

For Release at 6 a.m. EST, September 12, 2002

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New Checklist Offered for IRBs & Ethical Committees to Prevent Fraud, Non-Compliance and Human Subject Harm in Clinical Trials

Boston, MA – September 12, 2002 – CenterWatch and Bert Spilker & Associates today announce a collaborative effort to publish a checklist designed to assist research professionals and institutional review boards (IRBs) and ethical committees (ECs) to best ensure the safety and ethical treatment of human subjects enrolled in clinical trials. Clinical research investigators can complete and submit the checklist to their IRBs/ECs along with the study protocol. The checklist is available free of charge to clinical research and IRB/EC professionals and can be downloaded from the CenterWatch web site at www.centerwatch.com/irbchecklist.

“This simple checklist will help protect institutions where the research is conducted, will help protect the IRBs/ECs evaluating the research plan, will help protect the research investigators conducting the research and, most importantly, will help protect the subjects participating in the clinical study,” said Bert Spilker, Ph.D., M.D., an independent consultant in Bethesda, Md., and former Senior Vice President of Scientific and Regulatory Affairs for the Pharmaceutical Research and Manufacturers of America. “The checklist is essentially a fail-safe system that will help prevent problems from ‘falling through the cracks,’ and thus, this approach would ensure that a predetermined set of important information was provided to IRBs or ECs,” he said.

The initial checklist currently contains 14 questions across areas related to financial disclosure, considerations for vulnerable patient populations, the informed consent process, and study protocol design. CenterWatch and Bert Spilker & Associates anticipate that the checklist will be refined and may grow over time as research professionals and IRBs/ECs add to it. Suggestions for additional questions and modifications are encouraged and should be sent to Dr. Spilker directly at bspilker@comcast.net. Updated checklists will be posted periodically on the CenterWatch web site.

Said CenterWatch publisher, Ken Getz, “We decided to offer this checklist free of charge as part of an ongoing commitment to offer practical and useful resources that help improve our global system of human subject protection in clinical research.” Getz is also the co-author of the recently published *Informed Consent*, a guidebook designed to educate study volunteers about the risks and benefits of participating in clinical trials.

About CenterWatch

CenterWatch is a Boston-based information services company that focuses on the clinical trials industry. CenterWatch offers a variety of publications and services for clinical research professionals, IRBs, patients and health consumers. Along with disease-specific reports and profiles of centers that conduct clinical trials, CenterWatch publishes a variety of print and searchable online databases, including directories of several thousand drugs in clinical trials, drugs recently approved by the FDA, and clinical trial results. In addition, the CenterWatch web site lists more than 42,000 ongoing clinical trials seeking volunteers. An estimated eight million people will visit the CenterWatch web site at www.centerwatch.com to view these trial listings. CenterWatch is a part of The Thomson Corporation (NYSE:TOC) and a subsidiary of Thomson Healthcare, publishers of the Physicians Desk Reference®.

For a full description of CenterWatch books and resources that focus on protecting study volunteers in clinical research, please go to www.centerwatch.com or call 1-617-856-5224.

About Bert Spilker & Associates, LLC

Bert Spilker & Associates (BS&A) is a virtual consulting company that provides the services of world class expert consultants to conduct research, work on policy and assist with all aspects of drug development projects. Bert has assembled a group of over 150 independent associates who are available to assist him in most aspects of drug discovery, drug development and strategy setting. BS&A strives to build long-term relationships with clients based on knowledge of his clients’ culture, research, products and services. For more information, please visit www.bertspilker.com.

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