Elm & Carlton Streets
Buffalo, New York 14263

Institutional Review Board

Approval Notice

This institution has an approved assurance of compliance on file with HHS which covers this activity FWA 00006731 Federal Wide Assurance identification number

November 14, 2017

Theresa Hahn, PhD

Theresa.Hahn@RoswellPark.org

Dear Dr. Hahn:

On 11/14/2017, the IRB reviewed the following submission:

Type of Submission:	Modification and Continuing Review
Type of Review:	☐ Full Board ☒ Expedited ☐ Exempt ☐ Non-Human Research
Special Determinations:	Waiver of HIPAA authorization; Waiver/alteration of the consent process
Title of Study:	Analysis of Total CD34 + Cell Dose and Survival After Myeloablative and Reduced Intensity Conditioning Regimens for Allogeneic Peripheral Blood Cell Transplantation
Investigator:	Theresa Hahn
IRB ID:	MODCR00000531 / EDR 231112
Funding:	None
Grant ID:	None
IND, IDE, or HDE:	None
Documents Reviewed:	

The IRB approved the study from 11/14/2017to 12/5/2018 inclusive. Before 12/5/2018 or within 30 days of study closure, whichever is earlier, you are to submit a continuing review with required explanations. You can submit a continuing review by navigating to the active study and clicking Create Modification / CR.
If continuing review approval is not granted on or before 12/5/2018, approval of this study expires after that date.

Please be advised that only the IRB approved and stamped consent form can be used to enroll subjects.

The principal investigator is responsible for ensuring that the research complies with all applicable regulations. Any modifications in the research project are subject to approval by the Board prior to initiation by the investigator. The Board reserves the right to stop the research for violations of regulatory or IRB requirements.

A progress report must be submitted to the IRB at least one month prior to the expiration date noted above for continuing review as required by federal regulations and/or institutional requirements.

Please be advised that your research study may be audited periodically by the IRB for compliance.

This activity has been reviewed and approved by an IRB in accordance with the requirements of 45 CFR 46, including its relevant Subparts. This protocol fulfills, when applicable, requirements for certifying FDA status for each investigational new drug or device.

The study documents have been submitted to Clinical Research Services (CRS) Compliance Office for processing prior to release and protocol implementation. Please contact CRS Compliance for information regarding the protocol implementation release date.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103), including the reporting of Unanticipated Problems and any other Reportable New Information.

Sincerely,
Donald Handley MSc, MBA
Camille P Wicher, PhD, Esq., RN, MSN