[SITE NAME]

STANDARD OPERATING PROCEDURE

Title:		No.: ISCORE-RC-120.00	
Electronic Signatures		Page 1 of 3	
		Date of Issuance: dd, month, yyyy	Date Effective: dd, month, yyyy
		Supersedes: NA	
Prepared by:	Reviewed by:	Approved by:	

Purpose:
This standard operating procedure (SOP) describes the guidelines followed by the [Site Location], [Site Name], [Site Institution] and affiliated health systems for the use of electronic signatures to ensure that the regulatory requirements are met.

Scope:
This SOP describes the mechanisms used for electronic signatures applied to clinical research essential documents under the predicate rule using systems for which this site is responsible for, in accordance with 21 CFR Part 11.

Materials:
NA

Definitions:
Electronic signature:
A computer data compilation of any symbol or series of symbols executed, adopted or authorized by an individual to be the legally binding equivalent of an individual's handwritten signature.

Responsibility:
This SOP applies to the [Site Name] Institutions and associated clinical departments actively engaged in clinical research involving human subjects.

Procedure:

Electronic signatures are legally binding and are the equivalent of their handwritten counterparts, and so may be used in place of a traditional “wet” signature.

1. Research Personnel
    a. Access for signatory purposes must be assigned to research personnel and procedures must be used to confirm the identity of the person signing the record.
    b. Individuals with signatory authority must be trained on system requirements, responsibilities and accountability.
    c. User IDs and passwords are unique to one individual and shall not be shared.
    d. Individuals with signatory authority are responsible for activities conducted under their user ID and are expected to take all precautions to safeguard their password and files to prevent inappropriate use.

2. Electronic signatures, must:
    a. Be unique to one individual requiring ID and password
    b. Clearly indicate the printed name of the signatory
    c. Define the meaning associated with the signature (e.g. author, reviewer, approver)
    d. Be linked to an electronic record to prevent duplication, transference to another individual and validates the signature to show that the document was not altered after the application of the digital signature.

3. System Requirements
    a. Systems used should be assessed to ensure e-signatures are software generated, traceable and must comply with applicable regulatory requirements.
    b. Once the electronic signature has been applied the electronic file itself contains the information needed to validate the signature and to show that the document was not altered after the application of the digital signature.
    c. Digital certificates may be purchased from a third-party certificate authority that provides identifying information, is forgery resistant, and can be verified through the official, trusted agency that issues it.

References

Code of Federal Regulations: Title 21 CFR Part 11
21 CFR Part 50, 21 CFR Part 312, 21 CFR Part 812
Guidance for Industry Part 11, Electronic Records; Electronic Signatures — Scope and Application
International Conference on Harmonisation; Good Clinical Practice Consolidated Guidelines.

History of Revisions to SOP

Effective Date	Nature of Revision