

**FOR IMMEDIATE RELEASE:**

**Conducting Multi-Center Trials: New Recommendations and Tool for Research**

*Durham, North Carolina - January 30, 2013* - A collaborative research team established by the Clinical Trials Transformation Initiative (CTTI) created a new tool and recommendations to improve the efficiency and quality of multi-center clinical trials.

That tool and their recommendations, included in the article "Using Central IRB's for Multicenter Clinical Trials in the United States," are published in the January 30, 2013 issue of the journal *PLOS ONE* (<http://dx.plos.org/10.1371/journal.pone.0054999>).

Multi-center clinical trials are conducted to provide high-quality, statistically sound evidence to answer medical questions. Typically, each participating center submits the study protocol to its individual institutional review board (IRB). The process of multiple reviews can lead to significant study delays; furthermore, patients may be treated differently at different sites as a result, leading to confusion.

A research team headed by Kathryn Flynn, Ph.D., assistant professor of medicine at MCW, recommends that one IRB instead serve as a central IRB to approve and monitor multi-center studies. Historically, the Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP), components of the U.S. Department of Health and Human Services (HHS), have recommended using central IRB's, but some research institutions have expressed reservations.

"To help with this, we developed a guide to support communication between a research institution and a central IRB as they develop an agreement about who will do what for a given trial," said Dr. Flynn. "We hope sponsors in a position to do so require the use of central IRB review for multisite trials, to allow stakeholders to gain experience that may foster greater comfort and trust with that model."

Jerry Menikoff, M.D., J.D., director of OHRP said, "The conduct of today's science increasingly would benefit from the use of a single IRB to review multi-site studies. This issue was a focus of the July 2011 Advance Notice of Proposed Rulemaking, the next steps to which are now under consideration by HHS. The work by the Clinical Trials Transformation Initiative to identify major concerns about the use of this type of IRB review, and to spell out suggestions to address those concerns, could help to smooth the ongoing transition to more centralized review."

Speaking on how the use of centralized IRBs relates to patients, Jeff Allen, PhD, Executive Director of Friends of Cancer Research said, "IRBs play a critical role in protecting clinical trial participants. However, it's important to periodically review the processes used to ensure that research is not being inappropriately slowed. The use of central IRBs can continue to provide the necessary patient protection while streamlining the clinical research process, both of which are essential for the development of promising new therapies."

Co-authors of the paper are Cynthia Hahn, Feinstein Institute for Medical Research; Judith Kramer, Devon Check, Carrie Dombeck and Kevin Weinfurt, Duke University School of Medicine; Jane Perlmutter, Gemini Group; Soo Bang, Celgene Corporation; and Felix Khin-Maung-Gyi, Chesapeake IRB.

Established by Duke University and the FDA as a public-private partnership in 2007, CTTI comprises over 60 member organizations working to identify practices that will improve the quality and efficiency of clinical trials. More information about CTTI and its project is available at [www.ctti-clinicaltrials.org](http://www.ctti-clinicaltrials.org).

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