



September 28, 2009

The Office of Research (OR) is committed to helping faculty, staff, and students effectively navigate the requirements for conducting ethical and responsible research at Ohio State. I am pleased to announce that OR has recently implemented a number of enhancements designed to facilitate your research, minimize regulatory and administrative burdens, and ensure the safety and welfare of research participants. Information about some of our recent initiatives is provided below.

Flexibility in the Regulations – “Un-checking the Box”

Ohio State recently revised Section 4 of its Federalwide Assurance (FWA) with the U.S. Office for Human Research Protections (OHRP). “Un-checking the box” removes an institution’s pledge to apply the federal regulations (and its subparts) to all human subjects research, irrespective of funding source. This action places sole responsibility for oversight of non-federally funded and unfunded research with the university, rather than with OHRP. This provides the university with flexibility in applying federal human subjects protection requirements to research that is not federally funded. This change does NOT eliminate the ethical requirement for Institutional Review Board (IRB) review of human subjects research at Ohio State.

Institutional Review Board Application Revisions

The “Initial Review of Human Subjects Research” application has been revised to facilitate submission and review of proposed human subjects research. Questions related to research performance sites and risks of research participation have been revised. Appendices describing radiation use and involvement of decisionally-impaired adults in research are now available. Use of the new form will be effective November 1, 2009. For a more complete description of changes to the application, [click here](#).

Informed Consent Template Revisions – Biomedical and Cancer IRBs

The templates for informed consent for medical research and HIPAA research authorization have been revised. New language has been incorporated that further explains the confidentiality of research-related information for participants involved in medical research. The modified templates are posted on the Office of Responsible Research Practices (ORRP) [website](#) and will be required for all new submissions (biomedical or cancer) as well as continuing reviews for applicable studies with open enrollment.

Human Research Protection Program Policies Posted

OSU Human Research Protection Program (HRPP) policies were developed to provide investigators with guidance about federal and university requirements for human subjects research. All HRPP policies have been recently approved by the [IRB Policy Committee \(IPC\)](#) and are now posted on the ORRP website. I encourage you to send feedback and suggestions about HRPP policies as well as the IRB and ORRP to IRBPolicy@osu.edu.

Assistance for Researchers with INDs and IDEs

The College of Medicine Office of Research (COM/OR) provides consultation for all university investigators obtaining investigational new drug applications (INDs) or investigational device exemptions (IDEs) for human subjects research. Cecil Smith, assistant vice president, Research Safety, and Jill Springer, compliance director, College of Medicine, are available to assist investigators with FDA requirements for INDs and IDEs. Documentation of COM/OR review for first-time IND and IDE holders will be required for IRB approval. For assistance, contact the College of Medicine Office of Research at 614-292-2595.

Quality Improvement Activities

A new quality improvement (QI) program to promote and maintain ethical research conduct and compliance with applicable regulations and institutional policies for human subjects protections is being developed. One aspect of this program will involve providing individual assistance and advice to researchers. Protocols selected at random will be visited by a team who will provide guidance on ways to enhance the quality of human subjects protections for the project. For additional information, contact Ellen Patricia in the Office of Responsible Research Practices at 614-688-5556 or patricia.1@osu.edu.

Feedback/Questions

For further information or to provide feedback, please contact Tani Prestage in the Office of Responsible Research Practices at 614-292-0214 or prestage.2@osu.edu.

Janet M. Weisenberger, PhD

Senior Associate Vice President for Research

Office of Research

208 Bricker Hall

190 North Oval Mall

Columbus, OH 43210

Phone: 614-247-4764

weisenberger.21@osu.edu

