Stanley Manne
Children's Research Institute™

DATE: 31 August 2021

TO: Industry Sponsors

FROM: Kristine Martens-Ackeret, JD, Associate Director, Office of Sponsored Programs

RE: Industry Sponsored Research Start-up

Stanley Manne Children's Research Institute (SMCRI) is committed to conducting clinical studies with efficient clinical trial activation timelines. SMCRI acts as a liaison assisting sponsors and contract research organizations to identify, coordinate and/or facilitate pediatric clinical studies conducted at Ann & Robert H. Lurie Children's Hospital of Chicago.

SMCRI is focused on improving study start-up. To assist us in our efforts to decrease study activation timelines we require receipt of all required study start-up documents to initiate your study intake. Our goal is to have a finalized contract & budget negotiation complete within 130 days, with initial feedback provided in about 90 days. Start-up documents required include:

1. Final Study Protocol
2. Informed Consent Form Templates
3. Draft Clinical Trial Agreement
4. Budget (Sponsor's initial offer)
5. Investigator Brochure & Manuals (Lab, Imaging, Pharmacy, etc.)
   Note: Draft versions of the IB and applicable manuals are required at a minimum to begin our intake process. If providing draft, they must include sufficient detail for our ancillary service area to conduct their feasibility assessment and budget estimates. Significant changes to these documents require additional review and will impact the budget and timeline to study activation.

Following local protocol implementation planning, ancillary service evaluation, and scientific reviews, all processes (IRB, budgeting, contracting) move forward concurrently. Resources regarding IRB policies, meeting dates & roster may be found on our website. Please contact the Clinical Trials Office at CRS@luriechildrens.org with any questions. We look forward to your collaboration.

Kind Regards,

Kristine Martens-Ackeret, JD
Associate Director, Office of Sponsored Programs