Cancer Requisition Form

The University of Chicago Genetic Services Laboratories
5841 South Maryland Avenue, Room G701/MC0077, Chicago, IL 60637
Toll Free: 888.824.3637 | Local: 773.834.0555 | Fax: 773.702.9130
ucgslabs@genetics.uchicago.edu | dnatesting.uchicago.edu | CLIA#: 14D0917593 | CAP#: 18827-49

Patient Information

Name: *Last* _____ *First* _____ **Date of Birth:** _____

Gender: ☐ Male ☐ Female **MRN:** _____

Ethnicity: ☐ Caucasian ☐ African-American ☐ Hispanic ☐ Asian ☐ Ashkenazi Jewish ☐ Other _____

Ordering Physician Information

REPORTING RESULTS: Reports will only be faxed out. Please check the boxes below for those who should receive by fax.

☐ **Referring Physician:** _____
Phone: _____ Fax: _____
Email: _____

☐ **Genetic Counselor:** _____
Phone: _____ Fax: _____
Email: _____

☐ **Referring Lab:** _____
Phone: _____ Fax: _____
Email: _____

Patient Clinical History*

REQUIRED INFORMATION. NECESSARY FOR TESTING

Indication of testing and/or ICD-10 code for testing: _____

☐ **No Personal history of cancer**

☐ **Personal history of cancer, type(s):** _____ Age at diagnosis: _____

Results of previous genetic testing: _____

**We recommend also providing detailed clinic notes, results of previous genetic testing and a detailed family pedigree, to aid in interpretation of genetic findings.*

Patient Family History

REQUIRED INFORMATION. NECESSARY FOR TESTING

☐ **No Family History of Cancer**

☐ **Family history of cancer – please specify cancer types, ages of onset and relationship to patient:** _____

_____

☐ **Other relevant family history:** _____

Sample Information

Date Sample Drawn: _____ **Specimen Type:** ☐ Fibroblast Culture ☐ Peripheral Blood** ☐ DNA** ☐ Buccal swab** ☐ Saliva**

**Note: peripheral blood or DNA extracted from blood sample is not accepted for patients with a current or past diagnosis of MDS or leukemia, or who have a history of bone marrow transplant. Please send fibroblast culture instead. Skin fibroblast samples are preferred for patients with lymphoma, however blood can be accepted ONLY if there is no blood involvement. Blood is accepted for patients with bone marrow failure disorders unless they have a history of MDS/leukemia. Saliva/buccal samples are not recommended for patients with hematological malignancies such as MDS/leukemia. Please contact the laboratory for further information.

Specimen Requirements: 2X T-25 flasks of cultured fibroblasts or 3-10cc blood in an EDTA (purple top) tube (if sending blood sample, please see above note). Please see our website for requirements for other specimen types, and shipping requirements. No Saturday or holiday deliveries.

Ordering Checklist

☐ Test Requisition Form *(required)*
☐ Completed Indication for Testing/ICD-10 study code *(required)*
☐ Completed Billing Information *(required)*
☐ Completed Research Consent Form *(recommended)*

For Office Use Only

TEST REQUESTS - Requisition Form

The University of Chicago Genetic Services Laboratories

Familial Myelodysplastic Syndrome and Acute Leukemia testing

**Note: blood samples not accepted for patients with a previous diagnosis of MDS/leukemia. Skin fibroblast culture recommended.

- ☐ Comprehensive Familial Myelodysplastic Syndrome/Acute Leukemia Panel
- ☐ Tier 1: Familial Myelodysplastic Syndrome/Acute Leukemia Panel
- ☐ Tier 2: Familial Myelodysplastic Syndrome/Acute Leukemia Panel
- ☐ Hereditary Leukemia and Breast Cancer Panel

Hereditary Breast and Ovarian Cancer testing

- ☐ Ashkenazi Jewish *BRCA1/BRCA2* founder mutations
- ☐ BRCA1 and BRCA2 mutation analysis
- ☐ BRCA1, BRCA2 and PALB2 mutation analysis
- ☐ BRCA1, BRCA2 and TP53 mutation analysis
- ☐ Comprehensive Hereditary Breast and Ovarian Cancer Panel
- ☐ Hereditary Breast and Ovarian Cancer High Risk Panel
- ☐ Hereditary Leukemia and Breast Cancer Panel

Hereditary Cancer (Multiple Types) testing

- ☐ Comprehensive Hereditary Cancer Panel

Hereditary Colorectal Cancer testing

- ☐ Colorectal Polyposis Panel
- ☐ Comprehensive Hereditary Colorectal Cancer Panel
- ☐ Hereditary Colorectal Cancer High Rsik Panel
- ☐ Lynch Syndrome Panel

Hereditary Gastric Cancer testing

- ☐ Hereditary Gastric Cancer Panel

Hereditary Lymphoma testing

**Note: skin fibroblast culture preferred for patients with a previous diagnosis of lymphoma. Blood accepted only if there is no blood involvement.

