BILH REDCap eConsent and Research
FDA 21 CFR Part 11 Statement of Compliance
Verified: February 2023

FDA Regulation CFR 21, Part 11, Section 11.1(a) provides guidance on the use of electronic systems. These regulations cover electronic signatures, records, and handwritten signatures captured for electronic records as "equivalent to paper records and handwritten signatures executed on paper."

21 CFR Part 11 affects many factors associated with the software and electronic records:

- Data integrity: Ensuring processes and procedures are implemented to ensure authenticity, integrity, and confidentiality
- Data retrieval: Having tools in place to easily access documentation
- Validation: Documenting how a system is expected to work and completing tests to make sure the system functions as expected
- Audit trails: Traceability to understand what changed, when it changed, and who made the change
- Operational controls: Create automated workflows to ensure processes are followed in a logical sequence
- Security controls: Ensuring activities are restricted to the appropriate users for each activity within your platform.

Part 11 also affects electronic signatures. Replacing a wet ink signature, eSignatures include the printed name, a time stamp, and the meaning of the signature. Through an eSignature process, you need to ensure proper identification to avoid falsification. This requires highly regulated workflows and documentation control.

BILH affirms that the **REDCap eConsent** and **Research Project** systems fully comply with the technical requirements for Electronic Records per CFR 21, Part 11, Sections related to Controls for Closed Systems, and the technical requirements for Electronic Signatures.