From: Beers Block, Patricia
Sent: Wednesday, June 22, 2005 9:01 AM
To: [redacted]
Subject: FW: 21 CFR 11

-----Original Message-----
From: Beers Block, Patricia On Behalf Of OC GCP Questions
Sent: Wednesday, June 22, 2005 9:00 AM
To: [redacted]
Subject: RE: 21 CFR 11

Dear [redacted],

Part 11 applies to records in electronic form that are created, modified, maintain, archived, retrieved, or transmitted under any records requestiome set forth in Agency regulations. Part 11 also applies to electronic records submittted to FDA under the Food, Drug and Cosmetic Act (e.g., IND and NDA electronic submissions), and the Public Health Service Act, even if these records are not specifically idenftied in FDA regulations. For example, the FD&C Act requires that drugs be approved before marketing. The IND (21 CFR 312) and NDA (21 CFR 314) regulations require that certain information be submitted to FDA; when that information is submitted in electronic form, Part 11 applies to these records. The same rules apply for devices under IDE (21 CFR 812) and PMA (21 CFR 814) regulations, and for those records required to be maintained under the Informed Consent regulations (21 CFR 50) and the Institutional Review Board regulations (21 CFR 56).

FDA recently clarified its intentions with regard to the enforcement of Part 11 in the agency's "Guidance for Industry Part 11, Electronic Records; Electronic Signatures Scope and Application". You can access this document at http://www.fda.gov/ohrms/dockets/98fr/5667fnl.pdf. This guidance explains the conditions under which FDA considers part 11 to be applicable to records or signatures, and FDA's intention to use enforcement discretion with regard to part 11 requirements for validation, audit trails, record retention, and record copying.

Briefly, FDA considers part 11 to be applicable to records or signatures in electronic form when:

1) records that are required to be maintained by FDA regulations (in your case, IND and IDE regulations) and that are maintained in electronic form in place of paper format;

2) records that are required to be maintained by regulation that are maintained in electronic form in addition to paper format, and that are relied on to perform regulated activities;

3) records submitted to FDA under regulations (even if such records are not specifically identified in FDA regulations) in electronic format; and

4) electronic signatures that are intended to be the equivalent of handwritten signatures, initials, and other general signings required by FDA regulations.

I hope this information is helpful to you. If you need any additional information, please feel free to contact me again.

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, June 17, 2005 11:40 AM
To: webmail@oc.fda.gov
Subject: 21 CFR 11

I work in research [redacted] and I have a question that relates to 21 CFR 11. I would like to know what FDA's requirements are as they relate to 21 CFR 11 and official correspondence sent to an investigator or sponsor from the IRB. I don't believe this correspondence is required to meet the standards of 21 CFR 11 but several sponsors think it does. Can you provide an interpretation for me in order that my office may correctly follow the regulation? Thank you,

[redacted]