Dear Investigators and Members of the Community of Clinical Investigations:

I am sorry that your approval from this IRB was a punishing and costly experience. On March 29, 2012, the Office of Compliance in the FDA's CBER imposed restrictions against any site doing FDA regulated research under BioMed IRB approval, namely, a prohibition on enrolling subjects if you did not change IRBs. I apologize that you had to try to figure out why the FDA took this action, and had to pay the costs to change oversight to other IRBs in order to remain a clinical investigator able to enroll human research subjects in your trials.

The restrictions are a surprise. The time frame before they will be lifted remains a mystery even with the FDA. We continue to seek a lifting of the restrictions and I will gladly update the particular actions taken.

The common ground appears to be having the BioMed IRB change in the way that we are seen by the FDA. The fix is that we have to look to the FDA as they see an IRB from a hospital or major academic medical center. Specifically, we have to add many more MDs to the membership roster and have higher levels of MD participation in discussions and votes by a quorum of the IRB.

I am sorry for all disruptions to your studies that the restrictions have caused. I am sorry for the costs you have to pay for changing oversight to other IRBs. In particular, I share the sense of added further pain for the investigators and sponsors who waited for us to find a remedy with the FDA. At least the other IRBs get a boost from this FDA sequence of action/inaction. The BioMed IRB has not closed but we are shut down from being a choice of IRBs by the FDA. We will not quit, we will continue to show the FDA our efforts to meet their expectations of us. Our aim is to have the restrictions lifted.

I continue to be grateful for those of you offering encouragement. I also want to thank the MDs asking about the possibility of joining the IRB roster and participating as a voting scientific member at future IRB meetings. The immediate solution is adding participation by more MDs.

We will be showing progress towards roster additions and minute-taking steps to the FDA. We may learn more at our meeting with the Office of Compliance team that imposed the restriction, unless they again delay the scheduled meeting, on the afternoon of Thursday, May 3.

We are doing everything we can to have the restrictions lifted. We cannot undo the punishment you have suffered but we will keep you informed and are ever grateful for your responses as we keep asking for your continuing encouragement.

Fred Fox for BioMed IRB April 26, 2012