IRB Frequently Asked Questions

Where may I find the IRB’s e-signature policy in accordance with 21 CFR 11 Electronic Records; Electronic Signatures?

- The UTHSCSA IRB’s use of electronic signature is not subject to part 11 because the electronic signatures we use meet the FDA’s definition of a flattened digital signature. As a result, our use of these signatures falls into the realm of “use of computers to generate paper printouts of electronic records, and those paper records meet all the requirements of the applicable predicate rules and persons rely on the paper records to perform their regulated activities.” Thus, our limited use of digital signatures on our documents that can be printed is not generally considered to be "using electronic records in lieu of paper records" under §§ 11.2(a) and 11.2(b). In these instances, the use of computer systems in the generation of paper records would not trigger part 11” by the FDA. For more information:
  - [http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm](http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm)