WEILL CORNELL MEDICAL COLLEGE

Consent Form for Clinical Investigation

Project Title: Predicting Response to Your Myelodysplastic Syndromes (MDS) Treatment

Research Project # 1411015656

Principal Investigator: Sangmin Lee, M.D.

MRN: _____ **Subject:** _____

INSTITUTION: Weill Cornell Medical College

INTRODUCTION:
You are invited to consider participating in a clinical database and tissue bank. You were selected as a possible participant because you have a diagnosis of Myelodysplastic Syndromes (MDS) and have been treated for that condition by your physician. It is important that you read and understand general principles that apply to all who take part in this project. Taking part is entirely voluntary. You may decide not to participate or you may decide to stop participating in the study at any time without loss of any benefits to which you are entitled. The purpose and nature of the clinical database and tissue bank, possible risks, your rights as a participant, and other information are discussed below. You are urged to ask any questions you have with members of the research team. You should take whatever time you need to discuss the research with your physician and family. The decision to participate or not to participate is yours. If you decide to participate, please sign and date where indicated at the end of this form.

Portions of the clinical database and tissue bank will take place at facilities of New York-Presbyterian Hospital (NYPH), where the investigators are members of the medical staff. New York-Presbyterian Hospital is neither a sponsor nor an investigator for this study.

WHY IS THE RESEARCH BEING DONE?
The purpose of this project is to collect and store patient information (including protected health information) and blood samples and to make these available for future research about MDS and other related hematology and oncology-related disorders. Abnormalities in gene methylation are common in MDS, one of the goals of this study is to characterize the gene methylation profile of blood samples from MDS subjects to further gain insight into MDS. Investigators at Weill Cornell Medical College (WCMC) and collaborators at other institutions are collecting information about patients with MDS, as well as studying their tissue in the laboratory. By studying the clinical course of patients with MDS and by performing additional laboratory studies, we hope to learn more about these disorders.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
Participants in the study are referred to as subjects. We hope to enroll 50 subjects with diagnosis of MDS who have previously been treated with azacitidine or decitabine.

WHAT IS INVOLVED IN THE RESEARCH?
The purpose of this consent form is to ask your permission to collect your clinical information and tissue samples for research purposes. If you take part, we may record your clinical information in a database. Most of this information will be derived from your treating doctor's record. If you are not seen at WCMC-

NYPH, we will contact you or your doctor to update our information. It is very important that our records are as complete as possible. Therefore, if you plan to move, please update us with your new contact information. We may periodically ask you to complete questionnaires that ask about your disease and symptoms relating to your disease.

If you take part in this study, we will collect blood samples from you at the times you are already having samples collected at your doctor's office. You will not be required to have additional needle sticks or blood draws as part of this study. If you have the blood sample drawn outside of WCMC-NYPH, we will provide you with blood collection kit, shipping label, and shipping box. You will have blood collected at your doctor's office with the blood collection kit, and you will mail the blood sample to WCMC using the shipping kit and instructions provided to you. By signing this consent form and checking the appropriate boxes, you agree to give these samples to WCMC for research purposes.

Many of the studies to be performed have been planned at this time, but others will be thought of later as new information comes to light. Examples of this use include, but are not limited to, evaluation of genes (DNA), methylation of genes, and proteins. Genetic material contains information about many different traits, like a personal diary. The traits being tested are heritable, which means that they may be passed on from generation to generation within families. Because genetic testing can have consequences for you as well as your family members, please read this consent form carefully before making a decision about whether or not to participate.

HOW LONG WILL I BE IN THE CLINICAL DATABASE AND TISSUE BANK?

This research involves long-term follow-up. We think you will be in the study for as long as you are alive. You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first. The clinical information and tissue you give WCMC under this study will be kept in a database/tissue bank or used by another party forever. Unless you cancel it, permission for WCMC researcher to use or share your protected health information for their research will never end.

HIPAA AUTHORIZATION TO USE/DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

Purposes for Using or Sharing Protected Health Information: If you decide to join this study, WCMC researchers need your permission to use your protected health information. If you give permission, Weill Cornell Medical College (WCMC) and/or NewYork-Presbyterian Hospital (NYPH) researchers may use your information or share (disclose) information about you for their research that is considered to be protected health information.

Voluntary Choice: The choice to give WCMC and/or NYPH researcher's permission to use or share your protected health information for their research is voluntary. It is completely up to you. No one can force you to give permission. However, you must give permission for WCMC and/or NYPH researchers to use or share your protected health information if you want to participate in the study. If you decline to sign this form, you cannot participate in this study, because the researchers will not be able to obtain and/or use the information they need in order to conduct their research. Refusing to give permission will not affect your ability to get usual treatment, or health care from WCMC and/or NYPH.

Protected Health Information To Be Used or Shared: Government rules require that researchers get your permission (authorization) to use or share your protected health information. Your medical information may be disclosed to authorized public health or government officials for public health

activities when required or authorized by law. If you give permission, the researchers could use or share with the people identified in this authorization any protected health information related to this research from your medical records and from any test results including, but not limited to genetic testing, HIV testing, and hepatitis testing.

Other Use and Sharing of Protected Health Information: If you give permission, the researchers could also use your protected health information to develop new procedures or commercial products. They could share your protected health information with the research sponsor, the WCMC IRB, inspectors who check the research, government agencies and research staff. The information that may be shared could include your medical record number and your research record related to this database/tissue bank. They may not be considered covered entities under the Privacy Rule and your information would not be subject to protections under the Privacy Rule.

