Subject's Name_____
Subject's Medical Record # _____
MCC #: 20585

CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Study Title:	**Development of a Quality of Life Decision-Making Model for Older Patients with Acute Myeloid Leukemia**
Sponsor:	**National Institute of Nursing Research (NINR an Institute of the NIH)**
Principal Investigator: (Study Doctor)	**Sara Tinsley, PhD APRN AOCN**
Telephone: (24 hour number)	**813-745-8986** **800-456-3434**
Address:	**12902 Magnolia Drive** **Tampa, FL 33612**

You are being asked to take part in a research study called: **Development of a Decision-Making Model for Older Patients with Acute Myeloid Leukemia.**

The information in this document should help you to decide if you would like to participate. The person who is in charge of this research study is **Sara Tinsley, PhD, APRN. This person is called the Principal Investigator**. This research will be conducted at Moffitt Cancer Center.

This research is being paid for by the National Institute of Nursing Research of the National Institutes of Health.

Why is this research being done?

The purpose of this study is to describe the differences in quality of life (QOL) among newly diagnosed patients diagnosed with acute myeloid leukemia (AML) to help design a patient decision-making QOL model for aligning patients' choice of treatment with what matters the most to them.

We are trying to determine if patient factors, such as age, gender, symptoms, level of fatigue, performance status and functional status can help us determine which chemotherapy treatment provides the best QOL for individual patients. Another aspect of this study is to learn if certain aspects of your leukemia, such as amount of leukemia cells called blasts, number of transfusions and chromosome changes of your blood cells can help us provide better recommendations for chemotherapy treatment, again focused on QOL. If survival is your goal, this information will also be monitored based on the information gathered.

What will happen during this study?

If you take part in this study, you will be asked to spend 6 months in the study. You will have the opportunity to review the questionnaires prior to signing and dating this consent form.

These questionnaires will be administered in 5 study visits which will take approximately 30-60 minutes each time, for a total of 150-300 minutes. The study visits will occur prior to chemotherapy treatment, and at 1 month, 2 months, 3 months, and 6 months following chemotherapy treatment. We will attempt to arrange for study visits at times that are convenient for you. Patients with AML are normally seen at least monthly for the first 6 months following chemotherapy treatment.

Each study visit will take 30-60 minutes at which time you will complete the following instruments.

1. Functional assessment of cancer therapy-leukemia version (FACT-Leu) to measure QOL;

2. Memorial symptoms assessment short form to measure whether you are experiencing certain symptoms, and how distressing they are to you;

3. Brief Fatigue inventory to measure the amount of fatigue that you have and how much it interferes with parts of your life.

By signing and dating this consent, you are also giving permission for the study staff to collect information about the unique aspects of your leukemia including cytogenetics, blast percentage, and the number of transfusions that you have received, your age, and gender. Information will also be noted, whether chemotherapy treatment is considered intense or non-intense.

A study visit is one you have with the person in charge of the study or study staff. All participants will complete the questionnaires at designated time points.

Why am I being asked to participate in this study?

You are being asked to take part because you are at least 60 years of age, newly diagnosed with AML confirmed by a pathologist and are within 7 days of starting treatment.

How many people will take part in this study?

It is anticipated that 220 participants will enroll, with an expected 150 individuals to complete the study who have AML and are 60 years of age and older.

What other choices do you have if you do not participate?

Your participation is voluntary, and you may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start. Since this is not a treatment study, your alternative is to not participate.

We do not know if you will receive any benefit from your participation. The most common and most serious risks that may be related to taking part in this research include being uncomfortable when asked to answer study specific questions. *If this occurs, you will be referred to our social worker for further discussion and support.* There may be a risk of loss of confidentiality, and there may be risks which are currently unknown.

What are the potential benefits if you take part in this study?

We are unsure whether you will receive any benefits if you take part in this study. However, this research may help us learn more about whether individual patient factors and disease characteristics will help patients make better choices with their treating team to align their

treatment with goals of treatment, whether for survival or better QOL, even if survival is shortened.

Will my results be kept confidential?

Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential. You may be emailed a PDF copy of this signed and dated consent form. There may be risks of loss of privacy and confidentiality if the PDF copy of this consent form is viewed and/or stored on a personal electronic device (PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena. Also, the PDF copy of the consent may not be able to be permanently removed from a PED.

WILL IT COST ANYTHING TO BE IN THIS STUDY?

There is no cost to participate.

WHAT IF I GET HURT OR SICK WHILE I AM IN THIS STUDY?

If you need emergency care:

- Call 911 or go to your nearest emergency room right away. Moffitt Cancer Center does not have an emergency room or the facilities to provide emergency care.

If you do NOT need emergency care:

- Call or go to your regular doctor. It is important that you tell your regular doctor that you are participating in a research study. If possible, take a copy of this consent form with you when you go.

WILL I GET PAID?

You will receive up to a total of $60 in compensation in the form of physical and/or e-gift cards from Target as a token of appreciation for your time and effort for completing the questionnaires at the multiple time points. $20 will be provided upon completion of the questionnaire at baseline, followed by $10 for every follow-up questionnaire completed (30-Day, 60-Day, 90-Day, and 180-Day).

WHAT HAPPENS IF YOU DECIDE NOT TO TAKE PART IN THIS STUDY?

You should only take part in this study if you want to participate. You should not feel that there is any pressure to take part in this study to please the study investigator or study staff. You are free to participate in this research or withdraw at any time. If you decide not to take part:

- You will not be in trouble or lose any rights you normally have.
- You will still have the same health care benefits.
- Your regular medical care will not change.

