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**Statement on University of Arizona Compliance with 21 CFR Part 11**

The University of Arizona (U of A) maintains that the electronic systems listed below are substantially compliant with 21 CFR Part 11 (Part 11) requirements. Neither the University's institutional review board nor, to our knowledge, any individual University researcher functioning as a sponsor and/or investigator has been cited for non-compliance with Part 11.

Under Part 11, the Food and Drug Administration (FDA) considers electronic records to be equivalent to paper records, and electronic signatures equivalent to traditional handwritten signatures. It applies to any paper records required by statute or agency regulations and supersedes any existing paper record requirements by providing that electronic records may be used in lieu of paper records. Electronic signatures which meet the requirements of the rule will be considered to be equivalent to full handwritten signatures, initials, and other general signings required by agency regulations.

Persons that create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and when appropriate, the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed record as not genuine. 21 CFR Part 11 provides a list of requirements for both open and closed systems to include:

- System access be limited to authorized individuals
- Operational system checks be used to enforce permitted sequencing of steps and events as appropriate
- Authority checks be used to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform operations
- Device checks be used to determine the validity of the source of data input or operation instruction
- Written policies be established and adhered to holding individuals accountable and responsible for actions initiated under their signatures, so as to deter record and signature falsification.

U of A researchers performing FDA-regulated studies may rely on this certification of substantial compliance with Part 11 requirements.

**U of A Validated Electronic Systems:**

- **Huron eIRB:** May 11, 2026
- **Advarra OnCore/eReg Binder:** June 11, 2026
- **REDCap:** June 23, 2026
- **Adobe Document Cloud:** July 2, 2026