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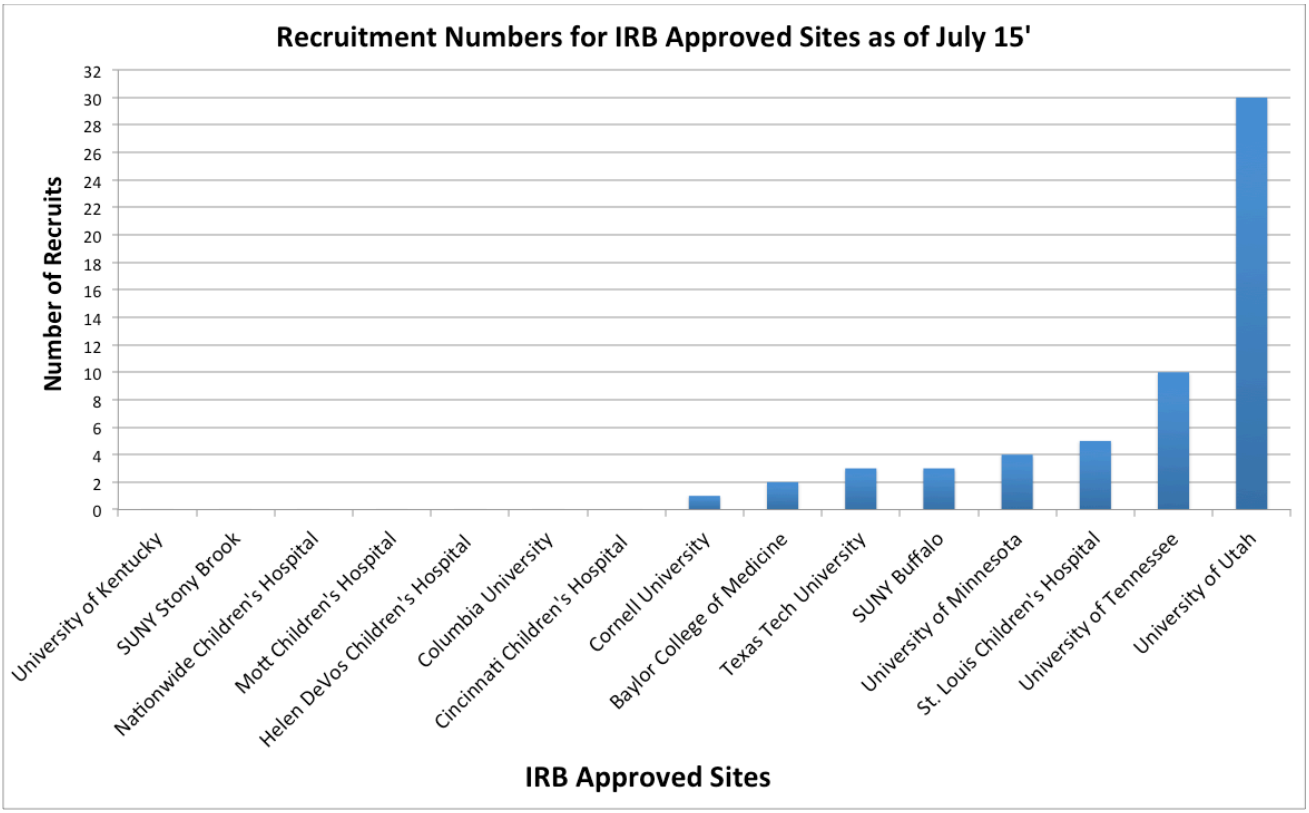
GIGA-kids News & Updates

New Recruitment Numbers & IRB Approved Sites

Our most recent recruitment total is 57 patients! We are doing great, but we also hope to double our recruitment rates with all of the newly IRB-approved sites. Please refer to *Figure 1* (below) for the breakdown of these numbers between the approved sites. Our first 57 patients are shared among 8 out the 14 recruiting sites. Again, Dr. Nelson and his team at the University of Utah are still taking the lead in the way of recruitment.
For the coordinators at the newly approved clinical sites -- please remember that we are providing each participant with a $25 gift card. If you are an IRB approved site and have yet to receive a batch of gift cards, please contact Drew Bradbury (dab2213@cumc.columbia.edu). Another reminder, an MTA must be in place between your institution and Columbia before blood samples can be exchanged. Of the 14 sites that are IRB approved, we are still waiting on 4 sites to finalize the MTAs. Please make sure to complete the paperwork as soon as possible.

Figure 1: *Total Recruitment Numbers for GIGA Kids – as of July 21, 2015*



Genotyping and Exome Sequencing – Building Our Pilot Genetic Cohort

All samples collected for the GIGA kids study to date have been successfully processed and high quality DNA has been extracted. These patients are currently undergoing both genome-wide SNP genotyping and Exome Sequencing. This effort will generate the required preliminary data for our planned NIH grant application to sustain the GIGA-kids project and allow for larger studies. **Note that we plan to genotype and sequence the first 200 patients recruited into the study!!!** For those of you unfamiliar with genetic approaches, Exome Sequencing is a technique used for sequencing all protein-coding segments of a genome. It allows for detection of rare coding alleles that may contribute to disease risk. In addition, we are performing genome-wide SNP genotyping (1.6 million SNPs) to analyze ancestry and determine genotypes at known the GWAS loci. **This is a great opportunity to have your patients included in genetic discovery studies right from the start.** Therefore, please make an effort to send us as many patients as possible in the coming months. Of course, the sooner we reach the number of 200, the sooner we can generate strong supporting data for the grant and continue these efforts on a much larger scale.

DUA – Who has one, who doesn't

There are still some sites that also have not started the DUA process. This document is required to use our electronic data entry forms in OpenClinica.

Before you can access OpenClinica, you must have already completed a DUA with Nationwide! Corinna Bowers who is running this process can assist you with any questions you may have related to DUA.

Please be aware that for some Clinical Trials Offices, this process can be lengthy and so the sooner you follow-up, the quicker you can begin enrollment.

As mentioned before, you can begin recruitment while the DUA is pending even without the access to OpenClinica. Temporarily, you can use the paper form of the CRF that will be provided it to by our coordinator. This is encouraged only to be done momentarily for your own sake so to not back yourself up on the entry of data into the website later on.

If you are a site that has been IRB approved and have yet to begin the DUA application, please reach out to Corinna or Drew and they will gladly point you in the direction needed to gain access OpenClinica and begin data entry.

Contact Information:
DUA – Nationwide
Corinna Bowers
Corinna.Bowers@nationwidechildrens.org

MTA – CUMC
Melanie Foley
mf2162@cumc.columbia.edu

Interested in participating in the GIGA Kids Study?

Our clinical coordinator can help and support you along the IRB application process.
Contact Drew Bradbury,
dab2213@cumc.columbia.edu

Figure 2: *Progress Report on all confirmed sites– as of July 21, 2015*