May 6, 2010

Dear Research Colleague,

The Food and Drug Administration Amendments Act (FDAAA) of 2007 (PRS and U.S. Public Law 110-85) requires mandatory registration and results reporting for certain clinical trials of drugs, biologics, and devices. You have been identified as an Ohio State investigator with one or more registered clinical trials. If your trial(s) was registered to comply with the FDAAA requirements, please take a few minutes to read the information below.

It is important that you know who the “responsible party” is for registration and reporting of your clinical trial(s). In most cases, the sponsor of the trial will be the responsible party. However, in cases where you, as the principal investigator, are responsible for conducting the trial, have access to and control over the data from the clinical trial, and have the right to publish the results of the clinical trial, the FDAAA allows the sponsor to delegate all registration and reporting responsibilities, making you the “responsible party.” This is very important because failure to meet the reporting requirements (e.g., trial results and adverse events) in a timely manner can result in substantial penalties (i.e., monetary fines) being levied against you as the responsible party.

Additional requirements for responsible parties will become effective later this year. Beginning in September 2010, responsible parties will be required to post lay summaries of the study protocol and the study results as well as a description of the quality assurance procedures used throughout the trial. Further, we anticipate that the FDA will soon amend informed consent regulations for applicable drug, biologic, and device investigations – requiring that a statement be included verifying that the clinical trial information has been or will be submitted to the National Institutes of Health/National Library of Medicine for inclusion in the trial registry databank. We will provide you with updates as we learn more.

Please don’t hesitate to contact Jill Springer in the College of Medicine Office of Research (jill.springer@osumc.edu or 292-4767) for questions, additional guidance, or help in navigating these regulatory requirements. For information specific to your grant/contract, please contact your Sponsored Program Officer.

Sincerely,

Janet M. Weisenberger, PhD
Senior Associate Vice President for Research
Office of Research

Clay Marsh, MD
Senior Associate Vice President for Research
Office of Health Sciences