Children's Hospital of Philadelphia

Informed Consent and HIPAA Authorization Form

Study Title: A prospective cohort study to define infectious burden, the seroprevalence of vaccine preventable pathogens and immune recovery in the first year following completion of therapy in patients with acute lymphoblastic leukemia (ALL)

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You, or your child, may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

In the sections that follow, the word "we" means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to your child.

Study Overview

You are being asked to take part in this research study because you have been diagnosed with Acute Lymphoblastic Leukemia (ALL) and have recently completed or will complete chemotherapy in the next three months.

While receiving chemotherapy, we know that the immune system is suppressed and that you are at a higher risk of infection. However, after finishing chemotherapy, we do not know the exact time that the immune system recovers and if you are still at a higher risk of infection until that time.

One purpose of this research study is to get an in-detail account of all infections you may have in your first year off chemotherapy. The study team wants to better understand how often they occur so that we can better help guide our patients about their risk.

Another purpose of the research study is to better understand how the immune system recovers after you finish chemotherapy. The study team wants to see if we can track your immune system recovery through blood work. This includes measuring whether your immune system remembers the vaccines that you got before starting chemotherapy.

If you agree to take part, your participation will last for approximately 1 year and will involve:

- Review of your medical records.
- An initial screening visit.

- Three subsequent in-person study visits during your regularly scheduled oncology visits.
- Monthly phone calls to ask about any possible infections you have had.
- Research blood tests.

There will be no direct benefit to you from taking part in this study. The study team hopes that in the future, the information learned from this study will benefit other children who have completed ALL chemotherapy.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time. If you do not choose to take part in this study, you can discuss treatment options with your doctor.

Please see below for additional details about the study.

How many people will take part?

About 115 children diagnosed with ALL will take part in the study, including 63 patients from CHOP. About 330 healthy patients from CHOP will also be included.

What are the study procedures?

Some of the procedures in this study will be repeated several times. Tests that are part of your regular, routine medical care will continue to be performed. Additional tests may be performed if any of your initial test results are not normal. The study involves the following tests and procedures.

Blood Draw:	Study staff will collect a little more than one and a half tablespoons of blood from you to measure the recovery of your immune system. We will collect these samples at 3, 6, and 12 months after you finish chemotherapy. We will try to collect blood at the same time as blood draws done as a part of normal clinical procedures. We will try not to stick you more than once. Subjects of very low weight may have less blood taken than other subjects. By agreeing to participate in the study, you agree to give these samples to CHOP for research purposes.
Medical Record Review:	Study staff will look for specific information in your medical records. We will look at the records for this information in the one-year period after you finish chemotherapy. We will collect data about your medical history, current health, diagnosis, treatments, medications and results of clinical tests.
Interviews:	A team member will call you and take your medical history monthly, along with a listing of any medications you are taking. Throughout the study you will be asked to report if you have had any infections, required a medication for an infection, and if you have visited your doctor, urgent care office, or the emergency department.

Visit Schedule

Visit	Purpose	Main Procedures	Duration
Visit 1	Screening visit	Consent meeting	1 hour
Visit 2, approx. day 90 or 3 months after completion of chemotherapy (+/- 4 weeks)	Routine visit	Lab tests	30 minutes
Visit 3, approx. day 180 or 6 to 8 months after completion of chemotherapy *(May occur up to 4 weeks prior to 6-month mark or 8 weeks after, depending on your clinic visit schedule)*	Routine Visit	Lab tests	30 minutes
Visit 4, approx. day 365 or 1 year after completion of chemotherapy *(May occur up to 6 weeks prior to one-year mark or 8 weeks after, depending on your clinic visit schedule)*	End of Study	Lab tests	30 minutes

What will be done with my data and specimens during this study?

During the study, we will collect blood samples from you. By agreeing to participate in the study, you agree to give these samples to CHOP for research purposes.

Will I receive any results from the tests done as part of this study?

Results from tests done as part of the study will not be shared.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to your study doctor or your regular doctor.

Taking blood may cause some pain, bleeding or bruising at the spot where the needle enters your body. Rarely, taking blood may cause fainting or infection. To minimize these risks, the study staff will try, when possible, to collect blood at the time of a clinical blood draw.

As with any study involving collection of data, there is the possibility of breach of

confidentiality of data. Every precaution will be taken to secure participants' personal information to ensure confidentiality.

Each participant will be given a study code number after consent. During the study, this number will be used instead of names and other private information. Study staff will use this number for blood samples and in the database. Study staff will keep a separate list that will link each participant's name to the study code number for future reference and communication.

Are there any benefits to taking part in this study?

There will be no direct benefit to you from taking part in this study. The study team hopes that in the future, the information learned from this study will benefit other children who have completed therapy for ALL.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

Can the study doctor take you out of the study early?

The study doctor may take you off of the study if:

- Your condition worsens.
- The study is stopped.
- You cannot meet all the requirements of the study.
- New information suggests taking part in the study may not be in your best interests.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. This will include information from your medical records, observations from clinical procedures, interviews, imaging studies and results from laboratory tests. Information related to your

medical care at CHOP will go in your medical record. This could include physical exams, imaging studies (x-rays or MRI scans) or tests done in the clinical lab.

Medical records are available to CHOP staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.
- Merck & Co., who is sponsoring this research;
- Your samples/data will be shared with outside laboratories and institutions (such as the laboratory at the Mayo Clinic), who will analyze and store your samples. Your samples/data will only include your study ID number, an ID number specific to the sample and the date the sample was collected. The outside laboratories will not know who you are. Private information such as your name, birth date or medical record number will not be shared with them. Tests run by outside laboratories will not appear in your medical record.
- If you agree, your data will be shared through databases that may be publicly available to anyone. The data will not include identifiers like your name, medical record number or date of birth. To use your data, researchers must promise not to try to re-identify you. You can tell us at the end of this form whether you will allow us to share your data in this way.
- Non-identifiable data will also be shared with other researchers at CHOP and at other participating institutions that are part of the Children's Oncology Group. This is an organization of hospitals and clinics around the world that treat children with cancer.

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Brian Fisher
The Children's Hospital of Philadelphia
Division of Pediatric Infectious Diseases

Roberts Center for Pediatric Research
2716 South Street, Room 10-362
Philadelphia, PA 19146

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

Will there be any additional costs?

There will be no additional costs to you by taking part in this study

The study sponsor is providing financial support and material for all experimental procedures, as listed above, for this study. The following research procedures will be paid by the study sponsor:

- Blood tests for immune system recovery and vaccine memory

Will you be paid for taking part in this study?

You will not receive any payments for taking part in this study.

Who is funding this research study?

This study is supported by the Merck & Co. Merck & Co. is a drug company that makes the vaccines being studied in this research project. Merck & Co. is giving money to Children's Hospital for the costs of the study. The results of the study will be reported to Merck & Co. If the study reveals information that may be useful for a new purpose, this could benefit Merck & Co financially. The funding of this study may change over time.

Please ask Dr. Fisher or Dr. Chehab if you have any questions about how this study is funded.

What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. Fisher, at 773-505-3130. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

What will be done with my data and specimens when this study is over?

As part of the study, we will collect blood as well as data regarding your medical care. We may wish to use this information and these samples in future studies looking at future.analysis of infections or immune system recovery in pediatric patients with ALL. There is no time limit on how long your samples will be stored.

The information and samples will be given a unique code and will not include information that can identify you. A Master List containing information which links your unique code to your identifiable information will be kept on secure research servers at CHOP. This can only be accessed by approved study staff at CHOP. Specimens labeled with your study ID and the specimen collection date may be kept permanently in a central laboratory freezer. Only the study doctors and those working with them on this study will be able to see information that can identify you.

We will use and may share data and/or specimens for future research, including genetic studies that could involve genome-wide sequencing (the analysis of the complete set of DNA in a cell). They may be shared with researchers/institutions outside of CHOP. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

Optional Consent for Use of Identifiable Data or Specimens for Future Research

As part of the study, we will collect blood as well as data regarding your medical care. We may wish to use this information and these samples in future studies looking at future analysis of infections or immune system recovery in pediatric patients with cancer. There is no time limit on how long your samples will be stored.

Research could occur at CHOP, or at outside institutions, which could include for profit companies. The information and samples will be given a unique code and may include information that can identify you. Information that can identify you may be kept permanently in a computer database at CHOP.

We may not ask for your consent before using or sharing your de-identified specimens or data. You will not receive any results or financial benefit from the future research done on your specimens or data. We may share your de-identified specimens or data with outside researchers who will use them for future research.

If you leave the study, you can ask to have the data collected about you removed or the samples destroyed. You can also ask us to remove information that identifies you from the data or samples. This may not be possible if your samples and data have already been

shared.

Please indicate whether you will allow the identifiable data or samples to be used for future research by putting your initials next to one of the following choices:

_____(initials) NO, my identifiable (data and/or specimens) may not be used for future research. They may be used for this study only.

_____(initials) YES, my identifiable (data and/or specimens) may be used for other future research studies.

Optional Consent for Collection of Environmental and Insurance Data

As an optional part of this study, we are also interested in researching whether the environment around the area where patients live, and patients' health insurance status, have any impact on health. To study these factors, we would like to collect some additional information, including your full zip code (your full zip code is the zip code plus four digits on your mailing address) and information on the type of health insurance you have. We will not collect your full address.

