

APPENDIX A: CONSENT AND ASSENT FORMS

Appendix A1: Adult Case Consent



*Do not write
in this space*

(Adult Case: childhood case, now 18 or older, Flesch-Kincaid Reading level 7.6)

CONSENT TO VOLUNTEER FOR THIS RESEARCH STUDY

Exposure Assessment of Children with Acute Lymphocytic or Myelocytic Leukemia and a Comparison Population in Sierra Vista, Arizona

Thank you for taking the time to learn about this research study. This form tells about the study being done by the Arizona Department of Health Services (ADHS), the Cochise County Health Department (CCHD), and the Centers for Disease Control and Prevention (CDC). We want to collect blood, cheek cells and urine from people so we can try to learn more about the causes of childhood leukemia in Sierra Vista. We want to invite you to take part in this research study because you had (have?) leukemia and live in Sierra Vista. We hope you will take the time to read this form and that you will agree to take part in this research study. If you have any questions about this form while reading it, please let us know; we will be happy to help you in any way we can.

Please read this consent form carefully. If you decide that you would like to be a part of the research study, please sign at the end of this form. We would also like to invite your immediate family members to take part in this study. Immediate family members include your mother, father, and any full, half, or step-siblings who live with you. We will give each of your family members their own consent form.

While you are here, we will collect samples of blood, urine and cheek cells from you. If your parents(s) or former guardians agree to be part of the study we will ask them about your mother's pregnancy with you, and your family's medical history. Your visit to the county clinic offices may last as long as 30-45 minutes.

Purpose

Recently, the Arizona Department of Health Services found that there were more children with Acute Lymphocytic Leukemia (ALL) and Acute Myelocytic Leukemia (AML) in Sierra Vista than would be expected by chance. The ADHS has asked the CDC to help try to find a reason for this and to test urine, blood, and cheek cells from people in Sierra Vista. We hope that the tests and the discussions with community members will help us find out if there is anything in the air or water or soil to worry about. We also hope to find out more about what causes childhood leukemia.

This research study has two main parts, asking questions about people's health and getting a little bit of their blood, urine, and cheek cells. We will give a questionnaire to you and/or other members of your family who can answer the questions. Then we will take samples of your blood, urine, and cells from inside your cheeks. We will test these samples for chemicals, radioactive substances, and infectious agents. We may test your DNA for genes that could affect leukemia. The DNA samples will only be used for research about leukemia. We will not do any other kinds of genetic tests.

Freedom of Choice

Joining this study is up to you. You may choose to not join. If you don't join or join and then decide to drop out, nothing will happen to you.. Before you decide to join or not, you should know what will happen and have all your questions answered. If you have any questions about the study or about these consent forms, please ask anyone here or call Carol Rubin or Beverly Kingsley at CDC (770/488-3410); we will be happy to answer any questions you may have.

Payment

You do not have to pay to be in this study. We will not pay you for being in this study.

What will happen?

If you choose to be in this study, we will take 21 ml (about 1 to 1 1/2 tablespoons) of blood from a vein in your arm. First we will clean the skin by gently rubbing it with alcohol. The needle stick may hurt a little for a few seconds. You may have a bruise afterwards. The person taking the blood will be very careful. We will collect cheek cells by brushing the inside of each cheek with a soft brush for 30 seconds. It will not hurt to give a sample of cheek cells. You will provide 32.5ml (approximately 1 ounce) of urine. It will not hurt to give a urine sample. We will get DNA from part of your blood sample and from your cheek cells. We will store the samples at CDC with a research code number not your name. Any genetic tests we do on your DNA are for leukemia research only. Experts will advise CDC about which tests to do. We may look for differences in genes that tell your body how to break down toxic substances or fix damaged DNA. We may also look for viruses that may cause cancer. We don't think the genetic test results will change how your doctors treat you so we will not send you results of the genetic tests. We do think this genetic research may help us understand leukemia better. CDC will also save some of the blood and urine from this study with the research code number, not your name, in case we need to

do more tests in the future. We will not test your blood and urine for HIV, or the presence of alcohol or drugs. During the study, we will talk with your parent(s)/guardian(s) about your medical and pre-natal history. The interview form will have a research code number, not your name on it. Answers to the interview questions will be kept private.

Benefits

We do not think this study will tell us what caused your leukemia or change how your doctors treat you. We will tell you about the results of the tests we do on your blood and urine. We will send a report about what we learn to every one in this study. This report will not have any information that would identify you.

By giving us DNA for genetic testing, you will help us and other scientists and doctors understand why some people get ALL/AML and others do not. We will send you a report of the research findings that will not include any personal identifying information. But if we learn something about your DNA that might affect your health or your decision to have children, we will tell you personally. If this were to happen, you should tell your doctor about this. If your doctor wants to do more DNA tests you will have to pay for them.

Privacy

We will protect your privacy as much as the law allows. We will not put your name on the blood, urine, or cheek cell samples. Instead, these samples will have a research code number. We will keep all the research records and test results in locked files and only research staff will be allowed to look at them.

CDC will save a part of your blood and urine samples in the case we need to do more laboratory tests. CDC will give the laboratory test results to the CCHD and ADHS only by code number. Biological samples will be stored for an unspecified amount of time, until sufficient testing has been conducted. Personal identifiers will be

linked to biological specimens (and survey data) for as long as they are stored, in case there becomes biologically significant information that should be relayed to the person from which the sample came.

cell samples destroyed or removed from the biosampling research study, please call Dr. Carol Rubin (770/488-3410).

We will keep any forms with your private information in a locked file, separate from the answers to the questionnaire. CDC will store your DNA for future genetic research using only a research code number. The code number will allow CDC to link the laboratory tests and questionnaire data to the genetic studies. In spite of all the things we do to protect your identity, it might be possible for someone to know you were in this study because of the small number of children with leukemia in Sierra Vista.

We will keep a list with your name and research code number on it so that we can send you the results of the tests done on your blood and urine. This list will be kept in a locked file separate from the samples and completed questionnaire. We will protect your privacy as much as the law allows. When we talk or write about this research study, we will not include your name or any facts that might identify you.

Your name, telephone number, and address are on this consent form so that we can contact you while we are doing this research study. We will keep this consent form in a locked file separate from the rest of the data.

Right to Refuse/Withdraw

It is your choice whether or not to be in this study. Nothing will happen to you if you decide to not be in this study. You may skip any question you don't want to answer. You may stop answering questions any time you want. You will still get the same medical care from your doctor whether you are in the research study or not. Nothing will happen to you if you decide to stop being in this study. If at any time in the future, you would like to have your interview information, or your blood, urine, or cheek

For more information

We will give you a copy of this form to keep. If you have any questions, concerns, or complaints about this research study, please contact:

For questions about this research study or if you think you have been harmed by this study

Dr. Timothy Flood, Arizona Department of Health Services, (602) 542-7331

Dr. Carol Rubin, Centers for Disease Control and Prevention, (1-770-488-3406 and leave a message).

Dr. Gary Spivey, Cochise County Health Department, (520) 432-9433

For questions about your rights as part of a research study

The office of the CDC's Deputy Associate Director for Science (1-800-584-8814)

Thank you for considering being in this research study.

Carol Rubin, D.V.M., M.P.H.

Centers for Disease Control and Prevention

Timothy Flood, M.D

Arizona Department of Health Services

Gary Spivey, M.D, M.P.H

Cochise County Health Department

Case Adult:

We are asking you to be part of this research study. You may be in the study by indicating your consent to the items below. You may consent to all, some, or none of the items.

To be in this study, please sign your initials in the box next to each item you agree to.

	The collection of up to 21 ml (1 to 1 ½ tablespoons) of your blood from the vein in your arm.
	The collection of 32.5ml (approximately 1 ounce) of your urine in a cup.
	The removal of cells from the inside of your mouth with a cheek brush (soft bristle swab) to provide DNA for test for genes that may play a role in ALL/AML.
	The storage of part of your blood, urine, and cheek cell samples at CDC to be used for future studies about the causes of ALL/AML.

I have read the consent form (or someone has read it to me). I agree to be in this research study. I have put my initials by the parts of the study I agree to be part of.

Signature of Case Adult: _____ Today's Date: ___/___/___

Name of Case Adult (print): _____

Street Address: _____

City: _____
State: _____ Zip: _____

Phone number: _____

Appendix A1 (cont'd): Adolescent (age 12-17) Case Assent



*Do not write
in this space*

(Adolescent Case Assent:
12-17 years old, Flesch-Kincaid
reading level 6.2)

ASSENT TO VOLUNTEER FOR THIS RESEARCH STUDY

Exposure Assessment for Children with Acute Lymphocytic or Myelocytic Leukemia and a Comparison Population in Sierra Vista, Arizona

Your parents have said that you be in a research study about childhood leukemia in Sierra Vista. We would like to invite you to join our study. We you will agree to be a part of it. If you have any questions while reading this form, please feel free to ask any of us.

Please read this form. It will tell you about the study and what will happen if you decide to join. If you want to be in this study, please sign at the end of the form.

