



FDA 21 CFR Part 11 Statement

CFR 21, Part 11, Section 11.1(a) states clearly that electronic records in compliance with Part 11 criteria shall be considered by the agency to be "trustworthy, reliable, and generally equivalent to paper records".

- (a) The regulations in this part set forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

Further, CFR 21, Part 11, Section 11.1(d) states clearly that electronic records meeting the requirements "may be used in lieu of paper records":

- (d) Electronic records that meet the requirements of this part may be used in lieu of paper records, in accordance with 11.2, unless paper records are specifically required.

IRBNet is proud to affirm that the IRBNet system is fully compliant with the technology requirements for Electronic Records per CFR 21, Part 11, Section 11.10 - Controls for Closed Systems, and the technology requirements for Electronic Signatures per CFR 21, Part 11 Subpart C - Electronic Signatures.