INFORMED CONSENT FOR CLINICAL RESEARCH

A Randomized Controlled Trial of Individual Psychosocial Interventions for Cancer Patients

Participant Informed Consent

You have been asked to participate in a research study. In order to decide whether or not you should agree to be part of this research study, you should know enough about its risks and benefits in order to make a sound judgment. This process is known as informed consent.

A member of the study staff will explain the research study to you. Research studies include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your family and friends.

This consent form gives you detailed information about the research study. Once you understand the study, its risks, and its benefits, you will be asked to sign the form if you wish to take part. You will be given a copy to keep.

Why is this study being done?

The aim of this study is to compare the benefits of three types of individual treatment programs for cancer patients: Meaning-Centered counseling, Supportive counseling, and Enhanced Usual Care. Many cancer patients use counseling or other resources to help with the emotional burden of their illnesses. Counseling often helps them cope with cancer by giving them a place to express their feelings. "Meaning-Centered" counseling aims to teach you how to maintain or even increase a sense of meaning and purpose in their lives, despite cancer. "Supportive" counseling is intended to help you cope with cancer by giving you a place to express your feelings and get support. Enhanced Usual Care is intended to offer you referrals and resources that are matched to your individual needs in addition to the care you are already receiving at MSKCC.

Is there a potential conflict of interest for this study?

There are no known investigator and/or institutional conflicts of interest for this study.

How was I selected to be in this study?

You have been selected to be in this study because you have non-localized and/or recurrent cancer.

How many people will take part in the study?

A total of 414 people will take part in this study at Memorial Sloan Kettering Cancer Center. In this study, one third will receive Meaning-Centered counseling, one third will receive Supportive counseling, and one third will receive Enhanced Usual Care.

What will happen if I take part in this research study?

Before you begin the study …

Before you begin the study we will conduct a screening interview to determine if you are eligible for this study.

This screening interview will take about 20-30 minutes.
We will ask you about your background (e.g. age, ethnicity, education and marital status), medical history, and your physical and emotional well-being, We will also ask you about which treatment you would prefer.

After you complete the questionnaires if you are eligible for participation, you will be assigned to one of the three treatment programs on a random basis. This means you have an equal chance of being in any of the programs.

Then we will describe the treatment programs we are studying and if you are eligible for the study, you will be asked which type of treatment program you would prefer to receive. You will then be randomly assigned to one of the three types of treatment programs. A research study assistant will call you to tell you what type of treatment you will receive and when it will start.

During the study…

If you choose to take part, then you will be asked to do the following:

If you are put into the Meaning-Centered counseling program, it will focus on how to maintain or even increase a sense of meaning and purpose in your life. Each meeting will have a discussion that deals with a specific topic such as what is meaningful to you and how has cancer changed this. In addition, written exercises will be assigned during the session or for homework and participants will also have the option of completing a larger project on their own based on these themes. You will meet with a counselor individually for seven weekly 1 hour sessions.

If you are put into the Supportive counseling program, it will focus on helping you cope with cancer by giving you a place to express your feelings and get support. During each session you will be asked to share your concerns and discuss how you are feeling about these issues. You will meet with a counselor individually for seven weekly 1 hour sessions.

All research study counselors are either MSKCC-employed mental health clinicians or non-MSKCC employed mental health clinicians contracted to work on specific research studies. We use the services of non-MSKCC mental health clinicians as study counselors so that we can best accommodate your schedule and availability to attend Meaning-Centered or Supportive counseling sessions. All clinicians, whether employed by MSKCC or hired per research study, have at minimum a Masters degree and are qualified and experienced mental health clinicians trained in the counseling program you will receive.

If you are randomized to the Enhanced Usual Care program, you will be given referrals based on your individual needs. You will also receive additional written materials with information on

how to cope better when you have cancer and additional resources that may be helpful. You will complete assessments three times and based on the results will be given referrals if needed tailored to your individual needs after each time.

Therapy sessions will be audio recorded. If you choose to allow us, we may transcribe some of these recordings for academic, educational, or training purposes, and some sessions may also be video recorded. At the end of this consent, we will ask for your permission to audio and video record your sessions and to transcribe your audio recordings. Video recording of sessions and transcription of audio recordings are optional. You can choose not to allow video recording and/or transcription and still participate.

Recording the sessions will help us make sure that the interventions are being carried out as planned. Each recording will have a code number to protect your confidentiality. In addition, some sessions may take place in front of a two way mirror in order to be observed for training and supervision purposes. You may ask to stop the recording at any time or to not be observed during the intervention and such requests will not influence your participation in the study or any of your medical care.