Purpose

Recently, the Arizona Department of Health Services found more children with leukemia (ALL/AML) in Sierra Vista than expected. ADHS has asked the Centers for Disease Control and Prevention (CDC) to help them do a research study. We want to take blood, urine, and cells from inside your cheek to help us learn more about why children are getting sick with leukemia. We may also do genetic tests on your samples. We will only test your DNA to help us understand genetics related to ALL/AML. We won't look for other things.

We would like for you to be part of this research study. But it is up to you to decide if you want to join or not. No one will make you do this if you don't want to. Nothing will happen to you if you decide not to join the study. Before you decide, you should know what will happen in the study. We will give you a chance to ask us questions about the study and have all your questions answered. If you have any questions as you read this form, please ask.

What will happen?

If you choose to be in this research study, we will take 21 ml (about 1 to 1 1/2 tablespoons)

of blood from a vein in your arm. First we will clean the skin by gently rubbing it with alcohol. The needle stick may hurt a little for a few seconds. You may have a bruise afterwards. The person taking the blood will be very careful. We will collect cheek cells by brushing the inside of each cheek with a soft brush for 30 seconds. It will not hurt to give a sample of cheek cells. We will ask you to give us some urine sample in a cup. It will not hurt to give a urine sample. We think it will take less than half an hour for us to get blood urine and cheek cells from you.

Your specimens will not have your name or other personal identifying information on them. Your blood and urine will not be tested for HIV, or the presence of alcohol or drugs.

Risks

Other than a little pain and a chance of bruising from the blood draw we don't think there are any risks to you from being in this study.

Benefits

We don't think that what we learn in this study will change how your doctor is treating you or help you get well. We think it might help us understand more about childhood leukemia and may help children in the future.

Privacy

We will keep what we learn about you and your family as part of this study as private as the law allows. We will store the consent form and other papers with your name on them separate from your answers. We will only put a research code number and not your name on the blood, urine, and cheek cell samples. We will not include your name on any reports we write about this study. Still because there are only a small number of children in Sierra Vista with Leukemia, it might be possible for someone to know you were part of this study.

Right to Refuse/Withdraw

It is your choice whether to be in this research study. You can expect the same medical care from your doctor whether you are in the research study or not. Nothing will happen to you if you choose not to be in this study. You may decide to stop being in this study any time. Nothing will

happen to you if you decide to drop out of this study. If you agree to be in the study and change your mind and want to have your blood, urine, or cheek cell samples destroyed or taken out of the leukemia research study, please call Dr. Carol Rubin at (770/488-3410).

For more information

We will give you a copy of this form to keep. If you have any questions, concerns, or complaints about this research study, please contact:

For questions about this research study or if you think you have been harmed by this research study

Dr. Timothy Flood, Arizona Department of Health Services (602) 542-7331

Dr. Carol Rubin, Centers for Disease Control and Prevention, (1-770-488-3406 and leave a message).

For questions about your rights as part of a research study

The office of the CDC Deputy Associate Director for Science (1-800-584-8814)

Dr. Gary Spivey, Cochise County Health Department, (520) 432-9433

Thank you for considering being in this research study.

Timothy Flood, MD
Arizona Department of Health Services

Carol Rubin, D.V.M., M.P.H.
Centers for Disease Control and Prevention

Gary Spivey, M.D., M. P. H.
Cochise County Health Department

We are asking you to be part of our research study. If you want to be part of this study you can check the parts you will help us with. You may agree to all or some of the things listed below. If you don't want to be in this study you don't have to do mark or sign anything.

To be in this study, please write your initials in the box next to each item you agree to.

	Letting us take up to 21 ml (1 to 1 ½ tablespoons) of blood from your arm with a needle.
	Giving us some of your urine in a plastic cup.
	Letting us test some of your DNA that we get by brushing the inside of your cheek with a soft brush.
	Letting us save part of your blood, urine, and cheek cell samples at CDC to be test later for causes of ALL/AML.

I have read the consent form (or someone has read it to me) and I agree to be in this study. I have put my initials by the parts of the study I agree to be in.

(Signature) (Date)

(Printed name)

Street Address: _____

City: _____ State: _____ Zip: _____

Phone number (area code): _____

Appendix A2: Adult Comparison Consent



(Adult Control)

*Do not write in
this space*

CONSENT TO VOLUNTEER FOR THIS RESEARCH STUDY
Exposure Assessment of Children with Acute Lymphocytic or Myelocytic Leukemia and a
Comparison Population in Sierra Vista Arizona

Thank you for taking the time to learn about this biosampling research study. This form tells about the study being done by the Arizona Department of Health Services (ADHS), the Cochise County Health Department (CCHD), and the Centers for Disease Control and Prevention (CDC). We want to collect blood, cheek cells, and urine from people so we can try to learn more about the causes of childhood leukemia in Sierra Vista. We want to invite you to take part in this biosampling research study as someone who has not had leukemia and lives in Sierra Vista. We hope you will take the time to read this form and that you will agree to take part in this research study. If you have any questions about this form while reading it, please let us know; we will be happy to help you in any way we can.

Please read this consent form carefully. If you decide that you would like to be a part of the biosampling research study, please sign where indicated at the end of this form. We would also like to invite your immediate family members also take part in this biosampling research study. Immediate family members include your mother and father, or legal guardians who live with you. We will give each of your immediate family members with the consent forms they need.

While you are here, we will collect samples of your blood, urine and cheek cells, and ask you a few questions. Your visit to the county clinic offices may last as long as 30 - 45 minutes.

Purpose

Recently, the Arizona Department of Health Services found that there were more children with Acute Lymphocytic Leukemia (ALL) and Acute Myelocytic Leukemia (AML) in Sierra Vista than would be expected by chance. The ADHS has asked the CDC to help try to find a reason for this and to test urine, blood, and cheek cells from people in Sierra Vista. We hope that the tests and the discussions with community members will help us find out if there is anything in the air, water or soil to worry about. We also hope to find out more about what causes childhood leukemia.

This biosampling research study has two main parts, asking questions about people's health and getting a little bit of their blood, urine and cheek cells. We will give a questionnaire to you and /or other members of your family who can answer the questions. Then we will take samples of your blood and urine, and cells from inside your cheeks. We will analyze these samples for chemicals, radioactive substances, and infectious agents. We may test your DNA for genes that could affect leukemia. The DNA samples will only be used for research about leukemia. We will not do any other kinds of genetic tests.

Joining this study is up to you. You may choose to not join. If you don't join or join and then decide to drop out, nothing will happen to you. Before you decide to join or not join,, you should know what will happen and have all your questions answered. If you have any questions about the

biosampling research study or about these consent forms, please ask anyone here, or call Carol Rubin or Beverly Kingsley at CDC at 770/488-3410 and we will be happy to answer any questions you may have.

Payment

You do not have to pay to be in this study. We will not pay you for being in this study.

What will happen?

If you choose to be in this study, we will take about 21 ml (about 1 to 1 1/2 tablespoons) of blood from a vein in your arm. First we will clean the skin by gently rubbing it with alcohol. The needle stick may hurt a little for a few seconds. You may have a little bruise afterwards. The person taking the blood will be very careful. It will not hurt to give a sample of cheek cells. We will collect cheek cells by brushing the inside of each cheek with a soft brush for 30 seconds. You will provide 32.5ml (approximately 1 ounce) of urine. It will not hurt to give a urine sample.

We will get DNA from part of your blood sample and from your cheek cell sample. We will store the samples at CDC using a research code number, not your name. Any genetic tests we do on your DNA are for leukemia research only. Experts will advise CDC about which tests to do. We may look for differences in genes that tell your body how to break down toxic substances or fix damaged DNA. We may also look for viruses that may cause cancer. We don't think the genetic test results will change how your doctors treat you, so we will send you results of the genetic tests. We do think this genetic research may help us understand leukemia better.

CDC will also save some of the blood and urine collected in this biosampling research study by a code number, not your name in case we need to do more tests in the future. We will not test your blood for HIV, or the presence of alcohol or drugs.

During the biosampling research study, we will ask you a few brief questions. The interview form will have a research code

number; not your name on it. . Answers to the interview questions will be kept private.

Benefits

We do not think that this study will tell us what is causing leukemia in Sierra Vista. We will tell you about the results of the tests we do on your blood and urine. We will send a report about what we learn to every one in this study. This report will not have any information that would identify you.

By giving us DNA for genetic testing, you will be helping us and the other scientists, and doctors understand why some people get ALL/AML and others do not. We will send you a report of the research findings that will not include any personal identifying information. But if we learn something about your DNA that might affect your health or your decision to have children we will tell you personally. If this were to happen, you should tell your doctor about this. If your doctor wants to do more DNA tests, you will have to pay for them.

Privacy

We will protect your privacy as much as the law allows. We will not put your name on the blood, urine, or cheek cell samples. Instead, these samples will have a research code number. We will keep all the research records and test results in locked files and only research staff will be allowed to look at them.

CDC will save a part of your blood and urine samples in the case that we need to do more laboratory tests. CDC will give the laboratory test results to the CCHD and ADHS only by code number. Biological samples will be stored for an unspecified amount of time, until sufficient testing has been conducted. Personal identifiers will be linked to biological specimens (and survey data) for as long as they are stored, in case there becomes biologically significant information that should be relayed to the person from which the sample came.

