulties. The protocol for the experiment states that the mice will be treated only if they exhibit obvious signs of pain or discomfort.

When she mentions her concerns to another postdoctoral fellow, he suggests not raising the issue with the rest of the lab. The mice will be euthanized as soon as the experiment is over, and their nutritional status probably has little or no effect on the drug treatment. Furthermore, if it proved necessary to change the experimental protocol, the previous work would be invalidated and the Institutional Animal Care and Use Committee would need to be notified.

1. What can Hua do to get more information about the issue?
2. If she decides to raise the issue with others, what is the best way to do so?
3. Should the original protocol have been approved?

mals, which applies to all animal research supported by the National Institutes of Health, requires institutions "to establish and maintain proper measures to ensure the appropriate care and use of all animals involved in research, research training, and biological testing." The policy requires adherence with both the Animal Welfare Act and the *Guide for the Care and Use of Laboratory Animals*, a document prepared and regularly updated by committees under the National Research Council. Guidance for researchers who use animals recommends that researchers carefully consider the "three R's" of animal testing alternatives: reduction in the numbers of animals used, refinement of techniques and procedures to reduce pain and distress, and replacement of conscious living higher animals with insentient material. Anyone who plans to use animals in research or teaching must be familiar with

the relevant regulations and the guide and must receive appropriate training before beginning work.

The Animal Welfare Act and the *Policy on the Humane Care and Use of Laboratory Animals* both require institutions to have Institutional Animal Care and Use Committees (IACUCs), which include experts in the care of animals and members of the public. These committees review and approve research proposals using animals, oversee animal care programs and facilities, and respond to concerns about the use of animals in research. Also, private organizations like the American Association for the Accreditation of Laboratory Animal Care accredit research institutions using existing regulations and the guide as standards.

LABORATORY SAFETY IN RESEARCH

In addition to human participants and animal subjects in research, governmental regulations and professional guidelines cover other aspects of research, including the use of grant funds, the sharing of research results, the handling of hazardous materials, and laboratory safety.

These last two issues are sometimes overlooked in research, but no researcher or scientific discipline is immune from accidents. An estimated half million workers in the United States handle hazardous biological materials every day. A March 2006 explosion at the National Institute of Higher Learning in Chemistry in Mulhouse, France, killed a distinguished researcher and caused $130 million in damage.

Researchers should review information and procedures about safety issues at least once a year. A short checklist of subjects to cover includes:

- appropriate usage of protective equipment and clothing
- safe handling of materials in laboratories
- safe operation of equipment
- safe disposal of materials
- safety management and accountability
- hazard assessment processes
- safe transportation of materials between laboratories
- safe design of facilities
- emergency responses
- safety education of all personnel before entering the laboratory
- applicable government regulations