

NIH SIREN Emergency Trials Network

Clinical Coordinating Center University of Michigan Lobby H, Suite H3100 24 Frank Lloyd Wright Drive Ann Arbor, MI 48106

734-232-2142

Clinical Coordinating Center University of Michigan

> William G. Barsan, MD Robert Silbergleit, MD Clifton Callaway, MD, PhD Principal Investigators Will Meurer, MD, MS Fred Korley, MD, PhD Adrianne Haggins, MD, MS

Valerie Stevenson, BAS, CCRP Administrative Director

Data Coordinating Center Medical University of South Carolina

> Valerie Durkalski, PhD Sharon Yeatts, PhD

Principal Investigators

National Institutes of Health

Jeremy Brown, MD Director, Office of Emergency Care Research Program Director, NINDS

Carolina Mendoza-Puccini, MD Robin Conwit, MD Scott Janis, PhD Program Directors NINDS

George Sopko, MD, MPH Program Director, NHLBI Michelle Culp, BSN, MPH Program Director NCATS

Award Hub Contact Principal Investigators

Opeolu Adeoye, MD University of Cincinnati Tom Aufderheide, MD Medical College of Wisconsin

Michelle Biros, MD, MS University of Minnesota

Clifton Callaway, MD, PhD University of Pittsburgh

Mohamud Daya, MD, MS Oregon Health & Science University

Nina Gentile, MD Temple University Joshua Goldstein, MD, PhD

Massachusetts General Hospital Peter Kudenchuk, MD

University of California, San Francisco Brian O'Neil, , MD

Wayne State University Sidney Starkman, MD University of California, Los Angeles David Wright, MD Emory University BOOST-3 Protocol Revision: BOOST-3 Study Protocol Version 3

This revision of the BOOST-3 clinical trial protocol does not involve any substantive changes to the research or the safety or experiences of human subjects. Rather this new version is just intended to clarify several items in the protocol about which we have been answering questions and providing additional training since the protocol was initiated. It also corrects some minor mistakes, and numerous typographical, formatting, and grammatical errors that we have accumulated over time. Important clarifications in the eligibility criteria include a more specific description of how to implement the exclusion for poor bilateral pupillary response, and correction of the intended PF ratio threshold for exclusion. Both of these changes in the protocol simply clarify or correct the protocol to reconcile it with, and reinforce, the study team training that has already been used since the start of the trial. Extensive clarifications in the tier treatment descriptions better reflect the wording and descriptions of the clinical interventions as used in practice, but do not actually alter the treatments recommended to be used to respond to ICP or brain tissue hypoxia events.

Raumbray Quarte

Ramon Diaz-Arrastia, MD, PhD BOOST-3 Procotol PI

MD, FECH, FNCS

Lori Shutter, MD BOOST-3 Clinical PI

William Barn

William Barsan, MD BOOST-3 Contact PI, SIREN CCC PI

Sharen D. Yeatts

Sharon Yeatts, PhD BOOST-3 Biostatistical PI, SIREN DCC PI