We want to measure these factors because there is evidence that suggests the environment a person lives in can have an impact on health, but whether it plays a role in this group of patients is not well understood.

This part of the study is optional. You may still participate in the study even if you do not want to have this information collected.

Please initial below to indicate whether you will allow your information related to environment and insurance status to be collected as part of this research:

_____(initials) NO, information on environment and insurance may NOT be collected for this study.

_____(initials) YES, information on environment and insurance MAY be collected for this study.

Optional Consent to Complete Household Survey

As another optional part of this study, we are also interested in gathering information about the life of the patient and their family outside of the hospital. This information is intended to help researchers study ways to provide better patient care in the future. If you would like to participate in this part of the study, you will be given a link to an online survey that will take about 3 minutes to complete. The survey will ask questions about the patient/family's life related to topics such as housing, utilities, food, and money. Some questions may feel personal or difficult to answer, so even if you agree to participate in the survey, you may skip questions or stop taking the survey at any time. Survey answers will be kept confidential and will not be shared with your treatment team or placed in the patient's medical record.

This part of the study is optional. You may still participate in the study even if you do

not want to complete the survey.

Please initial below to indicate whether you would like to complete this survey as part of this research:

_____(initials) NO, I would NOT like to participate in this survey.

_____(initials) YES, I WOULD like to participate in this survey.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your child's participation. You are also authorizing the use of your/your child's health information as discussed above. If you don't agree to the collection, use and sharing of health information, you cannot participate in this study. **NOTE:** *A foster parent is not legally authorized to consent for a foster child's participation.*

Name of Subject	
Signature of Subject (18 years or older)	Date
Name of Authorized Representative (if different than subject)	Relation to subject: ☐ Parent ☐ Legal Guardian ☐ Legally Authorized Representative
Signature of Authorized Representative	Date

Child Assent to Take Part in this Research Study

For children capable of providing assent:

I have explained this study and the procedures involved to_____in terms he/she could understand and that he/she freely assented to take part in this study.

_____
Person Obtaining Assent

_____ _____
Signature of Person Obtaining Assent Date

This study has been explained to me and I agree to take part.

_____ _____
Signature of Subject (optional) Date

For children unable to assent:

I certify that_____was not capable of understanding the procedures involved in the study sufficiently to assent to study participation.

_____
Person Responsible for Obtaining Assent

_____ _____
Signature of Person Responsible Date

STUDY SUMMARY DOCUMENT (NON-ENGLISH SPEAKERS)
Consent to Take Part in this Research Study and Authorization to Disclose Health Information for Research

Name of Subject

Name of Authorized Representative (if different than subject)

Relation to subject:
☐ Parent ☐ Legal Guardian

The research study and consent form have been explained to the subject or parent/legal guardian.

By signing this form, you are indicating that you have answered the subject's or parent's/legal guardian's questions, they have agreed to take part in this research study and they are legally authorized to consent to their or their child's participation. They have also agreed to let CHOP use and share their or their child's health information as explained above. If they don't agree to the collection, use and sharing of their or their child's health information, they cannot participate in this study.

Person Obtaining Consent

Signature of Person Obtaining Consent

Date:

Witness/Interpreter

By signing this form, you are indicating that

- The information in the Summary Document as well as any additional information conveyed by the person obtaining consent was presented to the subject in a language preferred by and understandable to the subject; and
- The subject's questions were interpreted and the responses of the person obtaining consent were presented in a language preferred by and understandable to the subject.
- At the conclusion of the consent conference, the subject was asked in a language preferred by and understandable to the subject if s/he understood the information in the Summary Document as well as any additional information conveyed by the person obtaining consent (including responses to the subject's questions) and responded affirmatively.

Name of Witness/Interpreter

Signature of Witness/Interpreter

Date: _____

Child Assent to Take Part in this Research Study

For children capable of providing assent:

I have explained this study and the procedures involved to_____in terms he/she could understand and that he/she freely assented to take part in this study.

_____
Person Obtaining Assent

_____ _____
Signature of Person Obtaining Assent Date

Witness/Interpreter

By signing this form, you are indicating that

- The information in the Summary Document as well as any additional information conveyed by the person obtaining assent was presented to the subject in a language preferred by and understandable to the subject; and
- The subject's questions were interpreted and the responses of the person obtaining assent were presented in a language preferred by and understandable to the subject.

At the conclusion of the consent conference, the subject was asked in a language preferred by and understandable to the subject if s/he understood the information in the Summary Document as well as any additional information conveyed by the person obtaining assent (including responses to the subject's questions) and responded affirmatively.

_____ _____
Name of Witness/Interpreter Signature of Witness/Interpreter

_____
Date