DAIDS Electronic Information Systems (EIS) Policy Training

June 2021

Time	Session	Lead
0:00 – 0:10 *(10 min)*	**Introduction**	DAIDS
0:10 – 0:15 *(5 min)*	**21 CFR Part 11** • Purpose, scope, implications for regulatory compliance • What types of software fall under the purview of 21 CFR Part 11 • How the DAIDS EIS Evaluation Checklist helps to ensure compliance	Frontier Science
0:15 – 0:25 *(10 min)*	**Determining which systems require a checklist** • Systems used for administrative vs. clinical trial purposes • Systems subject to Part 11 • Systems that do not require a checklist	Frontier Science
0:25 – 1:00 *(35 min)*	**DAIDS EIS Evaluation Checklist: Sections 1.0 – 9.0** 1. How to complete contact section 2. How to complete System Risk Assessment section 3. How to complete section 1.0: Validation a. What is considered validation? b. Introduction of the section on risk mitigations 4. How to complete section 2.0: Access and Controls 5. How to complete section 3.0: Protection of Records a. What is "the retention period"? b. What is considered "backup"? c. How do you know whether the system is set up to protect against viruses and malware? 6. How to complete section 4.0: Access to Records a. How might you document requests for access and access removal? 7. How to complete section 5.0: Audit Trails 8. How to complete section 6.0: Operational Checks a. What does it mean to have checks to ensure steps are performed in the correct order? b. What does it mean to include prompts to ensure consistent use of terminology? c. What does it mean to include checks to identify invalid values and alert the user? d. What does it mean to prevent default data entries? 9. How to complete section 7.0: Authority Checks 10. How to complete section 8.0: Device Checks 11. How to complete section 9.0: Training a. What is considered adequate documentation of training?	Frontier Science
1:00 – 1:15 *(15 min)*	**DAIDS EIS Evaluation Checklist: Sections 10.0 – 12.0** 1. How to complete section 10.0: Policies	SCHARP

	○ What is considered a “written policy”? Does it need to be formally signed and version-controlled? 2. How to complete section 11.0: System Documentation ○ How does the audit trail for change control differ from the audit trail in section 5.0? 3. How to complete section 12.0: Controls for Open Systems ○ How do you know if data are encrypted “in motion” or “at rest”?	
1:15 – 1:35 *(20 min)*	**DAIDS EIS Evaluation Checklist: Sections 13.0 – 23.0** 1. Electronic Signature Requirements a. What is considered an electronic signature? How do you know whether you need to complete this section? 2. How to complete section 13.0: Electronic Signature Components 3. How to complete section 14.0: Signature as Electronic Record 4. How to complete section 15.0: Electronic Signature Linking 5. How to complete section 16.0: Electronic Signature Uniqueness 6. How to complete section 17.0: Identity Verification 7. How to complete section 18.0: Electronic Signature Certification 8. How to complete section 19.0: Electronic Signature Components a. What does “collaboration of at least two individuals” mean? 9. How to complete section 20.0: Biometric Electronic Signatures a. What is considered a “biometric electronic signature”? 10. How to complete section 21.0: Electronic Signature Management 11. Reviewing and Approving the DAIDS EIS Evaluation Checklist (Section 22.0 – 23.0)	SCHARP
1:35 – 1:50 (15 min)	**Implementation Instructions** 1. How to assess which software requires a checklist ○ Does the electronic system collect data that will be submitted to any regulatory authority? ○ Would the records, such as essential documents, be required to reconstruct the trial? 2. When to submit an updated checklist 3. Where to find the latest copy of the checklist on the DAIDS website 4. Whom to contact with questions	SCHARP
1:50 – 2:00 (10 min)	**Closing**	DAIDS