Dear Site PI,

I am very pleased that your PICU site will participate in our "CDR Implementation Trial." Here are some of the more important things you should know.

(1) For more complete information about your responsibilities in this study, visit our PediBIRN website at www.pedibirn.com. More specifically, read the document titled "NIH Proposal."

(2) As overall Study PI, I am highly motivated to see this "CDR Implementation Trial" executed smoothly and effectively. To that end, you should feel completely free to contact me at any time, about anything related to this trial. My cell phone number is (703) 674-8989, and my email address is kphymel@gmail.com.

(3) Please submit your IRB application at your earliest possible convenience. You can use my approved IRB application as a template for your own. If helpful, I will draft your IRB application for you. Just send me your IRB application template.

(4) Please work with your Research Coordinator to devise a plan to [1] ensure full compliance with all required study procedures and methods, [2] monitor PICU admission logs carefully, [3] capture complete data on *every* eligible patient, and [4] respond promptly to "data queries" or other requests from the Study PI.

(5) During the trial, at the beginning of every month, you will be asked to report the number of eligible patients admitted to your PICU over the preceding month. To minimize sampling bias, data from participating sites that fail to capture complete data regarding at least 90% of their eligible patients will be excluded from all analyses.

(6) Our network Governance Agreement insures that the scientific collaboration between the trial participants will be one in which all are invested for the common good. For complete details, visit www.pedibirn.com.

(7) Participating sites have been randomly selected to participate as intervention sites (n=4) or control sites (n=4). Our four *intervention* sites are Primary Children's Hospital, Children's Mercy Hospital, Connecticut Children's Medical Center, and Children's Hospital of Richmond. Our four *control* sites are Texas Children's Hospital, University of Texas Health Sciences Center at San Antonio, Wesley Medical Center, and Children's Hospital of Omaha.

(8) We estimate that all sites will admit less than four eligible patients per month, and that complete data capture will require only a minimal commitment of time. Study participants at our four intervention sites will capture more data, have additional responsibilities, and have longer participation in this trial than participants at our control sites. For more information, visit www.pedibirn.com.

(9) Data will be captured in an access controlled, REDCap data registry. At the four intervention sites, you will capture complete data on forms 0 through 5 every time an eligible patient is admitted to your PICU. At the four control sites, you will only complete (and have access to) data forms 2, 4 and 5.

(10) At the four intervention sites, PICU providers and child abuse consultants—who are the actual subjects of this trial—will be required to provide written informed consent for study participation. At all eight sites, we will seek a waiver of *parental* consenting requirements.

(11) Please review data forms 2, 4 and 5 to verify that all of the *patient-related* data that you will capture is data captured routinely as your "standard of care."

(12) To gain familiarity with online data capture, I request that you and/or your Research Coordinator enter complete data regarding three or more fictitious patients into the REDCap data registry at your earliest possible convenience. This will also allow us to "test drive" the registry. The link to the registry can be found at www.pedibirn.com.

(13) Both you and your Research Coordinator will need login credentials to access this registry. Your local PICU and child abuse docs will not likely need to do so. To establish login credentials, visit our website at www.pedibirn.com.

(14) Prior to launch of the trial, I will arrange a mutually agreeable time to visit each site personally to review the protocol, answer your questions, spend time with your clinician-investigators (if desired), and assure your complete understanding of study protocol, methods and procedures.

(15) Finally, and most importantly, please know with absolute certainty that I fully recognize how very busy your PICU and child abuse doctors are, and will do my very best to minimize the impact of trial participation on their clinical duties. To that end, I hope and expect that you will help me find ways for us to "work smarter, not harder" as we execute this study.

By your signatures below, please certify that…

(1) You have reviewed the complete contents of the PediBIRN website,
(2) You agree to abide by the terms of this Letter of Agreement and our network Governance Agreement,
(3) You will adhere to the study methodology detailed in the "NIH proposal" and in the template for IRB application,
(4) You will respond expeditiously to all "data queries" and other requests from the Study PI,
(5) All of the patient-related data to be captured in this "CDR Implementation Trial" are data routinely captured while providing "standard of care" treatment to your acutely head-injured children less than 3 years of age,
(6) You have entered complete test data regarding three or more fictitious patients into the REDCap database; and…
(7) You accept the terms of this voluntary commitment to participate actively in the "CDR Implementation Trial."

To affirm your understanding, please sign, print, scan and return this letter to me (in PDF format) via email (kphymel@gmail.com).

_____ Site Principal Investigator

_____ Site Research Coordinator

_____ Participating Site

_____ Date