

MEDICAL RECORD**CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY**

- Adult Patient or
- Parent, for Minor Patient

INSTITUTE: National Cancer Institute

STUDY NUMBER: 11-C-0016 PRINCIPAL INVESTIGATOR: Daniel H. Fowler, M.D.

STUDY TITLE: Rapamycin-Resistant T Cell Therapy of Multiple Myeloma: Relapse Prevention and Relapse Therapy

Continuing Review Approved by the IRB on 12/19/16

Amendment Approved by the IRB on 02/16/17 (O)

Date posted to web: 03/03/17

Addendum to 11-C-0016

This addendum provides new information about the study "Rapamycin-Resistant T Cell Therapy of Multiple Myeloma: Relapse Prevention and Relapse Therapy" on which you are enrolled. The information in the consent you signed previously is unchanged.

The NIH Clinical Center Pharmaceutical Development Service (PDS) helps prepare the stem cells used in this study. The PDS was recently closed down by NIH leadership after a vial of contaminated material was discovered on another study just before it was supposed to be given to a research participant. The PDS is undergoing a full review and changes are being made to make sure that processes are in place to prevent anything like this from happening again. The FDA and NIH decided that it might be better and safer to make an exception to the PDS shutdown for some research studies as long as those decisions are made on a case by case basis. The stem cells used for T cell transplant received one of those exceptions because it would be potentially very harmful for you to not receive the cells. Before giving the exception, the FDA and NIH determined that the risk to you from receiving the stem cells that includes the portions made by the PDS, before all of the reviews and changes to the PDS are finished, is extremely low.

PATIENT IDENTIFICATION**CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY**

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- Parent, for Minor Patient

NIH-2514-1 (07-09)

P.A.: 09-25-0099

File in Section 4: Protocol Consent (2)

COMPLETE APPROPRIATE ITEM(S) BELOW:

A. Adult Patient's Consent

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.

Signature of Adult Patient/
Legal Representative

Date

Print Name

B. Parent's Permission for Minor Patient.

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.

(Attach NIH 2514-2, Minor's Assent, if applicable.)

Signature of Parent(s)/ Guardian

Date

Print Name

C. Child's Verbal Assent (If Applicable)

The information in the above consent was described to my child and my child agrees to participate in the study.

Signature of Parent(s)/Guardian

Date

Print Name

**THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE
FROM DECEMBER 19, 2016 THROUGH DECEMBER 18, 2017.**

Signature of Investigator

Date

Signature of Witness

Date

Print Name

Print Name