UNT Health Science Center, Fort Worth, Texas
&
Cook Children's Health Care System
Fort Worth, Texas

PERMISSION TO PARTICIPATE IN RESEARCH AND USE OR DISCLOSE YOUR PROTECTED HEALTH INFORMATION

Department: [redacted]

Title of Research: [redacted]

Sponsor: [redacted]

Investigators: [redacted]

Telephone #: [redacted]

This is an invitation to participate in research. This document is intended to help you understand your rights as a research participant. Please take your time to make your decision. Feel free to discuss it with physicians, family and friends. The Research Team may include licensed practitioners such as physicians, as well as other licensed practitioners who will supervise this research.

If you are the parent or guardian of a child who is under the age of 18 years, reading and signing this document on behalf of that child, the words "you", "your", "I" or "me" refers to your child.

[redacted]

Subject Initials: _____
Date: _____

Why is this study being done?

Leukemia is the most common type of cancer diagnosed in children under age 20. Our white blood cells have "natural killer cells" (NK cells) that have the ability to fight and kill infections such as a virus. NK-cells also work to kill tumor cells and other cells that are not normal for our bodies. Researchers have found several substances (proteins) on the outside of the NK cells that seem to stimulate other cells that they come into contact with. The NK cells can then destroy the abnormal cells. This is important because it tells us that by changing the proteins on the surface of the NK cells we may be able to find important clues regarding the cause of cancers and other diseases in people.

Also short term genetic changes of tumor suppressor genes commonly known as CpG hypermethylation have been identified as a common event in patients with cancer (in particular, patients with leukemia). The goal of this study is to find out whether or not the proteins on the surface of the NK cells are the same or different for children who have leukemia but are from different racial and ethnic backgrounds. We want to find out whether there is any difference in short term genetic changes and expression of cell surface proteins in white blood cells of children with acute lymphoblastic leukemia (ALL) as compared to children who do not have ALL. There will be thirty five children with ALL and thirty five children who do not have ALL between the ages of 2 and 21 years in this study.

The thirty five ALL study participants will be recruited from Cook Children's Health Care System (CCHCS) and thirty five non-ALL (healthy) study participants will be recruited at UNT Health Science Center (UNTHSC).

What will happen in this research?

In this study we will have two groups of participants. One group will include participants who are newly diagnosed with acute lymphoblastic leukemia (ALL) and who have not undergone any chemotherapy treatments. The other group will include those participants who do not have ALL and are healthy.

First, you and your parent(s), or the person who takes care of you, will be asked to complete a questionnaire. This questionnaire will include questions about you and your parent's demographical information. It will take no more than 10 - 15 mins to complete the questionnaire. If you are above the age of 18 yrs, you, and not your parents, will be asked to fill out the questionnaire.

If you have ALL, before your cancer doctor gives you chemotherapy (which is not part of this study), you will have some routine tests. When these routine tests are done, we would like to ask your permission to collect about an extra half (1/2) tablespoon of blood from you for this research study. We will also ask your permission to collect another half tablespoon of blood after 3 weeks of receiving your first round of chemotherapy. We will collect your blood samples when blood is being collected for routine purposes so that you do not have an extra needle stick.

[redacted]

Subject Initials: _____
Date: _____

If you do not have ALL, we will ask your permission to collect half a tablespoon of blood only once during the study by a needlestick. If possible, we will collect this blood at the same time routine blood work is being drawn so that you do not have an extra needle stick.

Once we collect the samples from all participants, we will label them with numbers instead of names. The office where your blood is collected will keep a key (list) which links the number on your sample with your identity. However, the sample will only be labeled with the number assigned to your sample, not your identifiable information. We will only use your samples for research. We will analyze the expression of immune receptors (proteins) and short term genetic changes in the DNA obtained from your blood sample. Results from any of the studies done with your samples will not list your name or anything about you. Also, these results will not be put in your health record. With your permission your sample will be kept in a protected freezer indefinitely for future research work.

Because we don't know the importance of the research results, we will not be giving them to your doctor or to you.

In addition, if you decide later that you no longer want your blood sample to be used for research, you can ask your doctor to have any remaining sample discarded. If you choose this, the information already gained from the sample will still be included in this study but your sample will not be used for future studies.

Please read the following carefully. Circle "Yes" or "No" to let us know if you want or do not want to be in the study, and put your initials next to your choice.

I agree to allow extra blood samples as well as my DNA to be collected from me for research to learn about certain differences between the white blood cells of people with ALL and the white blood cells of people without ALL.

Yes _____ No _____

I agree to allow any extra blood as well as my DNA to be kept for use in future research to learn about, prevent, or treat other health problems such as diabetes, other cancers, Alzheimer's disease, heart disease or other related diseases.

Yes _____ No _____

What are the risks of this study?

There are two kinds of possible risk to being in this study. The first is that blood collection using a needle may cause pain, bruising and bleeding at the injection site (where the needle goes through the skin). In rare cases infection can occur following a needle stick.

[redacted]

Subject Initials: _____
Date: _____

However, we will use standard safety steps to take your blood sample in an effort to minimize the risks of complications from a needle stick.

