



21 CFR Part 11 – Attestation and Agreement for Electronic Signatures

This form is to document that the signator of this document is authorized to use the DAIDS-ES system, and understands that their electronic signature (eSignature) is used to electronically sign database records.

Definitions:

- **Electronic Signature:** An electronic signature is a computer data compilation of any symbol or series of symbols that have been executed, adopted, or authorized by an individual to be the legally-binding equivalent of that individual's handwritten signature.
- **EAE:** Expedited Adverse Experience.
- **DAIDS Adverse Experience Reporting System (DAERS):** A system used by DAIDS to collect and process EAE information for DAIDS related protocols.
- **Statement of the Investigator Form FDA 1572:** Form submitted by each investigator responsible for working on DAIDS IND protocols.
- **Investigator of Record (IoR) Agreement:** Investigator documentation required by DAIDS for non-IND studies. The agreement contains the same information as the FDA Form 1572.

In compliance with U.S. federal law 21 CFR Part 11 on Electronic Signatures, I, the undersigned, hereby certify that I understand and agree to the following statements below:

Statement being certified	Yes	No
My eSignature shall be unique to me and shall not be reused by, or reassigned to, anyone else.		
I am to be held responsible for all actions initiated under my eSignature.		
My eSignature is the legal equivalent of my traditional handwritten signature.		
I will only use my DAIDS provided eSignature in the DAERS system to sign electronic forms on one or more DAIDS sponsored studies on which I am authorized (i.e., protocols listed on the form FDA 1572 or IoR Agreement).		
I understand that all my actions on electronic records will be attributed to me based on my access code (username and password), and that my eSignature will be used solely to sign certain records that require a signature.		
I will use my eSignature only for those assigned tasks that I have the education, training, and experience to perform.		

Name (please print):		
Title:		
Site Designation (CRS ID/Name):		
My handwritten signature is:		
My initials are:		Date of signature: