**Emory+Children’s Pediatric Research Retreat**

**Friday January 27, 2012**

**Pediatric Medical and Surgical Devices/Diagnostics Roundtable Discussion Notes**

Barbara D. Boyan – Chair

Kevin Maher – Chair

Wilbur Lam – Chair

Boyan:

* Currently pediatric technologies are no profitable for companies, and therefore, there is not much incentive for them to develop these kinds of technologies.
* Today, clinicians have to modify adult technologies and devices to use in children. Wouldn’t it be great to make these technologies for children from its conception?
* These technologies might be under the orphan category of the FDA.
* The Atlanta Pediatric Device Consortium (APDC) is an FDA funded national platform to develop devices for the pediatric population.

Lam:

* We currently have an ideal situation: Children’s Healthcare of Atlanta providing the largest patient base population in the nation, Georgia Tech, a top notch engineering school and Clinicians and Scientists engaged in doing pediatric research.
* We have the resources to make clinicians part time inventors.

Maher:

* We would like for Atlanta to be the headquarters of pediatric device development.
* We count with the Saint Joseph Translational Research Institute (SJTRI) which is a GLP animal facility. The FDA was impressed during their last visit. This is one of the great resources that APDC has and it is all here locally.
* We are working on getting long-term funding commitments to drive pediatric devices research and development. We are not only working with surgical devices, but everything that is considered a device per FDA standards.

Opened to the public:

Chris Ward from GTRI

* GTRI has thousands of engineers working on developing technologies on a daily bases. This resource is here to help clinicians and scientists take their ideas into prototypes.

Matthew Paden:

* KIDS project is currently part of the APDC. They have been working on it for over 6 years, and during the initial years, they were struggling with funding and resources. Following FDA funding, its been like a snowball effect of resources.
* KIDS is a dialysis machine designed for children. The current solution for children’s that need dialysis is to use an adult machine, but the liquid replacement measurements are not consistent. This causes the children to be dehydrated and is not good for them. Dr. Paden used Georgia Tech’s engineering to refine the process and worked on a prototype.

McCarty:

* In Cystic Fibrosis research there is a need for a point of care biomarkers detection equipment. He will talk more with Wilbur Lam about this technology and the possibilities of further developing them.

Tiffany Kraft:

* Currently works at the Global Center for Medical Innovation, and they will be providing design, prototyping and testing.

**Other questions and/or ideas:**

* If you have an idea, who should you contact?
  + Please contact: Maribel Baker at Maribel.baker@bme.gatech.edu, from the Atlanta Pediatric Device Consortium. She will help you find the right collaborator at Georgia Tech. Stacy Heilman at sheilma@emory.edu will be the contact for Emory and Children’s.
* Georgia Tech has senior design students every year that need projects. If you have an idea please send it to Franklin Bost at franklin.bost@bme.gatech.edu.
* What constitutes a device?
  + The FDA defines a device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
* recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
* intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
* intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."