To the extent permitted by law, under no circumstances will any information linking you to specific test results be disclosed to any individual or organization without your written consent.

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health 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 that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Nor does this Federal law prohibit discrimination on the basis of an already manifest genetic disease or disorder.

WHAT ARE THE RISKS OF THE STUDY?

Risk of Blood Sample Collection

You will have a blood sample collected using the collection kit mailed to you when you have standard blood work drawn at your doctor's office. There is no additional risk associated with having an extra blood sample collected.

Risk of Clinical Information Collection

Your clinical information (including protected health information) is being collected while you are participating. This information may be shared with other investigators. Since your personal health information will be used, there is the risk of loss of confidentiality. Every effort will be made to protect your privacy. The government does not require everyone who might see your information to keep it confidential, so it might not remain private.

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. We use a coding system that protects the identity of individuals who provide samples. The coding system has been reviewed and approved by the Institutional Review Board (IRB). However, we cannot guarantee absolute confidentiality. If information goes to an outside entity then the privacy rule may not apply. You will not be identified personally in any reports or publications resulting from this research study. Your personal information may be disclosed if required by law. Organizations that may request to inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as:

- Representatives of Weill Cornell Medical College and NewYork-Presbyterian Hospital
- The Institutional Review Board (IRB)
- The Office of Human Research Protection (OHRP)

By signing this consent form, you authorize access to this confidential information. You also authorize the release of your medical records to WCMC by any other hospitals or institutions where you might receive medical care of any kind while you are participating in this research study.

ARE THERE ANY BENEFITS TO TAKING PART IN THE CLINICAL DATABASE AND TISSUE BANK?

We cannot and do not guarantee that you will receive any benefits from this study. We hope to learn more about MDS and how to treat them.

DISCLOSURE OF RESULTS

To the extent permitted by law, under no circumstances will any information linking you to specific test results be disclosed to any individual or organization without your written consent.

TEST RESULTS AND FUTURE CONTACT:

There may be circumstances when WCMC would like to contact you regarding your samples. For example, it is possible that genetic tests will show a link between your genetic information and a disease or condition. Knowing this information may help you make choices about you or your family's health care. However, some individuals prefer not to know about their genetic information. At the end of this document, you will have the opportunity to tell us whether or not you want to be contacted in the future. Your decision about future contact will not affect your ability to participate in this research.

Risks and Benefits of Future Contact: WCMC wants you to know that there may be both risks and benefits to consenting to future contact.

The potential risks include: You may be upset to learn that you have a greater chance of having a disease or condition. Even if genetic tests show that you do not have a greater risk of disease, you may still be upset if you know that others in your family have that higher risk of disease.

The potential benefits include: You may benefit from the knowledge that you or your family have a predisposition to a certain disease or condition. This knowledge may help you make informed decisions concerning your lifestyle and health care.

FUTURE TESTING

The samples that you give to WCMC could one day lead to discoveries using methods and tests not yet developed. To that end, WCMC would like to keep the samples for as long as they are deemed useful for research purposes. This research could potentially be used for purposes not specified above.

You have the right to withdraw your consent at any time, and may request that the samples you give to WCMC be destroyed. If you choose to do so, contact your study doctor. Although you are free to withdraw your consent, it is possible the samples may have already been used for research purposes and data derived from such research will not be destroyed. In that event, WCMC will promptly destroy any remaining samples. Additionally if WCMC has shared the samples with third parties, WCMC will not be able to destroy the samples. Also, cancelling your permission will not apply to clinical information (including protected health information) that has already been used or shared.

COMMERCIAL INTEREST

Materials or data obtained from you in this research may be used for commercial purposes. It is the policy of WCMC not to provide financial compensation to you should this occur.

WHAT ARE THE COSTS?

You will not incur any additional costs to you or your insurance company by participating in this research study.

COMPENSATION FOR PARTICIPATION

You will not receive compensation for participating in this study. You should not expect anyone to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in this research study.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this clinical database and tissue bank is voluntary. You may choose to not take part in the research or to stop participating at any time. If you choose to not participate or to stop participating, your regular care will not be affected nor will your relations with WCMC, your physicians, or other medical personnel. In addition, you will not lose any of the benefits to which you are entitled. We will tell you about new information that may affect your health, welfare, or participation in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the research study, or if you think that something unusual or unexpected is happening, you may call Dr. Sangmin Lee at WCMC or one of the investigators at (646)962-2700. You may also contact your local treating physician. If you have questions about your rights as a research participant, contact WCMC IRB Office. Direct your questions to: Institutional Review Board at:

Address: 1300 York Ave, Box 89
New York, New York 10065

Telephone:(646) 962-8200

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Principal Investigator: Sangmin Lee, M.D.

TISSUE BANK ACKNOWLEDGEMENT:

☐ Investigators may store my tissue.

☐ Investigators may share my clinical information and tissue with researchers at outside institutions.

☐ I agree to be contacted in the future for any or all purposes* including research purposes, provision of general information about research findings, and information about the tests done on the samples that may affect me or my family. *Checking here does not mean I will be contacted about future research findings.

☐ I would like to be contacted about future research findings.

SUBJECT'S STATEMENT:

I, the undersigned, have been informed about this research study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent form. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this research study. I am free to withdraw from the research study at any time without need to justify my decision. This withdrawal will not in any way affect my future treatment or medical management and I will not lose any benefits to which I otherwise am entitled. I agree to cooperate with Dr. Sangmin Lee and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

_____	_____	_____
Signature of Subject	Printed Name	Date / Time