All participants will be asked to complete a set of self-report questionnaires before they begin the treatment program and about 4, 7 and 15 weeks after they start the treatment program. The questionnaire will take about 45-60 minutes to complete. These assessments are generally completed in person. However, if necessary we can arrange for you to complete them by mail, phone, or email. If you are in the Meaning-Centered program, we will also you to fill out an optional weekly session rating after each session. This will take about 2-3 minutes, but you can choose not to complete it. With your permission, we may also contact your doctor after you begin the study for information about your medical treatment.

You will be asked questions about the following areas:

a) Questions about your physical and psychological symptoms and quality of life
b) Questions about your religious beliefs and spiritual well-being
c) Questions about your social support and stress levels

After the study…

After you have completed the above steps, there is nothing further you must do.

How long will I be in the study?

You will be asked to take part in the study for about 15-22 weeks.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest or if the study is stopped.

What side effects or risks can I expect from being in the study?

We do not expect any physical side effects or risks with this study. There is a small chance that you may become upset by the discussions or by some of the questions we will ask you. The research staff conducting the sessions is well trained mental health professionals. They will be there during the sessions and afterwards to help provide further help. If you become very upset because of taking part in this study, you will also be offered a referral for care by the MSKCC Psychiatry staff. You will be billed for these additional services.

Are there benefits to taking part in the study?

This study may or may not benefit you. By taking part in this study, you may receive 7 weeks of Meaning Centered or Supportive Counseling free of charge or be provided with referrals to specifically meet your needs. It may help reduce the emotional difficulties you may be experiencing. We hope that what we learn from the study will help other patients in the future.

Will I receive the results from the study?

You will not receive any results from this study.

Do I have to take part in this study?

The choice to take part in this study or not is yours. Make your choice based on what we have explained to you and what you have read about the study. Whether you decide to participate in this study or not, you do have the opportunity to receive counseling and support services to help you cope with the stressors of cancer illness and treatment through either the MSKCC Department of Social Work as well as through consultation with a member of the Clinical staff of the MSKCC Department of Psychiatry.

Will my medical information be kept private?

Every effort will be made to keep your study records private. It is the responsibility of the research staff at Memorial Hospital to make sure that your records are managed to protect your privacy. If information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. Trained staff at Memorial Hospital may review your records if necessary. Access to your medical information will be limited to those listed in the Research Authorization Form, which is a part of the informed consent process.

A description of this clinical trial may be available on http://www.ClinicalTrials.gov. 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.

What are the costs of taking part in this study?

It does not cost anything to be in the study. You will be responsible for transportation to and from the hospital where the interventions will take place. However, you may choose to receive a $20 travel reimbursement for travel to the therapy sessions or assessments. In addition, if you

complete all four of the study assessments you will receive a $20 gift card to Barnes & Noble as a thank you for your time and participation. If you are randomized to Enhanced Usual Care you will be given referrals at no charge. However, if you choose to accept these referrals you may be billed for these services by these providers.

What happens if I am injured because I took part in this study?

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. You will be responsible for costs associated with therapy sessions you receive outside of this study.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor William Breitbart, M.D. at 646-888-0020.

Any hospital that does research on people has an institutional review board (IRB). This board reviews all new studies to make sure that the patient's rights and welfare are protected. The IRB at MSKCC has reviewed this study.

For a non-physician whom you may call for more information about the consent process, research patients' rights, or research related injury is Jorge Capote, RN, Patient Representative, telephone number: (212) 639-8254.

Recording of Sessions:

The counseling sessions will be audio taped in order to make sure the treatment programs are all run in the same way. These audio taped sessions may be transcribed. In addition, some sessions may be video recorded. These videos and transcripts may be used for academic, educational, or training purposes. If you do not agree, your sessions will not be videotaped and/or transcribed. However, you can still participate in the study.

Please indicate you understand you will be audio recorded as part of this study.

- ☐ *Yes, I understand I will be audio recorded as part of this study.*

Please indicate if you agree to be video recorded.

- ☐ *Yes, I agree to be video recorded.*
- ☐ *No, I do not wish to be video recorded but still wish to participate.*

Please indicate if your audio taped sessions can be transcribed.

- ☐ *Yes, I agree that you can transcribe my audio taped sessions.*
- ☐ *No, I do not wish for my sessions to be transcribed but still wish to participate.*

Contacting Your Doctor:

With your permission, we may contact your doctor during the study for information about your medical treatment. If you do not agree to this, we will not contact your doctor for this purpose.

Please indicate if you agree to allow us to contact your doctor for information about your medical treatment.

- ☐ *Yes, I give you permission to contact my doctor for this purpose.*
- ☐ *No, I do not wish for you to contact my doctor for this purpose.*

Future Studies:

Someone may contact me in the future to ask me to take part in more research.