If you do not sign and date this form, you will not be able to take part in this research study. However, your care outside of this study and benefits will not change. To withdraw your consent

and leave the study, contact the study investigator at the contact information listed on page one of this form. If you withdraw your consent:

- You will no longer be able to be a participant in this research study;
- We will stop collecting new information about you;
- We will use the information collected prior to your withdrawal. This information may already have been used or shared with others, or we may need it to complete and protect the validity of the research; and
- Study staff may need to follow-up with you if there is a medical reason to do so.

ARE THERE REASONS THE STUDY DOCTOR OR SPONSOR MIGHT TAKE ME OUT OF THE STUDY LATER?

Even if you want to stay in the study, there may be reasons the study doctor or study staff will need to take you out of it. Your study doctor has the right to take you out of the study at any time with or without your agreement. Your participation may be ended without your consent for different reasons, including the following:

- If the study doctor believes, for any reason, that it is in your best interest.
- If other causes prevent you from continuing in this study.
- If the Sponsor decides to end the study.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment and because of federal law, we must obtain your written authorization before we use or disclose your information for this study.

By signing and dating this form, you are permitting researchers at Moffitt Cancer Center and Tampa General Hospital to use personal health information for research purposes within its organized health care arrangements. You are also allowing the Moffitt Cancer Center and Tampa General Hospital to disclose your personal health information to outside organizations or individuals that participate in this study. We may publish what we find out from this study. If we do, we will not let anyone know your name. We will not publish anything that would directly let people know who you are.

Identifiers might be removed from your identifiable private information or identifiable biospecimens collected during this study and could then be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

WHO WILL DISCLOSE, RECEIVE, AND/OR USE YOUR INFORMATION?

Your records are confidential, and they will be kept in a secure environment and protected to the full extent of the law.

To do this research, the following people and/or organization(s) will be allowed to disclose, use, and receive your information, but they may only use and disclose the information to the other parties on this list, to you or your personal representative, or as permitted by law:

- Every research site for this study, including Moffitt Cancer Center and Tampa General Hospital, and each site's study team, research staff and medical staff.
- Any person who provides services or oversight responsibilities in connection with this study.
- Members of Moffitt Cancer Center and Tampa General workforce who provideservices in connection with this study.
- The person who is responsible for the study nationwide or worldwide (study chairperson).
- Any laboratories, individuals, and organizations that use your health information in connection with this study.
- Any sponsor of the study, including the following sponsors: NIH (NINR)
- Any federal, state, or local governmental agency that regulates the study (such as] the U.S. Food and Drug Administration (FDA) and Florida Department of Health (FDH). The U.S. Department of Health & Human Services (DHHS), Office for Human Research Protections (OHRP).
- Other government agencies in this or other countries.
- The designated Protocol Review and Monitoring Committees, , Privacy Boards, Data and Safety Monitoring Board and their related staff that have oversight responsibilities for this study.
- The National Cancer Institute in evaluating the ongoing research of the Moffitt Cancer Center as a Comprehensive Cancer Center.

The organizations and people listed above may employ or pay various consultants and companies to help them understand, analyze and conduct this study. All of these people may not be known now, but if you would like to have more specific information about this at any time during the study, you may ask the study doctor and your questions will be answered.

Moffitt Cancer Center and Tampa General Hospital cannot guarantee the privacy of your information, or block further use or distribution, after the information has left Moffitt Cancer Center or Tampa General Hospital. Others listed above may further disclose your information, and it may no longer be covered by federal privacy regulations. If all information that does or can identify you is removed from your records, the remaining information will no longer be subject to this authorization and may be used or shared for other purposes. You might have the right to see and copy your health records related to this research. You might not be able to see or copy some of your records until after all participants finish the study. If it is necessary for your care, your records will be provided to you or your regular doctor.

WHAT INFORMATION WILL BE USED OR DISCLOSED?

By signing and dating below, you authorize the use and disclosure of your entire study record and any medical or other records held by Moffitt Cancer Center and Tampa General Hospital, including, but not limited to, HIV/AIDS, mental health, substance abuse or genetic information. The purpose for the uses and disclosures you are authorizing is to conduct the study explained to you during the informed consent and research authorization process and to ensure that the information relating to that study is available to all parties who may need it for research purposes.

Your authorization to use your health information will never expire unless and until you expressly revoke it in writing to the study doctor listed on the first page of this form.

Any data collected before your letter will continue to be used as necessary to preserve the integrity of the study, however no additional information will be collected after you withdraw your authorization.

You do not need to sign this form, but if you do not, you cannot participate in this study.

You will receive a signed and dated copy of this form.

CERTIFICATE OF CONFIDENTIALITY

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the study investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) There is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) You have consented to the disclosure, including for your medical treatment; or
3) The research information is used for other scientific research, as allowed by federal regulations protecting research participants.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this study or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the study investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you have questions, concerns or complaints about the study, please contact the study investigator at the telephone number listed on the first page of this consent document.

WHERE CAN I GET MORE INFORMATION?

You may call the National Cancer Institute's (NCI) Information Service at:
1-800-4-CANCER (1-800-422-6237).

Visit the NCI's Websites at:

- CancerTrials: comprehensive clinical trial information at: http://cancertrials.nci.nih.gov
- CancerNet: accurate cancer information including PDQ at: http://cancernet.nci.nih.gov

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

STATEMENT OF CONSENT AND AUTHORIZATION

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records.

_____
Printed Name of Participant

_____ _____ _____
Signature of Participant Date Time

STATEMENT OF PERSON OBTAINING INFORMED CONSENT / RESEARCH AUTHORIZATION

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____
Printed Name of Person Explaining Consent

_____ _____ _____
Signature of Person Explaining Consent Date Time