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

***For Use when a Primary or Main Site Protocol from a Sponsor or Lead Site Is Provided to the Study Team.***

**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.**

1. **CHILDREN'S PRINICPAL INVESTIGATOR:**
2. **PROTOCOL TITLE:**
3. **VERSION DATE:**
4. **NUMBER OF SUBJECTS TO BE ENROLLED AT CHILDREN’S or DATE RANGE FOR CHART REVIEWS-**
5. **DO ANY STUDY PROCEDURES SPECIFIC TO CHILDREN’S DIFFER FROM THE MAIN PROTOCOL?**

Yes *(Please complete section 6)*

No *(Skip to section 7)*

1. **SUMMARY OF STUDY PROCEDURES -**
2. **DOES INCLUSION/EXCLUSION CRITERIA SPECIFIC TO CHILDREN’S DIFFER FROM THE MAIN PROTOCOL?**

Yes *(Please complete section 8)*

No *(Skip to section 9)*

1. **INCLUSION/EXCLUSION CRITERIA -**
2. **WILL SPANISH-SPEAKING SUBJECTS BE INCLUDED IN THIS STUDY?**

Yes

No

1. **HOW DOES THE STUDY TEAM PLAN TO CONSENT SPANISH-SPEAKING SUBJECTS?**

Fully Translated Consent Documents

Spanish Short Form

N/A

1. **DO RECRUITMENT PROCEDURES SPECIFIC TO CHILDREN’S DIFFER FROM THE MAIN PROTOCOL?**

Yes *(Please complete section 12)*

No *(Skip to section 13)*

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

1. **WHAT WAIVERS ARE BEING REQUESTED?**

Waiver of Consent

Waiver of Documentation of Consent/Alteration of HIPAA

Partial HIPAA Waiver

Full HIPAA Waiver

Not Applicable

1. **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.” Also state whether or not the only data used for this study is Children’s data. If data from other institutions will be used, specify those locations as well (includes Emory Healthcare data).*

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

1. **CHILDREN’S DEPARTMENTS USED-**