



July 11, 2008

Tim Wysocki, PhD  
Chair, Nemours Florida IRB  
Nemours Children's Clinic  
807 Children's Way  
Jacksonville, FL 32207

**Re: Rebuttal Letter for IRB Continuing Review for Protocol ASCT0631(PBMTC SCT051) "A Phase III Randomized Trial of G-CSF Stimulated Bone Marrow vs. Conventional Bone Marrow as a Stem Cell Source In Matched Sibling Donor Transplantation"**  
Sponsor: Children's Oncology Group

Dear Dr. Wysocki,

The following responses are in regards to the issues addressed by the Nemours Florida Institutional Review Board in reference to the above listed protocol.

The Board requested more information about COG Pediatric IRB approval as well as a better description of the patient risk and benefits. After having spoken with the study chair, the attached documents were provided to aide the Nemours IRB with its decision.

Thank for your committee's attention to detail regarding this protocol.

For additional questions or information, please contact:

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Sincerely,  
██████████, Clinical Research Associate for Eric Sandler, M.D.