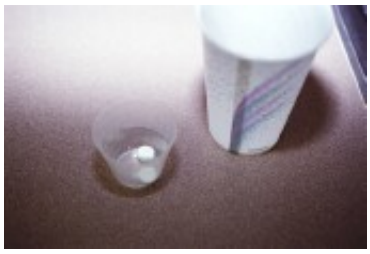
SPIRIT 2013 clinical trial protocol guidelines issued

10 January 2013



A panel of experts, including trial investigators, trial coordinators, and representatives from ethics and regulatory agencies, has developed the Standard Protocol Items: Recommendations for Interventional Trials 2013 guidelines for the minimum content of a clinical trial, according to a statement published online Jan. 8 in the *Annals of Internal Medicine*.

(HealthDay)—A panel of experts, including trial investigators, trial coordinators, and representatives from ethics and regulatory agencies, has developed the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 guidelines for the minimum content of a clinical trial, according to a statement published online Jan. 8 in the *Annals of Internal Medicine*.

Noting that existing guidelines for protocols vary in their scope and recommendation, seldom describe development, and rarely cite stakeholder involvement or evidence to support their recommendations, An-Wen Chan, M.D., D.Phil., of the University of Toronto, and colleagues developed a 33-item SPIRIT checklist to serve as a guideline for the minimum content of a clinical trial protocol. The authors collaborated with 115 key stakeholders, including trial investigators; health care professionals; and representatives from research ethics, industry, and regulatory agencies.

The authors report that the checklist applies to protocols for all clinical trials, with a focus on content, and recommends a full description of the planned trial. The SPIRIT recommendations aim to facilitate drafting of protocols by offering a standard for content. The transparency and completeness of trial protocols would be enhanced by adherence to SPIRIT, benefiting investigators, trial participants, funders, ethics committees, and other relevant parties.

"An extensive range of stakeholders could benefit from widespread use of the SPIRIT 2013 statement and its explanatory paper. Pilot-testing and informal feedback have shown that it is particularly valuable for trial investigators when they draft their protocols," the authors write. "It can also serve as a training tool for new investigators, peer reviewers, and research ethics committee or institutional review board members."

Several authors disclosed financial ties to the pharmaceutical industry.

More information: Abstract
Full Text