- ☐ Tier 1: Hereditary Lymphoma and Immunodeficiency Panel
- ☐ Tier 2: Hereditary Lymphoma and Immunodeficiency Panel

Hereditary Melanoma testing

- ☐ Hereditary Melanoma Sequencing Panel
- ☐ Hereditary Melanoma Deletion/Duplication Panel

Hereditary Mixed Polyposis Syndrome

- ☐ *SCG5/GREM1* targeted duplication testing (founder mutation)

Hereditary Paraganglioma and Pheochromocytoma testing

- ☐ Hereditary Paraganglioma and Pheochromocytoma Panel

Hereditary Prostate Cancer testing

- ☐ Hereditary Prostate Cancer Panel

Hereditary Thyroid Cancer testing

- ☐ Hereditary Thyroid Cancer Panel

Inherited Bone Marrow Failure Disorders

**Note: Blood accepted for patients with bone marrow failure ONLY if there is no history of MDS/leukemia.

- ☐ Diamond-Blackfan Anemia Sequencing Panel
- ☐ Diamond-Blackfan Anemia Deletion/Duplication Panel
- ☐ Comprehensive Telomere Biology Disorder / Dyskeratosis Congenita Panel
- ☐ Telomere Biology Disorder / Dyskeratosis Congenita Sequencing Panel
- ☐ Telomere Biology Disorder / Dyskeratosis Congenita Deletion/ Duplication Panel
- ☐ Fanconi Anemia Sequencing Panel
- ☐ Fanconi Anemia Deletion/Duplication Panel
- ☐ Comprehensive Bone Marrow Failure Panel
- ☐ Inherited Bone Marrow Failure Sequencing Panel
- ☐ Inherited Bone Marrow Failure Deletion/Duplication Panel
- ☐ Severe Congenital Neutropenia Sequencing Panel
- ☐ Severe Congenital Neutropenia Deletion/Duplication Panel

Thrombocytopenia

- ☐ Thrombocytopenia Sequencing Panel

Rhabdoid Tumor Predisposition Syndrome

- ☐ *SMARCA4* Sequencing
- ☐ *SMARCA4* Deletion/Duplication

Targeted Mutation Analysis

(Testing for a previously detected mutation or sequence change)

Requires prior approval by UCGS Lab Staff if this is a gene for which we do not offer full sequencing.

Gene: _____Change:_____

☐ Symptomatic ☐ Asymptomatic

Name of Proband/UofC Lab Number: _____

Relationship to Proband: _____

Single Gene Sequence Analysis

Any gene included in one of our sequencing panels can also be ordered individually. Please contact UCGS Lab Staff for prior approval before ordering.

Gene Requested:_____

Single Gene Deletion/Duplication Analysis

Any gene included in one of our deletion/duplication panels can also be ordered individually. Please contact UCGS Lab Staff for prior approval before ordering.

Gene Requested:_____

The UNIVERSITY of CHICAGO
Genetic Services
www.dnatesting.uchicago.edu

BILLING OPTIONS

All samples received with incomplete billing information will delay processing time.
Test cancelled while "in progress" will be billed for the amount of work completed up to that point.
*Please forward all billing questions to: youtlaw@bsd.uchicago.edu or call (**773-834-8220**).*

Patient Name: *Last* _____ *First* _____ (MI): _____ Date of Birth: _____

1.) Institutional Billing *(Pre-payment is required for all samples referred from outside the US or Canada.)*

Billing Institution: _____ PO#: _____

Financial Contact: _____ Phone: _____ Fax: _____

Address: _____ City: _____ State: _____ Zip: _____

Email (required): _____

2.) Self-Pay

We accept all major credit cards. Please call our office (773-834-8220) for credit card processing.

