**Department of Pediatrics Administrative Policy for Industry-Sponsored Studies**

4% Departmental Fee

Under Dr. Cohen’s direction, the Department of Pediatrics (DOP) instituted a 4% DOP Fee in July of 2016 for all industry-sponsored research to help support the department’s research infrastructure. The 4% fee is based on a percentage of start-up costs, as well as the anticipated number of subjects. It is built into budgets as a study cost (like start-up or IRB fees), so it is billed to the sponsor and not the investigator. The 4% DOP Fee is collected by the Pediatric Research Office (PRO). Cheryl Perry (cperry@uab.edu), PRO Administrative Director, is available to assist research teams that need to provide justification to sponsors regarding this fee, or who need help calculating the amount of the fee. She can provide wording to send to sponsors or a letter signed by Dr. David Kimberlin, who is the DOP Vice Chair for Clinical and Translational Research. The DOP Fee is subject to overhead, but the PRO only collects the direct portion of costs.

The typical initial justification provided to sponsors is below:

The Department of Pediatrics administrative fee is overseen by the departmental Pediatric Research Office, or PRO.  This Office supports all components of clinical trials conducted within the Department.  It ensures that study personnel are thoroughly trained, that specimen collection and handling meet all appropriate research standards, that specimen storage capacity is adequate for the needs of the trials conducted here, and that all regulatory requirements are fully followed by the research team.  It also ensures sufficient research space and facilities for study personnel, including study monitors, and award administration.  By providing these services and facilities in a centralized fashion, the PRO ensures that the data generated in the conduct of a clinical trial fully support regulatory approvals and clearances for the product under investigation.

Budget, Regulatory, and Study Implementation Costs

Some investigators have study teams that are experienced in budget building/negotiation and regulatory paperwork for industry-sponsored studies, but others might not have the experience or time to handle these tasks. Those who want help should contact the PRO. Depending upon availability, budgets can be done by either Cheryl Perry in the PRO or by trained research coordinators who are part of the CCTS Clinical Research Support Program (CRSP). Cheryl will work with CRSP to determine who can be most helpful for specific studies. CRSP personnel are also available for regulatory assistance for industry studies and Cheryl can include them in the process if needed. Finally, CRSP can also provide coordinator support for study implementation. All of these costs (e.g., budget building/negotiation, regulatory assistance, study coordinators) are built into budgets so that they are covered by the industry sponsor rather than the investigator or division. Budget and regulatory assistance is built in to the start-up fees and coordinator expenses are part of per subject costs. All costs will be billed to the study by either the PRO (if Cheryl provides assistance) or by CRSP (if they assist).