It is crucial to the health of all Americans that research on emergency care be conducted. The relatively young fields of emergency medicine and emergency medical services are hindered by the number of unanswered questions in their specialty. It is also vital that research be conducted ethically and in a manner that respects patients' right to autonomy. Unfortunately, the need for emergency research and the need for subject autonomy are nearly impossible to reconcile. Therefore, we must balance these two needs as much as possible even though there is no way to completely meet the needs of both.

The draft FDA guidance represents the best possible solution to balancing these two needs. I support the regulation and the draft guidance. However, it is vital that the lessons learned from prior experiences with these regulations be considered.

In particular, the FDA must work with researchers, sponsors, and IRB's to better define "community" for community consultation. The goal of this process is to engage in two-way dialog between those responsible for study design and those who might become study subjects without the benefit of providing informed consent. However, it is difficult to find people who are interested in attending such meetings and it is difficult to explain the research process in general and the research study in specific to the general public in a way that allows for meaningful dialog. At present this part of the regulation seems to be interpreted as getting as many people as possible of varied backgrounds and having them agree the study should be conducted. We need more information, study, and consensus to develop guidelines for how to make this a more useful process that results in a meaningful information exchange. At present, I have no recommendations to improve this process but the process must be studied and improved so that it becomes a meaningful process without becoming an exercise that is completed simply for the purpose of meeting the guidelines and not to attain any valuable feedback from the "community".

Secondly, we need to consider at what point and how families should be approached so that they can reasonably provide informed consent for continued participation of their loved one in research. At present this is interpreted as obtaining consent as soon as they are present. However, is it reasonable to expect families to make a decision about research at the same time that they find out their loved one has a critical condition? Is it truly ethical to expect that they are going to make the best decision for their family at that point? I would submit that during a more traditional research trial informed consent is considered a process, where potential subjects are invited to bring the information home and talk it over with their family and loved ones before making a decision. Shouldn't informed consent after using the exception to informed consent be considered in the same way? That is, immediate decision making should not be required or expected and obtaining patient or family consent should be considered a process where decisions are not made at the spur of the moment but after a careful weighing of all the risks and benefits after coming to terms with the events that have occurred that put them in a position to be involved in emergency research.

Further, given that it is likely that patients with negative outcomes might be the most likely to deny consent, consideration should be given to providing vital status and relevant complication information to researchers on patients who refuse to participate. Allowing researchers to keep de-identified records of study group assignment and outcome, including relevant complications, will ensure that subjects who withdraw

consent do not bias study results. This is particularly important since patients with negative outcomes are probably the most likely to refuse to consent to further participation. Granted this is a slippery slop toward conducting research without respect for a person's autonomy, but it seems vital to insure that some benefit comes from the risk these patients have already incurred even if it is societal benefit, and to ensure that it does not result in societal harm by leading researchers to come to the wrong conclusions.

Finally, as a former IRB member the presence of a national advisory board that can provide scientific and exception to informed consent procedures expertise would be welcomed. However, care must be taken not to create a system that greatly lengthens the time for IRB review or is more cumbersome for researchers to navigate then the present system. For this to be successful an advisory body would need to have the ability to recruit scientific experts and persons with exception to informed consent experience as needed.