



[June 7, 2010]

Tim Wysocki, Ph.D., C.I.P.
Chair, Nemours Oncology Institutional Review Board
Nemours Foundation
10140 Centurion Parkway North
Jacksonville, Florida 32256

Re: Secretary's Determination on the Research Protocols:

COG Protocol ASCT0631: 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 *and*

COG Protocol ASCT0631D: A Comparison of Acute and Long-Term Toxicities in Bone Marrow Donors with and without G-CSF Treatment Prior to Harvest: A Companion Study to ASCT0631

Formerly:

COG Protocol ASCT0631: 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

Principal Investigator: Eric Sandler, MD
NCI Grant No. PASCT0631#R02PAPP01

Dear Dr. Wysocki:

Thank you for your previous communications on the Children's Oncology Group (COG) protocol entitled, *COG ASCT0631: 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*.

Based on correspondence from COG and the National Cancer Institute's (NCI's) Central Institutional Review Board (CIRB), we understand that a separate protocol has been developed for the donors participating in this research study to address the six stipulations outlined in the June 11, 2009 letter from the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA). On behalf of the Assistant Secretary for Health, Department of Health and Human Services (HHS), and the Commissioner, FDA, OHRP finds that all of the stipulations have been met in the revised protocols, entitled, *COG ASCT0631: 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* and *COG ASCT0631D: A Comparison of*

Page 2 - Tim Wysocki, Ph.D., C.I.P.

Acute and Long-Term Toxicities in Bone Marrow Donors with and without G-CSF Treatment Prior to Harvest: A Companion Study to ASCT0631. These revised protocols were reviewed and approved by NCI's CIRB and forwarded to OHRP.

The research in the revised protocols conforms with the requirements of the HHS regulations at 45 CFR 46.407 and the FDA regulations at 21 CFR 50.54, and now may proceed, relying upon the HHS support provided by the NCI, National Institutes of Health under grant number PASCT0631#R02PAPP01.

This concludes the 45 CFR 46.407 and 21 CFR 50.54 review process. It is the responsibility of the Nemours Foundation to ensure that an IRB designated on its Federalwide Assurance continues to oversee the conduct of this research study and conducts continuing review of this protocol.

We are sending a similar notification to the NCI Central IRB. Please do not hesitate to contact us with any questions. Thank you for your continuing commitment to the protection of human subjects.

Sincerely,

[/s/ J. Menikoff, M.D., J.D.]

Jerry Menikoff, M.D., J.D.
Director
Office for Human Research Protections

cc:

Dr. Eric Sandler, Nemours
Dr. Jacquelyn Goldberg, NCI Central IRB
Dr. Amy Patterson, NIH
Ms. Sarah Carr, NIH
Dr. Joanne Less, FDA
Dr. Dianne Murphy, FDA
Dr. Robert Nelson, FDA
Dr. Sara Goldkind, FDA
Dr. Stephan Grupp, Children's Hospital of Philadelphia
Dr. Edward E. Bartlett, OHRP