FDA Comment re Draft Guidance for IRBs, Clinical Investigators and Sponsors; Exception from Informed Consent Requirements for Emergency Research [Docket No. 2006D-0331]

This comment is consistent with the goals of *La Cesta Consultants, LLC* promoting a conscientious culture in human research, specializing in human research protection program development and accreditation and the development of community participation in human research. It is made in light of the commentary by Kipnis, King and Nelson[*] detailing oversight concerns regarding proprietary protocols, derailing of IRB disapprovals and FDA-granted Special Protocol Assessment in research conducted under the emergency research waiver. It directs attention to the fact that the Draft Guidance and the appended Suggested Flow Chart for 50.24 Studies omit consideration of the best-case scenario: when an enrolled non-consenting individual regains capacity to engage in the informed consent process. Under such circumstances the informed consent process should commence at the earliest feasible opportunity providing the non-consenting enrollee with a detailed account, to date, of events relevant to his/her participation in the study; the standard elements of informed consent (21 CFR Subpart B); the information provided to and gathered from community consultation, and a commitment to provide post-study results. In addition to the best-case scenario, the guidance should include consideration of scenarios where an enrolled non-consenting individual's capacity to engage in the informed consent process has been cognitively impaired. The post hoc informed consent process and its documentation need to be thoughtfully considered and its implementation detailed in the proposed investigational plan. The inclusion of these scenarios in the guidance on the development of investigational plans grounds the conduct of emergency research conducted with a consent waiver in a tradition consistent with principles of respect, beneficence and justice. Inclusion of these scenarios is respectful of the restored autonomy of the non-consenting enrollee; extends the potential benefit of emergency research to a previously excluded vulnerable population and justly allows that the immediate benefit of emergency research flow to those who assumed the immediate risk.

[*] Kipnis, K, King, NMP and Nelson, RM, "Trials and Errors: Barriers to Oversight of Research Conducted under the Emergency Research Consent Waiver," *IRB: Ethics & Human Research* 28, No. 2 (2006) 16-19.