

Stanley Manne Children's Research Institute™

DATE: 12 May 2022
TO: Industry Sponsors
FROM: Ashley Hoambrecker
RE: Industry Sponsored Research Start-up

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

The research institute 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 (IB) & Manuals (Lab, Imaging, Pharmacy, etc.)

Note: At a minimum, draft versions of the IB and applicable manuals are required to begin our intake process. If providing drafts, they must include sufficient detail for our ancillary service areas 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 Office of Clinical and Community Trials at OCCT@luriechildrens.org with any questions. We look forward to our collaboration.

Sincerely,



Ashley Hoambrecker
Director of Operations
Office of Clinical and Community Trials

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