

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO (UCSF)
ASSENT TO BE IN A RESEARCH STUDY**

Study Title: CC#110819: A Pilot Trial of Clofarabine Added to Standard Busulfan and Fludarabine for Conditioning Prior to Allogeneic Hematopoietic Cell Transplantation

**Assent Form
For children 7-12 years old**

Why are we meeting with you?

We want to tell you about something we are doing called a research study. A research study is when doctors collect a lot of information to learn more about something. Dr. Christopher Dvorak and some other doctors are doing a study to learn more about how to make transplant better. After we tell you about it, we will ask if you'd like to be in this study or not.

Why are we doing this study?

We want to find out how your body responds to a different combination of drugs before you have a blood cell transplant (when doctors give you new blood). So we are getting information from lots of boys and girls like you.

In the whole study, there will be up to 31 people (children and adults) who either have cancer or another disease.

What will happen to you if you are in this study?

Only if you agree, these things will happen:

To see if you can be in the study, the doctors will need to do the steps below:

1. The doctors will take a small amount of your blood to see if you can be in the study. The blood will be taken by a needle in your arm or your line (the thin tube under your skin).
2. You will have pictures taken of your heart. The doctor will ask you to lie on your left side while the doctor uses a computer to take pictures of your heart.
3. You will have to breathe in and out of a machine so the doctor can measure how well you breathe.

If the doctor says that you can be in the study, the steps below will be done:

1. You will stay in the hospital for 6 - 8 weeks.
2. A thin tube will be placed under your skin near your neck so it will be easier to give you medications and take your blood.
3. A small amount of your blood will be drawn. That means it will be taken by the thin tube under your skin. This will happen almost every day before your blood cell transplant.
4. A few days before your blood cell transplant, different medicines will be given through the thin tube under your skin.
5. The doctors will ask you questions about how you feel.
6. While you are in the hospital for your blood cell transplant, the doctors will take a small amount of your blood taken from the thin tube under your skin in order to study how you are doing on the transplant.

Will this study hurt?

You will be asleep while the doctor places the thin tube under your skin. This will not hurt. Giving you medicine and taking blood from the thin tube will not hurt.

Will you get better if you are in this study?

No, this study won't make you feel better or get well. But the doctors might find out something that will help other children like you later.

Do you have any questions?

You can ask questions any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else.

Do you have to be in this study?

No, you don't. No one will be mad at you if you don't want to do this. If you don't want to be in this study, just tell us. Or if you do want to be in the study, tell us that. And, remember, you can say yes now and change your mind later. It's up to you.

If you don't want to be in this study, just tell us.

If you want to be in this study, just tell us.

The doctor will give you a copy of this form to keep.

SIGNATURE OF PERSON CONDUCTING ASSENT DISCUSSION

I have explained the study to _____ (*print name of child here*) in language
he/she can understand, and the child has agreed to be in the study.

Date

Signature of Person Conducting Assent Discussion

Name of Person Conducting Assent Discussion (*print*)