

INCLUSION OF CHILDREN – INFORMATICS AND ANALYTICS CORE

Children age 6 and older will be included in the study cohort, as their brains will have reached a sufficient level of development by that age to likely be influenced by the identical parameters affecting epileptogenesis as are adults. Said conversely, we have no targeted evidence that would lead us to exclude youths from this effort at this time because of chronological age alone. We recognize, however, that brain maturation continues well into the mid-twenties and thus will devote close attention in the evaluation of all under-aged participants to ensure that they do not represent a physiologically or medically different class of injury or post-injury trajectories than the remainder of the enrolled cohort. Recruitment and assessment of children will occur only at the collaborating institution in which all the participating professionals involved are full-time critical care pediatric specialists. As is true for all studies involving underage participants, consent to participate will be carefully discussed with and approved by the child's family and legally authorized representative in full accordance with all applicable state regulations.

Following 45 CFR §46.406, we acknowledge that this research may involve greater than minimal risk and may have no prospect of direct benefit to individual subjects, but it is likely to yield generalizable knowledge about the subject's disorder or condition. Subject to approval by the relevant institutional IRBs, we will make clear to the child's family and legally authorized representative that:

- (a) The risk of participation in this study represents a minor increase over minimal risk,
- (b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations, and
- (c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition, which is of vital importance for the understanding or amelioration of the subjects' disorder or condition.

To accomplish this, we will craft all informed consent activity and text with

- d) adequate provisions for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408.