- ☐ *Yes, I would like to be contacted about future studies*
- ☐ *No, I would not like to be contacted about future studies*

RESEARCH AUTHORIZATION

A Randomized Controlled Trial of Individual Psychosocial Interventions for Cancer Patients

Research Participant Name: _____

Research Participant MRN :_____

Information about you and your health is personal. It is "Protected Health Information." We cannot use any of your health information for research unless you tell us that we can. If you take part in this research, the people or organizations that can look at your information are listed below. You will have to sign this form to tell us we have your permission to share your protected health information.

The following persons and/or organizations may use or disclose your information for purposes related to this research:

- The people in charge of the study and their assistants and support staff.

The following persons and/or organizations may look at your information for purposes related to this research:

- Members and staff of the hospital's Office of Clinical Research, Computing Resource Group that manages research databases, Data Safety Monitoring Board, and the Quality Assurance Committee.
- Members and staff of the hospital's Institutional Review Board and Privacy Board.
- The National Cancer Institute, National Institutes of Health, U.S. Food and Drug Administration, and other agencies responsible for oversight.
- The following sponsor(s) of this research: Memorial Sloan Kettering Cancer Center
- Others: Barry Rosenfeld, Ph.D. (Fordham University) and his staff at Fordham University; and Ubiqus transcription company.

The following information will be used and/or disclosed for this research:

- Your entire research record.
- HIV-related information. This includes any information showing that you had an HIV-related test, have HIV infection, HIV-related illnesses or AIDS, or any information that could mean you might have been exposed to HIV. New York State requires us to obtain this consent.
- HIV-related information collected during this study if you choose to disclose it when talking to any of the staff.
- Your medical records from the hospital
- The following information: Questionnaires, audio recordings (required), transcripts (optional), and/or video recordings (optional) of counseling sessions.

If you sign this form, it means you are giving us permission to share your protected health information. We can only share it with the people or organizations describe above. The purpose for the use and sharing of this information is to conduct this study. This signed form allows us to make sure that everyone who needs information related to this study can get it.

Your protected health information may also be used for your research treatment, to collect payment for care you receive while on the study (when applicable), and to run the business operations of the hospital.

Some of the people or organizations listed above may not be subject to privacy laws. This means they could share your information again.

You do not have to sign this form. If you do not sign it, you will not be able to take part in the study. Your health care outside the study will not be affected. The payment for your health care or your health benefits will not be affected.

You have the right to withdraw from the study at any time. If you sign this authorization form, you also the right to withdraw it at any time. If you withdraw it, we cannot use or share anymore of your research data. If the hospital has already used or shared your information, it cannot be taken back. This authorization allows us to use your information until you say we cannot use it anymore. If you want to withdraw your authorization, write to: William Breitbart, M.D.at the Department of Psychiatry & Behavioral Sciences Memorial Sloan Kettering Cancer Center.

Notice About HIV-Related Information

Once we have shared your HIV-related information, it can only be shared again if federal or state laws allow it. You have the right to ask for a list of any people who get your HIV-related information that are not listed above. There are two agencies to help protect your rights. Call them if you think you have been singled out or harmed because of HIV-related information.

- New York State Division of Human Rights: (888) 392-3644

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Statement of professional obtaining consent

I have fully explained this clinical research study to the participant or his/her Legally Authorized Representative (**LAR**). In my judgment and the participant's or that of his/her Legally Authorized Representative, there was sufficient access to information, including risks and benefits to make an informed decision.

Consenting Professional Must Personally Sign & Date		
Assent (Minor between the ages of 7 and less than 18): If the participant is a minor, I have obtained his/her assent to participate in the study to the best of their ability to understand. ☐ **YES** ☐ **NO** ☐ **N/A (Adult or Child <7)**		
Consenting Professional's Signature		**Date:**
Consenting Professional's Name (Print)		

Participant's (or Legally Authorized Representative's (LAR)) statement

I have read this form with the description of the clinical research study. I have also talked it over with the consenting professional to my satisfaction. By signing below, I am agreeing to the following: (1) to voluntarily be a participant in this clinical research study (2) authorizing for the use and disclosure of my/their protected health information (data about myself) and (3) that I received a signed copy of this consent form.

Participant/LAR Must Personally Sign & Date		
Participant/LAR Signature		**Date:**
Participant/LAR Name (Print)		
LAR Relationship to Participant		

Witness Signature (If Required)

☐ **Non-English Speaking Participant Witness and/or Interpreter:** I declare that I am fluent in both English and participant's (or LAR) language and confirm that the consent discussion was appropriately translated for the participant (or LAR).

☐ **Other:** I confirm that the consent discussion was appropriate for the participant's (or LAR's) understanding of the study.

Name of Witness: _____

Signature of Witness: _____ Date: _____

The Participant/Legally Authorized Representative Must Be Provided With A Signed Copy Of This Form.