BILH REDCap Security and Validation Guidelines

Background:

REDCap is the world's leading free Electronic Data Collection (EDC) solution, developed and maintained by Vanderbilt University as part of the federal CTSA grant program. With over 6,300 licensed sites in 151 countries and 2.3 million users, it is simple to use, easy to support and actively maintained for new features and security updates. BILH developed several REDCap server solutions for IRB, QI/QA, administrative, eConsent, and FDA-regulated CFR 21 Part 11 projects.

Security Guidelines:

BILH Research Operations understands the importance of information security and data confidentiality. Researchers, research participants, and care providers need to know that the organization entrusted with their personal information will treat that data with the utmost care. Working with BILH Compliance and Information Services, we have dedicated resources to ensure data is always protected even in a rapidly changing technology and regulatory environment.

BILH follows industry best practices to protect all data and application systems. Our organization adheres to Federal Information Security Modernization (FISMA) to protect the confidentiality and privacy of research information. Our Information Security practices undergo regular reviews, during which our privacy and security policies, our data management systems, and our IT infrastructure are tested by an independent external auditor. A report of our annual review is available upon request. Our organization implements comprehensive security controls, including:

- Mandatory annual data security training for all employees;
- Mandatory background checks and confidentiality agreements for all employees;
- Limiting access to office facilities and equipment to authorized personnel only;
- System logging and monitoring;
- Disaster recovery plans, which are tested regularly;
- Automatic tracking of data transmissions;
- Secure, encrypted storage and transmission of all sensitive data; and
- Managed access rights.

All of our policies for data security adhere to HIPAA and the Health Information Technology for Economic and Clinical Health Act (HITECH) regulations. We adhere to the Minimum Necessary Requirement standard of the HIPAA Privacy Rule when implementing research projects.

REDCap Support Infrastructure:

Our BILH REDCap instances are hosted on AWS EC2 server instances that were provisioned by Information Services. These instances are maintained with BILH IS oversight and are continually monitored and scanned to ensure ongoing compliance with all BILH security guidelines. This infrastructure ensures the REDCap host environments are appropriately optimized for security. If/when security scans identify issues that need redress, these issues are classified with a vulnerability score and prioritized for remediation. The server instances are maintained as part of the IS infrastructure, and all scheduled backups and disaster recovery protocols are provisioned and handled by BILH Information Services.

REDCap CFR 21 Part 11 Validation Environment:

While REDCap has 21 Part 11 compliant features, each site must provide validation that the environment meets the federal requirements. BILH's initial validation was completed with an external consultant to coordinate the project and assist in the development of ongoing processes to maintain the validation status. The validation effort took months and generated 1,000 pages of documentation. These documents and scripts allow us to demonstrate the 21 Part 11 compliant features are validated as properly functioning in our REDCap environment. These core documents are updated when OS, server, and REDCap application updates occur. This ensures continued alignment as the underlying REDCap application changes over time. We released the two validated 21 Part 11 REDCap platforms in February of 2023. We support the same model on our additional two REDCap platforms. We take pride in being early adopters of REDCap and in maintaining it as a best practices data environment for our researcher for the past fifteen years.