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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 *(Please complete section 10)*

No *(Skip to section 11)*

1. **HOW DOES THE STUDY TEAM PLAN TO CONSENT SPANISH-SPEAKING SUBJECTS? -**
2. **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. **IF A WAIVER IF BEING REQUESTED, PLEASE PROVIDE JUSTIFICATION FOR THE WAIVER.**

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.”*

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-**