

Dr. Mustafa Sahin, MD, PhD  
Children's Hospital Boston  
300 Longwood Avenue, CLS 13074  
Boston, MA 02115

Darcy Krueger, MD, PhD  
Cincinnati Children's Hospital Medical Center  
333 Burnet Avenue, MLC 2015  
Cincinnati, OH 45229

Oct 16th, 2011

Dear Drs. Sahin and Krueger:

I am writing this letter in support of your grant submission titled, "Early biomarkers of Autism Spectrum Disorders in infants with Tuberous Sclerosis Complex". I agree to fully cooperate with you with regard to the management of subject data. StudyTRAX® will be the database repository for this study. StudyTRAX has been used as a data repository for numerous NIH sponsored research projects and contains multiple levels of security to ensure HIPAA compliance and appropriate user access (access control, audit control, data integrity, user authentication, and transmission security). As we discussed, I will assist with the effort to setup and deploy the StudyTRAX system in accordance with your study requirements and to ensure all data sets are de-identified as defined in the HIPAA privacy regulation 45 C.F.R. §164.514 (b)(2).

As you know, StudyTRAX is the data management system used by the neurofibromatosis (NF) consortium data center for all research protocols. By utilizing this established data center and StudyTRAX, your study will benefit by immediately leveraging a substantial amount of work, processes, and technology infrastructure already in place. I do not anticipate any major difficulties implementing your study.

I look forward to working with you.

Sincerely,



John Putzke, Ph.D., M.S.P.H.  
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