21 CFR part 11 Compliance for UNMC and Nebraska Medicine

What is 21 CFR part 11?

The Federal requirements that contains requirements to assure the agency that electronic signatures are the legally binding equivalent of a person's handwritten signature.

Does my clinical research protocol need a part 11 compliant computer system?

1) Does your protocol fall under the purview of the FDA?
2) Is your protocol conducted under an approved IND?
3) Is your protocol conducted under an approved IDE?
4) Does your sponsor, grant (NIH), or other agency, specify that your computer system must comply with 21 CFR part 11?

If you answered YES to any of the questions, then you need to use a 21 CFR part 11 compliant system.

What computer systems at UNMC and Nebraska Medicine are 21 CFR part 11 compliant?

One Chart (Epic) the electronic medical record for Nebraska Medicine

Forte Electronic Data Capture (EDC)

References for 21 CFR part 11 compliance

https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm563785.pdf

http://www.fda.gov/regulatoryinformation/guidances/ucm125067.htm

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085281.htm

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=11