



MEMORANDUM

September 27, 2021

TO WHOM IT MAY CONCERN

FROM: Kimberly Summers, PharmD, Director of Research Protection Programs

RE: IRB approval notifications

The UTHSA IRBs are authorized to review and approve applications to conduct human subjects research. Actions taken to approve research are documented in written notifications to the Principal Investigator (PI). The format for written notification to the PI was revised on April 2, 2021. As of that date, electronically generated notices, not letters, were adopted as the notification format. The notices do not contain a signature block. DHHS regulations 45 CFR 46 and FDA regulations 21 CFR 56 state "An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity." The regulations do not state the notification must be in the form of a signed letter.

Official IRB determinations are documented either by IRB minutes (applies to all IRBs registered with OHRP: IRB00000553, IRB00002691, IRB00002692 and IRB00009608) or an Expedited Review determination document utilizing an electronic signature. The UTHSCSA IRB's use of electronic signature in this way 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 [click here](#).