



MEDIA RELEASE

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CTTI to Support NIH Workgroup in Developing Evaluation Plan for Single IRB Policy

Comprehensive evaluation plan will offer standard approach for assessing whether sIRB review is improving quality and efficiency in multicenter clinical research

Durham, N.C. – Dec. 12, 2018 – The National Institutes of Health (NIH) has selected the Clinical Trials Transformation Initiative (CTTI) to support a workgroup that will develop a comprehensive plan for assessing the NIH's new single institutional review board (sIRB) policy. The policy, which became effective in January, requires U.S. sites participating in nonexempt multicenter human subjects research funded by the NIH to use a sIRB for ethical review, with the goal of improving the quality and efficiency of clinical research.

"For nearly a decade, CTTI has championed the adoption of sIRBs for multicenter clinical trials," said Pamela Tenaerts, executive director at CTTI. "We are excited to use our expertise to craft an evaluation plan for the NIH policy, and to design standard evaluation methods that can be used by academic organizations, research sponsors, and others who are interested in implementing sIRBs."

Sites in multicenter clinical trials have typically relied on their own IRBs to conduct required ethical reviews, often leading to needless repetition across sites. The goal of the NIH's new sIRB policy is to enhance and streamline the review process for multicenter studies so that research can proceed as quickly as possible and research oversight may be improved.

"Use of a sIRB holds great promise for multisite clinical research by reducing unnecessary administrative burdens and systemic inefficiencies while protecting the safety and well-being of research participants," said Jodi Black, deputy director of the NIH's Office of Extramural Research. "Through the work of CTTI and our policy workgroup, NIH will obtain a rigorous and feasible evaluation plan to determine the effectiveness of the sIRB policy for multisite research."

In collaboration with the workgroup, CTTI will review existing sIRB evaluation methods and conduct interviews to develop a framework that describes the goals of the evaluation, defines key concepts, identifies stakeholders, and outlines potential evaluation approaches.

"The new NIH policy and updated Common Rule make it critical to develop a way to evaluate the impact of the sIRB requirement and the ways in which it is being implemented," said Stephen Rosenfeld, IRB chair for Quorum Review, Inc., and chair of the Secretary's Advisory Committee on Human Research Protections for the U.S. Department of Health and Human Services (DHHS). "With its deep familiarity with the promise and challenges of sIRBs, CTTI is

well positioned to help NIH develop an evaluation plan for its own sIRB policy and translate that evaluation methodology so it can be used by others in the clinical research community.”

CTTI has developed a number of recommendations and resources to support sIRB adoption and the NIH referenced CTTI's work in a 2014 draft policy recommending the use of sIRBs. Currently, CTTI is gathering information from sponsors, investigators, IRB members, and research and regulatory coordinators to determine actions that the NIH, the U.S. Food and Drug Administration, and the Office for Human Research Protections can take to help the research community adopt sIRB review.

About the Clinical Trials Transformation Initiative (CTTI)

The Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and the U.S. Food and Drug Administration, seeks to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. Comprised of more than 80 member organizations—representing academia, clinical investigators, government and regulatory agencies, industry, institutional review boards, patient advocacy groups, and other groups—CTTI is transforming the clinical trials landscape by developing evidence-based solutions to clinical research challenges. Many regulatory agencies and organizations have applied CTTI's nearly 20 existing recommendations, and associated resources, to make better clinical trials a reality. Learn more about CTTI projects, recommendations, and resources at www.ctti-clinicaltrials.org.

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