**Franciscan Children’s**

**Institutional Review Board (IRB)**

**Instructions for Submitting an** **Application to Conduct Research at Franciscan**

-All research studies must be reviewed and approved by the IRB ***prior to project initiation***.

-A copy of the blank IRB Application should be saved from the Franciscan public (‘p’) drive or the internal employee website [https://thefran.franciscanchildrens.org/content/page/IRB templates](https://thefran.franciscanchildrens.org/content/page/IRB%20template)

completed and signed by the research study’s principal investigator (PI) and Department Director and be submitted to the IRB Administrator via email (SaiSankeerth.Madakasira@franciscanchildrens.org) along with **all** supporting documentation (e.g. Informed Consent Forms, CITI training certificates for All Study (research) personnel & CV/Resumes, Surveys/Questionnaires, all Participant [patient] facing material).

-The IRB is scheduled to meet once per month (1st week of every month) and applications must be received **2 weeks prior** to being placed on the following month’s agenda. A list of monthly IRB meeting dates and respective document deadlines is included on the IRB tab of the Fran intranet.

-Once the IRB has reviewed the submitted application, the PI will be notified via email of the application’s disposition as follows:

* Full Approval;
* Approval with Limited Modifications (requires revisions and/or clarifications **before** beginning work with participants;
* Deferred for Response (requires revisions **prior** to beginning any work on the research project);
* Deferred (protocol insufficient, needs to be rewritten prior to resubmission) or
* Disapproved (safety or other concerns that cannot be overcome).

**Progress Reports to the IRB**

-Upon review and approval of a new application, the study PI will be notified of the interval in which the IRB requires a continuing review report. Continuing Reviews are due at a minimum of once per year.

-A suggested Continuing Review template can be found on the public ‘p’ drive as well as on the internal employee website [https://thefran.franciscanchildrens.org/content/page/IRB templates](https://thefran.franciscanchildrens.org/content/page/IRB%20template)

**Questions?**

IRB Administrator: SaiSankeerth.Madakasira@franciscanchildrens.org