We will keep any forms with your private information in a locked file, separate from the answers to the questionnaire. Data

entry personnel will not be given nor have access to your personal identification information.

CDC will store your DNA for future genetic research using only a research code number. The code number will allow CDC to link the laboratory tests and questionnaire data to the genetic studies. In spite of all the things we do to protect your identity, it might be possible for someone to know you were in the study because of the small number of people in Sierra Vista.

We will keep a list with your name and research code number on it so that we can send you the results of the tests done on

your blood and urine. This list will be kept in a locked file separate from the collected samples and completed questionnaire. We will protect your privacy as much as the law allows. When we talk or write about this biosampling research study, we will not include your name or any facts that might identify you.

Your name, telephone number, and address are on this consent form so that we can contact you while we are conducting this research biosampling research study. We will keep this consent form in a locked file separate from the rest of the data.

Right to Refuse/Withdraw

It is your choice whether or not to be in this study. Nothing will happen to you if you decide not to be in this study. You may skip any question you don't want to answer. You may stop answering questions any time you want. You will still get the same medical care from your doctor whether you are in the research study or not. Nothing will happen to you if you decide to stop being in this study. If at any time in the future, you would like to have your interview information, or the samples from your home, or your blood, urine, or cheek cell samples destroyed or removed from the biosampling research study, please call Dr. Carol Rubin (770/488-3410).

For more information

We will give you a copy of this form to keep. If you have any questions, concerns, or complaints about this biosampling research study, please contact:

For questions about this research biosampling research study or if you think you have been harmed by this biosampling research study

Dr. Timothy Flood, Arizona Department of Health Services, (602) 542-7331

Dr. Carol Rubin, Centers for Disease Control and Prevention, (1-770-488-3406 and leave a message).

Dr. Gary Spivey, Cochise County Department of Health, (520) 432-9433

For questions related to your research rights

The Office of the CDC's Deputy Associate Director for Science (1-800-584-8814)

Thank you for considering being in this research study.

Carol Rubin, D.V.M., M.P.H.
Centers for Disease Control and Prevention

Dr. Timothy Flood, M.D
Arizona Department of Health Services

Dr. Gary Spivey, M.D M.P.H
Cochise County Department of Health

As described above, you are being asked to volunteer for this research study in a research biosampling research study. You may volunteer for this research study by indicating your consent to the items below. You may consent to all, some, or none of the items.

To be in this biosampling research study, please sign your initials in the box next to each item you agree to.

	The removal of up to 21 ml (1 to 1 ½ tablespoons) of your blood from the vein in your arm..
	The collection of 32.5ml (approximately 1 ounce) of your urine in a cup.
	The removal of cells from the inside of your mouth with a cheek brush (soft bristle swab) to provide DNA for test for genes that may play a role in ALL/AML.
	The storage of part of your blood, urine, and cheek cell samples at CDC to be used for future studies about the causes of ALL/AML.

I have read the consent form (or someone has read it to me) and I agree to be in this biosampling research study, I have put my initials by the parts of the biosampling research study I agree to be part of. .

(Signature) (Date)

(Printed name)

Street Address: _____

City: _____ State: _____ Zip: _____

Phone number (area code): _____



*Do not
write in this*

(Adolescent Control Assent:
Age 12-17 years)

ASSENT TO VOLUNTEER FOR THIS RESEARCH STUDY
Exposure Assessment of Children with Acute Lymphocytic or Myelocytic Leukemia and a
Comparison Population in Sierra Vista Arizona

Your parents have said that you could take part in a research study of childhood leukemia in Sierra Vista. We would like to invite you to join our research study and hope you will agree to be a part of it. If you have any questions about this form at any time while filling it out, please don't hesitate to ask.

Thank you for taking the time to learn about this biosampling research study. This form tells about the study being done by the Arizona Department of Health Services (ADHS), the Cochise County Health Department (CCHD), and the Centers for Disease Control and Prevention (CDC). We want to collect blood, cheek cells, and urine from people so we can try to learn more about the causes of childhood leukemia in Sierra Vista. We want to invite you to take part in this biosampling research study as someone who has not had leukemia and lives in Sierra Vista. We hope you will take the time to read this form and that you will agree to take part in this research study. If you have any questions about this form while reading it, please let us know; we will be happy to help you in any way we can.

Please read this consent form carefully. If you decide that you would like to be a part of the biosampling research study, please sign where indicated at the end of this form. We would also like to invite your immediate family members also take part in this biosampling research study. Immediate family members include your mother and father, or legal guardians who live with you.

We will give each of your immediate family members with the consent forms they need.

While you are here, we will collect samples of your blood, urine and cheek cells, and ask you a few questions. Your visit to the county clinic offices may last as long as 30 - 45 minutes.

Purpose

Recently, the Arizona Department of Health Services found that there were more children with Acute Lymphocytic Leukemia (ALL) and Acute Myelocytic Leukemia (AML) in Sierra Vista than would be expected by chance. The ADHS has asked the CDC to help try to find a reason for this and to test urine, blood, and cheek cells from people in Sierra Vista. We hope that the tests and the discussions with community members will help us find out if there is anything in the air, water or soil to worry about. We also hope to find out more about what causes childhood leukemia.

This biosampling research study has two main parts, asking questions about people's health and getting a little bit of their blood, urine and cheek cells. We will give a questionnaire to you and /or other members of your family who can answer the questions. Then we will take samples of your blood and urine, and cells from inside your cheeks. We will analyze these samples for chemicals, radioactive substances, and infectious agents. We may test your DNA for genes that could affect leukemia. The DNA samples will only be used for research about leukemia. We will not do any other kinds of genetic tests.

Joining this study is up to you. You may choose to not join. If you don't join or join and then decide to drop out, nothing will happen to you. Before you decide to join or not join,, you should know what will happen and have all your questions answered. If you have any questions about the biosampling research study or about these consent forms, please ask anyone here, or call Carol Rubin or Beverly Kingsley at CDC at 770/488-3410 and we will be happy to answer any questions you may have.

Payment

You do not have to pay to be in this study. We will not pay you for being in this study.

What will happen?

If you choose to be in this study, we will take about 21 ml (about 1 to 1 1/2 tablespoons) of blood from a vein in your arm. First we will clean the skin by gently rubbing it with alcohol. The needle stick may hurt a little for a few seconds. You may have a little bruise afterwards. The person taking the blood will be very careful. It will not hurt to give a sample of cheek cells. We will collect cheek cells by brushing the inside of each cheek with a soft brush for 30 seconds. You will provide 32.5ml (approximately 1 ounce) of urine. It will not hurt to give a urine sample.

We will get DNA from part of your blood sample and from your cheek cell sample. We will store the samples at CDC using a research code number, not your name. Any genetic tests we do on your DNA are for leukemia research only. Experts will advise CDC about which tests to do. We may look for differences in genes that tell your body how to break down toxic substances or fix damaged DNA. We may also look for viruses that may cause cancer. We don't think the genetic test results will change how your doctors treat you, so we will send you results of the genetic tests. We do think this genetic research may help us understand leukemia better.

CDC will also save some of the blood and urine collected in this biosampling research study by a code number, not your name in

case we need to do more tests in the future. We will not test your blood for HIV, or the presence of alcohol or drugs.

During the biosampling research study, we will ask you a few brief questions. The interview form will have a research code number; not your name on it. . Answers to the interview questions will be kept private.

Benefits

We do not think that this study will tell us what is causing leukemia in Sierra Vista. We will tell you about the results of the tests we do on your blood and urine. We will send a report about what we learn to every one in this study. This report will not have any information that would identify you.

By giving us DNA for genetic testing, you will be helping us and the other scientists, and doctors understand why some people get ALL/AML and others do not. We will send you a report of the research findings that will not include any personal identifying information. But if we learn something about your DNA that might affect your health or your decision to have children we will tell you personally. If this were to happen, you should tell your doctor about this. If your doctor wants to do more DNA tests, you will have to pay for them.

Privacy

We will protect your privacy as much as the law allows. We will not put your name on the blood, urine, or cheek cell samples. Instead, these samples will have a research code number. We will keep all the research records and test results in locked files and only research staff will be allowed to look at them.

CDC will save a part of your blood and urine samples in the case that we need to do more laboratory tests. CDC will give the laboratory test results to the CCHD and ADHS only by code number. Biological samples will be stored for an unspecified amount of time, until sufficient testing has been conducted. Personal identifiers will be linked to biological specimens (and survey data) for as long as they are stored, in case

there becomes biologically significant information that should be relayed to the person from which the sample came.

We will keep any forms with your private information in a locked file, separate from the answers to the questionnaire. Data entry personnel will not be given nor have access to your personal identification information.

CDC will store your DNA for future genetic research using only a research code number. The code number will allow CDC to link the laboratory tests and questionnaire data to the genetic studies. In spite of all the things we do to protect your identity, it might be possible for someone to know you were in the study because of the small number of people in Sierra Vista.

We will keep a list with your name and research code number on it so that we can send you the results of the tests done on your blood and urine. This list will be kept in a locked file separate from the collected samples and completed questionnaire. We will protect your privacy as much as the law allows. When we talk or write about this biosampling research study, we will not include your name or any facts that might identify you.

