



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
National Institutes of Health

National Institute of Diabetes and  
Digestive and Kidney Diseases  
Bethesda, Maryland 20892

December 3, 2010

Thomas R. Ziegler, MD  
Assistant Professor of Medicine  
Emory University School of Medicine  
1365 Clifton Road, N.E.  
Atlanta, GA 30322

Dear Dr. Ziegler:

The Data and Safety Monitoring Board (DSMB) for your study "Efficacy and Mechanisms of Glutamine Dipeptide in the SICU" held their eighth meeting by teleconference on November 16, 2010. Conflict of interest status was reviewed with all members of the DSMB; no conflicts were identified.

The DSMB voted unanimously to endorse continuation of the study; the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) concurs with this endorsement. No safety issues were identified at this time. The DSMB made a few suggestions regarding the conduct of the study and the DSMB reports. The NIDDK concurs with all recommendations of the DSMB; you are to comply with the all the recommendations included in the summary. The DSMB was complimentary of the work done to date on this project; the NIDDK endorses their complimentary remarks.

It is your responsibility to assure that your IRB, and that of all of the other investigators participating in this study, are informed of the DSMB recommendations and the NIDDK's concurrence. A copy of the DSMB meeting summary and this letter should be forwarded to all respective IRBs.

As always, if I may be of further assistance to you, please do not hesitate to ask. The DSMB will meet again in approximately six months, but as you know, I will be retired from Federal service by then. I have enjoyed working with you and the GLND team and wish you all the very best as you complete the GLND trial.

Sincerely yours,

A handwritten signature in purple ink that reads "Carolyn W. Miles".

Carolyn Miles, PhD  
Director, Clinical Obesity and Nutrition Program  
Division of Digestive Diseases and Nutrition  
National Institute of Diabetes and  
Digestive and Kidney Diseases

Encl: DSMB meeting summary

Cc: Dr. Stephen James, Director, DDN  
Ms. Marilyn Rosendorf, NIDDK Grants Management Specialist