CRC Policy for Working on CHB Studies Regulated by the FDA

The Clinical Research Center provides assistance with project coordination, data management, and statistics for a variety of CHB investigator-initiated research studies. For those studies that are FDA regulated, the CHB Principal Investigator (PI) must ensure the following before the Clinical Research Center can agree to provide these services to the investigator:

- CHB PI agrees to take responsibility for ensuring compliance with all regulatory requirements and adherence to the study protocol by providing consistent leadership and oversight of the study's progress and the research staff;
- Adequate resources are available as determined by the CRC leadership team to implement the study according to the IRB approved study protocol and industry partner requirements, where relevant;
- CRC staff with appropriate expertise and experience are available to work on the project at the time of funding; and
- There is no conflict of interest with CRC personnel working on the project as defined by the Children's Hospital CCI policies and procedures.

The CRC will require having a study protocol that has been approved by the IND or IDE holder, the academic department of the CHB PI, and the Children's CCI. The CRC will also require the CHB PI provide the data collection and reporting requirements of the study in advance of our preparation of a budget or determination of staffing needs and availability. Where relevant, these requirements should also be included in the Clinical Trials Agreement and reviewed by CRC before it is signed by the CHB PI. It should be noted that the CRC itself does not assume responsibility of a CRO as defined in §312.52 and cannot commit to provide data or results that would be considered acceptable for an NDA submission to the FDA.