Publication Instructions:

BMT CTN Protocol 0302
- Primary and Ancillary Studies –

The requirements below are for publications and presentations made pursuant to the primary BMT CTN Study 0302 and 0302 correlative studies; (1) Analysis of Serum Biomarkers Related to aGVHD Treatment Responsiveness; and (2) Pharmacogenetics of Steroid Responsiveness in aGVHD. For other ancillary studies, please contact the e-mail below.

Acknowledgment Requirements:

For all Publications, Reports, Presentations, Symposiums, etc.

"Support for this study was provided by grant #U10HL069294 to the Blood and Marrow Transplant Clinical Trials Network from the National Heart, Lung, and Blood Institute and the National Cancer Institute, along with contributions by Eisai Inc., Hospira Inc., Roche Laboratories Inc., and Immunex Corporation, a wholly owned subsidiary of Amgen Inc. The content is solely the responsibility of the authors and does not necessarily represent the official views of the above mentioned parties."

Additional Language for Publications on the Ancillary Studies: Pharmacogenetics of steroid Responsiveness in *aGVHD and Analysis of Serum Biomarkers Related to aGVHD Treatment Responsiveness* - "Additional support was provided to the Blood and Marrow Transplant Clinical Trials Network by the Division of Allergy, Immunology, and Transplantation, National Institute of Allergy and Infectious Diseases for the ancillary studies, Analysis of Serum Biomarkers Related to aGVHD Treatment Responsiveness' and 'Pharmacogenetics of Steroid Responsiveness in aGVHD.'"

(Also see below.)

For correlative studies utilizing biospecimens and/or clinical data obtained from the NHLBI Biologic Specimen and Data Repository Information Coordinating Center, include the following as applicable:

If the Research Plan involves collaboration with Study Investigators, acknowledge the source of the data by including language similar to the following either in the acknowledgement or in the text of the manuscript:

"This manuscript was prepared using BMT CTN 0302 Research Materials obtained from the NHLBI."

If the Research Plan does not involve collaboration with Study investigators, or if the Study has ended, use the following language:

"This manuscript was prepared using BMT CTN 0302 Research Materials obtained from the NHLBI Biologic Specimen and Data Repository Information Coordinating Center and does not necessarily reflect the opinions or views of the BMT CTN 0302 or the NHLBI."

Manuscripts and abstracts resulting from the Research Plan should not use the name of the Study in the title of the manuscript/abstract unless the title clearly denotes the source of the Research Materials as being from the NHLBI Biologic Specimen and Data Repository Information Coordinating Center.

The following language should be inserted in the acknowledgements for all BMT CTN Studies that utilize CIBMTR data:
The CIBMTR registry is supported primarily by the U24-CA76518 from the National Cancer Institute, the National Heart, Lung, and Blood Institute, and the National Institute of Allergy and Infectious Diseases and from HHSH234200637015C (HRSA/DHHS) to the Center for International Blood and Marrow Transplant Research.

Review Requirements:

For all Publications, Reports, Presentations, Symposiums, etc.

BMT CTN: Abstracts, presentations, and proposed publications relating to data obtained from BMT CTN protocols or to activities of BMT CTN Committees or Protocol Teams are to be submitted to the DCC for review.

Eisai Inc.: A draft copy of all publications and a summary of data resulting from the project shall be provided to Eisai, when such information is ready to be made available to the public. Eisai shall have **at least 30 consecutive days** prior to such public availability to review information, submit questions, and provide comments with the express understanding that all decisions regarding publication will be at the sole discretion of the investigators, unless Eisai's objections relate to information provided by Eisai as confidential, prior to commencing the research project. Eisai shall be allowed to purge its confidential information from the publications or summary of data.

Hospira Inc.: A draft copy of all publications and a summary of data resulting from the project shall be provided to Hospira, when such information is ready to be made available to the public and in a timely manner after the **9 month** patient follow-up period as specified in the study protocol. Hospira shall have **at least 30 consecutive days** to review information, submit questions, and provide comments with the express understanding that all decisions regarding publication will be at the sole discretion of the investigators, unless Hospira's objections relate to information provided by Hospira as confidential, prior to commencing the research project.

Roche Laboratories: When requested by Roche, NMDP shall provide Roche with a draft copy of all publications and a summary of data resulting from the project, when such information is ready to be made available to the public. Roche shall have up to **45 consecutive days** prior to such public availability to review information, submit questions, and provide comments with the express understanding that all decisions regarding publication will be at the sole discretion of the investigators, unless Roche's objections relate to information provided by Roche as confidential, prior to commencing the research project. If Roche believes that any proposed publication contains any information relating to patentable items, the disclosure of such proposed publication to any third party shall be delayed for up to an additional **90 days** to permit the filing of a patent application.

Immunex / Amgen: Prior to submission for publication or presentation, Amgen shall be provided (1) **30 days** to review and to request, in writing, to remove all confidential information from a **manuscript** and (2) **15 day** to review and to request, in writing, to remove all confidential information from any **poster presentation, abstract or other written or oral material** which describes the results of the study. These restrictions do not apply to written or oral material displayed or transmitted within the BMT CTN, among the PI, the investigators, and their staff as part of the performance of the protocol, and to cognizant federal agencies or departments as part of the reporting requirements of the protocol.

Questions regarding the above requirements may be directed to the Data Coordinating Center, NMDP Contracts & Procurement Department at NMDP_BMTCTN_Pub@nmdp.org.