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# Merck Statement on Voluntary Submission of Clinical Research Protocols for its Investigational and Approved Products

## Terms:

[Company Statements](#)

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WHITEHOUSE STATION, N.J., July 1, 2011 – Today Merck said the company is strengthening its publications policy as part of its continuing, voluntary commitment to increase transparency about how it conducts business.

Effective July 1, when Merck submits a manuscript on a study of an investigational or an approved medicine or vaccine to a biomedical journal, Merck will include the protocol and statistical analysis plan as part of the submission package. Merck previously supplied this material only upon request. Upon a journal's acceptance of the manuscript for publication, Merck will provide the journal with the opportunity to post on its web site, at journal's discretion, the key sections of the protocol, including the objectives and hypotheses, patient inclusion and exclusion criteria, study design and procedures, efficacy and safety measures, the statistical analysis plan, and any amendments relating to those sections.

To ensure that information proprietary to the company is not made available publicly, Merck will require that certain sections, including the "background" and "rationale" sections of the study protocol be redacted prior to posting. The company will, however, always provide the full, non-redacted protocol to journal editors.

"It's our responsibility to make available important information about our products and the science on which they are based, and do so in an objective, accurate and balanced way," said Michael Rosenblatt, M.D., Merck executive vice president and chief medical officer. "Proactively sharing our study protocols will enhance the exchange of ideas within the scientific and medical community, and ultimately lead to a better understanding of the benefits and risks of our products among health care professionals and patients."

## About Merck's Transparency Efforts

Merck is committed to industry-leading standards of transparency. This update to our publications policy is another significant step the company is taking to respond to stakeholder feedback and public interest across many aspects of our business, from research and development to sales and marketing practices. More information about Merck's transparency initiative is available at [www.merckresponsibility.com](http://www.merckresponsibility.com). Merck's guidelines for publication of clinical trials are available at [www.merck.com/research/discovery-and-development/clinical-development/Merck-Guidelines-for-Publication-of-Clinical-Trials-and-Related-Works.pdf](http://www.merck.com/research/discovery-and-development/clinical-development/Merck-Guidelines-for-Publication-of-Clinical-Trials-and-Related-Works.pdf).

## About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit [www.merck.com](http://www.merck.com).

## Merck Forward-Looking Statement

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Such statements may include, but are not limited to, statements about the benefits of the merger between Merck and Schering-Plough, including future financial and operating results, the combined company's plans, objectives, expectations and intentions and other statements that are not historical facts.

Such statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements.

The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the possibility that the expected synergies from the merger of Merck and Schering-Plough will not be realized, or will not be realized within the expected time period; the impact of pharmaceutical industry regulation and health care legislation; the risk that the businesses will not be integrated successfully; disruption from the merger making it more difficult to maintain business and operational relationships; Merck's ability to accurately predict future market conditions; dependence on the effectiveness of Merck's patents and other protections for innovative products; the risk of new and changing regulation and health policies in the United States and internationally and the exposure to litigation and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2010 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)).

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