**From:** Beers Block, Patricia on behalf of OC GCP Questions
**Sent:** Tuesday, April 19, 2005 1:22 PM
**To:** [redacted]
**Subject:** RE: 21 CFR Part 11 (electronic records)

Dear [redacted],

If the IRB relies on electronic records to meet record keeping requirements, these records and the computerized system used to generate the records are subject to the controls described in Part 11. However, if the IRB relies on paper records that are prepared by printing out information from electronic records, then Part 11 controls are not needed. This may sound a bit confusing but if you refer to the Guidance for Industry published in August 2003 entitled "Part 11 Electronic Records; Electronic Signatures; Scope and Application Guidance" (see http://www.fda.gov/ohrms/dockets/98fr/5667fnl.pdf ), pages 5-6, you will better understand when electronic records and the systems used to create electronic records need to be Part 11 compliant.

In terms of compliance with Part 11, there are several ways in which electronic records can be reliably preserved to meet both the regulatory requirements for IRB record keeping and record preservation. For instance, e-mail can be a useful way to transmit electronic records (e.g., pdf formatted meeting minutes; approval letters) to parties (e.g., Clinical Investigators; IRB members) provided the e-mail accounts are assigned to one user and are password or biometrically protected. E-mail messages, by their nature, are reliable electronic records. Each message is timed and dated and includes an electronic signature (e.g., the name of the person creating the e-mail message). Changes to e-mail messages are obvious and easily detected. When attaching pdf formatted records to e-mail messages, the original information is preserved in this record and meets Part 11 record retention requirements.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs
OSHC/Office of the Commissioner
301-827-3340

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
**From:** [redacted]
**Sent:** Friday, April 08, 2005 4:28 PM
**To:** OC GCP Questions
**Subject:** 21 CFR Part 11 (electronic records)

*Re: IRB record keeping and correspondence*

Just wanted to check with your interpretation of 21 CFR Part 11, shall an IRB be compliant with 21 CFR Part 11 for its record keeping requirements with research investigators ?  In other words, for electronic transmissions from the IRB and signatures, do those communications need to be compliant with the regulation ?
Thanks,

[redacted]