



AN INTERVIEW WITH DR. JEREMY SUGARMAN & DR. KEVIN WEINFURT

Co-chairs of the Regulatory/Ethics Core

Interviewed by Liz Wing, MA, Coordinating Center Staff Writer

We recently interviewed Drs. Jeremy Sugarman and Kevin Weinfurt, co-chairs of the [Regulatory/Ethics Core](#) to ask them to reflect on the first 5 years of the Core as well as on the challenges ahead.

How would you describe the first 5 years of the Regulatory/Ethics Core?

The Core has enabled the work of the NIH Collaboratory by facilitating stakeholder conversations and discussions with key personnel about the appropriate ethical and regulatory pathways to follow in conducting pragmatic clinical trials. For example, we facilitated a series of discussions on the specific ethical/regulatory challenges of each Demonstration Project at the planning phase. These discussions included Demonstration Project principal investigators and some team members, leadership of the Regulatory/Ethics Core, NIH staff, Collaboratory Coordinating Center personnel, and representatives from the Office for Human Research Protections.

During the 5 years, the Core also conducted conceptual and empirical research intended to inform the emerging issues related to the ethical conduct of pragmatic clinical trials. This work has led to the creation of a substantial body of scholarship contributing to the ongoing policy and ethics debates about pragmatic clinical trials.

What accomplishments of your Core are you most proud of?

We're pleased with the depth and breadth of the Core's scholarship, which in addition to scholarship produced by individual members includes:

- An initial publication delineating complexities that must be unraveled to enable vital research while also protecting the rights, interests, and welfare of research participants ([JAMA 2014](#)).
- An article describing results from a workshop on the ethical and regulatory issues of pragmatic cluster-randomized trials ([Clin Trials 2015](#)).
- A [special series of Clinical Trials](#) (October 2015) devoted to a deeper exploration of 11 key regulatory and ethical challenges of PCTs with examples from each of the Demonstration Projects.

Core members also partnered with researchers outside the NIH Collaboratory to develop a [special supplement](#) (2016) of *American Journal of Bioethics: Empirical Bioethics* documenting various topics in the ethics of research in usual care settings.

What do you see as the biggest impact of your Core to date?

When the Core began, the regulatory/ethical landscape for pragmatic clinical trials was not well defined. The Core's work has contributed to both mapping and navigating the emerging landscape, and has enabled the Demonstration Projects to move forward in ways that satisfied ethical and regulatory criteria.

The Core has also been instrumental in encouraging a spirit of curiosity and collaboration among stakeholders to actively resolve the regulatory and ethical challenges of conducting pragmatic clinical trials.

“The Core has facilitated key discussions about the appropriate ethical and regulatory pathways to follow in conducting pragmatic clinical research.”

– *Drs. Sugarman and Weinfurt*

What work is important to tackle going forward?

The Core will assist the new Collaboratory Demonstration Projects in handling their regulatory and ethical challenges. We'll be keeping a close eye on the emerging regulatory space with respect to human subject protections in case we need to modify our approaches. And we'll be looking for opportunities to empirically evaluate the approaches we've developed in real-time in pragmatic clinical trials.

