INSTITUTE: National Cancer Institute

STUDY NUMBER: 11-C-0073 PRINCIPAL INVESTIGATOR: Nirali N. Shah, M.D.

STUDY TITLE: A Phase I Study of NK Cell Infusion Following Allogeneic Peripheral Blood Stem Cell Transplantation from Related or Matched Unrelated Donors in Pediatric Patients with Hematologic Malignancies

Continuing Review Approved by the IRB on 08/21/17
Amendment Approved by the IRB on 01/08/16 (P) Date Posted to Web: 09/26/17

Standard - Addendum

## INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary**.**

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your personal physician or other health professional.

If you are signing for a minor child, "you" refers to "your child" throughout the consent document.

You are currently enrolled in a clinical trial that includes administration of a cellular product that was prepared and/or was frozen using a reagent prepared in the NIH Clinical

Center's Pharmaceutical Development Section (PDS). NIH recently discovered that two vials of a different product produced in the PDS had become contaminated. In a subsequent FDA inspection of the facility, several problems were identified that may have contributed to this problem. NIH is working to correct these problems. Currently, we have no evidence that any patient has been harmed or any evidence that that the product you will receive is contaminated. In addition, the risk for such contamination appears to be very small and the cell product you will receive has already undergone sterility testing in the NIH's microbiology department and had no evidence of being infected. Nonetheless, NIH has decided that, out of an abundance of caution, any materials produced by the PDS should be withheld until alternative plans can be made or that an exemption may be granted for the use of this product. In your case, we believe the cell product you will receive is safe and with your permission we will release the product to you, given we believe the risk of using this product is small and is outweighed by an important clinical need.

## OTHER PERTINENT INFORMATION

**1. Confidentiality.** When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

**2. Policy Regarding Research-Related Injuries.** The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

**3. Payments.** The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

**4. Problems or Questions.** If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Nirali Shah, M.D., Building 10-CRC, Room 1-1621, Telephone: 301-451-0390. You may also call the Clinical Center Patient Representative at 301-496-2626.

**5. Consent Document.** Please keep a copy of this document in case you want to read it again.

| **COMPLETE APPROPRIATE ITEM(S) BELOW:** | |
|---|---|
| **A. Adult Patient's Consent**<br>I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.<br><br>_____ _____<br>Signature of Adult Patient/ Legal Representative Date<br><br>_____<br>Print Name | **B. Parent's Permission for Minor Patient.**<br>I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study.<br>(Attach NIH 2514-2, Minor's Assent, if applicable.)<br><br>_____ _____<br>Signature of Parent(s)/ Guardian Date<br><br>_____<br>Print Name |
| **C. Child's Verbal Assent (If Applicable)**<br>The information in the above consent was described to my child and my child agrees to participate in the study.<br><br>_____ _____ _____<br>Signature of Parent(s)/Guardian Date Print Name | |
| **THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM AUGUST 21, 2017 THROUGH AUGUST 20, 2018.**<br><br>_____ _____ _____ _____<br>Signature of Investigator Date Signature of Witness Date<br><br>_____ _____<br>Print Name Print Name | |