Important notice: *We will not be responsible for refunding any "cost differential" that may occur as a result of a patient seeking any type of reimbursement.*

☐ Wire Transfer (Please include 'Genetics Services Laboratories' and invoice numbers to ensure proper receipt.)
Electronic funding information, as follows: The Northern Trust Bank **– (Physical Address)** 50 S. LaSalle Street, Chicago, IL 60675
ABA/Routing No.: 071000152, International SWIFT Code: CNORUS44, University of Chicago Wire Account No.: 28509

Amount $_____(USD) Date of Transfer: _____ Name of Institution: _____

☐ Check/Money Order **(Make check/money order payable to: *The University of Chicago Genetic Services*)** Amount Enclosed $_____
(Please note: All bank fees for returned checks will be added to the original charge of patient invoice)

3.) Insurance Billing **– please note this option is available for a limited number of tests. Please see our website for more details.** ***Prices listed on our website are not applicable for insurance billing, please contact us for insurance pricing information. We do NOT accept Illinois or any out-of-state Medicaid)*** *A legible photocopy of the front and back of the insurance card and insurance authorization must be included.*

ICD-10 Diagnosis Code(s): _____ **(*Must be provided or insurance cannot be filed.*)**

Policyholder Name: _____ Date of Birth: ____/____/_____ Gender: ☐ Male ☐ Female

Policyholder Address: _____ City: _____ State: _____ Zip: _____

Relationship to the Patient: ☐ Self ☐ Spouse ☐ Dependent ☐ Other Preauthorization # (*if applicable*): _____

Name of Primary Insurance: _____ Policy No. _____ Group No.: _____

Insurance Address: _____ City: _____ State: _____ Zip: _____

PCP/Referring Physician Name: _____ NPI #: _____

Name of Secondary Insurance: _____ Policy No.: _____ Group No.: _____

Insurance Address: _____ City: _____ State: _____ Zip: _____

The policy holder's signature to the following statement: I hereby authorize any physician who treated or attended to me or my dependent(s) to furnish any medical information requested. In consideration of services rendered, I hereby transfer and assign to the University of Chicago Genetic Services Laboratories any benefits of insurance I may have. I assume responsibility for the balance of the cost of testing not paid by my insurance company. A photocopy of this authorization shall be considered as effective and valid as original.

Authorized Signature: _____ Date: ____/____/_____

CONSENT/AUTHORIZATION BY SUBJECT FOR PARTICIPATION IN A RESEARCH PROTOCOL FOR THE BETTER UNDERSTANDING OF THEIR GENETIC CONDITION

Protocol Number: 15-1252

Name of Subject :_____

Medical History Number:_____

STUDY TITLE: Molecular Genetic Studies of Inherited Hematological Malignancies

Research Team: Zejuan Li, M.D., Ph.D.
5841 S. Maryland Ave. Room G701 MC 0077, Chicago, IL 60637
Telephone: 773-834-0555, Toll Free (888) UC-GENES or (888) 824-3637

You are being asked to participate in a research study. A member of the research team will explain what is involved in this study and how it will affect you. This consent form describes the study procedures, the risks and benefits of participation, as well as how your confidentiality will be maintained. Please take your time to ask questions and feel comfortable making a decision whether to participate or not. This process is called informed consent. If you decide to participate in this study, you will be asked to sign this form. Throughout this consent form, "you" will refer to you or your child, as appropriate.

WHY IS THIS STUDY BEING DONE?

You are being asked to participate in this study because you have been diagnosed with a hematological malignancy or have a predisposition to hematological malignancies. The purpose of this study is to learn more about the genetic causes of inherited hematological malignancies tested in our lab, gather more information about these diseases, and experiment with new methods that may be better for testing. This research is being done because the genes associated with the majority of inherited hematological malignancies still remain unknown and identification of these genes is critical for diagnosis and treatment.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 300 people will take part in this study at the University of Chicago.

WHAT IS INVOLVED IN THE STUDY?

You have already been or will be asked to collect a saliva, buccal, blood, or skin sample from you for use in clinical genetic testing. Dr. Li only will to use leftover samples that have already been collected or will be collected as part of your regular care for research study.

