A key determinant of the success of a clinical trial is the recruitment of a study population of an adequate size. Participant recruitment is considered by many to be the most difficult aspect of the research process. Low rates of recruitment result in:

- Longer durations
- Increased costs
- Less statistical power
- Questionable validity of the results
- Possible termination of the trial

In 2003 when HIPAA laws were enacted to protect human subjects’ health information, it became necessary for researchers working within clinical settings to develop a HIPAA compliant process to screen and potentially recruit participants for clinical trials. At Brooks Rehabilitation Hospital we collected data on CVA admission and the ability to get authorization to contact for research purposes from 2004 to 2010. We were successful in this endeavor as indicated in Table 1. Below. This one time authorization did not allow us to track participants across a period of recovery and had limited information regarding diagnosis, resulting disability and functional status. This led to the development of the Brooks Active Research Registry (BARR).

The Brooks Rehabilitation Clinical Research Center needed to develop a recruitment process that included the following features:

- An IRB approved process allowing for waiver of documentation of informed consent
- The ability to recruit the same participant for multiple clinical trials
- The ability to update across a period of time
- A secure database that would coordinate with web recruitment and consent
- A process that captured multiple recruitment venues into one dynamic database. See Figure 1.

The infrastructure for research recruitment with BARR has proven to be a very effective process for obtaining and maintaining a database that allows for initial entries and updates in broad diagnostic and disability categories. The costs for the IRB, Clinical Conductor and personnel are approximately $20,000 per year. This cost was initially supported by research infrastructure but now has support from the revenue generated from the recruitment budgets for individual trials ($23,000 in 2013). The success of the registry depends on the support of the various clinical sites within Brooks Rehabilitation’s admission process. There is an ongoing need to broaden the ability to obtain authorization or permission to contact and directly recruit. We face the challenge of developing the strategies within the clinical organization and community to inform patients about the opportunities to participate in clinical research and subsequently build the registry. We plan to further utilize the tracking mechanisms available through Clinical Conductor to cast and analyze clinical trial success.

This work would not have been possible without the support of the administration of Brooks Rehabilitation and the teamwork of many individuals in the admissions and marketing departments.

REFERENCES

- Marks, John R., NINDS Clinical Trials in Stroke: Lessons Learned and Future Directions. Stroke 2007; 38:3020
- Sullivan, Jean, Subject Recruitment and Retention: Barriers to Success. Applied Clinical Trials Online, April, 2004