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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:**

**ADDENDUM VERSION DATE:**

**DATE RANGE OF CHARTS TO BE REVIEWED-**

**SUMMARY OF STUDY PROCEDURES -**

**INCLUSION/EXCLUSION CRITERIA -**

**METHOD OF RECRUITMENT-** *(Please be sure to include a list of data to be pulled from charts.)*

**CONSENT PROCEDURES-** *Explain in detail how, when and where and by whom consent is obtained, and the timing of the consent at Children’s. Please be sure to include consent and HIPAA waivers if applicable.*

**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-**