This study involves genetic research, and your samples will be stored and used for future research studies on your genes. The cells of your body contain deoxyribonucleic acid (DNA). DNA is passed down from your parents and carries the genes that determine your physical makeup, including diseases that you might be susceptible to developing. Acquired changes in these genes can also determine how aggressive a cancer is and/or the ideal treatment options for that cancer. If the testing is positive, you will be instructed to discuss the results of the genetic testing with Amy Knight Johnson, a genetic counselor who is a member of the study team, or you will be assisted in locating genetic counseling services through your doctor or in your community.

You will also have the option to "opt-out" of receiving any individual results, even if clinically actionable and related to the specific study they have enrolled in (e.g. gene mutation that increased your risk of developing hematological malignancies) and/or to opt-out of receiving results that are clinically actionable, but incidental in that they are not related to the specific study that the patient enrolled in (e.g. identifying a genetic mutation in a gene that increases the risk for cardiovascular disease in someone who enrolled on a hematological malignancy study). Anticipating that there will be a growing list of genes for which actionable mutations are discovered, this opt-out clause will allow the investigators to focus on the most relevant gene findings relative to the disease under study.

You will also have the option to "opt-in" of receiving individual results including clinically actionable incidental findings. The clinically actionable incidental findings will be reported back to you and your parents if you are under the age 18.

Because the goal of the study is to learn more about the genetic causes of inherited hematological malignancies, you will be asked to provide information about the study to adult members of your family who might be interested in participating.

During this study, Dr. Li and her research team will collect information about you for the purposes of this research, which consists of any health information related to your diagnosis (such as date of birth, medical record number, primary diagnosis, symptoms, family history, and outcome).

Your doctor may be contacted for additional Protected Health Information (PHI) about you, which consists of any health information related to your diagnosis (such as date of birth, medical record number, primary diagnosis, clinical features, relevant and family history, outcome). The data collected will be used to develop a database of patients being tested for genetic diseases and will be kept for the duration of the database. This study will look at how often different genetic mutations happen, novel genetic mutations associated with inherited hematological malignancies and clinical information related to the mutation.

HOW LONG WILL I BE IN THE STUDY?

We think you will be in the study as long as your DNA sample remains in our laboratory. The study results will be kept in your research record and be used by the research team indefinitely. When the study ends, your personal information will be removed from all results. Any information shared with your doctor may be included in your medical record and kept forever.

Dr. Li may decide to take you off of the study without your consent if:

- You are unable to meet the requirements of the study;
- Your medical condition changes;
- New information becomes available that indicates that participation in this study is not in your best interest; or
- If the study is stopped.

WHAT ARE THE RISKS OF THE STUDY?

There is a minimal amount of risk of loss of confidentiality. We will take every precaution to ensure that your data are kept confidential. There may be other risks that could arise which are not reasonably foreseeable. If new information becomes available which could influence

your willingness to continue, this new information will be discussed with you. There is also a potential for the identification of incidental findings unrelated to inherited hematological malignancies but of medical value for patient care. The American College of Medical Genetics and Genomics (ACMG) recently published recommendations on incidental findings for clinical exome sequencing. Mutations identified in a list of 59 genes are recommended for reporting to clinicians. If you do not "opt-out" of receiving any individual results or incidental findings, you will be contacted by Dr. Li or one of the Co-Investigators of this study and offered genetic counseling to discuss the significance of the findings if a genetic abnormality is discovered and has the potential to impact the health significantly. The genetic counseling is free of charge to you.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may be direct medical benefit to you. We may identify a cause for the genetic disease in you and/or your family. If a mutation is identified in your DNA through our testing, your doctor and/or genetic counselor will be notified, another sample will be collected from you to confirm the mutation and clinical report will be issued. Our study may also be helpful in finding the genetic causes of inherited hematological malignancies and will benefit doctors and patients as a group. We hope the information learned from this study will benefit other individuals with inherited hematological malignancies in the future.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you may choose not to participate. The decision whether or not you wish to participate in this study will not affect your care at the University of Chicago Medical Center.

WHAT ARE THE COSTS?

There will be no costs to you or your insurance company resulting from your participation in this research study. However, you or your insurance company will be responsible for costs related to your usual medical care.

WILL I BE PAID FOR MY PARTICIPATION?

You will not be paid to participate.

WHAT ABOUT CONFIDENTIALITY?

Study records that identify you will be kept confidential. All of your personal information will be entered into a password-protected database to prevent access to non-authorized personnel. If your data is shared with other researchers, all patient identifiers will be removed. The data collected in this study will be used for the purpose described in the form. By signing this form, you are allowing the research team access to your medical records, which include Protected Health Information. Protected Health Information (PHI) consists of any health information that is collected about you, which could include your medical history and new information collected as a result of this study. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago.

