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Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852  
<http://www.accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm>

Subject: Docket No. 2006D-0331: Draft Guidance for Institutional Review Boards, Clinical Investigators and Sponsors: Exception from Informed Consent Requirements for Emergency Research

Quintiles Transnational Corp., a clinical research organization which provides outsourcing services to the pharmaceutical and biotechnology industry, appreciates the opportunity to comment on the above Guidance for Institutional Review Boards, Clinical Investigators. The proposed guidance has been reviewed and discussed by representatives of Quintiles internal Research Ethics Board, the Council on Research Ethics (CORE). Additionally, Quintiles was present at the FDA public hearing on 11 October 2006. See FDA Notice at 71 Fed. Reg. 51143 (August 29, 2006).

The objective of this proposed guidance is recognizably a great challenge, as the FDA, pharmaceutical industry, IRBs, and treating physicians wrestle with identifying the ideal balance of providing potentially life-saving treatments and therapies with protecting vulnerable populations of individuals not capable of giving informed consent or actively refusing enrollment. Such equipoise is a very commendable goal.

Overall, Quintiles agrees with the guidance provided by the FDA regarding the exception from informed consent requirements for emergency research. The elaboration on 21 CFR 50 for emergency consent exemptions provided Quintiles with additional perspective on key issues with clinical research in such trials. Specifically, the sections regarding subject exclusion, definition of therapeutic windows, and contact of family members were practical and helpful.

Community consultation and public disclosure are two of the more complex principles permitted in 21 CFR 50.24. Section VIII of this guidance provided further definition and clarity of how these activities would be conducted. As stated in the guidance (VIII.A.), "each community consultation process will be unique, based on the community(ies) involved and the specific nature of the investigation. There is no single, set way to accomplish this requirement."

Quintiles appreciates the opportunity to provide comment to this proposed guidance. In summary, Quintiles concurs with the guidance provided by the FDA and applauds the agency's efforts to provide clarity and offer practical advice and considerations for the conduct of emergency clinical trials.

Sincerely yours,

Cassandra S. Kennedy  
Vice President, Clinical Quality Assurance  
Quintiles Transnational  
Vice Chair for Operations, Council on Research Ethics