MULTIPLE PD/PI LEADERSHIP PLAN

[redacted], MD and [redacted], MMED, PhD, will provide oversight of the entire Program and development and implementation of all policies, procedures and processes. In these roles, Dr. [redacted] and Dr.[redacted] will be responsible for the implementation of the scientific agenda, the leadership Plan, and the specific aims and will ensure that systems are in place to guarantee institutional compliance with US and [Country redacted] laws, and DHHS and NIH policies including biosafety, human subjects research, data and facilities.

Specifically, Dr. [redacted] will have primary responsibility for study clinical activities and data management at the [redacted] site, as he has substantial expertise in the management of critically ill children with severe [redacted] in the resource limited [redacted] setting. This will include study recruitment, informed consent, enrollment, clinical care, and follow-up. He will work with Dr. [redacted], who will be in charge of [redacted] testing, to make sure this is done accurately, and will supervise the data management team on site. Dr. [redacted] will have primary responsibility for the extensive lab testing, given his expertise in [redacted] pathogenesis and lab testing of biomarkers. He will work closely with Dr. [redacted], director of the [redacted] lab, who will be in charge of this testing on site, to ensure validity, accuracy, reproducibility and rigor of lab testing. Dr. [redacted] will also be responsible for working with Drs. [redacted], [redacted], [redacted] and [redacted] to supervise transport and set-up of the [redacted], EEG and [redacted] equipment, and with these co-investigators and Drs. [redacted], [redacted] and [redacted] on site to conduct training of on-site personnel in the skills needed in each area to do accurate and complete testing, upload results appropriately, and troubleshoot when problems or errors occur. Drs. [redacted] and [redacted] will together be responsible for reviewing, analyzing and interpreting result with Drs. [redacted] and [redacted], as well as with the individual experts in specific areas of testing (e.g., EEG results with Drs. [redacted] and [redacted]). Drs. [redacted] and [redacted] will interact weekly (or more often as needed) by email and monthly by Zoom call or in person in [Country redacted] or the US, to supervise overall conduct of the study, as their overlapping expertise will be important for all Aims. Dr. [redacted] will serve as contact PI and will assume fiscal and administrative management including maintaining communication among PIs and key personnel through monthly meetings. He will be responsible for communication with NIH and submission of annual reports. Publication authorship will be based on the relative scientific contributions of the PIs and key personnel.