UNIVERSITY OF CALIFORNIA, IRVINE
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

Hematologic Malignancies Biorepository for human research

You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed below will be available to answer your questions.

In the instance of parental permission, "You" refers to "Your child."

RESEARCH TEAM
Lead Researcher
Angela G. Fleischman M.D., Ph.D.
Department of Medicine
Division of Hematology/Oncology
24-Hour Telephone Number/Pager: (949) 824-2559

Other Researchers
Richard Van Etten M.D., Ph.D.
Robert Edwards M.D., Ph.D.
Deepa Jeyakumar M.D.
Kanwarpal Kahlon M.D.
Susan O'Brien M.D.
Leonard Sender M.D.
Edward Nelson M.D.
Minh-ha Tran D.O.
James Jerkins M.D.
Jessica Belmonte M.D.
Yung Lyou M.D. Ph.D.
Sarment Sarkissian M.D.
Phu Tran M.D.
Ziad Khan M.D.
Karen Sommers N.P.
Christina Kirk N.P.
Annamarie Bedia N.P.

STUDY LOCATION:
University of California, Irvine

STUDY SPONSOR:
University of California, Irvine

WHY IS THIS RESEARCH STUDY BEING DONE?

UC Irvine Medical Center is both a treatment and a research hospital. As a patient here, you may be treated by some doctors who are also researchers performing studies to improve treatments currently available. Your doctor is inviting you to participate in the research study described below.

The purpose of this informed consent form is to give you information about the research study. As you read the consent form, please feel free to discuss any part of it with the study doctor. Reading this informed consent form and participating in this study are completely voluntary. You are free to decide not to participate in this research study, and you may decide to stop participating in this research study at any time. Your doctor and this hospital will continue to care for you regardless of what you decide about this research study.

Scientists and clinicians at this institution are working together to discover new ways to treat cancer and new ways to make current treatments safer and more effective. In order to conduct this research, we need to study samples of normal and disease tissue obtained from normal volunteers and our patients. In order to minimize the discomfort and risk to subjects, we are seeking to collect tissue that is left over from studies that are required for your evaluation and care and are already being done. In certain circumstances (blood draw and bone marrow aspiration) we are seeking to collect a small amount of tissue in addition to the sample that would be collected for your routine care. Except for giving samples of blood, you will *not* be asked to undergo any procedure solely for the purpose of obtaining a sample for this study.

You are being asked to take part in this research study because you have or are being evaluated for a hematologic malignancy, bone marrow disorder, or immune system disorder.

This research study involves the collection and storage of blood and other tissue for later research testing. It is not currently known how samples donated to the repository will be used at this time. These research tests may be developed during the time you are a patient at UC Irvine Medical Center, or in some cases, years later. Any researcher at UCI or their academic collaborators may request permission to use samples from the repository. Frozen de-identified samples will be provided to researchers after their plans have been evaluated and approved by the UCI review board that oversees human research (IRB). These tests may provide additional information that will be helpful in understanding cancer and other diseases, but it is unlikely that what we learn from these studies will benefit you directly. These studies may benefit other patients in the future. The research performed on these samples may include the study of genetics, including the subject's DNA code, parts or the DNA code or even whole genome sequencing. Samples from the repository will not be used to create cell lines.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

All patients followed in the Hematology/Oncology Clinics at UC Irvine Medical Center with hematologic malignancy, bone marrow disorder or immunologic disease will be invited to participate in this research study. Up to 500 people may participate in this research at UCI.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?

Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

Inclusion Requirements

You can participate in this study if you have or are being evaluated for a blood disorder

Exclusion Requirements

You cannot participate in this study if you are pregnant.

HOW LONG WILL THE STUDY GO ON?

This study will take a small amount of sample when you get a blood, bone marrow or lymph node biopsy. This will occur at least one time. By signing this consent you allow us to take a portion of the sample for subsequent blood draws or biopsies in the future as well.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?

As a subject in this research study you are being asked to donate an extra 30 ml (approximately two tablespoons) for adults and 10 to 30 ml (approximately one to two tablespoons) for children of blood up to 4 times per year for as long as you are a patient at this institution. In order to minimize discomfort and

inconvenience for you, this blood will be collected at the same time you have other blood work done as part of your routine care.

If you undergo a bone marrow biopsy, you will be asked to donate up to an additional 15 ml (approximately one tablespoon) of marrow for adults, 1 to 15 ml (approximately one to 3 teaspoons) for children depending on age. Bone marrow biopsy involves inserting a needle into a bone in the hip. If you agree to have marrow removed for research, the procedure will only be prolonged for a few seconds as extra marrow is drawn up through the needle after the sample has been collected for your clinical use. The needle will not be repositioned or reinserted to obtain marrow for research. If you undergo a biopsy of other tissue (such as a lymph node or a tumor), any portion removed as part of your clinical care, but not consumed for analysis may be stored.

