INFORMED CONSENT FOR CLINICAL RESEARCH

Communication Skills Intervention to Promote Transition into Survivorship: *Patients, Longitudinal Phase*

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 purpose of this study is to improve the communication skills of physicians who treat lymphoma patients. In our prior research, we observed the communication skills of doctors who treat lymphoma patients and considered areas for improvement. Now, we are testing new models of consultation to promote communication about wellness rehabilitation and survivorship after chemotherapy and/or radiation.

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 are being asked to take part in this study because:

- You are at least 18 years of age.
- You have been diagnosed with either Hodgkin's disease or diffuse Large B-cell Lymphoma.
- You have finished your lymphoma treatment.
- Your doctor has agreed to participate in this study.

How many people will take part in the study?

In total, we will enroll 288 patients to this portion of the study. About 80 of these patients will take part in the study at MSKCC. The remaining patients will take part in this phase of the study at one of the other three participating sites: Maimonides, Moffitt/ Tampa General Hospital, and MD Anderson.

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

Before you begin the study …

We may have reviewed your medical record to verify that you are eligible to participate in this study.

During the study…

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

- Attend an audio-recorded initial end-of-treatment consultation with your doctor. This visit is standard practice for your lymphoma care. Typically your doctor will review your scans with you and confirm that your chemotherapy treatment has ended.

- After this consultation, we will ask you to complete a survey at the clinic called the baseline questionnaire. It takes about 45 minutes to complete. You can complete the questions yourself or we can ask them. It asks questions about:
  - demographic information
  - your knowledge about your lymphoma
  - cancer worry
  - quality of life
  - sexual functioning
  - your perception of your clinician's empathy
  - your satisfaction with the consultation

- Attend a 15-minute consultation with your doctor about one month after your end-of-treatment visit in which the doctor will talk about your rehabilitation and survivorship. This visit will be audio recorded. After this visit, you will be asked to complete a somewhat briefer questionnaire about the visit that takes 30 minutes to complete. This visit is not is not part of standard care. This study aims to find out if there are benefits to adding this consultation.

- We will also audio record your standard 3-month check-up visit that you will have with your doctor. At this time, we will also ask you to fill out a short survey that will take about 50 minutes to complete.

- We will also contact you at 6, 9 and 12 months after the initial end-of-treatment visit with your doctor. Each time we will ask you to complete a survey taking around 40-60 minutes to complete. The 6 and 12 month surveys include an audio-recorded interview with a member of the research staff. This interview can take place in person or over the phone. We will then have RA Fisher Ink LLC, a transcription service, type up what was said during the interview from the recording.

After the study…

Once you complete the last survey, 12 months after enrolling, you will have completed your participation in the study. After you have finished the study, the research staff may call you to better understand an answer you gave. We will review your medical record on occasion to check on your health.

How long will I be in the study?

You will be asked to take part in the study for about 12 months.

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; if you do not follow the study rules; or if the study is stopped.

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

There are no physical risks involved with this study.

You may feel nervous about having your consultations with your doctor recorded. We encourage you to tell your doctor if you do feel nervous in this manner.

There is a small chance that you may become upset by sharing your thoughts about your doctor's communication or about your own quality-of-life. You can choose not to answer any questions that upset you. If any of these questions indicate that you feel upset and/or you would like to discuss your feelings, we will talk with you and/or give you a referral for counseling. You will be billed for these additional services.

Are there benefits to taking part in the study?

You may not benefit directly from the study. However, you may benefit from knowing that what you tell us may help researchers to provide training in how to improve the quality of communication between physicians and patients and specifically lymphoma cancer survivors.

Will I receive the results from the study?

We will be happy to share the overall results of the study with you when they are available. Please let us know if you wish to receive a report by contacting the research staff at (646)-888-0019.

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.

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.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drugs Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily without your consent, information that would identify you as a participant in the research project under the following circumstances. For this study no voluntary disclosures will be made.

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?

There are no costs to take part in this study. A consultation fee will not be charged for the 15 minute doctor's visit that occurs about 1 month after your end-of-treatment doctor's visit. This visit is not part of your standard care for lymphoma. This study aims to find out if there are

benefits to adding this consultation. All other of your doctors' visits are part of your standard care and you will be billed for them.

For your time and effort, you will receive $20 on completing the second questionnaire and $30 on completing the third questionnaire. You will also receive $40 at 6 months, $50 at 9 months and $60 at 12 months. Overall, you will be compensated $200 in total for filling out these questionnaires.

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. The study will not pay for the medical treatment.

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 Steven Horwitz, MD at (212) 639-3045.

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.

Optional Question

Please note: This section of the informed consent form asks whether we may contact you in the future to tell you about other research studies that you may wish to take part in. You can still be a part of this study even if you say 'no' to this section.

Please read the question below and circle "Yes" or "No".

May MSKCC contact you in the future to see if you might be interested in taking part in other research studies?

YES NO

RESEARCH AUTHORIZATION

Communication Skills Intervention to Promote Transition into Survivorship: *Patients, Longitudinal Phase*

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:
    - Members of research teams at participating sites
    - RA Fisher Ink LLC- Transcription Services

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: audio recordings of consultations with your doctor and surveys

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: Steven Horwitz, MD at the Department of Medicine, 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 (800) 523-2437 or (212) 480-2493
- New York City Commission of Human Rights (212) 306-7450 or (212) 306-7500

INFORMED CONSENT FOR CLINICAL RESEARCH

Communication Skills Intervention to Promote Transition into Survivorship: *Patients, Longitudinal Phase*

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.