Your name, telephone number, and address are on this consent form so that we can contact you while we are conducting this research biosampling research study. We will keep this consent form in a locked file separate from the rest of the data.

Right to Refuse/Withdraw

It is your choice whether or not to be in this study. Nothing will happen to you if you decide not to be in this study. You may skip any question you don't want to answer. You may stop answering questions any time you want. You will still get the same medical care from your doctor whether you are in the research study or not. Nothing will happen to you if you decide to stop being in this study. If at any time in the future, you would like to have your interview information, or the samples from your home, or your blood, urine, or cheek cell samples destroyed or removed from the biosampling research study, please call Dr. Carol Rubin (770/488-3410).

For more information

We will give you a copy of this form to keep. If you have any questions, concerns, or complaints about this biosampling research study, please contact:

For questions about this research biosampling research study or if you think you have been harmed by this biosampling research study

Dr. Timothy Flood, Arizona Department of Health Services, (602) 542-7331

Dr. Carol Rubin, Centers for Disease Control and Prevention, (1-770-488-3406 and leave a message).

Dr. Gary Spivey, Cochise County Department of Health, (520) 432-9433

For questions related to your research rights

The Office of the CDC's Deputy Associate Director for Science (1-800-584-8814)

Thank you for considering being in this research study.

Carol Rubin, D.V.M., M.P.H.
Centers for Disease Control and Prevention

Dr. Timothy Flood, M.D
Arizona Department of Health Services

Dr. Gary Spivey, M.D M.P.H
Cochise County Department of Health

As described above, you are being asked to volunteer for this research study in a research biosampling research study. You may volunteer for this research study by indicating your consent to the items below. You may consent to all, some, or none of the items.

To be in this biosampling research study, please sign your initials in the box next to each item you agree to.

	The removal of up to 21 ml (1 to 1 ½ tablespoons) of your blood from the vein in your arm..
	The collection of 32.5ml (approximately 1 ounce) of your urine in a cup.
	The removal of cells from the inside of your mouth with a cheek brush (soft bristle swab) to provide DNA for test for genes that may play a role in ALL/AML.
	The storage of part of your blood, urine, and cheek cell samples at CDC to be used for future studies about the causes of ALL/AML.

I have read the consent form (or someone has read it to me) and I agree to be in this biosampling research study, I have put my initials by the parts of the biosampling research study I agree to be part of. .

(Signature) (Date)

(Printed name)

Street Address: _____

City: _____ State: _____ Zip: _____

Phone number (area code): _____

Appendix A3: Child Assent (age 7 to less than 12)



*Please do not
write in this space*

(Child Assent: Age 7-11, Flesch-Kincaid reading level 4.6)

ASSENT TO VOLUNTEER FOR THIS RESEARCH STUDY
Exposure Assessment of Children with Acute Lymphocytic or Myelocytic Leukemia and a
Comparison Population in Sierra Vista Arizona

I want to tell you about a research study we are doing. We are trying to find out why some children in Sierra Vista are getting sick from a kind of cancer called leukemia. We want to find out if there is something in the air or water or dirt near where you live that might be making people sick. We want children who do have leukemia and children who don't have leukemia to be part of our study, and we are asking if you would help us because you do not have leukemia.

We want you to help us with this study by letting us get a little bit of your blood, giving us some of your pee, and letting us rub a soft brush, sort of like a tooth brush, inside your mouth. We will test your blood, pee, and the cheek cells we get from inside your mouth for things that might help us know why some people are getting sick.

Your parents have said you be part of this research study if you want. But it is up to you to decide if you want to or not. If you don't want to be part of this, that's OK. Nothing will happen to you. If say yes now but change your mind later and want to stop, that's also OK.

What will happen?

If you let us, we will clean your arm by gently rubbing it with alcohol. Then we will take a little bit of blood from your arm with a needle. Next we will rub a soft brush on the inside of your mouth a few times. This might tickle or be uncomfortable but it shouldn't hurt. Then we will ask you to go into the bathroom and pee into a cup for us. If you want your parents to help you they can.

We will also ask your parents about your health and some things about them. All the answers they give us are private. We will not tell anyone who is not working on this research study what they said.

We will test your blood, pee, and the cheek cells for things that might help us know why some people are getting sick. We will send your parents a report that tells what we found in the tests.

Will it hurt?

The needle stick in your skin may hurt a little for a few seconds. The person taking the blood will be very careful. You might have a bruise afterward. It will not hurt for us to get cheek cells or for you to pee into a cup.

Will it help me? We don't think we will learn anything from this study that will help you, but if we do we will tell your parents. We do think this might help other children some day.

We want to save your samples.

We might want to do more tests on your blood, pee, and cheek cells later. We would like you to let us save some samples of your blood, pee, and cheek cells in a freezer at CDC so that we can test them later. You can still be in the study but not let us save your samples.

Do you have questions?

You might want to ask us or your parents about this before you make up your mind about being in this study. This is when you can do that. If you have questions for any of us let us know. If you want to talk with your parents tell us and we'll leave so you can talk to them. Please check the items you agree to:

- You will let us get and test some of your blood, pee and cheek cells for our study.
- You agree to let CDC save some of your blood, urine, and cheek cells to test later.

(Child's signature)

(Date)

(Child's printed name)

Street Address: _____

City: _____ State: _____ Zip: _____

Phone number: _____

Appendix A4: Case Families Consent



(Case Family)

Do not write in this space

CONSENT TO VOLUNTEER FOR THIS RESEARCH STUDY

Exposure Assessment of Children with Acute Lymphocytic or Myelocytic Leukemia and a Comparison Population in Sierra Vista, Arizona

Thank you for taking the time to learn about this research study. This form tells about the study being done by the Arizona Department of Health Services (ADHS), the Cochise County Health Department (CCHD), and the Centers for Disease Control and Prevention (CDC). We want to collect blood, cheek cells and urine from people so we can try to learn more about the causes of childhood leukemia in Sierra Vista. We want to invite you to take part in this research study because you had (have?) leukemia and live in Sierra Vista. We hope you will take the time to read this form and that you will agree to take part in this research study. If you have any questions about this form while reading it, please let us know; we will be happy to help you in any way we can.

Please read this consent form carefully. If you decide that you would like to be a part of the research study, please sign at the end of this form. We would also like to invite your immediate family members to take part in this study. Immediate family members include your mother, father, and any full, half, or step-siblings who live with you. We will give each of your family members their own consent form.

While you are here, we will collect samples of blood, urine and cheek cells from you. If your parents(s) or former guardians agree to be part of the study we will ask them about your mother's pregnancy with you, and your family's medical history. Your visit to the county clinic offices may last as long as 30-45 minutes.

Purpose

Recently, the Arizona Department of Health Services found that there were more children with Acute Lymphocytic Leukemia (ALL) and Acute Myelocytic Leukemia (AML) in Sierra Vista than would be expected by chance. The ADHS has asked the CDC to help try to find a reason for this and to test urine, blood, and cheek cells from people in Sierra Vista. We hope that the tests and the discussions with community members will help us find out if there is anything in the air or water or soil to worry about. We also hope to find out more about what causes childhood leukemia.

This research study has two main parts, asking questions about people's health and getting a little bit of their blood, urine, and cheek cells. We will give a questionnaire to you and/or other members of your family who can answer the questions. Then we will take samples of your blood, urine, and cells from inside your cheeks. We will test these samples for chemicals, radioactive substances, and infectious agents. We may test your DNA for genes that could affect leukemia. The DNA samples will only be used for research about leukemia. We will not do any other kinds of genetic tests.

Freedom of Choice

Joining this study is up to you. You may choose to not join. If you don't join or join and then decide to drop out, nothing will happen to you.. Before you decide to join or not, you should know what will happen and have all your questions answered. If you have any questions about the study or about these consent forms, please ask anyone here or call Carol Rubin or Beverly Kingsley at CDC (770/488-3410); we will be happy to answer any questions you may have.

Payment

You do not have to pay to be in this study. We will not pay you for being in this study.

What will happen?

If you choose to be in this study, we will take 21 ml (about 1 to 1 1/2 tablespoons) of blood from a vein in your arm. First we will clean the skin by gently rubbing it with alcohol. The needle stick may hurt a little for a few seconds. You may have a bruise afterwards. The person taking the blood will be very careful. We will collect cheek cells by brushing the inside of each cheek with a soft brush for 30 seconds. It will not hurt to give a sample of cheek cells. You will provide 32.5ml (approximately 1 ounce) of urine. It will not hurt to give a urine sample. We will get DNA from part of your blood sample and from your cheek cells. We will store the samples at CDC with a research code number not your name. Any genetic tests we do on your DNA are for leukemia research only. Experts will advise CDC about which tests to do. We may look for differences in genes that tell your body how to break down toxic substances or fix damaged DNA. We may also look for viruses that may cause cancer. We don't think the genetic test results will change how your doctors treat you so we will not send you results of the genetic tests. We do think this genetic research may help us understand leukemia better. CDC will also save some of the blood and urine from this study with the research code number, not your name, in case we need to

do more tests in the future. We will not test your blood and urine for HIV, or the presence of alcohol or drugs. During the study, we will talk with your parent(s)/guardian(s) about your medical and pre-natal history. The interview form will have a research code number, not your name on it. Answers to the interview questions will be kept private.

