

## **Grant Paragraph on StudyTRAX**

The purpose of the study database is to track subject enrollment, capture data elements in a series of short, well-designed forms all available on-line via a secure web portal, and facilitate data analysis and publication of results. The database application, called StudyTRAX, uses MS SQL Server as the back end relational database, and completely integrates study management (e.g., create forms, run study, collect data) with the manuscript generation process. The program can support one or more research studies, is presently being used at dozens of major academic research centers to support numerous NIH funded projects and is available commercially (<http://www.sciencetrax.com>). The HIPAA privacy rules and HIPAA security rules mandate that covered entities have in place appropriate policies and procedures to protect the confidentiality and security of protected health information. In compliance with these regulations, the database security features of StudyTRAX target multiple levels including the data element (e.g., restricted access to fields), user (e.g., password authentication access), application (e.g., role-based access to features, access audit trails), and hosting services (e.g., firewall, secure sockets layer). Taken together, these features ensure access control, audit control, data integrity, user authentication, and transmission security. The research project(s) will be set up in StudyTRAX to ensure exported datasets are de-identified as defined in the HIPAA privacy regulation [45 C.F.R. §164.514 (b)(2)]. A 21 CFR Part 11 compliance document is available upon request from the creators of the software, a company called ScienceTRAX, LLC.

## **IRB note**

StudyTRAX is a 21 CFR part II compliant research software application that limits user access to the appropriate study, site and role. Transmitted data is encrypted using a secure sockets layer (SSL).

## **Application Hosting (if ScienceTRAX hosting application)**

ScienceTRAX hosted solutions are fully HIPAA Compliant and ensure access control, audit control, data integrity, user authentication, and transmission security. ScienceTRAX uses the data center services of Rackspace, a premier hosting company. Rackspace offers top of the line hosting facilities. As a summary of the Rackspace facilities: (1) Access to data center is secured by Biometric hand scanners and monitored 24x7 by closed circuit cameras. (2) Public access to data center is strictly forbidden. Only level three technicians are permitted in the data center. (3) HVAC [Heating Ventilation Air Conditioning] systems are used to completely circulate and filter all the air every 90 seconds. (4) Continuous UPS [Uninterrupted Power Supply] systems keep all servers up and running in the event of a total power outage. (5) Diesel engines are located on-site to provide power for extended power outages. (6) Enterprise-class routing equipment used in conjunction with multiple fiber carriers to ensure zero downtime due to network access.

All server requests are transmitted over SSL using 128-bit encryption. All of our servers have several layers of data and access protection: (1) A dedicated, managed Cisco router firewall, (2) A redundant array of independent disk [RAID] Level 5 is used to ensure that data will not be lost if a hard drive fails between backups, (3) A system level back up is performed nightly and retained for 2 weeks and are stored in the data center, (4) a database level backup up is performed nightly and retained for 2 months and are stored at the data center and a backup server in at ScienceTRAX [Austin, TX], (5) a database integrity check is performed nightly, (6) all database indexes are updated weekly.