**Instructions for Using the Study Start-Up Management Tools**

The overarching goal of these materials is to help sites efficiently assess study start up materials and help shorten the duration of time and create efficiency to align with I-ACT for Children’s mission.

* Core to I-ACT for Children’s mission is to accelerate and enhance the quality of pediatric clinical trials
* To help achieve that mission, we have a commitment to ensure that I-ACT for Children network sites are distinguished by their ability to streamline trial processes that can otherwise slow trials down.
* These tools are designed to help you develop and negotiate trial budgets with sponsors as quickly and efficiently as possible.
* The tools are based on budgeting best practices from several of our network sites.
* Meanwhile, we are working with our industry Members to develop standardized budget templates and will use these tools to inform those templates.

We have developed the following three tools:

1. Rate Sheet: Start-Up, Management and Close-Out Fees
2. Justification Start-Up Cost Tool (Word version)
3. Justification Start-Up Cost Tool (Excel version)

How to use them:

* + - 1. Please review and modify to capture your site-specific start-up, invoiceable and close-out fees.
			2. You can use one, two or all three tools; it depends on your process and what works best at your site.
			3. Some sites find that budget negotiation for start-up, invoiceable and close-out fees is smoother if they bundle all fees together, so that is captured at the end of the rate sheet.

Some sponsors, however, require detailed justification for site fees. The justification start-up cost tool is designed to help you save time by providing those justification details along with your proposed budget.

Please contact Kim Jennings kim.jennings@iactc.org with any questions.