Benefits

We do not think this study will tell us what caused your leukemia or change how your doctors treat you. We will tell you about the results of the tests we do on your blood and urine. We will send a report about what we learn to every one in this study. This report will not have any information that would identify you.

By giving us DNA for genetic testing, you will help us and other scientists and doctors understand why some people get ALL/AML and others do not. We will send you a report of the research findings that will not include any personal identifying information. But if we learn something about your DNA that might affect your health or your decision to have children, we will tell you personally. If this were to happen, you should tell your doctor about this. If your doctor wants to do more DNA tests you will have to pay for them.

Privacy

We will protect your privacy as much as the law allows. We will not put your name on the blood, urine, or cheek cell samples. Instead, these samples will have a research code number. We will keep all the research records and test results in locked files and only research staff will be allowed to look at them.

CDC will save a part of your blood and urine samples in the case we need to do more laboratory tests. CDC will give the laboratory test results to the CCHD and ADHS only by code number. Biological samples will be stored for an unspecified amount of time, until sufficient testing has been conducted. Personal identifiers will be

linked to biological specimens (and survey data) for as long as they are stored, in case there becomes biologically significant information that should be relayed to the person from which the sample came.

cell samples destroyed or removed from the biosampling research study, please call Dr. Carol Rubin (770/488-3410).

We will keep any forms with your private information in a locked file, separate from the answers to the questionnaire. CDC will store your DNA for future genetic research using only a research code number. The code number will allow CDC to link the laboratory tests and questionnaire data to the genetic studies. In spite of all the things we do to protect your identity, it might be possible for someone to know you were in this study because of the small number of children with leukemia in Sierra Vista.

We will keep a list with your name and research code number on it so that we can send you the results of the tests done on your blood and urine. This list will be kept in a locked file separate from the samples and completed questionnaire. We will protect your privacy as much as the law allows. When we talk or write about this research study, we will not include your name or any facts that might identify you.

Your name, telephone number, and address are on this consent form so that we can contact you while we are doing this research study. We will keep this consent form in a locked file separate from the rest of the data.

Right to Refuse/Withdraw

It is your choice whether or not to be in this study. Nothing will happen to you if you decide to not be in this study. You may skip any question you don't want to answer. You may stop answering questions any time you want. You will still get the same medical care from your doctor whether you are in the research study or not. Nothing will happen to you if you decide to stop being in this study. If at any time in the future, you would like to have your interview information, or your blood, urine, or cheek

For more information

We will give you a copy of this form to keep. If you have any questions, concerns, or complaints about this research study, please contact:

For questions about this research study or if you think you have been harmed by this study

Dr. Timothy Flood, Arizona Department of Health Services, (602) 542-7331

Dr. Carol Rubin, Centers for Disease Control and Prevention, (1-770-488-3406 and leave a message).

Dr. Gary Spivey, Cochise County Health Department, (520) 432-9433

For questions about your rights as part of a research study

The office of the CDC's Deputy Associate Director for Science (1-800-584-8814)

Thank you for considering being in this research study.

Carol Rubin, D.V.M., M.P.H.

Centers for Disease Control and Prevention

Timothy Flood, M.D

Arizona Department of Health Services

Gary Spivey, M.D, M.P.H

Cochise County Health Department

Case Child's Parent/Guardian 1:

As described above, we are asking you to be part of this study. You may be in the research study by indicating your consent to the items below. You may consent to all, some, or none of the items.

To be in this study, please sign your initials in the box next to each item you agree to.

	The removal from you of up to 21 ml (1 to 1 ½ tablespoons) of your blood from the vein in your arm.
	The collection from you of 32.5ml (approximately 1 ounce) of your urine in a cup.
	The removal of cells from the inside of your mouth with a cheek brush (soft bristle swab) to provide DNA for test for genes that may play a role in ALL/AML.
	The storage of part of your blood, urine, and cheek cell samples at CDC to be used for future studies about the causes of ALL/AML.

I have read the consent form (or someone has read it to me). I agree to be in this biosampling research study, I have put my initials above indicating which parts of the biosampling research study I agree to volunteer for this research study in.

Signature of Parent/Guardian 1: _____ Date: __/__/__

Name of Parent/Guardian 1 (print): _____

Street Address: _____

City: _____
State: _____ Zip: _____

Phone number: _____

Case Child's Parent/Guardian 2:

As described above, we are asking you to be part of this study. You may be in the research study by indicating your consent to the items below. You may consent to all, some, or none of the items.

To be in this study, please sign your initials in the box next to each item you agree to.

	The removal from you of up to 21 ml (1 to 1 ½ tablespoons) of your blood from the vein in your arm.
	The collection from you of 32.5ml (approximately 1 ounce) of your urine in a cup.
	The removal of cells from the inside of your mouth with a cheek brush (soft bristle swab) to provide DNA for test for genes that may play a role in ALL/AML.
	The storage of part of your blood, urine, and cheek cell samples at CDC to be used for future studies about the causes of ALL/AML.

I have read the consent form (or someone has read it to me). I agree to be in this biosampling research study, I have put my initials above indicating which parts of the biosampling research study I agree to volunteer for this research study in.

Signature of Parent/Guardian 2: _____ Date: ___/___/___

Name of Parent/Guardian 2 (print): _____

Other Related Adult Living with Case Child *(if applicable)*

As described above, we are asking you to be part of this study. You may be in the research study by indicating your consent to the items below. You may consent to all, some, or none of the items.

To be in this study, please sign your initials in the box next to each item you agree to.

	The removal from you of up to 21 ml (1 to 1 ½ tablespoons) of your blood from the vein in your arm.
	The collection from you of 32.5ml (approximately 1 ounce) of your urine in a cup.
	The removal of cells from the inside of your mouth with a cheek brush (soft bristle swab) to provide DNA for test for genes that may play a role in ALL/AML.
	The storage of part of your blood, urine, and cheek cell samples at CDC to be used for future studies about the causes of ALL/AML.

I have read the consent form (or someone has read it to me). I agree to be in this biosampling research study, I have put my initials above indicating which parts of the biosampling research study I agree to volunteer for this research study in.

Signature of Other Related Adult living with Case Child: _____

Date: ___/___/___

Name of Other Related Adult living with Case Child (print): _____

As described above, we are asking your children (case child and all siblings under 18 years of age) to be part of this research biosampling research study. You may allow your children to be in the biosampling research study by indicating your consent to the items below. You may consent to all, some, or none of the items.

I (Parent or Legal Guardian) have read the consent form and agree that my children listed below may be in this biosampling research study. In addition, I indicate with my initials which parts of the biosampling research study that each child can volunteer for this research study in.

Child 1: *Case Child*

Child's Name:

first middle father's surname mother's surname

Signature of Parent/ Guardian: _____ Date: ___/___/___

Name of Parent/Guardian (print): _____

By my initials, I consent for this child to volunteer for this research study in the following parts of this research biosampling research study.

	The removal from him/her of up to 21 ml (1 to 1 ½ tablespoons) of his blood from a vein in his/her arm..
	The collection from him/her of 32.5ml (approximately 1 ounce) of his/her urine in a cup.
	The removal of cells from the inside of his/her mouth with a cheek brush (soft bristle swab) to provide DNA for test for genes that may play a role in ALL/AML.
	The storage of a portion of his/her blood, urine, and cheek cell samples at CDC to be used for future studies about the causes of ALL/AML.

Child 2

Child's Name:

first

middle

father's surname

mother's surname

By my initials, I consent for this child to volunteer for this research study in the following parts of this research biosampling research study

	The removal from him/her of up to 21 ml (1 to 1 ½ tablespoons) of his/her blood from a vein in his/her arm. .
	The collection from him/her of 32.5ml (approximately 1 ounce) of his/her urine in a cup.
	The removal of cells from the inside of his/her mouth with a cheek brush (soft bristle swab) to provide DNA for test for genes that may play a role in ALL/AML.
	The storage of a portion of his/her blood, urine, and cheek cell samples at CDC to be used for future studies about the causes of ALL/AML.

Child 3

Child's Name:

first

middle

father's surname

mother's surname

By my initials, I consent for this child to volunteer for this research study in the following parts of this research biosampling research study

	The removal from him/her of up to 21 ml (1 to 1 ½ tablespoons) of his/her blood from a vein in his/her arm.
	The collection from him/her of 32.5ml (approximately 1 ounce) of his/her urine in a cup.
	The removal of cells from the inside of his/her mouth with a cheek brush (soft bristle swab) to provide DNA for test for genes that may play a role in ALL/AML.
	The storage of a portion of his/her blood, urine, and cheek cell samples at CDC to be used for future studies about the causes of ALL/AML.

Child 4

Child's Name:

first middle father's surname mother's surname

By my initials, I consent for this child to volunteer for this research study in the following parts of this research biosampling research study

	The removal from him/her of up to 21 ml (1 to 1 ½ tablespoons) of his/her blood from a vein in his/her arm.
	The collection from him/her of 32.5ml (approximately 1 ounce) of his/her urine in a cup.
	The removal of cells from the inside of his/her mouth with a cheek brush (soft bristle swab) to provide DNA for test for genes that may play a role in ALL/AML.
	The storage of a portion of his/her blood, urine, and cheek cell samples at CDC to be used for future studies about the causes of ALL/AML.

