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October 24, 2006

Carolyn Hommel
Good Clinical Practice Program
Division of Docket Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20852

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

Dear Ms. Hommel:

The Council on Governmental Relations (COGR) is an association of more than 170 research universities and their affiliated academic medical centers and research institutes, concerned with the influence of regulations, policies, and practices on the performance of research. COGR's member institutions conduct much of the clinical research sponsored in the United States through their academic medical centers and affiliated hospitals and clinics. The institutions are responsible to ensure that their investigators and institutional review boards meet the Food and Drug Administration's (FDA) requirements for the conduct of emergency research. As a consequence, this guidance is of particular interest to our community.

We believe that the guidance provides important clarity to the management of emergency research conducted under the exception from the requirement to obtain informed consent from each subject prior to enrollment in the clinical investigation. This exception has enabled institutions to conduct very important research. The additional guidance on the community consultation and public disclosure are helpful and the accompanying flow chart in Appendix B offers a valuable roadmap for the review and approval process.

The determination of the adequacy of the community consultation and the assessment of the community's opinions and concerns is often one of the more complex aspects of the IRB's review. Without restricting the flexibility the FDA regulations and this guidance provide, additional examples or further discussion of assessing the effectiveness of community consultations plans and practices could be helpful. We agree that each

consultation process will be unique based on the community and nature of the investigation but determining whether the feedback received is meaningful or not is difficult. The FDA's perspective on standards or criteria to be used for different types of studies – whether a drug or device study – and different types of potential participant groups in making a determination of adequate and effective would be helpful.

Finally, can the community consultation and public disclosure occur simultaneously? The flow chart for 50.24 studies, in Appendix B, separates the community consultation and public disclosure into two discrete activities, requiring two separate review and approvals by the IRB. We recognize that each activity has a separate goal or purpose and warrants separate consideration by the IRB. We believe, however, that public disclosure before the study and community consultation can occur at the same time and may enhance the information provided to and consultation with the community. As part of the review of the planned public disclosure, we would recommend adding to the examples of the frequency of disclosure (Section B.1. When) IRB consideration of the length of the study.

We appreciate this guidance, as it will assist us in meeting our responsibilities when conducting research in emergency settings.

Sincerely,

Anthony P. DeCrappeo
President