

Appendix C-1: Optimal Solutions Group LLC. Data Management Security Protocols

Data management security protocols ensure restricted access to data and confidentiality of data maintained on the system and in reports. For example, Optimal uses secure intranets to maintain project-related files, and its secure servers use industry-standard methods such as firewalls, monitored access logs, virus protection, encrypted connections, password-protected accounts, and user authentication mechanisms to ensure the confidentiality of the survey design, test data, and subsequent analyses. Optimal maintains a biometrically (physically) secure environment and employs a data security officer who oversees Optimal's data. All Optimal staff members are HIPAA compliance trained, with recertification completed every two years. To support the development and delivery of services, Optimal has made significant investments in a flexible, effective technology infrastructure to ensure the communication, accessibility, and security of information and the ability to submit deliverables in a timely and effective manner.

System Environment

The security approach used to protect the restricted-use data (RUD) is based upon Defense in Depth principles. Security protections have been designed to address controls relative to people, technologies, and operations with technologies focused on defending the network/perimeter, the enclave, the computing environment, and the supporting structures. In general, the RUD enclave consists of a single web portal accessible only via a virtual private network and remote desktop software. The server does not have access to the World Wide Web, nor does it have public IP addresses open. Access is only granted via the secure VPN connection. Power continuity is provided by a state-of-the-art 8 hour UPS that will ensure that during any generator failure back-up power systems will provide ample capacity to keep servers running. Upon contract award, Optimal will draft a data security plan with input from FNS.

FTPS

Optimal uses a secure File Transfer Protocol (FTPS) server to transfer data between an endpoint, such as a user's workstation, and Optimal's data server. The FTPS server utilizes a cryptographic protocol called Secure Socket Layer (SSL), which provides secure transmission of data over FTP. Optimal's FTPS server meets standards set forth by Federal Information Processing Standard (FIPS) publication 140-2. The cryptographic module used by Optimal's FTPS server is a FIPS 140-2 validated cryptographic module that meets the highest possible security standards. End users can connect to Optimal's FTPS server using a variety of secure FTP clients. Each user that connects to Optimal's FTPS server will have a unique username and password and will only have access to their own data. Access logs are kept for security review purposes. The server that runs the FTPS server is protected by a firewall, anti-virus protection, and protocols designed to restrict access to the server in order to maintain security.

In order to securely transfer data to Optimal Solutions Group, you must use a File Transfer Protocol (FTP) client that supports FTPS (FTP over Secure Sockets Layer [SSL]). Many commercial FTP programs support FTPS. If you do not currently have any FTP software on your computer, Optimal can provide information on downloading and using an FTP client. If you

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are unsure whether your software is capable of FTPS, please contact Optimal's technical assistance team for assistance. Optimal's technical assistance team also will ensure that your FTP client is setup properly and is operating in a secure, HIPAA compliant mode. All file transfers between sponsors and Optimal's data server meet CMS and HHS requirements by complying with HIPAA requirement 164.312(e)(1) Transmission Security, and by using a validated Federal Information Processing Standards (FIPS) 140-2 cryptographic module.

Secure Servers

Optimal operates several secure servers to meet the data security needs of various projects. These servers are protected using industry standard methods such as firewalls, monitored access logs, virus protection, and encrypted connections to each server. Data can be analyzed using statistical packages and other applications located on each server, eliminating the need to move the data to an unsecured location. The STATA and SPSS software, for example, are running in a secure, virtual environment to analyze and report on a wide variety of datasets. Running on remote servers allows the data to be analyzed from a single location by authorized Optimal employees from a variety of locations.

Furthermore, Optimal's servers used to access, transmit, receive or store ePHI are located in a physically secure environment with 24/7 surveillance and monitoring. All system accounts are password protected and user authentication mechanisms are implemented to control user access to the system. Optimal employs a security patch and update procedure that ensures that all relevant security patches and updates are promptly applied based on the severity of the vulnerability corrected. Optimal's servers are located on a secure network with firewall protection. The only network access to the servers allowed is through a secure Virtual Private Network (VPN) connection. All unused and unnecessary services are disabled on the servers.

Optimal will conduct analyses on the electronic data in several ways. All analyses will be conducted on Optimal's secure data server which meets HIPAA's administrative, physical, and technical guidelines for storing, transmitting and accessing ePHI and other sensitive information. Optimal employees will connect to Optimal's data server using a secure Virtual Private Network (VPN). Data analyzed for the project will stay on Optimal's secure data server and will not be downloaded to any workstations. Optimal will use server-based STATA and SPSS to analyze the data. Analyses generated will be exported to a database, also hosted on Optimal's data server, for reporting purposes. Optimal will perform qualitative analyses on raw and analyzed data. Results of these analyses will be entered into Optimal's database and will be used for reporting purposes.

HIPAA

Optimal ensures data security and integrity by strictly adhering to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) security guidelines. Optimal's employees are trained in HIPAA security and HIPAA awareness. Server and workstation security requirements ensure that protected health information (PHI) and other sensitive information are handled properly at all times. Sensitive data are encrypted during transmission and storage.

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Physical and virtual access to secure data are monitored, controlled, and only granted on an asneeded basis.

Optimal performs a rigorous, on-going HIPAA risk-assessment process. Optimal's risk assessment committee identifies security and HIPAA risks throughout the organization. From there, the committee works to mitigate any risk to an acceptable level. Results of the risk assessment process are stored for reporting purposes.