Child 5

Child's Name:

first middle father's surname mother's surname

By my initials, I consent for this child to volunteer for this research study in the following parts of this research biosampling research study

	The removal from him/her of up to 21 ml (1 to 1 ½ tablespoons) of his/her blood from a vein in his/her arm.
	The collection from him/her of 32.5ml (approximately 1 ounce) of his/her urine in a cup.
	The removal of cells from the inside of his/her mouth with a cheek brush (soft bristle swab) to provide DNA for test for genes that may play a role in ALL/AML.
	The storage of a portion of his/her blood, urine, and cheek cell samples at CDC to be used for future studies about the causes of ALL/AML.



(Control Family)

Do not write in this space

CONSENT TO VOLUNTEER FOR THIS RESEARCH STUDY
Exposure Assessment of Children with Acute Lymphocytic or Myelocytic Leukemia and a
Comparison Population in Sierra Vista Arizona

Thank you for taking the time to learn about this biosampling research study. This form tells about the study being done by the Arizona Department of Health Services (ADHS), the Cochise County Health Department (CCHD), and the Centers for Disease Control and Prevention (CDC). We want to collect blood, cheek cells, and urine from people so we can try to learn more about the causes of childhood leukemia in Sierra Vista. We want to invite you to take part in this biosampling research study as someone who has not had leukemia and lives in Sierra Vista.. We hope you will take the time to read this form and that you will agree to take part in this research study. If you have any questions about this form while reading it, please let us know; we will be happy to help you in any way we can.

Please read this consent form carefully. If you decide that you would like to be a part of the biosampling research study, please sign where indicated at the end of this form. We would also like to invite your immediate family members also take part in this biosampling research study. Immediate family members include your mother and father, or legal guardians who live with you. We will give each of your immediate family members with the consent forms they need.

While you are here, we will collect samples of your blood, urine and cheek cells, and ask you a few questions. Your visit to the county clinic offices may last as long as 30 - 45 minutes.

Purpose

Recently, the Arizona Department of Health Services found that there were more children with Acute Lymphocytic Leukemia (ALL) and Acute Myelocytic Leukemia (AML) in Sierra Vista than would be expected by chance. The ADHS has asked the CDC to help try to find a reason for this and to test urine, blood, and cheek cells from people in Sierra Vista. We hope that the tests and the discussions with community members will help us find out if there is anything in the air, water or soil to worry about. We also hope to find out more about what causes childhood leukemia.

This biosampling research study has two main parts, asking questions about people's health and getting a little bit of their blood, urine and cheek cells. We will give a questionnaire to you and /or other members of your family who can answer the questions. Then we will take samples of your blood and urine, and cells from inside your cheeks. We will analyze these samples for chemicals, radioactive substances, and infectious agents. We may test your DNA for genes that could affect leukemia. The DNA samples will only be used for research about leukemia. We will not do any other kinds of genetic tests.

Joining this study is up to you. You may choose to not join. If you don't join or join and then decide to drop out, nothing will happen to you. Before you decide to join or not join,, you should know what will happen and have all your questions answered. If

you have any questions about the biosampling research study or about these consent forms, please ask anyone here, or call Carol Rubin or Beverly Kingsley at CDC at 770/488-3410 and we will be happy to answer any questions you may have.

Payment

You do not have to pay to be in this study. We will not pay you for being in this study.

What will happen?

If you choose to be in this study, we will take about 21 ml (about 1 to 1 1/2 tablespoons) of blood from a vein in your arm. First we will clean the skin by gently rubbing it with alcohol. The needle stick may hurt a little for a few seconds. You may have a little bruise afterwards. The person taking the blood will be very careful. It will not hurt to give a sample of cheek cells. We will collect cheek cells by brushing the inside of each cheek with a soft brush for 30 seconds. You will provide 32.5ml (approximately 1 ounce) of urine. It will not hurt to give a urine sample.

We will get DNA from part of your blood sample and from your cheek cell sample. We will store the samples at CDC using a research code number, not your name. Any genetic tests we do on your DNA are for leukemia research only. Experts will advise CDC about which tests to do. We may look for differences in genes that tell your body how to break down toxic substances or fix damaged DNA. We may also look for viruses that may cause cancer. We don't think the genetic test results will change how your doctors treat you, so we will send you results of the genetic tests. We do think this genetic research may help us understand leukemia better.

CDC will also save some of the blood and urine collected in this biosampling research study by a code number, not your name in case we need to do more tests in the future. We will not test your blood for HIV, or the presence of alcohol or drugs.

During the biosampling research study, we will ask you a few brief questions. The interview form will have a research code

number; not your name on it. Answers to the interview questions will be kept private.

Benefits

We do not think that this study will tell us what is causing leukemia in Sierra Vista. We will tell you about the results of the tests we do on your blood and urine. We will send a report about what we learn to every one in this study. This report will not have any information that would identify you.

By giving us DNA for genetic testing, you will be helping us and the other scientists, and doctors understand why some people get ALL/AML and others do not. We will send you a report of the research findings that will not include any personal identifying information. But if we learn something about your DNA that might affect your health or your decision to have children we will tell you personally. If this were to happen, you should tell your doctor about this. If your doctor wants to do more DNA tests, you will have to pay for them.

Privacy

We will protect your privacy as much as the law allows. We will not put your name on the blood, urine, or cheek cell samples. Instead, these samples will have a research code number. We will keep all the research records and test results in locked files and only research staff will be allowed to look at them.

CDC will save a part of your blood and urine samples in the case that we need to do more laboratory tests. CDC will give the laboratory test results to the CCHD and ADHS only by code number. Biological samples will be stored for an unspecified amount of time, until sufficient testing has been conducted. Personal identifiers will be linked to biological specimens (and survey data) for as long as they are stored, in case there becomes biologically significant information that should be relayed to the person from which the sample came.

We will keep any forms with your private information in a locked file, separate from the answers to the questionnaire. Data

entry personnel will not be given nor have access to your personal identification information.

CDC will store your DNA for future genetic research using only a research code number. The code number will allow CDC to link the laboratory tests and questionnaire data to the genetic studies. In spite of all the things we do to protect your identity, it might be possible for someone to know you were in the study because of the small number of people in Sierra Vista.

We will keep a list with your name and research code number on it so that we can send you the results of the tests done on

your blood and urine. This list will be kept in a locked file separate from the collected samples and completed questionnaire. We will protect your privacy as much as the law allows. When we talk or write about this biosampling research study, we will not include your name or any facts that might identify you.

Your name, telephone number, and address are on this consent form so that we can contact you while we are conducting this research biosampling research study. We will keep this consent form in a locked file separate from the rest of the data.

Right to Refuse/Withdraw

It is your choice whether or not to be in this study. Nothing will happen to you if you decide not to be in this study. You may skip any question you don't want to answer. You may stop answering questions any time you want. You will still get the same medical care from your doctor whether you are in the research study or not. Nothing will happen to you if you decide to stop being in this study. If at any time in the future, you would like to have your interview information, or the samples from your home, or your blood, urine, or cheek cell samples destroyed or removed from the biosampling research study, please call Dr. Carol Rubin (770/488-3410).

For more information

We will give you a copy of this form to keep. If you have any questions, concerns, or complaints about this biosampling research study, please contact:

For questions about this research biosampling research study or if you think you have been harmed by this biosampling research study

Dr. Timothy Flood, Arizona Department of Health Services, (602) 542-7331

Dr. Carol Rubin, Centers for Disease Control and Prevention, (1-770-488-3406 and leave a message).

Dr. Gary Spivey, Cochise County Department of Health, (520) 432-9433

For questions related to your research rights

The Office of the CDC's Deputy Associate Director for Science (1-800-584-8814)

Thank you for considering being in this research study.

Carol Rubin, D.V.M., M.P.H.
Centers for Disease Control and Prevention

Dr. Timothy Flood, M.D
Arizona Department of Health Services

Dr. Gary Spivey, M.D M.P.H
Cochise County Department of Health

Control Child's Parent/Guardian 1:

As described above, we are asking you to be part of this study. You may be in the research study by indicating your consent to the items below. You may consent to all, some, or none of the items.

To be in this study, please sign your initials in the box next to each item you agree to.

	The removal from you of up to 21 ml (1 to 1 ½ tablespoons) of your blood from the vein in your arm.
	The collection from you of 32.5ml (approximately 1 ounce) of your urine in a cup.
	The removal of cells from the inside of your mouth with a cheek brush (soft bristle swab) to provide DNA for test for genes that may play a role in ALL/AML.
	The storage of part of your blood, urine, and cheek cell samples at CDC to be used for future studies about the causes of ALL/AML.

I have read the consent form (or someone has read it to me). I agree to be in this biosampling research study, I have put my initials above indicating which parts of the biosampling research study I agree to volunteer for this research study in.

Signature of Parent/Guardian 1: _____ Date: ___/___/___

Name of Parent/Guardian 1 (print): _____

Street Address: _____

City: _____
State: _____ Zip: _____

Phone number: _____

Control Child's Parent/Guardian 2:

As described above, we are asking you to be part of this study. You may be in the research study by indicating your consent to the items below. You may consent to all, some, or none of the items.