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including Office of Human Research Protections (OHRP). In addition, representatives of the University of Chicago, including the Institutional Review Board, a committee that oversees the research at the University of Chicago, may also view the records of the research. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

If health information is shared outside the University of Chicago, the same laws that the University of Chicago must obey may not protect your health information.

The results from tests and/or procedures performed as part of this study may become part of your medical record.

During your participation in this study, you will not be able to access your medical records related to this study. This will be done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. Dr.Li is not required to release to you research information that is not part of your medical record.

This consent form will be kept by the research team for at least six years. The study results will be kept in your research record and be used by the research team indefinitely". At the time of study completion, either the research information not already in your medical record will be destroyed or information identifying you will be removed from study results. Any research information in your medical record will be kept indefinitely.

Data from this study may be used in medical publications or presentations. Your name and other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval at that time.

The Genetic Information Nondiscrimination Act (GINA)

The Genetic Information Nondiscrimination Act (GINA) is a federal law that may help protect you from health insurance or employment discrimination based on genetic information. GINA is a federal law that will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research;
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. If you choose not to participate in this study, your care at the University of Chicago/University of Chicago Medical Center will not be affected. You may choose not to participate at any time during the study. Leaving the study will not affect your care at the University of Chicago/University of Chicago Medical Center.

Taking part in this study is voluntary. If you choose not to participate in this study, your care at the University of Chicago/University of Chicago Medical Center will not be affected. You may choose not to participate at

any time during the study. Leaving the study will not affect your care at the University of Chicago/University of Chicago Medical Center.

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. Li in writing at the address on the first page. Dr. Li may still use your information that was collected prior to your written notice.

You will be given a signed copy of this document. This consent form document does not have an expiration date.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You have talked to your doctor and/or genetic counselor about this study and you had the opportunity to ask questions concerning any and all aspects of the research. If you have further questions about the study, you may call Dr. Zejuan Li at (773) 834-0555.

If you have any questions concerning your rights in this research study you may contact the Institutional Review Board, which is concerned with the protection of subjects in research projects. You may reach the Committee office between 8:30 am and 5:00 pm, Monday through Friday, by calling (773) 702-6505 or by writing: Institutional Review Board, University of Chicago, 5751 S. Woodlawn Ave., McGiffert Hall, Chicago, Illinois 60637.

Consent

ASSENT OF A CHILD (UNDER AGE 18)

The research project and the procedures associated with have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will receive a signed copy of this consent form for my records.

I agree to participate in this study. My participation is voluntary and I do not have to sign this form if I do not want to be part of this research study.

Signature of Subject:_____

Date: _____ **Time:** _____AM/PM (Circle)

PARENT/GUARDIAN/ OR LEGALLY AUTHORIZED REPRESENTATIVE

I give my permission for my child/relative/the person I represent to participate in the above described research project.

Signature of Legally Authorized Representative:

_____

Date: _____ **Time:** _____AM/PM (Circle)

SUBJECT (AGE 18 OR OLDER)

The research project and the procedures associated with it have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will receive a signed copy of this consent form for my records.

I agree to participate in this study. My participation is voluntary and I do not have to sign this form if I do not want to be part of this research study.

Signature of Subject:_____

Date: _____ **Time:** _____AM/PM (Circle)

Please specify below whether you would like to receive the results of this analysis.

No, I am not interested in learning the results of this analysis:

_____ (Initial here) Date: _____

Yes, I want to learn of these results and welcome contact in the future:

_____ (Initial here) Date: _____

Please specify below if you wish to receive or not receive unrelated incidental findings, which are not related to inherited hematological malignancies.

I wish to receive information about incidental findings unrelated to inherited hematological malignancies. _____ (Initial here)
Date: _____

I do NOT wish to receive information about incidental findings unrelated to inherited hematological malignancies. _____ (Initial here)
Date: _____

PERSON OBTAINING CONSENT

I have explained to _____ the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to the subject and family.

Signature of Person Obtaining Consent:

_____

Date: _____ **Time:** _____AM/PM (Circle)

INVESTIGATOR/PHYSICIAN

Signature of Investigator/Physician:

_____

Date: _____ **Time:** _____AM/PM (Circle)