Navigating the IRB Process

Reprinted here from the Winter 2008 issue of AAHRPP Advance are tips written by J. Michael Oakes, Ph.D., University of Minnesota, to help behavioral and social scientists navigate the Institutional Review Board (IRB) process.

• Know the ethical issues involved and design your study so that it addresses these issues. Familiarize yourself with the Belmont Report and the federal regulations to protect research participants.

• Communication is critical. If you have a question about the review process, talk with your IRB administrator. If you disagree with an IRB decision, review the regulations and then request an in-person meeting to discuss the situation and ways to resolve it.

• Design your study so that it reflects your respect for research participants. Communicate honestly and meaningfully with prospective participants. Use a consent process that is easy for the participants to understand.

• Educate your IRB members about behavioral and social science research. Consider volunteering to serve on the IRB.

• Remember that research with human participants is a privilege, not a right, and that IRBs are peer review groups designed to enhance the quality of research and research protections.

Adverse Biosafety Form

The NIH Guidelines state that Institutional Biosafety Committees (IBCs) should report “any significant problems, violations of the NIH Guidelines, or any significant research-related incidents and illnesses” to NIH OBA within 30 days. The Office of the Vice President for Research also mandates the IBC to “assess the safety of recombinant DNA projects as well as biological and public health risks.”

In order to make these assessments, the IBC needs to be made aware of any serious adverse (i.e., life-threatening) event; any noncompliance with NIH Guidelines; any illness that is dangerous to humans, animals, and/or the environment; or any significant accident with the potential to cause such an illness.

Investigators should inform the IBC of all accidents or adverse events within 48 hours of the occurrence, using the “Adverse Biosafety Event Report Form” found on the IBC website under the Forms tab (www.compliance.iastate.edu/ComplianceWeb/bphcForms.aspx.html).

Examples of reportable incidents include:

• Spills or accidents in BL2 laboratories, resulting in any overt exposures;
• Spills or accidents occurring in BL3 laboratories, resulting in any overt or potential exposures;
• Accidents that lead to personal injury or illness;
• Accidents that lead to a breach of containment (e.g., skin punctures with needles containing rDNA, escape or improper disposition of a transgenic animal, failure to follow animal biosafety containment procedures in an animal care facility);
• Spills of high-risk recombinant materials occurring outside of a biosafety cabinet;
• Failure by an employee to adhere to the containment and biosafety practices articulated in the NIH Guidelines, etc.