To be in this study, please sign your initials in the box next to each item you agree to.

	The removal from you of up to 21 ml (1 to 1 ½ tablespoons) of your blood from the vein in your arm.
	The collection from you of 32.5ml (approximately 1 ounce) of your urine in a cup.
	The removal of cells from the inside of your mouth with a cheek brush (soft bristle swab) to provide DNA for test for genes that may play a role in ALL/AML.
	The storage of part of your blood, urine, and cheek cell samples at CDC to be used for future studies about the causes of ALL/AML.

I have read the consent form (or someone has read it to me). I agree to be in this biosampling research study, I have put my initials above indicating which parts of the biosampling research study I agree to volunteer for this research study in.

Signature of Parent/Guardian 2: _____ Date: __/__/__

Name of Parent/Guardian 2 (print): _____

Other Related Adult Living with Control Child *(if applicable)*

As described above, we are asking you to be part of this study. You may be in the research study by indicating your consent to the items below. You may consent to all, some, or none of the items.

To be in this study, please sign your initials in the box next to each item you agree to.

	The removal from you of up to 21 ml (1 to 1 ½ tablespoons) of your blood from the vein in your arm.
	The collection from you of 32.5ml (approximately 1 ounce) of your urine in a cup.
	The removal of cells from the inside of your mouth with a cheek brush (soft bristle swab) to provide DNA for test for genes that may play a role in ALL/AML.
	The storage of part of your blood, urine, and cheek cell samples at CDC to be used for future studies about the causes of ALL/AML.

I have read the consent form (or someone has read it to me). I agree to be in this biosampling research study, I have put my initials above indicating which parts of the biosampling research study I agree to volunteer for this research study in.

Signature of Other Related Adult living with Control Child: _____

Date: ___/___/___

Name of Other Related Adult living with Control Child (print):

As described above, we are asking your children (control child and all siblings under 18 years of age) to be part of this research biosampling research study. You may allow your children to be in the biosampling research study by indicating your consent to the items below. You may consent to all, some, or none of the items.

I (Parent or Legal Guardian) have read the consent form and agree that my children listed below may be in this biosampling research study. In addition, I indicate with my initials which parts of the biosampling research study that each child can volunteer for this research study in.

Child 1: *Control Child*

Child's Name:

first middle father's surname mother's surname

Signature of Parent/ Guardian: _____ Date: ___/___/___

Name of Parent/Guardian (print): _____

By my initials, I consent for this child to volunteer for this research study in the following parts of this research biosampling research study.

	The removal from him/her of up to 21 ml (1 to 1 ½ tablespoons) of his blood from a vein in his/her arm..
	The collection from him/her of 32.5ml (approximately 1 ounce) of his/her urine in a cup.
	The removal of cells from the inside of his/her mouth with a cheek brush (soft bristle swab) to provide DNA for test for genes that may play a role in ALL/AML.
	The storage of a portion of his/her blood, urine, and cheek cell samples at CDC to be used for future studies about the causes of ALL/AML.

Child 2

Child's Name:

first

middle

father's surname

mother's surname

By my initials, I consent for this child to volunteer for this research study in the following parts of this research biosampling research study

	The removal from him/her of up to 21 ml (1 to 1 ½ tablespoons) of his/her blood from a vein in his/her arm. .
	The collection from him/her of 32.5ml (approximately 1 ounce) of his/her urine in a cup.
	The removal of cells from the inside of his/her mouth with a cheek brush (soft bristle swab) to provide DNA for test for genes that may play a role in ALL/AML.
	The storage of a portion of his/her blood, urine, and cheek cell samples at CDC to be used for future studies about the causes of ALL/AML.

Child 3

Child's Name:

first

middle

father's surname

mother's surname

By my initials, I consent for this child to volunteer for this research study in the following parts of this research biosampling research study

	The removal from him/her of up to 21 ml (1 to 1 ½ tablespoons) of his/her blood from a vein in his/her arm.
	The collection from him/her of 32.5ml (approximately 1 ounce) of his/her urine in a cup.
	The removal of cells from the inside of his/her mouth with a cheek brush (soft bristle swab) to provide DNA for test for genes that may play a role in ALL/AML.
	The storage of a portion of his/her blood, urine, and cheek cell samples at CDC to be used for future studies about the causes of ALL/AML.

Child 4

Child's Name:

first middle father's surname mother's surname

By my initials, I consent for this child to volunteer for this research study in the following parts of this research biosampling research study

	The removal from him/her of up to 21 ml (1 to 1 ½ tablespoons) of his/her blood from a vein in his/her arm.
	The collection from him/her of 32.5ml (approximately 1 ounce) of his/her urine in a cup.
	The removal of cells from the inside of his/her mouth with a cheek brush (soft bristle swab) to provide DNA for test for genes that may play a role in ALL/AML.
	The storage of a portion of his/her blood, urine, and cheek cell samples at CDC to be used for future studies about the causes of ALL/AML.

Child 5

Child's Name:

first middle father's surname mother's surname

By my initials, I consent for this child to volunteer for this research study in the following parts of this research biosampling research study

	The removal from him/her of up to 21 ml (1 to 1 ½ tablespoons) of his/her blood from a vein in his/her arm.
	The collection from him/her of 32.5ml (approximately 1 ounce) of his/her urine in a cup.
	The removal of cells from the inside of his/her mouth with a cheek brush (soft bristle swab) to provide DNA for test for genes that may play a role in ALL/AML.
	The storage of a portion of his/her blood, urine, and cheek cell samples at CDC to be used for future studies about the causes of ALL/AML.



Do not write in this space

(Control Family, Flesch-Kincaid reading level 7.5)

CONSENT TO VOLUNTEER as PILOT PARTICIPANTS
Exposure Assessment of Children with Acute Lymphocytic or Myelocytic Leukemia and a Comparison Population in Sierra Vista Arizona

Thank you for taking the time to learn about this research study. This form tells about a study being done by the Arizona Department of Health Services (ADHS), the Cochise County Health Department (CCHD), and the Centers for Disease Control and Prevention (CDC). In the study, we want to collect blood, cheek cells and urine from people so we can try to learn more about the causes of childhood leukemia in Sierra Vista. We want to invite you and other members of your family to serve as pilot participants for this study to ensure the process runs smoothly. The results of your tests will not be included in the study results. You will be given your individual study results. We hope you will take the time to read this form and that you will agree to be pilot participants. If you have any questions about this form while reading it, please let us know; we will be happy to help you in any way we can.

Purpose

Recently, the Arizona Department of Health Services found that there were more children with Acute Lymphocytic Leukemia (ALL) and Acute Myelocytic Leukemia (AML) in Sierra Vista than would be expected by chance. The ADHS has asked the CDC to help try to find a reason for this. CDC will test urine, blood, and cheek cells from people in Sierra Vista. We hope that the tests will help us find out if there is anything in the air or water or soil to worry about. We also hope to find out more about what causes childhood leukemia.

Please read this consent form carefully. If you decide that you would like to be pilot participants, please sign at the end of this form.

This research study has two main parts, asking questions about people's health and getting a little bit of their blood, urine, and cheek cells. We will give a questionnaire to you and other members of your family who can answer the questions. Then we will take samples of blood, urine, and cells from inside the mouth from you and your children. We will test these samples for chemicals, radioactivity, and infectious agents. We may test your DNA for genes that could affect leukemia. The DNA samples will only be used for research about leukemia. We will not do any other kinds of genetic tests.

Freedom of Choice

Volunteering as a pilot participant is up to you. You may choose to not serve as pilots. If you choose not to, nothing will happen to you. Before you decide you should know what will happen and have all your questions answered. If you have any questions about the study or about these consent forms, please ask anyone here or call Carol Rubin or Beverly Kingsley at CDC (770/488-3410); we will be happy to answer any questions you may have.

Payment

You do not have to pay to be a pilot participant. We will not pay you for being a pilot.

What will happen?

If you choose to be a pilot participant, we will take 21 ml (about 1 1/2 tablespoons) of blood from a vein in your arm. First we will clean the skin by gently rubbing it with alcohol. The needle stick may hurt a little for a few seconds. You may have a bruise afterwards. The person taking the blood will be very careful. We will collect cheek cells by brushing the inside of each cheek with a soft brush for 30 seconds. It will not hurt to give a sample of cheek cells. You will give us about 1 ounce of urine. It will not hurt to give a urine sample. We will do this to everyone in your family who agrees to it. Your visit to the county clinic offices may last as long as 30-45 minutes.

We will get DNA from part of your blood sample and from your cheek cells. We will store the samples at CDC with a research code number not your name. Any genetic tests we do on your DNA are for leukemia research only. Experts will advise CDC which tests to do. We may look for differences in genes that tell your body how to break down toxic substances or fix damaged DNA. We may also look for viruses that may cause cancer. We don't think the genetic test results will change how your doctors treat you so we will not send you results of the genetic tests. We do think this genetic research may help us understand leukemia better.

CDC will also save some of the blood and urine from this study with the research code number, not your name, in case we need to do more tests in the future. We will not test your blood and urine for HIV, or the presence of alcohol or drugs.