The second kind of risk involves the possibility of information about your blood analyses getting used by someone who should not have it. In an effort to maintain confidentiality and to keep your sample safe, we will remove your name and replace it with a study number as described above.

If you do not have ALL and are participating in this study, your blood sample will be used to compare to those who do have ALL to find out if possible factors and markers that might be related to leukemia are correct. Your medical information will not be shared with anyone. Once samples have been collected, your name will be removed from the sample and only the sample number/ age / gender / race-ethnicity, will be kept with your sample.

We will take as much care to protect your information about your sample, questionnaire and the results as possible. Study information will be kept in a locked cabinet with access only to those involved in the study. Samples will be coded and the identity of the participant will not be revealed to personnel doing the biochemical and/or statistical analyses.

Will I benefit from this research?

The research that may be done with the samples is not designed to help you during your present treatment. It might help people who have cancer or other diseases in the future.

Are there alternatives to this study?

You may choose not to participate in this study. Whether you choose to participate or not, your treatment and/or medical care will remain the same.

What about the costs and compensation?

Participation in this research study will not require any additional costs for you or your insurance company.

University of North Texas Health Science Center (UNTHSC), Cook Children's Health Care System (CCHCS) and the sponsor of this research have not set aside any funds to compensate (pay) you in case you are injured as a result of taking part in this research study. You will receive no payment for taking part in this research.

In the case of injury or illness resulting from this research, emergency medical treatment is available; however, you or your insurance company will be responsible for the costs associated with any emergency medical treatment that is necessary. In the event that you need continuing medical care and/or hospitalization as a result of injury or illness resulting from the research, you or your insurance company will be responsible for the costs associated with such treatment.

Subject Initials: _____
Date: _____

Will my records be kept confidential?

Efforts will be made to keep your personal information private. Unfortunately, complete privacy cannot be assured. Information about you may be disclosed as allowed by law. Published results of this research will not identify you as a participant in any way.

The Health Information Portability and Accountability Act (HIPAA) was written to make sure that the privacy of patients and their families is respected by the people that use your Protected Health Information (PHI). Protected Health Information includes any information that relates to your past, present, or future physical or mental health or condition; the health care being provided to you; or the past, present, or future payment for the health care that was, is or will be provided to you. PHI (any information that could identify you) may include:

- Name
- County of residence
- Gender
- Diagnosis
- Disease Status
- Birthdate
- Zip Code
- Race/Ethnicity
- Diagnosis Date

UNTHSC and CCHCS is dedicated to the protection of your personal, medical, and financial information. However, if you are enrolled in research, it may be necessary to submit your PHI to fulfill the objectives of the research as is outlined above.

What else should I know?

- The choice to give permission (authorization) for UNTHSC and CCHCS researchers to use or share (disclose) your protected health information (PHI) is voluntary. No one can force you to give permission. However, you must give permission if you want to be in the research. Sharing the information includes sending it to the sponsor.
- UNTHSC and CCHCS will keep all patient information private in accordance with federal law. However, once your information has been shared, UNTHSC and CCHCS cannot guarantee that it will remain protected.
- Your standard, non-research care will not be affected in any way whether or not you give permission.
- By signing this document, you are allowing UNTHSC, CCHCS and the research team led by the Principal Investigator, [redacted], to use and/or disclose your PHI for the purpose of participating in this research.

How long can my information be used or shared?

- Unless you withdraw your permission in writing, the CCHCS researchers can continue to use or share your information indefinitely or until the study is totally closed and the sponsor is no longer interested in the outcome of participants.

[redacted]

Subject Initials: _____
Date: _____

- If you choose to withdraw your permission, the information that was used or disclosed prior to your withdrawal will continue to be used by the sponsor of the research.
- At the time of withdrawal of your permission/participation in the research, your PHI will no longer be submitted for use to the sponsor.

What are my rights as a research participant?

You have the right to know about the release of your PHI. You have the right to withdraw your participation at any and all levels of participation at any time. You have the right to have all your questions and concerns addressed and answered to the best of our ability.

What if I have questions or problems?

You may contact your study doctor or research team if you have questions or problems regarding this research.

You may also contact the Chairman of the IRB, UNTHSC at 817-735-0409 or the current Chairperson of the IRB [redacted] for information regarding your rights as a research participant.

A representative of the IRB could contact you for information about your experience with this research. You have the right to answer or refuse to answer any questions the representative of the IRB may ask. Any conversations initiated by the IRB are in an effort to ensure the integrity of the research conduct and will be kept confidential.

STATEMENT OF CONSENT

Your signature below means that you want to take part in this research. It also means that you understand this research and that your PHI will be shared as described above.

Your signature below certifies the following:

- You have read (or been read) the information provided above
- You have received answers to your questions at this time
- You have freely decided to participate in this research
- You understand that you are not giving up any of your legal rights

You will receive a copy of this document for your files.

_____

PRINTED NAME OF PARTICIPANT

SIGNATURE OF PARTICIPANT DATE

Not required if participant is less than 18 years old, per regulatory guidelines.

