

ACRO

ASSOCIATION OF CLINICAL
RESEARCH ORGANIZATIONS

July 8, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

[Docket No. 2004N-0133]

Dear Sirs:

The Association of Clinical Research Organizations (ACRO) was formed in 2002 to represent clinical research organizations (CROs), a key partner with pharmaceutical, biotechnology and medical device companies in the conduct of thousands of clinical trials each year. ACRO member companies provide a wide range of research and development services to help these research sponsors bring new drugs and new treatments to patients safely and quickly. In fact, research sponsors often transfer to a CRO some or all of the regulatory responsibilities stipulated by applicable FDA regulations, including 21 CFR Part 11. ACRO member companies employ more than 40,000 people worldwide, conduct research in 60 countries, and represent a multi-billion dollar industry. On behalf of ACRO, I am pleased to submit the following general comments on the above-referenced docket. (Individual member companies and other CROs may submit separately additional and/or more detailed comments.)

ACRO applauds the Agency's original intent in Part 11 to ensure the reliability, accuracy and integrity of electronic records and signatures, while at the same time encouraging the innovative development of electronic systems for use, within clinical trials. However, like other stakeholders, over time ACRO members have become increasingly concerned about the apparently expanding scope of Part 11 applicability to all computerized systems, no matter what function they have or do not have in the conduct of clinical trials. Thus, ACRO appreciates the September 5, 2003 guidance, which indicated that the FDA would "narrowly interpret the scope of Part 11" and "exercise enforcement discretion with respect to all part 11 requirements under certain circumstances." Further, ACRO strongly supports the Agency's announced intention to re-examine Part 11 and to engage in additional rulemaking to modify Part 11.

ACRO notes that CROs have been involved in the implementation of a wide range of computer-based applications meant to improve the efficiency and speed of the clinical research process. From the perspective of CROs, for which the actual conduct of clinical trials is a major part of their business activity, the most significant difficulty in

227 Massachusetts Avenue, NE
Suite 300
Washington, DC 20002
e info@acrohealth.org
t 202 543 4018
f 202 543 5327

interpreting and complying with the requirements of Part 11 relates to the lack of specificity of the predicate rules within the Good Clinical Practice (GCP) standards promulgated by the Agency. In contrast to the generally clear record, signature and other specified requirements of Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP), the FDA regulations for GCPs are less prescriptive regarding required records and signatures. Unlike the predicate rules for GMP and GLP, GCP regulations do not clearly identify records to be maintained or signed. As a result, there has been industry-wide confusion and variability in interpretation as to the applicability of Part 11 and exactly which GCP requirements constitute “predicate” rules. As a result, ACRO believes there is a pressing need for the FDA to state explicitly that Part 11 applies only to required records and signatures. Where the Agency sees a critical need for application of Part 11 to GCPs, it should revise those specific GCP requirements so as to clarify what are truly “predicate” rules.

In addition to clarifying the application of Part 11 to GCP predicate rules, ACRO recommends that the FDA publish meaningful guidance in regard to risk assessment and risk management vis-à-vis the requirements of Part 11. To date, the Agency’s discussion of risk-based approaches has been focused largely on GMP issues. CROs and others that use computer-based information technologies in clinical research would be well served by guidance that explicates risk and decision-making parameters in relation to specific clinical trial activities and concerns

As the FDA evaluates potential changes to Part 11, ACRO suggests that much of the original intent of the regulation could be accomplished via additional guidance and/or regulation to address three areas: 1) clarify whether Part 11 applies to GCPs; 2) clarify what predicate rules apply to GCPs; and 3) articulate applicability and interpretability of Part 11 for GCPs based on risk management principles. On behalf of the Association of Clinical Research Organizations (ACRO), thank you for the opportunity to provide these comments.

Sincerely,

Douglas Peddicord, Ph.D.
Executive Director
(202) 543-4018