During the visit to the clinic, we will ask about your medical and pre-natal history. The interview form will also have a research code number, not your name on it. We will keep the answers from the interview private.

Benefits

We do not think that serving as a pilot participant will benefit you; it will benefit the study and community. We will tell you about the results of the tests we do on your

blood and urine after the study is complete. Your results will not be part of the study itself, but will only be given to you.

By giving us DNA for genetic testing, you will help us and other scientists and doctors understand why some people get ALL or AML and others do not. If we learn something about your DNA that might affect your health or your decision to have children, we will tell you personally. If this were to happen, you should tell your doctor about this. If your doctor wants to do more DNA tests you will have to pay for them.

Privacy

We will protect your privacy as much as the law allows. We will not put your name on the blood, urine, or cheek cell samples. Instead, these samples will have a research code number. We will keep all the research records and test results in locked files and only research staff will be allowed to look at them. We will keep any forms with your name in a locked file, separate from the answers to the questionnaire. In spite of all the things we do to protect your identity, it might be possible for someone to know you were in this study because of the small number of people in this study.

We will keep a list with your name and research code number on it so that we can send you the results of the tests done on your blood and urine. This list will be kept in a locked file separate from the samples and completed questionnaire. We will protect your privacy as much as the law allows. When we talk or write about this research study, we will not include your name or any facts that might identify you or your child(ren).

Your name, telephone number, and address are on this consent form so that we can contact you while we are doing this research study. We will keep this consent form in a locked file separate from the rest of the data.

CDC will save a part of your blood and urine samples in the case we need to do more

laboratory tests. CDC will give the laboratory test results to the CCHD and ADHS only by code number. Biological samples will be stored for an unspecified amount of time, until sufficient testing has been conducted. We will keep a link between your name and the research code on the blood, urine, and DNA for as long as they are stored. We will do this so that if we learn anything that might be important to you, we can tell you about it.

CDC will store your DNA for future genetic research using only a research code number. The code number will allow CDC

to link the laboratory tests and questionnaire data to the genetic studies.

Right to Refuse/Withdraw

It is your choice whether or not to be pilot participants for this study. Nothing will happen to you if you decide to not be pilot participants. You may skip any question you don't want to answer. You may stop answering questions any time you want. You may still be a pilot participant if some of your family decides not to. If at any time in the future, you would like to have your blood, urine, or cheek cell samples destroyed or removed from the laboratory please call Dr. Carol Rubin (770/488-3410).

For more information

We will give you a copy of this form to keep. If you have any questions, concerns, or complaints about this research study, please contact:

For questions about this research study or if you think you have been harmed by this study

Dr. Timothy Flood, Arizona Department of Health Services, (602) 542-7331

Dr. Carol Rubin, Centers for Disease Control and Prevention, (1-770-488-3406 and leave a message).

Dr. Gary Spivey, Cochise County Health Department, (520) 432-9433

For questions about your rights as part of a research study

The office of the CDC's Deputy Associate Director for Science (1-800-584-8814)

Thank you for considering being pilot participants.

Carol Rubin, D.V.M., M.P.H.

Centers for Disease Control and Prevention

Timothy Flood, M.D

Arizona Department of Health Services

Gary Spivey, M.D, M.P.H

Cochise County Health Department

Pilot Child's Parent/Guardian 1 Consent:

I have read the consent form or it has been read to me. I have been given a chance to ask questions. I agree that my child listed below may be a pilot participant. I have initialed below the study parts I agree to.

	Answering questions about my health history
	Letting about 1 ½ tablespoons of blood be taken from the vein in my arm
	Giving about an ounce of my urine in a cup
	Letting cells from the inside my cheek be collected with a soft bristle brush to get DNA to test for genes that may play a role in ALL/AML

Parent /Guardian 1 Signature: _____

Printed Name: _____ Today's Date: ___/___/___

Consent for storage

CDC would like to save part of your blood, urine, and cheek cells for future studies of childhood leukemia. You may agree to allow this or you may choose to not allow your specimens to be used this way. Your choice will not affect your medical treatment or enrolment in this study.

_____ Yes I agree to let CDC save part of my blood, urine, and cheek cell samples for future studies about childhood leukemia.

_____ No I do not want any of my blood, urine or cheek cells to be saved for other studies.

Parent/Guardian 1 Signature: _____

Printed Name: _____ Today's Date: ___/___/___

Street Address: _____

City: _____

State: _____ Zip: _____

Phone number: _____

Pilot Child's Parent/Guardian 2 Consent:

I have read the consent form or it has been read to me. I have been given a chance to ask questions. I agree that my child listed below may be a pilot participant. I have initialed below the parts I agree to.

	Answering questions about my health history
	Letting about 1 ½ tablespoons of blood be taken from the vein in my arm
	Giving about an ounce of my urine in a cup
	Letting cells from the inside my cheek be collected with a soft bristle brush to get DNA to test for genes that may play a role in ALL/AML

Parent /Guardian 2 Signature: _____

Printed Name: _____ Today's Date: ___/___/___

Consent for storage

CDC would like to save part of your blood, urine, and cheek cells for future studies of childhood leukemia. You may agree to allow this or you may choose to not allow your specimens to be used this way. Your choice will not affect your medical treatment or enrolment in this study.

_____ Yes I agree to let CDC save part of my blood, urine, and cheek cell samples for future studies about childhood leukemia.

_____ No I do not want any of my blood, urine or cheek cells to be saved for other studies.

Parent/Guardian 2 Signature: _____

Printed Name: _____ Today's Date: ___/___/___

Street Address: _____

City: _____

State: _____ Zip: _____

Phone number: _____

Other Related Adult Living with Pilot Child Consent *(if applicable)*

I have read the consent form or it has been read to me. I have been given a chance to ask questions. I agree to be a pilot participant. I have initialed below the parts I agree to.

	Answering questions about my health history
	Letting about 1 ½ tablespoons of blood be taken from the vein in my arm
	Giving about an ounce of my urine in a cup
	Letting cells from the inside my cheek be collected with a soft bristle brush to get DNA to test for genes that may play a role in ALL/AML

Other adult Signature: _____

Printed Name: _____ Today's Date: ___/___/___

Consent for storage

CDC would like to save part of your blood, urine, and cheek cells for future studies of childhood leukemia. You may agree to allow this or you may choose to not allow your specimens to be used this way. Your choice will not affect your medical treatment or enrolment in this study.

_____ Yes I agree to let CDC save part of my blood, urine, and cheek cell samples for future studies about childhood leukemia.

_____ No I do not want any of my blood, urine or cheek cells to be saved for other studies.

Other adult Signature: _____

Printed Name: _____ Today's Date: ___/___/___

Street Address: _____

City: _____

State: _____ Zip: _____

Phone number: _____

As described above, we are asking your children (control child and all siblings under 18 years of age) to be pilot participants for this biosampling research study. You may allow your children to be pilot participants in the biosampling research study by indicating your consent to the items below. You may consent to all, some, or none of the items.

I have read the consent form or it has been read to me. I have had a chance to ask questions I agree that my child listed below may be a pilot participant. In addition, I indicate with my initials which part that each child can take part in.

Child 1: *Pilot Child* Child's Name: _____

_____ first middle father's surname mother's surname

	Answering questions about his/her health history
	Letting about 1 ½ tablespoons of blood be taken from the vein in the arm
	Giving about an ounce of urine in a cup
	Letting cells from the inside the cheek be collected with a soft bristle brush to get DNA to test for genes that may play a role in ALL/AML

Signature of Parent/ Guardian: _____

Printed Name: _____ Today's Date: ___/___/___

Consent for storage

CDC would like to save part of your child's blood, urine, and cheek cells for future studies of childhood leukemia. You may agree to allow this or you may choose to not allow your child's specimens to be used this way. Your choice will not affect your child's medical treatment or enrolment in this study.

_____ Yes I agree to let CDC save part of my child's blood, urine, and cheek cell samples for future studies about childhood leukemia.

_____ No I do not want any of my child's blood, urine or cheek cells to be saved for other studies.

Signature of Parent/ Guardian: _____

Printed Name: _____ Today's Date: ___/___/___

Child 2

I have read the consent form or it has been read to me. I have had a chance to ask questions I agree that my child listed below may be a pilot participant. In addition, I indicate with my initials which part that each child can take part in.

Child's Name: _____

first middle father's surname mother's surname

	Answering questions about his/her health history
	Letting about 1 ½ tablespoons of blood be taken from the vein in the arm
	Giving about an ounce of urine in a cup
	Letting cells from the inside the cheek be collected with a soft bristle brush to get DNA to test for genes that may play a role in ALL/AML

Signature of Parent/ Guardian: _____

Printed Name: _____ Today's Date: ___/___/___

Consent for storage

CDC would like to save part of your child's blood, urine, and cheek cells for future studies of childhood leukemia. You may agree to allow this or you may choose to not allow your child's specimens to be used this way. Your choice will not affect your child's medical treatment or enrolment in this study.

_____ Yes I agree to let CDC save part of my child's blood, urine, and cheek cell samples for future studies about childhood leukemia.

_____ No I do not want any of my child's blood, urine or cheek cells to be saved for other studies.

Signature of Parent/ Guardian: _____

Printed Name: _____ Today's Date: ___/___/___
