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**Children’s Addendum for Multi-Site Studies**

**Please complete each section accurately and completely in order to provide CHOA IRB with the relevant information to assess risk-benefit ratio specific to CHOA.**

**CHILDREN'S PRINICPAL INVESTIGATOR:**

**PROTOCOL TITLE:**

**VERSION DATE:**

**NUMBER OF SUBJECTS TO BE ENROLLED AT CHILDREN’S-**

**SUMMARY OF STUDY PROCEDURES -**

**INCLUSION/EXCLUSION CRITERIA -**

**METHOD OF RECRUITMENT-** *(if different from main protocol)*

**CONSENT PROCEDURES-** *Explain in detail how, when and where and by whom consent is obtained, and the timing of the consent at Children’s.*

**DATA SAFETY AND MONITORING/ DATA SHARING-** *Be specific on how data will be handled at Children’s, as well as how data will be transferred to sponsor or primary study site. For studies not covered by a clinical trial agreement, please include the following language required by Business Intelligence for data use agreements: “Data will be stored on each users secure servers and not downloaded to external devices, including laptops. The information, even if de-identified, will be destroyed at the expiration of the project.”*

**PRIVACY AND CONFIDENTIALITY-***Describe methods used at Children's to protect the privacy of subjects and maintain confidentiality of data collected.*

**CHILDREN’S DEPARTMENTS USED-**