News Release

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Clinical Trials: Do Participants Feel Safe?

Potential participants in clinical trials may not have a clear understanding of the methods used by researchers to ensure the safety of investigational drugs they are given. That finding is the subject of a new paper from the Clinical Trials Transformation Initiative (CTTI) published in *Clinical Trials (http://ctj.sagepub.com/content/early/2013/05/03/1740774513484394)*.

A CTTI collaborative research team headed by Kathryn Flynn, Ph.D., assistant professor in the department of medicine at the Medical College of Wisconsin (MCW), and an investigator in MCW's Center for Patient Care & Outcomes Research, conducted a study to assess study participants' attitudes and beliefs surrounding the safety of investigational drugs and biologics used in clinical trials.

Minimizing the risk to study participants is a key requirement of ethical research; also essential is to respect participants' autonomy by sharing with them important information about the safety of the study as that information becomes available. However, little is known about how much study participants actually understand or what they expect from a safety standpoint.

In this study, the researchers conducted focus groups with former study participants and individuals who had never participated in a clinical trial. Focus group members understood clinical research generally, but they had limited understanding of safety monitoring. They had a wide range of expectations about who should monitor and communicate safety information. While it was not a focus of this study, the focus group members spontaneously expressed concerns about potential financial conflicts of interest in monitoring and reporting serious adverse events.

"In general, we noted unease among potential study participants about their safety, and a desire to have more information communicated from sponsors to investigators and research participants," said Dr. Flynn. "We think that engaging patient advocates in the design of clinical trials might ease some of the concerns expressed in this qualitative study."

"This is the first study that examines what patients expect their clinicians and themselves to be told about safety information during the conduct of a trial," said Nancy Roach, patient advocate and chair of the board of directors for Fight Colorectal Cancer. "The chasm between what

patients think and what really happens is striking. It is critical to understand patient expectations if we hope to actually achieve patient-centered clinical trials."

Co-authors of the paper are Judith M. Kramer, M.D., M.S., Carrie Dombeck, M.A., and Kevin Weinfurt, Ph.D., Duke University School of Medicine;

Established by Duke University and the U.S. Food and Drug Administration in 2007 as a public-private partnership, CTTI comprises more than 60 member organizations working to identify and promote practices that will increase the quality and efficiency of clinical trials.

About the Medical College of Wisconsin

The Medical College of Wisconsin is the state's only private medical school and health sciences graduate school. Founded in 1893, it is dedicated to leadership and excellence in education, patient care, research and service. More than 1,200 students are enrolled in the Medical College's medical school and graduate school programs. A major national research center, it is the largest research institution in the Milwaukee metro area and second largest in Wisconsin. In FY 2010 – 11, faculty received more than $175 million in external support for research, teaching, training and related purposes, of which more than $161 million is for research. This total includes highly competitive research and training awards from the National Institutes of Health (NIH). Annually, College faculty direct or collaborate on more than 2,200 research studies, including clinical trials. Additionally, more than 1,350 physicians provide care in virtually every specialty of medicine for more than 400,000 patients annually.

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