

GIGA-kids News & Updates

October 2020 Update

Welcome Back!

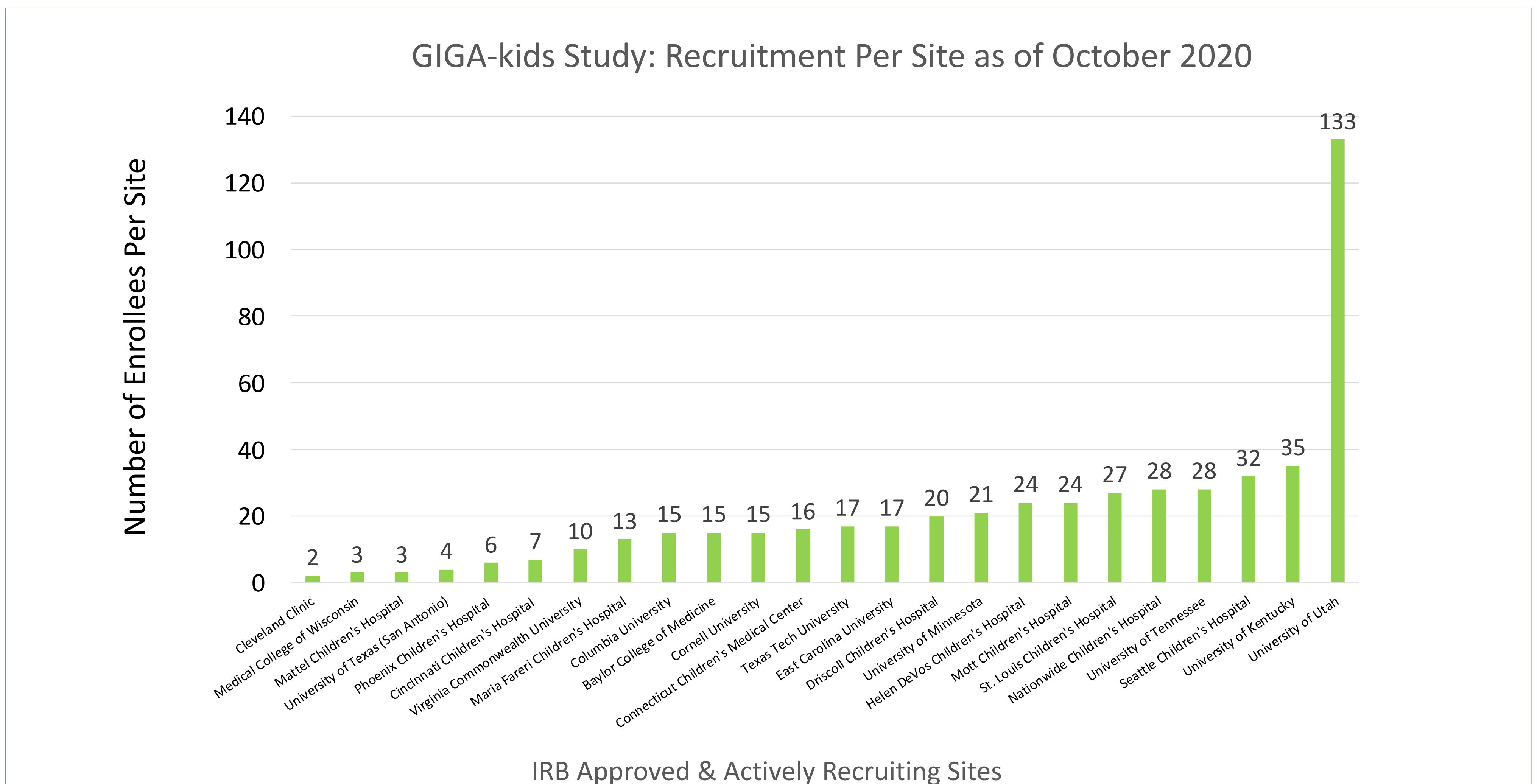
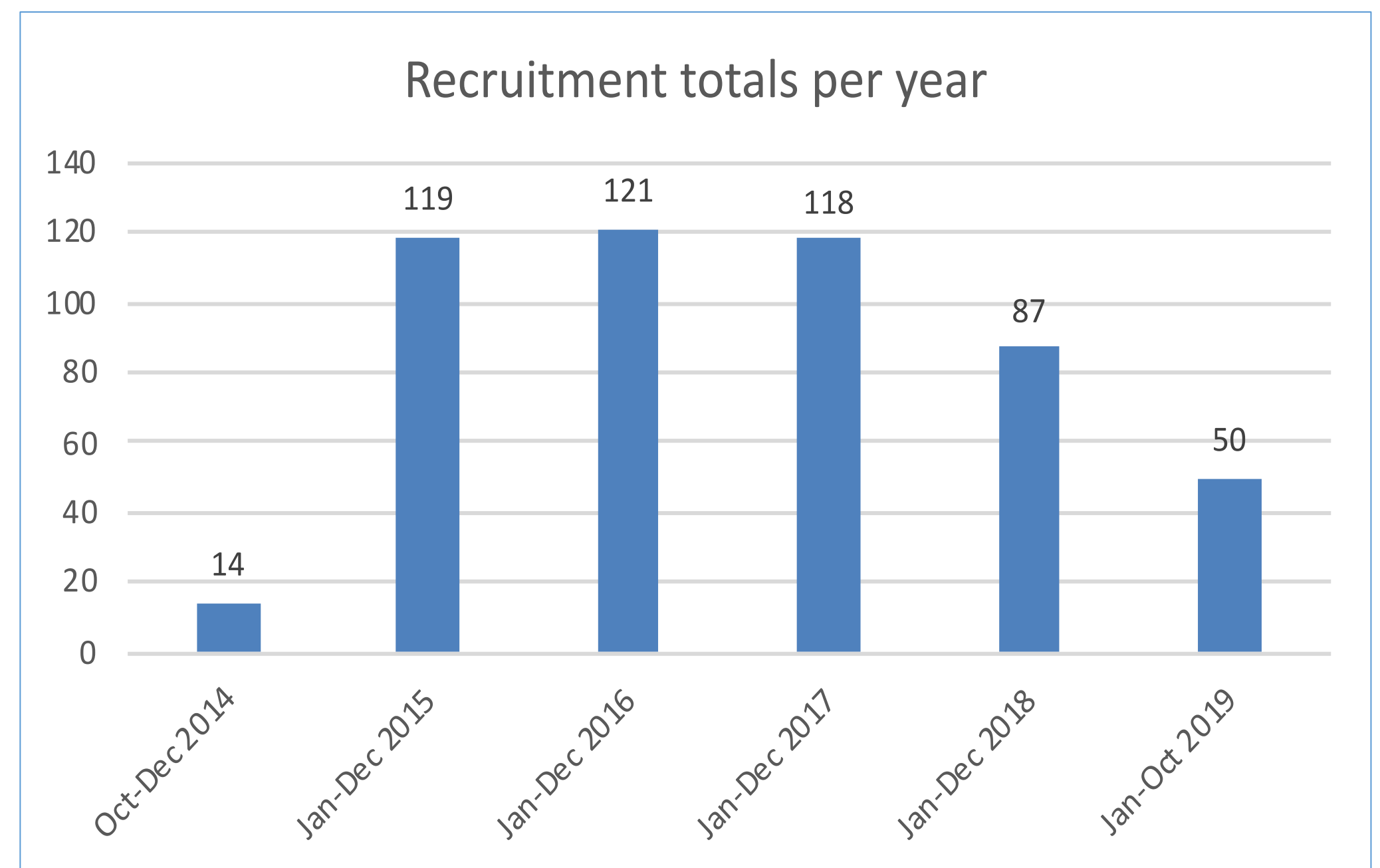
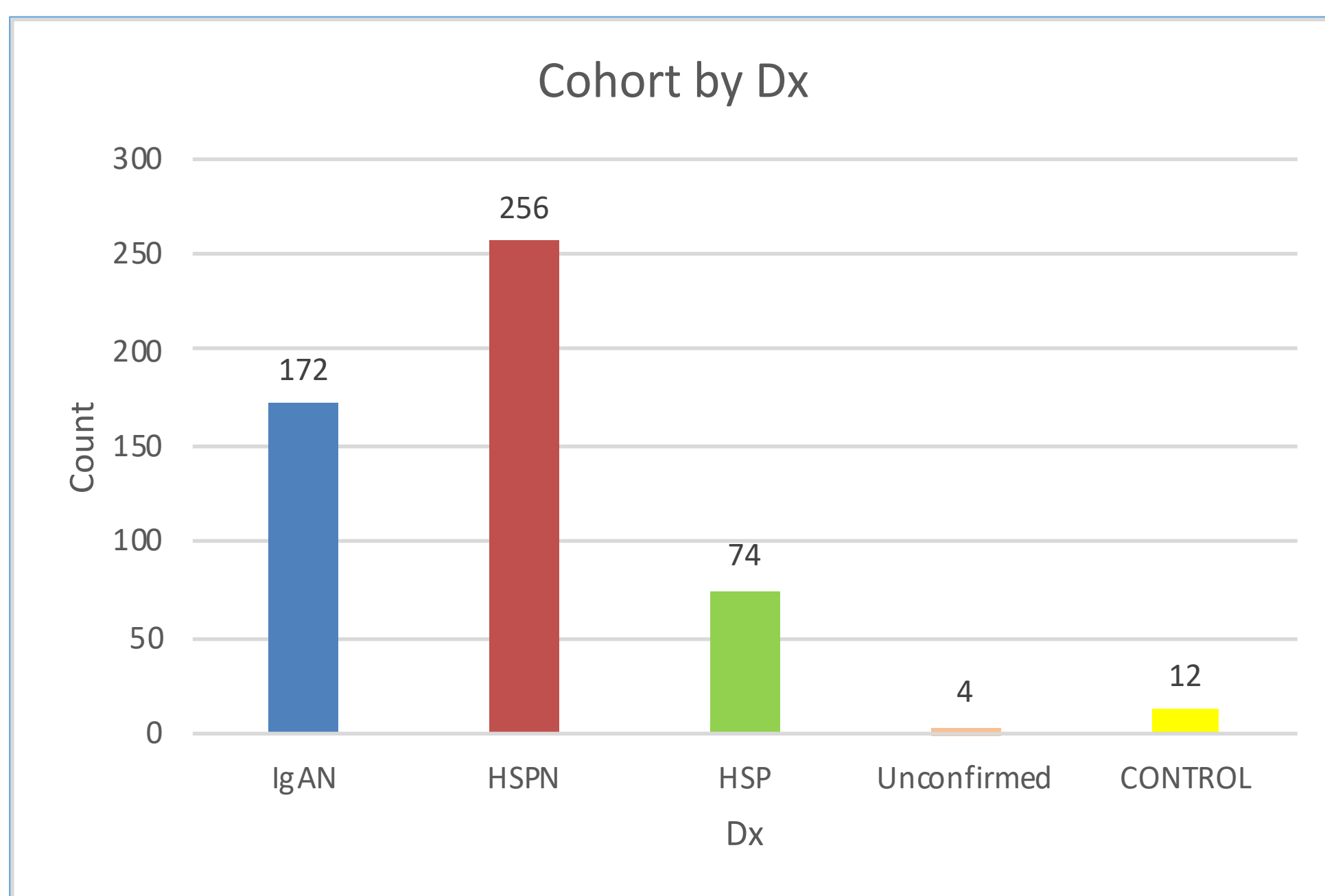
Hello, GIGA-kids PIs, Coordinators & Friends. These past sixth months have been tumultuous and unpredictable for everyone – as many of you are aware, we had to pause study operations beginning in March and were only able to reopen fully at the end of August. We are excited to be up and running again and will make sure to keep you all up to date on any COVID related changes. Finally, I want to Thank You all for your patience and your commitment to GIGA-kids.

