Behavioral clinical trials: Considerations for design and conduct using the new NIH study protocol template
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OBJECTIVES: SPECIFIC AIMS: (1) To discuss key differences of behavioral clinical trials from trials involving drugs, devices, and biologics and (2) to discuss NIH efforts to provide a study protocol template for use by investigators conducting behavioral clinical trials. METHODS: STUDY POPULATION: A working group was convened by NIH to refine the commonly used protocol template required for investigators conducting Phase 2 or 3 NIH-funded clinical trials. The committee met by phone regularly for 4 months to review, discuss, and refine each section of the template as needed to include aspects relevant to behavioral trials. RESULTS: ANTICIPATED RESULTS: The behavioral trial protocol template draft has been created and is being further modified by feedback from the research community. DISCUSSION: SIGNIFICANCE OF IMPACT: Use of the NIH behavioral trial protocol template is expected to enhance the quality of any behavioral study, because the template and supporting materials were developed with the unique aspects of behavioral research in mind.

Building the next generation of translational researchers in health disparities
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OBJECTIVES: SPECIFIC AIMS: Translational research involves researchers’ teams working together to address health issues. However, successful translational researchers in health disparities require a set of competencies and skills. In order to increase the number of new minority investigators in translational research focused on health disparities, the Hispanics-in-Research Collaborative (SoHM) and the Puerto Rico Clinical and Translational Research Consortium designed and implemented a webinar series “Fostering the Next Generation of Researchers in Health Disparities.”

METHODS: STUDY POPULATION: From March 31 to July 14, 2017, this webinar series offered the theoretical perspectives of health disparities, research methodology specific to its study, and intervention strategies to address health disparities in communities through minority investigators. National and local interdisciplinary experts were the presenters. Participants’ experience and impact were assessed through a self-administered questionnaire. RESULTS: ANTICIPATED RESULTS: A total of 78 minority investigators participated in this webinar. Overall, participants indicated that the webinar improved their knowledge and skills about health disparities research.

DISCUSSION: SIGNIFICANCE OF IMPACT: Results guide the programs actions plans to enhance and support the translational researchers’ capacity. Diverse capacity building initiatives including peer-to-peer education, online course, tailored coaching, and other interventions have been designed to address researchers’ needs. This webinar was a pathway to build the next generation of translational researchers in health disparities.