# Franciscan Children’s

**Continuing Review to Institutional Review Board**

IRB number and Study Title:

**Principal and Co-Investigator(s):**

**IRB Approval Date:** / /

**Continuing Review Due Date:** / /

**Date of Review submission:** / /\_\_

**Requesting Continuation? Yes \_\_\_\_\_ No \_\_\_\_\_**

**Requesting Continuation and changes? Yes \_\_\_\_\_ No \_\_\_\_\_**

**Notification of study termination? Yes \_\_\_\_\_ No \_\_\_\_\_**

**Progress to Date:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Initiated** | **Ongoing** | **Complete** |
| Participant Recruitment |  |  |  |
| Informed Consent/Assent |  |  |  |
| Data Collection |  |  |  |
| Data Analysis |  |  |  |
| **Report of Findings/Dissemination** |  |  |  |

**Study Summary and Progress to Date**

This continuing review should provide the IRB with a description of the progress of the study over the past approval period, and the study’s current status. In addition to stating the study purpose and methods, please address the following:

-progress towards achieving research objectives (including # of participants recruited and consented; a summary of any withdrawal of participants, and/or any complaints about the research from participants or others since the last IRB review);

-If appropriate, please provide a brief summary of any amendments to the research approved by the IRB since the IRB’s initial review or the last continuing review;

- any new and relevant information, published or unpublished, since the last IRB review (including information about risks associated with the research);

-barriers to meeting research objectives and strategies to overcome barriers;

-analysis of any unanticipated problems or delays and previously reported adverse events (e.g. injury to participant, data security breach); and

-dissemination activities to date.

**Personnel**

Are you requesting approval for a change in study personnel?

New investigator \_\_\_\_\_ New study staff \_\_\_\_\_

Comments:

**Reliance**

Does this study involve additional institutions to Franciscan Children’s Hospital?

Yes \_\_\_\_\_ No \_\_\_\_\_\_

Is there a current Reliance Agreement in place?

Yes \_\_\_\_\_ No \_\_\_\_\_\_

Comments:

**Conflict of Interest**

Do any of the investigators have a financial interest (royalty, equity or consulting) in the study?

Yes \_\_\_\_\_\_ (previously reported to IRB)

Yes \_\_\_\_\_\_ (New: please describe):

No \_\_\_\_\_\_\_

Comments:

**Funder(s) and Status**

Support Pending \_\_\_\_\_ Support Awarded \_\_\_\_\_\_ No funding \_\_\_\_\_Funding has ended\_\_\_\_\_

Funding Source and amount:

Comments:

**Additional Information/Comments:**

**Questions?**

IRB Administrator: SaiSankeerth.Madakasira@franciscanchildrens.org