

INCLUSION OF CHILDREN – PROJECT 3 – BIOMARKERS OF HUMAN EPILEPTOGENESIS AFTER TRAUMATIC BRAIN INJURY

This Project will include children who have reached age 6 and above at time of enrollment. At least one collaborating institution sees exclusively pediatric trauma and was selected for this reason. The recruitment of children for this Project will not follow any exact quota system but is anticipated to reflect the general distribution of ages as shown in large-scale epidemiologic studies of traumatic injury and hospitalization. While these reports differ in their estimates due to differences across countries and states as well as substantial methodological differences, we estimate that from 7 to 16% of the overall study enrollment will be of persons aged 6 through 18.

Even while the brain is undergoing substantial development all evidence to date indicates that the child's brain is equally as vulnerable to epileptogenesis as the adult brain, and thus there are limited compelling reasons to exclude children. The lower age limit of 6 was selected due to inherent barriers in the MR and rsfMRI scanning protocols (a major task within Project 3) as they require the participant, if awake, to be sufficiently responsive to verbal commands; experience indicates that verbal development prior to age 6 is likely insufficient for such procedures. In all instances involving minors, strict adherence will be made to all applicable state and federal regulations (specifically Subpart D of 45 CFR 46 and 21 CFR 50) for children's involvement in research and for surrogate and child consenting, and to further local requirements as may be directed by the institutional review boards. Eligibility of the LAR will follow the exact specifications for such eligibility, which vary on a state-by-state basis; these are outlined at:

http://www.americanbar.org/content/dam/aba/administrative/law_aging/2014_default_surrogate_consent_statutes.authcheckdam.pdf.

In addition to the signed consent itself, all discussions about study participation and consent with an eligible child and parents or LARs will be documented in full and kept as part of the study's permanent record.

Though states differ, in California the consenting process for children is premised on recognition that children do not have the legal capacity to "consent" to participate in research. They will be involved in the process if they are able to "assent" by having a study explained to them and/or by reading a simple form about the study, and then giving their verbal choice about whether they want to participate or not. They may also provide a written assent if they are older. The assent process takes into account the child's experience and level of understanding, assures an element of cooperation and a feeling of inclusion on the part of the child, and also illustrates the investigator's respect for the rights and dignity of the child in the context of research. We note that, in California, if there are two parents available to give permission but they disagree about allowing their child to participate in the study, the child may not be enrolled unless that disagreement can be resolved. State-by-state differences in this topic will be observed in full.