The samples of blood and other tissue we collect may be retained in the laboratory indefinitely. You will not have access to the samples once they have been donated, nor will you or your doctor be informed of the results of any testing of your samples. We may share portions of your tissue with other researchers working in other institutions. If your samples are shared with other researchers, your identity will remain strictly anonymous. You have the option to have the samples removed from storage and destroyed at any time by telling your doctor or Dr. Fleischman, orally or in writing.

In the future, people who do research on your blood and/or other tissue may need to know more about your health and treatment history. Dr. Fleischman or her designates may review records that exist at the time samples are collected, as well as medical records that may be generated about you in the future. Your identity will be removed from any medical record information before it is given to any researcher in order to protect your privacy. Your identity will not be released to any participating researcher.

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?

We will obtain samples only in the context of your clinical care, no extra blood draws or biopsies are required. By participating in this research study it may mean that procedures such as bone marrow biopsy are prolonged by a few seconds. As with all research studies there is a risk of breach of confidentiality, we have taken precautions to minimize this risk to you.

You should talk to the research team about any side effects you experience while taking part in the study.

Risks and side effects related to the procedures include:

The risks of a needle stick to draw blood include a mild amount of pain from the needle stick, and bruising or infection at the site of the blood draw. If you will undergo a biopsy, those risks will be discussed with you by your doctor. Every effort will be made to respect and maintain your privacy. Loss of confidentiality of your medical information is a risk of participation.

Your tissue may be used for genetic research (about diseases or risks that are passed on in families). Even if your tissue is used for this kind of research, the results will not be available to you or your doctor.

UNKNOWN RISKS

There may be risks to being in this study that we don't know about now. You will be informed of any changes in the way the study will be done and any additional identified risks to which you may be exposed.

ARE THERE BENEFITS TO PARTICIPATING IN THIS STUDY?

Participant Benefits

You will not directly benefit from participation in this study. No results derived from any research performed your samples will be provided to you.

Benefits to Others or Society
Your participation may provide generally useful knowledge for a better understanding of hematologic malignancies and their treatment in the future.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?
There are no alternative treatments or procedures available. The only alternative is not to participate in this study.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?
Compensation
You will not be compensated for your participation in this research study.

Reimbursement
You will not be reimbursed for any out of pocket expenses, such as parking or transportation fees.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?
There is no cost to you or your insurer/third party payer for participation in this study.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?
It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number listed at the top of this form.

If you are injured as a result of being in this study, UCI will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or billed to you or your insurer just like other medical costs, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For more information about this, you may call UCI Human Research Protections (949) 824-6068 or (949) 824-2125 or by e-mail at IRB@research.uci.edu

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?
You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

If you experience any of the side effects listed above, if your health worsens, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you elect to withdraw or are withdrawn from this research study, you may choose to:
1) Withdraw your specimens from continued use
2) Request to remove the code linking any of your samples to identifiable information
3) Request that no additional access to the subject's medical record will be continued for the purposes of the biorepository.

You have the option to have the samples removed from storage and destroyed at any time by telling your doctor or Dr. Fleischman, orally or in writing.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?

Subject Identifiable Data

All identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. This includes your name, age, sex, and medical history. Only the de-identified coded number will remain attached to your actual specimen.

Data Storage

Research data will be maintained in paper format in a secure location at UCI. Only authorized individuals will have access to it.

Research data will be stored electronically on a secure network in an encrypted file.

Data Retention

The researchers intend to keep the research data in a repository indefinitely. Other researchers may have access to the data for future research. Any data shared with other researchers, will not include your name or other personal identifying information.

WHO WILL HAVE ACCESS TO MY STUDY DATA?

The research team, authorized UCI personnel, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

Any information derived from this research project that personally identifies you will not be released or disclosed by these entities without your separate written consent, except as specifically required by law. Research records provided to authorized, non-UCI entities will not contain identifiable information about you. Publications and/or presentations resulting from this study will not include identifiable information about you.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy

UCI's NCI-Designated Cancer Center or the Sponsor registers National Cancer Institute (NCI)-supported clinical trials with NCI though their Clinical Trials Reporting Program (CTRP) to provide study related information. The data provided will include the following identifiable information that may identify you: birth month/year and five-digit zip code. NCI uses the data to manage and enhance the nation's investment in cancer research.

ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY?

Use of Specimens

Any specimens (e.g., tissue, blood, urine) obtained for this study will become the property of the University of California, Irvine (UCI). Once you provide the specimens you may not have access to them. Use of the specimens could result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the University. You will not receive any money or other benefits derived from any commercial products or other products that may be developed from the use of your specimens.

Genetics

A Federal law, called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and employers of 15 or more persons to discriminate

against you based on your genetic information. This means that they may not use your genetic information when making decisions regarding insurability. GINA does not, however, protect against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. If you would like more information about GINA go to: http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf.

Investigator Financial Conflict of Interest
No one on the study team has a disclosable financial interest related to this research project.

