OnlineCRF

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21 CFR Part 11 Requirements

Compliance checklist

OnlineCRF is compliant with the following requirements:

System Validation and Operability

- ✓ System validation to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.
- ✓ Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.
- ✓ Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.
- ✓ Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.
- ✓ Use of appropriate controls over systems documentation including:
  - Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance;
  - Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.
- ✓ Controls for Identification Codes and Passwords.
- ✓ Limiting system access to authorized individuals.

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Audit Trails and Records

- ✓ Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records.
- ✓ Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:
  - The printed name of the signer.
  - The date and time when the signature was executed.
  - The meaning (such as review, approval, responsibility, or authorship) associated with the signature.
- ✓ Ability to generate accurate and complete copies of records in both human readable and electronic forms suitable for inspection, review, and copying by the agency.
- ✓ Records are protected in order to enable their accurate retrieval throughout the retention period.

Electronic Signatures

- ✓ Each electronic signature shall be unique to the one individual and shall not be reused by or reassigned to anyone else.
- ✓ Before an organization establishes, assign, certifies, or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify:
  - The identity of the individual.
  - The electronic signatures are unique to an individual.
  - The electronic signatures are ever reused by, or reassigned to anyone else.
  - The identity of an individual is verified before an electronic signature is allocated.
- ✓ The printed name of the signer, the date and time when the signature was executed and the meaning associated with the signature shall be subject to the same controls as for electronic records and shall be included as part of the electronic record (such as electronic display or printout).

- ✓ Electronic signatures that are not based upon biometric shall employ at least two distinct identification components such as an identification code and password:
  - When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using at least one electronic signature component that is only executable by and designed to be used only by the individual.
  - When an individual executes one or more signings not performing during a single, continuous period of controlled system access, each sign shall be executed using all of the electronic signature components.
- ✓ The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.
- ✓ Electronic signatures that are not based upon biometric shall be used only by their genuine owners.

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