PRINTED NAME OF PARENT OR LEGALLY AUTHORIZED GUARDIAN

SIGNATURE OF PARENT OR LEGALLY AUTHORIZED GUARDIAN DATE

□ N/A – not required if English consent is being used in conjunction with non-English Short Form, per regulatory guidelines. _____
Initials and Date
(Person Obtaining Consent)

PRINTED NAME OF WITNESS

SIGNATURE OF WITNESS DATE

As witness, you attest that the consent and treatment have been presented to the parents/legal guardian, their questions have been answered and they agree to participate in this research.

□ N/A – Witness not required per regulatory guidelines. Subject and/or legally authorized representative fluent and literate in the language of the written consent form._____
Initials and Date
(Person Obtaining Consent)

PRINTED NAME OF PERSON OBTAINING CONSENT

SIGNATURE OF PERSON OBTAINING CONSENT DATE

Note: Informed consent must be performed in language understandable to the legally authorized parent/guardian. This requires use of either a full, translated consent document approved by the CCHCS IRB or a translated, IRB-approved "short-form" and a translator for the consent process.

[redacted]

Subject Initials: _____
Date: _____

[redacted]

Assent Agreement to Be In Research (Participants 13-17 Years)

This is an invitation to be in a research study. This form explains the study. You should ask questions and talk to your parents and doctors about anything that you do not understand.

Why is this study being done?

In this study, we want to look at some cells in your blood called the white blood cells. We want to learn whether certain substances (called proteins) are the same or different for children who have leukemia but are from different racial and ethnic backgrounds. We also want to see if the genetic changes in the white blood cells of people with acute lymphoblastic leukemia (ALL) are different from the changes in the white blood cells of people without ALL.

To do these tests we will ask your permission to collect some blood samples from you. We plan to enroll thirty five children with ALL and thirty five children who do not have ALL on this study.

What will happen in this study?

First, you and your parent(s), or the person who takes care of you, will be asked to complete a questionnaire. This questionnaire will include questions about you and your parent's demographical (race, age etc.) information. It will take no more than 10 - 15 mins to complete the questionnaire.

If you have ALL, before your cancer doctor gives you chemotherapy (which is not part of this study), you will have some routine tests. When these routine tests are done, we would like to ask your permission to collect about an extra half table spoon of blood from you for this research study. We will also ask your permission to collect another half table spoon of blood after 3 weeks of receiving your first round of chemotherapy. We will collect your blood samples only when blood is being collected for routine purposes. This way you will not need to have any extra procedures (such as needle stick) for us to get the extra blood samples.

[redacted]

IRB APPROVED

NOV 13 2008

University of North Texas
Health Science Center

Subject Initials: _____
Date: _____

If you do not have ALL, we will ask your permission to collect half a tablespoon of blood only once during the study. We are collecting your blood sample because we want to compare how different your white blood cells behave from the white blood cells of people with ALL. We will collect your blood sample by needlestick.

Once we collect the samples from all participants, we will label them with numbers instead of names. This way no one will be able to look at your sample and know that it is yours. We will only use your samples for research. Results from any of the studies done with your samples will not list your name or anything about you. Also, these results will not be put in your health record.

Please read the following carefully. Circle "Yes" or "No" to let us know if you want or do not want to be in the study, and put your initials next to your choice.

I agree to allow extra blood samples as well as my DNA to be collected from me for research to learn about certain differences between the white blood cells of people with ALL and the white blood cells of people without ALL.

Yes _____ No _____

I agree to allow any extra blood as well as my DNA to be kept for use in future research to learn about, prevent, or treat other health problems such as diabetes, other cancers, Alzheimer's disease, heart disease or other related diseases).

Yes _____ No _____

What are the risks of this study?

The blood collection may cause a little pain, bruising, bleeding, and very rarely, infection. However, we will use standard (normal) safety steps to collect blood from you.

Also, there is a small chance that someone could receive information about your participation who should not have it. We will do everything we can to make sure that this does not happen. We will put your medical records in a locked cabinet so that your name, address, and phone number will be kept private. The chance that this information will be given to someone else is very small.

Will this study help me?

This study may not help you directly, but it will help us to better understand how childhood leukemia happens. We hope that this information might help other children with cancer someday.

Subject Initials: _____
Date: _____

Are there other ways to help me?

You could choose not to take part in this study.

Will I get paid for being in this study?

You will not get paid for being in this study.

What else do I have to do?

If you are in the study, always ask questions if you don't understand something.

CHILD'S CHOICE

Checking the "Yes" box means you want to be in the study. Checking the "No" box means you don't want to be in the study.

Remember, you don't have to be in the study if you don't want to. Nobody can make you be in it. Even if you start, you can quit whenever you want.

If you don't want to be in the study, we will try to do other things to help you. If you want to quit later, we will still try to help you in other ways.

Do you want to be in the study? ☐ Yes ☐ No

_____	_____	_____
DATE	CHILD'S NAME (PRINTED)	CHILD'S SIGNATURE
_____	_____	_____
DATE	NAME OF PERSON EXPLAINING STUDY	SIGNATURE

IRB APPROVED

NOV 13 2008

University of North Texas
Health Science Center

[redacted]

Subject Initials: _____
Date: _____