1. UCI researchers may contact me in the future to ask me to take part in other research studies.

YES	NO

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?
If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

A 24-hour number is also listed on the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any suggestions, problems or concerns you may have about the study, please contact UCI's Office of Research by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@research.uci.edu or at 5171 California Avenue, Suite 150, Irvine, CA 92697.

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?

You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights" to keep. **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

Note: As the research described in this form involves your protected health information (PHI), you will be asked to sign separate UC HIPAA Research Authorization form for the use of your PHI.

I agree to participate in the study.

Subject Signature	**Date**
Printed Name of Subject	
Legally Authorized Representative/Guardian Signature	***Date***
Printed Name of Legally Authorized Representative/Guardian	***Relationship to Subject***
Signature of Person Obtaining Informed Consent *(Individual must be listed on Page 1 of this consent)*	**Date**
Printed Name of Person Obtaining Informed Consent	

A witness signature is required on this consent form only if: (Researchers: check which one applies)

☐ Consent is obtained from the subject via the Short Form process, as approved by the IRB.
☐ The subject has decision-making capacity, but cannot read, write, talk or is blind.
☐ The subject's guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
☐ The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive research procedures).

Note: The witness must be impartial (i.e. not a member of the subject's family, not a member of the study team).

For the witness:

I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

_____ _____

Witness Signature **Date**

(If no witness signature is required, this witness signature section of the consent form may be left blank).

_____

Printed Name of Witness

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 5171 California Avenue, Suite 150, Irvine, CA 92697.

IRB# 2014-1709

University of California Irvine Health
Permission to Use Personal Health Information for Research

Study Title (or IRB Approval Number if study title may breach subject's privacy):
Hematologic Malignancies Biorepository for human research

Principal Investigator Name:
Angela Fleischman

Sponsor/Funding Agency (if funded):

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, the University of California or your health care provider cannot release your health information for research purposes unless you give your permission. Your information will be released to the research team which includes the researchers, people hired by the University or the sponsor to do the research and people with authority to oversee the research. If you decide to give your permission and to participate in the study, you must sign this form as well as the Consent Form. This form describes the different ways that UC Irvine Health can share your information with the researcher, research team, sponsor and people with oversight responsibility. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released by UC Irvine Health it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team.

B. What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing: **UC Irvine Health** to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records, financial records and other information that can identify you.

☐ Entire Medical Record	☒ Lab & Pathology Reports	☐ Emergency Department Records
☒ Ambulatory Clinic Records	☐ Dental Records	☐ Financial records
☒ Progress Notes	☒ Operative Reports	☐ Imaging Reports
☐ Other Test Reports	☐ Discharge Summary	☒ History & Physical Exams
☐ Other (describe)	☐Consultations	☐Psychological Tests

C. Do I have to give my permission for certain specific uses?

Yes. The following information will only be released if you give your specific permission by putting your initials on the line(s).

___ I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.
___ I agree to the release of HIV/AIDS testing information.
___ I agree to the release of genetic testing information.
___ I agree to the release of information pertaining to mental health diagnosis or treatment.

D. Who will disclose and/or receive my Personal Health Information?

Your Personal Health Information may be shared with these people for the following purposes:

1. To the research team for the research described in the attached Consent Form;
2. To others at UC with authority to oversee the research
3. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections, the research sponsor University of California, Irvine or the sponsor's representatives including but not limited to the contract research office of University of California, Irvine, or government agencies in other countries.

E. How will my Personal Health Information be shared for the research?

If you agree to be in this study, the research team may share your Personal Health Information in the following ways:

1. To perform the research
2. Share it with researchers in the U.S. or other countries;
3. Use it to improve the design of future studies;
4. Share it with business partners of the sponsor; or
5. File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

F. Am I required to sign this document?

No, you are not required to sign this document. You will receive the same clinical care if you do not sign this document. However, if you do not sign the document, you will not be able to participate in this research study.

G. Optional research activity

If the research I am agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process, I understand I can choose to agree to have my information shared for those activities or not.

☐ I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.

__X__ This section does not apply to this study.

H. Does my permission expire?

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over.

I. Can I cancel my permission?

You can cancel your permission at any time. You can do this in two ways. You can write to the researcher or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used for limited purposes. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

J. Signature

Subject

If you agree to the use and release of your Personal Health Information, please print your name and sign below. You will be given a signed copy of this form**.**

_____

Subject's Name (print)--*required*

_____ _____

Subject's Signature Date

Parent or Legally Authorized Representative

If you agree to the use and release of the above named subject's Personal Health Information, please print your name and sign below.

_____ _____

Parent or Legally Authorized Representative's Name (print) Relationship to the Subject

_____ _____

Parent or Legally Authorized Representative's Signature Date

Witness

If this form is being read to the subject because s/he cannot read the form, a witness must be present and is required to print his/her name and sign here:

_____

Witness' Name (print)

_____ _____

Witness' Signature Date