Breaking the silence after a study ends

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While an estimated 2.3 million people in the United States take part in clinical trials every year, there currently exists no formal requirement to inform them of study results, an oversight that leaves participants confused, frustrated, and, in some cases, lacking information that may be important to their health. In an article published today in the *Archives of Neurology*, researchers at the University of Rochester Medical Center have proposed a novel and effective approach to disseminate the results of clinical trials to study volunteers.

Industry, government, and academic researchers are dependent upon the willing participation of millions of individuals to fill the estimated 50,000 clinical trials conducted every year that evaluate the safety and efficacy of experimental drugs and medical devices.

Researchers are only required to inform participants in instances when new information arises that may affect their willingness to continue participation. However, neither federal guidelines nor institutional review boards generally require disclosure of results at the conclusion of a study – even if the study is halted. Consequently, many research participants never learn the outcome of studies in which they volunteer.

"Individuals who volunteer to participate in clinical research frequently expose themselves to risks, both known and unknown," said neurologist Ray Dorsey, M.D., the report's author. "Because of their participation, they should be informed of the results of these studies in a timely and personalized manner."

In recent years, there have been several high-profile examples in which information has been either withheld from participants (and the public), participants were not directly informed of study results, or they learned about negative study results indirectly from other sources such as the media. Despite recent federal efforts to mandate communications in instances when the product is approved, researchers are still not required to disclose results in instances when the drug or device has been tested in patients but – because of unfavorable results – abandoned before it is submitted for regulatory approval.

The paper details efforts of researchers to communicate the results of a clinical trial for an experimental drug (ethyl-EPA) for Huntington's disease. The results of the study – which showed no significant difference between the group of patients who received the drug and those who received the placebo – were also published today in the Archives of Neurology. The research was sponsored by the drug's manufacturer, Amarin Neuroscience, and conducted by the Huntington Study Group, an international network of researchers based in Rochester. The 12-month study included 316 adults with Huntington's disease and was conducted at 41 sites in the U.S. and Canada.

Over the course of the trial, the scientists and the sponsor developed a communication plan to inform participants of the study results. The goal was to directly inform participants within 48 hours of the official release of study results; federal securities law requires companies to publicly disclose study results if they have a material financial impact.

The plan included a mix of electronic communication and personal outreach. Information on the results was posted to the study's website and emailed to members of the Huntington's disease community. Additionally, study coordinators called each of the participants directly. Rochester neurologist Ira Shoulson, M.D., the study's principal investigator, and the CEO of Amarin Neuroscience also held a

conference call which was open to all study participants and investigators during which they summarized the study results and then fielded questions.

The researchers surveyed participants after the communication efforts and found that more than half (56%) learned of the results of the study within 48 hours of the initial public release in 2007 by the company – the vast majority (73%) via a telephone call from the study staff. Participants reported a high level of satisfaction with the way results were communicated and had developed a strong understanding of the drugs benefits and risks.

"It is critical that we treat participants as partners in research," said Shoulson. "It is our hope that the commitment that the investigators and sponsor made to communicate the results of the clinical trial in a timely and personalized manner to research participants will set the standard for future clinical trials."

Source: University of Rochester

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