

Le Bonheur Children's Hospital is host to numerous research activities being conducted under the auspices of the Children's Foundation Research Institute (CFRI). The CFRI functions as the "glue" that holds the research enterprise together and moves it forward in a coordinated and efficient manner. At its helm are Scientific Director Dennis Black, MD, and Director, Christopher Smith. The CFRI provides investigators with expertise, guidance, and resources to conduct research.

Things to KNOW and DO before starting a Research Study at Le Bonheur Children's Hospital:

- ✓ UTHSC IRB is the primary IRB for all pediatric protocols conducted at Le Bonheur Children's Hospital.
- ✓ The Clinical Trials Advisory Committee (CTAC) must review any PI initiated study that would qualify for an IRB Full Board review. It is advised that you review your study summary with the CTAC prior to the IRB submission. Please contact, Kerry Moore, Manager of Regulatory and Compliance, to schedule your presentation.
- ✓ If your study is initiated by a commercial sponsor, CFRI will manage the contract (CDA and CTA) and all financial issues related to the study. Please contact CFRI Director of Grant Administration/Contract Development, Venessa Spearman.
- ✓ If your study involves sharing medical information (PHI or a limited data set) with other institutions, a Data Use Agreement should be signed between CFRI and the Institution receiving the data. Please contact Venessa Spearman.
- ✓ Should you need any help completing your IRB submission for PI initiated studies, the CFRI IRB Coordinator will be glad to help you.
- ✓ All personnel involved in the study should complete the credentialing process with Methodist Le Bonheur Healthcare. Please contact Kerry Moore for requirements and necessary forms.
- ✓ You must contact any hospital departments that are to perform procedures or tests for your study and request signed authorization from the department director(s). Please contact Kerry Moore to obtain the required form that you will need to complete.
- ✓ Participants in Le Bonheur research studies must be under 45 years of age. Any study that involves participants between 22 and 44 years of age must have written approval from each Hospital Division Chief where study-related services would be performed. Once the approval is given, research requests must be presented and approved by the Clinical Trials Advisory Committee. Please contact Kerry Moore for more information.

Meet the CFRI Team; they are here to help you with the process:

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