Now for our regularly scheduled programming...As of October 1st, 2020 there are 23 actively recruiting GIGA-kids sites. Total recruitment is presently at **N=518 participants**, including 506 cases and 12 healthy controls.

Starting on October 20th, Olivia will be hosting **Zoom “office hours”** every Tuesday at 12PM EST. Details to follow.

As always please let us know how we can best support your recruitment efforts, and do not hesitate to reach out to Olivia Balderes (ob2214@cumc.columbia.edu) with questions, concerns, or suggestions.

Feel free to pass along this newsletter to colleagues and collaborators or share via social media.



Fall 2020 Virtual PNRG Meeting

First, the warmest Thank You to Corinna Bowers for going above and beyond to organize, moderate and Zoom troubleshoot this fall's PNRG meeting.

Though we missed seeing everyone in person, it was wonderful to connect virtually – Coordinators met the afternoon of Thursday, October 1st, and participated in interactive trainings and panels led by the Coordinator Meeting Planning Committee. Notable presentations included a segment on consenting for genetic studies, electronic Informed Consent and evaluating site readiness for specific studies. We will be reviewing the data on interest in supplementary trainings that was collected during the session in the coming weeks.

Dr. Nelson provided an GIGA study progress update to the larger PNRG on Friday, October 2nd.

Consenting for Studies with Genetic Components

- ▶ Does your institution have a **Genetic Research Consent Training** for Coordinators?
- ▶ Would you be interested in taking advantage of such a training if it were provided *by the PNRG*?

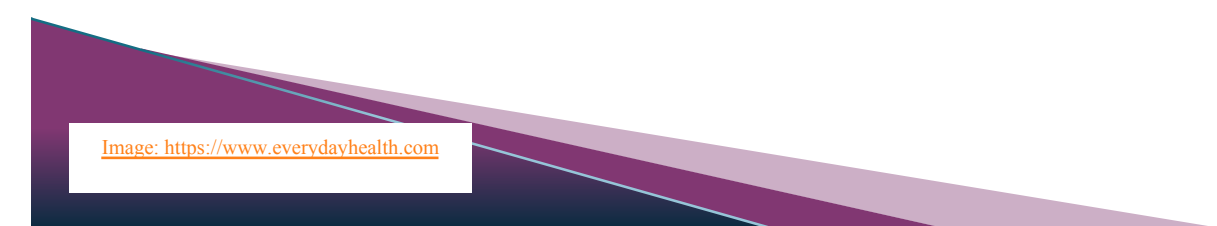


Figure 4: Slide from the Thursday coordinator training segment on Informed Consent for Genetic Studies.

Let's Talk Tech!

The COVID-19 pandemic has forced many, if not all of us, to make changes in how we conduct research, manage studies and evaluate study design. For this reason, the GIGA-kids PIs and the study management team have decided to pilot an option for electronic Informed Consent.

Electronic Informed Consent, or eIC, refers to the use of interactive interfaces – digital, video, audio – to engage and educate a potential participant on study aims and details. eIC has been shown to improve comprehension and streamline communication. RedCap is one of the most used eIC platforms and allows the research team to tailor the consent process to an individual study and deploy & collect consent documents via RedCap's built-in tools.

Dr. Nelson's team at U. of Utah are in the process of creating and piloting a local electronic version of the GIGA-kids consent, which we hope to make available to all sites, after evaluating for site need/preferences and tool effectiveness.

Study Documents

Right before the March 2020 study pause, the legal department here at Columbia had been working with dedicated MTA Liaisons at all GIGA sites (former and active) to update the GIGA-kids MTA language. I am happy to report that 75% of sites have completed this process! I will be sending emailed reminders to sites who have not finalized the updated MTA language in the coming days.

Additionally, Nationwide's legal team has been working to update the language for the GIGA-kids Data Use Agreement (DUA), to mirror the changes made to the MTA. For any *new* or *interested sites*, the process for finalizing the DUA is taking slightly longer than usual as the Nationwide team is waiting to finalize the new language before formalizing a DUA with any new site.

We thank you for your patience and will work to get you information on the DUA timeline as soon as it is available!

Important Contact Information:

DUA/OpenClinica – Nationwide: Corinna Bowers
Corinna.Bowers@nationwidechildrens.org

IRB/MTA – CUMC: Melanie Foley
mf2162@cumc.columbia.edu

Interested in participating in the GIGA Kids Study?

Our Coordinator for the GIGA-kids study, Olivia Balderes, can guide you through the IRB application process, and help to answer any questions you may have regarding study protocol, or recruitment.

Email: ob2214@cumc.columbia.edu
T: (212) 851 - 5216